REGISTRATION REPORT
Part A

Risk Management

Product code: Adexar

Active Substance: Epoxiconazole 62.5 g/L
Fluxapyroxad 62.5 g/L

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: BASF SE

Submission Date: 05/04/2013

Date : 02 June 2017

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PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration/registration of Adexar containing Epoxiconazole and Fluxapyroxad in Germany. This evaluation is required subsequent to the inclusion of Epoxiconazole and Fluxapyroxad on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and where appropriate the addendum for Germany The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to Adexar where that data has not been considered in the EU review. Otherwise assessments for the safe use of Adexar have been made using endpoints agreed in the EU review of Epoxiconazole and Fluxapyroxad.

This document describes the specific conditions of use and labelling required for Germany for the re-registration/registration of Adexar.

Appendix 1 of this document provides a copy of the final product authorisation Germany.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.
Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by BASF SE for re-registration in Germany of Adexar,

1.2 Annex I inclusion

Epoxiconazole is approved under 2008/107 and Reg. (EU) No 540/2011 on 01/01/2013. Expiration of approval: 30/04/2019.

The approval provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on epoxiconazole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 July 2008 shall be taken into account.
In this overall assessment Member States must pay particular attention to:

— the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,
— the dietary exposure of consumers to the epoxiconazole (triazole) metabolites,
— the potential for long-range transport via air,
— the risk to aquatic organisms, birds and mammals. Conditions of authorisation shall include risk mitigation measures, where appropriate.
The Member States concerned shall ensure that the notifier submits to the Commission further studies addressing the potential endocrine disrupting properties of epoxiconazole within two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.
The Member States concerned shall ensure that the notifier presents to the Commission not later than 30 June 2009 a monitoring programme to assess the long-range atmospheric transport of epoxiconazole and related environmental risks. The results of this monitoring shall be submitted as a monitoring report to the Commission by 31 December 2011 at the latest.
The concerned Member States shall ensure that the notifier submits within two years from the entry into force of this Directive, at the latest, information on residues of epoxiconazole metabolites in primary crops, rotational crops and products of animal origin and information to further address the long-term risk to herbivorous birds and mammals.

Fluxapyroxad is approved under Reg. (EU) No 589/2012 on 01/01/2013. Expiration of approval: 31/12/2022.

The approval provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fluxapyroxad, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to groundwater, if the active substance is applied under vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The purity given in this entry is based on a pilot plant production. The examining Member State shall inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

These concerns were all addressed in the evaluation.

1.3 Regulatory approach

To obtain approval the product Adexar must (where appropriate) meet the conditions of the approval of epoxiconazole and fluxapyroxad and be supported by dossiers satisfying the requirements, with an assessment to Uniform Principles, using the agreed endpoints.

This application was submitted in order to allow the re-registration of Adexar in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Adexar, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1, 5, 6 and 7 and Part C.

1.5 Letters of Access

Letter of Access is not necessary, because BASF is the owner of both active ingredients.

2 Details of the authorisation

2.1 Product identity

Product Name	Adexar
Authorization Number (for re-registration)	026958-00
Function	fungicide, plant growth regulator
Applicant	BASF SE, Germany
Composition	62.5 g/L fluxapyroxad 62.5 g/L epoxiconazole
Formulation type	Emulsifiable Concentrate [Code: EC]
Packaging	0.1 – 10 L container, HDPE/PA 50 L container (fluorinated HDPE)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

2.2.2 R and S phrases under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
Repr. 1B, Acute Tox. 4, Skin Sens. 1, Eye Irrit. 2, Carc. 2	
Hazard pictograms:	
GHS07	exclamation mark
GHS08	health hazard
GHS09	environment
Signal word:	
Danger	
Hazard statements:	
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>.
H360Df	May damage the unborn child. Suspected of damaging fertility.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects
Precautionary statemtents:	
Not proposed for all sections by zRMS Germany, to be decided by applicant	
P501	Dispose of contents/container to ..

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208-0167 - Contains purasolve (2-ethylhexyl-S-lactate). May produce an allergic reaction.	

2.2.3 R and S phrases under Directive 2003/82/EC (Annex IV and V)

None

2.2.3 Other phrases

2.2.4.1 Restrictions linked to the PPP under Regulation (EC) No 547/2011

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.

SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB110	The directive concerning requirements for personal protective gear in plant protection, „Personal protective gear for handling plant protection products“ of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS2202	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMFC2	Mode of action (FRAC-group): C2 (for fluxapyroxad)
WMFG1	Mode of action (FRAC-group): G1 (for epoxiconazole)
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.

2.2.4.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Integrated pest management (IPM)/sustainable use	
WW7041 For use 011	Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management.
Ecosystem protection	
NW 605-1 All uses	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*". Drift reduction by 90% * 75 % * 50% 5 m
NW 606 All uses	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 5 m

2.3 Product uses

GAP-Table of intended uses for Germany

GAP: 2014-07-29

PPP (product name/code)	**Adexar**	**Formulation type:**	**EC**
active substance 1	**Epoxiconazole**	**Conc. of as 1:**	**62.5 g/L**
active substance 2	**Fluxapyroxad**	**Conc. of as 2:**	**62.5 g/L**
Applicant:	**BASF**	**professional use**	☒
Zone(s):	**central EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F*	NW605-1 (50%: 5 m) NW606 (5 m) * The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

002	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
003	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
004	DE	wheat TRZSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
005	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
006	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of	a) 2	a) 2 L/ha	a) as1: 0.125 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)

						infestation and/or when first symptoms become visible	b) 2 (21 d)	b) 4 L/ha	as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha			
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
010	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b)	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)

						visible			as1: 0.25 kg as/ha as2: 0.25 kg as/ha			
012	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
013	DE	barley HORVX	F	Ramularia leaf spot disease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 32 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	for susceptible varieties and at increasing global radiation NW605-1 (50%: 5 m) NW606 (5 m)
015	DE	rye SECCE	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)

									as/ha			
017	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
018	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
019	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
020	DE	triticale TTLSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)
021	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita*	spraying	BBCH 30 - 69 from spring at	a) 2	a) 2 L/ha	a) as1: 0.125 kg	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)

				PUCCRE		beginning of infestation and/or when first symptoms become visible	b) 2 (21 d)	b) 4 L/ha	as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha			
022	DE	triticale TTLSS	F	septoria-species *Septoria* spp. SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	NW605-1 (50%: 5 m) NW606 (5 m)

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:

The appearance of the product is that of a clear red-brown liquid with a moderate aromatic odour. It is not explosive, has no oxidizing properties, the self ignition temperature is 282 °C. In aqueous solution, it has a pH value around 5.0. The observed changes of the active substance content and the physical properties after 24 months storage at 23 °C are negligible. Therefore, the formulation meets the requirements of the shelf life specifications for at least 2 years under practical conditions.

Although after 52 weeks storage at 23 °C in the emulsion stability test some precipitation of the active ingredient occurred, additional tests on suspensibility have shown that the product can be applied without adverse effects under practical use conditions.

The technical characteristics are acceptable for an emulsifiable concentrate formulation.

Implications for labelling: None

Compliance with FAO specifications:
There are no FAO specifications available for fluxapyroxad or epoxiconazole.

Compliance with FAO guidelines:
The product Adexar complies with the general requirements for EC formulations according to the FAO/WHO manual (2010).

Compatibility of mixtures:
A complete report regarding physical and chemical compatibility of the tank mixes with different formulations has been submitted which has demonstrated compatibility. These tank mixes can therefore be mentioned on the product label for Adexar.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of Adexar has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

The active substances can be quantified using the analytical HPLC method AFL0755/02. The method was developed for quantifying epoxiconazole and fluxapyroxad in Adexar (BAS 701 00 F).
The validation data of method AFL 0755/02 with respect to precision, accuracy, linearity and specificity prove that the method is suitable to determine the content of fluxapyroxad and epoxiconazole in the emulsifiable concentrate (EC) formulation BAS 701 00 F.
There is no CIPAC method available for the determination of epoxiconazole and fluxapyroxad in emulsifiable concentrate (EC) formulations like Adexar (BAS 701 00 F).
The analytical method APL0594/01 is applicable to determine the content of thr relevant impurity toluene in the formulation BAS 701 00 F by GC/MS.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of epoxiconazole and fluxapyroxad in food of plant and animal origin, soil, water and air. Residues of epoxiconazole in body fluids and tissues can be determined by suitable analytical methods as well. Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be also applied for the product.
Epoxiconazole residues can be monitored in plants by LC-MS/MS and GC-MS, in food of animal origin, soil and water by GC-MS and GC-ECD, in air by GC-ECD and in body fluids and tissues by GC-MS and GC-ECD.
Fluxapyroxad residues can be monitored in food of plant and animal origin, soil, water and air by LC-MS/MS. Methods for body fluids and tissues are not required because fluxapyroxad is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).
However, the following minor data gap has been identified according to the requirements of SANCO/825/00 rev. 8.1:

- The validation of an analytical method for the determination of epoxiconazole in fatty plant matrix in an independent laboratory (ILV) is missing.

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

Adexar was not the representative formulation in the EU review of the active ingredients fluxapyroxad and epoxiconazole. Therefore, relevant data were provided by the applicant. Adexar containing 62.5 g/L fluxapyroxad and 62.5 g/L epoxiconazole is of moderate oral toxicity and has a low toxicity with respect to acute dermal and inhalation route of exposure. It is irritating to the skin and irritating to the eyes of rabbits.

Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for BAS 701 00 F/Adexar

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
LD_{50} oral, rat (OECD 423)	> 500 mg/kg bw, < 2000 mg/kg bw	Yes	H302

LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None
LC_{50} inhalation, rat (OECD 403)	6.65 mg/L air for males, 5.84 mg/L air for females	Yes	None
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None
Eye irritation, rabbit (OECD 405)	Irritant	Yes	H319
Eye irritation, rabbit (OECD 405)	Irritant	Yes	H319
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	H317
Supplementary studies for combinations of plant protection products	No data – not required		

Additional toxicological information relevant for classification/labelling of BAS 701 00 F/Adexar

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)**	**Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)**
Toxicological properties of active substances (relevant for classification of product)	Epoxiconazole (6.0 % (w/w))	H351 (≥ 1 %) H360D (≥ 0.3 %)) H360f (≥ 3 %)	H351 H360Df
	Fluxapyroxad (6.0 % (w/w))	H351 (≥ 1 %)	H351
Toxicological properties of non-active substances (relevant for classification of product)	Propionic acid, 2-hydroxy-,2-ethylhexyl ester (2-Ethylhexyl-S-lactate) (CAS-No. 186817-80-1), 42.0 % (w/w))	H317; EUH208 (≥ 0.1 %)	Contains purasolve (2-ethylhexyl-S-lactate). May produce an allergic reaction.
Further toxicological information	No data – not required		

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

Operator exposure to Adexar was not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure was assessed against the AOEL agreed in the EU review (fluxapyroxad 0.04 mg/kg bw/day and epoxiconazole 0.008 mg/kg bw/day). Data on dermal absorption of Adexar was provided and considered acceptable. Operator exposure was modelled using UK OPEX and German models.

According to the model calculations, it can be concluded that the risk for the operator using Adexar on cereals is acceptable with the use of personal protective equipment described in 2.2.4.1.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

Bystander exposure to Adexar was not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for epoxiconazole and fluxapyroxad will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

Worker exposure to Adexar was not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded for both active substances under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed

Implications for labelling resulting from operator, worker, bystander assessments:

See 2.2

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

The data available are considered sufficient for risk assessment. The limit values as laid down in EU residue legislation (Reg. (EU) No 978/2011) for residues of epoxiconazole in/on wheat and rye grain (0.6 mg/kg) and barley (1.5 mg/kg) are sufficient to cover residues anticipated consequent to the intended use of the product on these crops. The limit values as laid down in EU residue legislation (Reg. (EU) No 978/2011) for residues of fluxapyroxad in/on wheat and rye grain (0.4 mg/kg) and barley (2 mg/kg) are sufficient to cover residues anticipated consequent to the intended use of the product on these crops.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The chronic and the short-term intake of fluxapyroxad residues are unlikely to present a public health concern:

ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	63.5 % (based on DE children, 2-4 years, mean body weight)
NTMDI (% ADI) according to NVS II	65.9 % (based on DE children, 2-4 years, individual consumption/body weight ratio)
ARfD	0.25 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	wheat: 0.1% (based on UK, 4-6 years) rye: 0.1% (based on UK infant) barley: 0.2% (based on NL adult, 60 kg bw) (no processing factors were considered)
NESTI (NVS II) (% ARfD)	wheat: <0.1% (based on DE child, 2-4 years) rye: <0.1% (based on DE child, 2-4 years) barley: 0.2% (based on general population) (no processing factors were considered)

Summary of the chronic and the short-term intake of epoxiconazole:

ADI	0.008 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	97.2 % (based on DK child diet)
NTMDI (% ADI) according to NVS II	73.6 % (based on DE child 2-4 years)
ARfD	0.023 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	wheat: 0.9% (based on UK, 4-6 years) rye: 0.4% (based on UK infant) barley: 2.7% (based on NL adult, 60 kg bw) (no processing factors were considered)
NESTI (NVS II) (% ARfD)	wheat: 1% (based on DE child, 2-4 years) rye: 0.4% (based on DE general population) barley: 2% (based on DE general population) (no processing factors were considered)

As triazole metabolites (TDM) are not unique to epoxiconazole and a common approach on EU level is still outstanding, no risk assessment was performed on TDM which may be formed from epoxiconazole in plant metabolism and soil. To this end the risk assessment is provisional in nature.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product ADEXAR (BAS-70100-FW-0-EC) in its intended uses in cereals BBCH (30-69) is documented in detail in the core assessment of the plant protection product ADEXAR (BAS-70100-FW-0-EC) dated from 08/10/2013 performed by Germany.
The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of ADEXAR (BAS-70100-FW-0-EC) in Germany according to its intended use in cereals (Use No. 1-22).

Table: Intended uses and risk envelopes

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 1-22	cereals/ BBCH 30-69	spraying /	2 x, 21d, spring 1. 70 % 2. 90 %	Fluxapyroxad: 2 x 125= 250, Epoxiconazole: 2 x 125= 250	Fluxapyroxad: 1. 37.5 2. 12.5 Epoxiconazole: 1. 37.5 2. 12.5

Epoxiconazole:
The active substance is under laboratory conditions slowly degraded in soil. Half lives reach values up to 266.5 days. The only metabolite 1,2,4-triazol occurs with a maximum of 6.6 after 175 days. Under field conditions a similar degradation rate is demonstrated with a max. DT_{50} of 226 days. DT90 values clearly exceed one year therefore also accumulation in soil needs to be assessed. For the metabolite 1,2,4 Triazol field data is available showing a DT_{50} of 60.5 days (slow phase).
Epoxiconazole is highly absorbed in soil with a Kfoc of 1087 whereas the metabolite 1,2,4 triazol is absorbed weaker with a Kfoc of 89 days.
In the water/sediment study the active substance is transferred into the sediment and only the metabolite BF 480 entriazole is detected with 34 % in the sediment. Degradation of epoxiconazole in water is slow with deg. Time of $DegT_{50}$ of 71 days (geo.mean).

Fluxapyroxad

No new studies have been submitted regarding route and rate of degradation in soil of Fluxapyroxad. The geometric mean laboratory DT_{50} corrected to standard temperature and moisture conditions to be used in FOCUS groundwater and surface water modelling was 183 d. The maximum laboratory DT_{50} for BAS 700F when corrected to standard moisture and temperature conditions was 424 days with a corresponding DT_{90} of > 1000 days triggering the requirement for field dissipation studies (based on best fit degradation kinetics). For modelling purposes the field studies were used. Two metabolites occur during degradation in soil M700F001 and M700F002. Degradation times between metabolites vary with geo. mean of 5.4 days for M700F001 and a geo mean of 25.9 days for M700F2.
Adsortption to soil of active substance is strong with a Kfoc of 729. Metabolites are only weakly adsorbed to soil with Kfoc values of 2.6 and 7.6 for the metabolites M700F001 and M700F002.
In the water sediment system a third metabolite occurs in irradiated water (M700F007). The active substance dissipates from water phase with a DT_{50} of 3 days. No decline of concentrations in the sediment could be observed. This leads to default degradation times of 1000 days for the further exposure modeling.

Metabolites

No new study on the fate and behaviour of fluxapyroxad, epoxiconazole or ADEXAR (BAS-70100-FW-0-EC) has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.
The risk assessment for the metabolites of Fluxapyroxad has already been performed for EU approval (see EFSA Journal 2012;10(1):2522). The metabolites are considered ecotoxicologically not relevant. Therefore no new risk assessment hence no exposure assessment for these metabolites is necessary.
The risk assessment for the metabolites of epoxiconazole has already been performed for EU approval (see SANCO/136/08 – 11/07/2008, revised 28/09/2010). The metabolites are considered ecotoxicologically not relevant and did not penetrate into groundwater. Due to new data a revised exposure assessment for these metabolites is presented.

However, in the specific groundwater risk assessment for Germany considering the entry path surface run-off and drainage with subsequent bank filtration the soil metabolites of fluxapyroxad and epoxiconazole are included.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product ADEXAR (BAS-70100-FW-0-EC) in cereals according to use No 1-22 PECsoil was calculated for the active substances fluxapyroxad and epoxiconazole considering a soil depth of 1 cm. Due to the slow degradation of the active substances fluxapyroxad and epoxiconazole in soil the accumulation potential of fluxapyroxad and epoxiconazole was considered. Therefore PECsoil used for risk assessment comprises background concentration in soil (PECaccu) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PECact considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

Table: Results of PECsoil calculations

plant protection product:		BAS 701 00F				
use:		A				
Number of applications/intervall		2/ 21				
application rate:		125				
crop interception:		70%/ 90%				
active substance/ formulation		**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Fluxapyroxad		1	0.288 on d21	20	0.0148	0.3036
Epoxiconazole		1	0.3177 on d21	20	0.0077	0.3254
Metabolite 1,2,4-Triazole	Ff=100%	2.5	0.0056 on d383	20	0.0015	0.0071
BAS 701 00F/ Adexar	2.072 kg/ha	1	4.1440	20	0.0379	4.1819

The results for PEC soil for the active substances and their metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater

Results of modelling with FOCUS PELMO show that the active substances fluxapyroxad and epoxiconazole are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses in cereals (BBCH 30 - 69).
For the metabolite M700F001 of fluxapyroxad a groundwater concentration of ≥ 0.1µg/L cannot be excluded. For the metabolite M700F002 of fluxapyroxad a groundwater concentration of ≥ 0.75 µg/L cannot be excluded
For the metabolite 1,2,4-Triazole of epoxiconazole concentrations of ≥ 0.1µg/L in groundwater can be excluded

Table PEC$_{GW}$ at 1 m soil depth of Fluxapyroxad and its metabolites M700F001 and M700F002considered relevant for German exposure assessment

crop.	Szenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3		
		Fluxapyroxad	M700F001 Max. residues of slow/ fast DT50 of ai	M700F002 Max. residues of slow/ fast DT50 of ai
Winter cereals	Hamburg	0.001	0.295	2.462
Spring cereals	Hamburg	0.001	0.288	2.336

Table PEC$_{GW}$ at 1 m soil depth of Epoxiconazole and 1,2,4-Triazole considered relevant for German exposure assessment

crop	Szenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3		
		Epoxiconazole	Metabolite 1,2,4-Triazole	
Winter cereals	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.088 0.044
Spring cereals	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.083 0.0415

Consequences for authorization:

A further monitoring program for the metabolite 1,2,4 triazole is deemed necessary due to the nature of the metabolite which can be sourced by many azole fungicides. A detailed study plan needs to submitted and discussed with the responsible authorities in Germany.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

According modelling with EXPOSIT 3.01 groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Fluxapyroxad due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.
According modelling with EXPOSIT 3.01 groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Epoxiconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product ADEXAR (BAS-70100-FW-0-EC) in cereals according to use No 1-22 PECsw was calculated for the active substances fluxapyroxad and epoxiconazole considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.
The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substances fluxapyroxad and epoxiconazole is < 10^{-5} Pa.. Hence the active substances fluxapyroxad and epoxiconazole are regarded as non-volatile. Therefore, exposure of surface water by the active substances fluxapyroxad and epoxiconazole due to deposition following volatilization was not considered.
The concentration of the active substances fluxapyroxad and epoxiconazole in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.

Table: Results of PECsoil calculations

plant protection product:	BAS 701 00F					
use:	A					
Number of applications/intervall	2/ 21					
application rate:	125					
crop interception:	70%/ 90%					
active substance/ formulation		**PECsw (spray-drift) - 1m [µg/l]**	**PECsw (run-off) - ditch [µg/l]**	**PECsed (incl. accu) [µg/kg]**	**PECdrain autuum/ winter/early spring [µg/l]**	**PECdrain Spring/summer [µg/l]**
Fluxapyroxad		1.817	0.34	142.68	0.02	0.01
Epoxiconazole		1.769	0.24	32.4	0.02	0.01
BAS 701 00F/ Adexar	2.072 kg/ha	32.9	-	-	-	-

The results for PEC surface water for the active substances and their metabolites were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

The vapour pressures at 20 °C of the active substances fluxapyroxad and epoxiconazole are < 10^{-5} Pa. Hence the active substances fluxapyroxad and epoxiconazole are regarded as non-volatile. Therefore exposure of surface water by the active substances fluxapyroxad and epoxiconazole due to deposition following volatilization does not need to be considered.

Implications for labelling resulting from environmental fate assessment:

For the authorization of the plant protection product BAS 701 00 F following labelling and conditions of use are mandatory:

Classification and labelling
Based on the data on the active substances fluxapyroxad and epoxiconazole the plant protection product BAS 701 00 F are considered to be not readily degradable in the sense of the CLP regulation.
The formulation BAS 701 00 F is regarded as a candidate for R 53

R and S phrases under Directive 2003/82/EC (Annex IV and V)
none

Other labels /conditions of use
Labelling
none

Conditions of use:
none

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

A full risk assessment according to Uniform Principles for the plant protection product ADEXAR (BAS-70100-FW-0-EC) in its intended uses in cereals (BBCH 30 - 69) is documented in detail in the core assessment of the plant protection product ADEXAR (BAS-70100-FW-0-EC) dated from 08/10/2013 performed by Germany. The intended use of ADEXAR (BAS-70100-FW-0-EC) in Germany is generally covered by the uses evaluated in the course of the core assessment by Germany.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of ADEXAR (BAS-70100-FW-0-EC) in Germany according to its intended use in cereals (BBCH 30 - 69) (use No. A).

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Table: Toxicity of fluxapyroxad and epoxiconazole to birds and mammals with reference to agreed endpoints

Study type	Test substance	Species	Results
Acute oral toxicity	fluxapyroxad (BAS700F)	*Colinus virginianus*	LD_{50} > 2000 mg a.i./kg bw/d[1)]
Long-term toxicity and reproduction		*Anas platyrhynchos*	NOEC = 33.6 mg/kg bw/d[1)]
Acute oral toxicity	epoxiconazole	*Colinus virginianus*	LD_{50} > 2 000 mg a.s./kg b.w. [1)]
Long-term toxicity and reproduction		*Colinus virginianus*	NOEL = 1.0 mg as./kg b.w./day [2;1)]
Acute oral toxicity	BAS 70 100-F (ADEXAR)	*Colinus virginianus*	LD_{50} > 2 000 mg product/kg b.w*)
Acute oral toxicity	fluxapyroxad (BAS700F)	Rat	LD_{50} >2000 mg a.i./kg bw/d[1)]
Multigeneration		Rat	NOAEL = 10 mg a.i./kg bw/d[1)] Impaired body weight development in F1 offspring
Acute oral toxicity	Metabolite M700F007	Rat	LD_{50} >500 < 2000 mg a.i./kg bw/d[1]
Acute oral toxicity	epoxiconazole	Rat	LD_{50} > 3160 mg a.s./kg bw [1]
Long-term toxicity and reproduction		Rat	NOAEC = 25 mg a.s./kg diet NOAEL = 2.3 mg a.s./kg bw/day [1]
Acute oral toxicity	Metabolite 1,2,4-triazole (= BF 480-16)	Rat	LD_{50} = 1648 mg a.s./kg bw [1]
Long-term toxicity and reproduction		Rat	NOAEL = 15 mg a.s./kg bw/day [1]

fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522
Epoxiconalzole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Daily Dose [mg/kg b.w./day] calculated based on study data for food consumption and body weight.
BAS 70 100-F: *) new study submitted by the notifier

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).
Based on the presumptions of the Tier 1 and Tier 2, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances epoxiconazole and fluxapyroxad according to the intended use of the formulation ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30 - 69) achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds. No increased toxicity caused by the formulated product could be demonstrated.
Based on the presumptions of the screening step and higher Tiers, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals. No increased toxicity caused by the formulated product could be demonstrated.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Results of aquatic risk assessment for the intended for uses of ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30 -69) based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.

Table: Ecotoxicological endpoints for aquatic species exposed to fluxapyroxad and epoxiconazole and ADEXAR (BAS-70100-F) with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity
Chronic toxicity to fish			
Pimephales promelas	epoxiconazole	FLC 54 d	**NOEC = 0.003 mg/L** (growth F1) NOEAEC = 0.01 mg/L (growth F2)
Sediment dwelling organisms			
Chironomus riparius	epoxiconazole	21 d	NOEC = 0.0625 mg/L[1]
Chironomus riparius	BF 480-entriazole	28d	**NOEC = 0.03 mg/L[1]**
Toxicity to aquatic plants			
Lemna gibba	epoxiconazol	7 d	E_rC_{50} = 0.0138 mg/L

	e	static	**E_bC_{50} = 0.0043 mg/L**[1]
Lemna gibba	ADEXAR (BAS 701 00F) batch 204438	7 d	ErC_{50} = 0.215 mg/L **EbC_{50} = 0.063 mg/L** EbC_{50} = 0.078 mg/L

ELS = early life stage; FLC = full life cycle
fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522
epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Daily Dose [mg/kg b.w./day] calculated based on study data for food consumption and body weight.
1,2,4-triazole : EU agreed endpoint EFSA Scientific report No. 138 (2008)

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances fluxapyroxad and epoxiconazole are $< 10^{-5}$ Pa. Hence the active substances fluxapyroxad and epoxiconazole are regarded as non-volatile. Therefore exposure of surface water by the active substances fluxapyroxad and epoxiconazole due to deposition following volatilization does not need to be considered.
The aquatic risk assessment of spray drift entries in surface water by the use of ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30 -69) according to use No. A is based on the chronic effects of epoxiconazole to aquatic plants (epoxiconazole E_bC_{50} = 0.0043 mg/L (*Lemna gibba*)) and a sediment study with *Chironomus riparius* and BF 480-entriazole (NOEC = 0.03 mg/L). Therefore a risk assessment was conducted for sediment organisms with the metabolite BF 480-entriazole.

Based on the relevant toxicity of the active substance epoxiconazole, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to ADEXAR (BAS-70100-FW-0-EC) according to the use No A only achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (buffer stripe or drift reducing technique) are applied.

2. Exposure by surface run-off and drainage

The concentration of the active substance epoxiconazole in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.01.
The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substance epoxiconazole (contained in ADEXAR) due to run-off and drainage according to the use No A achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.

Consequences for authorization:

For the authorization of the plant protection product (BAS-70100-FW-0-EC) the following labelling and conditions of use are mandatory:

Required Labelling

NW 262	The product is toxic for algae. [Fluxapyroxad: *Pseudokirchneriella subcapitata*: EC_{10} = 0,224 mg a.s./L]
NW 264	The product is toxic for fish and aquatic invertebrates. [epoxiconazole: LC_{50} = 3.14 mg/L (*O. mykiss*), EC_{50} = 8.69 mg/L (*Daphnia magna*)]
NW 265	The product is toxic for higher aquatic plants. [epoxiconazole: EbC_{50} = 0.0043 mg/L (*Lemna gibba*)] [ADEXAR (BAS 701 00F): ErC_{50} = 0.215 mg/L mg/L (*Lemna gibba*)]

Safety precautions / Conditions of use

Uses 00-001 – 00-021	NW 468 NW 605-1/606 (50% - 5m, 0% - 5m)

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

The recommended use pattern for Adexar includes application in cereals at a maximum application rate of up to 2 L product/ha. This maximum single application rate is equivalent to 2072 g product/ha.

Bees may be exposed to Adexar by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) are 3.0 and 2.4, respectively, thus, far below of the trigger of 50. It is concluded that Adexar will not adversely affect bees or bee colonies when used as recommended.

Other non-target arthropods

Non-target arthropods living in the crop can be exposed to residues from ADEXAR (BAS-70100-FW-0-EC) by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. Exposure of non-target arthropods living in non-target off-field areas to ADEXAR (BAS-70100-FW-0-EC) will mainly be due to spray drift from field applications.

The risk assessment is based on a ER_{50} of > 4 l Prod./ha derived from a 3 D study on *T.pyri.*.

Based on the calculated rates of ADEXAR (BAS-70100-FW-0-EC) in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria HQ ≤ 2 resp. TER ≥ 10 (Tier 1) or of less than 50% effects at calculated drift rates resp. TER ≥ 5 (higher Tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

3.1.6.4 Effects on Earthworms and Other Soil Marco-organisms (Part B, Section 6, Point 10.6)

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing fluxapyroxad and epoxiconazole whenever contamination of soil may occur as a result of the intended uses of ADEXAR (BAS-70100-FW-0-EC).

Relevant for the risk assessment are the chronic endpoints tested with earthworms (NOEC 87.9 mg product/ kg) and springtails (NOEC 12.5 mg product/kg).

Based on the predicted concentrations of ADEXAR (BAS-70100-FW-0-EC) in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10, but the longterm risk for other non-target soil organisms following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an unacceptable longterm risk for not-target soil organisms due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label. Further refinement is required.

The notifier submitted a higher tier study on Collembola (Schabio & Eichler, 2013).
In their report “BASF DoclD 2012/1143242”, Schabio and Eichler present the results of a survey designed in 2013 to investigate the effects of BAS 702 00 F on soil Collembola under field conditions.
In a weight of evidence approach it is considered that,

- firstly, the dosing in the study displayed much higher application rates as the intended uses of ‘Adexar’ (application rates approx doubled in the field study);
- secondly, the individual numbers in the first sampling date were fairly high, so that statistically significant effects on collembola abundance and on abundance of dominant species could in principle be detected;
- thirdly, effects on single species were detected at the first and second sampling date. One species was reduced at the third sampling date, but only in the lower application rate and not in the higher application rate;
- fourthly, the toxic reference had a statistically significant effects on collembola abundance and on single species (for some species detectable differences were found till the end of the experiment);
- fifthly, the application pattern of ‘Adexar’ according to the intended uses in the GAP of this application might well spam from beginning of April till Mai.

Therefore the risk for collembola community in the field after application of ‘Adexar’ according to the intended uses in the GAP of this application is considered acceptable.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

However, the active substance fluxapyroxad meets the trigger on degradation in soil ($DT_{90field}$= 370 d) and the potential chronic risk for matter breakdown resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) was assessed.

To assess potential effects of the exposure of ADEXAR (BAS-70100-FW-0-EC) on the breakdown of organic matter by soil organisms, two litter bag studies were carried out with ADEXAR (BAS 701 00 F). The first study (ICS-Nr 73862) was reported in the DAR and the EFSA Journal. The second study (ICS-Nr. 73863) was performed after submission of the EU Dossier for BAS 700 F for Annex I inclusion. For a summary, please refer to the core assessment.

The application rates applied in these studies reflected the worse case recommended GAP in cereals, however the resulting worst case PECsoil concentrations do not cover the predicted PECaccu calculations for the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals (1.71 and 4.2 mg a.s./kg soil for the worst case PECsoil from the studies and PECaccu calculations, respectively).

Moreover, in the study performed with the higher application rates, clear increases in litter bags degradation were observed. Although these biological effects were significantly smaller than 25%, they were clearly concentration dependent.

In agreement with current risk assessment according to the European Guidance Document on Terrestrial Ecotoxicology, the risk to soil macro-organisms following the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label can be considered as acceptable.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

For the active ingredients in ADEXAR (BAS-70100-FW-0-EC), fluxapyroxad and epoxiconazole and their metabolites, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil. Considering concurrent exposure to both the active ingredients in ADEXAR (BAS-70100-FW-0-EC) at the time of application, a low risk to soil microflora is also concluded.

Based on the predicted concentrations of ADEXAR (BAS-70100-FW-0-EC) in soils, the risk to soil microbial processes following exposure to fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Terrestrial plants

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. For details please refer to the core assessment Part B, section 6, chapter 6.9.

The risk assessment is based on a ER_{50} of > 2 l Prod./ha derived from a seedling emergence and a vegetative vigour study.

Based on the predicted rates of ADEXAR (BAS-70100-FW-0-EC) in off-field areas, the TER values describing the risk for non-target plants following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation of ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

Implications for labelling resulting from ecotoxicological assessment:

For the authorization of the plant protection product ADEXAR (BAS-70100-FW-0-EC) the following labelling and conditions of use are mandatory:

Classification and labelling

Relevant toxicity	E_rC_{50} = 0.215 mg/L ADEXAR/L (*Lemna gibba*) E_bC_{50} = 0.0063 mg ADEXAR/L (*Lemna gibba*)
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, dangerours for the environment
Risk phrases	R 50/53
Classification and labelling according to Regulation 1272/2008	
Hazard sysmbol	GHS09
Signal word	Warning
Hazard statement	H410 H411

Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use

All uses:

NW 468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Use No. 001-021:

NW 605-1 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".

Drift reduction by	90%	*
	75 %	*
	50%	5 m

NW 606 The only case in which the product may be applied without loss

reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro.

5 m

<u>Other labels</u>

NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 265	The product is toxic for higher aquatic plants.

3.1.7 Efficacy (Part B, Section 7, Point 8)

Adexar is a fungicide with a broad spectrum of activity against important leaf and ear diseases in wheat, barley, rye and triticale.

According to the results presented, the dose of 2.0 L/ha of Adexar provided the optimum overall level of activity and was effective against all the major cereal diseases for which activity of Adexar is claimed. As a result, the proposed rate of 2.0 L/ha should be considered as the minimum effective dose to deliver broad spectrum control under a wide range of environmental conditions. The presented data also demonstrated that Adexar, when applied at the proposed rate of 2.0 L/ha, gave at least an equivalent level of performance to the tested standard products against the different cereal diseases. Furthermore, measurements of the thousand grain mass and hL weight confirmed the response in terms of grain quality to applications of Adexar in the presence of fungal diseases. A positive response in grain quality is demonstrated for each use.

In conclusion, the results support the claim made in the introduction that Adexar is an efficient broad-spectrum fungicide which provides a positive control of important pathogens in cereals. The fungicide provides a rapid and particularly long-lasting fungicidal action against the pathogens listed.

Concerning to resistance risk it is concluded for both actives a medium to high risk depending on the pathogen. In the case of *Pyrenophora teres* resistant strains are currently found, thus, for the use no 011 a label advice is foreseen that resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management.

Adexar is classified as not harmful for populations of relevant beneficial insects but harmful for populations of relevant beneficial predatory mites and spiders. The use of the product poses no risk for soil quality.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.
With respect to analytical methods (formulation) an authorisation can be granted.
With respect to analytical methods for residues an authorisation can be granted.
With respect to toxicology, residues and consumer protection an authorisation can be granted.

From the efficacy point of view all applied uses can be granted for authorisation.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

An authorisation is recommended.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

Further groundwater monitoring data on the epoxiconazol metabolite 1,2,4 – triazole is required.

Appendix 1 – Copy of the product authorisation

- Will be inserted in the final version.

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions drawn by the competent authority. The final version of the label is not available, because the layout is the sole responsibility of the applicant and will not be checked again.

Appendix 3 – Letter of Access

- Will be inserted in the final version.
-

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.026958-00/00.81655

DATUM 2. Juni 2017

ZV1 026958-00/00

Adexar

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	62,5 g/l	Fluxapyroxad
	62,5 g/l	Epoxiconazol
Zulassungsnummer:	026958-00	
Versuchsbezeichnungen:	BAS-70100-FW-0-EC	
Antrag vom:	5. April 2013	

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 30. April 2020.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	**Schadorganismus/ Zweckbestimmung**	**Pflanzen/-erzeugnisse/ Objekte**	**Verwendungszweck**
026958-00/00-017	Braunrost (Puccinia recondita)	Roggen	
026958-00/00-021	Braunrost (Puccinia recondita)	Triticale	
026958-00/00-001	Braunrost (Puccinia recondita)	Weizen	
026958-00/00-003	DTR-Blattdürre (Drechslera tritici-repentis)	Weizen	
026958-00/00-009	Echter Mehltau (Erysiphe graminis)	Gerste	
026958-00/00-015	Echter Mehltau (Erysiphe graminis)	Roggen	
026958-00/00-019	Echter Mehltau (Erysiphe graminis)	Triticale	
026958-00/00-005	Echter Mehltau (Erysiphe graminis)	Weizen	
026958-00/00-002	Gelbrost (Puccinia striiformis)	Weizen	
026958-00/00-020	Halmbruchkrankheit (Pseudocercosporella herpotrichoides)	Triticale	
026958-00/00-004	Halmbruchkrankheit (Pseudocercosporella herpotrichoides)	Weizen	
026958-00/00-014	Minderung nichtparasitärer Blattflecken	Gerste	
026958-00/00-011	Netzfleckenkrankheit (Pyrenophora teres)	Gerste	
026958-00/00-012	Rhynchosporium secalis	Gerste	
026958-00/00-018	Rhynchosporium secalis	Roggen	

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
026958-00/00-007	Septoria nodorum	Weizen	
026958-00/00-022	Septoria-Arten (Septoria spp.)	Triticale	
026958-00/00-006	Septoria-Blattdürre (Septoria tritici)	Weizen	
026958-00/00-013	Sprenkelkrankheit (Ramularia collo-cygni)	Gerste	
026958-00/00-010	Zwergrost (Puccinia hordei)	Gerste	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

(NW468)

Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.

Begründung:

Aufgrund der Auswirkungen der Wirkstoffe Epoxiconazol und Fluxapyroxad gegenüber aquatischen Organismen (z.B. Epoxiconazol: NOECLemna gibba = 4,3 µg a.s./L) besitzt das o.g. Pflanzenschutzmittel einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d.h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels Adexar übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Auflage im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes (§ 1 Nr. 4 PflSchG) durchsetzbar zu begegnen.

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	**Verpackungs-material**	**Anzahl**		**Inhalt**		
		von	**bis**	**von**	**bis**	**Einheit**
Kanister	HDPE, fluoriert	1		50,00		l
Kanister	HDPE/PA	1		0,10	10,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Kennzeichnungsauflagen:

(NN3002)
Das Mittel wird als schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

(NW262)
Das Mittel ist giftig für Algen.

(NW264)
Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB110)
Die Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ist zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SF245-01)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

(SS110)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen beim Umgang mit dem unverdünnten Mittel.

(SS120)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS2101)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen beim Umgang mit dem unverdünnten Mittel.

(SS2202)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(SS530)
Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

(SS610)
Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

(WMFC2)
Wirkungsmechanismus (FRAC-Gruppe): C2

(WMFG1)
Wirkungsmechanismus (FRAC-Gruppe): G1

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Sonstige Auflagen:

(WH952)
Auf der Verpackung und in der Gebrauchsanleitung ist die Angabe zur Kennzeichnung des Wirkungsmechanismus als zusätzliche Information direkt jedem entsprechenden Wirkstoff-namen zuzuordnen.

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 5 PflSchG verbunden:

Dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit sind Unterlagen zu den nachfolgend aufgeführten Punkten und den dabei jeweils genannten Terminen vorzulegen:
Antragspunkt:
KIIA 7.12 (1,2,4-Triazol)
Termin:
31. Dezember 2017
Forderung:
Vorlage eines Konzeptes einer weiterführenden Grundwassermonitoringstudie für den Wirkstoff Epoxiconazol und den Metaboliten 1,2,4-Triazol innerhalb von 6 Monaten und anschließend die Vorlage von jährlichen Zwischenberichten und nach Rücksprache mit den beteiligten Behörden nach Abschluss der Studie einen Endbericht gem. § 36(5) PflSchG.
Begründung:
Mit Schreiben vom 29.04.2014 legte die TDMG den Report "Retrospective Survey of 1,2,4-Triazole in Groundwater Samples From Monitoring Sites in Areas With High Levels of Triazole Fungicide Usage" vor. Im Ergebnis des Survey sind laut TDMG keine Einträge des Metaboliten 1,2,4-Triazol > 0,1 µg/L im Grundwasser zu erwarten.
Der vorgelegte Bericht enthält zwar initiale Informationen über den Gehalt von 1,2,4-Triazol im Grundwasser aus bereits abgeschlossenen bzw. laufenden Monitoringstudien nach Anwendung in Getreide und Raps, kann aber das geforderte zulassungsbegleitende Grundwasser-Monitoring (mit den konservativeren Parametern (Zuckerrübe-, Gemüsekultur, Anwendungshäufigkeit, Wirkstoffauswahl) nicht ersetzen. Die Informationen aus dem vorgelegten Report (siehe oben) reichen nicht aus, um ein Grundwasserrisiko durch den Metaboliten 1,2,4-Triazol über die Anwendung von Pflanzenschutzmitteln auszuschließen.
Da der Metabolit 1,2,4-Triazol nicht in den Überwachungsprogrammen der Länderbehörden berücksichtigt ist und gemäß aktuellen Recherchen vermutlich auch nicht durch Wasserver-

sorgungsunternehmen im Grund- und Rohwasser untersucht wird, fehlen weiterhin geeignete Daten zur Bewertung des Grundwasserrisikos durch den Metaboliten. Zum Schutz der Ressource Grundwasser ist gem. Art. 4 Abs. 3 Buchstabe b der Verordnung (EG) Nr. 1107/2009 eine sichere Anwendung zu gewährleisten.
Die Forderung nach einem zulassungsbegleitenden Grundwasser-Monitoring für den o.g. Wirkstoff bleibt somit weiterhin bestehen. Auf die Notwendigkeit einer Abstimmung des Studiendesigns sowie potentieller Studienstandorte mit dem Umweltbundesamt wird ausdrücklich hingewiesen.

Unter Berücksichtigung der für die Erarbeitung dieser Unterlagen sowie ihrer Prüfung erforderlichen Zeitdauer sind die Studien zu den oben genannten Terminen vorzulegen. Ich weise darauf hin, dass mir § 36 Abs. 5 S. 3 PflSchG für den Fall der nicht fristgerechten Erfüllung dieser Auflage die Möglichkeit eröffnet, das Ruhen der Zulassung anzuordnen. Ferner eröffnet mir in diesem Fall § 49 Abs. 2 Nr. 2 VwVfG auch die Möglichkeit des Widerrufs der Zulassung.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H302)
Gesundheitsschädlich bei Verschlucken.

(H317)
Kann allergische Hautreaktionen verursachen.

(H319)

Verursacht schwere Augenreizung.

(H351)
Kann vermutlich Krebs erzeugen <Expositionsweg angeben, sofern schlüssig belegt ist, dass diese Gefahr bei keinem anderen Expositionsweg besteht>.

(H360Df)
Kann das Kind im Mutterleib schädigen. Kann vermutlich die Fruchtbarkeit beeinträchtigen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(H411)
Giftig für Wasserorganismen, mit langfristiger Wirkung.

(EUH 208-0167)
Enthält Purasolve (2-ethylhexyl-S-Lactat). Kann allergische Reaktionen hervorrufen.

(EUH 401)
Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):
(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):
- keine -

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB6641)
Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)
Das Mittel wird als nicht schädigend für Populationen relevanter Nutzinsekten eingestuft.

Weitere Hinweise und Bemerkungen
Momentan gibt es aus dem Bereich der toxikologischen Bewertung seitens des BVL keinen Vorschlag für P-Sätze gemäß Verordnung (EG) Nr. 1272/2008 (CLP-Verordnung).

Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 026958-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 69
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Gelbrost (Puccinia striiformis)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: DTR-Blattdürre (Drechslera tritici-repentis)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Halmbruchkrankheit (Pseudocercosporella herpotrichoides)

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Stadium der Kultur: 30 bis 32

Anwendungszeitpunkt: Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1
- für die Kultur bzw. je Jahr: 2

Anwendungstechnik: spritzen

Aufwand:

- 2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Weizen
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Echter Mehltau (Erysiphe graminis)
Pflanzen/-erzeugnisse/Objekte:	Weizen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die $EbC50 = 4,3$ µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Septoria-Blattdürre (Septoria tritici)
Pflanzen/-erzeugnisse/Objekte:	Weizen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die $EbC50$ = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-007

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Septoria nodorum

Pflanzen/-erzeugnisse/Objekte: Weizen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Weizen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-009

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Echter Mehltau (Erysiphe graminis)
Pflanzen/-erzeugnisse/Objekte:	Gerste
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen
- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
Begründung:
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-010

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Zwergrost (Puccinia hordei)
Pflanzen/-erzeugnisse/Objekte:	Gerste
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-011

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Netzfleckenkrankheit (Pyrenophora teres)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(WW7041)
Für den Wirkstoff, bzw. einen Wirkstoff dieses Mittels, wurden Resistenzen nachgewiesen. Anwendung nur im Rahmen eines geeigneten Resistenzmanagements.

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-012

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rhynchosporium secalis

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-013

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Sprenkelkrankheit (Ramularia collo-cygni)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-014

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Minderung nichtparasitärer Blattflecken
Pflanzen/-erzeugnisse/Objekte:	Gerste
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	32 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
- Erläuterungen:	bei anfälligen Sorten und bei Anstieg der Globalstrahlung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Gerste Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils gel-

tenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-015

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Echter Mehltau (Erysiphe graminis)
Pflanzen/-erzeugnisse/Objekte:	Roggen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Roggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-017

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Roggen

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 69
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Roggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-018

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Rhynchosporium secalis
Pflanzen/-erzeugnisse/Objekte:	Roggen
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Roggen Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
Begründung:
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-019

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Triticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-020

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Halmbruchkrankheit (Pseudocercosporella herpotrichoides)
Pflanzen/-erzeugnisse/Objekte:	Triticale
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 32
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Triticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten

Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
<u>Begründung:</u>
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
<u>Begründung:</u>
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-021

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (Puccinia recondita)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 69
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F)	Freiland: Triticale Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

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reduzierte Abstände: 50% 5 m, 75% *, 90% *
Begründung:
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
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5 m
Begründung:
Siehe unter NW605-1.

Anlage 1 zugelassene Anwendung: 026958-00/00-022

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Septoria-Arten (Septoria spp.)

Pflanzen/-erzeugnisse/Objekte: Triticale

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 61
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	2
- für die Kultur bzw. je Jahr:	2
- Erläuterungen Anzahl Behandlungen:	zeitlicher Abstand der Behandlungen mindestens 21 Tage
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

(F) Freiland: Triticale
Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmin-

dernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 5 m, 75% *, 90% *
Begründung:
Das Pflanzenschutzmittel Adexar bzw. der darin enthaltene Wirkstoff Epoxiconazol weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Wasserpflanen auf. Bewertungsbestimmend ist hier die EbC50 = 4,3 µg a.s./L, Lemna gibba.
Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 8 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Epoxiconazol in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Bewertungsbericht zu entnehmen.

(NW606)
Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.
5 m
Begründung:
Siehe unter NW605-1.

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information
Detailed summary of the risk assessment

Product code:	**BAS 701 00 F (Adexar)**	
Active Substance:	**epoxiconazole**	**62.5 g/L**
	fluxapyroxad	**62.5 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**BASF SE Germany**
Submission Date:	**15/03/2013**
Date:	**02 June 2017**

Table of Contents

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product Adexar (BAS 701 00 F) containing the active substances epoxiconazole and fluxapyroxad which were approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Epoxiconazole** (Reg. (EU) No 540/2011)	**Fluxapyroxad** (Reg. (EU) No 589/2012)
Purity of active substance	min 920 g/kg	min 950 g/kg
Relevant impurities	–	Toluene: max 1 g/kg

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of Adexar (BAS 701 00 F) can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

BASF SE
Crop protection
Global registration management
P.O. Box 120
D-67114 Limburgerhof
Germany

Contact person: [redacted]
Tel.No:
Fax No:
E-mail:

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Epoxiconazole: minimum 920 g/kg

Fluxapyroxad: minimum 980 g/kg

relevant impurity: toluene max 0.6 g/kg

Further information/justification is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name: Adexar, Morex, Pexan, Tenax XM

Company code number: BAS 701 00 F

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure epoxiconazole:	62.5 g/L
content of pure fluxapyroxad:	62.5 g/L

limits epoxiconazole:	56.3 - 68.8 g/L
limits fluxapyroxad:	56.3 - 68.8 g/L

Technical active substance:

content of technical epoxiconazole at minimum purity (92.0 %):	67.9 g/L	(6.5 % w/w)
content of technical fluxapyroxad at minimum purity (98.0 %):	63.8 g/L	(6.1 % w/w)

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number	
1.4.3.1	ISO common name	Epoxiconazole	Fluxapyroxad
1.4.3.2	CAS No.	135319-73-2	907204-31-3
1.4.3.2	EINECS No.	–	–
1.4.3.2	CIPAC No.	609	828
1.4.3.2	ELINCS	406-850-2	–
1.4.3.3	Salt, ester anion or cation present	–	–

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

BAS 701 00 F does not contain any impurity in a concentration of toxicological, ecotoxicological or environmental significance.

In fluxapyroxad, toluene has been considered as relevant and its content in the technical material should not exceed 1 g/kg (see regulation (EU) No 589/2012). The origin of this impurity is given in the draft assessment report Vol 4 for Annex I inclusion/Approval of fluxapyroxad.

Toluene is not a decomposition product and therefore cannot be generated from the active ingredient or the related impurities during storage.

Epoxiconazole does not contain any impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type: Emulsifiable concentrate Code: EC

IIIA 1.6 Function

The product will be used as fungicide.

IIIA 1.7 Other/Special Studies

Evaluations in chapter 9 of this dossier refer to physical-chemical data on epoxiconazole which have not yet been peer reviewed. These data are summarized in appendix 3.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

Table 1: Summary of the physical, chemical and technical properties of the plant protection product

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and physical state (IIIA 2.1)	Visual assessment and organoleptic determination	Batch 204438, fluxapyroxad: 61.9 g/L; epoxiconazole: 62.0 g/L	The preparation is a clear red-brown liquid with a moderate aromatic odour. The product shows no change after storage at 54 °C for 14 d or 2 years at ambient temperature.	Y	Kroehl, T., 2008a, 2008/1083472 Kroehl, T., 2011a, 2011/1048128	Acceptable
Explosive properties (IIIA 2.2.1)	OECD 113	Batch 204423, fluxapyroxad: 62.4 g/L; epoxiconazole: 62.7 g/L	The exothermic decomposition energy determined by a DSC is < 500 J/g. The test substance is not considered to have explosive properties	Y	Fischer, S., 2008a, 2008/1009261	Acceptable.
Oxidizing properties (IIIA 2.2.2)	EEC A 21	Batch 204423,	The main pressure rise time of the test mixture is longer than the main pressure rise time of the reference mixture. The test substance is not considered to be an oxidising substance	Y	Fischer, S., 2008a, 2008/1009261	Acceptable.
Flash point (IIIA 2.3.1)	EEC A 9	Batch 204438	Flash point 96 °C	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.
		Batch 204423	Flash point 102.5 °C	Y	Fischer, S., 2008a, 2008/1009261	
Flammability (IIIA 2.3.2)	UN Recommen-dations on the	Batch 204423	Experience shows that the substance forms stable emulsion in water and	Y	Fischer, S., 2008a, 2008/1009261	Acceptable as additional

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	transport of dangerous good, Manual of tests and criteria, Appendix 6		it is not expected to liberate a gas in contact with water.			information
Auto-flammability (IIIA 2.3.3)	EEC A15	Batch 204423	Auto-flammability app. 282 °C (self-ignition temperature)	Y	Fischer, S., 2008a, 2008/1009261	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)			not required, based on pH of the formulation	Y		Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	Batch 204438	Before storage: pure water, 20 °C: 5.1 CIPAC water D: 5.4 After 2 weeks, 54 °C: pure water, 20 °C: 4.9 CIPAC water D: 5.1 After 7 days, 0° C: pure water, 20 °C: 5.1 CIPAC water D: 5.3 After 2 years, 23 °C: pure water, 20 °C: 4.6 CIPAC water D, 1.0 %: 4.5	Y	Kroehl, T., 2008a, 2008/1083472 Kroehl, T., 2011a, 2011/1048128	Acceptable.
Kinematic viscosity (IIIA 2.5.1)	OECD 114	Batch 204438	40 °C: 8.9×10^{-6} m²/s (calculated)	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable. R 65 is not triggered, but aspiration hazard, Cat 1 / H304 is

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
						possible.
Dynamic viscosity (IIIA 2.5.2)	OECD 114	Batch 204438	shear rate = 100 s^{-1}: 20 °C: 20.9 mPa s 40 °C: 9.1 mPa s	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.
		Batch 204438	After 2 years, 23 °C: 20.2 mPa s	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable.
Surface tension (IIIA 2.5.3)	OECD 115 / EEC A5.	Batch 204438	0.08 %, 20 °C: 32.5 mN/m 2.0 %, 20 °C: 30.5 mN/m neat, 25 °C: 31.7 mN/m	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.
Relative density (IIIA 2.6.1)	EEC A 3	Batch 204438	Before storage: d_4^{20} = 1.036 After 2 weeks, 54 °C: d_4^{20} = 1.036	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.
		Batch 204438	After 2 years, 23 °C: d_4^{20} = 1.036	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable.
Bulk or tap density (IIIA 2.6.2)			not required for liquid formulations			Acceptable.
Storage Stability after 14 days at 54º C (IIIA 2.7.1)	CIPAC MT 46.3 HPLC/RP-AFL0755/02	Batch 204438	Storage material: PA/PE- coextruded packs. The content of the active substance does not decrease > 5 %. Content of epoxiconazole: before storage: 62.00 g/L after storage: 61.68 g/L Content of fluxapyroxad: before storage: 61.93 g/L	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
			after storage: 61.95 g/L The changes of the physical and chemical properties are negligible.			
Stability after storage for other periods and/or temperatures (IIIA 2.7.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Minimum content after heat stability testing (IIIA 2.7.3)			The content of the active substance does not decrease > 5 %.			Acceptable.
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3 CIPAC MT 1	Batch 204438	Homogeneous liquid with < 0.05 ml crystalline separation. The product shows good low temperature stability, the effects are negligible. The crystallisation temperature was found to be < -20° C	Y (N)	Kroehl, T., 2008a, 2008/1083472	Acceptable.
Ambient temperature shelf life (IIIA 2.7.5)	2 years, 23 °C: HPLC AFL0755/02 GC/MS APL0594/01	Batch 204438, fluxapyroxad: 61.9 g/L; epoxiconazole: 62.0 g/L	Storage material: PA/PE-coextruded packs (0.25 and 1 L) Average temperature: 23 °C. Content of epoxiconazole: before storage: 62.0 g/L after storage: 62.7 g/L Content of fluxapyroxad: before storage: 61.9 g/L after storage: 62.6 g/L Content of toluene:	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable. Study will be continued to the 156 week data point.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			Only after storage: 0.025 g/L Seal intact, no corrosion and no other influence of the product on the original container was observed. The emulsion stability tests showed traces of precipitated material after 24 hours of standing time, which could not be re-emulsified completely. The formulation is based on partly water soluble solvent. Due to the dissolution of the EC-solvents in water and the very poor water solubility of the active ingredient fluxapyroxad, the solvation capacity of solvents decreases in water. Thus, a time depending (> 2h waiting period) formation of solid particles in form of precipitated solid active ingredient fluxapyroxad is observed. However the results of the suspensibility test after 2 and 24 hours standing time, showed that sufficient amount of the active substances (99 – 101 %) are suspended in the spray liquid to give a good and homogeneous mixture during spraying.			
Shelf life in months	-		Please refer to 2.7.5			Acceptable.

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
(if less than 2 years) (IIIA 2.7.6)						
Wettability (IIIA 2.8.1)			not required for liquid formulations			Acceptable.
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	Batch 204438	CIPAC water D, 0.08 %: Before storage 10s: 20 mL 1 min: 14 mL 3 min: 12 mL 12 min: 8 mL 2 weeks, 54 °C 10s: 16 mL 1 min: 14 mL 3 min: 12 mL 12 min: 10 mL CIPAC water D, 2.0 %: Before Storage 10s: 10 mL 1 min: 8 mL 3 min: 6 mL 12 min: 6 mL 2 weeks, 54 °C 10s: 10 mL 1 min: 6 mL 3 min: 6 mL 12 min: 2 mL	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch 204438	CIPAC water D, 0.08 %: After 2 years, 23 °C: 10s: 24 mL 1 min: 18 mL 3 min: 16 mL 12 min: 12 mL CIPAC water D, 2.0 %: After 2 years, 23 °C: 10s: 8 mL 1 min: 4 mL 3 min: 0 mL 12 min: 0 mL	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable.
Suspensibility (IIIA 2.8.3.1)	CIPAC MT 184	Batch 204438	After 2 years, 23 °C: CIPAC water D, 0.08 %: Standing time 2 h: Epoxiconazole: 99 % Fluxapyroxad: 99 % Standing time 24 h: Epoxiconazole: 101 % Fluxapyroxad: 100 % CIPAC water D, 2.0 %: Standing time 2 h: Epoxiconazole: 99 % Fluxapyroxad: 99 % Standing time 24 h: Epoxiconazole: 99 %	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable. Study was conducted based on not completlely re-emulsifiability after two years at ambient temperature, see. 2.7.5 and 2.8.7.1.

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
			Fluxapyroxad: 99 %			
Spontaneity of dispersion (IIIA 2.8.3.2)			not required for EC formulations			Acceptable.
Dilution stability (IIIA 2.8.4)			not required for EC formulations			Acceptable.
Dry sieve test (IIIA 2.8.5.1)			not required for EC formulations			Acceptable.
Wet sieve test (IIIA 2.8.5.2)			not required for EC formulations			Acceptable.
Particle size distribution (IIIA 2.8.6.1)			not required for EC formulations			Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)			not required for EC formulations			Acceptable.
Dust content (IIIA 2.8.6.3)			not required for EC formulations			Acceptable.
Particle size of dust (IIIA 2.8.6.4)			not required for EC formulations			Acceptable.
Friability and attrition (IIIA 2.8.6.5)			not required for EC formulations			Acceptable.
Emulsifiability (IIIA 2.8.7.1)	CIPAC MT 36.3	Batch 204438	CIPAC water A and D, 0.08 %: Before storage 0 h: spontan emulsifiable little froth 0.5 h: 0 mL cream 0 mL oil	Y	Kroehl, T., 2008a, 2008/1083472	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			0 mL sediment 2 h: 0 mL cream 0 mL oil 0 mL sediment/cream 24 h: traces of solid material spontan re-emulsifiable 24.5 h: 0 mL cream 0 mL oil 0 mL sediment/cream After 2 weeks, 54 °C 0 h: spontan emulsifiable little froth 0.5 h: 0 mL cream 0 mL oil 0 mL sediment 2 h: 0 mL cream 0 mL oil 0 mL sediment/cream 24 h: traces of solid material spontan re-emulsifiable 24.5 h: 0 mL cream 0 mL oil 0 mL sediment CIPAC water D, 2.0 %: Before storage 0 h: spontan emulsifiable no froth 0.5 h: <1 mL cream 0 mL oil 0 mL sediment 2 h: <1 mL cream 0 mL oil 0 mL sediment			

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			24 h: 1 mL oil spontan re-emulsifiable 24.5 h: <1 mL cream 0 mL oil 0 mL sediment After 2 weeks, 54 °C 0 h: spontan emulsifiable little froth 0.5 h: <1 mL cream 0 mL oil 0 mL sediment 2 h: <1 mL cream 0 mL oil 0 mL sediment/cream 24 h: spontan re-emulsifiable 24.5 h: <1 mL cream 0 mL oil 0 mL sediment			
Emulsifiability (IIIA 2.8.7.1)	CIPAC MT 36.3	Batch 204438	After 2 years, 23 °C: CIPAC water a and D, 0.08 %: 0 h: spontan emulsifiable no froth 0.5 h: 0 mL cream 0 mL oil 0 mL sediment 2 h: 0 mL cream 0 mL oil 0 mL sediment 24 h: traces of solid material not completely re-emulsifiable 24.5 h: 0 mL cream 0 mL oil 0 mL sediment	Y	Kroehl, T., 2011a, 2011/1048128	Acceptable. Solvents in formulation are partly water soluble

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			traces of solid material CIPAC water D, 2.0 %: 0 h: spontan emulsifiable no froth 0.5 h: 0 mL cream <1 mL bottom oil 0 mL sediment 2 h: 0 mL cream <1 mL bottom oil 0 mL sediment 24 h: <1 mL bottom oil spontaneously re-emulsifiable 24.5 h: 0 mL cream 0 mL oil 0 mL sediment			
Dispersibility (IIIA 2.8.7.1)			not required for EC formulations			Acceptable.
Flowability (IIIA 2.8.8.1)			not required for EC formulations			Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)			not required for EC formulations			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			not required for EC formulations			Acceptable.
Physical compatibility of tank mixes (IIIA 2.9.1)	ASTM 1518-05 - mixing by hand - evaluation after standing for different	Batch 204423	Adexar (BAS70100F) was tested for physical compatibility with 9 formulations of the types EC, SC, WG and SL. All mixtures were	N	Auweter, H., 2009a, 2009/1070974	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	times - additional characteri-zations		determined to be physically compatible and can be used in spray applications. In all mixtures no lumping, no flocculation occurred, but a running agitator should be used in all mixtures. The mixtures appeared to be homogeneous.			
Chemical compatibility of tank mixes (IIIA 2.9.2)	ASTM 1518-05 - mixing by hand - evaluation after standing for different times - additional characterizations	Batch 204423	Fluxapyroxad and Epoxiconazol, the active substances Adexar (BAS70100F), are stable in diluted aqueous conditions. Therefore none of the functional groups are likely to react under normal tank mix conditions. Corbel, Comet/ Platoon, Flexity, CCC 750, Terpal, Medax Top, Starane 200, Mageos MD, and Sumicidin Alpha are approved commercial products for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed. Therefore BAS70100F is apparently chemically compatible with the tested products.	N	Auweter, H., 2009a, 2009/1070974	Acceptable.

Test or study & Annex point	**Method used / deviations**	**Test material purity and specification**	**Findings**	**GLP Y/N**	**Reference**	**Acceptability / comments**
Distribution to seed (IIIA 2.10.1)			not intende for seed treatment			Acceptable
Adhesion to seeds (IIIA 2.10.2)			not intended for seed treatment			Acceptable
Miscibility (IIIA 2.11)			Not required by regulation (EU) 2011/545.			Acceptable.
Dielectric breakdown (IIIA 2.12)			Not required by regulation (EU) 2011/545.			Acceptable.
Corrosion characteristics (IIIA 2.13)			Not required by regulation (EU) 2011/545.			Acceptable.
Container material (IIIA 2.14)			Not required by regulation (EU) 2011/545.			Acceptable.
Other/special studies (IIIA 2.15)			none			Acceptable.

IIIA 2.16 Summary and Evaluation of Data Presented Under Points 2.1 to 2.15

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a clear red-brown liquid with a moderate aromatic odour. It is not explosive, has no oxidizing properties, the self ignition temperature is 282 °C. In aqueous solution, it has a pH value around 5.0. The observed changes of the active substance content and the physical properties after 24 months storage at 23 °C are negligible. Therefore, the formulation meets the requirements of the shelf life specifications for at least 2 years under practical conditions.

Although after 52 weeks storage at 23 °C in the emulsion stability test some precipitation of the active ingredient occurred, additional tests on suspensibility have shown that the product can be applied without adverse effects under practical use conditions.

The technical characteristics are acceptable for an emulsifiable concentrate formulation.

Experimental testing of the product's physico-chemical and technical characteristics:

No experimental testing was conducted at the BVL laboratory.

Implications for labelling:

None.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Insert information.

IIIA 3.2 Nature of the Effects on Harmful Organisms

Insert information on mode of action and effects.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

IIIA 4.1 Packaging and Compatibility with the Preparation

Packaging Summary

Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

IIIA 4.1.1 Description and specification of the packaging

Adexar (BAS701 00 F) is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE). They are sealed by foil seals, protected by screw caps of polyethylene.

0,15 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
0,25 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 63 mm diameter x 126 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
0,5 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 69 mm diameter x 185 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
1 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	approx. 42 mm inner diameter
	closure:	Polypropylene/Polyethylene screw cap
	seal:	Induction seal
1 litre eco-bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	approx. 54 mm inner diameter
	closure:	Polypropylene/Polyethylene screw cap
	seal:	gasket
3 litre container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 190 mm x 140 mm x 241 mm
	opening:	approx. 54 mm inner diameter
	closure:	polyethylene screw cap
	seal:	Induction seal
5 litre container	Material	PA/PE (Coex)
	Shape/size:	rectangular / approx. 190 mm x 140 mm x 313 mm
	Opening:	54 mm inner diameter
	Closure:	polypropylene screw cap
	Seal:	HF-seal

5 litre eco-container	Material	PA/PE (Coex)
	Shape/size:	rectangular / approx. 185 mm x 136 mm x 313 mm
	Opening:	54 mm inner diameter
	Closure:	polypropylene screw cap
	Seal:	gasket
10 litre container	Material	PA/PE (Coex)
	Shape/size:	rectangular / approx. 230 mm x 165 mm x 375 mm
	Opening:	54 mm inner diameter
	Closure:	polypropylene screw cap
	Seal:	induction-seal
10 litre eco-container	Material	PA/PE (Coex)
	Shape/size:	rectangular / approx. 230 mm x 187 mm x 358 mm
	Opening:	54 mm inner diameter
	Closure:	polypropylene screw cap
	Seal:	gasket

IIIA 4.1.2 Suitability of the packaging and closures

Report:	4.1.2/1, Schreiner B., 2009a
Title:	BAS 701 00 F, EU-Performance-Test, AGRO-Packagings (<= 10 L) made of HDPE with fluorinated barrier
Document No:	BASF DocID 2009/1041497
Guidelines:	<none>
GLP	No, not subject to GLP regulations

The damaging effects of BAS 701 00 F on test specimens made of HDPE with fluorinated barrier does not exceed the damaging effects of the model liquid Pfl-Fr 2323. The chemical compatibility of the HDPE with fluorinated barrier material with the intended product in comparison with model liquid Pfl-Fr 2323 is verified. Rate of permeation: <0.008 g/lh; approved.

The packaging complies with ADR/RID regulations having been tested using the test methods in accordance with ADR and appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued. They are labelled individually with all the use instructions.

Report:	Schreiner, B. , 2009b
Title:	BAS 701 00 F, EU-Performance-Test, AGRO-Packagings (<= 10 L) made of Coex-materials (HDPE with barrier layer)
Document No:	BASF Doc ID 2009/1041498

Guidelines:	<none>
GLP	No, not subject to GLP regulations

The damaging effects of BAS 701 00 F on test specimens made of Coex PE/PA material does not exceed the damaging effects of the model liquid Pfl-Fr 2323.

The chemical compatibility of the Coex (PA/PE) material with the intended product in comparison with model liquid Pfl-Fr 2323 is verified. Rate of permeation: <0.008 g/lh; approved.

The packaging complies with ADR/RID regulations having been tested using the test methods in accordance with ADR and appropriate to the pack type and material and classification of the contents and an appropriate UN certificate issued. They are labelled individually with all the use instructions.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Kroehl, T., 2009a
Title:	BAS 700 F/Epoxiconazole 62.5/62.5 g/L EC - chemical and physical stability of formula BAS 701 00 F when stored for up to 3 years in PA/PE-coextruded packs
Document No:	BASF Doc ID 2009/1100382
Guidelines:	OECD Principles of Good Laboratory Practice, GLP Principles of the German Chemikaliengesetz (Chemicals Act)
GLP	Yes

After 52 weeks storage at 23°C the PA/PE-coextruded packs remain in good condition. No corrosion and no other influence of the product on the original container were observed. Neither the appearance of the product nor its properties are altered by the container material. An interaction between BAS 701 00 F and its original container was not observed.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Report:	Nolte, M., 2008a
Title:	BAS 701 00 F: Effectiveness of procedures for cleaning application equipment and protective clothing
Document No:	BASF Doc ID 2008/1028071
Guidelines:	<none>
GLP	No, not subject to GLP regulations

Any surplus spray mix is to be diluted at the ratio 1:10 with water, and to be sprayed onto the previously treated area, according to the use instructions. Common agricultural practice implies cleaning of application equipment with water. This will remove any remainders of BAS 701 00 F so efficiently that no plant damage can be caused when the equipment is used subsequently for the treatment of different crops.

Protective clothing will be cleaned effectively when washed with usual laundry detergents.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	Nolte, M., 2008a
Title:	BAS 512 00 F: Effectiveness of procedures for cleaning application equipment and protective clothing
Document No:	BASF Doc ID 2008/1028071
Guidelines:	<none>
GLP	No, not subject to GLP regulations

The highest recommended concentration for BAS 701 00 F is 2 litre formulation/ha in minimum 100 litre water/ha. Any surplus spray mix is to be diluted at the ratio 1:10 with water, and to be sprayed onto the previously treated area, according to the use instructions. This remainder is diluted during the preparation of the next 1000L spray broth. Only 0.3% of the original concentrations of A.I. are left over in the new filling.

There is a large safety margin that plan damage can be excluded when the application equipment is subsequently used for crop treatment again.

When the field sprayer is being cleaned with water after the use of BAS 701 00 F in the worst possible case, the contamination in the spray liquid immediately afterwards is negligible.

The protective clothes of the applicators of agrochemicals are usually made of cotton. The polar surface of the fibre presents little affinity to the non-polar active ingredients. Therefore, usual laundering with detergents will either suspend or dissolve any contamination efficiently.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

The safety data sheet contains advice for the use and transportation of the product based on scientific tests.

IIIA 4.4.1 Warehouse storage

See chapter 4.4

IIIA 4.4.2 User level storage

See chapter 4.4

IIIA 4.4.3 Transport

See chapter 4.4

IIIA 4.4.4 Fire

See chapter 4.4

IIIA 4.4.5 Nature of protective clothing proposed

See chapter 4.4

IIIA 4.4.6 Characteristics of protective clothing proposed

See chapter 4.4

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

See chapter 4.4

IIIA 4.4.8 Procedures to minimise the generation of waste

See chapter 4.4

IIIA 4.4.9 Combustion products likely to be generated in the event of fire

See chapter 4.4

IIIA 4.5 Detailed Procedures for Use in the Event of an Accident During Transport, Storage or Use

The safety data sheet contains advice for the use and transportation of the product based on scientific tests.

IIIA 4.5.1 Containment of spillages

See chapter 4.5

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

See chapter 4.5

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

See chapter 4.5

IIIA 4.5.4 Protection of emergency workers and bystanders

See chapter 4.5

IIIA 4.5.5 First aid measures

See chapter 4.5

IIIA 4.6 Neutralisation Procedure for Use in the Event of Accidental Spillage

IIIA 4.6.1 Details of proposed procedures for small quantities

A neutralization procedure for small quantities of BAS 701 00 F cannot be proposed

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

See point 4.6.1

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

See point 4.6.1

IIIA 4.6.4 Details of proposed procedures for large quantities

A neutralization procedure for large quantities of BAS 701 00 F cannot be proposed.

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

See point 4.6.4

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

See point 4.6.4

IIIA 4.7 Pyrolytic Behaviour of the Active Substance

Due to halogen content in the active ingredient and the formulants of less than 60 %, combustion of BAS 701 00 F in a waste incinerator plant does not raise concern about the formation of halogenated dibenzodioxins/-furans.

IIIA 4.8 Disposal Procedures for the Plant Protection Product

IIIA 4.8.1 Detailed instructions for safe disposal of product and its packaging

For purposes of disposal, combustion of BAS 701 00 F in a licensed incinerator is recommended. This method of disposal applies also to contaminated packages, which cannot be cleaned or reused. Although it is possible to incinerate the product at lower temperatures, combustion at approx. 1100 °C with a residence time of about 2 sec. is advised. By doing so, i.e., operating the incinerator according to the conditions laid down in council directive 94/67/EEC respectively in directive 2000/76/EC of the European Parliament, one will achieve complete combustion and minimize the formation of undesired by-products in the off-gases.

Users are requested to triple rinse empty primary packages as described in the ECPA "Guidelines for the rinsing of agrochemical containers", 1993. Pressure rinsing or integrated pressure rinsing of the packaging material achieves a similar or even better result. The rinse must be added to the spray liquid.

To minimize waste of packages it is recommended that empty and rinsed containers be delivered to local container collection stations. If these do not exist, empty and rinsed containers must be rendered unusable and disposed of according to local regulations.

IIIA 4.8.2 Methods other than controlled incineration for disposal

No other methods for disposal of BAS 701 00 F than those described under 4.8.1 are available.

IIIA 4.9 Other/Special Studies

The studies mentioned in the previous sections were deemed to be sufficient.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

See EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

MRLs are set at European level; see Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

Proposals for classification and labeling of BAS 701 00 F in accordance with the EC Directive on dangerous preparations 1999/45/EC and Directive 2001/59/EC (as amended) are presented below:

Physico-chemical properties

Table 11.3-1 Physico-chemical properties

Study Type	**Findings** **(triggered risk phrase)**	**Reference**
Explosivity	Not explosive (-)	Fischer, S., 2008a, 2008/1009261
Oxidizing properties	Not oxidizing (-)	Fischer, S., 2008a, 2008/1009261
Flammability	Auto-ignition temperature is 282 °C	Fischer, S., 2008a, 2008/1009261
Content of hydrocarbon	approx. 30 % w/w (-)	Composition see part C
Viscosity	The kinematic viscosity at 40°C is $8.9 \cdot 10^{-6}$ m^2s^{-1}	Kroehl, T., 2008a, 2008/1083472
Surface tension	neat, 25 °C: 31.7 mN/m	Kroehl, T., 2008a, 2008/1083472

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used in support of the evaluation

Annex point/ reference No (OECD)	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.1, 2.3.1, 2.4.2, 2.5.1, 2.5.2, 2.5.3, 2.6.1, 2.7.1, 2.7.4, 2.8.2, 2.8.7.2, 2.8.7.3	Kroehl, T.	2008	BAS 700 F/Epoxiconazole 62.5/62.5 g/L EC - physical and chemical properties of formula BAS 701 00 F - accelerated storage stability for up to 2 weeks at 54°C in PA/PE-coextruded packs, 2008/1083472! 311607_2, GLP: Y, published: N	Y	BAS	1
KIIIA1 2.1, 2.4.2, 2.7.2, 2.8.2, 2.8.7.2, 2.8.7.3	Kroehl, T.	2009	BAS 700 F/Epoxiconazole 62.5/62.5 g/L EC - chemical and physical stability of formula BAS 701 00 F when stored for up to 3 years in PA/PE-coextruded packs - 52 weeks report 2009/1100382! 311611_2 GLP: Y, published: N	Y	BAS	5
KIIIA1 2.2.1, 2.2.2, 2.3.1, 2.3.2, 2.3.3	Fischer, S.	2008	Evaluation of physical and chemical properties according to Directive 94/37/EC (67/548/EC Annex V) 2008/1009261! SIK08/0547 GLP: Y, published: N	Y	BAS	1

Annex point/ reference No (OECD)	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 2.4.2, 2.5.2, 2.6.1, 2.7.5, 2.8.2, 2.8.3.1, 2.8.7.1	Kroehl, T.	2011	BAS 700 F/Epoxiconazole 62.5/62.5 g/L EC - chemical and physical stability of formula BAS 701 00 F when stored for up to 3 years in PA/PE-coextruded packs - 104 weeks report 2011/1048128! 311611_2 GLP: Y, published: N 2518464 /	Y	BAS	1
KIIIA1 2.9.1 (OECD)	Auweter, H.	2009	Physical and chemical compatibility in aqueous tank mixtures of BAS 701 00 F 2009/1070974 GLP: N, published: N 2438154 /	Y	BAS	1
KIIIA1 2.9.2 (OECD)	Auweter, H.	2009	Physical and chemical compatibility in aqueous tank mixtures of BAS 701 00 F 2009/1070974 GLP: N, published: N 2438156 /	Y	BAS	1
KIIIA 4.1.2/1	Schreiner B.	2009 a	BAS 701 00 F, EU-Performance-Test, AGRO-Packagings (<= 10 L) made of HDPE with fluorinated barrier BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2009/1041497 No, not subject to GLP regulations Unpublished	No	BASF	1

Annex point/ reference No (OECD)	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA 4.1.2/2	Schreiner B.	2009 b	BAS 701 00 F, EU-Performance-Test, AGRO-Packagings (<= 10 L) made of Coex-materials (HDPE with barrier layer) BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2009/1041498 No, not subject to GLP regulations Unpublished	No	BASF	1
KIIIA 4.2.1/1	Nolte M.	2008 a	BAS 701 00 F: Effectiveness of procedures for cleaning application equipment and protective clothing BASF SE, Limburgerhof, Germany Fed.Rep. 2008/1028071 No, not subject to GLP regulations Unpublished	No	BASF	1
KIIIA 4.2.2/1	Nolte M.	2008 a	BAS 701 00 F: Effectiveness of procedures for cleaning application equipment and protective clothing BASF SE, Limburgerhof, Germany Fed.Rep. 2008/1028071 No, not subject to GLP regulations Unpublished	No	BASF	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2: Critical Uses – Justification and GAP tables

See B.7

GAP rev. (No), date: year-month-day

PPP (product name/code)	**product name / code**	**Formulation type:**	**type**
active substance 1	**active substance 1**	**Conc. of as 1:**	**conc.**
active substance 2	**active substance 2**	**Conc. of as 2:**	**conc.**
active substance …	**active substance ...**	**Conc. of as:…**	**conc.**
safener safener		**Conc. of safener:**	**conc.**
synergist	**synergist**	**Conc. of synergist:**	**conc.**
Applicant:	**company**	**professional use**	☐
Zone(s):northern/central/southern/EU		**non professional use**	☐

Verified by MS: yes/no

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001												
002												
003												
004												
005												

Appendix 3: Physical and chemical properties of the active substance epoxiconazole

These following data refer to studies that have been submitted to match protected data.

Section (Annex point)	Study	Purity [%]	Method	Results	Reference	Acceptability / Comments
B.2.1.3.1 (IIA 2.3)	Vapour pressure	99.6	EEC A 4; OECD 104	3.5×10^{-7} Pa (20°C) 8.8×10^{-7} Pa (25°C) extrapolated from measurements between 100 °C - 130 °C	Kroehl, 2008 (BVL no 2438126)	acceptable additional information *LOEP:* *< 1 x 10^{-5} Pa (20 °C) (99.1%) extrapolated from measurements at 70 °C*
B.2.1.3.2 (IIA 2.3)	Volatility, Henry's law constant		Calculation	1.65×10^{-5} Pa m^3 mol^{-1}	Rahn, 2008 (BVL no 2438127)	acceptable additional information *LOEP:* *< 4.7·x 10^{-4} Pa m^3 mol^{-1} (20°C)*

List of data

Annex point/ reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIA 2.3.1 (OECD)	Kroehl, T.	2008	Vapour Pressure of Epoxiconazole (BAS 480 F, Reg.No. 205 259) 2008/1052188 GLP: Y, published: N 2438126	Y	BAS	1
KIIA 2.3.2 (OECD)	Rahn, R.T.	2008	Henry s law constant for epoxiconazole 2008/1097170 GLP: N, published: N 2438127	Y	BAS	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code:	**BAS 701 00 F (Adexar)**
Active Substance:	**epoxiconazole 62.5 g/L**
	fluxapyroxad 62.5 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**BASF SE Germany**
Submission Date:	**15/03/2013**
Date:	**02 June 2017**

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product Adexar (BAS 701 00 F) containing the active substances epoxiconazole and fluxapyroxad which were approved according to Regulation (EC) No 1107/2009 and (EU) No 540/2011.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Information on the detailed composition of Adexar (BAS 701 00 F) can be found in the confidential dossier of this submission (Registration Report- Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was not provided because there was no request.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of epoxiconazole and fluxapyroxad were not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

No samples were provided because there was no request.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of epoxiconazole and fluxapyroxad and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission. Additional studies to support the registration of Adexar (BAS 701 00 F) not previously assessed are given below. All relevant data are provided and are considered adequate.

IIIA 5.2.1 Description of the analytical methods for the determination of the active substance in the plant protection product

Please refer to chapter 5.2.2 as Adexar (BAS 701 00 F) contains two active substances.

IIIA 5.2.2 For preparations containing more than one active substance, description of method for determining each in the presence of the other

The following analytical method for the determination of the active substances in the plant protection product performed on Adexar (BAS 701 00 F) has not previously been reviewed.

Report:	5.2.2/1, Bentz A., Siebecker M., 2008a
Title:	Quantitative determination of the active ingredients Reg. No. 5 094 351 and epoxiconazole in BAS 701 00 F by HPLC
Document No:	BASF Doc ID 2008/1033958
Guidelines:	EPA 830.1800, EEC 96/46, SANCO/3030/99 rev. 4 (11 July 2000), OECD Principles of Good Laboratory Practice, GLP Principles of the German Chemikaliengesetz (Chemicals Act)
GLP	No

The method AFL0755/02 is applicable to the determination of the contents of the active ingredients BAS 700 F (fluxapyroxad, nominal content of 62.5 g/I) and epoxiconazole (nominal content of 62.5 g/I) in the EC-formulation BAS 701 00 F.
The active ingredients are determined by HPLC-analysis with UV detection and external quantification.

Report:	5.2.2/2, Bentz A., Siebecker M., 2008b
Title:	Validation of the analytical HPLC-method AFL0755/01: Quantitative determination of the active ingredients Reg. No. 5 094 351 and epoxiconazole in BAS 701 00 F by HPLC
Document No:	BASF Doc ID 2008/1005506
Guidelines:	EPA 830.1800, EEC 96/46, SANCO/3030/99 rev. 4 (11 July 2000), OECD Principles of Good Laboratory Practice, GLP Principles of the German Chemikaliengesetz (Chemicals Act)
GLP	Yes

Analytical method AFL0755/02 supersedes analytical method AFL0755/01. The method APL0755/01 contains typographical errors in chapter 9. These have been corrected in the revised version AFL0755/02 which contains exactly the same analytical conditions as described in version 01. Therefore, the validation study done for AFL0755/01 (DocID 2008/1005506) is valid for method AFL0755/02.

Method description
The analytes are determined by HPLC on an Uptisphere HSC 3 µm (150 x 4.6 m) at 30°C column temperature, using external calibration. Injection volume is 3 µl. The separation is achieved by using gradient flow conditions for the detection and quantification of the actives (1.0- 1.5 ml/min). Detection is performed with a diode- array detector DAD at 230 nm wavelength. The mobile phase consists of 1000

ml acetonitrile and 1000 ml water + 1 ml acetic acid. The analytes are quantified by comparing the specific response ratios of the samples with those of standards of known quality.

Method validation

The validation data of method AFL0755/01 were determined for the formulation Adexar (BAS 701 00 F). It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of epoxiconazole and fluxapyroxad in emulsifiable concentrate (EC) formulation Adexar (BAS 701 00 F).

Table containing the methods and validation of the methods (formulation Adexar (BAS 701 00 F))

Analyte	Linearity n = 5	Accuracy n = 6 Mean [%]	Repeatability n = 6 [%RSD]	Specificity/Interferences
epoxiconazole	0.5 – 1.5 times of expected concentration r = 1.0000	100.66	1.024	No interferences were noted. Chromatograms of formulation with and without active ingredients present were submitted.
fluxapyroxad	0.5 – 1.5 times of expected concentration r = 1.0000	100.84	0.521	No interferences were noted. Chromatograms of formulation with and without active ingredients present were submitted.

Summary

The active substances can be quantified using the analytical HPLC method AFL0755/02. The method was developed for quantifying epoxiconazole and fluxapyroxad in Adexar (BAS 701 00 F).

The validation data of method AFL 0755/02 with respect to precision, accuracy, linearity and specificity prove that the method is suitable to determine the content of fluxapyroxad and epoxiconazole in the emulsifiable concentrate (EC) formulation BAS 701 00 F.

IIIA 5.2.3 Applicability of existing CIPAC methods

There is no CIPAC method available for the determination of epoxiconazole and fluxapyroxad in emulsifiable concentrate (EC) formulations like Adexar (BAS 701 00 F).

IIIA 5.2.4 Description of analytical methods for the determination of relevant impurities

A validated analytical method has been developed for the determination of the relevant impurity toluene in preparations containing fluxapyroxad.

The following analytical method has not previously been reviewed and is provided in support of this assessment.

Report:	5.2.4/1, Siebecker M.,Bentz A.,2009a
Title:	Determination of toluene in BAS 700 F TGAI and formulation by GC/MS Headspace
Document No:	BASFDocID 2009/1116594
Guidelines:	<none>
GLP	No

Method description

After preparation the samples are equilibrated in a static headspace sampler at elevated temperature and then transferred into a gas chromatographic column (Restek RTX 200, 60m x 0.32mm i.d., 1.5µm film thickness) which separates volatile components by increasing boiling points. Eluted toluene is identified by a MS detector and quantified by linearity using an authentic reference item with known content.

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Method validation

Report:	5.2.4/2, Siebecker M.,Bentz A.,2010a
Title:	Validation of analytical method APL0594/01: Determination of toluene in BAS 700 F TGAI and formulation by GC/MS headspace
Document No:	BASFDocID 2009/1116595
Guidelines:	2004/10/EC, EEC 91/414, EEC 96/46, CIPAC Guidelines on method validation, SANCO/3029/99 rev. 4 (11 July 2000), US EPA OPPTS Harmonized Test Guideline 830.1000, US EPA OPPTS Harmonized Test Guideline 830.1800, OECD Principles of Good Laboratory Practice, GLP Principles of the German Chemikaliengesetz (Chemicals Act)
GLP	Yes

In the method APL0594/01 the content of toluene is determined by peak area measurement using the GC-MS detection and applying linear regression analysis using an authentic reference item with known content. The analytical method for the determination of toluene has been validated with the EC-formulation BAS 701 00 F containing 62.5 g/L fluxapyroxad. The validation data of method APL0594/01 with respect to linearity, accuracy, precision and specificity prove that the method is suitable to determine the content of toluene in formulations containing fluxapyroxad.

Table containing the validation of the method (formulation Adexar (BAS 701 00 F).

Component	**Linearity** **n = 5**	**Accuracy** **n = 10** **Mean [%]**	**Repeatability** **n = 5** **[%RSD]**	**Specificity/Inteferences**
toluene	1.14 – 761.5 mg/L r = 0.9999	97.7 (at 22 ppm) 92.5 (at 120 ppm) 90.8 (at 600 ppm)	1.49 RSRr = 6.54 %	No significant interferences between fluxapyroxad, toluene and the formulation formulants could be observed. Chromatograms of the authentic reference item batch of fluxapyroxad and formulation with impurity toluene were submitted.

LOQ: 22 ppm (related to weighted formulation sample)

Summary

The identity of toluene was proven by comparison of the retention time of the authentic reference item with the retention time in the test item. It was confirmed by GC/MS investigations of the solutions containing toluene specified in method and determination of typical molar fragments of toluene.
The fortification experiments demonstrate, that the analytical method APL0594/01 is applicable to determine the content of toluene in the fluxapyroxad formulation BAS 701 00 F.

IIIA 5.2.5 Description of analytical methods for the determination of formulants

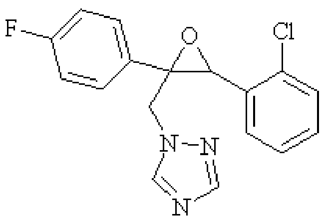
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of epoxiconazole

The conclusion regarding the peer review of the analytical methods for residues of epoxiconazole are summarized in EFSA Scientific Report (2008), 138, 1-80.

Table 5.3-1: Information on the active substance epoxiconazole

Name of component of residue definiton **substance code** **IUPAC name** **formula**	**Structural formula**
Epoxiconazole BAS 480 F (2RS, 3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1,2,4-triazole $C_{17}H_{13}ClFN_3O$	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-2: Relevant residue definitions

Matrix	**Relevant residue**	**Reference** **Remarks**
Plant material	Epoxiconazole	Regulation (EU) No 978/2011, annex III part A
Foodstuff of animal origin	Epoxiconazole	Regulation (EU) No 978/2011, annex III part A

Soil	Epoxiconazole	EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Surface water	Epoxiconazole	EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Drinking/ground water	Epoxiconazole	EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Air	Epoxiconazole	generally defined, classified as Xn, EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Body fluids/tissue	Epoxiconazole	classified as T

Table 5.3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.05 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, acidic commodities	0.05 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, dry commodities	0.05 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, high oil content	0.05 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.1 mg/kg	Regulation (EU) No 978/2011, annex III part A
Meat	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Milk	0.002 mg/kg	Regulation (EU) No 978/2011, annex III part A
Eggs	0.02 mg/kg	Regulation (EU) No 978/2011, annex III part A
Fat	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Liver, kidney	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Soil	0.05 mg/kg	Common limit
Drinking water	0.1 µg/L	General limit for drinking water
Surface water	4.3 µg/L	E_bC_{50} *Lemna gibba*; EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Air	2.4 µg/m^3	AOEL sys: 0.008 mg/kg bw/d EFSA Scientific Report (2008) 138, 1-80, ASB2012-3620
Tissue (meat or liver)	0.1 mg/kg	Classified as T
Body fluids	0.05 mg/L	Classified as T

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of Epoxiconazole in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of epoxiconazole in plant matrices is given in the following tables. For the detailed evaluation of additional study it is referred to Appendix 2.

Table 5.3-4: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	ASB2008-5464 MET1999-1331 *)	ASB2008-5464	MET2001-277 *)
Acidic	ASB2008-5464 MET1999-1331 *)	ASB2008-5464	MET2001-277 *)
Fatty	MET1999-1331	Missing	MET2001-277 *)
Dry	ASB2008-5464 MET1999-1331 *)	ASB2008-5464	MET2001-277 *)
Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*) EU agreed method (see Draft Assessment Report)

Table 5.3-5: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Keller, 1991, RIP2003-1512, section B.7.1.1 of DAR
Not required, because:	

Extraction efficiency with methanol: wheat forage: 93 – 98.5 % of TRR, wheat straw: 93.4 % of TRR, wheat grain: 17.8% of TRR. For grain, additional extraction with methanol/water (1+1, v/v) yielded in another 38.8 % of TRR (total 55.6 % of TRR). The fraction of epoxiconazole in extract was >90 % and about 80 % of TRR in forage and straw, respectively. In grain no parent was detected. Therefore no justification for using a different solvent compared to the monitoring method is required.

Table 5.3-6: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
Anonymous, 2008 ASB2008-5464	High water content, acidic, dry	0.01 mg/kg	LC-MS/MS, RP18 column, ESI+, m/z 330→121, 330→102	Confirmation and ILV included; QuEChERS method, EN15662:2008	Additional study, see appendix 2
Weeren, Pelz, 1999 MET1999-1331	Dry, high water content, acidic, fatty	0.01 mg/kg 0.02 mg/kg	GC-MS, DB-5MS, m/z 192	DFG S19; no confirmation	Section B.5.2.1 of DAR
Lehmann, Mackenroth, 2001 MET2001-277	High water content, acidic, dry, fatty	0.01 mg/kg	LC-MS/MS, RP18 column, ESI+, m/z 330→ 141	No confirmation	Section B.5.2.1 of DAR

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of epoxiconazole in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of epoxiconazole in animal matrices is given in the following tables. New studies were not provided.

Table 5.3-7: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
Milk	Tilting, 1994 *)	Brett, 1997 *)	Bacher, 2005 *)
Eggs	Tilting, 1994 *)	Brett, 1997 *)	Bacher, 2005 *)
Meat	Tilting, 1994 *)	Brett, 1997 *)	Bacher, 2005 *)
Fat	Tilting, 1994 *)	Brett, 1997 *)	Bacher, 2005 *)
Kidney, liver	Tilting, 1994 *)	Brett, 1997 *)	Bacher, 2005 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-8: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Kohl, 1990, RIP2003-1507, section B.7.2.1 of DAR
Not required, because:	

Extraction efficiency with methanol: milk: 84-96 % of TRR; meat: 60-91 % of TRR; fat: 61-96 % of TRR; liver: 31-77 % of TRR; kidney: 69-91 % of TRR. Fraction of epoxiconazole in extract: milk: 53 % of TRR; meat: 59 % of TRR; fat: 91 % of TRR; liver: 33 % of TRR; kidney 22 % of TRR.

Table 5.3-9: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Tilting, 1994, MET1999-372	Milk; eggs, meat, liver, kidney, fat	0.001 mg/kg 0.01 mg/kg	GC-ECD, DB-5	No confirmation	DAR, vol. 3, 5.2.2
Brett, 1997, MET1999-847	Milk; eggs, meat, liver, kidney, fat	0.001 mg/kg 0.01 mg/kg	GC-ECD, RTx-5	ILV of Tilting, 1994, no confirmation	DAR, vol. 3, 5.2.2
Bacher, 2005, MET2006-173	Milk; eggs, meat, liver, kidney, fat	0.001 mg/kg 0.01 mg/kg	GC-MS/MS, CPSil8CB, m/z 192→138, 192→157	Confirmation included	DAR, vol. 3, 5.2.2

IIIA 5.3.1.4 Description of Methods for the Analysis of Epoxiconazole in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and possible data gaps for analysis of epoxiconazole in soil is given in the following tables. New studies were not provided.

Table 5.3-10: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Epoxiconazole	Grote, 2001 *)	Tilting, 1990 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-11: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Grote, 2001, MET2003-481	0.01 mg/kg	GC-MS, DB-1701, m/z 192	No confirmation	section B.5.3.1 of DAR
Tilting, 1990, MET1999-363	0.01 mg/kg	GC-ECD, DB1701	No confirmation	section B.5.3.1 of DAR

IIIA 5.3.1.5 Description of Methods for the Analysis of Epoxiconazole in Water (OECD KIII A 5.6)

An overview of the acceptable methods and possible data gaps for analysis of epoxiconazole in surface and drinking water is given in the following table. New studies were not provided.

Table 5.3-12: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Epoxiconazole	Drinking water	Grote, 2001 *)	Tilting, 1990 *)
Epoxiconazole	Surface water	Grote, 2001 *)	Keller, 1999 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-13: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Grote, 2001, MET2003-482	Drinking water, surface water	0.05 µg/L	GC-MS, DB-XLB, m/z 192, 194	Section B.5.3.2 of DAR
Tilting, 1990,MET1999-367	Drinking water	0.05 µg/L	GC-ECD, DB1701	Section B.5.3.2 of DAR
Keller, 1999, MET1999-1330	Surface water	0.5 µg/L	GC-ECD, DB1701	Section B.5.3.2 of DAR

IIIA 5.3.1.6 Description of Methods for the Analysis of Epoxiconazole in Air (OECD KIII A 5.7)

An overview of the acceptable methods and possible data gaps for analysis of epoxiconazole in air is given in the following table. New studies were not provided.

Table 5.3-14: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method

Epoxiconazole	Zangmeister, 1999 *)	Not necessary

*) EU agreed method (see Draft Assessment Report)

Table 5.3-15: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Zangmeister, 1999 MET2000-27	0.09 µg/m^3	GC-ECD, DB-1701 column	No confirmation	DAR, vol. 3, B.5.3.3

IIIA 5.3.1.7 Description of Methods for the Analysis of Epoxiconazole in Body Fluids and Tissues (OECD KIII A 5.8)

An overview of the acceptable methods and the data gaps (if appropriate) for analysis of epoxiconazole in body fluids and tissues is given in the following table. New studies were not provided.

Table 5.3-16: Overview of suitable primary and confirmatory methods for body fluids and tissues

Component(s) of residue definition	Primary method	Confirmatory method
epoxiconazole in body fluids	Hartl, 2002 *	Hartl, 2002 *
epoxiconazole in body tissues	Bacher, 2005 *	Bacher, 2005 *

*EU agreed method (see Draft Assessment Report)

Table 5.3-17: Methods for body fluids (blood)

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Hartl, 2002 MET2002-316	0.01 mg/kg	GC-ECD, DB-XLB	Confirmation included by GC-MS, DB-XLB, m/z 192	DAR, vol. 3 B.5.4

Table 5.3-18: Methods for tissues (meat, liver, kidney)

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Bacher, 2005 MET2006-173	0.01 mg/kg	GC-MS/MS, CPSil8CB, m/z 192→138, 192→157	Confirmation included	DAR, vol. 3, 5.2.2

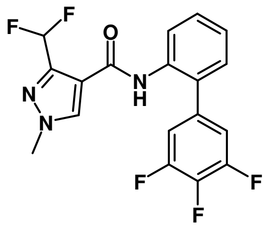
IIIA 5.3.1.8 Other Studies/ Information

none

IIIA 5.3.2 Evaluation of fluxapyroxad

The conclusion regarding the peer review of the analytical methods for residues of fluxapyroxad are summarized in EFSA Journal 2012;10(1): 2522, ASB2012-3723

Table 5.3-19: Information on the active substance fluxapyroxad

Name of component of residue definiton **substance code** **IUPAC name** **formula**	**Structural formula**
Fluxapyroxad (BAS 700 F 3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide $C_{18}H_{12}F_5N_3$	

IIIA 5.3.2.1 Overview of residue definitions and levels for which compliance is required

Compared to the residue definition proposed in the Draft Assessment Report (incl. its addenda) the current legal residue definition is identical.

Table 5.3-20: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Fluxapyroxad	Regulation (EU) No 978/2011, annex III part A
Foodstuff of animal origin	Fluxapyroxad	Regulation (EU) No 978/2011, annex III part A
Soil	Fluxapyroxad	EFSA Journal 2012;10(1): 2522, ASB2012-3723
Surface water	Fluxapyroxad	EFSA Journal 2012;10(1): 2522, ASB2012-3723
Drinking/ground water	Fluxapyroxad	Minimal requirement of the Drinking Water Act (Trinkwasser-VO) EFSA Journal 2012;10(1): 2522, ASB2012-3723
Air	Fluxapyroxad	Generally defined (proposed as Xn)
Body fluids/tissue	Not residue relevant	Not classified as T / T+

Table 5.3-21: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	0.01 mg/kg	Regulation (EU) No 978/2011, annex

		III part A
Plant, acidic commodities	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, dry commodities	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, high oil content	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Meat	0.005 mg/kg	Regulation (EU) No 978/2011, annex III part A
Milk	0.003 mg/kg	Regulation (EU) No 978/2011, annex III part A
Eggs	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Fat	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Liver	0.01 mg/kg	Regulation (EU) No 978/2011, annex III part A
Soil	0.05 mg/kg	common limit
Drinking/ground water	0.1 µg/L	general limit for drinking water
Surface water	36 µg/L	NOEC *Pimephales promelas*; EFSA Journal 2012;10(1): 2522, ASB2012-3723
air	12 µg/m^3	AOEL sys: 0.04 mg/kg bw/d, EFSA Journal 2012;10(1): 2522, ASB2012-3723
Tissue (meat or liver)	Not required	Not classified as T / T+
Body fluids	Not required	Not classified as T / T+

IIIA 5.3.2.2 Description of Analytical Methods for the Determination of Residues of Fluxapyroxad in Plant Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of fluxapyroxad in plant matrices is given in the following tables. New studies were not provided.

Table 5.3-22: Overview of independently validated methods and confirmatory methods for food and feed of plant origin (always required for first 4 matrix types)

Matrix type	Primary method	ILV	Confirmatory method
High water content	Lehmann, 2009 *)	Class, 2009 *)	Lehmann, 2009 *)
Acidic	Lehmann, 2009 *)	Class, 2009 *)	Lehmann, 2009 *)
Fatty	Lehmann, 2009 *)	Class, 2009 *)	Lehmann, 2009 *)
Dry	Lehmann, 2009 *)	Class, 2009 *)	Lehmann, 2009 *)

Difficult	Not required for the intended GAP	Not required for the intended GAP	Not required for the intended GAP

*) EU agreed method (see Draft Assessment Report)

Table 5.3-23: Statement on extraction efficiency

	Method for products of plant origin
Required, available from:	Rabe, 2009, ASB2010-7939
Not required, because:	

Tomato plants were treated with 3 x 100 g a.s./ha of aniline-U-^{14}C- and pyrazole-4-^{14}C-fluxapyroxad. After harvesting the fruits were extracted with methanol. Extraction efficiency ranged between 97 – 98 % TRR. Parent fluxapyroxad accounted for more than 94 % of TRR in the methanol extract. Additionally the extraction efficiency of different solvents was compared. Water/methanol/2N hydrochloric acid (70/25/5, v/v/v) and water/methanol (50/50, v/v) used in the monitoring methods showed as well extraction efficiencies > 95 % TRR. Consequently, extraction efficiency has been proven.

Table 5.3-24: Methods suitable for the determination of residues (enforcement) in products of plant origin

Author(s), year	Matrix group	Method LOQ	Principle of method	Comment	Evaluated in section
Lehmann, 2009 ASB2010-7730	High water content, dry, acidic, fatty difficult (coffee beans green)	0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included, also for metabolites M700F002, M700F008, M700F048	Vol. 3, section B.5.2.1 of DAR, ASB2013-4548
Class, 2009 ASB2010-7731	High water content, dry, acidic, fatty	0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included, ILV of Lehmann, 2009	Vol. 3, section B.5.2.1 of DAR, ASB2013-4548

IIIA 5.3.2.3 Description of Analytical Methods for the Determination of Residues of Fluxapyroxad in Animal Matrices (OECD KIII A 5.3.1)

An overview of the acceptable methods and possible data gaps for analysis of fluxapyroxad in animal matrices is given in the following tables. New studies were not provided.

Table 5.3-25: Overview of independently validated methods and confirmatory methods for food and feed of animal origin (if appropriate)

Matrix type	Primary method	ILV	Confirmatory method
Milk	Hopf, 2009 *)	Class, 2009 *)	Hopf, 2009 *)
Eggs	Hopf, 2009 *)	Class, 2009 *)	Hopf, 2009 *)
Meat	Hopf, 2009 *)	Class, 2009 *)	Hopf, 2009 *)
Fat	Hopf, 2009 *)	not required	Hopf, 2009 *)
Kidney, liver	Hopf, 2009 *)	Class, 2009 *)	Hopf, 2009 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-26: Statement on extraction efficiency

	Method for products of animal origin
Required, available from:	Grosshans, 2009, ASB2010-7945
Not required, because:	

Lactating goats were fed with aniline-U-^{14}C- und pyrazole-4-^{14}C-fluxapyroxad at 12 mg/kg feed for 8 consecutive days. After sacrifice, the following extraction efficiencies were obtained for each tissue analyzed:
Meat: 85 % and 90 % TRR following extraction with methanol and. acetonitrile/water (80/20, v/v), respectively. Parent fluxapyroxad accounted for 12 % TRR.

Fat: 105 % and 118 % TRR following extraction with acetonitrile and acetonitrile/water (80/20, v/v) respectively. Parent fluxapyroxad accounted for 34 - 44 % TRR.

Milk: 90 % and 88 % TRR following extraction with acetonitrile and acetonitrile/water (80/20, v/v) respectively. Parent fluxapyroxad accounted for 13 - 20 % TRR.

Liver: 30 % TRR following extraction with methanol and acetonitrile/water (80/20, v/v) respectively. Parent fluxapyroxad accounted for 3 - 4 % TRR.

Kidney: 92 % and 90 % TRR following extraction with methanol and acetonitrile/water (80/20, v/v) respectively. Parent fluxapyroxad accounted for 5 - 7 % TRR.

Similar extraction efficiency was observed for methanol and acetonitrile compared to acetonitrile/water (80/20, v/v) which is used in the monitoring method. With the exception of liver, where only 30 % TRR was extracted with both solvents, sufficient extraction efficiency was demonstrated for all matrices.

Table 5.3-27: Methods suitable for the determination of residues (enforcement) in products of animal origin

Author(s), year	Matrix	Method LOQ	Principle of method	Comment	Evaluated in
Hopf, 2009 ASB2010-7734	Milk, egg meat, fat, liver, kidney	0.001 mg/kg 0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included	Vol. 3, section B.5.2.1 of DAR, ASB2013-4548
Class, 2009 ASB2010-7731	Milk, egg meat, liver	0.001 mg/kg 0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included, ILV of Hopf, 2009	Vol. 3, section B.5.2.1 of DAR, ASB2013-4548

IIIA 5.3.2.4 Description of Methods for the Analysis of Fluxapyroxad in Soil (OECD KIII A 5.4)

An overview of the acceptable methods and possible data gaps for analysis of fluxapyroxad in soil is given in the following tables. New studies were not provided.

Table 5.3-28: Overview of suitable primary and confirmatory methods for soil

Component(s) of residue definition	Primary method	Confirmatory method
Fluxapyroxad	Zangmeister, 2009 *)	Zangmeister, 2009 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-29: Methods for soil

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Zangmeister, 2009 ASB2010-7736	0.001 mg/kg	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included, also for metabolites M700F001, M700F002, M700F003	Vol. 3, section B.5.3.1 of DAR, ASB2013-4548

IIIA 5.3.2.5 Description of Methods for the Analysis of Fluxapyroxad in Water (OECD KIII A 5.6)

An overview of the acceptable methods and possible data gaps for analysis of fluxapyroxad in surface and drinking water is given in the following table. New studies were not provided.

Table 5.3-30: Overview of suitable primary and confirmatory methods for water

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
Fluxapyroxad	Drinking water, surface water	Zangmeister, 2009 *)	Zangmeister, 2009 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-31: Methods for drinking water and surface water

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Zangmeister, 2009 ASB2010-7738	0.03 µg/L	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included, also for metabolites M700F001, M700F002, M700F007	Vol. 3, section B.5.3.2 of DAR, ASB2013-4548

IIIA 5.3.2.6 Description of Methods for the Analysis of Fluxapyroxad in Air (OECD KIII A 5.7)

An overview of the acceptable methods and possible data gaps for analysis of fluxapyroxad in air is given in the following table. New studies were not provided.

Table 5.3-32: Overview of suitable primary and confirmatory methods for air

Component(s) of residue definition	Primary method	Confirmatory method
Fluxapyroxad	Zangmeister, 2009 *)	Zangmeister, 2009 *)

*) EU agreed method (see Draft Assessment Report)

Table 5.3-33: Methods for air

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Zangmeister, 2009 ASB2010-7739	0.06 µg/m^3	LC-MS/MS, C18, ESI+, m/z 382→342, 382→362	Confirmation included	Vol. 3, section B.5.3.3 of DAR, ASB2013-4548

IIIA 5.3.2.7 Description of Methods for the Analysis of Fluxapyroxad in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for body fluids and tissues are not required, because fluxapyroxad is not considered to be toxic or very toxic (T / T+) nor is it classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1).

IIIA 5.3.2.8 Other Studies/ Information

None

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions for epoxiconazole and fluxapyroxad except the following method:
Noticed data gap is:

- Validation of an analytical method for epoxiconazole in fatty plant matrix in an independent laboratory.

However, this data is not considered severe in the context of the present evaluation. It is considered appropriate to fill the data gap in the context of the next scheduled renewal of the active substance epoxiconazole on EU level or in the context of evaluation of existing MRLs of epoxiconazole according to Article 12 of Regulation (EC) No 396/2005.

Appendix 1 – List of data submitted in support of the evaluation

Annex point/ reference No (OECD)	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not	Data protection claimed	Owner	How considered in dRR Study-Status / Usage*
KIIIA1 5.2.2	Bentz, A.	2008	Quantitative determination of the active ingredients Reg.No. 5 094 351 and Epoxiconazole in BAS 701 00 F by HPLC, 2008/1033958! 311609_1, GLP: N, published: N	Y	BAS	1
KIIIA1 5.2.2	Bentz, A.	2008	Validation of the analytical HPLC-method AFL0755/01: Quantitative determination of the active ingredients Reg.No. 5 094 351 and Epoxiconazole in BAS 701 00 F by HPLC, 2008/1005506! 311609_1, GLP: Y, published: N	Y	BAS	1
KIIIA1 5.2.4	Siebecker, M., Bentz, A.	2009	Determination of Toluene in BAS 700 F TGAI and formulation by GC/MS Headspace, 2009/1116594, GLP: N, published: N	Y	BAS	1
KIIIA1 5.2.4	Siebecker, M., Bentz, A.	2010	Validation of analytical method APL0594/01: Determination of toluene in BAS 700 F TGAI and formulation by GC/MS headspace, 2009/1116595, GLP: Y, published: N	Y	BAS	1

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance epoxiconazole EFSA Scientific Report (2008) 138, 1-80 ASB2012-3620		Add
	EFSA	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluxapyroxad (BAS 700 F) EFSA Journal 2012;10(1):2522 ! EFSA-Q-2011-00395 EFSA Journal 2012;10(1):2522 ASB2012-3723		Add
	United Kingdom	2011	Fluxapyroxad: Draft Assessment Report ASB2013-4548		Add
KIIA 4.3	Anon.	2008	European Standard EN 15662:2008 - Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS(/MS) following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS-method // Pflanzliche Lebensmittel - Bestimmung von Pestizidrückständen mit GC-MS und/oder LC-MS/MS nach Acetonitril-Extraktion/Verteilung und Reinigung mit dispersiver SPE - QuEChERS-Verfahren EN 15662:2008 GLP: Open (1) No (12) Published: Yes (12) Open (1) BVL-1891180, BVL-1916668, BVL-1928802, BVL-1977903, BVL-2121949, BVL-2121995, BVL-2193372, BVL-2203046, BVL-2203046, BVL-2231017, BVL-2234627, BVL-2255528, BVL-2340307, ASB2008-5464	LIT	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3	Bacher, R.	2005	Epoxiconazole (BAS 480 F): Validation of an analytical confirmatory method for the determination of BAS 480 F in animal matrices 2005/1006485 ! 212410 ! P/B 837 G GLP: Open Published: Open BVL-2088959, MET2006-173	BAS	Y
KIIA 4.3	Brett, T. R.	1997	Independent laboratory validation of an analytical method for the determination of residues of Epoxiconazole in milk and tissues of animal origin CEMR-727 ! 97/11158 ! CEMS-727 GLP: Open Published: Open BVL-2088957, MET1999-847	BAS	Y
KIIA 4.3	Class, T.	2009	M700F002 (Reg.No. 5435595, metabolite of BAS 700 F): Independent laboratory validation (ILV) of BASF method numbers L0137/01 and L0140/02 for the determination of M700F002 in plant materials and animal matrices by LC/MS/MS 2009/1074614 ! 315767-2 GLP: Open Published: Open BVL-2156548, ASB2010-7732	BAS	N
KIIA 4.3	Class, T.; Jooß, S.	2009	BAS 700 F: Independent laboratory validation (ILV) of BASF method number L0137/01 and L0140/02 for the determination of BAS 700 F in plant materials and animal matrices by LC/MS/MS 2009/1074618 ! 315767-1 GLP: Open Published: Open BVL-2156547, ASB2010-7731	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3	Class, T.; Jooß, S.	2009	M700F008 (Reg.No. 5566402, metabolite of BAS 700 F): Independent laboratory validation (ILV) of BASF method number L0137/01 and L0140/02 for the determination of M700F008 in plant materials and animal matrices by LC/MS/MS 2009/1091115 ! 315767-3 GLP: Open Published: Open BVL-2156549, ASB2010-7733	BAS	N
KIIA 4.3	Funk, H.; Mackenroth, Ch.	2001	Determination of the stability of 205259 (BAS 480 F), 242009 (BAS 490 F), 285028 (BAS 505 F) and 300355 (BAS 510 F) in different solvents 2000/1014856 ! 41841 GLP: Open Published: Open BVL-2088952, MET2001-258	BAS	N
KIIA 4.3	Hopf, B.	2009	Validation of BASF Method No. 535/3 (L0076/03) for BAS 700 F in plant matrices 2009/1074615 ! 315766 GLP: Open Published: Open BVL-2156545, ASB2010-7729	BAS	N
KIIA 4.3	Hopf, B.; Mackenroth, C.	2009	Validation of the analytical method L0140/02: Method for the determination of BAS 700 F (Reg.No. 5094351) and its metabolites M700F002 (Reg.No. 5435595), M700F008 (Reg.No. 5566402) and M700F048 (Reg.No. 5570265) in animal matrices 2009/1074613 ! 315793 GLP: Open Published: Open BVL-2156550, ASB2010-7734	BAS	Y
KIIA 4.3	Lehmann, A.	2009	Validation of BASF method no. L0137/01 in plant matrices 2009/1074617 ! 324238 GLP: Open Published: Open BVL-2156546, ASB2010-7730	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3	Lehmann, A.; Mackenroth, Ch.	2001	Validation of BASF method no. 445/0: Determination of BAS 480 F in following plant matrices: Wheat plant without root, grain and straw, sugar beet, oilrape seed and orange 2000/1012401 ! 78591 ! method 445/0 GLP: Open Published: Open BVL-2088950, MET2001-277	BAS	Y
KIIA 4.3	Lehmann, A.; Mackenroth, Ch.	2002	Validation of BASF method No. 504/0: Determination of BAS 480 F in wheat grain 2001/1015027 ! 133243 ! method 504/0 GLP: Open Published: Open BVL-2088951, MET2003-475	BAS	N
KIIA 4.3	Macdougall, J.	2009	Independent laboratory validation of analytical method No. L0140/01 for the determination of BAS 700 F, M700F048, M700F008 and M700F002 in eggs, bovine, milk, liver and muscle by HPLC-MS/MS 2009/1074797 ! 315794 ! 215157 GLP: Open Published: Open BVL-2156551, ASB2010-7735	BAS	N
KIIA 4.3	Reinhard, K.	1996	Extractability of 14C-Epoxiconazole (BAS 480 F) residues from banana peel and pulp with aqueous methanol (according to method no. 309/1) 96/10930 ! 13580 ! method 309/1 GLP: Open Published: Open BVL-2088949, MET2003-484	BAS	N
KIIA 4.3	Steinhauer, S.	2002	Assessment of the multi-residue method DFG S19 (extended revision) for the determination of BAS 480 F (Epoxiconazole) in matrices of animal origin 2002/1006990 ! BAS-0203V ! G02-0023 ! 138715 ! method S19 GLP: Open Published: Open BVL-2088958, MET2003-476	BAS	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3	Tilting, N.	1992	Applicability of DFG multiresidue methods S 8 and S 19 for the determination of Epoxiconazole (LAB 205 259) 92/10992 ! S8/19-480F-92 ! 3414 ! method S8 ! method S19 GLP: Open Published: Open BVL-2088953, MET1999-364	BAS	N
KIIA 4.3	Tilting, N.	1993	Determination of Epoxiconazole in cereals by gas chromatography with internal standardization (Methode 309/1) 93/11581 ! 3884 ! method 309/1 GLP: Open Published: Open BVL-2088947, MET1999-369	BAS	N
KIIA 4.3	Tilting, N.	1994	Determination of Epoxiconazole in animal matrices by gas chromatography with internal standardization (Methode 332) 94/10528 ! 3949 ! method 332 GLP: Open Published: Open BVL-2088956, MET1999-372	BAS	Y
KIIA 4.3	Tilting, N.	1994	Determination of BAS 480 F (Epoxiconazole) in bananas, sugarbeets and coffee by gas chromatography with internal standardization (Validation of method no. 309/1) 94/11792 ! VAL-309/1-01-94 ! method 309/1 GLP: Open Published: Open BVL-2088948, MET1999-368	BAS	N
KIIA 4.3	Weeren, R. D.; Pelz, S.	1999	Validation of DFG method S 19 for the determination of Dimethenamid, Epoxiconazole, Fenpropimorph, Kresoxim-methyl, Metazachlor and Vinclozolin in various plant materials 99/11462 ! BAS-9902V ! M8020/99 ! method S 19 GLP: Open Published: Open BVL-2088954, MET1999-1331	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.3, KIIA 4.4	Tilting, N.	1990	Determination of LAB 205259 in cereals and soil by gas chromatography (Methode 309) 90/10194 ! 2810 ! method 309 GLP: Open Published: Open BVL-2088945, BVL-2088961, MET1999-363	BAS	Y
KIIA 4.3, KIIA 4.4	Tilting, N.	1993	Addendum No. 1 to BASF report No. 2810: Determination of LAB 205 259 in cereals and soil by gas chromatography (Methode 309) 93/11321 ! 2810 ! method 309 GLP: Open Published: Open BVL-2088946, BVL-2088962, MET2003-479	BAS	N
KIIA 4.3, KIIIA1 5.3.1	Lehmann, A.; Mackenroth, Ch.	2007	Validation of BASF method No. 535/1 in plant matrices 2006/1039427 ! 246631 ! method 535/1 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-2088955, BVL-2438175, RIP2007-463	BAS	N
KIIA 4.4	Grote, C.	2001	Validation of analytical method No. 479/0 - GC/MS determination of BAS 480 F (Epoxiconazole) in soil 2001/1010646 ! 99333 GLP: Open Published: Open BVL-2088963, MET2003-481	BAS	Y
KIIA 4.4	Tilting, N.	1990	GC method for the determination of LAB 205 259 in Soil - Methode 301 1990/0322 ! 2968 GLP: Open Published: Open BVL-2088960, MET1999-366	BAS	N
KIIA 4.4	Zangmeister, W.	2009	Validation of analytical method L0092: Determination of Reg.No. 5094351 and its metabolites Reg.No. 5069089, Reg.No. 5410775 and Reg.No. 5435595 in soil by HPLC/MS-MS 2008/1063799 ! 266245 GLP: Open Published: Open BVL-2156552, ASB2010-7736	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.4	Zangmeister, W.	2009	Validation of analytical method L0092: Determination of reg.no. 5094351 and its metabolites reg.no. 5069089, reg.no. 5410775 and reg.no. 5435595 in soil by HPLC/MS-MS - Amendment no. 1 dated 25.03.2010 2010/1043659 ! 5435595 GLP: Open Published: Open BVL-2156553, ASB2010-7737	BAS	N
KIIA 4.5	Grote, C.	2001	Validation of analytical method No. 461/0 - GC/MS determination of BAS 480 F ai (205 259) residues in tap water and surface water 2001/1010647 ! 70783 GLP: Open Published: Open BVL-2088966, MET2003-482	BAS	Y
KIIA 4.5	Keller, W.	1999	Validation of analytical method No. 300 - GC/ECD-determination of BAS 480 F (205259) residues in surface water 63439 ! 1999/11096 GLP: Open Published: Open BVL-2088965, MET1999-1330	BAS	Y
KIIA 4.5	Tilting, N.	1990	GC method for the determination of LAB 205 259 in water - Methode 300 1990/0526 ! 2774 GLP: Open Published: Open BVL-2088964, MET1999-367	BAS	Y
KIIA 4.5	Zangmeister, W.	2009	Validation of analytical method L0143/01: Determination of BAS 700 F and its metabolites M700F001, M700F002 and M700F007 in water by HPLC/MS-MS 2009/1069396 ! 314720 GLP: Open Published: Open BVL-2156554, ASB2010-7738	CFW	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 4.6, KIIIA1 5.5	Obermann, M.	2007	Validation of analytical method L0094/01: Determination of BAS 480 F and its metabolite Reg.No.226215 in sediment using HPLC-MS/MS 2007/1052644 ! 314502 GLP: Yes (1) Open (1) Published: Open (1) No (1) BVL-1947220, BVL-2438176, ASB2010-8856	BAS	N
KIIA 4.7	Zangmeister, W.	1999	Validation of analytical method 367/2: Determination of BAS 480 F (Reg.No. 205259) in air by GC-ECD 64231 ! 1999/11098 ! 367/2 GLP: Open Published: Open BVL-2088967, MET2000-27	BAS	Y
KIIA 4.7	Zangmeister, W.	2004	Validation of analytical method 367/2: Determination of BAS 480 F (Reg.No. 205 259) in air by GC-ECD - Report Amendment no. 1 2004/1015204 ! 367/2 ! 64231 GLP: Open Published: Open BVL-2088968, MET2006-784	BAS	N
KIIA 4.7	Zangmeister, W.	2009	Validation of BASF method L0142/01: Determination of BAS 700 F in air 2009/1069395 ! 314739 GLP: Open Published: Open BVL-2156555, ASB2010-7739	BAS	Y
KIIA 4.8	Hartl, M.	2002	Validation of analytical method no. 332 for the determination of BAS 480 F in blood 2002/1006989 ! 138718 GLP: Open Published: Open BVL-2088969, MET2002-316	BAS	Y
KIIA 4.8	Hartl, M.	2002	Amendment No. 1 to final report: Validation of analytical method No. 332 for the Determination of BAS 480 F in blood 2002/1011828 ! 138718 GLP: Open Published: Open BVL-2088970, MET2002-601	BAS	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.2.1	Keller, E.	1991	The metabolism of 14C-205 259 (14C-BAS 480 F) in wheat 91/11289 ! P90-M001 ! 3180 GLP: Open Published: Open BVL-2218088, RIP2003-1512	BAS	Y
KIIA 6.2.1	Rabe, U.	2009	Metabolism of BAS 700 F in tomatoes 2009/1017901 ! 315734 GLP: Open Published: Open BVL-2154427, ASB2010-7939	BAS	Y
KIIA 6.2.3	Grosshans, F.; Bretz, M.; Lutz, T.; Gläßgen, W. E.	2009	Metabolism of 14C-BAS 700 F (14C-Reg.No. 5094351) in lactating goat 2009/1074074 ! 315778 GLP: Open Published: Open BVL-2154433, ASB2010-7945	BAS	Y
KIIA 6.2.3	Kohl, W.	1990	The metabolism of 14C-LAB 205 259 in lactating goats 90/10170 ! P88-M012 ! P88-M013 ! 2770 GLP: Open Published: Open BVL-2218152, RIP2003-1507	BAS	Y
MIIIA1 Sec 2	Applicant	2013	Epoxiconazol + Fluxapyroxad / Adexar (BAS 701 00 F): Analytical methods - Tier 2, IIIA-5 - Draft Registration Report - Part B - Core assessment MIII / Sec. 2 / 2012/1321585 Ostermann Gabriele GLP: No Published: No BVL-2438324, BVL-2438325, ASB2013-9471	BAS	N

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 – Detailed evaluation of the additional studies relied upon

A 1.1 Analytical methods for epoxiconazole

A 1.1.1 Methods for enforcement of residues in food and feed of plant origin
A 1.1.1.1 Analytical method 1
A 1.1.1.2

Reference: OECD KII A, 4.3/01

Report: European Standard EN 15662:2008 - Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS(/MS) following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS-method, Anonymous, 2008, ASB2008-5464

Guideline(s): No

Deviations: Not applicable

GLP: Not applicable

Acceptability: Yes

Materials and methods

High water content commodities (cucumber), acidic commodities (lemon) and dry crops (wheat flour) are analyzed according to the multiresidue method EN 15662:2008 (QuEChERS method). The sample material is extracted by shaking with acetonitrile, sodium citrate, sodium hydrogencitrate sesquihydrate, magnesium sulfate and sodium chloride. After centrifugation the acetonitrile layer is shaken with PSA, and magnesium sulfate. The extracts are centrifuged and diluted. Final quantification is done by LC-MS/MS using a C18 column, electrospray ionization in positive mode and monitoring the MS/MS transitions m/z 330→121, 330→102

Results and discussions

Table A 1: Recovery results from the method validation of cucumber, lemon and wheat flour using the analytical method. Standards were prepared in matrix blank extracts

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
Cucumber	0.01 0.1	36 44	96 99	7 7	6 labs 6 labs
Lemon	0.01 0.1	28 34	98 99	9 5	6 labs 6 labs
Wheat flour	0.01 0.1	15 20	103 100	7 6	3 labs 4 labs

Table A 2: Characteristics for the analytical method used for the quantitation of epoxiconazole residues in cucumber, lemon and wheat flour

	epoxiconazole
Calibration function	Not stated
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	Not stated
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	Not stated
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	Yes
Assessment of matrix effects is presented (yes/no)	No
Interference >30% of LOQ in blank sample is absent (yes/no)	Yes

Conclusion

The multiresidue method EN15662:2008 (QuEChERS method) validated for epoxiconazole in high water content, acidic and dry commodities using MS/MS detection is accepted. The validated limit of quantification is 0.01 mg/kg. The applicability of the method is proven by proficiency tests in 3-5 labs

Comments of zRMS:	acceptable

DRAFT REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product code: Adexar (BAS 701 00 F)
Active Substance: Epoxiconazole 62.5 g/L
Fluxapyroxad 62.5 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE
Date: 02 June 2017

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3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on BAS 701 00 F/Adexar *

Product name and code	BAS 701 00 F/Adexar (BAS-70100-FW-0-EC)
Formulation type	Emulsifiable concentrate
Active substances (incl. content)	Epoxiconazole (BAS 480 F); 62.5 g/L Fluxapyroxad (BAS 700 F); 62.5 g/L
Function	Fungicide, growth regulator
Product already evaluated as the 'representative formulation' during the Annex I inclusion	No
Product previously evaluated in an other MS according to Uniform Principles	The product has already been registered in Austria, Belgium, Estonia, France, Germany, Ireland, Latvia, Lithuania, Luxembourg and the United Kingdom according to the applicant.

* Information on the detailed composition of BAS 701 00 F/Adexar can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

In accordance with Directives 67/548/EEC and 1999/45/EC and according to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 3.1-2: Justified proposals for classification and labelling

C&L according to Directives 67/548/EEC and 1999/45/EC	
Hazard symbol:	T
Indications of danger:	Toxic
Risk phrases:	22-36-40-43-61-62
Safety phrases:	53-1-2-13-24-26-36-37-39-45
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.
	'Contains 2-ethylhexyl-S-lactate (CAS-No. 186817-80-1). May produce an allergic reaction.'

C&L according to Regulation (EC) No 1272/2008	
Hazard classes, categories:	Repr. 1B, Acute Tox. 4, Skin Sens. 1, Eye Irrit. 2, Carc. 2,
Signal word:	Danger
Hazard statements:	H302-317-319-351-360Df
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'Contains 2-ethylhexyl-S-lactate (CAS-No. 186817-80-1). May produce an allergic reaction.' [EUH208]

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for BAS 701 00 F/Adexar

	Result	**PPE / Risk mitigation measures**
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage. - The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed. - Wear a faceshield when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling the undiluted product. - Wear standard protective gloves (plant protection) when handling/applying the product ready for application. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product. - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application. - Wear a rubber apron when handling the undiluted product.
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried.
Bystanders	Acceptable	None
Residents	Acceptable	None

The risk assessment according to the German model has shown that the estimated exposure towards epoxiconazole and fluxapyroxad in BAS 701 00 F/Adexar will not exceed the particular systemic AOEL for operators, workers, bystanders and residents. Operator exposure will be below the systemic AOEL only if prescribed PPE is worn. No specific PPE is necessary for workers.

The risk assessment according to the UK-POEM has shown that the estimated exposure towards epoxiconazole and fluxapyroxad in BAS 701 00 F/Adexar will exceed the systemic AOEL for epoxiconazole for operators irrespective whether PPE is worn or not.

However, as could be demonstrated by two operator exposure studies reflecting agronomic parameters normally assumed for exposure estimations according to the UK POEM, safe use of BAS 701 00 F/Adexar is possible provided prescribed PPE is worn.

Further reduction of exposure is to be expected due to necessary PPE allocated according to dangerous substances regulations.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in Table 3.1-4.

Table 3.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8			
Crops 1) and situation (e.g. growth stage of crop)	**F/G or I 2)**	**Application**		**Application rate**		**Remarks:** **(e.g. surfactant (L /ha))** **critical gap for operator, worker, bystander or resident exposure based on [*Exposure model*]**	**Acceptability of exposure assessment**			
		Method / Kind (incl. application technique 3))	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		**Operator**	**Worker**	**Bystander**	**Residents**
Wheat, barley, rye, triticale	F	Spraying LCTM	2 , 2 (21 d)	Epoxiconazole: 0.125 kg/ha, Fluxapyroxad: 0.125 kg/ha Epoxiconazole: 0.250 kg/ha, Fluxapyroxad: 0.250 kg/ha	100 - 400	German model				
						UK POEM				
						Exposure studies				

	Exposure acceptable without PPE / risk mitigation measures
	Further refinement and/or risk mitigation measures required
	Exposure not acceptable

1) Pooled critical GAPs with the same max. application rate per application and using the same application technique
2) F: field or outdoor application, G: greenhouse application, I: indoor application
3) LC: low crops, TM: tractor-mounted

3.2 Toxicological Information on Active Substances

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 3.2-1.

Table 3.2-1: Information on active substances

Epoxiconazole

Information on absorption rates of the active ingredient		
	Value	Source
oral	50 % used to correct AOEL	EFSA Scientific Report (2008) 138, 1-80 (2008-03-26) [ASB2012-3620]
inhalative	100 %	(default)
Reference doses		
	Value	Source
ADI	0.008 mg/kg bw	EFSA Scientific Report (2008) 138, 1-80 (2008-03-26) [ASB2012-3620]
AOEL-S	0.008 mg/kg bw/d	EFSA Scientific Report (2008) 138, 1-80 (2008-03-26) [ASB2012-3620]
ARfD	0.023 mg/kg bw	EFSA Scientific Report (2008) 138, 1-80 (2008-03-26) [ASB2012-3620]

Classification and proposed labelling	
with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Reg. (EC) No 944/2013 (i.e. 5th ATP amending Reg. (EC) No 1272/2008): T - Toxic R40 - Limited evidence of carcinogenic effect (Carc. Cat. 3) R62 - Possible risk of impaired fertility (Repr. Cat. 3)

	R61 - May cause harm to the unborn child (Repr. Cat. 2) Proposal Germany: none additional
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Reg. (EC) No 944/2013 (i.e. 5th ATP amending Reg. (EC) No 1272/2008) Carcinogenicity, cat. 2 Reproductive toxicity, cat. 1B H351 - Suspected of causing cancer H360Df- May damage the unborn child Suspected of damaging fertility Proposal Germany: none additional

Fluxapyroxad

Information on absorption rates of the active ingredient

	Value	Source
oral	68 %	EFSA Journal 2012;10(1):2522 (2011-12-16) ASB2012-3723
inhalative	100 %	(default)

Reference doses

	Value	Source
ADI	0.02 mg/kg bw	EFSA Journal 2012;10(1):2522 (2011-12-16) ASB2012-3723
AOEL-S	0.04 mg/kg bw/d	EFSA Journal 2012;10(1):2522 (2011-12-16) ASB2012-3723
ARfD	0.25 mg/kg bw	EFSA Journal 2012;10(1):2522 (2011-12-16) ASB2012-3723

Classification and proposed labelling

with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Table 3.2): substance not listed up to and including 1st ATP Proposal Germany: Xn - Harmful R40 - Limited evidence of carcinogenic effect (Carc. Cat. 3)
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Table 3.1): substance not listed up to and including 1st ATP Proposal Germany: Carcinogenicity, cat. 2 H351 - Suspected of causing cancer

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BAS 701 00 F/Adexar is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on BAS 701 00 F/Adexar can be found in the confidential dRR Part C.

Table 3.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for BAS 701 00 F/Adexar

Type of test, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Dir. 67/548/EEC)	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	> 500 mg/kg bw, < 2000 mg/kg bw	Yes	R22	H302	[redacted], S., 2008a
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	None	[redacted], S., 2008b
LC_{50} inhalation, rat (OECD 403)	6.65 mg/L air for males, 5.84 mg/L air for females	Yes	None	None	[redacted], 2008
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes	None	None	[redacted], 2008a
Eye irritation, rabbit (OECD 405)	Irritant	Yes	R36	H319	[redacted], 2008b
Eye irritation, rabbit (OECD 405)	Irritant	Yes	R36	H319	[redacted], 2012
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	R43	H317	[redacted], A. O., 2008
Supplementary studies for combinations of plant protection products	No data – not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of BAS 701 00 F/Adexar

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Dir. 67/548/EEC and/or in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Dir. 67/548/EEC, in Dir. 1999/45/EC and/or in Reg. 1272/2008)
Toxicological properties of active substances (relevant for classification of product)	Epoxiconazole (6.0 % (w/w))	R40 [1)] (≥ 1 %) [2)] R61 [3)] (≥ 0.5 %) [2)] R62 [3)] (≥ 5 %) [2)] H351 (≥ 1 %) [1)] H360D [3)] (≥ 0.3 %) [1)] H360f [3)] (≥ 3 %) [1)]	[1)] Reg. (EC) No 1272/2008 [2)] Dir. 1999/45/EEC [3)] Reg. (EC) No 944/2013 (i.e. 5th ATP amending Reg. (EC) No 1272/2008)	R40 R61 R62 H351 H360Df
	Fluxapyroxad (6.0 % (w/w))	R40 [3)] (≥ 1 %) [1)] H351 [3)] (≥ 1 %) [1)]	[3)] Proposal BfR and MSDS [#]	R40 H351

Toxicological properties of non-active substances (relevant for classification of product)	Propionic acid, 2-hydroxy-,2-ethylhexyl ester (2-Ethylhexyl-S-lactate) (CAS-No. 186817-80-1), 42.0 % (w/w))	R43; RA (≥ 0.1 %) 1) H317; EUH208 (≥ 0.1 %) 1)	MSDS ##	'Contains 2-ethylhexyl-S-lactate (CAS-No. 186817-80-1). May produce an allergic reaction.' EUH208 (Please, see wording above)
Further toxicological information	No data – not required			

MSDS: material safety data sheet by the applicant
Latest version of material safety data sheet by the manufacturer (2012), but up to now not submitted for this authorisation (data base BfR), in accordance with REACH Registration report

3.4 Toxicological evaluation of groundwater metabolites

3.4.1 M700F001 (Metabolite of Fluxapyroxad)

A summary of the toxicological evaluation for groundwater metabolite M700F001 is given in Table 3.4-1. No detailed summaries are provided if the studies have already been assessed and accepted at EU level.

Table 3.4-1: Summary of evaluation of the toxicity studies for M700F001

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity (OECD 423)	Rat LD_{50} oral: > 2000 mg/kg bw	Yes	[redacted], 2009* ASB2010-7890
Repeated dose 90-day oral toxicity (OECD 408)	Rat , NOAEL: 1000 mg/kg bw (highest dose tested), no adverse findings	Yes	[redacted] 2009* ASB2010-7904
Reverse mutation assay in *Salmonella typhimurium* and *Escherichia coli* (OECD 471)	Non-mutagenic	Yes	Schulz and Landsiedel , 2009* ASB2010-7905
In vitro chromosome aberration assay in Chinese hamster V79 cells (OECD 473)	Not clastogenic	Yes	Schulz and Landsiedel , 2009* ASB2010-7906
In vitro gene mutation test in CHO cells (HPRT locus assay) (OECD 476)	Not mutagenic	Yes	Schulz and Landsiedel , 2009* ASB2010-7903 ASB2010-7907
In vivo micronucleus test in bone marrow cells of the mouse (OECD 474)	Not clastogenic or aneugenic	Yes	[redacted], 2009* ASB2010-7908
Developmental toxicity in rabbit (OECD 414)	$NOAEL_{maternal/developmental}$ 250 mg/kg bw/d; Severe maternal toxicity ≥500 mg/kg bw/d in range-finding sutdies	Yes	[redacted], 2009* ASB2010-7909

*indicates that a study was reviewed at EU level

3.4.2 M700F002 (Metabolite of Fluxapyroxad)

A summary of the toxicological evaluation for groundwater metabolite M700F002 is given in Table 3.4-12. No detailed summaries are provided if the studies have already been assessed and accepted at EU level.

Table 3.4-2: Summary of evaluation of the toxicity studies for M700F002

Type of test, species (Guideline)	Result	Acceptability	Reference*
Acute oral toxicity (OECD 423)	Rat LD_{50} oral: > 2000 mg/kg bw	Yes	[redacted], 2009* ASB2010-7910
Repeated dose 28-day oral toxicity (OECD 407)	Rat , NOAEL: 15000 ppm (1165/1253 mg/kg bw/d m/f)	Yes	[redacted] 2008* ASB2010-7911
Repeated dose 90-day oral toxicity (OECD 408)	Rat , NOAEL: 1000 mg/kg bw (highest dose tested), no adverse findings	Yes	[redacted] 2009* ASB2010-7912
Reverse mutation assay in *Salmonella typhimurium* and *Escherichia coli* (OECD 471)	Non-mutagenic	Yes	Schulz and Landsiedel , 2007* ASB2010-7913
In vitro chromosome aberration assay in Chinese hamster V79 cells (OECD 473)	Not clastogenic	Yes	Schulz and Landsiedel , 2008* ASB2010-7914
In vitro gene mutation test in CHO cells (HPRT locus assay) (OECD 476)	Not mutagenic	Yes	Schulz and Landsiedel , 2008* ASB2010-7928
In vivo micronucleus test in bone marrow cells of the mouse (OECD 474)	Not clastogenic or aneugenic	Yes	[redacted], 2009* ASB2010-7929
Developmental toxicity in rabbit (OECD 414)	NOAEL $_{maternal:}$ 250 mg/kg bw/d; NOAEL $_{developmental}$: 300 mg/kg bw/d (highest dose tested)	Yes	[redacted] 2009* ASB2010-7916

*indicates that a study was reviewed at EU level

3.5 Dermal Absorption (IIIA 7.6)

A summary of the dermal absorption endpoints for the active substances in BAS 701 00 F are presented in the following table.

Table 3.5-1: Dermal absorption endpoints for active substances in BAS 701 00 F

	Epoxiconazole		Fluxapyroxad	
	Value	**Reference**	**Value**	**Reference**
Concentrate	1 %	New study reported in Appendix 2	2 %	New study reported in Appendix 2
Dilution (1:50)	9 %	New study reported in Appendix 2	4 %	New study reported in Appendix 2
Dilution (1:300)	60 %	New study reported in Appendix 2	8 %	New study reported in Appendix 2

3.5.1 Justification for proposed values - epoxiconazole

Proposed endpoint for epoxiconazole is based dermal absorption studies on a formulation identical to BAS 701 00 F/Adexar. The studies are summarized in Table 3.5-2. Full summaries of studies on the dermal absorption of epoxiconazole/BAS 701 00 F that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 3.5-2: Summary of dermal absorption studies for epoxiconazole

Test	**Concentrate**	**Spray dilution** (1:50 & 1:300)	**Formulation in study**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**	**Reference**
In vitro (human)	1 %	9 % & 60 %	BAS 701 00 F	Yes	Not necessary, since original product BAS 701 00 F was tested	Yes	**Fabian, E.,Mellert, W., 2012b [ASB2013-9339]**

3.5.2 Justification for proposed values - fluxapyroxad

Proposed endpoint for fluxapyroxad is based on dermal absorption studies on a formulation identical to BAS 701 00 F/Adexar. The studies are summarized in Table 3.5-3. No detailed summaries are provided if the studies have already been assessed and accepted at EU level. Full summaries of studies on the dermal absorption of Fluxapyroxad/BAS 701 00 F that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2.

Table 3.5-3: Summary of dermal absorption studies for fluxapyroxad

Test	**Concentrate**	**Spray dilution** (1:50 & 1:300)	**Formulation in study**	**Acceptability of study**	**Justification provided on representativity of study formulation for current product**	**Acceptability of justification**	**Reference***
In vitro (human)	2 %	4 % & 8 %	BAS 701 00 F	Yes	Not necessary, since original product BAS 701 00 F was tested	Yes	**Fabian, E.,Mellert, W., 2012° [ASB2013-9338]**

3.6 Exposure Assessment of Plant Protection Product

Table 3.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	BAS 701 00 F/Adexar (BAS-70100-FW-0-EC	
Formulation type	Emulsifiable concentrate	
Category	Fungicide, growth regulator	
Container sizes, short description		
Active substances (incl. content)	**Epoxiconazole (BAS 480 F)** 62.5 g/L	**Fluxapyroxad (BAS 700 F)** 62.5 g/L
AOEL systemic	0.008 mg/kg bw/d	0.04 mg/kg bw/d
Inhalative absorption	100 %	100 %
Oral absorption	50 %	68 %
Dermal absorption	Concentrate: 1 % Dilution: 9 % (dilution rate 1 : 50) 60 % (dilution rate: 1:300) (based on original product BAS 701 00 F)	Concentrate: 2 % Dilution: 4 % (dilution rate 1 : 50) 8 % (dilution rate: 1:300) (based on original product BAS 701 00 F)

3.6.1 Selection of critical uses and justification

The critical GAPs used for the exposure assessment of the plant protection product are shown in Table 3.1-4.

3.6.2 Operator exposure (IIIA 7.3)

3.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of BAS 701 00 F/Adexar according to the critical uses is presented in Table 3.6-2. Outcome of the estimation is presented in Table 3.6-3. Detailed calculations are in Appendix 3.

Table 3.6-2: Exposure models for intended uses

Critical uses	Various cereals (max. 2 L product/ha)
Model	German model [Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992]
Critical uses	Various cereals (max. 2 L product/ha)
Model	Revised UK-POEM [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical Association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992]

Table 3.6-3: Estimated operator exposure

		Epoxiconazole		Fluxapyroxad	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.125 kg a.s./ha					
German Model (Geometric mean) Body weight: 70 kg	no PPE[1)]	0.044629	**557.9**	0.007600	19.0
	+ Gloves during mixing/loading as well as gloves and protective garment during application	0.003147	39.3	0.000485	1.2
UK POEM (Application volume: 300 L/ha Container: 10 L, 63 mm closure Body weight: 60 kg	no PPE[2)]	0.1788	**2234.4**	0.0339	84.8
	+ Gloves during mixing/loading and application	0.0278	**347.7**	0.0050	12.6

1) no PPE: Operator wearing T-shirt and shorts
2) no PPE: Operator wearing long sleeved shirt, long trousers ("permeable") but no gloves

Assuming dose additivity for both active substances, the combined AOEL-S exploitation amounts to 40.5 % in the case above mentioned, when PPE is used (German model).

3.6.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out according to the German model indicate that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses provided respective PPE is worn, a study to measure operator exposure would not be necessary.

However, results of operator exposure estimations according to the UK POEM indicate that the acceptable operator exposure level (AOEL) will be exceeded under conditions of intended uses irrespective of whether PPE is worn or not. Therefore, two operator exposure studies have been provided by the applicant in which surrogate SC-formulations containing epoxiconazole were applied in cereals.
For a detailed description of the studies it is referred to Annex 4, operator exposure estimations for BAS 701 00 f/Adexar are presented below (see Table 3.6-4).

Table 3.6-4: Refined operator exposure estimations using measured surrogate exposure data

		Epoxiconazole	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Tractor (equipped with closed cabins) mounted boom spray application outdoors to low crops Application rate: 0.125 kg a.s./ha			
Body weight: 60 kg	no PPE [1)]	0.035837	**447.97**
	+ Gloves and coverall during mixing/loading and coverall during appl. (+ gloves during appl. only in the case of maintenance tasks) [2)]	0.000236	2.95

1) potential dermal exposure (75th percentile, see Table A 40) x respective dermal absorption for dilution ('worst case') + inhalation exposure (75th percentile, see Table A 40), devided by respective systemic AOEL
2) actual dermal exposure (75th percentile, see Table A 40) x respective dermal absorption for dilution ('worst case') + inhalation exposure (75th percentile, see Table A 40), devided by respective systemic AOEL

Using measured surrogate exposure data for operators it could be demonstrated that BAS 701 00 F/

Adexar can be safely applied even if a high work rate of 50 ha is taken into account. Under realistic conditions, i.e. assuming tractors equipped with cabins and modern application technique (for details, please see Appendix 4), the estimated operator exposure will not exceed the systemic AOEL for epoxiconazole provided PPE is worn by operators. Even if lower body weights were taken as a basis for exposure estimations compared to the measured body weights within the exposure studies (e.g. 60 kg according to the UK POEM versus 102 kg representing the 75th percentile in the studies), measured actual operator exposure would not exceed the systemic AOEL for epoxiconazole.

3.6.3 Worker exposure (IIIA 7.5)

3.6.3.1 Estimation of worker exposure

Table 3.6-5 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BAS 701 00 F/Adexar according to the critical uses. The outcome of the estimation is presented in Table 3.6-6. Detailed calculations are in Appendix 3.

Table 3.6-5: Exposure models for intended uses

Critical uses	Various cereals (max. 2 x 2 L product/ha)
Model	German re-entry model, Krebs et al. (2000) [Uniform Principles for Safeguarding the Health of Workers Re-entering Crop Growing Areas after Application of Plant Protection Products, Nachrichtenbl. Deut. Pflanzenschutzdienst., 52(1), p. 5-9]

Table 3.6-6: Estimated worker exposure

		Epoxiconazole		Fluxapyroxad	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate: 2 x 0.125 kg a.s./ha					
2 hours/day [1)], TC: 1500 cm^2/person/h [2)] Body weight: 60 kg	no PPE [3)]	0.00750	93.8	0.00100	2.5
	with PPE [4)]	0.00038	4.7	0.00005	0.1

1) 2 h/day for professional applications for maintenance, inspection or irrigation activities etc.
2) US-EPA policy paper [EPA, Science Advisory Council for Exposure; 2000; Agricultural Default Transfer Coefficients, Policy # 003.1, May 7 1998 revised 7 August 2000].
3) no PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves
4) with PPE: see 'Instructions for use'

3.6.3.2 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded for both active substances under conditions of intended uses, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

3.6.4 Bystander and resident exposure (IIIA 7.4)

3.6.4.1 Estimation of bystander and resident exposure

Table 3.6-7 shows the exposure model used for estimation of bystander and resident exposure to epoxiconazole and fluxapyroxad. The outcome of the estimation is presented in Table 3.6-8. Detailed calculations are in Appendix 3.

Table 3.6-7: Exposure models for intended uses

Critical uses	Various cereals (max. 2 x 2 L product/ha)
Model	Martin, S. et al. (2008) [Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel] and Bundesanzeiger (BAnz), 06 January 2012, Issue No. 4, pp. 75-76

Table 3.6-8: Estimated bystander and resident exposure

	Epoxiconazole		**Fluxapyroxad**	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: max. 2 x 0.125 kg a.s./ha				
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.003463	43.3	0.000462	1.16
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.002703	33.8	0.000361	0.90
Residents (adult) Drift rate: 2.38 % (1 m) Body weight: 60 kg	0.000711	8.9	0.000058	0.14
Residents (children) Drift rate: 2.38 % (1 m) Body weight: 16.15 kg	0.001135	14.2	0.000139	0.35

3.6.4.2 *Measurement of bystander and/or resident exposure*

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for epoxiconazole and fluxapyroxad will not be exceeded under conditions of intended uses, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

3.6.5 Statement on combined exposure

The product is a mixture of two active substances.
The combined toxicological effect of these active substances has not been investigated, since no harmonized evaluation concept is available on EU-level.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance epoxiconazole EFSA Scientific Report (2008) 138, 1-80 ASB2012-3620		Add
	EFSA	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluxapyroxad (BAS 700 F) EFSA Journal 2012;10(1):2522 ! EFSA-Q-2011-00395 ASB2012-3723		Add
KIIA 5.8	[redacted]	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Acute oral toxicity study in rats 2009/1018501 ! 10A0441/079106 ! 09-BF-OT009 GLP: Open Published: Open BVL-2153911, ASB2010-7910	BAS	Y
KIIA 5.8	[redacted]	2009	Reg.No. 5069089 (metabolite of BAS 700 F): Acute oral toxicity study in rats 2009/1072502 ! 10A0451/079119 ! 09-BF-OT049 GLP: Open Published: Open BVL-2153904, ASB2010-7890	BAS	Y
KIIA 5.8	[redacted]	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Repeated dose 90-day oral toxicity study in Wistar rats; Administration in the diet R958945_11265 ! 2009/1012026 ! 50S0441/07091 ! 47923616 [redacted] GLP: Open Published: Open BVL-2153913, ASB2010-7912	BAS	Y
KIIA 5.8	[redacted]	2008	Reg.No. 5435595 (metabolite of BAS 700 F): Repeated dose 28-day oral toxicity study in Wistar rats; - Administration in the diet 2008/1052054 ! 30S0441/07048 GLP: Open Published: Open BVL-2153912, ASB2010-7911	BAS	Y
KIIA 5.8	[redacted]	2009	Reg. No. 5069089 (metabolite of BAS 700 F): Repeated dose 90-day oral toxicity study in wistar rats - Administration in the diet 2009/1072503 ! 50S0451/07119 ! SYN508272_10896 [redacted] GLP: Open Published: Open BVL-2153905, ASB2010-7904	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2007	Reg.No. 5435595 (metabolite of BAS 700 F): Salmonella typhimurium / Escherichia coli reverse mutation assay (standard plate test and preincubation test) 2007/1051931 ! 40M0441/074079 GLP: Open Published: Open BVL-2153914, ASB2010-7913	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2008	Reg.No. 5435595 (metabolite of BAS 700 F): In vitro chromosome aberration assay in V79 cells 2008/1002741 ! 32M0441/074074 GLP: Open Published: Open BVL-2153915, ASB2010-7914	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2008	Reg.No. 5435595 (metabolite of BAS 700 F): In vitro gene mutation test in CHO cells (HPRT locus assay) 2008/1014199 ! 50M0441/074075 GLP: Open Published: Open BVL-2153916, ASB2010-7928	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 5.8	Schulz, M.; Landsiedel, R.	2009	Reg.No. 5069089 (metabolite of 700 F): In vitro gene mutation test in CHO cells (HPRT locus assay) 2009/1072392 ! 50M0451/074157 GLP: Open Published: Open BVL-2153908, ASB2010-7907	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2009	Reg.No. 5069089 (metabolite of BAS 700 F): Salmonella typhimurium/Escherichia coli reverse mutation assay (standard plate test and preincubation test) 2009/1072504 ! 40M0451/074195 GLP: Open Published: Open BVL-2153906, ASB2010-7905	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2009	Reg.No. 5069089 (metabolite of BAS 700 F): In vitro chromosome aberration assay in V79 cells 2009/1072505 ! 32M0451/074158 GLP: Open Published: Open BVL-2153907, ASB2010-7906	BAS	Y
KIIA 5.8	[redacted]	2009	Reg.No. 5069089 (metabolite of BAS 700 F): Micronucleus test in bone marrow cells of the mouse 2009/1072506 ! 26M0451/074181 GLP: Open Published: Open BVL-2153909, ASB2010-7908	BAS	Y
KIIA 5.8	[redacted]	2009	Reg.No. 5435595 (metabolite of BAS 700 F): Micronucleus test in bone marrow cells of the mouse 2009/1072508 ! 26M0441/074180 GLP: Open Published: Open BVL-2153917, ASB2010-7929	BAS	Y
KIIA 5.8	Schulz, M.; Landsiedel, R.	2009	Reg.No. 5069089 (metabolite of 700 F): In vitro gene mutation test in CHO cells (HPRT locus assay) Amendment No. 1 2009/1081058 ! 50M0451/074157 GLP: Open Published: Open BVL-2153930, ASB2010-7903	BAS	Y
KIIA 5.8	[redacted]	2009	Reg.No. 5069089 (metabolite of BAS 700 F): Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2009/1072507 GLP: Open Published: Open BVL-2153910; ASB2010-7909	BAS	Y
KIIA 5.8	[redacted]		Reg.No. 5435595 (metabolite of BAS 700 F) - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2009/1072509 BVL-2153919; ASB2010-7916	BAS	Y
KIIIA1 7.1.1	[redacted]	2008	BAS 701 00 F: Acute oral toxicity study in rats - Amendment No. 1 2008/1084675 ! 10A0497/079100 ! 08-BF-OT031 GLP: Yes Published: No BVL-2438179, ASB2010-8819	BAS	Y
KIIIA1 7.1.1	[redacted]	2008	BAS 701 00 F: Acute oral toxicity study in rats 2008/1031464 ! 10A0497/079100 ! 08-BF-OT031 GLP: Yes Published: No BVL-2438177, ASB2010-8818	BAS	Y
KIIIA1 7.1.2	[redacted]	2008	BAS 701 00 F: Acute dermal toxicity study in rats 2008/1031465 ! 11A0497/079101 ! 08-BF-DT032 GLP: Yes Published: No BVL-2438181, ASB2010-8820	BAS	Y
KIIIA1 7.1.3	[redacted]	2008	BAS 701 00 F: Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure 2008/1052073 ! 13I0497/077020 GLP: Yes Published: No BVL-2438183, ASB2010-8821	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIIA1 7.1.4	[redacted]	2008	BAS 701 00 F: Acute dermal irritation/corrosion in rabbits 2008/1052692 ! 18H0497/072263 GLP: Yes Published: No BVL-2438185, ASB2010-8822	BAS	Y
KIIIA1 7.1.5	[redacted]	2008	BAS 701 00 F: Acute eye irritation in rabbits 2008/1052693 ! 11H0497/072262 GLP: Yes Published: No BVL-2438187, ASB2010-8823	BAS	Y
KIIIA1 7.1.5	[redacted]	2012	BAS 701 00 F: Acute eye irritation in rabbits 2011/1281930 ! 11H0497/07X029 ! 11-BF-EI154 GLP: Yes Published: No BVL-2438189, ASB2013-9335	BAS	Y
KIIIA1 7.1.6	[redacted]	2008	BAS 701 00 F: Murine local lymph node assay (LLNA) 2008/1052694 ! 58H0497/072264 GLP: Yes Published: No BVL-2438191, ASB2010-8824	BAS	Y
KIIIA1 7.3.3	Blaschke, U.	2010	Determination of operator exposure (passive dosimetry) during typical activities associated with a ground boom application of BAS 480 31 F to cereal crops at farm locations in the United Kingdom and Germany, 2008 2010/1089364 ! 344806 GLP: Yes Published: No BVL-2438194, ASB2013-9336	BAS	Y
KIIIA1 7.3.3	Stadler, R.	2007	Determination of dermal and inhalation operator exposure for mixing/loading and application of BAS 601 KD F in cereals 2007/1033389 ! 263968 GLP: Yes Published: No BVL-2438193, ASB2009-4728	BAS	Y
KIIIA1 7.6	Fabian, E.; Mellert, W.	2012	14C-BAS 480 F in BAS 701 00 F: Study of penetration through human skin in vitro 2011/1149980 ! 10B0277/03B006 GLP: Yes Published: No BVL-2438207, ASB2013-9339	BAS	Y
KIIIA1 7.6	Fabian, E.; Mellert, W.	2012	14C-BAS 700 F in BAS 701 00 F: Study of penetration through human skin in vitro 2011/1248839 ! 10B0759/06B001 GLP: Yes Published: No BVL-2438205, ASB2013-9338	BAS	Y

*Y, Yes/relied on; N, No/not relied on; Add, Additional, Relied on/study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

No bridging is necessary since toxicological studies were performed on original product BAS 701 00 F.

Comments of zRMS:	Accepted

A 2.2 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Acceptable; no deviations, according to guidelines, used for evaluation

Reference:	7.1.1
Report	BAS 701 00 F: Acute oral toxicity study in rats, [redacted], 2008a, 2008/1031464, 10A0497/079100 (08-BF-OT031), ASB2010-8818 and BAS 701 00 F: Acute oral toxicity study in rats, amendment No. 1 [redacted], 2008, 2008/1084675, 10A0497/079100 (08-BF-OT031), ASB2010-8819
Guidelines:	OECD 423 (2001), Reg. (EC) 440/2008, B.1 tris (2008), U.S. EPA OPPTS 870.1100 (2002), Japan MAFF 12 Nosan No. 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rat, Wistar, Crl:WI (Han)
No. of animals (group size)	3 x 3 females (nulliparous and non-pregnant)
Doses	500 mg/kg bw and 2000 mg/kg bw
Exposure	Once by gavage
Vehicle (concentration of test substance)	2000 mg/kg bw: undiluted; 500 mg/kg bw: olive oil Ph.Eur./DAB (25 g/100 mL)
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats treated with BAS 701 00 F

Dose [mg/kg bw]	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Female rats				
500	0/2/3	60 min after appl.	--	> 500
500	0/0/3	--	--	> 500

2000	2/3/3	5 h after appl.	5 h after appl. – day 1	< 2000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats treated with BAS 701 00 F

Mortality:	Two animals of the 2000 mg/kg bw test group were found dead either within 5 hours at the day of application (day 0) or at day 1. No mortality occurred in the 500 mg/kg test groups.
Clinical signs:	Clinical signs observed in animals in the 2000 mg/kg test group revealed impaired and poor general state, dyspnea, salivation, staggering, abdominal position, atonia, ataxia, absent corneal and pain reflex, and red clammy snout (up to 5 hours after application). At the low dose salivation was observed in 2/6 animals during the first hour after administration.
Body weight:	Body weight gain of surviving animals was considered normal.
Macroscopic examination:	Macroscopic findings were restricted to the two high dose animals which died and consisted of red spotted discoloration of all lung lobes, red discoloration of the small intestine and its content or congestion of kidneys.

Conclusion

Under the experimental conditions, the oral LD_{50} of BAS 701 00 F/Adexar is higher than 500 mg/kg bw but less than 2000 mg/kg bw in rats. Thus, labeling with Xn; R22 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.3 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference:	7.1.2
Report	BAS 701 00 F: Acute dermal toxicity study in rats, [redacted], 2008b, 2008/1031465 (08-BF-DT032), ASB2010-8820
Guidelines:	OECD 402 (1987), Reg. (EC) 440/2008, B.3 (2008), U.S. EPA OPPTS 870.1200 (1998), Japan MAFF 12 Nosan No. 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rat, Wistar, Crl:WI (Han)
No. of animals (group size)	5 males and 5 females
Dose	5000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None

Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats treated with BAS 701 00 F

Dose [mg/kg bw]	Toxicological results [1)]	Duration of signs	Time of death	LD_{50} [mg/kg bw] (14 days)
Male rats				
5000	0/0/5	--	--	> 5000
Female rats				
5000	0/0/5	--	--	> 5000

[1)] Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats treated with BAS 701 00 F

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	The mean body weights of the male animals increased normally throughout the study period. Mean body weights of the female animals did not adequately increase during the first post-exposure observation week, probably due to the bandage procedure, but increased during the second week.
Macroscopic examination:	No macroscopic pathologic abnormalities were noted in the animals examined on the last day of observation.

Conclusion

Under the experimental conditions, the dermal LD_{50} of BAS 701 00 F/Adexar is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference: 7.1.3
Report: BAS 701 00 F: Acute inhalation toxicity study in Wistar rats - 4-hour liquid aerosol exposure,
[redacted], 2008,
2008/1052073, 13I0497/077020, ASB2010-8821
Guidelines: OECD 403 (1981),
Reg. (EC) 440/2008, B.2 (2008),
U.S. EPA OPPTS 870.1300 (1998)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rat, Wistar, HanRcc:WIST(SPF)
No. of animals (group size)	Group I: 5 males and 5 females (nulliparous and non-pregnant) Group II: 5 males and 5 females (nulliparous and non-pregnant)
Concentrations	Group I: 2.79 mg/L air and Group II: 6.00 mg/L air
Exposure	4 hours (nose-only; liquid aerosol)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentrations and exposure conditions

Nominal conc. [mg/L air]	Analytical conc. [mg/L air]	MMAD [1)] [µm]	GSD [2)] [µm]
4.84	2.79	1.0	4.1
14.38	6.00	1.4 (sample 1) 1.3 (sample 2)	3.8 (sample 1) 3.9 (sample 2)

1) MMAD = Mass Median Aerodynamic Diameter
2) GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats treated with BAS 701 00 F

Concentration [mg/L air]	Toxicological results [1)]	Duration of signs	Time of death	LC_{50} [mg/L air] (14 days)
Male rats				
2.79	0/5/5	hour 2 of expo. - day 14	--	> 2.79
6.00	1/5/5	hour 1 of expo. – day 14	day 0	6.65 [2)]
Female rats				
2.79	0/5/5	2 h after appl. – day 11	--	> 2.79
6.00	3/5/5	hour 1 of expo. – day 14	2 x day 0 1 x day 2	5.84 [2)]
Both sexes combined				
				6.18 [2)]

1) Number of animals which died/number of animals with clinical signs/number of animals used
2) Probit analysis

Table A 7: Summary of findings of acute inhalation toxicity study in rats treated with BAS 701 00 F

Mortality:	No mortality occurred at the concentration of 2.79 mg/L air. Three of five females and one of five males died at a concentration of 6.00 mg/L air.
Clinical signs:	Clinical signs were observed in animals at all dose levels and comprised visually increased

	respiration, abdominal respiration, laboured respiration, gasping, respiration sounds, and piloerection. Findings were observed from hour 1 during exposure to the end of the observation period at day 14. Additionally at the high dose group poor general state was noted from hour 1 of exposure onwards.
Body weight:	The mean body weights of the male animals increased throughout the study period at 2.79 mg/L air. Mean body weights of the female animals in the low dose group and of all high dose animals decreased during the first post exposure observation week but increased during the second week.
Macroscopic examination:	Necropsy findings of the male and female animals which died on study day 0 consisted of dark red discoloration and partly sunken surface of the lungs. Necropsy findings of the female animal that died on study day 2 consisted of severe dilatation of the small intestine with gaseous content. Apart from one male with a lung oedema there were no macroscopic findings observed in animals at terminal necropsy.

Conclusion

Under the experimental conditions, the inhalation LC_{50} of BAS 701 00 F/Adexar is estimated to be 6.65 mg/L air for males, 5.84 mg/L air for females and 6.18 mg/L air for both sexes combined. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference: 7.1.4
Report: BAS 701 00 F: Acute dermal irritation / corrosion in rabbits,
[redacted], 2008a,
2008/1052692, 18H0497/072263, ASB2010-8822
Guidelines: OECD 404 (2002),
EC Dir. 2004/73, B.4 (2004),
U.S. EPA OPPTS 870.2500 (1998),
Japan MAFF 12 Nousan No. 8147 (2000)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rabbit, New Zealand White A 1077 INRA (SPF)
No. of animals (group size)	3 males
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	7 days
Remarks	Application area was washed off after removal of the patch using polyethylenglycol and polyethylenglycol/water (1 : 1), successively.

Results and discussions

Table A 8: Skin irritation caused by BAS 701 00 F

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Erythema Oedema	2 1	2 0	2 0	1 0	1.7 0.0	7 1
2	Erythema Oedema	2 0	1 0	1 0	0 0	0.7 0.0	3 -
3	Erythema Oedema	2 0	2 0	1 0	1 0	1.3 0.0	7 -

[1)] scores in the range of 0 to 4

Clinical signs:	None

Conclusion

Under the experimental conditions, BAS 701 00 F/Adexar is not considered a skin irritant. Thus, no classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (IIIA1 7.1.5)

A 2.6.1 Study 1

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference: 7.1.5/01
Report: BAS 701 00 F: Acute eye irritation in rabbits,
[redacted], 2008b,
2008/1052693, 11H0497/072262, ASB2010-8823
Guidelines: OECD 405 (2002),
EC Dir. 2004/73, B.5 (2004),
U.S. EPA OPPTS 870.2400 (1998),
Japan MAFF 12 Nousan No. 8147 (2000)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rabbit, New Zealand White A 1077 INRA (SPF)
No. of animals (group size)	2 males and 1 female
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation into conjunctival sac)
Irrigation (time point)	Yes (24 hours after application with hand warm tap water)

Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	No examination of the eyes using fluorescein

Results and discussions

Table A 9: Eye irritation caused by BAS 701 00 F

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1 (male)	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 2 2	1 1 2 1	1 1 1 1	1 1 1 0	1.0 1.0 1.3 0.7	7 7 7 3
2 (male)	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 2 3	1 1 3 2	1 0 2 1	1 1 2 1	1.0 0.7 2.3 1.3	7 7 7 7
3 (female)	Corneal opacity Iritis Redness conjunctivae Chemosis conjunctivae	0 0 2 3	1 1 3 2	1 0 2 1	1 0 2 1	1.0 0.3 2.3 1.3	7 3 7 7

[1)] scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	Additional eye findings: scleral vessels circular injected (all animals), contracted pupils (all animals) and discharge of blood (two animals on day 2)

Conclusion

On the basis of the scores and under the experimental conditions, BAS 701 00 F/Adexar is not an eye irritant according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations. Nevertheless, due to severe, additional findings in the eyes labeling with Xi; R36 is considered necessary. On the other hand, BAS 701 00 F/Adexar is an eye irritant based on the scores according to Regulation (EC) No. 1272/2008 so that labelling with H319 is necessary.

A 2.6.2 Study 2

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference: 7.1.5/02
Report: BAS 701 00 F: Acute eye irritation in rabbits,
[redacted], 2012,
2011/1281930, 11H0497/07X029, 11-BF-EI154, ASB2013-9335
Guidelines: OECD 405 (2002),
Reg. (EC) 440/2008, B.5, (2008)
U.S. EPA OPPTS870.2400 (1998),
Japan MAFF 12 Nousan No. 8147 (2000)
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; 204438)
Species	Rabbit, New Zealand White Crl:KBL(NZW)
No. of animals (group size)	1 male and 2 females
Initial test using one animal	Yes
Exposure	0.1 mL (single instillation into conjunctival sac)
Irrigation (time point)	Yes (24 hours after application with hand warm tap water)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	Justification for repeating the *in vivo* eye irritaion study on BAS 701 00 F: In order to meet the requirements for Brazilian authorisation the eyes were examined using fluorescein at each reading.

Results and discussions

Table A 10: Eye irritation caused by BAS 701 00 F

Animal No.		**Scores after treatment [1)]**				**Mean scores (24-72 h)**	**Reversible [day]**
		1 h	**24 h**	**48 h**	**72 h**		
1 (male)	Corneal opacity	0	2	2	1	1.7	7
	Iritis	1	1	1	1	1.0	7
	Redness conjunctivae	1	2	2	2	2.0	14
	Chemosis conjunctivae	3	2	2	2	2.0	7
2 (female)	Corneal opacity	0	2	2	1	1.7	7
	Iritis	1	1	1	1	1.0	7
	Redness conjunctivae	2	2	2	2	2.0	7
	Chemosis conjunctivae	3	2	1	1	1.3	7
3 (female)	Corneal opacity	0	2	2	1	1.7	7
	Iritis	1	1	1	1	1.0	7
	Redness conjunctivae	2	2	2	2	2.0	14
	Chemosis conjunctivae	3	2	2	2	2.0	7

1) scores in the range of 0 to 4 for cornea opacity and chemosis, 0 to 3 for redness of conjunctivae and 0 to 2 for iritis

Clinical signs:	Additional eye findings: scleral vessels circular injected (all animals)

Conclusion

Under the experimental conditions, BAS 701 00 F/Adexar is an eye irritant. Thus, labelling with Xi; R36 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H319 according to Regulation (EC) No. 1272/2008.

A 2.7 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Acceptable, no deviations, according to guidelines, used for evaluation

Reference: 7.1.6
Report: BAS 701 00 F: Murine Local Lymph Node Assay (LLNA),

	[redacted], 2008, 2008/1052694, 58H0497/072264, ASB2010-8824
Guidelines:	OECD 429 (2002), Reg. (EC) 440/2008, B.42 (2008), U.S. EPA OPPTS 870.2600 (2003)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 701 00 F (07/0497-1; batch 204438)
Species	Mouse, CBA/J strain
No. of animals (group size)	Test substance group: 3 x 5 female mice Vehicle control goup: 5 female mice
Pre-test for dose selection:	Yes
Exposure (concentrations)	25 µL per ear; 3 %, 10 %, 50 % (w/w)
Vehicle	Methy ethyl ketone (MEK)
Reliability check	Alpha-Hexylcinnamaldehyde (10%, 30 % and 50 % w/w in acetone)
Remarks	None

Results and discussions

Table A 11: Results of skin sensitisation caused by BAS 701 00 F

	No. of animals	Concentration [%]	DPM / group	Stimulation index (SI)
BAS 701 00 F	5	3	500.9	0.56
	5	10	885.8	0.99
	5	50	2704.5	3.03
Test Vehicle Control Group	5	0	892.4	1.00
Positive control (January 2008)		10 30 50	not given	4.06, 7.77, 22.42

Clinical signs:	None There was also an increase in cell counts and in lymph note weights, but no relevant increase in ear weights was detected (taken as an indicator for irritation).

Conclusion

Under the experimental conditions, BAS 701 00 F/Adexar is a skin sensitiser. Thus, labelling with Xi; R43 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as labelling with H317 according to Regulation (EC) No. 1272/2008.

A 2.8 Supplementary studies for combinations of plant protection products (IIIA1 7.1.7)

No supplementary studies for combinations of plant protection products have been provided.

A 2.9 Data on co-formulants (III1 7.9)

A 2.9.1 Material safety data sheet for each co-formulant

Material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (IIIA 7.6)

Epoxiconazole

Report:	**Fabian, E.,Mellert, W., 2012b**
Title:	^{14}C-BAS 480 F in BAS 701 00 F - Study of penetration through human skin in vitro
Document No:	BASF DocID 2011/1149980
Guidelines:	OECD 428, OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
GLP	Yes

Material and Methods:
[Triazole-3,5-^{14}C] BAS 480 F (batch 291-3201, radiochemical purity 99.9%, specific activity 6.39 MBq/mg) was used to prepare radioactive BAS 701 00 F (formulation concentrate) as well as 1:50 and 1:300 spray dilutions. The dosing suspensions were prepared adding a respective amount of radiolabelled epoxiconazole to an adequate volume of non-radioactive BAS 701 00 F (Batch 204535), or radioactive epoxiconazole was added to BAS 701 00 F and subsequently diluted with tap water (1: 50 and 1:300 spray dilutions).
The penetration of BAS 480 F formulated as BAS 701 00 F through human dermatomed skin was determined using a modified Franz cell under static conditions equipped with dermatomed human skin at a thickness of 260-675 µm. Skin from 6 donors (2 donors for each dose) were used in this study. Diffusion cells (5, 5, and 10 for the high dose, the mid dose and the low dose, respectively) were loaded with 10 µl of one of the three respective dosing solutions. The test was performed under semi-occlusive conditions. In order to guarantee sufficient solubility of the BAS 480 F in the receptor fluid, ethanol/tap water (3+7, v/v), ethanol/tap water (1+9, v/v) and tap water served as receptor fluids for formulation concentrate, the 1:50 and 1:300 spray dilutions, respectively. After 8 hours the surface was washed twice using approx. 250 µL Texapon® N70 diluted 1:140 (w/w) in highly de-ionized water and once with 250 µL pure water. The skin was then wiped dry using cotton swabs. Thereafter the semi-occlusive cover of the cells was renewed and the penetration experiment continued for another 16 hours.
Samples of the receptor fluid were withdrawn 1; 2; 4; 6; 8; 10, and 24 hours after application. The removed volume was replaced by fresh receptor fluid. After the last sampling of receptor fluid, the contents of the individual receptor compartments was sampled and - like the receptor fluid samples taken during the course of the experiment - retained for analysis. The diffusion cells were dismantled and all parts were extracted in ethanol or Soluene®-350. The skin was removed and washed a second time. As

before, the cotton swabs and the washing solutions were retained for analysis. After the skin surface had dried, the stratum corneum was removed by tape stripping. The tapes were pooled into two samples (1st sample containing the first and second tape; 2nd sample containing the third until sixth tape) for analysis. The remaining skin and the tape strips were analyzed separately.

Table A 12: In-vitro dermal penetration of BAS 480 F formulated as BAS 701 00 F through human skin - Recovery data

Dose group		High dose (Formulation concentrate)		Mid dose (Spray dilution 1:50)		Low dose§ (Spray dilution 1:300)	
Target concentration	[mg/mL]	62.5		1.25		0.208	
Target dose	[µg/cm²]	625		12.50		2.08	
Mean actual applied dose	[µg/cm²]	624.4		13.2		2.21	
Number of cells used/Valid cells		5/5		5/5		10/4	
		Recovery [%]		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.	Mean	S.D.
Unabsorbed dose							
Skin washing after 8 hours		102.12	5.07	86.98	5.86	56.42	9.56
Skin washing after 24 hours		0.17	0.37	0.00	0.00	1.35	1.42
Donor chamber		0.00	0.00	0.00	0.00	0.00	0.00
Dose associated to skin							
Tape strip (1st pool, strips 1 -2)		0.00	0.00	0.00	0.00	0.00	0.00
Tape strips (2nd pool; strips 3 - 6)		0.00	0.00	0.00	0.00	0.01	0.01
Skin preparation		0.11	0.18	0.48	0.20	2.06	1.49
Absorbed dose							
Sum receptor samples incl. wash out		0.52	0.26	5.12	1.74	21.15	6.22
Receptor fluid		0.33	0.13	2.41	0.36	3.89	2.41
Receptor chamber wash		0.03	0.01	1.39	0.34	7.50	3.76
Receptor chamber		-	-	-	-	13.01	5.19
Total recovery#		**103.3**	**5.11**	**96.38**	**4.77**	**105.38**	**7.04**
Absorption essentially complete at end of study (>75% absorption within half the study duration)		**Yes**		**Yes**		**Yes**	
Absorption estimates when absorption not essentially completed (= absorbed dose + dose associated to skin - tape strips 1 and 2)		**NA**	**-**	**NA**	**-**	**NA**	**-**
Absorption estimates when absorption essentially completed (= absorbed dose + dose associated to skin - all tapes)		**1.0**	**0.47**	**9.40**	**2.22**	**47.61**	**12.76**
Absorption estimate normalized[b]		**NA**	**-**	**NA**	**-**	**NA**	**-**
Absorption estimates used for risk assessment[c]		**1**		**9**		**60**	

§ One cell was not assessed to be valid due to insufficient recovery. Five cells were assessed to be invalid due to insufficient recovery.
# values may not calculate exactly due to rounding of figures
a In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to 6th tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable
b Cells with insufficient recovery (<95%) were corrected by normalization of absorption estimate to 100% recovery
c In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) one standard deviation was added to the mean % dermal penetration in cases where the standard deviation was ≥ 25% of the mean value. This value was then rounded to the required number of significant figures.
NA: not applicable

Table A 13: In-vitro dermal penetration of BAS 480 F formulated as BAS 701 00 F through human skin - Penetration kinetics

Dose group	High dose (Formulation concentrate)		Mid dose (Spray dilution 1:50)		Low dose (Spray dilution 1:300)	
Target concentration [mg/mL]	62.5		1.25		0.208	
Target dose [µg/cm²]	625		12.50		2.08	
Mean actual applied dose [µg/cm²]	624.4		13.2		2.21	
Number of cells used/Valid cells	5/5		5/5		10/4	
	Mean cumulative absorption		Mean cumulative absorption		Mean cumulative absorption	
	[µg/cm²]	[%]	[µg/cm²]	[%]	[µg/cm²]	[%]
Sample time [h]						
1	0.00	0.00	0.03	0.20	0.19	8.49
2	0.00	0.00	0.23	1.77	0.29	12.97
4	0.75	0.12	0.48	3.64	0.40	18.00
6	1.91	0.31	0.62	4.66	0.48	21.64
8	3.10	0.50	0.74	5.61	0.53	24.17
10	4.00	0.64	0.85	6.40	0.59	26.60
24	4.42	0.71	0.92	6.92	0.61	27.80
Kp [$*10^{-5}$ cm/h]	0.93	-	14.78	-	94.86	-
Absorption rate [$\mu g/cm^2 \cdot h$]	0.61	-	0.21	-	0.21	-
Lag time [h]	2.92	-	0.91	-	0.21	-
% absorbed within 10 hours[a]		90%		93%		95%

a As no 12 hour value was determined the 10 hour value was used instead

Findings:

- Solubility in the receptor fluid was sufficient not to influence the diffusion process of the test substance (solubility in ethanol/water 3+7 (v/v), in ethanol/water 1+9 (v/v), and in tap water was 0.22 g/L, 0.031 g/l, and 7.1 mg/L, respectively). Receptor media ethanol/water 3+7 (v/v), ethanol/water 1+9 (v/v), and tap water were used for high dose, mid dose, and low dose, respectively.
- The mean total recovery was in the range of 96.38 to 105.38% for the low, mid and high dose levels with individual cell recoveries between 90.70 to 111.82%. Accordingly, the mean total recovery for high dose was 103.29%, with no cells below the threshold. The mean total recovery for mid dose was 96.38%, with one cell below (90.70%) and four above the threshold (103.94,

95.60, 96.31, and 95.35%). Since the dermal penetration estimate (10.01%) of the cell with less than 95% recovery were comparable with the range of the cells with greater than 95% recovery (7.72, 5.48, 11.29, and 10.10%) no adjustment of individual cell values was considered to be justified. The mean total recovery for low dose was 105.38%, with no cells below the threshold.

- In all dose groups absorption was essentially complete at end of study (>75% absorption within half the study duration) – after 10 hours 90 to 95% of the total penetrated radioactivity was recovered in the receptor media. Accordingly, no tape strips were included for calculation of dermal absorption.
- Nearly the entire dose (102.29%) was recovered from the skin washing, donor chamber and tape strips at the high dose. In case of the cells treated with the mid and low dose this value was 86.98% and 57.78%, respectively.
- The amount associated with the skin preparations was 0.11%, 0.48% and 2.06% for the high, mid and low dose, respectively.
- The absorbed dose, i.e. the sum of receptor samples, the receptor fluid recovered at the end of the experiment as well as the receptor chamber wash, amounted to 0.88%, 8.92% and 45.55% at the high, mid and low dose, respectively.
- The total absorption, which corresponds to the amount recovered from skin, both pools of tape strip samples and the absorbed dose, thus, sum up to 0.99%, 9.4% and 47.61% for the high, mid and low dose, respectively.
- A slow penetration of BAS 480 F was observed for the formulation concentrate as indicated by an absorption rate of 0.61 µg/cm^2·h and a permeability coefficient (Kp) of $0.93 \cdot 10^{-5}$ cm/h
- Based on the approx. 50-fold lower amount of applied test substance, the penetration at the spray dilution was moderate (absorption rate 0.21 µg/cm^2·h; Kp = $14.78 \cdot 10^{-5}$ cm/h).
- Based on the approx. 300-fold lower amount of applied test substance, the penetration at the spray dilution was moderate (absorption rate 0.21 µg/cm^2·h; Kp = $94.86 \cdot 10^{-5}$ cm/h).
- The cumulative absorbed dose found in the receptor fluid was about 0.71%, 6.92% and 27.80% at the high, mid and low dose, respectively, thus the % of dose penetration was higher for low dose spray dilution whereas the total amount of epoxiconazole penetrating was lowest.
- Overall, the cumulated absorbed dose (4.42 µg/cm^2) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (5.51 µg) for the high dose. The cumulated absorbed dose (0.92 µg/cm^2) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (1.18 µg) for the mid dose. The cumulated absorbed dose (0.61 µg/cm^2) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (1.00 µg) for the low dose.
- Since significant variation of replicates was observed in high and low dose groups (standard deviations of the absorption estimates were > 25% of the means); accordingly, the absorption estimate used for risk assessment was calculated as proposed in the guidance document by addition of one standard variation to the mean.

Conclusion/endpoint:

A slow and a moderate penetration of BAS 480 F formulated as BAS 701 00 F through dermatomed skin was observed in-vitro as formulation concentrate and spray dilutions, respectively. Summing up the absorbed dose with that associated to the skin membrane, dermal absorption rates of 1.0%, 9.0% and 60.0% were determined for the formulation concentrate and the spray dilutions (1:50 and 1:300), respectively.

Comments of zRMS:	Study acceptable despite some deviations according to OECD TG 428: Skin thickness 260-675 µm instead of normally 200-400 µm; donor chamber was semioccluded instead of unoccluded.

	Dermal absorption in this study considered to be 1 % for the concentrate, 9 % for the spray dilution 1:50 and 60 % for the spray dilution 1:300.

Fluxapyroxad

Report:	**Fabian, E., Mellert, W., 2012**
Title:	^{14}C-BAS 700 F in BAS 701 00 F - Study of penetration through human skin in vitro
Document No:	BASF DocID 2011/1248839
Guidelines:	OECD 428, OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
GLP	Yes

Material and Methods:

[Pyrazole-4-^{14}C] BAS 700 F (Batch 900-2201, Radiochemical purity 99.8%, Specific activity 5.4 MBq) was used to prepare radioactive BAS 701 00 F (formulation concentrate) as well as 1:50 and 1:300 spray dilutions. The dosing suspensions were prepared adding a respective amount of radiolabelled fluxapyroxad to an adequate volume of non-radioactive BAS 701 00 F (Batch 204534), or radioactive fluxapyroxad was added to BAS 701 00 F and subsequently diluted with tap water (1: 50 and 1:300 spray dilutions).
The penetration of BAS 700 F formulated as BAS 701 00 F through human dermatomed skin was determined using a modified Franz cell under static conditions equipped with dermatomed human skin at a thickness of 200-570 µm. Skin from 5 donors (2 donors for each dose) were used in this study. Diffusion cells (5, 10, and 5 for the high dose, the mid dose and the low dose, respectively) were loaded with 10 µl of one of the three respective dosing solutions. The test was performed under semi-occlusive conditions. In order to guarantee sufficient solubility of the BAS 700 F in the receptor fluid, ethanol/tap water (3+7, v/v), ethanol/tap water (1+9, v/v) and tap water served as receptor fluids for formulation concentrate, the 1:50 and 1:300 spray dilutions, respectively. After 8 hours the surface was washed twice using approx. 250 µL Texapon® N70 diluted 1:140 (w/w) in highly de-ionized water and once with 250 µL pure water. The skin was then wiped dry using cotton swabs. Thereafter the semi-occlusive cover of the cells was renewed and the penetration experiment continued for another 16 hours.

Samples of the receptor fluid were withdrawn 1; 2; 4; 6; 8; 10, and 24 hours after application. The removed volume was replaced by fresh receptor fluid. After the last sampling of receptor fluid, the contents of the individual receptor compartments was sampled and - like the receptor fluid samples taken during the course of the experiment - retained for analysis. The diffusion cells were dismantled and all parts were extracted in ethanol or Soluene®-350. The skin was removed and washed a second time. As before, the cotton swabs and the washing solutions were retained for analysis. After the skin surface had dried, the stratum corneum was removed by tape stripping. The tapes were pooled into two samples (1st sample containing the first and second tape; 2nd sample containing the third until sixth tape) for analysis. The remaining skin and the tape strips were analyzed separately.

Table A 14: In-vitro dermal penetration of BAS 700 F formulated as BAS 701 00 F through human skin - Recovery data

Dose group		**High dose**		**Mid dose§**		**Low dose**	
		(Formulation concentrate)		**(Spray dilution 1:50)**		**(Spray dilution 1:300)**	
Target concentration	[mg/mL]	62.5		1.25		0.208	
Target dose	[µg/cm²]	625		12.50		2.08	
Mean actual applied dose	[µg/cm²]	651.6		14.9		2.06	
Number of cells used/Valid cells		5/5		10/4		5/5	
		Recovery [%]		Recovery [%]		Recovery [%]	
		Mean	S.D.	Mean	S.D.	Mean	S.D.
Unabsorbed dose							
Skin washing after 8 hours		97.31	4.84	92.13	5.37	94.65	9.25
Skin washing after 24 hours		0.03	0.08	0.79	0.53	0.55	0.91
Donor chamber		0.00	0.00	0.11	0.22	0.00	0.00
Dose associated to skin							
Tape strip (1st pool, strips 1 -2)		0.00	0.00	0.00	0.00	0.00	0.00
Tape strips (2nd pool; strips 3 - 6)		0.06	0.14	0.07	0.14	0.00	0.00
Skin preparation		0.04	0.04	0.68	1.01	1.42	2.34
Absorbed dose							
Sum receptor samples incl. wash out		0.48	0.37	0.80	0.19	4.74	2.88
Receptor fluid		0.40	0.38	0.74	0.22	1.04	0.56
Receptor chamber wash		0.02	0.02	0.41	0.02	0.79	0.65
Total recovery#		**98.3**	**4.66**	**95.74**	**6.14**	**103.18**	**9.11**
Absorption essentially complete at end of study (>75% absorption within half the study duration)		**Yes**		**Yes**		**Yes**	
Absorption estimates when absorption not essentially completed (= absorbed dose + dose associated to skin - tape strips 1 and 2)		**NA**	**-**	**NA**	**-**	**NA**	**-**
Absorption estimates when absorption essentially completed (= absorbed dose + dose associated to skin - all tapes)		**0.94**	**0.75**	**2.63**	**0.93**	**7.98**	**1.61**
Absorption estimate normalized[b]		**NA**	**-**	**NA**	**-**	**NA**	**-**
Absorption estimates used for risk assessment[c]		**2**		**4**		**8**	

§ One cell of the second run was not assessed to be valid due to insufficient recovery. The 5 cells of the first run were assessed to be invalid due to aberrant kinetics

\# values may not calculate exactly due to rounding of figures

[a] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) the radioactivity in the second tape-strip pool (3rd to 6th tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable

[b] Cells with insufficient recovery (<95%) were corrected by normalization of absorption estimate to 100% recovery

[c] In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) one standard deviation was added to the mean % dermal penetration in cases where the standard deviation was ≥ 25% of the mean value. This value was then rounded to the required number of significant figures.

NA: not applicable

:

Table A 15: In-vitro dermal penetration of BAS 700 F formulated as BAS 701 00 F through human skin - Penetration kinetics

Dose group		High dose (Formulation concentrate)		Mid dose (Spray dilution 1:50)		Low dose (Spray dilution 1:300)	
Target concentration	[mg/mL]	62.5		1.25		0.208	
Target dose	[µg/cm²]	625		12.50		2.08	
Mean actual applied dose	[µg/cm²]	651.6		14.9		2.06	
Number of cells used/Valid cells		5/5		10/4		5/5	
		Mean cumulative absorption		Mean cumulative absorption		Mean cumulative absorption	
		[µg/cm²]	[%]	[µg/cm²]	[%]	[µg/cm²]	[%]
Sample time [h]							
1		0.00	0.00	0.01	0.04	0.02	0.95
2		0.00	0.00	0.06	0.39	0.05	2.61
4		1.60	0.25	0.12	0.80	0.08	3.68
6		1.99	0.31	0.15	0.99	0.09	4.42
8		2.35	0.36	0.17	1.14	0.10	5.02
10		7.53	1.17	0.19	1.26	0.12	5.75
24		5.77	0.89	0.20	1.35	0.13	6.00
Kp	[$*10^{-5}$ cm/h]	1.38	-	3.55	-	20.14	-
Absorption rate	[$\mu g/cm^2 \cdot h$]	0.90	-	0.05	-	0.044	-
Lag time	[h]	2.36	-	0.86	-	0.49	-
% absorbed within 10 hours[a]		131%		94%		96%	

[a] As no 12 hour value was determined the 10 hour value was used instead

Findings:

- Solubility in the receptor fluid was sufficient not to influence the diffusion process of the test substance (solubility in ethanol/water 3+7 (v/v), in ethanol/water 1+9 (v/v), and in tap water was 0.13 g/L, 0.02 g/l, and 3.88 mg/L, respectively). Receptor media ethanol/water 3+7 (v/v), ethanol/water 1+9 (v/v), and tap water were used for high dose, mid dose, and low dose, respectively.
- The mean total recovery was in the range of 95.74 to 103.18% for the low, mid and high dose levels with individual cell recoveries between 89.69 to 112.74%. Accordingly, the mean total recovery for high dose was 98.35%, with one cell below (91.33%) and four above the threshold (98.31, 99.90, 97.94, and 104.26%). Since the dermal penetration estimate (0.34%) of the cell with less than 95% recovery was comparable with the range of the cells with greater than 95% recovery (0.36, 1.23, 2.09, and 0.49%) no adjustment of individual cell values was considered to

be justified. The mean total recovery for mid dose was 95.74%, with two cells below (90.98 and 90.15%) and two above the threshold (99.21 and 102.60%). Since the dermal penetration estimates (2.13 and 1.65%) of the cells with less than 95% recovery were comparable with the range of the cells with greater than 95% recovery (1.75 and 2.28%) no adjustment of individual cell values was considered to be justified. The mean total recovery for low dose was 103.18%, with one cell below (89.69%) and four above the threshold (107.52, 112.74, 107.42, and 98.55%). Since the dermal penetration estimate (9.28%) of the cell with less than 95% recovery was comparable with the range of the cells with greater than 95% recovery (8.44, 8.21, 0.98, and 5.92%) no adjustment of individual cell values was considered to be justified.

- In all dose groups absorption was essentially complete at end of study (>75% absorption within half the study duration) – after 10 hours 94 to 131% of the total penetrated radioactivity was recovered in the receptor media. Accordingly, no tape strips were included for calculation of dermal absorption.
- Nearly the entire dose (97.41%) was recovered from the skin washing, donor chamber and tape strips at the high dose. In case of the cells treated with the mid and low dose this value was 93.11% and 95.20%, respectively.
- The amount associated with the skin preparations was 0.04%, 0.68% and 1.42% for the high, mid and low dose, respectively.
- The absorbed dose, i.e. the sum of receptor samples, the receptor fluid recovered at the end of the experiment as well as the receptor chamber wash, amounted to 0.90%, 1.95% and 6.57% at the high, mid and low dose, respectively.
- The total absorption, which corresponds to the amount recovered from skin, both pools of tape strip samples and the absorbed dose, thus, sum up to 1.0%, 2.7% and 7.99% for the high, mid and low dose, respectively.
- A slow penetration of BAS 700 F was observed for the formulation concentrate as indicated by an absorption rate of 0.90 $\mu g/cm^2 \cdot h$ and a permeability coefficient (Kp) of $1.38 \cdot 10^{-5}$ cm/h.
- Based on the approx. 50-fold lower amount of applied test substance, the penetration at the spray dilution was moderate (absorption rate 0.05 $\mu g/cm^2 \cdot h$; Kp = $3.55 \cdot 10^{-5}$ cm/h).
- Based on the approx. 300-fold lower amount of applied test substance, the penetration at the spray dilution was moderate (absorption rate 0.04 $\mu g/cm^2 \cdot h$; Kp = $20.14 \cdot 10^{-5}$ cm/h).
- The cumulative absorbed dose found in the receptor fluid was about 0.89%, 1.35% and 6.00% at the high, mid and low dose, respectively, thus the % of dose penetration was higher for low dose spray dilution whereas the total amount of fluxapyroxad penetrating was lowest.
- Overall, the cumulated absorbed dose (5.77 $\mu g/cm^2$) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (5.86 µg) for the high dose. The cumulated absorbed dose (0.20 $\mu g/cm^2$) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (0.29 µg) for the mid dose. The cumulated absorbed dose (0.13 $\mu g/cm^2$) calculated from the absorption time curves correspond well to the absorbed doses derived from the recovery assessments (0.14 µg) for the low dose.
- Since significant variation of replicates was observed in high and mid dose groups (standard deviations of the absorption estimates were > 25% of the means); accordingly, the absorption estimate used for risk assessment was calculated as proposed in the guidance document by addition of one standard variation to the mean.

Conclusion/endpoint:

A slow and a moderate penetration of BAS 700 F formulated as BAS 701 00 F through dermatomed skin was observed in-vitro as formulation concentrate and spray dilutions, respectively. Summing up the absorbed dose with that associated to the skin membrane, dermal absorption rates of 2.0%, 4.0% and

8.0% were determined for the formulation concentrate and the spray dilutions (1:50 and 1:300), respectively.

Comments of zRMS:	Study acceptable despite some deviations according to OECD TG 428: Skin thickness was 200-570 µm instead of normally 200-400 µm; donor chamber was semioccluded instead of unoccluded. Dermal absorption in this study considered to be 2 % for the concentrate, 4 % for the spray dilution 1:50 and 8 % for the spray dilution 1:300.

A 2.11 Other/Special Studies

There are no other special studies on this product.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (IIIA1 7.3.1)

A 3.1.1 Calculations for epoxiconazole

Table A 16: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.125	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	1	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	60	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.008	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 17: Estimation of operator exposure towards epoxiconazole using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in cereals					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1)] x DA) / BW		
(2.4 x 0.125 x 20 x 1%) / 70			(2.4 x 0.125 x 20 x 0.01 x 1%) / 70		
External dermal exposure	6	mg/person	External dermal exposure	0.06	mg/person
External dermal exposure	0.085714	mg/kg bw/d	External dermal exposure	0.000857	mg/kg bw/d
Systemic dermal exposure	**0.000857**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000009**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE x DA) / BW		
(0.38 x 0.125 x 20 x 60%) / 70			(0.38 x 0.125 x 20 x 0.01 x 60%) / 70		
External dermal exposure	0.95	mg/person	External dermal exposure	0.0095	mg/person
External dermal exposure	0.013571	mg/kg bw/d	External dermal exposure	0.000136	mg/kg bw/d
Systemic dermal exposure	**0.008143**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000081**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE x DA) / BW		
(1.6 x 0.125 x 20 x 60%) / 70			(1.6 x 0.125 x 20 x 0.05 x 60%) / 70		
External dermal exposure	4	mg/person	External dermal exposure	0.2	mg/person
External dermal exposure	0.057143	mg/kg bw/d	External dermal exposure	0.002857	mg/kg bw/d
Systemic dermal exposure	**0.034286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001714**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x PPE x DA) / BW		
(0.06 x 0.125 x 20 x 60%) / 70			(0.06 x 0.125 x 20 x 1 x 60%) / 70		
External dermal exposure	0.15	mg/person	External dermal exposure	0.15	mg/person
External dermal exposure	0.002143	mg/kg bw/d	External dermal exposure	0.002143	mg/kg bw/d
Systemic dermal exposure	**0.001286**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001286**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	11.1	mg/person	Total external dermal exposure	0.4195	mg/person
Total external dermal exposure	0.158571	mg/kg bw/d	Total external dermal exposure	0.005993	mg/kg bw/d
Total systemic dermal exposure	**0.044571**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.00309**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x PPE x IA) / BW		
(0.0006 x 0.125 x 20 x 100%) / 70			(0.0006 x 0.125 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0015	mg/person	External inhalation exposure	0.0015	mg/person
External inhalation exposure	0.000021	mg/kg bw/d	External inhalation exposure	0.000021	mg/kg bw/d

Systemic inhalation exposure	**0.000021**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000021**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A \times AR \times A \times IA) / BW$			$SIE_{OA} = (I_A \times AR \times A \times PPE \times IA) / BW$		
(0.001 x 0.125 x 20 x 100%) / 70			(0.001 x 0.125 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0025	mg/person	External inhalation exposure	0.0025	mg/person
External inhalation exposure	0.000036	mg/kg bw/d	External inhalation exposure	0.000036	mg/kg bw/d
Systemic inhalation exposure	**0.000036**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000036**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.004	mg/person	Total external inhalation exposure	0.004	mg/person
Total external inhalation exposure	0.000057	mg/kg bw/d	Total external inhalation exposure	0.000057	mg/kg bw/d
Total systemic inhalation exposure	**0.000057**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000057**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	3.124	mg/person	Total systemic exposure	0.2203	mg/person
Total systemic exposure	**0.044629**	**mg/kg bw/d**	**Total systemic exposure**	**0.003147**	**mg/kg bw/d**
% of AOEL	**557.9**	**%**	**% of AOEL**	**39.3**	**%**

1) reduction factor for gloves is 0.01 (professional appl.)
2) reduction factor for protective garment is 0.05 (professional appl.)

Table A 18: Estimation of operator exposure towards epoxiconazole using the UK-POEM

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)				
Active substance	**Epoxiconazole**			
Product	Adexar			
Formulation type	organic solvent-based			
Concentration of a.s.	62.5	mg/mL		
Dose	2	L preparation/ha	(0.125 kg a.s./ha)	
Application volume	300	L/ha		
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Container	10 litres 63 mm closure			
Work rate/day	50	ha		
Duration of spraying	6	h		
PPE during mix./loading	None			
PPE during application	None			
Dermal absorption from product	1	%		
Dermal absorption from spray	60	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	2	Litres product/ha		
Work rate	50	ha/day		
Number of operations	10	/day		
Hand contamination	0.5	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.5	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	300	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h

Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.5	mL/day	41.55	mL/day
Concen. of a.s. product or spray	62.5	mg/mL	0.417	mg/mL
Dermal exposure to a.s.	31.25	mg/day	17.313	mg/day
Percent absorbed	1	%	60	%
Absorbed dose	0.313	mg/day	10.388	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.417	mg/mL		
Inhalation exposure to a.s.	0.025	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.025	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	10.725	mg/day		
Operator body weight	60	kg		
Operator exposure	0.179	mg/kg bw/day		
Amount of AOEL	**2234.4**	**%**		

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)						
Active substance	**Epoxiconazole**					
Product	Adexar					
Formulation type	organic solvent-based					
Concentration of a.s.	62.5	mg/mL				
Dose	2	L preparation/ha	(0.125 kg a.s./ha)			
Application volume	300	L/ha				
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Container	10 litres 63 mm closure					
Work rate/day	50	ha				
Duration of spraying	6	h				
PPE during mix./loading	Gloves					
PPE during application	Gloves					
Dermal absorption from product	1	%				
Dermal absorption from spray	60	%				
EXPOSURE DURING MIXING AND LOADING						
Container size	10	Litres				
Hand contamination/operation	0,05	mL				
Application dose	2	Litres product/ha				
Work rate	50	ha/day				
Number of operations	10	/day				
Hand contamination	0.5	mL/day				
Protective clothing	Gloves					
Transmission to skin	10	%				
Dermal exposure to formulation	0.05	mL/day				
DERMAL EXPOSURE DURING SPRAY APPLICATION						
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles					
Application volume	300	spray/ha				
Volume of surface contamination	10	mL/h				
Distribution	Hands		Trunk		Legs	
	65%		10%		25%	
Clothing	Gloves		Permeable		Permeable	
Penetration	10%		5%		15%	
Dermal exposure	0.65		0.05		0.375	mL/h

Duration of exposure	6	h		
Total dermal exposure to spray	6.45	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.05	mL/day	6.45	mL/day
Concen. of a.s. product or spray	62.5	mg/mL	0.417	mg/mL
Dermal exposure to a.s.	3.125	mg/day	2.688	mg/day
Percent absorbed	1	%	60	%
Absorbed dose	0.031	mg/day	1.613	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.417	mg/mL		
Inhalation exposure to a.s.	0.025	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.025	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	1.669	mg/day		
Operator body weight	60	kg		
Operator exposure	0.028	mg/kg bw/day		
Amount of AOEL	**347.7**	**%**		

A 3.1.2 Calculations for fluxapyroxad

Table A 19: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.125	kg a.s./ha			
Area treated per day (A):	20	ha	**Dermal hands m/l ($D_{M(H)}$):**	2.4	mg/person/kg a.s.
Dermal absorption (DA):	2	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	8	% (dilution)	**Dermal body appl. ($D_{A(B)}$):**	1.6	mg/person/kg a.s.
Inhalation absorption (IA):	100	%	**Dermal head appl. ($D_{A(C)}$):**	0.06	mg/person/kg a.s.
Body weight (BW):	70	kg/person	**Inhalation m/l (I_M):**	0.0006	mg/person/kg a.s.
AOEL	0.04	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 20: Estimation of operator exposure towards fluxapyroxad using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in cereals					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x DA) / BW			$SDE_{OM(H)} = (D_{M(H)}$ x AR x A x PPE [1]) x DA) / BW		
(2.4 x 0.125 x 20 x 2%) / 70			(2.4 x 0.125 x 20 x 0.01 x 2%) / 70		
External dermal exposure	6	mg/person	External dermal exposure	0.06	mg/person
External dermal exposure	0.085714	mg/kg bw/d	External dermal exposure	0.000857	mg/kg bw/d
Systemic dermal exposure	**0.001714**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000017**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x DA) / BW			$SDE_{OA(H)} = (D_{A(H)}$ x AR x A x PPE [1]) x DA) / BW		
(0.38 x 0.125 x 20 x 8%) / 70			(0.38 x 0.125 x 20 x 0.01 x 8%) / 70		
External dermal exposure	0.95	mg/person	External dermal exposure	0.0095	mg/person
External dermal exposure	0.013571	mg/kg bw/d	External dermal exposure	0.000136	mg/kg bw/d
Systemic dermal exposure	**0.001086**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000011**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x DA) / BW			$SDE_{OA(B)} = (D_{A(B)}$ x AR x A x PPE [2]) x DA) / BW		
(1.6 x 0.125 x 20 x 8%) / 70			(1.6 x 0.125 x 20 x 0.05 x 8%) / 70		
External dermal exposure	4	mg/person	External dermal exposure	0.2	mg/person

External dermal exposure	0.057143	mg/kg bw/d	External dermal exposure	0.002857	mg/kg bw/d
Systemic dermal exposure	**0.004571**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000229**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x DA) / BW			$SDE_{OA(C)} = (D_{A(C)}$ x AR x A x PPE x DA) / BW		
(0.06 x 0.125 x 20 x 8%) / 70			(0.06 x 0.125 x 20 x 1 x 8%) / 70		
External dermal exposure	0.15	mg/person	External dermal exposure	0.15	mg/person
External dermal exposure	0.002143	mg/kg bw/d	External dermal exposure	0.002143	mg/kg bw/d
Systemic dermal exposure	**0.000171**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000171**	**mg/kg bw/d**
Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$			Total systemic dermal exposure: $SDE_O = SDE_{OM(H)} + SDE_{OA(H)} + SDE_{OA(B)} + SDE_{OA(C)}$		
Total external dermal exposure	11.1	mg/person	Total external dermal exposure	0.4195	mg/person
Total external dermal exposure	0.158571	mg/kg bw/d	Total external dermal exposure	0.005993	mg/kg bw/d
Total systemic dermal exposure	**0.007543**	**mg/kg bw/d**	**Total systemic dermal exposure**	**0.000428**	**mg/kg bw/d**
Operators: Systemic inhalation exposure after application in cereals					
Inhalation exposure during mixing/loading					
$SIE_{OM} = (I_M$ x AR x A x IA) / BW			$SIE_{OM} = (I_M$ x AR x A x PPE x IA) / BW		
(0.0006 x 0.125 x 20 x 100%) / 70			(0.0006 x 0.125 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0015	mg/person	External inhalation exposure	0.0015	mg/person
External inhalation exposure	0.000021	mg/kg bw/d	External inhalation exposure	0.000021	mg/kg bw/d
Systemic inhalation exposure	**0.000021**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000021**	**mg/kg bw/d**
Inhalation exposure during application					
$SIE_{OA} = (I_A$ x AR x A x IA) / BW			$SIE_{OA} = (I_A$ x AR x A x PPE x IA) / BW		
(0.001 x 0.125 x 20 x 100%) / 70			(0.001 x 0.125 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.0025	mg/person	External inhalation exposure	0.0025	mg/person
External inhalation exposure	0.000036	mg/kg bw/d	External inhalation exposure	0.000036	mg/kg bw/d
Systemic inhalation exposure	**0.000036**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000036**	**mg/kg bw/d**
Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$			Total systemic inhalation exposure: $SIE_O = SIE_{OM} + SIE_{OA}$		
Total external inhalation exposure	0.004	mg/person	Total external inhalation exposure	0.004	mg/person
Total external inhalation exposure	0.000057	mg/kg bw/d	Total external inhalation exposure	0.000057	mg/kg bw/d
Total systemic inhalation exposure	**0.000057**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000057**	**mg/kg bw/d**
Total systemic exposure: $SE_O = SDE_O + SIE_O$			Total systemic exposure: $SE_O = SDE_O + SIE_O$		
Total systemic exposure	0.532	mg/person	Total systemic exposure	0.03396	mg/person
Total systemic exposure	**0.007600**	**mg/kg bw/d**	**Total systemic exposure**	**0.000485**	**mg/kg bw/d**
% of AOEL	**19.0**	**%**	**% of AOEL**	**1.2**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

[2)] reduction factor for protective garment is 0.05 (professional appl.)

Table A 21: Estimation of operator exposure towards fluxapyroxad using the UK-POEM

Without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Fluxapyroxad**		
Product	Adexar		
Formulation type	organic solvent-based		
Concentration of a.s.	62.5	mg/mL	
Dose	2	L preparation/ha	(0.125 kg a.s./ha)
Application volume	300	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 63 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	None		
PPE during application	None		
Dermal absorption from product	2	%	
Dermal absorption from spray	8	%	
EXPOSURE DURING MIXING AND LOADING			

Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	2	Litres product/ha		
Work rate	50	ha/day		
Number of operations	10	/day		
Hand contamination	0.5	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0.5	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	300	spray/ha		
Volume of surface contamination	10	mL/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	mL/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	mL/day		
ABSORBED DERMAL DOSE				
	Mix/load		Application	
Dermal exposure	0.5	mL/day	41.55	mL/day
Concen. of a.s. product or spray	62.5	mg/mL	0.417	mg/mL
Dermal exposure to a.s.	31.25	mg/day	17.313	mg/day
Percent absorbed	2	%	8	%
Absorbed dose	0.625	mg/day	1.385	mg/day
INHALATION EXPOSURE DURING SPRAYING				
Inhalation exposure	0.01	mL/h		
Duration of exposure	6	h		
Concentration of a.s. in spray	0.417	mg/mL		
Inhalation exposure to a.s.	0.025	mg/day		
Percent absorbed	100	%		
Absorbed dose	0.025	mg/day		
PREDICTED EXPOSURE				
Total absorbed dose	2.035	mg/day		
Operator body weight	60	kg		
Operator exposure	0.034	mg/kg bw/day		
Amount of AOEL	**84.8**	**%**		

With PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)			
Active substance	**Fluxapyroxad**		
Product	Adexar		
Formulation type	organic solvent-based		
Concentration of a.s.	62.5	mg/mL	
Dose	2	L preparation/ha	(0.125 kg a.s./ha)
Application volume	300	L/ha	
Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		
Container	10 litres 63 mm closure		
Work rate/day	50	ha	
Duration of spraying	6	h	
PPE during mix./loading	Gloves		
PPE during application	Gloves		
Dermal absorption from product	2	%	
Dermal absorption from spray	8	%	
EXPOSURE DURING MIXING AND LOADING			

Container size	10	Litres			
Hand contamination/operation	0,05	mL			
Application dose	2	Litres product/ha			
Work rate	50	ha/day			
Number of operations	10	/day			
Hand contamination	0.5	mL/day			
Protective clothing	Gloves				
Transmission to skin	10	%			
Dermal exposure to formulation	0.05	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	300	spray/ha			
Volume of surface contamination	10	mL/h			
Distribution	Hands		Trunk	Legs	
	65%		10%	25%	
Clothing	Gloves		Permeable	Permeable	
Penetration	10%		5%	15%	
Dermal exposure	0.65		0.05	0.375	mL/h
Duration of exposure	6	h			
Total dermal exposure to spray	6.45	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0.05	mL/day		6.45	mL/day
Concen. of a.s. product or spray	62.5	mg/mL		0.417	mg/mL
Dermal exposure to a.s.	3.125	mg/day		2.688	mg/day
Percent absorbed	2	%		8	%
Absorbed dose	0.063	mg/day		0.215	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0.01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	0.417	mg/mL			
Inhalation exposure to a.s.	0.025	mg/day			
Percent absorbed	100	%			
Absorbed dose	0.025	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	0.303	mg/day			
Operator body weight	60	kg			
Operator exposure	0.005	mg/kg bw/day			
Amount of AOEL	**12.6**	**%**			

A 3.2 Worker exposure calculations (IIIA1 7.5.1)

A 3.2.1 Calculations for epoxiconazole

Table A 22: Input parameters considered for the estimation of worker exposure

Intended uses:	Cereals		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.125	kg a.s./ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	60	% ('worst case')			
AOEL	0.008	mg/kg bw/d			

Table A 23: Estimation of worker exposure towards epoxiconazole using the German re-entry model

Without PPE [1]			With PPE [2]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 1500 x 2 x 0.125 x 2 x 60%) / 60			(1 x 1500 x 2 x 0.125 x 2 x 5% x 60%) / 60		
External dermal exposure	0.75	mg/person	External dermal exposure	0.0375	mg/person
External dermal exposure	0.0125	mg/kg bw/d	External dermal exposure	0.000625	mg/kg bw/d
Total systemic exposure	0.45	mg/person	Total systemic exposure	0.0225	mg/person
Total systemic exposure	**0.0075**	**mg/kg bw/d**	**Total systemic exposure**	**0.000375**	**mg/kg bw/d**
% of AOEL	**93.8**	**%**	**% of AOEL**	**4.7**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves
2) acceptable only with PPE: see 'Instructions for use' (cf. Krebs et al., 2000)

A 3.2.2 Calculations for fluxapyroxad

Table A 24: Input parameters considered for the estimation of worker exposure

Intended uses:	Cereals		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.125	kg a.s./ha	**Transfer coefficient (TC):**	1500	cm²/person/h
Number of applications (NA):	2		**Work rate per day (WR):**	2	h/d
Body weight (BW):	60	kg/person	**PPE**	5	%
Dermal absorption (DA):	8	% ('worst case')			
AOEL	0.04	mg/kg bw/d			

Table A 25: Estimation of worker exposure towards fluxapyroxad using the German re-entry model

Without PPE [1]			With PPE [2]		
Worker (re-entry): Systemic dermal exposure after application in cereals					
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW			SDE_W = (DFR x TC x WR x AR x NA x PPE x DA) / BW		
(1 x 1500 x 2 x 0.125 x 2 x 8%) / 60			(1 x 1500 x 2 x 0.125 x 2 x 5% x 8%) / 60		
External dermal exposure	0.75	mg/person	External dermal exposure	0.0375	mg/person
External dermal exposure	0.0125	mg/kg bw/d	External dermal exposure	0.000625	mg/kg bw/d
Total systemic exposure	0.06	mg/person	Total systemic exposure	0.003	mg/person
Total systemic exposure	**0.00100**	**mg/kg bw/d**	**Total systemic exposure**	**0.00005**	**mg/kg bw/d**
% of AOEL	**2.5**	**%**	**% of AOEL**	**0.1**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves
2) acceptable only with PPE: see 'Instructions for use' (cf. Krebs et al., 2000)

A 3.3 Bystander and resident exposure calculations (IIIA1 7.4.1)

A 3.3.1 Calculations for epoxiconazole

Table A 26: Input parameters considered for the estimation of bystander exposure

Intended uses:	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.125	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	12.5	mg/m²		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	60	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.008	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 27: Estimation of bystander exposure towards epoxiconazole

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(12.5 x 2.77% x 1 x 60%) / 60			(12.5 x 2.77% x 0.21 x 60%) / 16.15		
External dermal exposure	0.34625	mg/person	External dermal exposure	0.072713	mg/person
External dermal exposure	0.005771	mg/kg bw/d	External dermal exposure	0.004502	mg/kg bw/d
Systemic dermal exposure	**0.003463**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.002701**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in cereals (via spray drift)					
SIE_B = (I*$_A$ x AR x A x T x IA) / BW			SIE_B = (I*$_A$ x AR x A x T x IA) / BW		
(0.001 / 360 x 0.125 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.125 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000035	mg/person	External inhalation exposure	0.00002	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure	0.207785	mg/person	Total systemic exposure	0.043647	mg/person
Total systemic exposure	**0.003463**	**mg/kg bw/d**	**Total systemic exposure**	**0.002703**	**mg/kg bw/d**
% of AOEL	**43.29**	**%**	**% of AOEL**	**33.78**	**%**

Table A 28: Input parameters considered for the estimation of resident exposure

Intended uses:	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.125	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.00125	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m^3
Dermal absorption (DA):	60	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	50	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.008	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 29: Estimation of resident exposure towards epoxiconazole

Adults			**Children**		
Residents: Systemic dermal exposure after application in cereals (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.00125 x 2 x 2.38% x 5% x 7300 x 2 x 60%) / 60			(0.00125 x 2 x 2.38% x 5% x 2600 x 2 x 60%) / 16.15		
External dermal exposure	0.043435	mg/person	External dermal exposure	0.01547	mg/person
External dermal exposure	0.000724	mg/kg bw/d	External dermal exposure	0.000958	mg/kg bw/d
Systemic dermal exposure	**0.000434**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000575**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in cereals (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External inhalation exposure	0.01657	mg/person	External inhalation exposure	0.00831	mg/person
External inhalation exposure	0.000276	mg/kg bw/d	External inhalation exposure	0.000515	mg/kg bw/d
Systemic inhalation exposure	**0.000276**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000515**	**mg/kg bw/d**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.00125 x 2 x % x 5% x 50% x 20 x 20 x 2 x 50%) / 16.15		
			External oral exposure	0.00119	mg/person
			External oral exposure	0.000074	mg/kg bw/d
			Systemic oral exposure	**0.000037**	**mg/kg bw/d**

			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.00125 x 2 x % x 20% x 25 x 50%) / 16.15		
			External oral exposure	0.000298	mg/person
			External oral exposure	0.000018	mg/kg bw/d
			Systemic oral exposure	**0.000009**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.042631	mg/person	Total systemic exposure	0.018336	mg/person
Total systemic exposure	**0.000711**	**mg/kg bw/d**	**Total systemic exposure**	**0.001135**	**mg/kg bw/d**
% of AOEL	**8.88**	**%**	**% of AOEL**	**14.19**	**%**

A 3.3.2 Calculations for fluxapyroxad

Table A 30: Input parameters considered for the estimation of bystander exposure

Intended uses:	Cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.125	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	12.5	mg/m^2		0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.000575	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	8	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.04	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 31: Estimation of bystander exposure towards fluxapyroxad

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(12.5 x 2.77% x 1 x 8%) / 60			(12.5 x 2.77% x 0.21 x 8%) / 16.15		
External dermal exposure	0.34625	mg/person	External dermal exposure	0.072713	mg/person
External dermal exposure	0.005771	mg/kg bw/d	External dermal exposure	0.004502	mg/kg bw/d
Systemic dermal exposure	**0.000462**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.00036**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in cereals (via spray drift)					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.125 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.125 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000035	mg/person	External inhalation exposure	0.00002	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000001	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000001**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure	0.027735	mg/person	Total systemic exposure	0.005837	mg/person
Total systemic exposure	**0.000462**	**mg/kg bw/d**	**Total systemic exposure**	**0.000361**	**mg/kg bw/d**
% of AOEL	**1.16**	**%**	**% of AOEL**	**0.90**	**%**

Table A 32: Input parameters considered for the estimation of resident exposure

Intended uses:	Cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.125	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
	0.00125	mg/cm^2		2600	cm^2/h (children)
Number of applications (NA):	2		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0	mg/m^3
Dermal absorption (DA):	8	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults)
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA):	68	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.04	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth	20	events/h

			(Freq):		
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Table A 33: Estimation of resident exposure towards fluxapyroxad

Adults			**Children**		
Residents: Systemic dermal exposure after application in cereals (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.00125 x 2 x 2.38% x 5% x 7300 x 2 x 8%) / 60			(0.00125 x 2 x 2.38% x 5% x 2600 x 2 x 8%) / 16.15		
External dermal exposure	0.043435	mg/person	External dermal exposure	0.01547	mg/person
External dermal exposure	0.000724	mg/kg bw/d	External dermal exposure	0.000958	mg/kg bw/d
Systemic dermal exposure	**0.000058**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000077**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in cereals (via vapour)					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External inhalation exposure		none	External inhalation exposure		none
Systemic inhalation exposure		**none**	**Systemic inhalation exposure**		**none**
			Residents: Systemic oral exposure (hand-to-mouth transfer)		
			$SOE_{R(H)}$ = (AR x NA x D x TTR x SE x SA x Freq x H x OA) / BW		
			(0.00125 x 2 x % x 5% x 50% x 20 x 20 x 2 x 68%) / 16.15		
			External oral exposure	0.00119	mg/person
			External oral exposure	0.000074	mg/kg bw/d
			Systemic oral exposure	**0.00005**	**mg/kg bw/d**
			Residents: Systemic oral exposure (object-to-mouth transfer)		
			$SOE_{R(O)}$ = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.00125 x 2 x % x 20% x 25 x 68%) / 16.15		
			External oral exposure	0.000298	mg/person
			External oral exposure	0.000018	mg/kg bw/d
			Systemic oral exposure	**0.000013**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_{R(H)} + SOE_{R(O)}$		
Total systemic exposure	0.003475	mg/person	Total systemic exposure	0.002249	mg/person
Total systemic exposure	**0.000058**	**mg/kg bw/d**	**Total systemic exposure**	**0.000139**	**mg/kg bw/d**
% of AOEL	**0.14**	**%**	**% of AOEL**	**0.35**	**%**

A 3.4 Combined exposure calculations for epoxiconazole and fluxapyroxad

Please, see respective paragraph under 3.6.5.

Appendix 4 Detailed evaluation of exposure studies relied upon (IIIA 7.3.3, IIIA 7.4.2, IIIA 7.5.4, IIIA 7.7)

A 4.1 Operator exposure study

A 4.1.1 Study 1

Reference:	7.3.3/01
Report	Determination of dermal and inhalation operator exposure for mixing/loading and application of BAS 601 KD F in cereals Stadler, R., 2007 2007/1033389, 263968, ASB2009-4728
Guideline:	OECD Series on Testing and Assessment No. 9 - Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application (Paris 1997)
GLP:	Yes
Acceptability:	Yes

Materials and methods

Measurements of operator exposure were conducted using a surrogate epoxiconazole-containing suspension concentrate (SC; BAS 601 KD F) with 100 g/L epoxiconazole on field crops. The study was conducted on 10 operators at 10 locations in the Southwest and East of Germany during September and October 2006. Exposure was monitored during mixing/loading and application of the spray solution, but it was not detected separately for the two individual tasks.
Operators were considered experienced in pesticide application. Their age was between 32 and 57 years. Their body weights were in the range of 85 kg to 110 kg with a mean of about 93 kg.

For mixing/loading there were two different scenarios, A and B, which are shortly characterised below:

A	Mixing/loading was performed as a standard procedure, i.e. conventional containers (5 L) of the product were handled by the operators (operator 1B, 2A-10A) in order to prepare the spray dilution.
B	Mixing/loading was performed using two different closed transfer systems (operator 1A, 2B-10B). **However, data recorded for subset B were not reported here and are not included into this risk assessment.**

Spraying equipment reflecting present standard of application technique, i.e. tractors with closed cabins, large tanks in the range of 2000 to 5200 liters and large spray booms with a width of 18 to 36 m, was used. Application was carried out with conventional tractor-mounted or tractor-drawn boom sprayers fitted with hydraulic nozzles All operators treated about 50 ha per day (48.0 - 53.5 ha/d), 1.25 L/ha of product were applied and water volumes of 100 – 200 L/ha were used.

Meteorological conditions were monitored during all workdays. Air temperatures ranged from 12°C to 32°C, the range of soil temperatures was 11°C to 25°C. Relative humidity of 55–100% was recorded, wind speed ranged from 0 m/s to 4 m/s.

Dosimeter

Dermal dosimeter

Dermal exposure was measured using two layers of whole body dosimeters (inner and outer dosimeter). Standard work clothing made from cotton/polyester fabric was chosen as the outer layer, whereas the inner dosimeter consisted of cotton underwear with long arms and legs.

Hand exposure was assessed by analysis of nitrile protective gloves (outer dosimeter) and hand wash samples (inner dosimeter). Hand wash samples were taken at times when the worker normally washed his hands. The operators were advised to use protective gloves for mixing/loading only. Therefore, operators did not need to wear protective gloves during application routinely except that they performed maintenance work on the sprayer, so that they could get into contact with spray liquid. Right and left gloves used per operator on a working day were pooled and subjected to a common analysis of the active substance contained. Hand wash samples to determine actual hand exposure were pooled as well.

At the end of the work period, head exposure was detected by face/neck wipes using 100 % cotton gauze pads which had been moistened with a mild soap solution. When the operator wished to wear a hat or a cap he was allowed to do so, but amounts of active substance were not determined on hats or caps.

At the end of the monitoring period outer and inner dosimeters were separated and cut into individual parts for subsequent analysis, as described below:

Outer dosimeter	**Inner dosimeter**
Both lower arms	Both lower arms
Both upper arms	Both upper arms
Chest	Chest
Back	Back
Both lower legs	Both lower legs
Both upper legs	Both upper legs
Protective gloves (right and left pooled)	Hand wash samples (right and left one pooled)
	Face/neck wipes

Potential dermal exposure (PDE) was calculated from residues on the work jacket, the pair of trousers, the underwear (vest & long-johns), the face/neck wipes, the hand-wash samples and the protective gloves. The actual dermal exposure (ADE) was calculated from the residues detected on/in the underwear (long sleeved vest & long-johns), the faces/neck wipes and the hand-wash samples.

<u>Inhalation dosimeters</u>
Operators were equipped with personal air sampling pumps (TENAX adsorption tubes) combined with an inhalable fraction sample collector located in the operator's breathing zone. The limit of quantification for epoxiconazole (LOQ) was 1 ng (0.001 µg). Air pump flow was calibrated to 2 L/min. For operators engaged in moderate physical labour a breathing volume of 20.83 L/min or 1.25 m³/h was taken into account. Thus, a conversion factor of **10.415** [20.83 L/min : 2 L/min = 10.415] was used to estimate inhalation exposure for operators.

<u>Storage of dosimeters</u>
Body dosimeters were removed, cut and kept in a cool box for transport to the laboratory. Samples were subsequently stored deep-frozen until analysis. Air samplers were stored in darkness at ambient temperatures until analysis.

<u>Field recoveries and analytical procedures</u>
The stability of the test item under field; storage and transport conditions in or on the sampling materials (coverall, inner dosimeters, facial swabs, protective gloves if necessary and air sampling filers) was assessed. For this purpose, the test item was applied under laboratory and under field conditions onto the

different sampling materials at two different concentrations (i.e. at the 10-fold and 100-fold of the LOQ). Subsequently, recoveries were analytically determined.

Active substance from all sampling materials – except for air samplers - was extracted using either methanol or methanol/water (1 : 1). The Tenax absorber tubes were extracted with acetone. Respective extracts were reduced to dryness and subsequently diluted in methanol : water (1:1). Aliquots of the extracts were appropriately analysed by LC/MS/MS.

Results and discussion

Analytical confirmation of the concentration of epoxiconazole in BAS 601 KD F
Three different batches of BAS 601 KD F were used in the study. The analytical confirmation of active substance concentrations gave the following results (Table A 34).

Table A 34: Analytical results for epoxiconazole concentrations in used BAS 601 KD F batches

Batch-No.	Nominal content epoxiconazole [g/L]	Analysed content epoxiconazole [g/L]
2032	100	91
2036	100	92.2
2037	100	94.5

The mean analytical concentration was 92.6 g epoxiconazole/L in the three batches. Therefore, a correction factor (i.e. **1.08**) was used to adjust all raw data in order to account for the difference in nominal active substance concentration of 100 g/L and actual epoxiconazole concentration.

Results of field or laboratory fortifications
The results of field, transport and concurrent laboratory fortification analyses demonstrated the storage and transport stability of the test item. Field recovery and lab recovery data for body dosimeters were in the range of 74 to 99% of the active substance initially applied. For air sampler units, recoveries were between 95 to 102%. Results are presented below (Table A 35).

Table A 35: Field and concurrent laboratory fortification rates

Matrix	Field recovery	Lab Recovery	Correction Factor #
Inner dosimeter	74 %	78 %	1.35
Face wipe	98 %	99 %	n.n.
Hand wash solution	92 %	99 %	n.n.
Outer dosimeter	92 %	95 %	n.n.
Gloves	88 %	87 %	n.n.
Air sampler	95 %	102 %	n.n.

According to guidelines a correction factor will not be necessary if the recovery values are within the 70 - 120% range

Nevertheless, based on the obtained recovery data a correction factor of **1.35** was applied to account for incomplete field and laboratory recoveries for inner body dosimeters. For all other matrices raw data were not corrected.

A summary of the amounts of epoxiconazole on outer and inner body dosimeters, in hand wash solutions, on/in gloves, in face and neck wipes as well as on air sampler absorption tubes is given in Table A 36.

Table A 36: Summary of operator exposure towards epoxiconazole when mixing/loading and spraying BAS 601 KD F in field crops

Operator	Outer body [µg]	Inner body [µg] *	Head [µg]	Gloves [µg]	Hands [µg]	Inhalation [µg] **, ***	Actual dermal exposure [µg] ***	Potential dermal exposure [µg] ***
1B	62.92	17.50	0.32	2805.00	12.00	0.45	32.20	3129.55
2A	134.27	2.01	0.34	4371.00	1.40	2.25	4.05	4869.74
3A	86.28	2.03	0.07	566.00	1.00	0.43	3.34	707.81
4A	450.43	2.96	0.43	2772.00	7.30	0.20	11.54	3491.77
5A	58.55	0.92	0.04	2565.00	2.00	0.08	3.19	2836.63
6A	713.19	4.10	0.73	8190.00	94.60	0.36	107.39	9722.83
7A	28.98	4.16	0.32	822.00	2.10	0.08	7.10	926.16
8A	663.00	3.96	1.12	7704.00	2.60	0.21	8.29	9044.65
9A	1217,23	8.42	0.42	3420.00	54.50	0.09	68.41	5076.62
10A	32.58	1.36	0.22	365.00	0.80	0.06	2.57	431.96
Geo.mean	159.18	3.29	0.28	2240.99	4.72	0.22	10.60	2679.56
75th percentile	609.86	4.14	0.43	4133.25	10.82	0.41	27.04	5024.90

* Data corrected for field recovery (factor 1.35, please, see text)

** Data adjusted for operator breathing volume of 20.83 L/min

*** Actual dermal exposure: inner body + head + hands; potential dermal exposure: outer body + inner body + head + gloves + hands; data corrected for actual epoxiconazole concentration in BAS 601 KD F (factor 1.08, please, see text)

Comments of zRMS:	The study is considered acceptable, according to guidelines, used for evaluation Text of report has been modified and data have been re-calculated by the RMS, applicant used a different breathing volume, i.e. 14 L/min, for operators, for example.

A 4.1.2 Study 2

Reference:	7.3.3/02
Report:	Determination of operator exposure (passive dosimetry) during typical activities associated with a ground boom application of BAS 480 31 F to cereal crops at farm locations in the United Kingdom and Germany, Blaschke, U., 2008, 2010/1089364, 344806, ASB2013-9336
Guideline:	OECD Series on Testing and Assessment No. 9 - Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application (Paris 1997)
GLP	Yes
Acceptability:	Yes

Materials and methods

Measurements of operator exposure were conducted using a surrogate epoxiconazole-containing suspension concentrate (SC; BAS 480 31 F) with 125 g/L epoxiconazole on field crops. The study was conducted on 15 operators at 13 locations in Germany and UK during May and June 2008. Exposure was monitored during mixing/loading and application of the spray solution (scenario A: operator 1-15). In addition, 14 operators were monitored during mixing/loading only (scenario B). However, data recorded for scenario B were not reported here and are not included into this risk assessment.
Operators were considered experienced in pesticide application. Their body weights were in the range of 72 kg to 145 kg with a mean of about 104 kg.

Spraying equipment reflecting present standard of application technique, i.e. tractors with closed cabins, large tanks in the range of 2000 to 4000 liters and large spray booms with a width of 18 to 30 m, was used. Application was carried out with conventional tractor-mounted or tractor-drawn boom sprayers fitted with standard hydraulic nozzles or with drift-reducing nozzles. All operators treated 50 ha per day, 1 L/ha of product was applied and water volumes of about 90 – 105 L/ha were used.

Meteorological conditions were monitored during all workdays. Air temperatures ranged from 11°C to 32°C. Relative humidity of 23–80% was recorded, wind speed ranged from 0 m/s to 2.5 m/s.

Dosimeter

Dermal dosimeter
Dermal exposure was measured using two layers of whole body dosimeters (inner and outer dosimeter). Standard work clothing made from cotton/polyester fabric was chosen as the outer layer, whereas the inner dosimeter consisted of cotton underwear with long arms and legs.

Hand exposure was assessed by analysis of nitrile protective gloves (outer dosimeter) and hand wash samples (inner dosimeter). Hand wash samples were taken at times when the worker normally washed his hands. The operators wore protective gloves during mixing/loading and also when handling contaminated surfaces, i.e. they did not need to wear protective gloves during application routinely. Right and left gloves used per operator on a working day were pooled and subjected to a common analysis of the active substance contained. Hand wash samples to determine actual hand exposure were pooled as well.

At the end of the work period, head exposure was detected by face/neck wipes using 100 % cotton gauze pads which had been moistened with a mild soap solution. When the operator wished to wear a hat or a cap he was allowed to do so, but amounts of active substance were not determined on hats or caps.

At the end of the monitoring period outer and inner dosimeters were separated and cut into individual parts for subsequent analysis, as described below:

Outer dosimeter	**Inner dosimeter**
Both lower arms	Both lower arms
Both upper arms	Both upper arms
Chest	Chest
Back	Back
Both lower legs	Both lower legs
Both upper legs	Both upper legs
Protective gloves (right and left pooled)	Hand wash samples (right and left one pooled)
	Face/neck wipes

Potential dermal exposure (PDE) was calculated from residues on the work jacket, the pair of trousers, the underwear (vest & long-johns), the face/neck wipes, the hand-wash samples and the protective gloves. The actual dermal exposure (ADE) was calculated from the residues detected on/in the underwear (long sleeved vest & long-johns), the faces/neck wipes and the hand-wash samples.

Inhalation dosimeters
Operators were equipped with personal air sampling pumps (TENAX adsorption tubes) combined with an inhalable fraction sample collector located in the operator's breathing zone. Air pump flow was calibrated to 1.5 L/min. For operators engaged in moderate physical labour a breathing volume of 20.83 L/min or 1.25 m³/h was taken into account. Thus, a conversion factor of **13.887** [20.83 L/min : 1.5 L/min = 13.887] was used to estimate inhalation exposure for operators.

Storage of dosimeters

Body dosimeters were removed, cut and kept in a cool box for transport to the laboratory. Samples were subsequently stored deep-frozen until analysis. Air samplers were stored in darkness at ambient temperatures until analysis.

Field recoveries and analytical procedures

The stability of the test item under field; storage and transport conditions in or on the sampling materials (coverall, inner dosimeters, facial swabs, protective gloves if necessary and air sampling filters) was assessed. For this purpose, the test item was applied under laboratory and under field conditions onto the different sampling materials at three different concentrations (i.e. at the 10-fold, 100-fold or 1000-fold of the LOQ, depending on the matrix). Subsequently, recoveries were analytically determined.

Active substance from all sampling materials – except for air samplers - was extracted using either methanol or methanol/water (1 : 1). The Tenax absorber tubes were extracted with acetone. Respective extracts were further diluted in acetone. Aliquots of all extracts were appropriately analysed by LC/MS/MS.

Results and discussion

Analytical confirmation of the concentration of epoxiconazole in BAS 601 KD F

One batch of BAS 480 31 F was used in the study. The analytical confirmation of active substance concentration gave the following result (Table A 34).

Table A 37: Analytical results for epoxiconazole concentrations in used BAS 480 31 F batches

Batch-No.	Nominal content epoxiconazole [g/L]	Analysed content epoxiconazole [g/L]
2547585	125	126.1

No correction for a difference in nominal active substance concentration of 100 g/L and actual epoxiconazole concentration is necessary.

Results of field or laboratory fortifications

The results of field, transport and concurrent laboratory fortification analyses demonstrated the storage and transport stability of the test item. Field recovery and lab recovery data for body dosimeters were in the range of 77.5 to 99 % of the active substance initially applied. For air sampler units, recoveries were between 98 to 106 %. Results are presented below (Table A 35).

Table A 38: Field and concurrent laboratory fortification rates

Matrix	Field recovery *	Lab Recovery *	Correction Factor #
Inner dosimeter	100 % ± 5.5 %	97.5 % ± 8.6 %	n.n.
Face wipe	105.7 % ± 20.6 %	93.0 % ± 6.0 %	n.n.
Hand wash solution	109.8 % ± 13.4 %	98.3 % ± 8.2 %	n.n.
Outer dosimeter	93.9 % ± 6.1 %	99.1 % ± 7.8 %	n.n.
Gloves	72.8 % ± 19.8 % +	86.6 % ± 8.3 %	
Gloves	77.5 % ± 14.5 % ++		1.29
Air sampler	98.3 % ± 16.9 %	106.0 % ± 4.3 %	n.n.

* Mean values
\+ 'worst case', all values included
++ except gloves which were blown from the table by a sudden wind gust
\# According to guidelines a correction factor will not be necessary if the recovery values are within the 70 - 120% range. However, no correction was applied in cases were the upper range was exceeded as the uncorrected values would result in a conservative overestimation of exposure.

Based on the obtained recovery data a correction factor of **1.29** was applied to account for incomplete field and laboratory recoveries for gloves. For all other matrices raw data were not corrected.

A summary of the amounts of epoxiconazole on outer and inner body dosimeters, in hand wash solutions, on/in gloves, in face and neck wipes as well as on air sampler absorption tubes is given in Table A 36.

Table A 39: Summary of operator exposure towards epoxiconazole when mixing/loading and spraying BAS 480 31 F in field crops

Operator	Outer body [µg]	Inner body [µg]	Head [µg]	Gloves [µg] *	Hands [µg]	Inhalation [µg] **	Actual dermal exposure [µg] ***	Potential dermal exposure [µg] ***
1	434.50	1.30	0.05	598.56	8.74	0.39	10.09	1043.15
2	4222.00	16.99	0.64	11537.76	141.00	0.08	158.63	15918.39
3	653.40	2.27	0.50	2383.92	7.54	0.22	10.31	3047.63
4	236.00	8.16	0.50	1806.00	52.20	0.54	60.86	2102.86
5	282.50	2.48	0.27	12.18	13.24	0.07	15.99	310.67
6	534.30	2.58	0.31	326.11	13.02	0.11	15.90	876.31
7	287.50	1.87	0.09	4633.68	3.56	0.64	5.52	4926.70
8	2645.00	10.49	0.25	1186.80	13.04	0.42	23.78	3855.58
9	392.20	1.63	0.15	794.90	3.26	14.46	5.03	1192.13
10	148.30	13.03	0.81	2745.12	15.34	0.86	29.18	2922.60
11	138.50	1.12	0.26	710.02	33.40	1.22	34.78	883.30
12	212.20	1.70	0.31	3952.56	11.42	0.72	13.43	4178.19
13	1041.00	6.10	0.49	70279.20	18.74	0.50	25.33	71345.53
14	6525.00	7.70	4.,52	29102.40	910.00	0.26	967.22	36594.62
15	2050.00	3.62	3.64	37668.00	224.00	0.21	231.26	39949.26
Geo.mean	620.21	3.71	0.47	2321.39	23.09	0.42	29.81	3901.27
75th percentile	1545.50	7.93	0.57	8085.72	42.80	0.68	47.82	10422.55

* Data corrected for field recovery (factor 1.29, please, see text)

** Data adjusted for operator breathing volume of 20.83 L/min

*** Actual dermal exposure: inner body + head + hands; potential dermal exposure: outer body + inner body + head + gloves + hands

Comments of zRMS:	The study is considered acceptable, according to guidelines, used for evaluation Text of report has been modified and data have been re-calculated by the RMS, applicant used a different breathing volume for operators, i.e. 14 L/min,, for example.

<u>General conclusion on the applicability of the surrogate studies to assess operator exposure under the current use conditions of BAS 701 00 F</u>

The surrogate field exposure studies conducted used liquid formulations applied to field crops using ground-boom sprayers with hydraulic nozzles. In the studies the exposure during mixing/loading and application was monitored together. The results are considered representative of equipment intended for large areas, i.e. corresponding to the data used in the UK agronomic parameters (50 ha/day). The application rate was 125 g a.i./ha with application volumes between 90 to 180 L/ha. The exposure data were generated using current standard application equipment (e.g. tractors with closed cabins in combination with large-tank ground-boom sprayers and wide spray booms). Thus, the use conditions of the field exposure studies is representative of the use conditions of BAS 701 00 F as it is applied today.

Table A 40 depicts the pooled exposure data from both above described studies normalised to individual body weights as well as to work rates of 50 ha per day. Since the application rate (125 g active substance/ha) is the same in case of the two exposure studies and intended uses of BAS 701 00 F no further normalisation of the data is considered necessary.

Table A 40: Extrapolated dermal and inhalative exposure of described operator exposure studies (see above) with ground boom sprayers standardised for a work rate of 50 ha/day and normalised to the individual body weight

Operator	Body weight [kg]	Treated area [ha]	Actual dermal exposure adjusted to 50 ha [µg/kg bw]	Potential dermal exposure adjusted to 50 ha [µg/kg bw]	Exposure via inhalation adjusted to 50 ha [µg/kg bw]
1B	86	48.60	0.3852	37.44	0.0054
2A	87	49.40	0.0471	56.65	0.0262
3A	90	49.80	0.0373	7.90	0.0048
4A	96	48.00	0.1252	37.89	0.0022
5A	85	51.90	0.0362	32.15	0.0009
6A	96	50.00	1.1186	101.28	0.0037
7A	110	51.00	0.0633	8.25	0.0007
8A	100	50.00	0.0829	90.45	0.0021
9A	85	50.00	0.8048	59.72	0.0011
10A	95	50.00	0.0271	4.55	0.0006
1	85	50.00	0.1187	12.26	0.0046
2	119	50.00	1.3331	133.63	0.0007
3	81	50.00	0.1273	37.60	0.0027
4	124	50.00	0.4908	16.89	0.0044
5	95	50.00	0.1683	3.24	0.0007
6	138	50.00	0.1152	6.33	0.0008
7	102	50.00	0.0541	48.28	0.0063
8	104	50.00	0.2286	36.97	0.0040
9	145	50.00	0.0347	8.21	0.0997
10	100	50.00	0.2918	29.10	0.0086
11	91	50.00	0.3822	9.69	0.0134
12	102	50.00	0.1317	40.95	0.0071
13	102	50.00	0.2483	699.41	0.0049
14	102	50.00	9.4825	358.70	0.0026
15	72	50.00	3.2119	554.80	0.0029
Geo.mean	98.40		0.2005	34.12	0.0033
75^{th} percentile	102.00		**0.3852**	**59.72**	**0.0054**

DRAFT REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: Adexar (BAS 701 00 F)

Active Substance: Epoxiconazole 62.5 g/L
Fluxapyroxad 62.5 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE

Date: 02 June 2017

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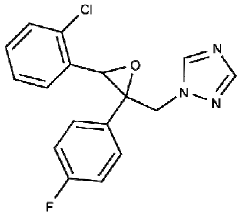
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Epoxiconazole

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Epoxiconazole
CAS number	133855-98-8

4.1.1.1 Storage stability

A summary of the storage stability data on epoxiconazole is given in the following table. Data that have been previously evaluated at EU level are described in detail in the DAR (Germany 2005, ASB2010-10473) and were evaluated in the framework of the peer review of the pesticide risk assessment of the active substance (ASB2012-3620).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of Epoxiconazole	Residues of epoxiconazole in wheat straw and grain were stable at -20°C, wheat plant at -12°C for at least 24 months (RIP2003-1503). Residues of epoxiconazole in wheat plant, wheat straw wheat grain, pea, peach, rape seed, sugar beet and head cabbage were stable at -20°C for at least 24 months (RIP2003-1533). Residues of epoxiconazole in animal matrices (milk, muscle, liver, kidney and fat) were stable at -18°C for up to 12 months (RIP2003-1534).

4.1.1.2 Metabolism in plants and plant residue definition(s)

A summary of the metabolism of epoxiconazole in plants is given in the following table. Data have been evaluated at EU level in the DAR (Germany 2005, ASB2010-10473), in an addendum to the DAR (Germany 2013, ASB2013-7187), in EFSA'S conclusion of the peer review (EFSA 2008; ASB2012-3620) and in EFSA's Reasoned Opinion concerning the modification of the existing MRLs for epoxiconazole in various cereals (EFSA 2011, ASB2012-3291).

Table 4.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Crops investigated include: cereals, fruits, roots/tubers, coffee. - Cereals (wheat, RIP2003-1512; RIP2003-1514): foliar application [^{14}C]-labelled triazole, 2 x 0.12 kg as/ha (GS BBCH 37 and BBCH 47-49) At harvest TRR were highest in straw (7-9.5 mg as-eq/kg) and lowest in grain (0.045 mg as-eq/kg). In grains the greater part of the radioactivity were re associated or incorporated into the starch fraction. No parent was found in grains. - Cereals (wheat, RIP2003-1508, RIP2003-1510, RIP2003-1511): foliar application; [^{14}C]-label in oxirane ring, 1 x 0.25 kg as/ha. At harvest TRR was highest in roots (ca. 3 mg as-eq/kg) and lowest in ears and grain (0.027 and 0.036 mg as-eq/kg, respectively). Unchanged parent made up the majority of the residue in forage and straw: In grains the greater part of the radioactivity were re associated or incorporated into the starch fraction. - Fruits (bananas, RIP9700204, RIP9700205, RIP9700245): foliar application, 4 x 150 g as/ha, [^{14}C]-labelled chlorophenyl- and fluorophenyl ring. Parent epoxiconazole was the main component of the residues in bananas and whole fruits (70 % TRR). - Root/tuber vegetables (sugar beet, RIP2000-4): foliar application, 2 x 150 g as/ha, ^{14}C-labelled fluorophenyl ring Parent epoxiconazole was the main component in sugar beet leaves (>90 % TRR) and in sugar beet roots (77 % TRR). - Coffee beans (RIP9700244): foliar application, 150 and 100 g as/ha, ^{14}C-labelled chlorophenyl- and fluorophenyl ring Residues <0.01 mg/kg, only epoxiconazole. - Coffee beans and leaves (ASB2011-10921): 2 foliar applications at 0.375 and 0.250 kg as/ha, both oxirane-2-^{14}C label and the triazole-3(5)-^{14}C label. Parent epoxiconazole main component in coffeee beans (37-62% TRR) and coffee leaves (73-86% TRR). The extent of epoxiconazole metabolism in plant is very limited, partly accompanied by uptake of triazole metabolites from soil and accumulation in wheat grain. In residue field studies a shift of the (-)/(+) enantiomer ratio was observed in samples of wheat, barley maize, pea) to (+), ranging from 1:1 to 1:4. In metabolism studies however no significant change of the ratio was seen in wheat (grain, forage) and coffe (beans, leaves) (ASB2011-10918)..

Rotational crops	RIP2003-1515: [Triazole-3(5)-^{14}C] label, 510 g a.s./ha to bare soil; PBI: 30, 120, 365 days; rotated crops: spring wheat, beans, carrots, lettuce TRRs were 0.065-0.147 mg as-eq/kg in lettuce, 0.072-0.200 mg as-eq/kg in carrot roots, 0.089-0.191 mg as-eq/kg in green beans and 1.137-0.744 mg as-eq/kg in wheat grain. Composition of residues was investigated for 30 day PBI samples of the above mentioned study (RIP2003-1519). Uptake factors from soil (TRR in rotational crop divided by TRR of soil) were 7.3 for wheat grain and 7.5 for wheat straw. In grain TA and TRR made up 54% and 26% of the TRR respectively; unlike for grain unchanged parent was the major component in straw (39% TRR) whereas TAA was 10% TRR and triazolyl-hydroxy-propionic acid was 16% TRR. RIP2003-1537: Chlorophenyl and fluorophenyl labels, 400 g/ha to bare soil; PBI: 30, 120, 365 days, rotated crops: radish, lettuce, wheat Formation of polar degradates at low individual concentrations. No structure could be elucidated. Besides these fractions unchanged parent was the major component of the residue. ASB2011-10925: [Triazole-3(5)-^{14}C] label, 400 g/ha to bare soil; PBI: 29, 120, 365 days, rotated crops radish, leaf lettuce, spring wheat TRRs were 0.04-0.016 mg as-eq/kg in lettuce leaf and at comparable levels in radish roots; higher residues were seen in wheat forage (0.23-0.48 mg as-eq/kg) and wheat chaff and grain (0.79-1.82 mg as-eq/kg, highest at PBI 120 d). Main compo-nent of the residue was TA, formed probably after uptake of triazole (not found in plant material) from soil.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Yes
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	Epoxiconazole was found hydrolytically stable under the representative processing conditions (RIP2003-1535).
Residue pattern in raw and processed commodities similar? (yes/no)	Yes
Plant residue definition for monitoring	Epoxiconazole (Reg. (EC) No 396/2005)
Plant residue definition for risk assessment	Epoxiconazole (provisional) The residue definition and dietary risk assessment is considered provisional due to *i)* uncertainties in the enantiomer ratio in plants and animals and *ii)* pending approach on how to tackle the impact of triazole derivative metabolites (TDM) in dietary risk assessment.
Conversion factor(s) (monitoring to risk assessment)	Not concluded

4.1.1.3 Metabolism in livestock and animal residue definition(s)

A summary of the metabolism of epoxiconazole in livestock is given in the following table. Data that have been previously evaluated at EU level are described in detail in the DAR (Germany 2005, ASB2010-10473), in EFSA's conclusion of the peer review (EFSA 2008; ASB2012-3620) and in EFSA's Reasoned Opinion concerning the modification of the existing MRLs for epoxiconazole in various cereals (EFSA 2011, ASB2012-3291).

Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	- Lactating goats (RIP2003-1507): 5 days, 0.5 and 10 mg/kg bw/day, 17 and 344 mg/kg feed, [^{14}C]-oxirane label Lactating goats (RIP2003-1516): 5 days, 0.5 mg/kg bw/day, [^{14}C]-oxirane label Lactating goats (RIP2003-1517): 5 days, 10 mg/kg bw/day [^{14}C]-oxirane label Most of the applied radioactivity was excreted. Transfer into milk, muscle and fat was low. Higher residues were seen in kidney and particularly liver. Major part of the residues was unchanged parent (50-60% TRR in muscle and fat, 33% in liver and 22% in kidney). - Lactating goats (ASB2011-10922, ASB2011-10923): [^{14}C]-triazole label, 12 mg/kg feed (0.35 mg/kg b.w.), 14 days. In milk 0.17-0.21% of TAR was found. 1.65 mg as-eq/kg, 0.24 mg as-eq/kg , 0.07 mg as-eq/kg and 0.04 mg as-eq/kg were found in liver, kidney, fat and muscle tissues, respectively. 1,2,4-triazole (M52; up to 70% TRR) and 480M06 were found at significant levels (12.5% in fat; not confirmed at higher dose rates probably due to laborious sample work-up); traces of parent (<10% in all samples). Extensive cleavage of parent compound was observed. No indication of accumulation in milk or tissues was seen. - Laying hens (RIP2000-551): [^{14}C]-oxirane label, 12 and 229 mg/kg feed, 6 days Laying hens (RIP2003-1518): [^{14}C]-oxirane label, 12 and 229 mg/kg feed, 6 days. Most of the applied radioactivity was excreted. In tissues, highest residues were determined in fat and liver. Major part in all animal tissues was parent (48-99 % in muscle, fat, skin and eggs of hens and 14 % TRR in hen liver). No accumulation in tissues was observed. Like for rats and plants there was a tendency also in goat metabolism of reduction of the (-) enantiomer compared to the (+) isomer enantiomer (ASB2011-10918).
Time needed to reach a plateau concentration in milk and eggs	5–7 days
Animal residue definition for monitoring	Epoxiconazole (Reg. (EC) No 396/2005)
Animal residue definition for risk assessment	Epoxiconazole (provisional) The residue definition and dietary risk assessment is considered provisional due to *i)* uncertainties in the enantiomer ratio in plants and animals and *ii)* pending approach on how to tackle the impact of triazole derivative metabolites (TDM) in dietary risk assessment.
Conversion factor(s) (monitoring to risk assessment)	Not concluded
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log $P_{O/W}$ = 3.3)

4.1.1.4 *Residues in rotational crops*

A summary of the field rotational crop studies on epoxiconazole is given in the following table. Data that have been previously evaluated at EU level are described in detail in the DAR (Germany 2005, ASB2010-10473), in EFSA's conclusion of the peer review (EFSA 2008; ASB2012-3620) and in EFSA's

Reasoned Opinion concerning the modification of the existing MRLs for epoxiconazole in various cereals (EFSA 2011, ASB2012-3291).

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	RIP2003-1538, RIP2003-1539 (addendum to RIP2003-1538): field study, Japan, application to wheat at 3x0.375 kg/ha with 7 day intervals, after harvest rotational crops rice, cucumber, spinach, potato, radish, soybean, sugar beet were planted RIP2003-1526: field study, UK, 12 sites, application to winter wheat, winter barley or spring barley, 3-4x 0.125-0.188 kg/ha, rotational crops cereals, potatoes, oilseed rape, turnips. Field studies show that under normal agricultural conditions parent residues were below the LOQ (0.05 mg/kg) in edible parts of rotational crops cultivated after cereals, which have been treated with exaggerated application rates of epoxiconazole (compared to cGAP). Thus, significant epoxiconazole residues are not expected in food and feed commodities obtained from succeeding crops (consequent to uses in compliance with cGAP). The occurrence of triazole metabolites was not investigated.

4.1.1.5 *Residues in livestock*

An actual calculation of the dietary burden (based on residue data reported in the EU and all relevant uses authorized in Germany) is provided in the following table.

Table 4.1-6: Calculation of the dietary burden (based on residue data reported in the EU)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
Kale/Cabbage	14	5	–	–	–	0.110 [a]	0.039	–	–	–
Sugar beet leaves and tops	16	–	–	30	25	1.440 [b]	–	–	2.700	2.250
Silage	20	–	80	–	–	0.730 [c]	–	2.920	–	–
Grains except maize	86	70	–	–	–	0.140 [d]	0.114	–	–	–
Bran (wheat and rye)	89	–	–	–	15	0.168 [e]	–	–	–	0.028
Straw (cereals)	86	–	20	50	–	15.400 [f]	–	3.581	8.953	–
Pulses	86	5	–	–	–	0.100 [g]	0.006	–	–	–
Beet roots	20	20	–	20	60	0.050 [h]	0.050	–	0.050	0.150
Intake (mg/kg dry weight feed)							**0.209**	**6.501**	**11.703**	**2.428**
Intake (mg/kg bw/d)							**0.013**	**0.236**	**0.502**	**0.097**
Intake (mg/animal/d)							**0.025**	**130.03**	**175.55**	**7.285**

[a] HR, based on GAP 3 x 125 g/ha, PHI 28 days
[b] HR, , EFSA 2012 (ASB2012-9643)
[c] STMR, EFSA 2012 (ASB2012-9643)
[d] STMR, , EFSA 2012 (ASB2012-9643)
[e] STMR , EFSA 2012 (ASB2012-9643)
[f] HR, , EFSA 2012 (ASB2012-9643)
[g] HR , EFSA 2012 (ASB2012-9643)

Table 4.1-7: Conditions of requirement of livestock feeding studies on epoxiconazole

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 6.5 (cow), 11.7 (beef)	yes 0.21	yes 2.4
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	Yes	Yes, but only at highly overdosed rates	Yes

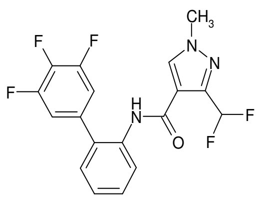
A summary of the available livestock feeding studies is given in the following table. The studies have been evaluated at EU level and outcomes are described in detail in the DAR (Germany 2005, ASB2010-10473), in EFSA'S conclusion of the peer review (EFSA 2008; ASB2012-3620) and in EFSA's Reasoned Opinion concerning the modification of the existing MRLs for epoxiconazole in various cereals (EFSA 2011, ASB2012-3291).

Table 4.1-8: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	Poultry:	Pig:
Feeding levels (mg/kg feed dry matter) in feeding studies	Cow: 5, 15, 50 RIP2003-455	Hen: 0.2, 0.6, 2, 4 ASB2011-10924	See ruminant:
Relevant dosing level (mg/kg feed dry matter) in feeding study	Dairy: 5 Beef: 15	0.2	5
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	0.12	<0.01	0.04
Kidney	0.013	<0.01	<0.01
Fat	<0.01	<0.01	<0.01
Milk	0.0015	--	--
Eggs	--	<0.01	--

4.1.2 Fluxapyroxad

Table 4.1-9: Identity of the active substance

Structural formula	
Common Name	Fluxapyroxad (BAS 700 F)
CAS number	907204-31-3

4.1.2.1 Storage stability

A summary of the storage stability data on fluxapyroxad is given in the following table. Data on frozen storage stability have been evaluated in the context of the peer review of fluxapyroxad (EFSA, 2012, ASB2012-3723) and were described in detail in the DAR (UK, 2011, ASB2013-4548).

Table 4.1-10: Stability of residues (Annex IIA, point 6.1)

Stability of fluxapyroxad and its metabolites M700F002, M700F008 and M700F048	Deep freeze (-20°C) stability of residues of Fluxapyroxad was demonstrated for at least 24 months in apples, tomatoes, triticale (whole plant), soya bean (seed), avocado (fruit), peas (dry seed), cereals (grain, straw), potatoes, grapes and lemons (ASB2010-7936). Deep freeze (-20°C) stability of residues of the metabolite M700F002 was demonstrated for at least 27 months in apples, tomatoes, triticale (whole plant), soya bean (seed), avocado (fruit), peas (dry seed), cereals (grain, straw), potatoes, grapes and lemons (ASB2010-7937). Deep freeze (-20°C) stability of residues of the metabolite M700F008 was demonstrated in a two years study in wheat (whole plant, grain, straw), soyabean (seeds), beans (dried seeds), lemons (ASB2013-1037). Deep freeze (-20°C) stability of residues of the metabolite M700F048 was demonstrated in a two years study in apple (fruit, juice), avocado (fruit), grape (fruit, raisins), lemon (fruit), tomato (fruit), dried pea (seed), soyabean (seed, refined oil), potato (tuber, crisps), cereals (grain, straw, whole plant), barley (beer) (ASB2013-1038).

4.1.2.2 *Metabolism in plants and plant residue definition(s)*

A summary of the results of metabolism studies is given in the following table. Except for the study on wheat involving seed treatment, all studies reflect foliar treatments. They have been evaluated in the context of the peer review of fluxapyroxad (EFSA, 2012, ASB2012-3723) and were described in detail in the DAR (UK, 2011, ASB2013-4548).

Table 4.1-11: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Cereals, fruiting vegetables, oilseeds, all with [U-^{14}C aniline] and [pyrazole-4-^{14}C] label - Spring wheat (ASB2010-7941): 2x 125 g as/ha foliar spray - Spring wheat (ASB2012-7150): 75 g as/100 kg seed; equiv. to 135 g as/ha - Tomato (ASB2010-7939): 3x 100 g as/ha foliar spray, 17, 10 and 3 days before harvest - Soybean (ASB2010-7940): 3x 60 g as/ha foliar spray at BBCH 16/17, 51-59 and 71-75, sampling of hay 22-34 DALA, beans at 34 DALA Metabolism studies conducted on three crop groups show that the metabolic pathway was comparable. Whilst the metabolic pattern was complex, in nearly all matrices fluxapyroxad was the major component of the residue. Only metabolites M700F002 and M700F048 represented amounts > 10 % TRR (in soybean seeds only). M700F002 is generated by cleavage of the carboxamide bond and desmethylation of the pyrazole ring, whereas M700F048 is generated by N-glucosidation of desmethyl metabolite M700F008. At levels < 10 % TRR the intermediate product M700F008, the “M700F005-like group” encompassing M700F005, M700F006, M700F041 and M700F042 and also M700F036, a structurally similar

	metabolite to M700F008 and M700F005, as well as numerous other substances resulting from conjugation, loss of the fluorine atom etc. occurred. Following foliar application, only limited translocation of the applied radioactivity into the non-treated plant parts was observed. Metabolic patterns were comparable for foliar application and seed treatment (wheat).
Rotational crops	Confined studies conducted with the aniline labelled (ASB2010-7958) and pyrazole labelled substance (ASB2010-7957) involving application of 250 g as/ha to bare soil; rotational crops spinach, radish and wheat sown at PBIs of 30, 120/149 and 365 days Translocation of radioactivity from soil into crops was observed for all PBI's and both labels. Main metabolic pathways were the hydroxylation of the biphenyl moiety and the N-desmethylation of the pyrazole moiety. The metabolic pathway in succeeding crops is similar to that observed in primary crops albeit TRRs in rotational crops were much lower than in plants treated after foliar spraying. The main component of the residue was parent substance and no compounds specific to rotational crops were identified.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	Stable at standard hydrolysis conditions simulating typical processing operations (ASB2010-7954).
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Fluxapyroxad This is in line with Reg. (EC) No 396/2005.
Plant residue definition for risk assessment	Fluxapyroxad This is in line with the EFSA Conclusion on the peer review of the risk assessment of fluxapyroxad (ASB2012-3723).
Conversion factor(s) (monitoring to risk assessment)	none

4.1.2.3 Metabolism in livestock and animal residue definition(s)

A summary of the specifics and the results of metabolism studies of fluxapyroxad in livestock is outlined in the following table. Data has been evaluated in the context of the peer review of fluxapyroxad (EFSA, 2012, ASB2012-3723) and was described in detail in the DAR (UK, 2011, ASB2013-4548).

Table 4.1-12: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Studies with fluxapyroxad - Lactating goat (ASB2010-7944, ASB2010-7945): aniline and pyrazole label, 11.4-11.6 mg/kg feed DM, equivalent to 0.4 mg/kg bw/day, eight consecutive days - Laying hens (ASB2010-7942, ASB2010-7943): aniline label, 11.5 mg/kg feed DM, equivalent to 1.59 mg/kg bw/day, 12 consecutive days

	In both species fluxapyroxad was rapidly excreted, mainly via faeces. An accumulation was not observed. Transformation into several metabolites was observed. Main components of the residue were fluxapyroxad and its metabolite M700F008. Two main transformation steps were identified: N-desmethylation of the pyrazole ring (resulting in M700F008) and hydroxylation of the biphenyl moiety (resulting in M700F005, M700F006, M700F041 and M700F042). No cleavage of the carboxamid bond was seen in animals, while cleavage products like M700F001 and M700F002 have been found in primary and succeeding plants. Studies with metabolite M700F002 Lactating goat (ASB2010-7946): pyrazole label, 11-12.5 mg/kg feed, equivalent to 0.4 mg/kg bw/day, 8 days The test item was rapidly excreted and was the only compound detected in the investigated matrices. Thus, metabolite M700F002 is not subject to biotransformation in goats. The residues transferred into milk and tissues/organs was low, with highest in kidneys at a level that was less than 0.02% of the administered dose. Laying hens (ASB2013-1039): pyrazole label, 13 mg/kg feed, corresponding to a daily mean of 0.84 mg/kg bw, 10 consecutive days Rapid excretion of the test item was observed (82.3% until sacrifice); Residue transfer into edible tissues and eggs was low: TRR was 0.004 mg/kg in eggs, 0.004 mg/kg in liver, 0.002-0.003 mg/kg in muscle, 0.002-0.006 mg/kg in fat tissues. The unchanged test item was the major component in all extracts.
Time needed for fluxapyroxad to reach a plateau concentration in milk and eggs	Milk: 5 days (livestock feeding study), but residue level did not persist over post feeding phase. Eggs: 10 days (hen metabolism study)
Animal residue definition for monitoring	Fluxapyroxad This is in line with Reg. (EC) No 396/2005.
Animal residue definition for risk assessment	Fluxapyroxad and M700F008, expressed as fluxapyroxad This is in line with the EFSA Conclusion on the peer review of the risk assessment of fluxapyroxad (ASB2012-3723).
Conversion factor(s) (monitoring to risk assessment)	Not concluded
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	Yes Fluxapyroxad is slightly fat soluble (log Pow at pH 7 = 3.13). Feeding studies indicate parent residues in fat at 0.024 mg/kg.

4.1.2.4 *Residues in rotational crops*

A summary of the field rotational crop studies on fluxapyroxad is given in the following table. Residues in rotational crops were also discussed in the framework of the peer review of the active substance fluxapyroxad (EFSA, 2012, ASB2012-3723) and data were described in detail in the DAR (UK, 2011, ASB2013-4548). MRLs have been implemented in EU residue legislation for some crop groups due to expected root uptake of residues from soil.

Table 4.1-13: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	ASB2010-7959 (interim report): sites in Spain, Italy, Greece and Germany, 2008 – 2009, application of 250 g as/ha onto bare soil, rotational crops cereals (wheat), root crops (carrot/radish) and leafy crops (cauliflower/broccoli, spinach/lettuce) planted at PBIs of 30, 120 and 365 days; samples taken at BBCH 32-65 (wheat forage), BBCH 89 (wheat grain/straw) or BBCH 49 (other crops) and analysed for fluxapyroxad and M700F001; M700F002. No significant residue levels of metabolites M700F002, M700F008 and M700F048 were recovered in the edible parts of the rotated crops at any of the PBIs (<0.01-0.02 mg/kg). In contrast, significant residues of unchanged fluxapyroxad were quantified in carrot roots (up to 0.08 mg/kg) and in immature lettuce and cauliflower leaves (0.03 and 0.06 mg/kg, respectively). The highest residues of fluxapyroxad were seen in straw at up to 0.42 mg/kg. In order to account for possible residues in rotated crops, MRL values were established for leafy vegetables (0.03 mg/kg), root and tuber vegetables except for tropical and potatoes (0.1 mg/kg), bulb vegetables (0.1 mg/kg), and brassica vegetables (0.07 mg/kg) (EFSA, ASB2012-3265).

4.1.2.5 Residues in livestock

An actual calculation of the dietary burden is provided in Table 4.1-14 . It considers the relevant uses authorized in Germany but is dominated by residues anticipated in imported commodities from outside the EU. The estimate widely reflects the calculations issued recently in an EFSA Reasoned Opinion in the framework of MRL modifications according to article 6 of Reg. (EC) No 396/2005 (ASB2012-3265).

Table 4.1-14: Calculation of the dietary burden (based on all relevant uses authorized in Germany and granted import tolerances)

Feedstuff	% DM	Percent of daily livestock diet (dry feed basis)				Residue (mg/kg)	Intake (mg/kg, dry feed basis)			
		Chicken 1,9 kg bw daily maximum feed (DM) 120 g	Dairy cattle 550 kg bw daily maximum feed (DM) 20 kg	Beef cattle 350 kg bw daily maximum feed (DM) 15 kg	Pig 75 kg bw daily maximum feed (DM) 3 kg		Chicken	Dairy cattle	Beef cattle	Pig
sugar beet leaves	16	--	30	30	25	4.17[a)]	0.000	7.819	7.819	8.516
barley grain	86	70	40	50	75	0.54[a)]	0.440	0.251	0.126	0.471
barley straw	86	--	20	50	--	10.11[a)]	0.000	2.351	5.878	0.000
pulses	86	10	--	--	--	0.06[a)]	0.007	0.000	0.000	0.000
sugar beet	20	20	10	--	--	0.07[a)]	0.070	0.035	0.000	0.000
				Intake (mg/kg dry weight feed)			0.517	10.46	13.82	6.987
				Intake (mg/kg bw/d)			0.033	0.380	0.592	0.279
				Intake (mg/animal/d)			0.062	209.1	207.3	20.96

[a)] EFSA, 2011 (ASB2012-3265)

Table 4.1-15: Conditions of requirement of livestock feeding studies on fluxapyroxad

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 10.5 (dairy) 13.8 (beef)	yes 0.52	yes 7.0
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	yes	yes	yes (ruminant study)

A brief summary of the available livestock feeding studies is given in the following table. Details of the studies were discussed in the context of the peer review of fluxapyroxad (EFSA, 2012, ASB2012-3723) as well as in the exercise of evaluating requests for import tolerances (ASB2012-3265) and were described in detail in the DAR (UK, 2011, ASB2013-4548).

Table 4.1-16: Results of livestock feeding studies (Annex IIA, point 6.4)

	Ruminant:	**Poultry:**	**Pig:**
Feeding levels (mg/kg feed dry matter) in feeding studies	Dairy cows: 3.2+0, 6.1+0.1, 18.2+0.3, 60.3+1.0; co-dosing parent+ M700F002 (ASB2010-7953)	Laying hens: 0.3+0.025, 0.6+0.05, 1.8+0.15, 6.0+0.5; co-dosing parent+ M700F002 (ASB2010-7951, amendments: ASB2010-7952, ASB2011-8313)	See ruminant
Relevant dosing level (mg/kg feed dry matter) in feeding study	6.1+0.1; 18.2+0.3	0.3+0.025; 0.6+0.05	6.1+0.1; 18.2+0.3
	Expected residue levels in animal matrices (mg/kg):		
Muscle	<0.01	<0.01	<0.01
Liver	0.026	<0.01	<0.01
Kidney	<0.01	--	<0.01
Fat	0.044	<0.01	<0.01
Milk	0.005	–	–
Eggs	–	0.003	–

4.2 Evaluation of the intended uses

4.2.1 Selection of critical use and justification

The critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

It is noted that although a table of GAPs for member states other than Germany was submitted (ASB2013-9458), it was stated by the applicant that no such authorization applications outside Germany have been submitted.

Table 4.2-1: Uses in DE and Critical Use in the central zone used for consumer intake and risk assessment (ASB2013-9457)

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days)** **(i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications)** **a) per use** **b) per crop/ season (h)**	**L product / ha** **a) max. rate / appl.** **b) max. total rate / crop/season**	**g, as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
001; 003	DE	wheat	F	brown leaf rust of cereals (*Puccinia recondita*); tan spot of cereals (*Drechslera tritici-repentis*)	spraying	BBCH 30-69 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
002; 005-007	DE	wheat	F	stripe rust of grasses (*Puccinia striiformis*); powdery mildew (*Erysiphe graminis*); leaf spot of wheat (Septoria tritici); septoria leaf spot of wheat	spraying	BBCH 30-61 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
004	DE	wheat	F	stem break of cereals (*Pseudocercosporella herpotrichoides*)	spraying	BBCH 30-32 from spring	a) 1 b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
009-013	DE	barley	F	powdery mildew (*Erysiphe graminis*); brown rust of barley (*Puccinia hordei*); net blotch (*Pyrenophora teres*); leaf blotch of cereals (*Rhynchosporium secalis*); Ramularia leaf spot disease (*Ramularia collo-cygni*)	spraying	BBCH 30-61 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
014	DE	barley	F	decrease of non-parasitic leaf spots	spraying	BBCH 32-61 from spring	a) 1 b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications) a) per use b) per crop/ season (h)**	**L product / ha a) max. rate / appl. b) max. total rate / crop/season**	**g, as/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**Water L/ha** **min / max**		
015; 018	DE	rye	F	powdery mildew (*Erysiphe graminis*); leaf blotch of cereals (*Rhynchosporium secalis*)	spraying	BBCH 30-61 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
017	DE	rye	F	brown leaf rust of cereals (*Puccinia recondita*)	spraying	BBCH 30-69 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
019; 022	DE	triticale	F	powdery mildew (*Erysiphe graminis*); septoria-species (*Septoria spp.*)	spraying	BBCH 30-61 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
020	DE	triticale	F	stem break of cereals (*Pseudocercosporella herpotrichoides*)	spraying	BBCH 30-32 from spring	a) 1 b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	
021	DE	triticale	F	brown leaf rust of cereals (*Puccinia recondita*)	spraying	BBCH 30-69 from spring	a) 2 (min. 21 d) b) 2	a) 2 b) 4	a) 125 Epoxiconazole 125 Fluxapyroxad b) 250 Epoxiconazole 250 Fluxapyroxad	100/400	F	

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

4.2.2 Wheat, rye, triticale

4.2.2.1 Residues in primary crops

In the following tables the results of those supervised residue trials are outlined which were selected for the assessment of the GAP in wheat, rye and triticale. For the detailed evaluation of the residue trials, it is referred to Appendix 2.

Table 4.2-2: Overview of the selected supervised residue trials for epoxiconazole in wheat

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (epoxiconazole)	Risk assessment (epoxiconazole)			
wheat grain	NEU	outdoor	7 x <0.01; 4 x 0.02; 3 x 0.03	7 x <0.01; 4 x 0.02; 3 x 0.03	0.015	0.03	1.0
wheat straw	NEU	outdoor	1.1; 1.4; 2 x 1.6; 1.7; 1.8; 2.1; 2.4; 2.5; 2 x 2.8; 3.0; 3.6; 4.2	1.1; 1.4; 2 x 1.6; 1.7; 1.8; 2.1; 2.4; 2.5; 2 x 2.8; 3.0; 3.6; 4.2	2.25	4.2	1.0

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Table 4.2-3: Overview of the selected supervised residue trials for fluxapyroxad in wheat

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (fluxapyroxad)	Risk assessment (fluxapyroxad)			
wheat grain	NEU	outdoor	<0.01; 3 x 0.01; 3 x 0.02; 4 x 0.03; 0.04; 0.06	<0.01; 3 x 0.01; 3 x 0.02; 4 x 0.03; 0.04; 0.06	0.02	0.06	1.0
wheat straw	NEU	outdoor	0.32; 0.4; 0.41; 0.44; 0.94; 2 x 0.95; 2 x 1.0; 1.6; 1.8; 2.8; 6.1	0.32; 0.4; 0.41; 0.44; 0.94; 2 x 0.95; 2 x 1.0; 1.6; 1.8; 2.8; 6.1	0.95	6.1	1.0

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

A number of further studies were also available reflecting the conditions of the GAP. They were, however, used as supplementary information only, due to reduced standards of documentation and a less sensitive analytical method (LOQ at 0.05 mg/kg in grain).

Residue data on wheat may also be used by means of extrapolation (SANCO 7525/VI/95 rev.9) to evaluate uses in rye and triticale.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant for the commodities under consideration.

4.2.2.3 Residues in processed commodities

The following table summarizes the results of wheat processing studies for epoxiconazole. More details are outlined in Appendix 2.

Table 4.2-4: Overview of the available processing studies for epoxiconazole in wheat grain

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF (a)	Mean PF (b)	Comments
low grade flour	4	0.5; 1.0; <2; 2.0	1.5	1.4	BASF 2003/1000945, study 02 10 47 003 RIP2003-1536
wholemeal flour		1.0; 1.0; 1.25; >2	1.13	1.3	
wholemeal bread		<0.5;0.66; 1.0; 1.0	0.83	0.8	
total bran		3.0; 3.5; >5; 5.3	4.25	3.7	
flour type 550		<0.3; <0.5; <0.5; 1.0	0.5	0.6	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The mean processing factor is obtained by calculating the mean of the individual processing factors of each processing study.

The following table summarizes the results of wheat processing studies for fluxapyroxad, which have already been described in detail in the DAR (UK 2011, ASB2013-4548). More details are outlined in Appendix 2.

Table 4.2-5: Overview of the available processing studies for fluxapyroxad in wheat grain

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF (a)	Mean PF (b)	Comments
Bran	4 studies, 2 replicates each	2.69; 2.87; 3.07; 3.49	2.97	3.1	BASF Doc ID 2009/7003065 ASB2010-7955
Flour		0.13; 0.15; 0.16; 0.51	0.16	0.24	
Bread, white		0.10; 0.11; 0.11; 0.34	0.11	0.17	
Whole meal		0.81; 0.86; 1.02; 1.42	0.94	1.04	
Bread, whole meal		0.54; 0.58; 0.71; 0.98	0.65	0.71	
Germ		0.74; 1.0; 1.37; 2.57	1.19	1.4	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The mean processing factor is obtained by calculating the mean of the individual processing factors of each processing study.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

No specific pre-harvest interval (PHI) is proposed as PHI is defined by the growth stage of application.

4.2.3 Barley

In the following tables the results of that supervised residue trials are outlined which were selected for the assessment of epoxiconazole and fluxapyroxad in barley. For the detailed evaluation of the residue trials, it is referred to Appendix 2.

Table 4.2-6: Overview of the selected supervised residue trials for epoxiconazole in barley

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	Median CF (d)
			Enforcement (epoxiconazole)	Risk assessment (epoxiconazole)			
barley grain	NEU	outdoor	2 x 0.05; 0.06; 2 x 0.07; 0.08; 0.09; 2 x 0.1; 0.11; 0.17; 0.24	2 x 0.05; 0.06; 2 x 0.07; 0.08; 0.09; 2 x 0.1; 0.11; 0.17; 0.24	0.085	0.24	1.0
barley straw	NEU	outdoor	0.74; 0.78; 1.0; 1.3; 1.4; 1.7; 2.0; 2.2; 2.5; 2.9; 6.6; 15	0.74; 0.78; 1.0; 1.3; 1.4; 1.7; 2.0; 2.2; 2.5; 2.9; 6.6; 15	1.85	15	1.0

(a): NEU, SEU, EU or Import (country code).

(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

Table 4.2-7: Overview of the selected supervised residue trials for fluxapyroxad in barley

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	Median CF [(d)]
			Enforcement (fluxapyroxad)	Risk assessment (fluxapyroxad)			
barley grain	NEU	outdoor	0.02; 0.046; 2 x 0.05; 2 x 0.08; 0.09; 0.11; 0.13; 0.17; 0.18; 0.24	0.02; 0.046; 2 x 0.05; 2 x 0.08; 0.09; 0.11; 0.13; 0.17; 0.18; 0.24	0.085	0.24	1.0
barley straw	NEU	outdoor	0.09; 0.11; 0.12; 0.19; 0.44; 0.47; 0.7; 0.74; 1.2; 1.5; 1.8; 2.5	0.09; 0.11; 0.12; 0.19; 0.44; 0.47; 0.7; 0.74; 1.2; 1.5; 1.8; 2.5	0.585	2.5	1.0

(a): NEU, SEU, EU or Import (country code).
(b): Median value of the individual trial results according to the risk assessment residue definition.
(c): Highest value of the individual trial results according to the risk assessment residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

4.2.3.1 *Distribution of the residue in peel/pulp*

Not relevant for the commodities under consideration.

4.2.3.2 *Residues in processed commodities*

The following table gives summarizes the results of processing studies for epoxiconazole residues in wheat grain. More details are outlined in Appendix 2.

Table 4.2-8: Overview of the available processing studies for epoxiconazole in barley grain

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF [(a)]	Mean PF [(b)]	Comments
beer	4	2 x <0.05; <0.06; <0.08	0.06	0.06	BAS 2003/1000946
trub (flocs)		2.3; 3.0; 3.53; 4.4	3.27	3.31	RIP2003-1532
yeast		0.65; 0.84; 1.0; 1.6	0.92	1.02	
brewer's malt		0.47; 0.6; 0.62; 0.65	0.61	0.59	
pearl barley		0.35; 0.36; 0.5; 0.55	0.4	0.44	
offal		8.2; 8.6; 10.8; 11.4	9.7	9.75	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The mean processing factor is obtained by calculating the mean of the individual processing factors of each processing study.

The following table gives summarizes the results of processing studies on fluxapyroxad residues in barley grain, which have already been described in detail in the DAR (UK, 2011 ASB2013-4548). More details are outlined in Appendix 2.

Table 4.2-9: Overview of the available processing studies for fluxapyroxad in barley grain

Processed commodity	Number of studies	Individual PFs (mg/kg)	Median PF [(a)]	Mean PF [(b)]	Comments
Pot Barley	4 studies, 2 replicates each	0.09; 0.11; 0.21; 0.39	0.16	0.20	BASF Doc ID 2009/7003177 ASB2010-7956
Bran		1.48; 1.73; 2.05; 2.39	1.89	1.91	
Flour		0.10; 0.10; 0.24; 0.45	0.17	0.22	
Brewing Malt		0.01; 0.01; 0.01; 0.02	0.01	0.01	
Malt Sprouts		0.16; 0.26; 0.30; 0.53	0.28	0.31	
Spent Grain		0.20; 0.25; 0.26; 0.37	0.255	0.27	
Spent Hops		0.11; 0.17; 0.17; 0.34	0.17	0.20	
Brewer´ yeast		0.10; 0.32; 0.35; 0.40	0.335	0.29	
Beer		0.09; 0.11; 0.21; 0.39	0.16	0.20	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The mean processing factor is obtained by calculating the mean of the individual processing factors of each processing study.

4.2.3.3 *Proposed pre-harvest intervals, withholding periods*

No specific pre-harvest interval (PHI) is proposed as PHI is defined by the growth stage of application.

4.3 Consumer intake and risk assessment

4.3.1 Epoxiconazole

The consumer intake and risk assessment is based on the input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-1: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
all commodities as laid down in Annex I to Reg. (EC) No 396/2005	variable	MRLs, as laid down in Reg (EU) No 978/2011	--	--
wheat, rye grain			0.015	STMR
barley grain			0.085	STMR

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.008 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	97.2 % (based on DK child diet)
NTMDI (% ADI) according to NVS II	73.6 % (based on DE child 2-4 years)
IEDI (EFSA PRIMo) (% ADI)	not necessary
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI and NEDI	none

ARfD	0.023 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	wheat: 0.9% (based on UK, 4-6 years) rye: 0.4% (based on UK infant) barley: 2.7% (based on NL adult, 60 kg bw) (no processing factors were considered)
NESTI (NVS II) (% ARfD)	wheat: 1% (based on DE child, 2-4 years) rye: 0.4% (based on DE general population) barley: 2% (based on DE general population) (no processing factors were considered)
Factors included in IESTI and NESTI	none

As triazole metabolites (TDM) are not unique to epoxiconazole and a common approach on EU level is still outstanding, no risk assessment was performed on TDM which may be formed from epoxiconazole in plant metabolism and soil. To this end the risk assessment is provisional in nature.

4.3.2 Fluxapyroxad

The consumer intake and risk assessment is based on the appropriate input values given in Table 8.3-3 and the toxicological reference values stated in Table 8.3-4. For the detailed calculation results it is referred to Appendix 3.

Table 4.3-3: Residue input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
all commodities as laid down in Annex I to Reg. (EC) No 396/2005	variable	MRLs, as laid down in Reg (EU) No 978/2011	--	--
wheat, rye grain			0.02	STMR
barley grain			0.085	STMR

Table 4.3-4: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.02 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	63.5 % (based on DE children, 2-4 years, mean body weight)
NTMDI (% ADI) according to NVS II	65.9 % (based on DE children, 2-4 years, individual consumption/body weight ratio)
IEDI (EFSA PRIMo) (% ADI)	not necessary
NEDI (NVS II) (% ADI)	not necessary
Factors included in IEDI and NEDI	none

ARfD	0.25 mg/kg bw
IESTI (EFSA PRIMo) (% ARfD)	wheat: 0.1% (based on UK, 4-6 years) rye: 0.1% (based on UK infant) barley: 0.2% (based on NL adult, 60 kg bw) (no processing factors were considered)
NESTI (NVS II) (% ARfD)	wheat: <0.1% (based on DE child, 2-4 years) rye: <0.1% (based on DE child, 2-4 years) barley: 0.2% (based on general population) (no processing factors were considered)
Factors included in IESTI and NESTI	none

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required for the commodities of plant origin under consideration (grain of wheat, rye, triticale and barley).

Based on the residue trials in wheat the following MRL would be needed:
$MRL_{OECD;EPOX}$ = 0.05 mg/kg (covered by established MRL of 0.6 mg/kg in wheat/triticale and rye)
$MRL_{OECD;FLUX}$ = 0.09 mg/kg (covered by established MRL of 0.4 mg/kg in wheat/triticale and rye)

Based on the residue trials in barley the following MRL would be needed.
$MRL_{OECD;EPOX}$ = 0.4 mg/kg (covered by established MRL of 1.5 mg/kg in barley)
$MRL_{OECD;FLUX}$ = 0.4 mg/kg (covered by established MRL of 2 mg/kg in barley)

With STMR for wheat/rye grain (0.04 mg/kg) and barley grain (0.14 mg/kg), and HR for wheat/rye straw (15.4 mg/kg) and barley straw (15.4 mg/kg) having been considered in EFSA's Reasoned opinion on the modification of existing MRLs for epoxiconazole in products of animal origin (ASB2012-9643), the existing EU MRLs set out for commodities of animal origin (and reflecting that feed intake) are not affected by the uses under consideration.

With STMR for wheat/rye grain (0.12 mg/kg), barley grain (0.54 mg/kg), and HR for wheat/rye straw (8.2 mg/kg) and barley straw (10.11 mg/kg) having been considered in EFSA's Reasoned opinion on setting of new MRLs for fluxapyroxad in various commodities of plant and animal origin (ASB2012-3265), the existing EU MRLs set out for commodities of animal origin (and reflecting that feed intake) are not affected by the uses under consideration.

4.5 Conclusion

The data available are considered sufficient for risk assessment.

The limit values as laid down in EU residue legislation (Reg. (EU) No 978/2011) for residues of epoxiconazole in/on wheat and rye grain (0.6 mg/kg) and barley (1.5 mg/kg) are sufficient to cover residues anticipated consequent to the intended use of the product on these crops.
The limit values as laid down in EU residue legislation (Reg. (EU) No 978/2011) for residues of fluxapyroxad in/on wheat and rye grain (0.4 mg/kg) and barley (2 mg/kg) are sufficient to cover residues anticipated consequent to the intended use of the product on these crops.

The chronic and the short-term intake of epoxiconazole and fluxapyroxad residues consequent to the intended uses are unlikely to present a public health concern.

As far as consumer health protection is concerned, the RMS Germany (BfR) agrees with the authorization of the intended uses.

Appendix 1 Reference list

Table A 1: Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
	EFSA	2008	Conclusion regarding the peer review of the pesticide risk assessment of the active substance epoxiconazole EFSA Scientific Report (2008) 138, 1-80 ASB2012-3620		Add
	EFSA	2011	Reasoned Opinion - Modification of the existing MRLs for Epoxiconazole in various cereals EFSA Journal 2011;9(3):2095 ! EFSA-Q-2010-01117 EFSA Journal 2011;9(3):2095, 1-33 ASB2012-3291		Add
	EFSA	2011	Reasoned opinion: Setting of new MRLs for Fluxapyroxad (BAS 700 F) in various commodities of plant and animal origin EFSA Journal 2011;9(6):2196 ! EFSA-Q-2010-01476 EFSA Journal 2011;9(6):2196., 1-68 ASB2012-3265		Add
	EFSA	2011	Conclusion on the peer review of the pesticide risk assessment of the active substance Fluxapyroxad (BAS 700 F) EFSA Journal 2012;10(1):2522 ! EFSA-Q-2011-00395 EFSA Journal 2012;10(1):2522 ASB2012-3723		Add
	EFSA	2012	Reasoned opinion on the modification of the existing MRLs for Epoxiconazole in products of animal origin EFSA Journal 2012;10(6):2795 ! EFSA-Q-2011-01259 ASB2012-9643		Add
	Germany (RMS)	1900	Epoxiconazole (Draft Assessment Report) GLP: Open Published: no ASB2010-10473		Add
	Germany (RMS)	1995	Epoxiconazole: Draft Assessment Report - confirmatory data, Vol.1 und Vol.3 B5,B7,B8,B9 ASB2013-7187		Add
	United Kingdom (RMS)	2011	Fluxapyroxad: Draft Assessment Report ASB2013-4548		Add
KIIA 6.1.1	Funk, H.; Mackenroth, Ch.	2001	Investigation of the stability of residues of BAS 480 F in plant matrices under normal storage conditions 2001/1015032 ! 58237 GLP: yes Published: no BVL-1865451, RIP2003-1533	BAS	Y
KIIA 6.1.1	Lehmann, A.	2009	Investigation of the storage stability of M700F008 in plant matrices 2009/1072400 ! 370501 GLP: Open Published: no BVL-2154426, ASB2010-7935	BAS	N
KIIA 6.1.1	Lehmann, A.; Mackenroth, C.	2011	Investigation of the storage stability of M700F008 in plant matrices 2011/1124183 GLP: yes Published: no BVL-2383629, ASB2013-1037	BAS	Y
KIIA 6.1.1	Radzom, M.	2009	Investigation of the storage stability of the BAS 700 F metabolite M700F048 in plant matrices and processed commodities 2009/1072399 ! 362486 GLP: yes Published: no BVL-2154425, ASB2010-7938	BAS	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.1.1	Radzom, M.	2010	Investigation of the storage stability of BAS 700 F in plant matrices 2010/1009624 ! 315768 GLP: yes Published: no BVL-2154423, BVL-2378585, ASB2010-7936	BAS	Y
KIIA 6.1.1	Radzom, M.	2010	Investigation of the storage stability of the BAS 700 F metabolite M700F002 in plant matrices 2010/1009625 ! 324239 GLP: yes Published: no BVL-2154424, BVL-2378621, ASB2010-7937	BAS	Y
KIIA 6.1.1	Radzom, M.; Mackenroth, C.	2009	Investigation of the storage stability of the BAS 700 F metabolite M700F002 in plant matrices 2009/1072398 ! 324239 GLP: yes Published: no BVL-1985770, ASB2010-8858	BAS	N
KIIA 6.1.1	Rawle, N. W.; Jones, S. D.	1999	Stability of residues of Epoxiconazole (BAS 480 F) in tissues of animal origin stored at less than -18°C 99/11191 ! CEMR-875 GLP: yes Published: no BVL-2218156, RIP2003-1534	BAS	Y
KIIA 6.1.1	Richter, M.	2011	Investigation of the storage stability of BAS 700 F metabolite M700F048 in plant matrices and processed commodities 2011/1125600 GLP: yes Published: no BVL-2383631, ASB2013-1038	BAS	Y
KIIA 6.1.1	Tilting, N.	1992	Two years storage stability study of Epoxiconazole residues in wheat and soil 92/11693 ! DE/F/LST01/90 ! 3608 GLP: Open Published: no BVL-2218074, RIP2003-1503	BAS	Y
KIIA 6.2.1	Bretz, M.; Ockert, M.; Gläßgen, W. E.	2009	Metabolism of BAS 700 F in soybean 2009/1017387 ! 315733 GLP: yes Published: no BVL-2154428, ASB2010-7940	BAS	Y
KIIA 6.2.1	Bross, M.	2009	Metabolism of 14C-BAS 700 F in wheat after foliar treatment 2009/1048403 ! 315732 GLP: yes Published: no BVL-2154429, ASB2010-7941	BAS	Y
KIIA 6.2.1	Grosshans, F.; Schopfer, C.; Bross, M.; Kuhnke, G.	2010	Metabolism of 14C-BAS 700 F in wheat after seed treatment application 2009/1112531 GLP: yes Published: no BVL-2378634, ASB2012-7150	BAS	Y
KIIA 6.2.1	Hafemann, C.; Labib, S.	2009	Metabolism of 14C-BAS 480 F in coffee 2009/1074837 ! 345838 GLP: Yes Published: No BVL-2089394, ASB2011-10921	BAS	Add
KIIA 6.2.1	Hamm, R. T.	1988	Uptake of 14C-BAS 480 F by spring wheat 88/10368 ! P87-E007 GLP: Open Published: no BVL-2218080, RIP2003-1508	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.2.1	Hamm, R. T.	1995	Plant uptake study with 14C-BAS 480 F (Chlorophenyl-U-14C) in banana 95/11005 ! 13577 GLP: yes Published: no BVL-2097985, RIP9700204	BAS	Y
KIIA 6.2.1	Hamm, R. T.	1995	Plant uptake study with 14C-BAS 480 F (Fluorophenyl-U-14C) in banana 95/11006 ! 15302 GLP: Open Published: Open BVL-1865456, RIP9700205	BAS	Y
KIIA 6.2.1	Hamm, R. T.	1997	Plant uptake of 14C-BAS 480 F by coffee plants and characterization of the radioactive residues in coffee beans 97/10535 ! 15305/26003 GLP: yes Published: no BVL-2087518, RIP9700244	BAS	Y
KIIA 6.2.1	Hamm, R. T.	1999	Metabolism of BAS 480 F in sugar beet 49241 ! 1999/11655 GLP: yes Published: no BVL-2218076, RIP2000-4	BAS	Y
KIIA 6.2.1	Hofmann, M.	1990	Plant uptake study with 14C-BAS 480 00 F in spring wheat 90/0245 ! P89-E050 ! 2754 GLP: yes Published: no BVL-2218084, RIP2003-1514	BAS	Y
KIIA 6.2.1	Keller, E.	1991	Characterizations and identifications of metabolites of 14C-205 259 (14C-BAS 480 F) in spring wheat 91/10285 ! P88-M004 ! 2995 GLP: yes Published: no BVL-2218089, RIP2003-1511	BAS	Y
KIIA 6.2.1	Keller, E.	1991	The metabolism of 14C-205 259 (14C-BAS 480 F) in wheat 91/11289 ! P90-M001 ! 3180 GLP: yes Published: no BVL-2218088, RIP2003-1512	BAS	Y
KIIA 6.2.1	Rabe, U.	2009	Metabolism of BAS 700 F in tomatoes 2009/1017901 ! 315734 GLP: yes Published: no BVL-2154427, ASB2010-7939	BAS	Y
KIIA 6.2.1	Reinhard, K.	1996	Metabolism of 14C-Epoxiconazol (BAS 480 F) in banana 96/10929 ! 13578 GLP: yes Published: no BVL-2097987, RIP9700245	BAS	Y
KIIA 6.2.1	Ritter, A.	1989	14C-LAB 205 259 (14C-BAS 480 F): Analyses of plant parts of spring wheat grown under greenhouse and outdoor conditions 89/10169 ! RCC 093420 ! P87-C018 GLP: yes Published: no BVL-2218091, RIP2003-1510	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.2.1	Schreiner, D.; Deppermann, N.	2011	Re-analysis of samples which were generated during wheat and soybean metabolism studies with 14C-BAS 700 F (BASF DocID 2009/1048403 and BASF DocID 2009/1017387) 2011/1141383 GLP: yes Published: no BVL-2383627, ASB2013-1036	BAS	N
KIIA 6.2.2	[redacted]	2009	14C-BAS 700 F: Absorption, distribution and excretion after repeated oral administration in laying hens 2009/1065025 ! 02B0440/076006 GLP: yes Published: no BVL-2154430, ASB2010-7942	BAS	Y
KIIA 6.2.2	[redacted]	2010	^{14}C-Reg.No. 5435595 (metabolite of BAS 700 F) - Absorption, distribution and excretion after repeated oral administration in laying hens 2009/1083000 GLP: yes Published: no BVL-2383636, ASB2013-1040	BAS	N
KIIA 6.2.2	[redacted]	1999	The metabolism of 14C-Epoxiconazole (14C-BAS 480 F) in laying hens 99/10202 ! P93-M003 GLP: yes Published: no BVL-2218150, RIP2000-551	BAS	Y
KIIA 6.2.2	[redacted]	2010	The metabolism of 14C-M700F002 (metabolite of BAS 700 F) in laying hens 2009/1078621 GLP: yes Published: no BVL-2383635, ASB2013-1039	BAS	Y
KIIA 6.2.2	[redacted]	2009	The metabolism of 14C-BAS 700 F in laying hens 2009/1069223 ! 315779 GLP: yes Published: no BVL-2154431, ASB2010-7943	BAS	Y
KIIA 6.2.2	[redacted]	1993	The metabolism of 14C-Epoxiconazole in hens 93/11221 ! BSF/511 ! BSF 511 GLP: yes Published: no BVL-2218151, RIP2003-1518	BAS	Y
KIIA 6.2.2	[redacted]	2009	Magnitude of residues in eggs and tissues of laying hens following multiple oral administration of BAS 700 F and M700F002 (Amendment 1 dated 10.02.2010) 2010/1029664 ! 214965 ! 30467 ! 2009/1074799 ! 315796 ASB2010-7952	BAS	Add
KIIA 6.2.2 / KIIA 6.2.3	[redacted]	2011	Epoxiconazole (BAS 480 F): Enantiomer ratio in commodities of plant and animal origin 2011/1102465 GLP: No Published: No BVL-2089369, BVL-2089396, BVL-2089404, BVL-2089427, ASB2011-10918	BAS	Add
KIIA 6.2.2	[redacted]	2010	Magnitude of residues in tissues and eggs of laying hens following multiple oral administrations of Epoxiconazole 2010/1140930 ! 358577 ! IF-10/01559733 GLP: Yes Published: No BVL-2089428, ASB2011-10924	BAS	Add

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.2.3	[redacted]	2004	14C-BAS 480 F - Absorption, distribution and excretion after repeated oral administration in lactating goats 2005/1027565 ! 036004Bb0051 ! 02B0277/036004 GLP: Yes Published: No BVL-2089402, ASB2011-10922	BAS	Add
KIIA 6.2.3	[redacted]	2007	The metabolism of 14C-BAS 480 F (Epoxiconazole) in lactating goats 2005/1027545 ! 151738 GLP: Yes Published: No BVL-2089403, ASB2011-10923	BAS	Y
KIIA 6.2.3	[redacted]	2009	14C-BAS 700 F: Absorption, distribution and excretion after repeated oral administration in lactating goats 2009/1065024 ! 02B0440/076005 GLP: yes Published: no BVL-2154432, ASB2010-7944	BAS	Y
KIIA 6.2.3	[redacted]	1989	Dosing of lactating goat with 0.5 mg (14-C)-LAB 205 259 ((14-C)-BAS 480-F)/kg body weight (incl. Addendum 1 dated 1990-06-20) 89/10196 ! P88-C003 ! NA 88 9764 GLP: n0 Published: no BVL-2218149, RIP2003-1516	BAS	Y
KIIA 6.2.3	[redacted]	1989	Dosing of lactating goat with 10 mg 14-C-LAB 205259 ((14-C)-BAS 480 F)/kg body weight 89/10197 ! P88-C003 ! NA 88 9764 GLP: no Published: no BVL-2218148, RIP2003-1517	BAS	Y
KIIA 6.2.3	[redacted]	2009	The metabolism of 14C-M700F002 (metabolite of BAS 700 F) in lactating goats 2009/1074682 ! 362496 GLP: yes Published: no BVL-2154434, ASB2010-7946	BAS	Y
KIIA 6.2.3	[redacted]	2009	Metabolism of 14C-BAS 700 F (14C-Reg.No. 5094351) in lactating goat 2009/1074074 ! 315778 GLP: yes Published: no BVL-2154433, ASB2010-7945	BAS	Y
KIIA 6.2.3	[redacted]	1990	The metabolism of 14C-LAB 205 259 in lactating goats 90/10170 ! P88-M012 ! P88-M013 ! 2770 GLP: yes Published: no BVL-2218152, RIP2003-1507	BAS	Y
KIIA 6.3	Balluff, M.	2001	Field residue study for the determination of residues of the active ingredient(s) after the maximum number of applications under open field conditions with BAS 480 27 F in winter cereals in Southern Europe, 2000 2001/1009088 ! 20003013/E1-FPWC GLP: yes Published: no BVL-1865487, RIP2003-1529	BAS	N
KIIA 6.3	Beck, J.; Lehmann, A.; Mackenroth, C.	2003	Study on the residue behaviour of Epoxiconazole in winter wheat after application of BAS 480 27 F under field conditions in France (S), Germany, United Kingdom and Spain, 2002 2002/1008783 ! 134503 GLP: yes Published: no BVL-1865480, RIP2003-1528	BAS	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.3	Beck, J.; Tilting, N.; Mackenroth, C.	1995	Study on the residue behaviour of BAS 481 03 F in cereals under field conditions in Germany, 1992 95/10661 ! DE/FR/01/92 GLP: yes Published: no BVL-1865486, RIP2003-1527	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F in wheat and triticale after application of Fa 5094351 18 F under field condition in France, UK, Spain and Germany, 2007 2007/1050092 ! 284416 GLP: yes Published: no BVL-2154436, ASB2010-7948	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F in barley after application of Fa 5094351 18F under field condition in France, UK, Spain and Germany, 2007 2007/1050093 ! 284410 GLP: yes Published: no BVL-2154438, ASB2010-7950	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F and Epoxiconazole in wheat and triticale after application of BAS 701 00 F, BAS 700 00 F and BAS 480 31 F under field condition in France, Italy, Spain, Greece, Netherlands and Germany, 2008 2009/1012124 ! 315842 GLP: yes Published: no BVL-2438209, ASB2010-8862	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F in barley after application of BAS 700 00 F, under field condition in France, Italy, Spain, UK, Greece, Netherlands and Germany, 2008 2009/1012125 ! 315850 GLP: yes Published: no BVL-2154437, ASB2010-7949	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F in wheat and triticale after application of BAS 700 00 F, under field condition in France, Italy, Spain, UK and Germany, 2008 2009/1012126 ! 315849 GLP: yes Published: no BVL-2154435, ASB2010-7947	BAS	Y
KIIA 6.3	Erdmann, H.-P.	2009	Study on the residue behaviour of BAS 700 F and Epoxiconazole in barley after application of BAS 701 00 F, BAS 700 00 F and BAS 480 31 F under field condition in France, Italy, Spain, Greece, Netherlands and Germany, 2008 2009/1012127 ! 315843 GLP: yes Published: no BVL-2438210, ASB2010-8863	BAS	Y
KIIA 6.3	Fuchs, A.; Tilting, N.; Raunft, E.	1996	Study on the residue behaviour of Epoxiconazole in sugar beet after treatment with BAS 480 21 F under field conditions in France and Spain, 1994 96/10275 ! EU/FR/04/94 GLP: yes Published: no BVL-2218153, RIP9700207	BAS	N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.3	Hauck, E. J.; Holzer, S.	2012	Study on the residue behaviour of Fluxapyroxad and Metconazole in wheat after treatment with BAS 712 00 F, BAS 700 00 F and BAS 555 00 F under field conditions in Germany, the United Kingdom, Spain, Italy, Northern France, The Netherlands, South France and Greece, 2011 2012/1016602 ! 385605 GLP: yes Published: no BVL-2449736, ASB2013-9474	BAS	N
KIIA 6.3	Hauck, E. J.; Holzer, S.	2012	Residue behaviour of Fluxapyroxad and Metconazole in wheat after treatment with BAS 712 00 F, BAS 700 00 F, BAS 555 00 F under field conditions in Germany, the United Kingdom, Spain, Italy, France, The Netherlands, Greece 2011 - 1. Addendum 2012/1124490 ! 385605 GLP: yes Published: no BVL-2449737, ASB2013-9475	BAS	N
KIIA 6.3	Jones, St.	2002	Study on the residue behaviour of BAS 480 F in cereals after application of BAS 480 27 F under field conditions in France (S), Italy, 2001 2001/1006146 ! 4890 ! 58241 GLP: yes Published: no BVL-1865449, RIP2003-1530	BAS	N
KIIA 6.3	Jones, St.	2003	Study on the residue behaviour of BAS 480 F in wheat and barley after application of BASF 480 27 F under field conditions in France (South) and Spain, 2002 2002/1014334 ! 141736 GLP: yes Published: no BVL-1865488, RIP2003-1531	BAS	N
KIIA 6.3	Perny, A.	2004	Study on the residue behaviour of Fenpropimorph and Epoxiconazole on sugar beets after application of BAS 481 08 F under field conditions in Greece and Spain, 2003 2004/1024749 ! 138622 GLP: yes Published: no BVL-1865459, RIP2006-2761	BAS	N
KIIA 6.3	Raunft, E.; Fegert, A.	1996	Study on the residue behaviour of Epoxiconazole in sugar beet after treatment with BAS 480 21 F under field conditions in Belgium, France, Germany, Spain and the Netherlands, 1995 96/10280 ! EU/FR/04/95 GLP: yes Published: no BVL-2218161, RIP9700208	BAS	N
KIIA 6.3	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Northern and Southern France and Italy, 2004 2006/1018052 ! 174997 ! IF-04/00168928 GLP: yes Published: no BVL-1865481, RIP2007-465	BAS	Y
KIIA 6.3	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in barley after treatment with BAS 480 31 F under field conditions in Germany, Denmark, England, Northern and Southern France, Spain, Italy and Greece, 2004 2006/1018053 ! 175003 ! IF-04/00166114 GLP: yes Published: no BVL-1865482, RIP2006-2759	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.3	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in barley after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Southern France and Northern France, 2005 2006/1029385 ! 189121 ! IF-05/00343235 GLP: yes Published: no BVL-1865450, RIP2006-2760	BAS	Y
KIIA 6.3	Reichert, N.	2006	Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Denmark, England and Northern France, 2005 2006/1029386 ! 189118 ! IF-05/00343181 GLP: Open Published: Open BVL-1865489, RIP2007-469	BAS	Y
KIIA 6.3	Schroth E.; Martin, E.	2011	Study on the residue behavior of BAS 700 F after seed treatment (with BAS 700 02 F) with different loading rates in wheat under field conditions in Germany, United Kingdom, France (North and South), Greece, Italy and Spain, 2010 2010/1224092 GLP: yes Published: no BVL-2138082, BVL-2378646, ASB2012-7151	BAS	N
KIIA 6.3	Schroth, E.	2005	Study on the residue behavior of Epoxiconazole on sugar beets after application of BAS 480 31 F under field conditions in Spain and Greece, 2004 2004/1032625 ! 174994 ! 04/PF/005 GLP: yes Published: no BVL-1865491, RIP2006-2762	BAS	N
KIIA 6.3	Schulz, H.	1995	Determination of the residues of Epoxiconazol in sugar beet following treatment with BAS 480 21 F under field conditions in Italy 1994 95/10732 ! IF-94/05829-00 GLP: yes Published: no BVL-2218162, RIP9700206	BAS	N
KIIA 6.3	Schulz, H.	2007	1st Addendum to report: Study on the residue behaviour of BAS 480 F in wheat after treatment with BAS 480 31 F under field conditions in Germany, Sweden, England, Northern and Southern France and Italy, 2004 2007/1009641 ! 174997 ! IF-04/00168928 GLP: yes Published: no BVL-1865472, RIP2007-467	BAS	Y
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole in winter wheat, winter barley and spring barley after applications of BAS 48013F and BAS 48021F in 1992 93/10702 ! REF 192 ! TR 608 GLP no Published: no BVL-2218176, RIP2003-1520	BAS	Y
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole in winter wheat, winter barley and spring barley after applications of BAS 48021F in 1992 93/10704 ! REF 191 ! TR 607 GLP: no Published: no BVL-2218165, RIP2003-1521	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole and Fenpropimorph in winter wheat, winter barley and spring barley after applications of BAS 48106F in 1992 93/10705 ! REF 190 ! TR 606 GLP: no Published: no BVL-2218174, RIP2003-1522	BAS	Y
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole in winter wheat and spring barley following a single application of BAS 48013F in the UK in 1991 93/10709 ! REF 181 ! TR 601 GLP: no Published: no BVL-2218175, RIP2003-1523	BAS	Y
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole in barley following sequential applications of BAS 48013F in the UK during 1991 93/10710 ! REF 180 ! TR 600 GLP: no Published: no BVL-2218154, RIP2003-1524	BAS	Y
KIIA 6.3	Steggles, H. A.	1993	Residues of Epoxiconazole in winter wheat following sequential applications of BAS 48013F in the UK during 1991 93/10712 ! REF 179 ! TR 599 GLP: no Published: no BVL-2218171, RIP2003-1525	BAS	Y
KIIA 6.4.1	[redacted]	2009	Magnitude of residues in eggs and tissues of laying hens following multiple oral administration of BAS 700 F and M700F002 2009/1074799 ! 214965 ! 30467 ! 315796 GLP: yes Published: no BVL-2154439, ASB2010-7951	BAS	Y
KIIA 6.4.1	[redacted]	2010	Magnitude of residues in eggs and tissues of laying hens following multiple oral administration of BAS 700 F and M700F002 - Amendment no. 1 2010/1029664 ! 214965 ! 315796 ! 2009/1074799 ! 30467 GLP: yes Published: no BVL-2154440, ASB2011-8313	BAS	Y
KIIA 6.4.2	[redacted]	1998	Epoxiconazole feeding study in cows: Magnitude of the residue in tissues and milk CEMR-753 ! 98/10605 GLP: yes Published: no BVL-2218155, RIP2003-455	BAS	Y
KIIA 6.4.2	[redacted]	2009	Magnitude of residues in milk and tissues of dairy cows following multiple oral administrations of BAS 700 F and metabolite M700F002 2009/1074798 ! 285774 ! 30583 ! 31595 GLP: yes Published: no BVL-2154441, ASB2010-7953	BAS	Y
KIIA 6.5.1	Hassink, J.	2009	BAS 700 F: Hydrolysis at 90°C, 100°C and 120°C 2009/1049060 ! 324302 GLP: yes Published: no BVL-2154442, ASB2010-7954	BAS	Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Owner	How considered in dRR *
KIIA 6.5.1	von Götz, N.	1999	Hydrolysis of BAS 480 F at 90°C, 100°C, and 120°C 1999/11790 ! 58236 GLP: yes Published: no BVL-1865469, RIP2003-1535	BAS	Y
KIIA 6.5.3	Johnston, R. L.; Saha, M.	2009	Magnitude of BAS 700 F residues in processed fractions and/or aspirated grain fractions of the cereal grain wheat following applications of BAS 700 AE F 2009/7003065 ! 315760 GLP: yes Published: no BVL-2154443, ASB2010-7955	BAS	Y
KIIA 6.5.3	Johnston, R. L.; Saha, M.	2009	Magnitude of BAS 700 F residues in processed fractions of the cereal grain barley following applications of BAS 700 AE F 2009/7003177 ! 315759 GLP: yes Published: no BVL-2154444, ASB2010-7956	BAS	Y
KIIA 6.5.3	Renner, G.	2003	Determination of the residues of BAS 510 F and Epoxiconazole in winter wheat processing products following double application of BAS 549 KA F in Germany 2003/1000945 ! 02 10 47 003 GLP: Open Published: Open BVL-2218159, RIP2003-1536	BAS	Y
KIIA 6.5.3	Schulz, H.	2003	Determination of the residues of Epoxiconazole and BAS 510 F in barley and processed products following treatment with BAS 549 KA F under field conditions in Germany 2002 2003/1000946 ! IF-02/00006864 ! 104369 GLP: yes Published: no BVL-2218160, RIP2003-1532	BAS	Y
KIIA 6.6	Erdmann, H.-P.	2009	Interim report: Field rotational crop study with BAS 700 00 F, containing 62.5 g/L Reg.No. 5094351, applied to bare soil at 365, 120 and 30 days prior to planting of four rotational crops in Spain, Italy, Greece and Germany, 2008 - 2009 2009/1074616 ! 315743 GLP: yes Published: no BVL-2154447, ASB2010-7959	BAS	Y
KIIA 6.6	Gomyo, T.	1994	Certificate: Study on rotational crops cultivated in fields treated with Epoxiconazole 94/11921 ! EC-500 ! NISSO 1-9327NG GLP: no Published: no BVL-2218177, RIP2003-1539	BAS	Y
KIIA 6.6	Gomyo, T.; Sugioka, K.; Watanabe, E.	1994	Study on rotational crops cultivated in fields treated with Epoxiconazole 94/10195 ! EC-500 ! NISSO 1-9327NG GLP: no Published: no BVL-2218178, RIP2003-1538	BAS	Y
KIIA 6.6	Großhans, F.	1992	The identification of radioactive residues in wheat from a rotational crop study with [Triazol-14C]-205259 92/11055 ! P90-M012 ! 3434 GLP: yes Published: no BVL-2218179, RIP2003-1519	BAS	Y
KIIA 6.6	Hofmann, M.	1992	Rotational crop study with 14C-labelled 205259 92/11971 ! P89-E025 ! 3333 GLP: yes Published: no BVL-2218180, RIP2003-1515	BAS	Y

Annex point/ reference No	**Author(s)**	**Year**	**Title** **Report-No.** **Authority registration No**	**Owner**	**How considered in dRR ***
KIIA 6.6	Ikegami, F.; Komada, Y.; Kobori, M.; Hawkins, D. R.; Murakoshi, I.	1989	Biosynthesis of ß-(1,2,4-Triazol-1-yl)Alanine in higher plants MK-905-003 ! 1990/7001360 ! 0031-9422/90 GLP: no Published: yes BVL-2218181, RIP2003-1541	LIT	Y
KIIA 6.6	Massini, P.	1962	Aminotriazolylalanine: A metabolic product of Aminotriazole from plants MK-905-006 ! 15 ! 1963/7000002 GLP: no Published: yes BVL-2218182, RIP9800024	LIT	Y
KIIA 6.6	Schopfer, C.; Kuhnke, G.; Labib, S.; Ockert, M.	2009	Confined rotational crop study with 14C-BAS 700 F (Pyrazole label) 2009/1074683 ! 267319 GLP: yes Published: no BVL-2154445, ASB2010-7957	BAS	Y
KIIA 6.6	Schopfer, C.; Kuhnke, G.; Labib, S.; Ockert, M.	2009	Confined rotational crop study with 14C-BAS 700 F (Aniline label) 2009/1074684 ! 315741 GLP: yes Published: no BVL-2154446, ASB2010-7958	BAS	Y
KIIA 6.6	Steggles, H. A.	1993	Residues of Epoxiconazole in soil and in following crops in the UK after sequential applications of BAS 48013F in cereals in 1991 93/11043 ! TR 603 GLP: no Published: no BVL-2218184, RIP2003-1526	BAS	Y
KIIA 6.6	Veit, P.	2003	Confined rotational crop study with 14C-BAS 480 F 2003/1000950 ! 58242 GLP: yes Published: no BVL-2218185, RIP2003-1537	BAS	Y
KIIA 6.6	Veit, P.	2009	Confined rotational crop study with 14C-BAS 480 F (triazole label) 2009/1049695 ! 162667 GLP: yes Published: No BVL-2089436, ASB2011-10925	BAS	Y
MIIIA1 Sec 4	Applicant	2013	Epoxiconazol + Fluxapyroxad / Adexar (BAS 701 00 F): Residues in or on treated products, food and feed - Tier 2, IIIA-8 - Draft Registration Report - Part B - Core assessment MIII / Sec. 4 ! 2012/1321587 Ostermann Gabriele GLP: No Published: No BVL-2438328, BVL-2438329, ASB2013-9472	BAS	Y

* Y: Yes, relied on
N: No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Storage stability

No further study on storage stability submitted/needed.

A 2.2 Residues in primary crops

A 2.2.1 Nature of residues

No further study on nature of residues submitted/needed.

A 2.2.2 Magnitude of Epoxiconazole residues

Reference: KIIA 6.3

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Guideline(s): yes (Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2;
European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials

Deviations: no

GLP: yes

Acceptability: yes

Table A 2: Residues of epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 62.5 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAS 701 00 F (submitted to Adexar **006958-00**) treated with formulation BAS 701 00 F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F + BAS 480 31 F, EC (62.5 g/l Epoxiconazole, BAS 480 F)
Applicant : BASF Aktiengesellschaft

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Soft Wheat / Triticale
Submission date : 2010-06-17
Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 62.5 g/l Fluxapyroxad
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2009/1012124, study 315842, trial L080068, plot 2 Germany 74193 Stetten 2009-11-27	wheat / Tommi	1) 2007-10-13 (sowing) 2) 2008-06-04 - 2008-06-12 3) 2008-07-29	0.13 0.13	200 204	0.063 0.063	2008-05-14 2008-06-09	BBCH 69	green forage grain grain grain straw straw straw	1.6 **<0.01** <0.01 <0.01 1.6 2.0 2.1	0 35 42 50 35 42 50	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	 Water l/ha	 kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2009/1012124, study 315842, trial L080069, plot 2 France (North) 67160 Seebach 2009-11-27	wheat / Mercator	1) 2007-10-20 (sowing) 2) 2008-05-22 - 2008-05-30 3) 2008-07-18	0.13 0.13	203 206	0.063 0.063	2008-05-07 2008-05-29	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	3.3 1.1 0.16 **<u><0.01</u>** <0.01 1.6 0.91	0 35 35 42 49 42 49	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862
BASF2009/1012124, study 315842, trial L080073, plot 2 The Netherlands 6595 Gennep 2009-11-27	wheat / Limes	1) 2007-10-03 (sowing) 2) 2008-05-28 - 2008-06-07 3) 2008-07-30	0.13 0.12	200 195	0.063 0.063	2008-05-21 2008-06-06	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain grain straw straw	1.8 1.7 1.9 0.20 0.31 **<u><0.01</u>** <0.01 1.4 1.4	0 34 41 34 41 48 54 48 54	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862
BASF2009/1012124 study 315842, trial L080072, plot2 Germany 16818 Wustrau 2009-11-27	triticale / Magnat	1) 2007-09-26 2) 2008-06-02 - 2008-06-09 3) 2008-08-06	0.12 0.13	196 200	0.063 0.063	2008-05-13 2008-06-09	BBCH 69	green forage ears of grain rest of plant grain grain straw straw	2.1 0.23 1.5 **<u><0.01</u>** <0.01 1.1 1.6	0 36 36 43 49 43 49	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Active ingredient	:	Epoxiconazole (BAS 480 F)
Crop / crop group	:	Winter Soft Wheat
Submission date	:	2010-06-17
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	Epoxiconazole (BAS 480 F)

Content of a.i.	(g/kg or g/l)	:	125 g/l
Formulation	(e.g. WP)	:	SC
Commercial product	(name)	:	BAS 480 31 F (submitted to WN2 **006989-00** and **006958-00**) treated with formulation BAS 480 31 F, 5094351, SC (125 g/l Epoxiconazole, BAS 480 F)
Applicant		:	BASF Aktiengesellschaft

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowiing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2009/1012124, study 315842, trial L080068, plot 4 Germany 74193 Stetten 2009-11-27	wheat / Tommi	1) 2007-10-13 (sowing) 2) 2008-06-04 - 2008-06-12 3) 2008-07-29	0.13 0.13	202 204	0.063 0.063	2008-05-14 2008-06-09	BBCH 69	green forage grain grain grain straw straw straw	2.1 **<u><0.01</u>** <0.01 <0.01 2.8 3.2 3.6	0 35 42 50 35 42 50	analytical method: BASF L0076/01, 535/1 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862
BASF2009/1012124, study 315842, trial L080069, plot 4 Germany 67160 Seebach 2009-11-27	wheat / Mercator	1) 2007-10-20 (sowing) 2) 2008-05-22 - 2008-05-30 3) 2008-07-18 - 2008-07-19	0.12 0.13	197 209	0.063 0.062	2008-05-07 2008-05-29	BBCH 69	forage rest of plant ears of grain grain grain straw straw	3.8 1.7 0.11 **<u><0.01</u>** <0.01 1.8 1.7	0 35 35 42 49 42 49	analytical method: BASF L0076/01, 535/1 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-8862

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	The study is acceptable for purposes of evaluating the intended use

Reference:	KIIA 6.3
Report	RIP2003-1536
Guideline(s):	yes
Deviations:	Working Document of the Commission of the European Communities, DG for Agriculture, VI B II-1, Appendix B, 7029/VI/95 rev.5 Working Document of the Commission of the European Communities, DG for Agriculture, VI B II-1, Appendix E, 7035/VI/95 rev.5
GLP:	yes
Acceptability:	yes

Table A 3: Residues of epoxiconazole in wheat (processing)

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2004-08-24

Content of a.i. (g/kg or g/l) : 67 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : Champion (BAS 549 00 F) 005757-00
treated with BAS 549 KA F, SC (67 g/l Epoxiconazole + 233 g/l Boscalid)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation
(common name and content) : 233 g/kg Boscalid (BAS 510 F)
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 2003/1000945, study 02 10 47 003, trial FR 03/02/20 milling Germany 18276 Gülzow-Wilhelminenhof 2003-06-26	wheat / Trifter	1) 2001-10-19 (sowing) 2) 2002-06-10 - 2002-06-19 3) 2002-08-11	0.31 0.31	305 306	0.10 0.10	2002-05-23 2002-06-19	BBCH 69	grain, RAC low grade flour (toppings) wholemeal flour wholemeal bread middlings coarse bran wheat germs total bran flour type 550	0.02 0.01 0.02 <0.01 0.04 0.06 0.03 0.06 <0.01	53 53 53 53 53 53 53 53 53	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2003-1536

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 2003/1000945, study 02 10 47 003, trial FR 03/02/40 milling Germany 06429 Nienburg 2003-06-26	wheat / Cardos	1) 2001-09-29 (sowing) 2) 2002-05-30 - 2002-06-17 3) 2002-08-16	0.31 0.31	304 303	0.10 0.10	2002-05-17 2002-06-17	BBCH 69	grain, RAC low grade flour (toppings) wholemeal flour wholemeal bread middlings coarse bran wheat germs total bran flour type 550	0.03 0.06 0.04 0.02 0.11 0.16 0.06 0.16 <0.01	60 60 60 60 60 60 60 60 60	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2003-1536
BASF 2003/1000945, study 02 10 47 003, trial FR 03/02/50 milling Germany 96123 Litzendorf 2003-06-26	wheat / Ludwig	1) 2001-10-11 (sowing) 2) 2002-05-20 - 2002-06-19 3) 2002-07-31	0.31 0.30	308 302	0.10 0.10	2002-05-13 2002-06-19	BBCH 69	grain, RAC low grade flour (toppings) wholemeal flour wholemeal bread middlings coarse bran wheat germs total bran flour type 550	<0.01 0.02 0.02 <0.01 0.04 0.05 0.04 0.05 <0.01	42 42 42 42 42 42 42 42 42	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2003-1536
BASF 2003/1000945, study 02 10 47 003, trial FR 03/02/70 milling Germany 04668 Motterwitz 2003-06-26	wheat / Kanzler	1) 2001-10-24 (sowing) 2) 2002-06-09 - 2002-06-18 3) 2002-08-01	0.30 0.32	296 322	0.10 0.10	2002-05-17 2002-06-18	BBCH 69	grain low grade flour (toppings) wholemeal flour wholemeal bread middlings coarse bran wheat germs total bran flour type 550	0.02 0.02 0.02 0.02 0.05 0.06 0.05 0.07 <0.01	44 44 44 44 44 44 44 44 44	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 6 months RIP2003-1536

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	The study is acceptable and the results are plausibel.

Reference:	KIIA 6.3
Report	RIP2003-1522
Guideline(s):	no specified
Deviations:	not applicable
GLP:	no
Acceptability:	supplementary

Table A 4: Residues of Epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i.	(g/kg or g/l)	: 84 g/l
Formulation	(e.g. WP)	: SE
Commercial product	(name)	: Opus Top (BAS-48106-F) 004116-00 (submitted to W31 005527-00) treated with BAS 48016 F SE (84 g/l Epoxiconazole + 250 g/l Fenpropimorph) = Opus Top 004116-00
Applicant		: BASF Aktiengesellschaft

Indoors / outdoors	: Outdoors (European North)
Other a. i. in formulation (common name and content)	: 250 g/l Fenpropimorph
Residues calculated as	: Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF93/10705, BAS481F/WW/1 GB-Barton in Fabis, Notts 1993-03-31	wheat / Riband	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-21 1992-06-02	BBCH 57-61	grain straw	<0.05 0.86	76 76	analytical method: BASF method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522
BASF93/10705, BAS481F/WW/2 GB-Long Marston, Yorks 1993-03-31	wheat / Mercia	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-21 1992-06-03	BBCH 59-61	grain straw	<0.05 0.90	64 64	analytical method: BASF method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	supplementary information

Reference:	KIIA 6.3
Report	RIP2003-1520, RIP2003-1523, RIP2003-1525 (see reference list)
Guideline(s):	not specified
Deviations:	not applicable
GLP:	yes
Acceptability:	supplementary

Table A 5: Residues of Epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : Opus (BAS 480 13 F) **004183-00** (submitted to W31 005757-00) treated with formulation BAS 480 13 F (125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10702, BAS480BD/WW/1 GB-Stourbridge Worcs. 1993-03-31	wheat / Beaver	1) (sowing) 2) 3)	0.25 0.25	250 250	0.10 0.10	1992-05-25 1992-06-03	BBCH 57-59	grain straw	<0.05 <0.05 <0.05 6.4 5.7 5.6	76 76 76 76 76 76	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg max. sample storage: 10 months, replicate field samples RIP2003-1520
BASF 93/10702, BAS480BD/WW/2 GB-Melbourne Derbys 1993-03-31	wheat / Haven	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-28 1992-06-07	BBCH 57-59	grain straw total plant	<0.05 1.2 1.2	74 74 0	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1520

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10709, R480/07 GB-Gotham, Notts 1993-04-02	wheat / Galahad	1) (sowing) 2) 3)	0.25	250	0.10	1991-06-24	BBCH 59	plant plant plant plant grain straw	1.2 0.61 0.76 0.54 <0.05 0.81	0 7 14 28 65 65	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg max. sample storage: 10 months RIP2003-1523
BASF 93/10712, R480/01 GB-Long Marston, York 1993-04-02	wheat / Mercia	1) (sowing) 2) 3)	0.13 0.19 0.13	250 250 250	0.05 0.08 0.05	1990-12-21 1991-05-31 1991-07-01	BBCH 65	grain grain grain straw straw straw	<0.05 <0.05 <0.05 1.0 0.41 0.78	46 46 46 46 46 46	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 10 months, replicate field samples RIP2003-1525
BASF 93/10712, R480/02 GB-Cambridge 1993-04-02	wheat / Riband	1) (sowing) 2) 3)	0.13 0.19 0.13	250 250 250	0.05 0.08 0.05	1990-12-18 1991-05-29 1991-06-17	BBCH 59	grain straw	<0.05 0.42	63 63	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg max. sample storage: 10 months RIP2003-1525
BASF 93/10712, R480/03 GB-Newton Abbot, Devon 1993-04-02	wheat / Galahad	1) (sowing) 2) 3)	0.13 0.19 0.13	250 250 250	0.05 0.08 0.05	1991-01-16 1991-05-27 1991-06-17	BBCH 59	grain grain grain straw straw straw	<0.05 <0.05 <0.05 1.5 3.0 3.3	58 58 58 58 58 58	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg max. sample storage: 10 months, replicate field samples RIP2003-1525
BASF 93/10712, R480/04 GB-Woodenderby Lincs 1993-04-02	wheat / Riband	1) (sowing) 2) 3)	0.13 0.19 0.13	250 250 250	0.05 0.08 0.05	1990-12-21 1991-05-30 1991-06-24	BBCH 59	grain straw	<0.05 1.4	73 73	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg max. sample storage: 10 months RIP2003-1525

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary information.

Reference:	KIIA 6.3
Report	RIP2003-1520, RIP2003-1521 (see reference list)
Guideline(s):	not specified
Deviations:	not applicable
GLP:	yes
Acceptability:	supplementary

Table A 6: Residues of Epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : BAS 480 21 F (submitted to W31 **005757-00**)
treated with formulation BAS 480 21 F (125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10702, BAS480BD/WW/1-1 GB-Stourbridge Worcs. 1993-03-31	wheat / Beaver	1) (sowing) 2) 3)	0.25 0.25	250 250	0.10 0.10	1992-05-25 1992-06-03	BBCH 57-59	grain grain grain straw straw straw total plant	<0.05 <0.05 <0.05 7.8 3.6 3.0 4.9	76 76 76 76 76 76 0	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months, replicate field samples RIP2003-1520
BASF 93/10702, BAS480BD/WW/2-1 GB-Melbourne Derbys 1993-03-31	wheat / Haven	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-28 1992-06-07	BBCH 57-59	grain straw total plant	<0.05 0.85 2.9	74 74 0	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1520

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10704, BAS480F/WW/1 GB-Barton in Fabis, Notts 1993-03-31	wheat / Riband	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-21 1992-06-02	BBCH 57-61	grain straw	<0.05 4.4	76 76	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1521
BASF 93/10704, BAS480F/WW/2 GB-Long Marston, Yorks 1993-03-31	wheat / Mercia	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-21 1992-06-03	BBCH 59-61	grain straw	<0.05 0.78	64 64	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1521

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary.

Reference:	KIIA 6.3
Report	RIP2007-469
Guideline(s):	yes (Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs EU Guidance document on residue analytical methods, SANCO/825/00 rev.7
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 7: Residues of Epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2007-08-01

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : BAS 480 31 F (submitted to Juwel Top (BAS-49303-F) **024437-00**)
treated with BAS 480 31 F (SC, 125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2006/1029386, trial ALB/01/05 Denmark 5500 Middelfart 2006-10-06	wheat / Kris	1) 2004-09-27 (sowing) 2) 2005-06-28 - 2005-07-08 3) 2005-08-10 2005-08-21	0.13 0.13	200 200	0.063 0.063	no data 2005-07-08	BBCH 69	plant rest of plant ears of grain grain grain straw straw	1.6 1.2 0.30 0.02 **0.03** 1.4 2.5	0 27 27 35 42 35 42	analytical method: BASF method number 445/0 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 10 months RIP2007-469

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2006/1029386, trial DU2/01/05 Germany 74193 Stetten a.H. 2006-10-06	wheat / Isengrain	1) 2004-11-03 (sowing) 2) 2005-06-02 - 2005-06-12 3) 2005-08-12	0.13 0.13	200 200	0.063 0.063	no data 2005-06-30	BBCH 71	plant grain grain grain straw straw straw	2.3 0.02 **<u><0.02</u>** 0.02 3.0 2.5 2.7	0 28 35 41 28 35 41	analytical method: BASF method number 445/0 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 10 months RIP2007-469
BASF2006/1029386, trial FAN/01/05 France (North) 67160 Seebach 2006-10-06	wheat / Apache	1) 2004-10-11 (sowing) 2) 2005-05-29 - 2005-06-11 3) 2005-07-20 2005-07-21	0.13 0.13	200 200	0.063 0.063	no data 2005-06-07	BBCH 69	plant rest of plant ears of grain grain grain straw straw	2.5 1.3 0.52 <u><0.02</u> **<u>0.02</u>** 1.5 1.7	0 27 27 35 42 35 42	analytical method: BASF method number 445/0 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 10 months blind values [mg/kg] : plant (0 DAT): 0.04; grain (42 DAT): 0.04; straw (42 DAT): 0.17 RIP2007-469
BASF2006/1029386, trial OAT/01/05 United Kingdom OX277HN Bicester 2006-10-06	wheat / Xi 19	1) 2004-10-05 (sowing) 2) 2005-06-10 - 2005-06-25 3) 2005-08-03 2005-08-04	0.13 0.13	200 200	0.063 0.063	no data 2005-06-30	BBCH 71	plant grain grain grain straw straw straw	1.6 0.02 **<u>0.03</u>** 0.02 1.8 1.9 2.4	0 27 34 43 27 34 43	analytical method: BASF method number 445/0 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 10 months blind values: straw (34 DAT): 0.14 mg/kg RIP2007-469

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	RIP2007-465; RIP2007-467
Guideline(s):	yes (Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 8: Residues of Epoxiconazole in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Wheat

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2007-08-01

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : BAS 480 31 F (submitted to **024437-00/00**)
treated with BAS 480 31 F (SC, 125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing p 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatmentsp	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			p kg a.i./ha	p Water l/ha	p kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2006/1018052, 174997, trial DU2/08/24 Germany 74193 Stetten 2006-05-12	wheat / Transit	1) 2003-10-14 (sowing) 2) 2004-06-04 - 2004-06-17 3) 2004-08-12	0.13 0.13	200 200	0.063 0.063	no data 2004-06-30	BBCH 71	plant, w/o root ears of grain rest of plant grain grain straw straw	1.7 0.34 2.0 **<u>0.03</u>** <0.01 2.8 1.2	0 28 28 34 41 34 41	analytical methods: BASF method 504/0 und 445/0 (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, other 0.05 mg/kg, max. sample storage: 17 months RIP2007-467 (amendment) RIP2007-465

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing p 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatmentsp	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			p kg a.i./ha	p Water l/ha	p kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2006/1018052, 174997, trial FBM/08/04 France (North) 72800 Thoree les Pins 2006-05-12	wheat / Apache	1) 2003-10-28 (sowing) 2) 2004-05-29 - 2004-06-12 3) 2004-07-12	0.13 0.13	200 200	0.063 0.063	no data 2004-06-08	BBCH 65	ears of grain rest of plant grain grain straw straw shoot	1.6 4.4 0.01 **0.02** 3.0 4.2 1.5	28 28 35 42 35 42 0	analytical methods: BASF method 504/0 und 445/0 (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, other 0.05 mg/kg, max. sample storage: 17 months RIP2007-467 (amendment) RIP2007-465
BASF2006/1018052, 174997, trial HUS/04/04 Sweden 23791 Bjärred 2006-05-12	wheat / Kris C2	1) 2003-09-22 (sowing) 2) 2004-06-10 - 2004-06-24 3) 2004-08-27	0.13 0.13	200 200	0.063 0.063	no data 2004-07-13	BBCH 77	ears of grain rest of plant grain grain straw straw shoot	0.21 0.70 **<0.01** <0.01 0.91 1.1 1.6	28 28 35 43 35 43 0	analytical methods: BASF method 504/0 und 445/0 (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, other 0.05 mg/kg, max. sample storage: 17 months RIP2007-467 (amendment) RIP2007-465
BASF2006/1018052, 174997, trial OAT/11/04 United Kingdom OX277HN Bicester 2006-05-12	wheat / Xi19	1) 2003-09-18 (sowing) 2) 2003-06-01 - 2004-06-15 3) 2004-08-16	0.13 0.13	200 200	0.063 0.063	no data 2004-07-01	BBCH 83	grain grain grain straw straw straw shoot	<0.05 **0.02** 0.02 <2.0 2.6 2.8 1.9	27 35 43 27 35 43 0	analytical methods: BASF method 504/0 und 445/0 (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, other 0.05 mg/kg, max. sample storage: 17 months RIP2007-467 (amendment) RIP2007-465

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	RIP2003-1527
Guideline(s):	Yes, BBA Richtlinie Teil IV, 3-3 Prüfung des Rückstandsverhaltens – Allgemeine Hinweise zur Planung, Anlage und Durchführung für Rückstandsversuche, IVA Leitlinien für Rückstandsversuche, Teil IA und IB Guidelines on Producing Pesticide Residue Data from Supervised Trials (Rome 1990)
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 9: Residues of Epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SE
Commercial product (name) : submitted to **005527-00**
treated with BAS 481 03 F 125g/l Epoxiconazole + 375 g/l Fenpropimorph
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 375 g/l Fenpropimorph
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 95/10661, D08/51/92 Germany 85445 Oberding 1995-07-01	barley / Steffi	1) 1992-03-06 (sowing) 2) 1992-06-12 - 1992-06-20 3)	0.11 0.11 0.12	272 257 290	0.042 0.042 0.042	1992-06-01 1992-06-05 1992-06-10	BBCH 59	green forage ears of grain grain grain straw straw stalk	3.5 0.22 <0.05 <0.05 1.0 0.96 0.64	0 15 36 42 36 42 15	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 7 months RIP2003-1527

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 95/10661, D08/51/92-1 Germany 85445 Oberding 1995-07-01	barley / Steffi	1) 1992-03-06 (sowing) 2) 1992-06-12 - 1992-06-20 3)	0.11 0.12 0.12 0.12	267 292 292 297	0.042 0.042 0.042 0.042	1992-05-27 1992-06-01 1992-06-05 1992-06-10	BBCH 59	green forage ears of grain grain grain straw straw stalk	3.8 0.27 <0.05 <0.05 1.3 1.7 1.1	0 15 36 42 36 42 15	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 7 months RIP2003-1527

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Trials were not considered for reasons of overdosing.

Reference:	KIIA 6.3
Report	RIP2003-1522
Guideline(s):	not specified
not applicable	not applicable
GLP:	no
Acceptability:	supplementary

Table A 10: Residues of Epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i.	(g/kg or g/l)	:	84 g/l
Formulation	(e.g. WP)	:	SE
Commercial product	(name)	:	BAS 48016F (submitted to 005527-00) treated with BAS 48016F (84 g/l Epoxiconazole + 250 g/l Fenpropimorph)
Applicant		:	BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 250 g/l Fenpropimorph
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10705 BAS481F/SB/1 United Kingdom Whixley, Yorks 1993-03-31	Barley / Triumph	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-06-02 1992-06-12	BBCH 55-61	grain straw	<0.05 1.7	88 88	analyt. method: BASF method 309 (MOA 228) LOQ: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10705 BAS481F/SB/2 United Kingdom Long Marston, Yorks 1993-03-31	Barley / Corniche	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-06-03 1992-06-11	BBCH 59-65	grain straw	0.06 2.0	46 46	analyt. method: BASF method 309 (MOA 228) LOQ: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary for reasons of inadequate documentation.

Reference:	KIIA 6.3
Report	RIP2003-1520, RIP2003-1521, RIP2003-1523, RIP2003-1524 (it is referred to the reference list)
Guideline(s):	not specified
Deviations:	not applicable
GLP:	yes
Acceptability:	Supplementary

Table A 11: Residues of Epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : BAS 48013 F (submitted to **005527-00**)
treated with BAS 48013 F (125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10702, BAS480BD/SB/1-1 GB-Exton, Leics. 1993-03-31	Barley / Blenheim	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-31 1992-06-11[4)]	BBCH 57-59	grain grain grain straw straw straw	<0.05 <0.05 <0.05 0.71 0.79 0.45	53 53 53 53 53 53	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 10 months, replicate field samples RIP2003-1520
BASF 93/10704, BAS480F/SB/1 GB-Melbourne, Derbys 1993-03-31	Barley / Triumph	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-06-02 1992-06-12[4)]	BBCH 55-61	grain straw	<0.05 0.17	88 88	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1521

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10704, BAS480F/SB/2 GB-Long Marston, Yorks 1993-03-31	Barley / Corniche	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-06-03 1992-06-11[4)]	BBCH 59-65	grain straw	<0.05 1.5	46 46	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1521
BASF 93/10709, R480/17 GB-Ramsdell, Hants 1993-04-02	Barley / Galahad	1) (sowing) 2) 3)	0.25	250 250	0.10 0.10	1991-06-06	BBCH 39	plant plant plant plant grain straw	2.8 1.4 0.87 0.37 <0.05 0.74	0 7 14 30 68 68	analytical method: BASF Method Number 309 (MOA 228), LOQ' 0.05 mg/kg, max. sample storage: 10 months RIP2003-1523
BASF 93/10710, R480/13 GB-Craibstone, Aberdeen 1993-04-02	Barley / Camargue	1) (sowing) 2) 3)	0.19 0.13 0.13	250 250 250	0.080 0.050 0.050	1991-05-20 1991-06-05 1991-07-10	BBCH 59	grain straw	<0.05 0.39	51 51	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: no data RIP2003-1524
BASF 93/10710, R480/14 GB-Draycott, Derbys 1993-04-02	Barley / Hart	1) (sowing) 2) 3)	0.19 0.13 0.13	250 250 250	0.075 0.050 0.050	1991-06-02 1991-06-19 1991-07-01	BBCH 61-65	grain straw	<0.05 0.93	50 50	analytical method: BASF Method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: no data RIP2003-1524

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary for reasons of inadequate documentation.

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2003-10-31

Content of a.i.	(g/kg or g/l)	: 125 g/l
Formulation	(e.g. WP)	: SC
Commercial product	(name)	: BAS 48021 F (submitted to **005527-00**) treated with BAS 48021 F (125 g/l Epoxiconazole)
Applicant		: BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10702 BAS480BD/SB/1 GB-Exton, Leics. 1993-03-31	barley / Blenheim	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-31 1992-06-11[4)]	BBCH 57-59	grain grain grain straw straw straw total plant	<0.05 <0.05 <0.05 1.0 0.63 0.67 3.9	53 53 53 53 53 53 0	analytical method: BASF Method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months, replicate field samples RIP2003-1520

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary for reasons of inadequate documentation.

Reference:	KIIA 6.3
Report	RIP2003-1532
Guideline(s):	yes Commission of the European Communities; 7035/VI/95 rev.5 Biologische Bundesanstalt Part IV 3-4 Richtlinie für die Prüfung von Pflanzenschutzmitteln im Zulassungsverfahren; Prüfung des Rückstandsverhaltens - Rückstandsversuche an verarbeiteten pflanzlichen Erzeugnissen (Verarbeitungsrichtlinie)
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 12: Residues of Epoxiconazole in barley (processing)

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2004-08-24

Content of a.i. (g/kg or g/l) : 67 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : Champion 005757-00
treated with BAS 549 KA F, SC (67 g/l Epoxiconazole + 233 g/l Boscalid)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 233 g/kg Boscalid (BAS 510 F)
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BAS 2003/1000946, trial AT-02/003-1 milling process Germany 65326 Aarbergen-Panrod 2003-06-25	barley / Scarlett	1) 2002-03-12 (sowing) 2) 2002-06-13 - 2002-06-20 3) 2002-08-16	0.31 0.30	308 297	0.10 0.10	2002-05-27 2002-06-20	BBCH 69	grain (RAC) pearl barley pearling dust offal	0.22 0.11 0.97 1.8	59 59 59 59	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	 Water l/ha	 kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
BAS 2003/1000946, trial AT-02/003-2 milling process Germany 65510 Hünstetten-Görsroth 2003-06-25	barley / Scarlett	1) 2002-03-18 (sowing) 2) 2002-06-14 - 2002-06-20 3) 2002-07-30	0.29 0.30	291 294	0.10 0.10	2002-05-26 2002-06-20	BBCH 69	grain (RAC) pearl barley pearling dust offal	0.26 0.09 1.1 2.8	40 40 40 40	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532
BASF 2003/1000946, trial AT-02/003-3 milling process Germany 67585 Dorn-Dürkheim 2003-06-25	barley / Scarlett	1) 2002-03-06 (sowing) 2) 2002-06-04 - 2002-06-12 3) 2002-07-23	0.29 0.30	289 305	0.10 0.10	2002-05-24 2002-06-12	BBCH 69	grain (RAC) pearl barley pearling dust offal	0.22 0.12 0.80 1.9	41 41 41 41	analytical method:BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532
BASF 2003/1000946, trial AT-02/003-4 milling process Germany 55471 Kümbdchen 2003-06-25	barley / Barke	1) 2002-03-18 (sowing) 2) 2002-06-11 - 2002-06-19 3) 2002-08-07	0.30 0.30	295 301	0.10 0.10	2002-05-27 2002-06-19	BBCH 69	grain (RAC) pearl barley pearling dust offal	0.14 0.05 0.81 1.6	50 50 50 50	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532
BAS 2003/1000946, trial AT-02/003-3 brewing process Germany 67585 Dorn-Dürkheim 2003-06-25	barley / Scarlett	1) 2002-03-06 (sowing) 2) 2002-06-04 - 2002-06-12 3) 2002-07-23	0.29 0.30	289 305	0.10 0.10	2002-05-24 2002-06-12	BBCH 69	grain (RAC) malt germ offal beer yeast trub (flocs) brewer's grain brew brewer's malt	0.17 0.14 0.13 <0.01 0.11 0.51 0.10 <0.01 0.11	41 41 41 41 41 41 41 41 41	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532
BAS 2003/1000946, trial AT-02/003-1 brewing process Germany 65326 Aarbergen-Panrod 2003-06-25	barley / Scarlett	1) 2002-03-12 (sowing) 2) 2002-06-13 - 2002-06-20 3) 2002-08-16	0.31 0.30	308 297	0.10 0.10	2002-05-27 2002-06-20[4)]	BBCH 69	grain (RAC) malt germ offal beer yeast trub (flocs) brewer's grain brew brewer's malt	0.19 0.13 0.18 <0.01 0.16 0.67 0.09 <0.01 0.09	59 59 59 59 59 59 59 59 59	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 2003/1000946, trial AT-02/003-4 brewing process Germany 55471 Kümbdchen 2003-06-25	barley / Barke	1) 2002-03-18 (sowing) 2) 2002-06-11 - 2002-06-19 3) 2002-08-07	0.30 0.30	295 301	0.10 0.10	2002-05-27 2002-06-19	BBCH 69	grain (RAC) malt germ offal beer yeast trub (flocs) brewer's grain brew brewer's malt	0.13 0.15 0.17 <0.01 0.13 0.57 0.07 <0.01 0.08	50 50 50 50 50 50 50 50 50	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ's: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532
BAS 2003/1000946, trial AT-02/003-2 brewing process Germany 65510 Hünstetten-Görsroth 2003-06-25	barley / Scarlett	1) 2002-03-18 (sowing) 2) 2002-06-14 - 2002-06-20 3) 2002-07-30	0.29 0.30	291 294	0.10 0.10	2002-05-26 2002-06-20	BBCH 69	grain (RAC) malt germ offal beer yeast trub (flocs) brewer's grain brew brewer's malt	0.20 0.18 0.17 <0.01 0.32 0.46 0.13 <0.01 0.12	40 40 40 40 40 40 40 40 40	analytical method: BASF 504/0 (HPLC-MS/MS), LOQ's: 0.01 mg/kg, max. sample storage: 8 months RIP2003-1532

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	RIP2006-2759, RIP2006-2760
Guideline(s):	yes (Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 13: Residues of Epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Spring Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2007-08-01

Content of a.i. (g/kg or g/l) : 125 g/l
Formulation (e.g. WP) : SC
Commercial product (name) : BAS 480 31 F (submitted to Juwel Top **024437-00**)
treated with BAS 480 31 F (SC, 125 g/l Epoxiconazole)
Applicant : BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
2006/1018053,	barley /	1) 2004-04-22	0.13	200	0.063	no data	BBCH 77	ears of grain	0.70	27	analytical methods: BASF 445/0 +
ALB/10/04		(sowing)	0.13	200	0.063	2004-07-15		rest of plant,	2.4	27	504/0 (grain), (HPLC-MS/MS),
	Barke	2) 2004-06-25						grain	**0.11**	35	LOQ: grain 0.01 mg/kg, all others
Denmark		- 2004-07-05						grain	0.08	41	0.05 mg/kg,
5500 Middelfart		3) 2004-08-19						straw	1.0	35	max. sample storage: 13 months
		2004-09-02						straw	0.83	41	
2006-06-08								shoot	3.4	0	RIP2006-2759

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
2006/1029385, DU4/01/05 Germany 67229 Gerolsheim, Rheinlandpfalz 2006-10-06	barley / Scarlett	1) 2005-03-15 (sowing) 2) 2005-06-08 - 2005-06-15 3) 2005-07-17	0.13 0.13	200 200	0.063 0.063	no data 2005-06-08	BBCH 61	plant, whole, grain grain grain straw straw straw	5.2 0.08 0.06 **0.10** 13.0 8.3 15.4	0 28 35 42 28 35 42	analytical method: SOP-PA.0243 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 5 months RIP2006-2760
2006/1029385, HUS/01/05 Sweden 23791 Bjärred, Malmoe 2006-10-06	barley / Prestige	1) 2005-04-11 (sowing) 2) 2005-07-01 - 2005-07-14 3) 2005-08-17 2005-08-27	0.13 0.13	200 200	0.063 0.063	no data 2005-07-14	BBCH 69	plant, whole, ears of grain rest of plant, grain grain straw straw	3.2 0.47 0.94 **0.17** 0.14 1.7 1.0	0 28 28 35 42 35 42	analytical method: SOP-PA.0243 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 5 months RIP2006-2760

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-8863
Guideline(s):	yes (Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 14: Residues of epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2010-06-17

Content of a.i.	(g/kg or g/l)	:	125 g/l
Formulation	(e.g. WP)	:	SC
Commercial product	(name)	:	BAS 480 31 F (submitted to WN2 006989-00 and 006958-00) treated with formulation BAS 480 31 F, 5094351, SC (125 g/l Epoxiconazole, BAS 480 F)
Applicant		:	BASF

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation
(content and common name) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2009/1012127, study 315843, trial L080061, plot 4 The Netherlands 6595 AT Ottersum 2009-12-03	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.13 0.12	206 195	0.063 0.063	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	2.7 0.060 **0.050** 0.050 2.1 1.9 2.5	0 28 35 41 28 35 41	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 16 months ASB2010-8863

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2010-06-17

Content of a.i. (g/kg or g/l) : 62.5 g/l
Formulation (e.g. WP) : EC
Commercial product (name) : BAS 701 00 F (submitted to Adexar 006958-00)
Applicant : BASF

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) : 62.5 g/l Fluxapyroxad
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF2009/1012127, study 315843, trial L080061, plot 2 The Netherlands 6595 AT Ottersum 2009-12-03	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.13 0.13	207 209	0.063 0.063	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	2.8 0.050 0.050 **0.060** 1.8 2.1 2.9	0 28 35 41 28 35 41	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 16 months ASB2010-8863
BASF2009/1012127, study 315843, trial L080064, plot 2 France (North) 41500 Suevres 2009-12-03	barley / Cervoise	1) 2007-10-12 (sowing) 2) 2008-05-10 - 2008-05-19 3) 2008-06-15	0.12 0.14	197 217	0.063 0.063	2008-05-09 2008-05-19	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain straw	2.5 0.81 1.4 0.10 0.13 **0.050** 1.3	0 28 35 28 35 42 42	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, harvest interval: 2008-06-15 - 2008-06-30, max. sample storage: 17 months ASB2010-8863
BASF2009/1012127, study 315843, trial L080065, plot 2 Germany 16833 Lentzke 2009-12-03	barley / Campanile	1) 2007-09-17 (sowing) 2) 2008-05-12 - 2008-05-20 3) 2008-07-02	0.13 0.13	200 200	0.063 0.063	2008-05-02 2008-05-20[4)]	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	2.6 1.8 0.32 **0.10** 0.10 1.4 2.2	0 27 27 35 41 35 41	analytical method: BASF L0076/01 (535/1) (HPLC-MS/MS) BAS 480 F, LOQ: 0.01 mg/kg, max. sample storage: 17 months ASB2010-8863

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	RIP2003-1522
Guideline(s):	not specified
Deviations:	not applicable
GLP:	no
Acceptability:	supplementary

Table A 15: Residues of Epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	: 84 g/l
Formulation	(e.g. WP)	: SE
Commercial product	(name)	: BAS 48016F (submitted to 005527-00); treated with BAS 48016F (84 g/l Epoxiconazole + 250 g/l Fenpropimorph)
Applicant		: BASF

Active ingredient	: Epoxiconazole (BAS 480 F)
Crop / crop group	: Winter Barley
Submission date	: 2003-10-31
Indoors / outdoors	: Outdoors (European North)
Other a. i. in formulation (common name and content)	: 250 g/l Fenpropimorph
Residues calculated as	: Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10705 BAS481F/WB/1 GB-Osgathorpe, Leics. 1993-03-31	barley / Fighter	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-13 1992-05-20	BBCH 59-61	grain straw	<0.05 0.87	59 59	analytical method: BASF method Number 309 (MOA 228), LOQ's: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 93/10705 BAS481F/WB/2 GB-Whixley, Yorks 1993-03-31	barley / Pastoral	1) (sowing) 2) 3)	0.13 0.13	250 250	0.052 0.052	1992-05-13 1992-05-21	BBCH 59-61	grain straw	<0.05 0.76	67 67	analytical method: BASF method Number 309 (MOA 228), LOQ: 0.05 mg/kg, max. sample storage: 10 months RIP2003-1522

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary for reasons of inadequate reporting.

Reference:	KIIA 6.3
Report	RIP2006-2759, RIP2006-2760
Guideline(s):	yes Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 16: Residues of epoxiconazole in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Barley

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date : 2007-08-01

Content of a.i.	(g/kg or g/l)	:	125 g/l
Formulation	(e.g. WP)	:	SC
Commercial product	(name)	:	BAS 480 31 F (submitted to Juwel Top **024437-00**) treated with BAS 480 31 F (SC, 125 g/l Epoxiconazole)
Applicant		:	BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a.i. in formulation (content and common name) :
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)		(d)	(e)
2006/1018053, DU4/08/04 Germany 67165 Waldsee 2006-06-08	barley / Camera	1) 2003-08-25 (sowing) 2) 2004-06-05 - 2004-06-10 3) 2004-07-12	0.13 0.13	200 200	0.063 0.063	no data 2004-06-01	BBCH 71	rest of plant ears of grain grain grain straw straw shoot	1.1 0.57 **0.08** 0.07 2.0 1.0 2.8	28 28 35 42 35 42 0	analytical methods: BASF 445/0 + 504/0 (grain), (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, others all 0.05 mg/kg, max. sample storage: 13 months RIP2006-2759

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
2006/1018053, FAN/10/04 France (North) 67160 Seebach 2006-06-08	barley / Platine	1) 2003-10-01 (sowing) 2) 2004-05-06 - 2004-05-16 3) 2004-07-05	0.13 0.13	200 200	0.063 0.063	no data 2004-05-24	BBCH 73	rest of plant ears of grain grain grain straw straw shoot	2.7 0.19 **0.07** 0.06 1.1 1.4 4.9	29 29 35 42 35 42 0	analytical methods: BASF 445/0 + 504/0 (grain), (HPLC-MS/MS), LOQ' grain 0.01 mg/kg, others all 0.05 mg/kg, max. sample storage: 13 months RIP2006-2759
2006/1018053, OAT/12/04 United Kingdom OX6 9NB Bucknell, Bicester 2006-06-08	barley / Carat	1) 2003-09-24 (sowing) 2) 2004-05-20 - 2004-06-09 3) 2004-07-21 2004-07-22	0.13 0.13	200 200	0.063 0.063	no data 2004-06-09	BBCH 69	rest of plant ears of grain grain grain straw straw shoot	5.2 1.1 **0.24** 0.17 5.5 6.6 7.3	29 29 35 42 35 42 0	analytical methods: BASF 445/0 + 504/0 (grain), (HPLC-MS/MS), LOQ: grain 0.01 mg/kg, others all 0.05 mg/kg, max. sample storage: 13 months RIP2006-2759
2006/1029385, FAN/02/05 France (North) 67160 Seebach, Alsace 2006-10-06	barley / Platine	1) 2004-10-04 (sowing) 2) 2005-05-13 - 2005-05-22 3) 2005-07-07	0.13 0.13	200 200	0.063 0.063	no data 2005-05-25	BBCH 71	plant, whole, rest of plant, ears of grain grain grain straw straw	2.4 0.48 0.33 **0.09** 0.04 0.50 0.74	0 28 28 34 42 34 42	analytical method: SOP-PA.0243 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 5 months RIP2006-2760
2006/1029385, OAT/02/05 United Kingdom OX29 8EW Combe/ Stonesfield 2006-10-06	barley / Cannock	1) 2004-10-05 (sowing) 2) 2005-05-23 - 2005-06-07 3) 2005-07-15	0.13 0.13	200 200	0.063 0.063	no data 2005-06-09	BBCH 71	plant, whole, grain grain grain straw straw straw	1.9 0.05 **0.07** 0.06 0.49 0.72 0.78	0 28 35 41 28 35 41	analytical method: SOP-PA.0243 (HPLC-MS/MS), LOQ: 0.02 mg/kg, max. sample storage: 5 months RIP2006-2760

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	RIP2003-1527
Guideline(s):	yes BBA Richtlinie Teil IV, 3-3 Prüfung des Rückstandsverhaltens – Allgemeine Hinweise zur Planung, Anlage und Durchführung für Rückstandsversuche IVA Leitlinien füpr Rückstandsversuche, Teil IA und IB Guidelines on Producing Pesticide Residue Data from Supervised Trials (Rome 1990)
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 17: Residues of epoxiconazole in rye

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Active ingredient : Epoxiconazole (BAS 480 F)
Crop / crop group : Winter Rye

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Submission date 2003-10-31

Content of a.i.	(g/kg or g/l)	:	125 g/l
Formulation	(e.g. WP)	:	SE
Commercial product	(name)	:	BAS 481 03 F (submitted to **005527-00**) treated with BAS 481 03 F (125g/l Epoxiconazole + 375 g/l Fenpropimorph)
Applicant		:	BASF Aktiengesellschaft

Indoors / outdoors : Outdoors (European North)
Other a. i. in formulation (common name and content) : 375 g/l Fenpropimorph
Residues calculated as : Epoxiconazole (BAS 480 F)

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 95/10661 DU1/11/92 Germany 67117 Limburgerhof 1995-07-01	rye / Luchs	1) 1991-10-15 (sowing) 2) 1991-05-26 - 1991-06-24 3) 1991-07	0.13 0.12 0.13	304 295 306	0.042 0.042 0.042	1992-05-05 1992-05-12 1992-06-15	BBCH 75	ears of grain grain grain straw straw green forage stalk	0.16 <0.05 0.060 3.9 2.0 2.7 2.0	11 35 42 35 42 0 11	analytical method: BASF 309 and 309/1 (MOA 228) (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage 7 months RIP2003-1527

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
BASF 95/10661 DU1/11/92-A Germany 67117 Limburgerhof 1995-07-01	rye / Luchs	1) 1991-10-15 (sowing) 2) 1991-05-26 - 1991-06-24 3) 1991-07	0.13 0.13 0.12 0.13	314 310 295 312	0.042 0.042 0.042 0.042	1992-04-22 1992-05-05 1992-05-12 1992-06-15	BBCH 75	ears of grain grain grain straw straw green forage stalk	1.1 <0.05 0.070 4.6 3.0 2.1 2.5	11 35 42 35 42 0 11	analytical method: BASF 309 and 309/1 (MOA 228) (GC-ECD), LOQ: 0.05 mg/kg, max. sample storage 7 months RIP2003-1527

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Supplementary information due to overdosing.

A 2.2.3 Magnitude of Fluxapyroxad residues

Reference:	KIIA 6.3
Report	ASB2010-7947, ASB2010-7948, ASB2010-8862
Guideline(s):	yes Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 18: Residues of Fluxapyroxad in wheat and triticale

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	: 62.5 g/l	Active ingredient	:	Fluxapyroxad (BAS 700 F)
Formulation	(e.g. WP)	: EC	Crop / crop group	:	Winter Soft Wheat
Commercial product	(name)	: BAS 700 00 F 006979-00 (submitted to WN2 006989-00 and 006958-00) treated with formulation BAS 700 F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F)	Submission date	:	2010-06-16
Applicant		: BASF	Indoors / outdoors	:	Outdoors (European North)
			Other a.i. in formulation (content and common name)	:	
			Residues calculated as	:	8.1 Fluxapyroxad (BAS 700 F) 8.2 M700F002 8.3 M700F008, calculated as Fluxapyroxad 8.4 M700F048, calculated as Fluxapyroxad

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	Water l/ha	kg a.i./hl	Dates of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/ 1012126 study 315849, trial L080052, AC/08/012 Germany 67229 Gerolsheim 2009-08-26	wheat / Tommi	1) 2007-10-25 (sowing) 2) 2008-05-30 - 2008-06-05 3) 2008-07-20	0.13 0.12	204 196	0.063 0.063	2008-05-14 2008-06-05	 BBCH 69	green forage grain grain grain straw straw straw	1.9 **0.020** 0.010 0.020 0.99 1.7 1.8	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.030 <0.01 <0.01 <0.01 0.050 0.10 0.13	<0.01 <0.01 <0.01 <0.01 0.01 0.020 0.030	0 34 43 49 34 43 49	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7947
BASF2009/1012126, study 315849, trial L080053, AC/08/013 Germany 16833 Brunne 2009-08-26	wheat / Triso	1) 2007-11-08 (sowing) 2) 2008-06-05 - 2008-06-17 3) 2008-08-05	0.12 0.13	191 202	0.063 0.063	2008-05-23 2008-06-17	 BBCH 69	green forage rest of plant ears of grain grain grain straw straw	3.5 4.9 0.60 **0.060** 0.050 6.1 5.3	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.030 0.14 0.040 <0.01 <0.01 0.17 0.15	<0.01 <0.01 <0.01 <0.01 <0.01 0.020 0.01	0 34 34 41 49 41 49	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7947
BASF2009/1012126, study 315849, trial L080054, AC/08/014 United Kingdom CO11 2NF Manningtree, Essex 2009-08-26	wheat / Cordiale	1) 2007-10-22 (sowing) 2) 2008-06-02 - 2008-06-16 3) 2008-07-31	0.14 0.13	216 206	0.063 0.063	2008-05-22 2008-06-16	 BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain straw	2.0 1.8 2.5 0.36 0.43 **0.030** 2.8	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 0.080 0.10 0.030 0.030 <0.01 0.13	<0.01 <0.01 0.01 <0.01 <0.01 <0.01 0.01	0 36 43 36 43 42 42	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7947
BASF2009/1012126, study 315849, trial L080055, AC/08/015 France (North) 37230 Fondettes (Indre et Loire) 2009-08-26	triticale / Tremplein	1) 2007-10-11 (sowing) 2) 2008-05-15 - 2008-05-22 3) 2008-07-25	0.13 0.13	200 203	0.063 0.063	2008-05-09 2008-05-22	 BBCH 69	green forage ears of grain ears of grain ears of grain rest of plant rest of plant rest of plant grain straw	2.5 0.17 0.22 0.24 0.44 0.56 0.57 **0.030** 1.6	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 0.020 0.030 0.030 0.020 0.030 0.040 <0.01 0.070	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 35 42 48 35 42 48 67 67	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 11 months ASB2010-7947

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2007/ 1050092, study 284416, trial L070256 France (North) 67440 Kleingoeft 2009-09-03	triticale / Talentro	1) 2006-10-04 (sowing) 2) 2007-05-20 - 2007-05-26 3) 2007-07-17	0.13 0.13	206 203	0.063 0.063	2007-05-10 2007-05-24	BBCH 69	green forage ears of grain ears of grain ears of grain rest of plant rest of plant rest of plant grain straw	2.8 0.25 0.23 0.21 0.36 0.27 0.22 **<0.01** 0.32	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.030 0.040 0.030 0.040 0.030 0.030 0.020 <0.01 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 41 48 36 41 48 54 54	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7948
BASF2007/1050092, study 284416, trial L070253 Germany 67229 Gerolsheim 2009-09-03	wheat / Tommi	1) 2006-10-12 (sowing) 2) 2007-05-23 - 2007-05-31 3) 2007-07-15	0.13 0.13	204 200	0.063 0.063	2007-05-23 2007-05-31	BBCH 69	green forage grain grain grain straw straw straw	2.7 0.030 **0.040** 0.030 <0.01 1.0 0.86	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.050 <0.01 <0.01 <0.01 <0.01 0.10 0.080	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 42 48 36 42 48	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7948
BASF2007/1050092, study 284416, trial L070254 Germany 16833 Brunne 2009-09-03	wheat / Brilliant	1) 2006-09-25 (sowing) 2) 2007-05-18 - 2007-05-31 3) 2007-07-19	0.12 0.12	192 198	0.063 0.063	2007-05-13 2007-05-31	BBCH 69	green forage grain grain grain straw straw straw	2.3 **0.030** 0.030 0.040 0.50 0.80 1.0	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 <0.01 <0.01 0.070 0.090 0.080	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 41 49 36 41 49	analyt. method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7948
BASF2007/1050092, study 284416, trial L070255 United Kingdom CO11 2NF Manningtree, Essex 2009-09-03	wheat / Claire	1) 2006-11-06 (sowing) 2) 2007-06-01 - 2007-06-11 3) 2007-08-09	0.13 0.12	208 196	0.063 0.063	2007-05-22 2007-06-11	BBCH 69	green forage rest of plant rest of plant rest of plant ears of grain ears of grain ears of grain grain straw	1.7 0.23 0.17 0.27 0.13 0.15 0.24 **0.01** 0.44	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 0.030 0.030 0.060 0.020 0.020 0.030 <0.01 0.070	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 35 42 49 35 42 49 59 59	analyt. method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ for each analyte: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7948

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/1012124, study 315842, trial L080068, plot3 Germany 74193 Stetten 2009-11-27	wheat / Tommi	1) 2007-10-13 (sowing) 2) 2008-06-04 - 2008-06-12 3) 2008-07-29	0.13 0.13	200 204	0.063 0.063	2008-05-14 2008-06-09	BBCH 69	green forage grain grain grain straw straw straw	1.7 **0.020** 0.020 0.030 0.71 0.79 0.95	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 <0.01 <0.01 <0.01 0.080 0.12 0.13	<0.01 <0.01 <0.01 <0.01 <0.01 0.020 0.020	0 35 42 50 35 42 50	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 12 months ASB2010-8862
BASF2009/1012124, study 315842, trial L080069, plot3 Germany 67160 Seebach 2009-11-27	wheat / Mercator	1) 2007-10-20 (sowing) 2) 2008-05-22 - 2008-05-30 3) 2008-07-18	0.13 0.13	206 206	0.063 0.063	2008-05-07 2008-05-29	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	3.1 0.36 0.19 **0.01** 0.020 0.41 0.31	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.060 0.040 0.040 <0.01 <0.01 0.060 0.040	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 35 35 42 49 42 49	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 12 months ASB2010-8862

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-8862
Guideline(s):	yes Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 19: Residues of fluxapyroxad in wheat

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	:	62.5 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BAS 701 00 F (submitted to Adexar **006958-00**) treated with formulation BAS 701 00 F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F + BAS 480 31 F, EC (62.5 g/l Epoxiconazole, BAS 480 F)
Applicant		:	BASF

Active ingredient	:	Fluxapyroxad (BAS 700 F)
Crop / crop group	:	Winter Soft Wheat
Submission date	:	2010-06-17
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	62.5 g/l Epoxiconazole (BAS 480 F)
Residues calculated as	:	8.1 Fluxapyroxad 8.2 M700F002 8.3 M700F008, calculated as Fluxapyroxad 8.4 M700F048, calculated as Fluxapyroxad

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	 Water l/ha	 kg a.i./hl	Dates of treatments	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/1012124, study 315842, trial L080068, plot2 Germany 74193 Stetten 2009-11-27	wheat / Tommi	1) 2007-10-13 (sowing) 2) 2008-06-04 - 2008-06-12 3) 2008-07-29	0.13 0.13	200 204	0.063 0.063	2008-05-14 2008-06-09	BBCH 69	green forage grain grain grain straw straw straw	1.7 **<u>0.020</u>** 0.020 0.020 0.67 0.94 0.17	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 0.040 0.060 0.070	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 35 42 50 35 42 50	analytical method: BASF L0137/01 (UPLC-MS/MS) LOQ: 0.01 mg/kg, max. sample storage: 12 months ASB2010-8862
BASF2009/1012124, study 315842, trial L080069, plot2 France 67160 Seebach 2009-11-27	wheat / Mercator	1) 2007-10-20 (sowing) 2) 2008-05-22 - 2008-05-30 3) 2008-07-18	0.13 0.13	203 206	0.063 0.063	2008-05-07 2008-05-29	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	3.4 0.23 0.13 **<u>0.01</u>** 0.01 0.40 0.30	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.050 0.020 0.030 <0.01 <0.01 0.020 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 35 35 42 49 42 49	analytical method: BASF L0137/01 (UPLC-MS/MS) LOQ: 0.01 mg/kg, max. sample storage: 12 months ASB2010-8862
BASF2009/1012124, study 315842, trial L080073, plot2 The Netherlands 6595 Gennep 2009-11-27	wheat / Limes	1) 2007-10-03 (sowing) 2) 2008-05-28 - 2008-06-07 3) 2008-07-30	0.13 0.12	200 195	0.063 0.063	2008-05-21 2008-06-06	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain grain straw straw	2.1 1.0 1.3 0.26 0.34 <u>0.020</u> **<u>0.030</u>** 0.77 0.95	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 0.020 0.030 0.030 0.040 <0.01 <0.01 0.030 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 34 41 34 41 48 54 48 54	analytical method: BASF L0137/01 (UPLC-MS/MS) LOQ: 0.01 mg/kg, max. sample storage: 12 months ASB2010-8862

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-7955
Guideline(s):	yes OPPTS 860.1500 Crop Field Trials / OPPTS 860.1520 Processed Food/Feed / PMRA Directive 98-2, sections 9 and 10
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 20: Residues of fluxapyroxad in wheat (processing)

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	:	62.5 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BAS 700 00 F **006979-00** (submitted to WN2 006989-00 and 006958-00) treated with formulation BAS 700 AE F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F)
Applicant		:	BASF Aktiengesellschaft

Active ingredient	:	Fluxapyroxad (BAS 700 F)
Crop / crop group	:	Spring Soft Wheat
Submission date	:	2010-06-16
Indoors / outdoors	:	Outdoors (NAFTA)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	8.1 Fluxapyroxad (BAS 700 F) 8.2 M700F002 8.3 M700F008 8.4 M700F048

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003065, study 315760, trial RCN R080536, plot 2, replicate A, processing USA 98823 Ephrata, WA 2009-07-28	wheat / Dark Northern Spring	1) 2008-03-14 (sowing) 2) 3) 2008-08-08	0.50 0.50	187 188	0.27 0.27	2008-07-11 2008-07-18	BBCH 85	grain, RAC bread bran flour low grade meal germ middlings whole-meal flour whole-meal bread	0.22 0.030 0.72 0.050 0.050 0.22 0.040 0.23 0.16	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant R-11, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080536, plot 2, replicate B, processing USA 98823 Ephrata, WA 2009-07-28	wheat / Dark Northern Spring	1) 2008-03-14 (sowing) 2) 3) 2008-08-08	0.50 0.50	187 188	0.27 0.27	2008-07-11 2008-07-18	BBCH 85	grain, RAC bread bran flour low grade meal (toppings) germ middlings whole-meal flour whole-meal bread	0.23 0.020 0.66 0.020 0.080 0.29 0.050 0.23 0.16	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant R-11, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080536, plot 3, replicate A, processing USA 98823 Ephrata, WA 2009-07-28	wheat / Dark Northern Spring	1) 2008-03-14 (sowing) 2) 3) 2008-08-08	0.10 0.10	187 186	0.053 0.054	2008-07-11 2008-07-18	BBCH 85	grain, RAC aspirated grain fraction (grain dust)	0.040 6.6	<0.01 <0.01	<0.01 0.02	<0.01 <0.01	21 21	with Adjuvant R-11, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080536, plot 3, replicate B, processing USA 98823 Ephrata, WA 2009-07-28	wheat / Dark Northern Spring	1) 2008-03-14 (sowing) 2) 3) 2008-08-08	0.10 0.10	187 186	0.053 0.054	2008-07-11 2008-07-18	BBCH 85	grain, RAC aspirated grain fraction (grain dust)	0.040 11.1	<0.01 <0.01	<0.01 0.05	<0.01 <0.01	21 21	with Adjuvant R-11, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003065, study 315760, trial RCN R080537, replicate A, processing USA 83211 American Falls, ID 2009-07-28	wheat / 936	1) 2008-05-21 (sowing) 2) 3) 2008-09-12	0.50 0.51	186 181	0.27 0.28	2008-08-16 2008-08-22	BBCH 87	grain, RAC bread bran flour low grade meal (toppings) germ middlings whole-meal flour whole-meal bread	0.24 0.030 0.72 0.040 0.17 0.22 0.090 0.22 0.14	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant AGRI-DEX, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080537, replicate B, processing USA 83211 American Falls, ID 2009-07-28	wheat / 936	1) 2008-05-21 (sowing) 2) 3) 2008-09-12	0.50 0.51	186 181	0.27 0.28	2008-08-16 2008-08-22	BBCH 87	grain, RAC bread bran flour low grade meal (toppings) germ middlings whole-meal flour whole-meal bread	0.30 0.030 0.73 0.030 0.18 0.18 0.10 0.22 0.15	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant AGRI-DEX, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080602, replicate A, processing USA 83211 American Falls, ID 2009-07-28	wheat / Alturas	1) 2008-04-28 (sowing) 2) 3) 2008-09-03	0.51 0.51	157 188	0.32 0.27	2008-08-06 2008-08-12	BBCH 85	grain, RAC bread bran flour low grade meal germ middlings whole-meal flour whole-meal bread	0.69 0.070 1.9 0.10 0.24 0.81 0.23 0.60 0.40	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 0.01 <0.01 <0.01 0.012 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	22 22 22 22 22 22 22 22 22	with Adjuvant AGRI-DEX, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080602, replicate B, processing USA 83211 American Falls, ID 2009-07-28	wheat / Alturas	1) 2008-04-28 (sowing) 2) 3) 2008-09-03	0.51 0.51	157 188	0.32 0.27	2008-08-06 2008-08-12	BBCH 85	grain, RAC bread bran flour low grade meal (toppings) germ middlings whole-meal flour whole-meal bread	0.60 0.060 1.8 0.090 0.24 0.96 0.23 0.51 0.35	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 0.012 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	22 22 22 22 22 22 22 22 22	with Adjuvant AGRI-DEX, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003065, study 315760, trial RCN R080603, replicate A, processing USA 58267 Northwood, ND 2009-07-28	wheat / Glenn	1) 2008-05-08 (sowing) 2) 3) 2008-08-23	0.50 0.50	152 355	0.33 0.14	2008-07-26 2008-08-02	BBCH 83	grain, RAC bread bran flour low grade meal germ middlings whole-meal flour whole-meal bread	0.22 0.10 1.0 0.14 0.23 0.58 0.17 0.40 0.27	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 0.060 0.01 0.020 0.050 0.020 0.040 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant Latron B-1956, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955
BASF2009/7003065, study 315760, trial RCN R080603, replicate B, processing USA 58267 Northwood, ND 2009-07-28	wheat / Glenn	1) 2008-05-08 (sowing) 2) 3) 2008-08-23	0.50 0.50	152 355	0.33 0.14	2008-07-26 2008-08-02	BBCH 83	grain, RAC bread bran flour low grade meal germ middlings whole-meal flour whole-meal bread	0.31 0.080 0.85 0.13 0.20 0.78 0.17 0.35 0.25	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.030 <0.01 0.050 0.01 0.020 0.060 0.020 0.040 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21	with Adjuvant Latron B-1956, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQ: <0.002 mg/kg, max. sample storage: 7 months ASB2010-7955

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-7949, ASB2010-7950, ASB2010-8863
Guideline(s):	yes Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 21: Residues of fluxapyroxad in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	:	62.5 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BAS 700 00 F 006979-00 (submitted to WN2 006989-00 and 006958-00) formulation BAS 700 F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F)
Applicant		:	BASF Aktiengesellschaft

Active ingredient	:	Fluxapyroxad (BAS 700 F)
Crop / crop group	:	Winter Barley
Submission date	:	2010-06-16
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	
Residues calculated as	:	8.1 Fluxapyroxad (BAS 700 F) 8.2 M700F002 8.3 M700F008, calculated as Fluxapyroxad 8.4 M700F048, calculated as Fluxapyroxad

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/1012125, study 315850, trial L080045, plot 2 The Netherlands 6595 AT Ottersum 2009-09-14	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.083 0.084	200 202	0.042 0.041	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	1.9 0.093 0.089 0.080 1.1 0.55 0.86	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.014 <0.01 <0.01 <0.01 0.040 0.024 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 35 41 28 35 41	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7949
BASF2009/1012125, study 315850, trial L080045, plot 3 The Netherlands 6595 AT Ottersum 2009-09-14	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.13 0.13	201 205	0.063 0.063	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	3.2 0.13 **0.17** 0.17 1.4 1.6 1.8	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.014 <0.01 <0.01 <0.01 0.044 0.040 0.031	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 35 41 28 35 41	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7949
BASF2009/1012125, study 315850, trial L080046, plot 2 France 67160 Seebach 2009-09-14	barley / Platine	1) 2007-10-15 (sowing) 2) 2008-05-12 - 2008-05-20 3) 2008-07-01	0.087 0.087	209 209	0.042 0.042	2008-04-25 2008-05-20[4]	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain straw	2.2 0.15 0.20 0.25 0.39 0.14 0.43	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 0.019 0.028 <0.01 0.015	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 29 36 29 36 42 42	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7949
BASF2009/1012125, study 315850, trial L080046, plot 3 France (North) 67160 Seebach 2009-09-14	barley / Platine	1) 2007-10-15 (sowing) 2) 2008-05-12 - 2008-05-20 3) 2008-07-01	0.13 0.13	215 215	0.063 0.063	2008-04-25 2008-05-20	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain straw	2.8 0.41 0.48 0.44 0.50 **0.18** 0.74	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.013 0.011 0.014 0.030 0.031 <0.01 0.021	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 29 36 29 36 42 42	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7949
BASF2009/1012125, study 315850, trial L080047, plot 2 United Kingdom CO11 2NF Manningtree 2009-09-14	barley / Saffron	1) 2007-10-15 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-31	0.086 0.085	206 204	0.042 0.042	2008-05-08 2008-05-29	BBCH 69	green forage rest of plant rest of plant rest of plant ears of grain ears of grain ears of grain grain straw	1.00 0.15 0.18 0.11 0.056 0.044 0.033 0.026 0.23	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 0.013 0.019 0.016 <0.01 <0.01 <0.01 <0.01 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 34 42 28 34 42 63 63	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7949

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment kg a.i./ha	 Water l/ha	 kg a.i./hl	Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/1012125, study 315850, trial L080047, plot 3 United Kingdom CO11 2NF Manningtree 2009-09-14	barley / Saffron	1) 2007-10-15 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-31	0.13 0.13	212 206	0.063 0.063	2008-05-08 2008-05-29	BBCH 69	green forage rest of plant rest of plant rest of plant ears of grain ears of grain ears of grain grain straw	1.9 0.14 0.13 0.23 0.068 0.071 0.053 **<u>0.046</u>** 0.44	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.027 0.013 0.015 0.020 <0.01 0.011 0.01 <0.01 0.034	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 34 42 28 34 42 63 63	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 10 months ASB2010-7949
BASF2007/1050093, study 284410, trial L070246, plot 2 Germany 16833 Brunne 2009-09-10	barley / Campanile	1) 2006-09-15 (sowing) 2) 2007-05-06 - 2007-05-13 3) 2007-07-11	0.084 0.081	203 195	0.042 0.042	2007-04-21 2007-05-13	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	1.8 0.070 0.050 <u>0.040</u> **<u>0.050</u>** 0.090 0.090	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 36 43 48 43 48	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 23 months ASB2010-7950
BASF2007/1050093, study 284410, trial L070246, plot 3 Germany 16833 Brunne 2009-09-10	barley / Campanile	1) 2006-09-15 (sowing) 2) 2007-05-06 - 2007-05-13 3) 2007-07-11	0.13 0.13	202 204	0.063 0.063	2007-04-21 2007-05-13	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	2.4 0.11 0.11 **<u>0.080</u>** 0.080 0.11 0.12	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 <0.01 0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 36 43 48 43 48	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 23 months ASB2010-7950
BASF2007/1050093, study 284410, trial L070247, plot 2 France (North) 67160 Seebach 2009-09-10	barley / Platine	1) 2006-10-20 (sowing) 2) 2007-05-10 - 2007-05-17 3) 2007-07-06 - 2007-07-07	0.088 0.086	212 206	0.042 0.042	2007-04-26 2007-05-16	BBCH 69	green forage grain grain grain straw straw straw	1.7 0.040 **<u>0.050</u>** 0.050 0.19 0.16 0.12	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 43 50 36 43 50	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 23 months ASB2010-7950

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2007/1050093, study 284410, trial L070247, plot 3 France (North) 67160 Seebach 2009-09-10	barley / Platine	1) 2006-10-20 (sowing) 2) 2007-05-10 - 2007-05-17 3) 2007-07-06 - 2007-07-07	0.13 0.12	207 194	0.063 0.063	2007-04-26 2007-05-16	BBCH 69	green forage grain grain grain straw straw straw	2.9 **<u>0.13</u>** 0.10 0.10 0.47 0.37 0.21	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 <0.01 <0.01 0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 36 43 50 36 43 50	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 23 months ASB2010-7950
BASF2007/1050093, study 284410, trial L070248, plot 2 United Kingdom CO11 2NF Manningtree 2009-09-10	barley / Pearl	1) 2006-11-06 (sowing) 2) 2007-05-21 - 2007-05-31 3) 2007-07-31	0.088 0.086	211 209	0.042 0.041	2007-05-09 2007-05-31	BBCH 69	green forage rest of plant rest of plant rest of plant ears of grain ears of grain ears of grain grain straw	1.4 0.050 0.11 0.14 0.070 0.11 0.10 0.020 0.070	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 34 41 48 34 41 48 61 61	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7950
BASF2007/1050093, study 284410, trial L070248, plot 3 United Kingdom CO11 2NF Manningtree 2009-09-10	barley / Pearl	1) 2006-11-06 (sowing) 2) 2007-05-21 - 2007-05-31 3) 2007-07-31	0.13 0.13	208 213	0.063 0.063	2007-05-09 2007-05-31	BBCH 69	green forage rest of plant rest of plant rest of plant ears of grain ears of grain ears of grain grain straw	2.3 0.080 0.11 0.17 0.11 0.10 0.090 **<u>0.020</u>** 0.11	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 34 41 48 34 41 48 61 61	analytical method: BASF L0137/01 (UPLC-MS/MS for green forage, rest of plant and straw, HPLC-MS/MS for grain and ears), LOQ: 0.01 mg/kg, max. sample storage: 22 months ASB2010-7950
BASF2009/1012127, study 315843, trial L080061, plot 3 The Netherlands 6595 AT Ottersum 2009-12-03	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.13 0.11	202 181	0.063 0.063	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	2.6 0.090 <u>0.10</u> **<u>0.11</u>** 1.4 1.1 2.5	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 <0.01 <0.01 0.040 0.030 0.060	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 35 41 28 35 41	analytical method: BASF L0137/01 (UPLC-MS/MS), LOQ: 0.01 mg/kg, max. sample storage: 17 months ASB2010-8863

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-8863
Guideline(s):	yes Guideline fro the generation of data concerning residues as provided in Annex II, part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market. 1607/VI/97 rev.2; European Community Guideline 7029/VI/95 rev.5: General recommendations for the design, preparation and realization of residue trials European Community Guideline 7525/VI/95 rev.7:Comaprability , extrapolation, group tolerances and data requirements for setting MRLs
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 22: Residues of fluxapyroxad in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	:	62.5 g/l
Formulation	(e.g. WP)	:	EC
Commercial product	(name)	:	BAS 701 00 F (submitted to Adexar **006958-00**) formulation BAS 701 00 F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F + BAS 480 31 F, EC (62.5 g/l Epoxiconazole, BAS 480 F)
Applicant		:	BASF Aktiengesellschaft

Active ingredient	:	Fluxapyroxad (BAS 700 F)
Crop / crop group	:	Winter Barley
Submission date	:	2010-06-17
Indoors / outdoors	:	Outdoors (European North)
Other a.i. in formulation (content and common name)	:	62.5 g/l Epoxiconazole (BAS 480 F)
Residues calculated as	:	8.1 Fluxapyroxad (BAS 700 F) 8.2 M700F002 8.3 M700F008, calculated as Fluxapyroxad 8.4 M700F048, calculated as Fluxapyroxad

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/1012127, study 315843, trial L080061, plot 2 Netherlands 6595 AT Ottersum 2009-12-03	barley / Sequel	1) 2007-08-18 (sowing) 2) 2008-05-19 - 2008-05-29 3) 2008-07-07	0.13 0.13	207 209	0.063 0.063	2008-05-09 2008-05-27	BBCH 69	green forage grain grain grain straw straw straw	2.3 0.080 **0.090** 0.090 0.65 0.83 1.2	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.01 <0.01 <0.01 <0.01 0.020 0.030 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 35 41 28 35 41	analytical method: BASF L0137/01 (UPLC-MS/MS) BAS 700 F, LOQ: 0.01 mg/kg, max. sample storage: 17 months ASB2010-8863
BASF2009/1012127, study 315843, trial L080064, plot 2 France 41500 Suevres 2009-12-03	barley / Cervoise	1) 2007-10-12 (sowing) 2) 2008-05-10 - 2008-05-19 3) 2008-06-15 - 2008-06-30	0.12 0.14	197 217	0.063 0.063	2008-05-09 2008-05-19	BBCH 69	green forage rest of plant rest of plant ears of grain ears of grain grain straw	2.1 0.27 0.39 0.090 0.16 **0.080** 0.70	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 28 35 28 35 42 42	analytical method: BASF L0137/01 (UPLC-MS/MS)BAS 700 F, LOQ: 0.01 mg/kg, max. sample storage: 17 months ASB2010-8863
BASF2009/1012127, study 315843, trial L080065, plot 2 Germany 16833 Lentzke 2009-12-03	barley / Campanile	1)2007-09-17 (sowing) 2) 2008-05-12 - 2008-05-20 3) 2008-07-02	0.13 0.13	200 200	0.063 0.063	2008-05-02 2008-05-20	BBCH 69	green forage rest of plant ears of grain grain grain straw straw	2.1 1.3 0.60 0.20 **0.24** 1.3 1.5	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.020 0.020 <0.01 <0.01 0.020 0.030	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0 27 27 35 41 35 41	analytical method: BASF L0137/01 (UPLC-MS/MS) BAS 700 F, LOQ: 0.01 mg/kg, max. sample storage: 17 months ASB2010-8863

Remarks:
(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

Reference:	KIIA 6.3
Report	ASB2010-7956
Guideline(s):	yes OPPTS 860.1500 Crop Field Trials / OPPTS 860.1520 Processed Food/Feed / PMRA Directive 98-2, sections 9 and 10
Deviations:	no
GLP:	yes
Acceptability:	yes

Table A 23: Residues of fluxapyroxad in barley

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i.	(g/kg or g/l)	: 62.5 g/l		
Formulation	(e.g. WP)	: EC		
Commercial product	(name)	: BAS 700 00 F **006979-00** (submitted to WN2 006989-00 and 006958-00) treated with formulation BAS 700 AE F, 5094351, EC (62.5 g/l Fluxapyroxad, BAS 700 F)		
Applicant		: BASF Aktiengesellschaft		

Active ingredient	: Fluxapyroxad (BAS 700 F)
Crop / crop group	: Spring Barley
Submission date	: 2010-06-16
Indoors / outdoors	: Outdoors (NAFTA)
Other a.i. in formulation (content and common name)	:
Residues calculated as	: 8.1 Fluxapyroxad (BAS 700 F) 8.2 M700F002 8.3 M700F008 8.4 M700F048

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003177,	barley /	1) 2008-04-17	0.50	188	0.27	2008-07-18	BBCH 85	grain, RAC	2.5	<0.01	<0.01	<0.01	21	with adjuvant R-11,
study 315759, trial RCN	AC Metcalfe	(sowing)	0.51	189	0.27	2008-07-25		pearl barley	0.17	<0.01	<0.01	<0.01	21	analytical method: BASF
R080534,		2)						malt germs	0.50	<0.01	<0.01	<0.01	21	L0137/01 (HPLC-MS/MS),
replicate A, processing		3) 2008-08-15						malt	<0.01	<0.01	<0.01	<0.01	21	LOQs: 0.01 mg/kg,
								dregs	0.25	<0.01	<0.01	<0.01	21	max. sample storage:
USA								spent grain	0.71	<0.01	0.01	<0.01	21	9 months
98823 Ephrata, WA								yeast	0.41	<0.01	<0.01	<0.01	21	
								beer	0.040	<0.01	<0.01	<0.01	21	ASB2010-7956
2009-09-22								bran	3.3	<0.01	<0.01	<0.01	21	
								flour	0.20	<0.01	<0.01	<0.01	21	
BASF2009/7003177,	barley /	1) 2008-04-17	0.50	188	0.27	2008-07-18	BBCH 85	grain, RAC	3.1	<0.01	<0.01	<0.01	21	with adjuvant R-11,
study 315759, trial RCN	AC Metcalfe	(sowing)	0.51	189	0.27	2008-07-25		pearl barley	0.31	<0.01	<0.01	<0.01	21	analytical method: BASF
R080534,		2)						malt germs	0.33	<0.01	<0.01	<0.01	21	L0137/01 (HPLC-MS/MS),
replicate B, processing		3) 2008-08-15						malt	0.020	<0.01	<0.01	<0.01	21	LOQs: 0.01 mg/kg,
								dregs	0.37	<0.01	<0.01	<0.01	21	max. sample storage:
USA								spent grain	0.67	<0.01	<0.01	<0.01	21	9 months
98823 Ephrata, WA								yeast	0.080	<0.01	<0.01	<0.01	21	
								beer	0.020	<0.01	<0.01	<0.01	21	ASB2010-7956
2009-09-22								bran	5.2	<0.01	<0.01	<0.01	21	
								flour	0.33	<0.01	<0.01	<0.01	21	
BASF2009/7003177,	barley /	1) 2008-05-20	0.50	184	0.27	2008-08-16	BBCH 87	grain, RAC	2.5	<0.01	<0.01	<0.01	21	with adjuvant Agri-Dex,
study 315759, trial RCN	Baroness	(sowing)	0.50	185	0.27	2008-08-23		pearl barley	0.29	<0.01	<0.01	<0.01	21	analytical method: BASF
R080535,		2)						malt germs	0.75	<0.01	<0.01	<0.01	21	L0137/01 (HPLC-MS/MS),
replicate A, processing		3) 2008-09-13						malt	0.020	<0.01	0.040	<0.01	21	LOQs: 0.01 mg/kg,
								dregs	0.51	<0.01	<0.01	<0.01	21	max. sample storage:
USA								spent grain	0.57	<0.01	<0.01	<0.01	21	9 months
83211 American Falls, ID								yeast	1.4	<0.01	0.020	<0.01	21	
								beer	0.050	<0.01	<0.01	<0.01	21	ASB2010-7956
2009-09-22								bran	4.8	<0.01	<0.01	<0.01	21	
								flour	0.28	<0.01	<0.01	<0.01	21	

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003177, study 315759, trial RCN R080535, replicate B, processing USA 83211 American Falls, ID 2009-09-22	barley / Baroness	1) 2008-05-20 (sowing) 2) 3) 2008-09-13	0.50 0.50	184 185	0.27 0.27	2008-08-16 2008-08-23	BBCH 87	grain, RAC pearl barley malt germs malt dregs spent grain yeast beer bran flour	4.2 0.36 0.91 0.01 0.50 0.65 1.1 0.050 6.6 0.34	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 0.050 0.030 0.01 <0.01 0.020 <0.01 0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	21 21 21 21 21 21 21 21 21 21	with adjuvant Agri-Dex, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQs: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7956
BASF2009/7003177, study 315759, trial RCN R080600, replicate A, processing United States of America 83211 American Falls, ID 2009-09-22	barley / Conrad	1) 2008-05-16 (sowing) 2) 3) 2008-09-04	0.53 0.50	165 184	0.32 0.27	2008-08-06 2008-08-13	BBCH 85	grain, RAC pearl barley malt germs malt dregs spent grain yeast beer bran flour	3.5 0.66 0.81 0.020 0.58 0.80 1.2 0.040 6.5 0.68	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 0.01 0.020 0.01 <0.01 0.01 <0.01 0.040 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	22 22 22 22 22 22 22 22 22 22	with adjuvant Agri-Dex, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQs: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7956
BASF2009/7003177, study 315759, trial RCN R080600, replicate B, processing United States of America 83211 American Falls, ID 2009-09-22	barley / Conrad	1) 2008-05-16 (sowing) 2) 3) 2008-09-04	0.53 0.50	165 184	0.32 0.27	2008-08-06 2008-08-13	BBCH 85	grain, RAC pearl barley malt germs malt dregs spent grain yeast beer bran flour	3.0 0.67 1.1 0.020 0.46 0.79 0.91 0.050 6.6 0.83	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 <0.01 <0.01 0.020 <0.01 <0.01 <0.01 <0.01 0.040 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	22 22 22 22 22 22 22 22 22 22	with adjuvant Agri-Dex, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQs: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7956

1	2	3	4			5	6	7	8.1	8.2	8.3	8.4	9	10
Report-No. Location incl. postal code and date	Commodity/ Variety	Date of 1) Sowing 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments	Growth stage at last treatment	Portion analysed	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl									
	(a)	(b)				(c)		(a)					(d)	(e)
BASF2009/7003177, study 315759, trial RCN R080601, replicate A, processing United States of America 58267 Northwood, ND 2009-09-22	barley / Tradition	1) 2008-06-16 (sowing) 2) 3) 2008-09-16	0.50 0.50	327 328	0.15 0.15	2008-08-16 2008-08-24	BBCH 77	grain, RAC pearl barley malt germs malt dregs spent grain yeast beer bran flour	2.2 0.91 1.2 0.030 1.0 0.88 0.71 0.050 5.5 1.0	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.050 0.020 0.030 0.050 0.030 0.020 0.020 <0.01 0.11 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	23 23 23 23 23 23 23 23 23 23	with adjuvant Latron B-1956, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQs: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7956
BASF2009/7003177, study 315759, trial RCN R080601, replicate B, processing United States of America 58267 Northwood, ND 2009-09-22	barley / Tradition	1) 2008-06-16 (sowing) 2) 3) 2008-09-16	0.50 0.50	327 328	0.15 0.15	2008-08-16 2008-08-24	BBCH 77	grain, RAC pearl barley malt germs malt dregs spent grain yeast beer bran flour	2.2 0.79 1.2 0.020 0.49 0.73 0.79 0.040 5.1 0.95	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.050 0.020 0.020 0.050 0.01 0.01 0.020 <0.01 0.10 0.020	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	23 23 23 23 23 23 23 23 23 23	with adjuvant Latron B-1956, analytical method: BASF L0137/01 (HPLC-MS/MS), LOQs: 0.01 mg/kg, max. sample storage: 9 months ASB2010-7956

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable.

A 2.3 Residues in processed commodities

See A 2.2.2.

A 2.4 Residues in rotational crops

No new study on residues in rotational crops has been submitted.

A 2.5 Residues in livestock

No new study on residues in livestock has been submitted.

A 2.6 Other studies/information

None

Appendix 3 Pesticide Residue Intake Model (PRIMo revision 2)

Prepare workbook for refined calculations

Undo refined calculations

Epoxiconazole (F)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,008**	ARfD (mg/kg bw):	**0,023**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
8 97

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of AD
97,2	DK child	41,3	Wheat	33,1	Rye	7,4	Oats	
94,1	WHO Cluster diet B	64,0	Wheat	5,3	Barley	3,6	Fruiting vegetables	
77,1	UK Toddler	29,4	Wheat	28,6	Sugar beet (root)	6,7	Bananas	
70,3	DE child	30,8	Wheat	9,7	Bananas	7,9	Pome fruit	
69,0	NL child	35,6	Wheat	10,6	Bananas	4,2	Pome fruit	
68,1	WHO cluster diet D	48,8	Wheat	4,1	Barley	3,0	Rye	
67,6	IE adult	23,3	Barley	17,2	Wheat	4,9	Bananas	
64,5	WHO cluster diet E	29,6	Wheat	15,2	Barley	3,3	Root and tuber vegetables	
60,3	IT kids/toddler	49,8	Wheat	3,3	Bananas	1,9	Other cereal	
59,4	WHO Cluster diet F	27,0	Wheat	11,3	Barley	5,7	Rye	
57,8	UK Infant	19,7	Wheat	12,6	Sugar beet (root)	9,1	Bananas	
49,1	ES child	33,3	Wheat	6,3	Bananas	1,5	Citrus fruit	
48,7	SE general population 90th percentile	24,0	Wheat	11,3	Bananas	3,4	Root and tuber vegetables	
42,5	FR toddler	19,7	Wheat	8,1	Bananas	5,0	Root and tuber vegetables	
42,2	WHO regional European diet	22,3	Wheat	6,2	Barley	2,9	Root and tuber vegetables	
41,3	PT General population	29,4	Wheat	2,1	Bananas	1,8	Berries & small fruit	
38,0	IT adult	31,0	Wheat	1,3	Bananas	1,1	Fruiting vegetables	
35,6	ES adult	17,6	Wheat	9,2	Barley	2,3	Bananas	
33,7	NL general	15,5	Wheat	7,0	Barley	2,0	Bananas	
33,4	FR all population	24,7	Wheat	2,6	Berries & small fruit	1,6	Bananas	
30,4	UK vegetarian	15,4	Wheat	4,7	Sugar beet (root)	2,4	Bananas	
29,5	DK adult	15,1	Wheat	5,1	Rye	2,4	Bananas	
26,0	UK Adult	12,6	Wheat	5,0	Sugar beet (root)	2,2	Bananas	
25,6	LT adult	8,1	Rye	7,9	Wheat	2,2	Root and tuber vegetables	
21,5	FR infant	6,3	Wheat	4,5	Bananas	4,5	Root and tuber vegetables	
19,9	FI adult	7,4	Wheat	5,1	Rye	1,6	Oats	
7,8	PL general population	2,5	Root and tuber vegetables	1,5	Pome fruit	1,2	Bananas	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Epoxiconazole (F) is unlikely to present a public health concern.

Prepare workbook for refined calculations

Undo refined calculations

Fluxapyroxad

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,02**	ARfD (mg/kg bw):	**0,25**
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

xplain choice of toxicological reference values.
he risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
he pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
7 63

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of AD
63,5	DE child	44,5	Pome fruit	8,2	Wheat	2,0	Oats	
44,4	NL child	23,7	Pome fruit	9,5	Wheat	3,8	Beans (with pods)	
37,2	DK child	11,0	Wheat	10,5	Pome fruit	8,8	Rye	
37,1	IE adult	12,4	Barley	5,2	Pome fruit	4,6	Wheat	
36,8	WHO Cluster diet B	17,1	Wheat	4,9	Pome fruit	2,8	Barley	
36,3	UK Toddler	17,2	Sugar beet (root)	7,8	Wheat	6,6	Pome fruit	
32,3	WHO cluster diet E	8,1	Barley	7,9	Wheat	3,6	Pome fruit	
28,5	FR toddler	10,1	Pome fruit	8,3	Beans (with pods)	5,2	Wheat	
26,5	UK Infant	7,6	Sugar beet (root)	6,4	Pome fruit	5,2	Wheat	
24,2	WHO Cluster diet F	7,2	Wheat	6,0	Barley	2,7	Pome fruit	
24,2	WHO cluster diet D	13,0	Wheat	2,6	Pome fruit	2,2	Barley	
22,3	IT kids/toddler	13,3	Wheat	4,3	Pome fruit	1,7	Peaches	
21,7	FR infant	9,9	Pome fruit	6,3	Beans (with pods)	1,7	Wheat	
20,8	WHO regional European diet	5,9	Wheat	3,3	Barley	3,0	Pome fruit	
20,1	ES child	8,9	Wheat	5,7	Pome fruit	1,8	Beans (with pods)	
18,9	PT General population	7,8	Wheat	4,9	Pome fruit	1,8	Peaches	
18,1	ES adult	4,9	Barley	4,7	Wheat	3,9	Pome fruit	
17,3	NL general	4,7	Pome fruit	4,1	Wheat	3,7	Barley	
17,1	IT adult	8,3	Wheat	3,6	Pome fruit	1,9	Peaches	
16,7	SE general population 90th percentile	6,4	Wheat	4,9	Pome fruit	0,7	Peaches	
13,9	LT adult	7,1	Pome fruit	2,2	Rye	2,1	Wheat	
13,2	FR all population	6,6	Wheat	2,1	Pome fruit	1,1	Beans (with pods)	
12,5	UK vegetarian	4,1	Wheat	2,8	Sugar beet (root)	2,3	Pome fruit	
11,7	DK adult	4,0	Wheat	3,5	Pome fruit	1,4	Rye	
10,8	PL general population	8,1	Pome fruit	1,3	Plums	0,3	Other root and tuber vegetables	
10,3	UK Adult	3,4	Wheat	3,0	Sugar beet (root)	1,6	Pome fruit	
7,1	FI adult	2,0	Wheat	1,5	Pome fruit	1,4	Rye	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluxapyroxad is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: **BAS 701 00 F**

Active Substance(s): **fluxapyroxad (BAS 700 F) 62.5 g/L**
epoxiconazole (BAS 480 F) 62.5 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **BASF**
Date: **02 June 2017**

Table of Contents

Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product Adexar containing the active substances Fluxapyroxad and Epoxiconazole .in its intended uses in cereals according to Appendix 4. National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation BAS 701 00 F

Code	BAS 701 00F		
plant protection product	Adexar		
applicant	BASF		
date of application	05.04.2013		
Formulation type (WP, EC, SC, …; density)	EC		
active substance	Fluxapyroxad	Epoxiconazole	
Concentration of as	62.5 g/L	62.5 g/L	

5.2 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 5.2-1.

Table 5.2-1: Critical use pattern of BAS 701 00 F

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A	cereals/ BBCH 30-69	spraying /	2 x, 21d, spring 1. 70 % 2. 90 %	Fluxapyroxad: 2 x 125= 250, Epoxiconazole: 2 x 125= 250	Fluxapyroxad: 1. 37.5 2. 12.5 Epoxiconazole: 1. 37.5 2. 12.5

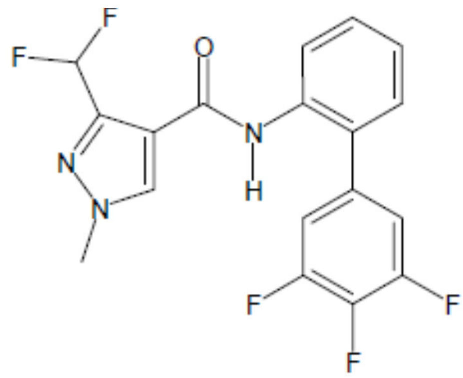
5.3 Information on the active substances

5.3.1 Fluxapyroxad

5.3.1.1 Identity, further information of Fluxapyroxad

Table 5.3-1: Identity, further information on Fluxapyroxad

Active substance (ISO common name)	Fluxapyroxad
IUPAC	3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluorobiphenyl-2-

	yl)pyrazole-4-carboxamide
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/01/2013
Conditions of approval	
Confirmatory data	
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	950
Molecular formula	C18H12F5N3O
Molecular mass	381.31
Structural formula	

5.3.1.2 Physical and chemical properties of Fluxapyroxad

Physical and chemical properties of Fluxapyroxad as agreed at EU level (see SANCO/7593/VI/97 final - 14/08/2000) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Fluxapyroxad relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	2.7×10^{-9}	SANCO/7593/VI/97 final - 14/08/2000
Henry's law constant (Pa × m^3 × mol^{-1})	3.028×10^{-7}	
Solubility in water (at 25 °C in mg/L)	3.44 mg /L at 20 °C (pH 7.00)	
Partition co-efficient (at 25 °), log P_{OW}	3.13 at 20 °C (pH 7)	
Dissociation constant, pKa	pKa (HL/H+L) = 12.58 ± 0.70 (calculated) pKa (H2L/H+HL) = -2.78 ± 0.50 (calculated) pKa (H3L/H+H2L) = -5.52 ± 0.50 (calculated) pKa was estimated using modelling	

	software version 6.00 from ACD/Labs	

5.3.1.3 Metabolites of Fluxapyroxad

Environmental occurring metabolites of Fluxapyroxad requiring further assessment according to the results of the assessment of Fluxapyroxad for EU approval are summarized in Table 5.3-3.

No new study on the fate and behaviour of Fluxapyroxad or BAS 701 00 F has been performed. Hence no potentially new metabolites need to be considered.

Table 5.3-3: Metabolites of Fluxapyroxad potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/Molecular formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance (EFSA Journal 2012;10(1):2522)**
M700F001	C6H6F2N2O2	Soil: Max. 12.1 % (mean value) on day 30 Irradiated Water: Max. 10.9 % at day 43	Aquatic organisms: Water: low risk Sediment:low risk Terrestrial organisms: low risk Groundwater: not relevant (Step 2/Step 3-4)[1)]
M700F002	C5H4F2N2O2	Soil: Max. 38.5 % (mean value) on day 120	Aquatic organisms: Water: low risk Sediment: low risk Terrestrial organisms: low risk Groundwater: risk assessed as low to the aquatic environmen
M700F007	C6H7F2N3O	Irradiated Water: Max. 7.5 % at day 57	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: not relevant

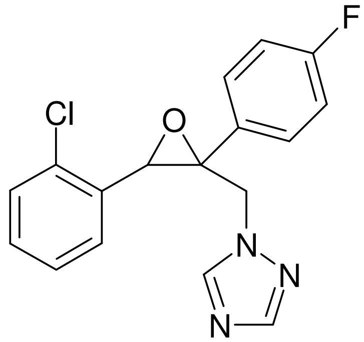
[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.3.2 Epoxiconazole

5.3.2.1 Identity, further information of Epoxiconazole

Table 5.3-4: Identity, further information on Epoxiconazole

Active substance (ISO common name)	Epoxiconazole
IUPAC	(2RS, 3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1,2,4-triazole
Function (e.g. fungicide)	Fungicide

Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/05/2009
RMS	Federal Republic of Germany
Minimum purity of the active substance as manufactured (g/kg)	920 g/kg
Molecular formula	C17H13ClFN3O
Molecular mass	329.76 g/mol
Structural formula	

5.3.2.2 Physical and chemical properties of Epoxiconazole

Physical and chemical properties of Epoxiconazole as agreed at EU level (see EPCO Manual E4-rev. April 2013) and considered relevant for the exposure assessment are listed in Table 5.3-5.

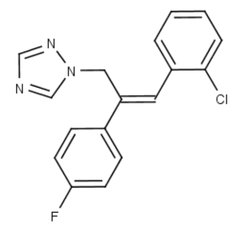
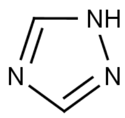
Table 5.3-5: EU agreed physical chemical properties of Epoxiconazole relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	< 1 x 10^{-5} extrapolated from measurement at 70°C (purity: 99.1%)	EPCO Manual E4-rev. April 2013
Henry's law constant (Pa × m^3 × mol^{-1})	< 4.7 x 10^{-4} (20°C)	
Solubility in water (at 25 °C in mg/L)	7.1 (deionised water) 8.4 (pH 3) (20°C)	
Partition co-efficient (at 25 °), log P_{OW}	3.3 no dependence on the pH value (deionised water)	
Dissociation constant, pKa	Epoxiconazole does not dissociate in water, no pKa value could be determined.	
Hydrolytic degradation	stable (pH 5-9, 25°C)	

5.3.2.3 Metabolites of Epoxiconazole

Environmental occurring metabolites of Epoxiconazole requiring further assessment according to the results of the assessment of Epoxiconazole or EU approval are summarized in Table 5.3-3.

Table 5.3-6: Metabolites of Epoxiconazole potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/Molecular formula**	**occurrence in compartments (Max. at day/**	**Status of Relevance** (SANCO/136/08 – 11/07/2008, revised 28/09/2010)
BF 480-entriazole	$C_{17}H_{13}ClFN_3$ 313.76 g/mol 	Sediment: Max. 32.3 % at day 59	Aquatic organisms: not relevant Terrestrial organisms: not relevant Groundwater: not relevant (Step 2
1,2,4-triazole	$C_2H_3N_3$ 69.1g/mol 	Soil: Max. 6.6 % at day 175 (increasing at end of study)	Aquatic organisms: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 3-4)

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Fluxapyroxad -Laboratory studies

No new studies have been submitted regarding route and rate of degradation in soil of Fluxapyroxad. The geometric mean laboratory DT_{50} corrected to standard temperature and moisture conditions to be used in FOCUS groundwater and surface water modelling was 177 d (for modeling purposes SFO fit was used, best fit kinetics is for triggering purposes). The maximum laboratory DT_{50} for BAS 701 00F when corrected to standard moisture and temperature conditions was 424 days with a corresponding DT_{90} of > 1000 days triggering the requirement for field dissipation studies (based on best fit degradation kinetics).

Table 5.4-1: Summary of aerobic degradation rates for Epoxiconazole - laboratory studies

Soil type		pH	DT_{50} (d) 20 °C pF2/10 kPa	Kinetic, Fit	Values in accordance to EU endpoint in LoEP
Bruch West, sandy loam, geomean n=3		7.1	70.3	SFO, 2.2/ SFO, 2/ SFO 1.4	Deviating, as SFO fit was used for modeling purposes
Arahal, silty clay loam		7.6	139	SFO, 6.9	yes
Kleve Keeken, loam		6.7	424	SFO, 2.2	yes
Nierswalde , silt loam, geomean n=2		6.4	236.8	SFO, 2.7/ SFO, 1.8	Deviating, as SFO fit was used for modeling purposes
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**		71		
	Geometric mean (d)		177		

For modelling purposes the field studies were used and presented in the next section.

Metabolite M700F001

The rates of degradation in soil of M700F001 were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-2.

Table 5.4-2: Laboratory studies of metabolite M700F001

Soil type		pH (H_2O)	DT_{50} (d) 20 °C pF2/10 kPa	Kinetic, Fit	Reference
Bruch West - Sandy loam		8.2	7.7*	25.1 SFO	LoEP/ Unold, Bayer 2009a
Li10 – Loamy sand		7	8.9	2.9 SFO	LoEP/ Unold, Bayer 2009b
LUFA 2.2 – Sand		6.5	5.2	1.1 SFO	LoEP/ Unold, Bayer 2009b
Wisconsin – Loamy sand		6.4	2.3	4.8 SFO	LoEP/ Unold, Bayer 2009b
Aggregated DT_{50} (n=4)	Coefficient of variation (%)		48		
	Geometric mean (d)		5.4		

*) The non-normalised DT_{50} of this soil is 10 days. This value of 10 days is the worst case DT_{50} used in the LoEP for PEC soil calculations.

Metabolite M700F002

As a result of the calculated DT90 values from the laboratory aerobic degradation studies exceeding 1 year field dissipation studies were performed with the metabolite M700F002 (Unold et al. (2009)).

For modelling purposes the field studies were used and presented in the next section.

5.4.1.2 Fluxapyroxad - Field studies

The field dissipation rates of Fluxapyroxad were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-3.

Table 5.4-3: Field degradation studies of Fluxapyroxad

soil / location	pH H_2O	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
silt loam, France	8.1		284	>1000	7 FOMC	132	7.7 SFO	LoEP Nov. 2011
loamy sand, Germany	5.6		140	>1000	8.5 FOMC	83.9	7.1 SFO	LoEP
silt loam, Germany	6.5		132	>1000	6.4 FOMC	28.5 fast 193 slow	4.6 HS	LoEP
silt loam, Italy	8.1		38.9 fast	854	6.7 HS	40.1 fast 224 slow	8.3 HS	LoEP
silty clay loam, Spain	8.4		124	882	8.4 FOMC	131	8 SFO	LoEP
Loam, UK	7.3		370 (alpha: 0.2056, beta: 13.1342)	>1000	6.8 FOMC	26.8 fast 187 slow	7.1 HS	LoEP
Geometric mean DT_{50} (days) slow					151 (n = 6)			
Geometric mean DT_{50} (days) fast					59.5 (n = 6)			

Metabolite M700F002

The field dissipation rates of M700F002 were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-4.

Table 5.4-4: Field degradation studies of metabolite M700F002

soil / location	pH H_2O	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Middelfart, Denmark	5.8		39.2	188	12, FOMC	17.9	SFO	Unold et al. 2009, LoEP Nov. 2011

Goch-Nierswalde, Germany	6.4		38	155	5.7, FOMC	23.1	SFO	LoEP
Poggio Renatico, Italy	7.7		37.4	186	7, FOMC	44.1	SFO	LoEP
Meauzac. Southern France	5.5		25.5	84.8	6.9, SFO	24.6	SFO	LoEP
Aggregated DT_{50} (n=4)	**Coefficient of variation (%)**	42						
	Geometric mean (d)	25.9						

5.4.1.3 Epoxiconazole -Laboratory studies

For modelling purposes the field studies were used and presented in the next section

Metabolite 1,2,4-triazole

For modelling purposes the field studies were used and presented in the next section

5.4.1.4 Epoxiconazole- Field studies

The field dissipation rates of Epoxiconazole were evaluated during EU assessment. No additional studies have been performed. The DT_{50} values are summarized in Table 5.4-5.

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Table 5.4-5: Field degradation studies of Epoxiconazole

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic, Parameters	DT_{50} (d) 20 °C, pF2	Fit, Kinetic	Reference
Silty clay, Achtum (Germany)	7.5	0-12	52	174	0.89	44	SFO	Tilting, 1991, 2007 Platz, 2002
Loamy sand, Boehl (Germany)	7.5	0-12	174	577	0.61	124	SFO	
Loamy sand, Bothkamp (Germany)	4.6	0-10	216	719	0.72	122	SFO	
Sandy loam, Havixbeck (Germany)	6.3	0-10	112	372	0.88	74	SFO	Hesse, 1992a Platz, 2002 Tilting, 2007
Loam, Stetten (Germany)	6.9	0-10	74	247	0.82	65	SFO	

Sandy loam, Oberding (Germany)	6.6	0-10	150	499	0.84	82	SFO	Hesse 1992b Platz, 2002 Tilting, 2007
Loamy sand, Birkenheide (Germany)	4.9	0-10	226	752	0.86	71	SFO	
Aggregated DT_{50} , n=7		**Coefficient of variation (%)**				36		
		Geomean (d)				78.7		
		Median (d)				74		

Metabolite 1,2,4-Triazole

A new soil dissipation study on 1,2,4-triazole (Tarara, 2010) is available (see Appendix 3, KIIIA 9.2.1/1). The normalisation of the experimental data to standard FOCUS reference conditions (20°C and 100% field capacity) was performed by Chapple, 2010 (see Appendix 3, KIIIA 9.2.1/2). The experimental results and the kinetic evaluation of the study, finalized after Annex I inclusion of epoxiconazole, are currently evaluated by UK's Chemicals Regulation Directorate (CRD). On behalf of the European Commission (EC), the British regulatory authority (CRD) evaluated residue data for all triazole metabolites in 2010.

The evaluation and proposed harmonised endpoint was sent to all EU member states for comment in July 2011 including also the kinetic evaluation of degradation (Chapple, 2010). A detailed evaluation of these studies was provided to all member states in 2011 ("Commission Regulation 1107/2009, Triazole Derived Metabolite: 1,2,4-Triazole, Proposed revision to DT50, Summary, Scientific Evaluation and Assessment; July 2011, revised September 2011.").

The respective $DegT_{50}$ values of the new study are summarized in Table 5.4-6.

Table 5.4-6: Field degradation studies of 1,2,4-Triazole

soil / location	**pH**	**depth (cm)**	**DT_{50} (d)**	**DT_{90} (d)**	**Fit, Kinetic, Parameters**	**DT_{50} (d) 20 °C, pF2**	**Fit, Kinetic**	**Reference**
Silt Loam/ Burscheid, Germany	7.06	50	7.8 α 0.4454	366.7 β 2.0966	FOMC, chi^2 =15.2	fast: 2.5 slow: 70.7 g = 0.655	DFOP, fixed g at 0.655, chi^2: 18.8%	Tarara (2010) Chapple (2010)
Sandy Loam, Little Shelford, UK	8.14	50	6.8 k1= 0.463	109.3 k2= 0.0154 g 0.4633	DFOP/ chi^2 = 17.8%	fast: 0.5 slow: 25.1 g = 0.458	DFOP, chi^2: 18.1%	

Silty Clay Loam/ Albaro, Italy	8.22	50	21.2 k1= 0.3500	207.4 k2= 0.0086 g 0.4000	DFOP/ chi^2 =10.7%,	fast: 1.4 slow: 59.8 g = 0.364	DFOP, chi^2: 10.6%	
Loam/ Vilobi d'Onyar, Spain	6.40	50	28.1 k1= 0.0632	717.6 k2= 0.0020 g 0.5732	DFOP/ chi2 =13.3%	fast: 4.6 slow: 126 g = 0.477	DFOP, chi^2: 12.7%	
Geometric Mean						60.5d (slow phase)/ 1.7 d (fast phase),	g=0.489	

5.4.2 Adsorption/desorption

Fluxapyroxad

No new studies have been submitted regarding adsorption/desorption in soil of Fluxapyroxad. The exposure modeling is based on the EU K_{foc} values as summarized in Table 5.4-8.

The volcanic soil of the Japanese island Obihiro is not considered for the arithmetic mean of the soils, because this soil whitout an amount of clay (according to the test report 0% on particles with a size of smaller than 2 µm as given in Table 5.4.-2) is not representative of the agricultural soils in the central zone.

Table 5.4-7 Characterization of the Obihiro soil

Soil Type	<2 µm	2 µm-50 µm	50 µm-2 mm	Water Content		Reference
Sandy loam	0.52	5.2	4.3	7.37%		Hassink, Stephahn 2009a

Table 5.4-8: K_f, K_{foc} and 1/n (Freundlich exponent) values for Fluxapyroxad

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
LUFA 2.1, Sand	0.52	5.2	4.3	818	0.945	Hassink, Stephahn 2009a)
Obihiro, Japan, sandy loam	2.74	5.6	15.2*	(556*)	(0.897*)	see above

Li 10, Loamy Sand	0.88	5.9	6.8	777	0.916	see above
New Jersey, Silt loam	0.90	6.3	8.6	955	0.921	see above
Nierswalde, Silt loam	1.63	6.5	17.9	1101	0.942	see above
LUFA 2.3, Sandy loam	1.09	6.9	5.7	527	0.875	see above
La Gironda, Silty Clay Loam	3.84	7.5	12.3	320	0.902	see above
California, Sandy Loam	0.41	7.6	2.5	603	0.900	see above
Arithmetic mean (whitout volcanic ash Obihiro)				729	0.914	

*) not considered

The K_{foc}/K_f values of Fluxapyroxad do not show any pH dependency.

Metabolite M700F001

Table 5.4-9: K_f, K_{foc} and 1/n (Freundlich exponent) values for Metabolite M700F001

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
LUFA 2.1, Sand	0.52	5.2	0.02	4.2	0.715	Hassink, Stephahn 2009
Li 10, Loamy Sand	0.88	5.9	0.03	3.6	1.047	see above
New Jersey, Silt loam	0.90	6.3	0.03	3.4	0.914	see above
Nierswalde, Silt loam	1.63	6.5	0.11	6.7	1.002	see above
LUFA 2.3, Sandy loam	1.09	6.9	0	0	1	see above
La Gironda, Silty Clay Loam	3.84	7.5	0	0	1	see above
California, Sandy Loam	0.41	7.6	0	0	1	see above
Arithmetic mean (whitout volcanic ash Obihiro*)				2.6	0.954	

*) The data for Obihiro are nor presented here, because they were not used.

Metabolite M700F002

Table 5.4-10: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M700F002

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
LUFA 2.1, Sand	0.52	5.2	0.07	13.1	0.969	Hassink, Stephan 2009

Li 10, Loamy Sand	0.88	5.9	0.04	4.8	0.842	see above
New Jersey, Silt loam	0.90	6.3	0.13	14.1	1.165	see above
Nierswalde, Silt loam	1.63	6.5	0.15	9	0.937	see above
LUFA 2.3, Sandy loam	1.09	6.9	0.06	5.6	1.078	see above
La Gironda, Silty Clay Loam	3.84	7.5	0.04	1	0.99	see above
California, Sandy Loam	0.41	7.6	0.02	5.6	0.764	see above
Arithmetic mean (whitout volcanic ash Obihiro)*				7.6	0.964	

*) The data for Obihiro are not presented here, because they were not used.

Epoxiconazole

A new study (Zirnstein 2005, see Appendix III) has been submitted regarding adsorption/desorption in soil of Epoxiconazole. The exposure modeling is based on this study together with the values already given in the LoEP. The K_{foc} values are summarized in Table 5.4-11

Table 5.4-11: K_f, K_{foc} and 1/n (Freundlich exponent) values for Epoxiconazole

Soil Type	**OC (%)**	**pH (water)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
Stand. Boden 2.1 (Sand)	0.5	6.0*	4.79	957	0.766	LoEP, Ochsenbein (1988)
Les Evouetttes* (Sandy loam)	0.74	4.75*	19.59	2647	0.813	
Itingen/BL* (Clay/Clay loam)	1.98	6.87*	21.78	1100	0.808	
Sp 3A, Altlußheim (Silty loam)	2.6	7.6	7.25	280	0.882	LoEP, Seher (2002)
Sp 6S, Siebeldingen (Clayey loam/clay)	2.0	7.3	7.50	380	0.910	
sand / loamy sand (Utrera, Spain)	0.42	6.4	8.24	1962	0.846	Zirnstein (2005)
loamy sand (Li 10 (1680), Germany)	0.87	7.3	9.27	1065	0.859	
sandy loam / loam (Forst H6, Germany)	1.61	7.4	14.8	922	0.882	
loam (LUFA 3A, Germany)	2.54	7.8	17.8	702	0.839	
sandy loam (LUFA 5M, Germany)	1.46	7.9	13.5	928	0.849	
Arithmetic mean				1093	0.845	

*) no information given if pH was determined in water or $CaCl_2$

Metabolite 1,2,4-Triazole

No new studies have been submitted regarding adsorption/desorption in soil of 1,2,4-triazole. The exposure modeling is based on the EU K_{foc} values as summarized in Table 5.4-11

Table 5.4-12: K_f, K_{foc} and 1/n (Freundlich exponent) values for 1,2,4-triazole

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Alpaugh (Silty clay)	0.696	8.8	0.833	120	0.897	Hawkins (1988)
Hollister (Clay Loam)	1.740	6.9	0.748	43	0.827	
Lawrenceville (Silty Clay Loam)	0.696	7.0	0.722	104	0.922	
Pachappa (Sandy Loam)	0.812	6.9	0.720	89	1.016	
Arithmetic mean				89	0.916	

5.4.3 Rate of degradation in water and sediment

Fluxapyroxad

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Fluxapyroxad (Ebert, 2003) reviewed in the DAR. The DT_{50} values of the water/sediment study are summarized in Table 5.4-14.

Table 5.4-13: Degradation in water/sediment of Fluxapyroxad

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DissT_{50}$/ water	Kinetic, Fit	$DissT_{50}$/ sed.	Kinetic, Fit	Reference
Berghauser Altrhein Speyer, Germany	>1000 d	HS, 0.8	FOMC DT90/ 3.32=26.4 d	FOMC, 1.4	No decline		
Ranschgraben Schifferstadt, Germany	694 d/ >1000 d	SFO, 0.8	FOMC DT90/ 3.32=79.5 d	FOMC, 2.5	No decline		
input FOCUS surface water	1000 d		1000 d		1000 d		LoEP September 2005

Epoxiconazole

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment study of Epoxiconazole reviewed in the DAR. The DT_{50} values of the water/sediment study are summarized in Table 5.4-14.

Table 5.4-14: Degradation in water/sediment of Epoxiconazole

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DegT_{50}$ water	Kinetic, Fit	$DegT_{50}$ sed.	Kinetic, Fit	Reference
Millstream pond, clayey loam	172.4d / 573d	SFO, 0.997	38.4/ 127.6d	SFO 0.987	Stable 1000d (FOCUS default)	-	Schnöder 2003 (LoEP)
Swiss Lake, sand	67.5d/ 224d	SFO, 0.989	93.1d/ 309.4d	SFO 0.987	61.4d/ 204d	SFO 0.975	Schnöder 2003 (LoEP
Geometric mean	107.9d		59.8		248		

Table 5.4-15: Degradation in water/sediment of metabolite BF 480-entriazole

Water/sediment system	$DegT_{50}$ / $DegT_{90}$ whole system	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ water	Kinetic, Fit	$DissT_{50}$/ $DegT_{50}$ sed.	Kinetic, Fit	Reference
Millstream pond, clayey loam	-	--	--	-	31.6		Schnöder 2003 (LoEP)
Swiss Lake, sand	-	-	-	-	65.2		Schnöder 2003 (LoEP

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

Table 5.5-1: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	BAS 701 00F
Crop:	**cereals**
Application rate:	a.i.: 125 g/ha; product: 2L/ha*1.036 (rel. density)
Number of application/interval:	2/ 21
Crop interception:	70%/ 90%

Table 5.5-2: Input parameter for active substance for PEC_{soil} calculation

Active substance	DT_{50}	value in accordance to EU endpoint

Fluxapyroxad	370 d (alpha:0.2056, beta: 13.1342) (field, worst case, non-normalised, see Table 5.4.-2)	Yes
Metabolite M700F001	10 d (non-normalised worst case laboratory studies)	yes
Metabolite M700F002	39.2 d (field, worst case, non-normalised, see Table 5.4.-3)	yes
Epoxiconazole	226 d (field, worst case, non-normalised)	yes
Metabolite 1,2,4-Triazole	parameters for DFOP 28.1d: k1=0.0632. k2=0.0020 g =0.5732 (field, worst case s, non-normalised)	No, the new field study (Tarara, 2010) was considered
BAS 701 00F	226 d	

Due to the slow degradation of Fluxapyroxad and Epoxiconazole in soil (DT_{90} > 365 d, field data) the accumulation potentials of Fluxapyroxad and Epoxiconazole need to be considered. Therefore an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} for a soil depth of 5 cm.

Beside PEC_{act} values also PEC_{twa}, 21 d values are required for risk assessment. PEC_{twa},21 d values are also presented in Table 5.5-3

Table 5.5-3: Results of PEC_{soil} calculation for application of BAS 701 00 F in cereals (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm)

active substance/ preparation		PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	tillage depth (cm)	PEC_{bkgd} (mg/kg)	PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)
Fluxapyroxad		0.0578 on d21	0.0539	20	0.0148	0.0726
Metabolite M700F001	Ff=100%	0.0023 on d29	0.002220	20	0.0006	0.0029
Metabolite M700F002	Ff=100%	0.0046 on d49	0.0045	20	0.0013	0.0059
Epoxiconazole		0.0635 on d21	0.0615	20	0.0077	0.0712
Metabolite 1,2,4-Triazole	Ff=100%	0.0028 on d383	0.0028	20	0.0015	0.0043
BAS 701 00F/ Adexar	2.072 kg/ha	0.8228		20	0.0379	0.8667

5.6 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

PEC_{sw} and PEC_{sed} calculations are provided according to the recommendations of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways drainage and runoff.

Fluxapyroxad

The relevant input parameters used for PEC calculation are summarized in the tables below.

Table 5.6-1: Input parameters for Fluxapyroxad for $PEC_{sw/sed}$ calculations

Parameter	**Endpoint used for $PEC_{sw/sed}$ calculation**	**Values in accordance to EU endpoint in LoEP**	**Remarks**
Active substance	Fluxapyroxad		
Molecular weight (g/mol)	381.3		
Saturated vapour pressure (Pa)	2.7×10^{-9}		
Water solubility (mg/L)	3.44		
Kf,oc (mL g-1)	729		Arithmetic mean (see Table 5.4-3)
Freundlich Exponent 1/n	0.914		Arithmetic mean
DT_{50},soil (d)	151	yes	Geomean (1st order, pF2,20°C)
DT_{50},water (d)	1000	yes	
DT_{50},sed (d)	1000	yes	Default value
Metabolite	**M700F001**		
Max. occurrence in soil	12.1%		
Max. occurrence in water	10.9		
Molecular weight (g/mol)	176.1		
Water solubility (mg/L)	39990		
Kf,oc (mL g-1)	2.6		Arithmetic mean (see Table 5.4-3)
DT_{50},soil (d)	5.4	yes	Geomean (1st order, pF2,20°C)
DT_{50},water (d)	1000	yes	
DT_{50},sed (d)	1000	yes	Default value
Metabolite	**M700F002**		
Molecular weight (g/mol)	162		
Max. occurrence in soil	70.5 %		According to LoEP: max. formation, plus remaining parent and M700F001 in soil as still increasing at strudy termination
Water solubility (mg/L)	31580		
Kf,oc (mL g-1)	7.6		Arithmetic mean (see Table 5.4-3)
DT_{50},soil (d)	25.9	yes	Geomean (1st order, pF2,20°C)

DT_{50},water (d)	1000	yes	
DT_{50},sed (d)	1000	yes	Default value
Metabolite	**M700F007**		
Molecular weight (g/mol)	175.1		
Max. occurrence in water/ sediment	17.7		According to LoEP: max. formation, plus remaining parent in water phase as still increasing at strudy termination
Water solubility (mg/L)	39990		
Kf,oc (mL g-1)	1		Arithmetic mean (see Table 5.4-3)
DT_{50},soil (d)	1	yes	Geomean (1st order, pF2,20°C)
DT_{50},water (d)	1000	yes	
DT_{50},sed (d)	1000	yes	Default value

Table 5.6-2: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	BAS 701 00 F
Use No. .	**1-9**
Crop:	**cereals**
Application rate:	2x 125 g/ha
Number of application/interval:	2/21
Crop interception:	Average crop cover

Results of FOCUS SW Step 1 and Step 2 calculations for the worst-case application scenario of BAS 701 00 F are summarized in the tables below.

Table 5.6-3: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Fluxapyroxad for the application of BAS 701 00 F in cereals according to use No 1-9

Fluxapyroxad	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		44.56	316.34
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	5.18 (2.77 single application)	36.27 (19.35 single application)
	South Europe Mar.-May	9.14 (4.84 single application)	65.10 (34.46 single application)
Metabolite M700F001	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		4.76	0.12
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	0.25 (0.20 single application)	0.01(0.01 single application)

	South Europe Mar.-May	0.40(0.34 single application)	0.01 (0.01 single application)
Metabolite M700F002	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		24.71	1.88
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	1.74 (1.11 single application)	0.13 (0.08 single application)
	South Europe Mar.-May	3.49(2.22 single application)	0.26 (017 single application)
Metabolite M700F007	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/kg)**
		0.19	0.00
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	0.16 (0.09single application)	0.00 (0,00single application)
	South Europe Mar.-May	0.16 (0.09single application)	0.00 (0,00single application)

Results of FOCUS SW Step 3 calculations for the worst-case application scenario of BAS 701 00 F are summarized in the tables below.

Table 5.6-4: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of BAS 701 00 F in spring cereals

Crop	**Scenario**	**Emergence date**	**Possible window of application** (27 d after emergence until (27 d after emergence +51d)) **[DayNr- DayNr]**
Spring cereals	D1, ditch	5/5	152-203
	D1, stream	5/5	152-203
	D3, ditch	1/4	118-169
	D4, pond	26/4	116-167
	D4, stream	26/4	116-167
	D5, pond	15/3	74-125
	D5, stream	15/3	74-125
	R4, stream	15/3	74-125

Table 5.6-5: Global maximum FOCUS Step 3 PECsw and PECsed values for Fluxapyroxad for the application of BAS 701 00 F in spring cereals

crop	**FOCUS STEP 3 Scenario**	**PEC_{sw} global max (µg/L)**	**Application dates**	**PEC_{SED} global max (µg/kg)**
Spring cereals	D1, ditch	2.515	17.6/ 8.7.	26.716
	D1, stream	1.585	17.6/ 8.7.	14.371
	D3, ditch	0.693	4.5. / 27.5.	0.497
	D4, pond	0.567	26.4./ 30.5	4.605

	D4, stream	0.846	26.4./ 30.5	1.552
	D5, pond	0.294	8.4./ 1-5.	3.713
	D5, stream	0.607	8.4./ 1-5.	0.650
	R4, stream	3.516	21.3./ 4.5.	2.654

Table 5.6-6: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of BAS 701 00 F in winter cereals

Crop	Scenario	Emergence date	**Possible window of application** (169 d after emergence until (169 d after emergence +51d)) **[DayNr- DayNr]**
Winter cereals	D1, ditch	25/9	72-123
	D1, stream	25/9	72-123
	D2, ditch	25/10	102-153
	D2, stream	25/10	102-153
	D3, ditch	21/11	129-180
	D4, pond	22/9	69-120
	D4, stream	22/9	69-120
	D5, pond	10/11	118-169
	D5, stream	10/11	118-169
	D6, ditch	30/11	138-189
	R1, pond	12/11	120-171
	R1, stream	12/11	120-171
	R3, stream	1/12	139-190
	R4, stream	10/11	118-169

Table 5.6-7: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Fluxapyroxad for the application of BAS 701 00 F in winter cereals

crop	FOCUS STEP 3 Scenario	PEC_{sw} global max (µg/L)	Application dates	PEC_{SED} global max (µg/kg)
Winter cereals	D1, ditch	4.000	29.3./ 25.4	34.393
	D1, stream	2.550	29.3./ 25.4	19.005
	D2, ditch	3.001	7.5./ 2.6.	20.623
	D2, stream	1.875	7.5./ 2.6.	12.058
	D3, ditch	0.693	15.5./ 21.6.	0.509
	D4, pond	0.616	19.3./ 18.4.	4.922

	D4, stream	0.936	19.3./ 18.4.	1.787
	D5, pond	0.201	11.5./ 9.6.	2.344
	D5, stream	0.639	11.5./ 9.6.	0.439
	D6, ditch	0.718	18.5./ 8.6.	1.669
	R1, pond	0.288	30.4./ 13.6.	2.280
	R1, stream	1.856	30.4./ 13.6.	2.480
	R3, stream	2.061	1.6./ 22.6	1.252
	R4, stream	2.131	4.5./ 27.5.	1.777

5.6.1 Accumulation in sediment

The accumulation of Fluxapyroxad in sediment has to be considered. After 100 days 76% Fluxapyroxad was detected in the sediment in the water sediment study.

The factor for multiplying the maximum concentration in sediment to reach the plateau concentration of BAS 701 00 F in sediment at steady state (PECsed,plateau) is:

factor for accumulation (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	3.47 (DT50 = 1000)

where

k Degradation rate in sediment (ln(2)/DT50) [d^{-1}]

t Time interval between growing seasons (365 days)

The overall accumulation PEC in sediment (PECsed,accu,overall) after multi-year use of of BAS 701 00 F is the sum of the maximum concentration in sediment and the plateau concentration at steady state.

The highest concentrations in sediment are 26.716 µg/kg for the scenario D1, ditch with spring cereals, and 34.393 µg/kg for the scenario D1, ditch with winter cereals.

This concentrations together with the plateau concentrations in the sediment (concentration in sediment x 3.47) result to the PECs sediment accumulation overall:

26.716 µg/kg + 92.704 µg/kg= 119.42 µg/kg (D1, ditch with spring cereals)

34.393 µg/kg + 119.344 µg/kg= 153.737 µg/kg (D1, ditch with winter cereals).

Epoxiconazole

The relevant input parameters used for PEC calculation are summarized in the tables below.

Table 5.6-8: Input parameters for Epoxiconazole for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for PECsw/sed calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Epoxiconazole		
Molecular weight (g/mol)	329.8	Yes	
Water solubility (mg/L)	7.1		
Kf,oc (mL g-1)	1093		Arithmetic mean
Freundlich Exponent 1/n	0.845		Arithmetic mean
DT_{50},soil (d)	78.7		Geomean (1st order, pF2,20°C) Laboratory data
DT_{50},water (d)	59.8	yes	Geomean (1st order, 20°C)
DT_{50},sed (d)	248	No, use of default value of 1000 for system A (there stable)	
DT_{50},whole system (d)	107.9		
Metabolite	**BF 480 entriazole**		
Molecular weight (g/mol)	313.8		
Max. occurrence in water/sediment system	32.3%		
Max. occurrence in soil	0.01%		
Kf,oc (mL g-1)	1000		Default value, leads to transfer to the sediment
Water solubility (mg/L)	Value from parent		
DT_{50},soil (d)	1d		Metabolite did not occur in aerobic soil studies
DT_{50},whole system (d	1000 (default)		
DT_{50},water (d)	1000 (default)		
DT_{50},sed (d)	65.2		Worst-case value of two water/sediment studies
Metabolite	**1,2,4-triazole**		
Molecular weight (g/mol)	69.1		
Water solubility (mg/L)	700000		
Max. occurrence in water/sediment system	0.01%		

Max. occurrence in soil	100%		Conservative assumption
DT_{50},soil (d)	60.5		Geomean (slow) field studies
Kf,oc (mL g-1)	89		Arithmetic mean
DT_{50},whole system (d	1000 (default)		
DT_{50},water (d)	1000 (default)		
DT_{50},sed (d)	1000 (default)		

Table 5.6-9: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of BAS 701 00 F in spring cereals

Crop	**Scenario**	**Emergence date**	**Possible window of application** (27 d after emergence until (27 d after emergence +51d)) **[DayNr- DayNr]**
Spring cereals	D1, ditch	5/5	152-203
	D1, stream	5/5	152-203
	D3, ditch	1/4	118-169
	D4, pond	26/4	116-167
	D4, stream	26/4	116-167
	D5, pond	15/3	74-125
	D5, stream	15/3	74-125
	R4, stream	15/3	74-125

Table 5.6-10: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of BAS 701 00 F in winter cereals

Crop	**Scenario**	**Emergence date**	**Possible window of application** (169 d after emergence until (169 d after emergence +51d)) **[DayNr- DayNr]**
Winter cereals	D1, ditch	25/9	72-123
	D1, stream	25/9	72-123
	D2, ditch	25/10	102-153
	D2, stream	25/10	102-153
	D3, ditch	21/11	129-180
	D4, pond	22/9	69-120
	D4, stream	22/9	69-120
	D5, pond	10/11	118-169
	D5, stream	10/11	118-169

	D6, ditch	30/11	138-189
	R1, pond	12/11	120-171
	R1, stream	12/11	120-171
	R3, stream	1/12	139-190
	R4, stream	10/11	118-169

Results of FOCUS SW calculations for the worst-case application scenario of BAS 701 00 F are summarized in the tables below.

Table 5.6-11: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Epoxiconazole and metabolites for the application of BAS 701 00 F in cereals according to use No 1-9

Epoxiconazole	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		36.21	378.45
	FOCUS Step 2	PECsw (µg/L)	PECsed (µg/L)
	North Europe, Mar.-May	3.92 (2.20 single application)	40.80 (22.79 single application)
	South Europe Mar.-May	6.92 (3.84 single application)	73.47 (40.63 single application)
Metabolite BF 480 entriazole	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		0.71	3.06
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	0.46 (0.35 single application)	2.46 (1.47 single application)
	South Europe Mar.-May	0.46 (0.35 single application)	2.46 (1.47 single application)
Metabolite 1,2,4-triazole	**FOCUS Step 1**	**PECsw (µg/L)**	**PECsed (µg/L)**
		15.61	13.89
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe, Mar.-May	1.33 (0.75 single application)	1.19 (0.66 single application)
	South Europe Mar.-May	2.66 (1.49 single application)	2.37 (1.335 single application)

Table 5.6-12: Global maximum FOCUS Step 3 PECsw and PECsed values for Epoxiconazole for the application of BAS 701 00 F in spring cereals

crop	FOCUS STEP 3 Scenario	PEC_{sw} global max (µg/L)	Application dates	PEC_{SED} global max (µg/kg)
Spring cereals	D1, ditch	1.067	17.6/ 8.7.	6.798
	D1, stream	0.607	17.6/ 8.7.	3.25
	D3, ditch	0.692	4.5. / 27.5.	0.659
	D4, pond	0.0493	26.4./ 30.5	0.691
	D4, stream	0.566	26.4./ 30.5	0.221

	D5, pond	0.0378	8.4./ 1-5.	0.331
	D5, stream	0.591	8.4./ 1-5.	0.0452
	R4, stream	2.211	21.3./ 4.5.	3.311

Table 5.6-13: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Epoxiconazole for the application of BAS 701 00 F in winter cereals

crop	FOCUS STEP 3 Scenario	PEC_{sw} global max (µg/L)	Application dates	PEC_{SED} global max (µg/kg)
Winter cereals	D1, ditch	1.000	29.3./ 25.4	7.004
	D1, stream	0.739	29.3./ 25.4	3.935
	D2, ditch	0.802	7.5./ 2.6.	4.592
	D2, stream	0.670	7.5./ 2.6.	3.415
	D3, ditch	0.693	15.5./ 21.6.	0.671
	D4, pond	0.0434	19.3./ 18.4.	0.627
	D4, stream	0.542	19.3./ 18.4.	0.210
	D5, pond	0.0252	11.5./ 9.6.	0.300
	D5, stream	0.638	11.5./ 9.6.	0.204
	D6, ditch	0.720	18.5./ 8.6.	2.221
	R1, pond	0.176	30.4./ 13.6.	1.610
	R1, stream	1.154	30.4./ 13.6.	3.298
	R3, stream	0.973	1.6./ 22.6	1.377
	R4, stream	1.241	4.5./ 27.5.	2.330

As supplemental information the results of the PECSW and PECsed calculations on Step 3 and Step 4 level of the notifier are described in Appendix 3, KIII 9.7.1/2(Spickermann, 2010). The results differ because of slightly different inputs and application dates. Additionally not all scenarios are given there.

5.6.2 Accumulation in sediment

The accumulation of Epoxiconazole in sediment has to be considered. After 100 days 61% Epoxiconazole was detected in the sediment in the water sediment study.

The factor for multiplying the maximum concentration in sediment to reach the plateau concentration of BAS 701 00 F in sediment at steady state (PECsed,plateau) is:

factor for accumulation (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	0.3 (DT50 = 172.4)

where

k Degradation rate in sediment (ln(2)/DT50) [d^{-1}]

t Time interval between growing seasons (365 days)

The overall accumulation PEC in sediment (PECsed,accu,overall) after multi-year use of of BAS 701 00 F is the sum of the maximum concentration in sediment and the plateau concentration at steady state.

Table 5.6-14: Overall accumulation PEC for Epoxiconazole for the application of BAS 701 00 F in spring cereals

crop	FOCUS STEP 3 Scenario	PEC_{SED} global max (µg/kg)	PEC_{SED} plateau= 0.3 x PEC_{SED}	PEC_{SED}, accu, overall= PEC_{SED} + PEC_{SED} plateau
Spring cereals	D1, ditch	6.798	2.0394	8.8374
	D1, stream	3.25	0.975	4.225
	D3, ditch	0.659	0.1977	0.8567
	D4, pond	0.691	0.2073	0.8983
	D4, stream	0.221	0.0663	0.2873
	D5, pond	0.331	0.0993	0.4303
	D5, stream	0.0452	0.01356	0.05876
	R4, stream	3.311	0.9933	4.3043

Table 5.6-15: Overall accumulation PEC for Epoxiconazole for the application of BAS 701 00 F in winter cereals

crop	FOCUS STEP 3 Scenario	PEC_{SED} global max (µg/kg)	PEC_{SED} plateau= 0.3 x PEC_{SED}	PEC_{SED}, accu, overall= PEC_{SED} + PEC_{SED} plateau
Winter cereals	D1, ditch	7.004	2.1012	9.1052
	D1, stream	3.935	1.1805	5.1155
	D2, ditch	4.592	1.3776	5.9696
	D2, stream	3.415	1.0245	4.4395
	D3, ditch	0.671	0.2013	0.8723
	D4, pond	0.627	0.1881	0.8151
	D4, stream	0.210	0.063	0.273
	D5, pond	0.300	0.09	0.39
	D5, stream	0.204	0.0612	0.2652
	D6, ditch	2.221	0.6663	2.8873
	R1, pond	1.610	0.483	2.093
	R1, stream	3.298	0.9894	4.2874
	R3, stream	1.377	0.4131	1.7901
	R4, stream	2.330	0.669	3.029

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and metabolites (Tier 1 and 2)

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC of Fluxapyroxad and the metabolites M700F001 and M700F002 in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

plant protection product	BAS 701 00 F
.	
application rate (kg as/ha)	0.0375 and 0.0125 (interception considered)
crop (crop rotation)	Cereals spring, winter cereals
relative application date	27 d and 48d after emergence (spring cereals), 169 d and 190 d after emergence (winter cereals)
interception (%)	70% and 90%
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Fluxapyroxad

Table 5.7-2: Input parameters related to active substance for PEC_{GW} modelling

Parent	**Fluxapyroxad**	**Remarks/Reference**
molecular weight (g/mol)	381.3	
DT_{50} in soil (d)	151 slow / 59.5 fast	
K_{foc}	729	
1/n	0.914	
plant uptake factor	0	

Table 5.7-3: Input parameters related to metabolites of Fluxapyroxad for PEC_{GW} modelling

Metabolite 1	**M700F001**	**Remarks/Reference**

molecular mass	176.1	
Formation fraction	1	
DT_{50} in soil (d)	5.4	
K_{foc}	2.6	
1/n	0.954	
plant uptake factor	0	
Metabolite 2	**M700F002**	**Remarks/Reference**
molecular mass	162.1	
Formation fraction	1	
DT_{50} in soil (d)	25.9	
K_{foc}	7.6	
1/n	0.964	

Table 5.7-4: PEC_{GW} at 1 m soil depth for Fluxapyroxad and its metabolites for the application of BAS 701 00 F in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Group A/use No. 1-9	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3		
		Fluxapyroxad	Metabolite M700F001 (max . amount of slow/ fast DT50 of ai)	Metabolite M700F002 (max. amount of slow/ fast DT_{50} of ai)
Winter cereals	Châteaudun	<0.001	0.015	**0.634**
	Hamburg	0.001	**0.231**	**2.106**
	Jokioinen	<0.001	**0.375**	**2.678**
	Kremsmünster	<0.001	0.068	**1.318**
	Okehampton	0.002	**0.121**	**1.362**
	Piacenza	0.001	0.091	**1.033**
	Porto	<0.001	**0.138**	**0.923**
	Sevilla	<0.001	**0.021**	**0.340**
	Thiva	<0.001	**0.025**	**0.471**
spring cereals	Châteaudun	<0.001	0.016	**0.538**
	Hamburg	0.001	**0.215**	**2.00**
	Jokioinen	<0.001	**0.392**	**2.474**
	Kremsmünster	<0.001	0.068	**1.283**
	Okehampton	0.001	**0.114**	**1.261**
	Porto	<0.001	**0.126**	**0.839**

According to the PECGW modelling with FOCUSPELMO 5.5.3 a groundwater contamination of the active substance Fluxapyroxad at a concentration of ≥ 0.1 µg/L is not expected for all FOCUS groundwater scenarios in case of winter cereals (Châteaudun, Hamburg, Jokoinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva) and all the FOCUS groundwater scenarios with spring cereals (Châteaudun, Hamburg, Jokoinen, Kremsmünster, Okehampton, and Porto) respectively.

For the metabolite M700F001 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in case of winter cereals and pring cereals for the FOCUS groundwater scenarios Hamburg, Jokoinen, Okehampton, and Porto.

For the metabolite M700F002 a groundwater concentration of ≥ 0.75 µg/L cannot be excluded for the FOCUS groundwater scenarios with winter cereals except Châteaudun and cannot be excluded for the FOCUS groundwater scenarios with spring cereals except Châteaudun.

An assessment of the relevance of both metabolites is necessary.

Epoxiconazole

The PEC of Epoxiconazole and the metabolite 1,2,4-Triazole in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO.

The DT_{50} values of the metabolite 1,2,4-Triazole are calculated with DFOP kinetics.

If degradation follows a bi-phasic kinetic FOCUS (2006) recommends splitting the application rate according to the factor g of the DFOP kinetic of the metabolite. Afterwards two separate simulations according to the split application rate for the fast and slow degradation are performed. Breaking the pesticide into two fractions introduces a small error when the Freundlich exponent is not one. However, a conservative estimate can be made when the Freundlich exponent is not one by doubling the application rate and then dividing the final answer by two (FOCUS, 2006).

plant protection product	BAS 701 00 F
application rate (kg as/ha)	0.0375 and 0.0125 (interception considered) After Duplication : 0.075 and 0.025 Fast: (0.075 and 0.025) x g= 0.037 and 0.012 Slow: (0.075 and 0.025) x (1-g)= 0.038 and 0.013
crop (crop rotation)	Cereals spring, winter cereals
relative application date	27 d and 48d after emergence (spring cereals), 169 d and 190 d after emergence (winter cereals)

Table 5.7-5: Input parameters related to active substance for PEC_{GW} modelling

Parent	Epoxiconazole	Remarks/Reference
molecular weight (g/mol)	329.8	
DT_{50} in soil (d)	78.7	

K_{foc}	1093	
1/n	0.845	
plant uptake factor	0.5	LoEP

Metabolite 1	1,2,4-Triazole	Remarks/Reference
molecular mass	69.1	
Formation fraction	1	
DT_{50} in soil (d)	1.7 (fast) / 60.5 (slow), g= 0.489, 1-g= 0.511	
K_{foc}	89	
1/n	0.916	
plant uptake factor	0	

Table 5.7-6: PEC_{GW} at 1 m soil depth for Epoxiconazole and its metabolite for the application of BAS 701 00 F in cereals (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Group A/use No. 1-9	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3		
		Epoxiconazole	1,2,4-Triazole	
Winter cereals	**Châteaudun**	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.009 0.0045
	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.088 0.044
	Jokioinen	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.034 0.017
	Kremsmünster	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.055 0.0275
	Okehampton	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.078 0.039
	Piacenza	<0.01	Fast:	<0.01

			Slow: (fast+slow) / 2:	0.053 0.0265
	Porto	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.069 0.0345
	Sevilla	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 <0.001 <0.01
	Thiva	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.004 0.002
spring cereals	**Châteaudun**	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.006 0.003
	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.083 0.0415
	Jokioinen	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.026 0.013
	Kremsmünster	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.049 0.0245
	Okehampton	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.067 0.0335
	Porto	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.054 0.027

According to the PEC_{GW} modelling with FOCUS PELMO 5.5.3 a groundwater contamination of the active substance Epoxiconazole at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenariosL.

For the metabolite 1,2,4-Triazole a groundwater concentration of ≥ 0.1 µg/L can be excluded in the FOCUS groundwater scenarios with spring and winter cereals.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance Fluxapyroxad is < 10^{-5} Pa. Hence the active substance Fluxapyroxad is regarded as non-volatile.

The vapour pressure at 20 °C of the active substance Epoxiconazole is < 10^{-5} Pa. / Hence the active substance Epoxiconazole is regarded as non-volatile.

Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance due to volatilization with subsequent deposition does not need to be considered e.g. using the program EVA.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
KIIIA 9.2.1/1	Tarara G.	2010 a	Determination of the residues of 1,2,4-Triazole in/on soil after spraying of 1,2,4-Triazole (1000 XX) in the field in Germany, Italy, Great Britain, and Spain Bayer CropScience AG, Monheim, Germany Fed.Rep. RA-2145/04 Yes Unpublished	Yes	TF	1)
KIIIA 9.2.1/2	Chapple A.C.	2010 a	Kinetic evaluation of the dissipation in soil of 1,2,4-Triazole under field conditions Bayer CropScience AG, Monheim, Germany Fed.Rep. MEF-10/069 No, not subject to GLP regulations Unpublished	No	TF	1)
KIIIA 9.3/1	Zirnstein M.	2005 a	Adsorption/desorption-study of BAS 480 F (Reg.No. 205 259) on five European soils BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2005/1012874 Yes Unpublished	Yes	BASF	1)
KIIIA 9.7.1/2	Spickermann G.	2010 c	Predicted environmental concentrations of BAS 480 F - Epoxiconazole and its metabolites in surface water and sediment following application to cereals and sugar beets BASF SE, Limburgerhof, Germany Fed.Rep.	No	BASF	5)

			2010/1093142 No, not subject to GLP regulations Unpublished			

*

1) accepted (study valid and considered for evaluation)

2) not accepted (study not valid and not considered for evaluation)

3) not considered (study not relevant for evaluation)

4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)

5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

Present the authority's evaluation of the study below each individual study.

KIIA 7 Fate and Behaviour in the Environment – Active Substance

KIIA 7.4/ KIIIA 9.3 Zirnstein M., 2005a

Reference:	9.3
Author:	Zirnstein M
Report:	Adsorption/desorption-study of BAS 480 F (Reg.No. 205 259) on five European soils
Date:	2005
Guideline(s):	OECD 106, EPA 163-1, EPA 540/9-82-021
Deviations:	-
GLP:	Yes
Acceptability:	Yes

<u>Materials and methods</u>

In laboratory batch experiments, the adsorption / desorption behaviour of radiolabelled epoxiconazole was investigated on five European soils. The five soils covered a range of pH (CaCl2) from 5.9 to 7.3, a range of organic carbon content from 0.42 % to 2.54 % and five different USDA textural classes: sand/loamy sand, loamy sand, sandy loam/loam, loam, and sandy loam.

For the determination of the adsorption isotherm, five different concentrations (2.33, 0.92, 0.23, 0.09 and 0.018 µg/ml) of the test item in 0.01 M CaCl2 solutions were used. The ratio of soil versus test solution was 1/4, and the measurements were performed at the adsorption equilibrium time of 24 hours for the five soils. The desorption part was carried out in two steps with the soil residue remaining from the adsorption isotherm determination by adding 0.01 M CaCl2 solution without test items.

The following adsorption parameters were measured for the test item epoxiconazole in each soil: distribution coefficients Kd and Koc at five concentration levels, the Freundlich adsorption coefficient Kf, the Freundlich exponent 1/n, and the corresponding Kfoc values.

<u>Results and discussions</u>

The Freundlich adsorption coefficients KF covered a range from 8.24 to 17.8 mL g-1 for the five soils. The lowest value was found with Utrera soil and the highest value with LUFA 3A soil. The corresponding Kfoc values ranged from 702 mL g-1 (LUFA 3A) to 1962 mL g-1 (Utrera soil). Ranging from 1/n = 0.839 to 0.882, the Freundlich adsorption exponent indicated a significant a non-linearity of the adsorption with the concentration.

Table A 2: Results from the adsorption experiments with epoxiconazole

Soil	Soil Type (USDA)	TOC (%)	pH ($CaCl_2$)	K_f (mL g^{-1})	1/n	K_{foc} (mL g^{-1})	K_d (mL g^{-1})	K_{oc} (mL g^{-1})
Utrera	sand / loamy sand	0.42	5.9	8.24	0.846	1962	10.3	2451
Li 10 (1680)	loamy sand	0.87	6.6	9.27	0.859	1065	11.3	1304
Forst H6	sandy loam / loam	1.61	7.1	14.8	0.882	922	18.2	1130
LUFA 3A	loam	2.54	7.3	17.8	0.839	702	24.0	945
LUFA 5M	sandy loam	1.46	7.3	13.5	0.849	928	17.8	1217

Comments of zRMS

acceptable

KIIIA1 9 Fate and Behaviour in the Environment – Plant protection product

KIIIA 9.2.1/1. Tarara G., 2010a

Reference:	9.2.1/1,
Author:	Tarara G., 2010a
Report:	Determination of the residues of 1,2,4-Triazole in/on soil after spraying of 1,2,4-Triazole (1000 XX) in the field in Germany, Italy, Great Britain, and Spain
Date:	2010
Guideline(s):	EEC 95/36 of 14 July 1995 amending 91/414/EEC, BBA IV 4-1, ECPA Guidance Document on Field Soil Dissipation Studies Aug. 1997, SETAC Procedures for assessing the environmental fate and ecotoxicity for pesticides (March 1995
Deviations:	-
GLP:	Yes
Acceptability:	Yes

Materials and methods

The dissipation of 1,2,4-triazole in soil under European field conditions was investigated after application on bare soil plots at four sites in Burscheid (Germany), Albaro (Italy), Little Shelford (Great Britain) and Vilobi d'Onyar (Spain). The sites were typical for the intended major uses of triazole-containing products and for the ecoregions of Northern and Southern Europe.

1,2,4-triazole was sprayed as an aqueous solution "1000 XX" once onto bare soil plots at a nominal test concentration of 66.7 µg/kg soil, corresponding to a nominal rate of 100 g test item/ha when assuming a soil density of 1.5 g/mL and a soil depth of 10 cm. After incorporation of 1,2,4-triazole residues into soil the actual rates applied were determined to 59-87% of the nominal application rate (day 0 soil analysis). The distance of control plots to treated plots was 5 m to 9.5 m. Dose verification conducted via application monitors yielded an average recovery of 86% of the target rate over all sites.

Grass was sown at the test plots shortly after application. The grass was kept short and later on mulched at three test sites with an exception for site Vilobi d'Onyar where no grass emerged in the course of the study. No irrigation was performed at any of the test sites in the course of the study.

Soil samples were taken 0 to 454 days post-application to a maximum depth of 50 cm. All soil specimens were stored at about -18°C within a maximum of 24 hours of being taken and remained frozen until analysis. Frozen soil cores were cut into 10 cm sections and soil segments of the same depth were pooled and homogenised and a representative portion of each depth was taken for residue analysis.

The soil samples were extracted in a heated ultrasonic bath at a temperature of 65 to 75°C with a mixture of acetonitrile/water (6/4, v/v) for one hour. After derivatisation to dansyl-triazole the triazole residues were determined by HPLC-MS/MS using internal stable labelled standards. The LOD and LOQ for 1,2,4-triazole in soil were 1.0 µg/kg and 3.0 µg/kg, respectively.

Residue values of 1,2,4-triazole in µg/kg dry soil were converted to residue rates in g/ha taking into account the standard soil density of 1.5 g/cm³, and were summed up for all depths between 0 and 50 cm analysed. Residue values were not corrected for procedural recoveries.

Results and discussions

The analytical results based on the measured residues for the whole soil profile in terms of [g/ha] are shown in Table A 3

Table A 3 Total residues of 1,2,4-triazole under field conditions in soil calculated to g/ha based on standard soil density and summed up for all depths analysed

R 2004 0876/5 (VGO8) Germany		R 2004 0877/3 (IT09) Italy		R 2004 0917/6 (ENG2) Great Britain		R 2004 0918/4 (SPA1) Spain	
Days after treatment	Mean value [g/ha]	Days after treatment	Mean value [g/ha]	Days after treatment	Mean value [g/ha]	Days after treatment	Mean value [g/ha]
0	87.5	0	63.3	0	63.8	0	59.3
1	58.5	1	62.0	1	64.1	1	48.3
3	53.0	3	40.7	2	37.7	3	44.9
8	52.8	7	45.3	7	34.7	8	46.0
14	30.3	14	29.6	14	24.6	16	27.0
28	31.2	25	35.6	28	31.1	28	34.4
59	15.5	60	20.6	63	9.6	64	17.1
91	10.5	90	16.7	91	6.0	93	18.3
121	14.1	119	14.3	135	6.6	132	23.4
185	11.7	180	10.5	191	3.9	210	17.9
364	5.3			364	0.8	330	11.1
451	4.8			454	0.0	415	10.7

The data for the test item 1,2,4-triazole were evaluated with the program KinGUI v. 1.1. The initial concentration at day 0 was included in the parameter optimisation procedure. Based on the chi2 confidence criterion and visual assessment the best fit kinetic model was chosen for the disappearance time evaluation. The calculated data are based on the quantifiable residues for the whole soil profile in terms of grams per hectare [g/ha]. A summary of results is given in Table A 4 with best fits highlighted in bold letters.

Table A 4: 1,2,4-triazole: calculation of disappearance times

Location	Kinetic Model	DT_{50} [days]	DT_{90} [days]	Visual Assessment	Chi^2
Burscheid R 2004 0876/5, VG08	SFO	22.9	75.9	-	24.9
	FOMC	**7.8**	**366.7**	**+**	**15.2**
	DFOP	11.3	241.6	o	18.5
Albaro R20040877/3, 1T09	SFO	48.8	162.2	o	17.9
	FOMC	16.3	>1000	+	11.3
	DFOP	**21.2**	**207.4**	**+**	**10.7**
Little Shelford R 2004 0917/6, ENG2	SFO	21.8	72.3	o	25.4
	FOMC	8.1	188.4	+	20.2
	DFOP	**6.8**	**109.3**	**+**	**17.8**
Vilobi d'Onyar R 2004 0918/4, SPA1	SFO	85.6	284.4	o	21.8
	FOMC	28.6	>1000	+	12.6
	DFOP	**28.1**	**717.6**	**+**	**13.3**

**VisuaI assessment: + = good o = medium - = bad*

Comments of zRMS

acceptable

KIIIA 9.2.1/2 Chapple A.C., 2010a

Reference:	9.2.1/1,
Author:	Chapple A.C., 2010a
Report:	Kinetic evaluation of the dissipation in soil of 1,2,4-Triazole under field conditions
Date:	2010
Guideline(s):	FOCUS Kinetics (2006)
Deviations:	-
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

Materials and methods

Half-lives were obtained after the normalisation of experimental data from four field studies to standard FOCUS reference conditions (20°C and 100% field capacity). Kinetic parameters were derived following the FOCUS kinetic guidance (2006).

Results

It was found that the degradation of 1,2,4-triazole can be described with the double first order in parallel (DFOP) kinetic model. Normalised DT50 values range from 25.1 to 126 days, derived from the slow phase of the DFOP kinetics, and from 0.5 to 4.6 days from the fast phase of DFOP kinetics.

Table A 5: FOCUS normalised field DT50 values of 1,2,4-triazole (referenced to 20 °C and 100% FC), appropriate for modelling

Location	**Model fitted:**	**Fast Phase (k_1) DT_{50} [d]**	**Slow Phase (k_2) DT_{50} [d]**	**"g"** [a]
Höfchen, DE	DFOP	2.5	70.7	0.655 [b]
Albaro, IT	DFOP	1.4	59.8	0.364
Little Shelford, UK	DFOP	0.5	25.1	0.458
Vilobi, SP	DFOP	4.6	126.0	0.477
Geometric mean:		1.68	60.5	0.489 [c]

Comments of zRMS

acceptable

KIIA 9.7.1 Spickermann, 2010

Reference:	9.7.1/2
Author:	Spickermann G., 2010c
Report:	Predicted environmental concentrations of BAS 480 F - Epoxiconazole and its metabolites in surface water and sediment following application to cereals and sugar beets
Date:	2010
Guideline(s):	FOCUS Kinetics (2006)
Deviations:	-
GLP:	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC SANCO/4802/2001 rev.2 245 pp.
Acceptability:	No, not subject to GLP regulations

Predicted environmental concentrations in surface water and sediment (PECsw and PECsed) were calculated for epoxiconazole according to the guidance of the FOCUS working group on surface water scenarios [FOCUS (2001)] following a twofold application of BAS 701 00 F to winter and spring cereals.

At Step 3, calculations are performed with the software tool SWASH (Surface WAter Scenarios Help). Within SWASH, the models PRZM and MACRO calculate water and substance fluxes that enter the water body via runoff/erosion and drainage, respectively. The model TOXSWA simulates the fate of the pesticide in the water body following loading caused by spray drift deposition and either runoff/erosion or drainage. The software PAT (Pesticide Application Tool) is implemented in the SWASH shell to determine actual application dates. The model selects appropriate dates from an application window that is specified by the user according to BBCH range, number of applications and interval between applications as given in the GAP. All models are described in FOCUS (2001).

At Step 4, the software tool SWAN (Surface Water Assessment eNabler) is used to prepare and run Step 4 calculations. SWAN creates step 4 input files for TOXSWA by modifying available Step 3 files according to mitigation measures specified by the user. Drift mitigation can be specified by selecting buffer zones of different width from the SWAN spray drift mitigation page, while runoff mitigation can be defined by manual input of reduction factors for runoff volume, erosion mass and runoff/erosion flux on the respective SWAN page. The model calculates reduced spray drift values and mass loadings that are written in Step 4 input files and then runs TOXSWA to obtain refined PEC values. The model is described in Goerlitz et al. (2007) [Goerlitz, G.; Rainbird, P.; Mackay, N.; Erzgraeber, B.; Davies, T. (2007) "A software tool for FOCUS step 4 surface water calculations." 17. SETAC Europa Annual Meeting, 20. - 24.05.2007 Porto/Portugal] and guidance on implementing mitigation in the model runs is given in the recommendations of the FOCUS workgroups on surface water [FOCUS (2001)] and landscape and mitigation factors [FOCUS (2007a) "Landscape And Mitigation Factors In Aquatic Assessment. Volume 1. Extended Summary and Recommendations." Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Assessment, EC Document Reference SANCO/10422/2005 v2.0, FOCUS (2007b): “Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 2. Detailed Technical Reviews”. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0].

For all calculations, the most recent model versions available at the time of report preparation were used: STEPS1-2 in FOCUS version 1.1, FOCUS-PRZM version 1.1.1, FOCUS-MACRO version 4.4.2 and FOCUS-TOXSWA version 3.3.1. The modelling runs were set up with SWASH version 3.1 and SWAN version 1.1.4.

For a summary of the environmental fate parameters of epoxiconazole used in model calculation on Step 3 to 4 level of the assessment, see Table A 6 below.

Table A 6 Summary of FOCUS input parameters for epoxiconazole

Parameter	Value	Remarks
Entry routes into surface water	Spray drift Runoff Drainage	-
Molecular weight [g mol^{-1}]	329.8	Phys.-chem. properties
Water solubility [mg L^{-1}]	7.1 (20°C)	Phys.-chem. properties
Vapor pressure [Pa]	3.5 x 10^{-7} (20°C)	Phys.-chem. properties
	DEGRADATION IN SOIL	
DT_{50} soil [d]	74	Geometric mean of field studies (n=8, standardised at 20°C)
Temperature correction function Reference temperature [°C] MACRO: [K^{-1}] PRZM: Q_{10} [-]	 20 0.095 2.58	EFSA opinion
Moisture correction function Reference moisture [-] PRZM / MACRO: moisture exponent [-]	 pF 2 0.7	FOCUS recommendation
SORPTION TO SOIL		
$K_{f,oc}$ [mL g^{-1}]	1073	Arithmetic mean (n=5)
1/n [-]	0.836	Arithmetic mean (n=5)
	DEGRADATION IN AQUATIC SYSTEMS	
DT_{50} whole system [d] (Step 1)	107.9	Geometric mean of two water/sediment studies
DT_{50} water [d] (Step 2, Step 3, Step 4)	59.8	Geometric mean of two water/sediment studies
DT_{50} sediment [d] (Step 2, Step 3, Step 4)	61.4	Value of the 'Swiss Lake' water/sediment system
DT_{50} crop [d] (Step 3, Step 4)	10	FOCUS recommendation
Temperature correction function Reference temperature [°C] TOXSWA: activation energy [J mol^{-1}]	 20 65400	EFSA opinion
	MANAGEMENT RELATED PARAMETERS	
Crop uptake factor [-]	0.5	FOCUS recommendation
Wash off coefficient PRZM: [cm^{-1}] MACRO: [mm^{-1}]	 0.05 0.5	FOCUS recommendation

The detailed application timing used for the calculations is shown in Table A 7.

Table A 7: Application timing for epoxiconazole in winter and spring cereals in the FOCUS scenarios (Step 3 and 4)

Scenario	Water body	Application window	Application dates according to PAT*
Winter cereals			
D3 - Vredepeel	ditch	15th March – 5th May (15th March – 14th April)**	16th March / 6th April (16th March)#
D4 - Skousbo	pond, stream	15th March – 5th May (15th March – 14th April)**	19th March / 18th April (19th March)#
D5- - La Jaillière	pond, stream	15th March – 5th May (15th March – 14th April)**	8th April / 1st May (8th April)#
R1 - Weiherbach	pond, stream	15th March – 5th May (15th March – 14th April)**	17th March / 26th April (17th March)#
R3 - Bologna	stream	15th February – 7th April (15th February – 17th March)**	19th February / 20th March (19th February)#
Spring cereals			
D3 - Vredepeel	ditch	15th May – 5th July (15th May – 14th June)**	14th May / 15th June (14th May)#
D4 - Skousbo	pond, stream	15th May – 5th July (15th May – 14th June)**	30th May / 4th July (30th May)#
D5- - La Jaillière	pond, stream	15th May – 5th July (15th May – 14th June)**	27th May / 18th June (27th May)#

Automatic calculation of application dates by PAT can lead to deviations from proposed intervals as application dates must match the climate criteria for an appropriate accordance to FOCUS guidance.
** in parenthesis: application window for a single application
# in parenthesis: application date for a single application

The global maximum concentrations of epoxiconazole after single and twofold application to winter and spring cereals are shown in Table A 8 to Table A 13.

Table A 8: Step 3 and 4: Global maximum concentrations of epoxiconazole in surface water following single application to winter cereals, considering spray drift and runoff mitigation at Step 4

Winter cereals Single application						
			Step 3	Step 4		
				Buffer zones:		
Location	Water body		Edge-of-field	5 m	10 m	
				Drift	Drift	D+R*
D3	ditch	PEC$_{sw,max}$ [µg L^{-1}]	0.789	0.214	0.113	-*
		dom. entry route:	Drift	Drift	Drift	-*
D4	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.027	0.024	0.017	-*
		dom. entry route:	Drift	Drift	Drift	-*
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.595	0.217	0.115	-*
		dom. entry route:	Drift	Drift	Drift	-*
D5	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.028	0.024	0.017	-*
		dom. entry route:	Drift	Drift	Drift	-*
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.636	0.232	0.123	-*
		dom. entry route:	Drift	Drift	Drift	-*
R1	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.043	0.042	0.041	0.018
		dom. entry route:	Runoff	Runoff	Runoff	Runoff
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.523	0.430	0.430	0.195
		dom. entry route:	Drift	Runoff	Runoff	Runoff
R3	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.737	0.432	0.432	0.191
		dom. entry route:	Drift	Runoff	Runoff	Runoff

Table A 9: Step 3 and 4: Global maximum concentrations of epoxiconazole in surface water following twofold application to winter cereals, considering spray drift and runoff mitigation at Step 4

Winter cereals Twofold application						
			Step 3	Step 4		
				Buffer zones:		
Location	Water body		Edge-of-field	5 m	10 m	
				Drift	Drift	D+R*
D3	ditch	PEC$_{sw,max}$ [µg L^{-1}]	0.690	0.179	0.093	-*
		dom. entry route:	Drift	Drift	Drift	-*
D4	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.035	0.032	0.032	-*
		dom. entry route:	Drift	Drainage	Drainage	-*
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.542	0.191	0.128	-*
		dom. entry route:	Drift	Drift	Drainage	-*
D5	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.037	0.032	0.023	-*
		dom. entry route:	Drift	Drift	Drift	-*
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.611	0.216	0.112	-*
		dom. entry route:	Drift	Drift	Drift	-*
R1	pond	PEC$_{sw,max}$ [µg L^{-1}]	0.097	0.095	0.092	0.041
		dom. entry route:	Runoff	Runoff	Runoff	Runoff
	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.709	0.709	0.709	0.322
		dom. entry route:	Runoff	Runoff	Runoff	Runoff
R3	stream	PEC$_{sw,max}$ [µg L^{-1}]	0.637	0.569	0.569	0.260
		dom. entry route:	Drift	Runoff	Runoff	Runoff

Table A 10: Step 3 and 4: Global maximum concentrations of epoxiconazole in surface water following single application to spring cereals, considering spray drift and runoff mitigation at Step 4

Spring cereals Single application				
Location	**Water body**		**Step 3**	**Step 4**
			Edge-of-field	**Buffer zones: 5 m**
				Drift
D3	ditch	$PEC_{sw,max}$ [µg L^{-1}]	0.790	0.214
		dom. entry route:	Drift	Drift
D4	pond	$PEC_{sw,max}$ [µg L^{-1}]	0.028	0.024
		dom. entry route:	Drift	Drift
	stream	$PEC_{sw,max}$ [µg L^{-1}]	0.655	0.239
		dom. entry route:	Drift	Drift
D5	pond	$PEC_{sw,max}$ [µg L^{-1}]	0.027	0.024
		dom. entry route:	Drift	Drift
	stream	$PEC_{sw,max}$ [µg L^{-1}]	0.727	0.266
		dom. entry route:	Drift	Drift

Table A 11: Step 3 and 4: Global maximum concentrations of epoxiconazole in surface water following twofold application to spring cereals, considering spray drift and runoff mitigation at Step 4

Twofold application				
Location	**Water body**		**Step 3**	**Step 4**
			Edge-of-field	**Buffer zones: 5 m**
				Drift
D3	ditch	$PEC_{sw,max}$ [µg L^{-1}]	0.693	0.180
		dom. entry route:	Drift	Drift
D4	pond	$PEC_{sw,max}$ [µg L^{-1}]	0.034	0.033
		dom. entry route:	Drainage	Drainage
	stream	$PEC_{sw,max}$ [µg L^{-1}]	0.590	0.208
		dom. entry route:	Drift	Drift
D5	pond	$PEC_{sw,max}$ [µg L^{-1}]	0.036	0.031
		dom. entry route:	Drift	Drift
	stream	$PEC_{sw,max}$ [µg L^{-1}]	0.638	0.225
		dom. entry route:	Drift	Drift

Table A 12: Global maximum concentrations of epoxiconazole in sediment following single and twofold application to winter cereals

Winter cereals Step 3 (edge-of-field)			
		Single application	**Twofold application**
Location	**Water body**	**$PEC_{sed,max}$ [µg kg^{-1}]**	
D3	ditch	0.471	0.542
D4	pond	0.182	0.407
	stream	0.061	0.159
D5	pond	0.180	0.286
	stream	0.020	0.064
R1	pond	0.438	0.853
	stream	0.489	1.102
R3	stream	0.436	0.924

Table A 13: Global maximum concentrations of epoxiconazole in sediment following single and twofold application to spring cereals

Spring cereals Step 3 (edge-of-field)			
		Single application	**Twofold application**
Location	**Water body**	**$PEC_{sed,max}$ [µg kg^{-1}]**	
D3	ditch	0.496	0.673
D4	pond	0.193	0.435
	stream	0.061	0.150
D5	pond	0.164	0.258
	stream	0.126	0.204

Comments of zRMS

supplemental information

Appendix 3 Table of Intended Uses justification and GAP tables

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	AT	Wheat, barley, rye, triticale	F	*Erysiphe graminis, Septoria spp. (only wheat and triticale), Puccinia spp., Drechslera tritici-repentis (only wheat), Pyrenophora teres (only barley), Rhynchosporium secalis (only barley and rye) Ramularia collo-cygni (only barley,) Decrease of non-parasitic leaf spots (only barley)*	spraying	spring BBCH 30 - 61	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria

2	AT	Wheat, barley, rye, triticale	F	*Pseudocercosporella herpotrichoides*	spraying	spring BBCH 30 - 32	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria
3	AT	Wheat, rye, triticale	F	*Puccinia recondita*	spraying	spring BBCH 30 – 69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria
4	BE	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	35	
5	CZ	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* (not triticale) *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-61	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-400	35	

7	IE, UK	Wheat, barley, rye, triticale, oats	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69 (malting barley 49)	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	Defined by last applicat ion	
8	NL	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	31-69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	35	
9	PL, SK	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	a) 1 b) 2 (21 days)	a) 1.33-2.0 b) 2.66-4.0	a) **0.166-0.250** 0.083-0.125* 0.083-0.125** b) **0.332-0.500** 0.166-0.250* 0.166-0.250**	100-300	35	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: BAS 701 00 F

Active Substance(s):

fluxapyroxad (BAS 700 F)	**62.5 g/L**
epoxiconazole (BAS 480 F)	**62.5 g/L**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: BASF

Date: 02 June 2017

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product BAS 701 00F in its intended uses in cereals is documented in detail in the core assessment of the plant protection product BAS 701 00F dated from 2013 performed by Germany

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product BAS 701 00F in Germany according to uses listed in Appendix 4.

Regarding PECgw relevant risk mitigation measures, if necessary, are documented in this document. PECsoil, PECsw are used for risk assessment to derive specific risk mitigation measures if necessary (see National addendum Germany, part B, section 6 and part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation BAS 701 00F

Code	BAS 701 00F		
plant protection product	Adexar		
applicant	BASF		
date of application	05.04.2013		
Formulation type (WP, EC, SC, …; density)	EC		
active substance	Fluxapyroxad	Epoxiconazole	
Concentration of as	62.5 g/L	62.5 g/L	

5.2 Proposed use pattern

The intended uses in Germany classified according the soil effective application rate (cumulative, disregarding degradation in soil) is presented in Table 5.2-1. Full details of the proposed uses that will be assessed is included in Appendix 4.

The intended uses in Germany (use No. 1-22) are covered by the core assessment performed by Germany.

Table 5.2-1: Classification of intended uses in Germany for BAS 701 00F

Group/ use No*	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 1-22	cereals/ BBCH 30-69	spraying /	2 x, 21d, spring 1. 70 % 2. 90 %	Fluxapyroxad: 2 x 125= 250, Epoxiconazole: 2 x 125= 250	Fluxapyroxad: 1. 37.5 2. 12.5 Epoxiconazole: 1. 37.5 2. 12.5

* For administrative purposes, each intended use of a plant protection product in Germany is assigned with an individual use number from the German Federal Office of Consumer Protection and Food Safety (BVL). A complete list of the individual GAPs in Germany together with their assigned use numbers is given in Appendix 4 of this Addendum.

5.3 Information on the active substances

5.3.1 Fluxapyroxad

Please refer to the core assessment (2013), part B, section 5, point 5.3.1.

5.3.2 Epoxiconazole

Please refer to the core assessment (2013), part B, section 5, point 5.3.1.

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5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.1.1 Fluxapyroxad

Please refer to the core assessment (2013), part B, section 5, point 5.4.1.

5.1.1 Epoxiconazole

Please refer to the core assessment (2013), part B, section 5, point 5.4.1.

5.4.2 Adsorption/desorption

5.4.2.1 Fluxapyroxad

Table 5.4-1: K_f, K_{foc} and 1/n (Freundlich exponent) values for Fluxapyroxad

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
LUFA 2.1, Sand	0.52	5.2	4.3	818	0.945	Hassink, Stephan 2009a)
Obihiro, Japan, sandy loam	2.74	5.6	15.2*	(556)	(0.897)	
Li 10, Loamy Sand	0.88	5.9	6.8	777	0.916	
New Jersey	0.90	6.3	8.6	955	0.921	
Nierswalde	1.63	6.5	17.9	1101	0.942	
LUFA 2.3	1.09	6.9	5.7	527	0.875	
La Gironda, Silty Clay Loam	3.84	7.5	12.3	320	0.902	
California, Sandy Loam	0.41	7.6	2.5	603	0.900	
Arithmetic mean (whitout Obihiro)				729	0.914	

Table 5.4-2: Statistic values according to INPUT DECISION 3.2 for Fluxapyroxad for PEC_{GW} modelling

correlation K_f and oc	Yes, p-value: 0.018	(p-Wert < significance level)
coefficient of variation K_{foc}	36	sufficiently low (≤ 60%)
Correlation K_f and pH	no	(p-Wert > significance level)
K_{foc}/K_f for PEC_{GW}	729	arithmetic mean all soils
1/n PEC_{GW}	0.914	arithmetic mean all soils

5.4.2.2 Metabolite M700F001

Table 5.4-3: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M700F001

Soil Type	**OC (%)**	**pH (-)**	**K_f (mL g^{-1})**	**K_{foc} (mL g^{-1})**	**1/n (-)**	**Reference**
LUFA 2.1, Sand	0.52	5.2	0.02	4.2	0.715	Hassink, Stephan 2009
Li 10, Loamy Sand	0.88	5.9	0.03	3.6	1.047	
New Jersey	0.90	6.3	0.03	3.4	0.914	
Nierswalde	1.63	6.5	0.11	6.7	1.002	
LUFA 2.3	1.09	6.9	0	0	1	
La Gironda, Silty Clay Loam	3.84	7.5	0	0	1	
California, Sandy Loam	0.41	7.6	0	0	1	
Arithmetic mean (whitout Obihiro)				2.6	0.954	
correlation K_f and oc	No, p-value: 0.375			(p-Wert > significance level)		
coefficient of variation K_{foc}	130			(> 60%)		
Correlation K_f and pH	No, p-value: 0.341			(p-Wert > significance level)		
coefficient of variation K_f	133			(>100)		
K_f for PEC_{GW}	Horizon 1-3: 0			10. percentil kf all soils		
1/n PEC_{GW}	0.954			arithmetic mean all soils		

5.4.2.3 Metabolite M700F002

Table 5.4-4: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite M700F002

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
LUFA 2.1, Sand	0.52	5.2	0.07	13.1	0.969	Hassink, Stephan 2009
Li 10, Loamy Sand	0.88	5.9	0.04	4.8	0.842	
New Jersey	0.90	6.3	0.13	14.1	1.165	
Nierswalde	1.63	6.5	0.15	9	0.937	
LUFA 2.3	1.09	6.9	0.06	5.6	1.078	
La Gironda, Silty Clay Loam	3.84	7.5	0.04	1	0.99	
California, Sandy Loam	0.41	7.6	0.02	5.6	0.764	
Arithmetic mean (whitout Obihiro)				7.6	0.964	
correlation Kf and oc		No, p-value: 0.224		(p-Wert > significance level)		
coefficient of variation Kfoc		62		(> 60%)		
Correlation Kf and pH		No, p-value: 0.288		(p-Wert > significance level)		
coefficient of variation Kf		71		(<100)		
Kf for PECGW		Horizon 1-3: 0.07		arithmetic mean kf all soils		
1/n PECGW		0.964		arithmetic mean all soils		

5.4.2.4 Epoxiconazole

The K_{foc} values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

For the active substance Epoxiconazole the coefficient of variation of the measured K_{foc} values is > 60% and the coefficient of variation of the measured/K_f values is < 100%. No correlation could be found between the K_{foc} / K_f values and pH of the soils. In this case, the arithmetic mean of the K_f values is used for the first three soil horizons of the model scenario Hamburg in FOCUS PELMO together with a default value of zero for the soil horizons 4-6.

Table 5.4-5: K_f, K_{foc} and 1/n (Freundlich exponent) values for Epoxixconazole

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
sand (Sp 2.1)	0.5	6.0*	4.79	957	0.766	LoEP, Ochsenbein (1988)
sandy loam (Les Evouetttes)	0.74	4.75*	19.59	2647	0.813	
clay/ clay loam (Itingen/BL)	1.98	6.87*	21.78	1100	0.808	
Silty loam: (Sp 3A, Altlußheim)	2.6	7.1	7.25	280	0.882	LoEP, Seher (2002)
clayey loam/clay (Sp 6S, Siebeldingen)	2.0	6.8	7.50	380	0.910	
sand / loamy sand (Utrera, Spain)	0.42	5.9	8.24	1962	0.846	Zirnstein (2005)
loamy sand (Li 10 (1680), Germany)	0.87	6.6	9.27	1065	0.859	
sandy loam / loam (Forst H6, Germany)	1.61	7.1	14.8	922	0.882	
loam (LUFA 3A, Germany)	2.54	7.3	17.8	702	0.839	
sandy loam (LUFA 5M, Germany)	1.46	7.3	13.5	928	0.849	
Arithmetic mean				1093	0.845	

*) no information given if pH was determined in water or $CaCl_2$

The pH correlation was not tested, because there was no further information about the pH determination in the study Ochsenbein 1988.

5.4.2.5 Metabolite 1,2,4-Triazole

No new studies have been submitted regarding adsorption/desorption in soil of 1,2,4-triazole. The exposure modeling is based on the EU K_{foc} values as summarized in The Kfoc values were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PECGW) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

For the active substance Epoxiconazole the coefficient of variation of the measured Kfoc values is > 60% and the coefficient of variation of the measured/Kf values is < 100%. No correlation could be found between the Kfoc / Kf values and pH of the soils. In this case, the arithmetic mean of the Kf values is used for the first three soil horizons of the model scenario Hamburg in FOCUS PELMO together with a default value of zero for the soil horizons 4-6.

Table 5.4-5: Kf, Kfoc and 1/n (Freundlich exponent) values for Epoxixconazole

Soil Type	**OC (%)**	**pH (-)**	**Kf (mL g-1)**	**Kfoc (mL g-1)**	**1/n (-)**	**Reference**
sand (Sp 2.1)	0.5	6.0*	4.79	957	0.766	LoEP, Ochsenbein (1988)
sandy loam (Les Evouetttes)	0.74	4.75*	19.59	2647	0.813	
clay/ clay loam (Itingen/BL)	1.98	6.87*	21.78	1100	0.808	
Silty loam: (Sp 3A, Altlußheim)	2.6	7.1	7.25	280	0.882	LoEP, Seher (2002)
clayey loam/clay (Sp 6S, Siebeldingen)	2.0	6.8	7.50	380	0.910	
sand / loamy sand (Utrera, Spain)	0.42	5.9	8.24	1962	0.846	Zirnstein (2005)
loamy sand (Li 10 (1680), Germany)	0.87	6.6	9.27	1065	0.859	
sandy loam / loam (Forst H6, Germany)	1.61	7.1	14.8	922	0.882	
loam (LUFA 3A, Germany)	2.54	7.3	17.8	702	0.839	
sandy loam (LUFA 5M, Germany)	1.46	7.3	13.5	928	0.849	
Arithmetic mean				1093	0.845	

*) no information given if pH was determined in water or CaCl2

The pH correlation was not tested, because there was no further information about the pH determination in the study Ochsenbein 1988.

Table 5.4-6: K_f, K_{foc} and 1/n (Freundlich exponent) values for 1,2,4-triazole

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1}	K_{foc} (mL $g^{-1)}$	1/n (-)	Reference
Alpaugh (Silty clay)	0.696	8.8	0.833	120	0.897	Hawkins (1988)
Hollister (Clay Loam)	1.740	6.9	0.748	43	0.827	
Lawrenceville (Silty Clay Loam)	0.696	7.0	0.722	104	0.922	

Pachappa (Sandy Loam)	0.812	6.9	0.720	89	1.016	
Arithmetic mean				89	0.916	

5.4.3 Rate of degradation in water/sediment

Fluxapyroxad

Please refer to the core assessment, part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Fluxapyroxad
accumulation potential in sediment	yes ($DT_{90,\text{whole system}}$ > 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	3.49 based on $DT_{50,\text{ whole system}}$ = 1000 (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 365 d

Epoxiconazole

Please refer to the core assessment (2013) part B, section 5, point 5.4.3.

Accumulation of active substance and relevant metabolites in the sediment

active substance	Epoxiconazole
accumulation potential in sediment	yes ($DT_{90,\text{whole system}}$ > 1 year, see core assessment, part B, section 5, chapter 5.4.3)
accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	0.3 based on $DT_{50,\text{ whole system}}$ = 172.4 (maximum, see core assessment, part B, section 5, chapter 5.4.3), t = 356 d

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for BAS 701 00F according to EU assessment considering 5 cm soil depth are given in the core assessment 2013, part B, section 5, chapter 5.5.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc}$ < 500 a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc}$ > 500 a soil depth of 1 cm is applied. As soil bulk density 1.5 g $cm^{-3}$is assumed.

Due to the slow degradation of the active substance Fluxapyroxad in soil (DT_{90} > 365 d,,) the accumulation potential of Fluxapyroxad needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for active substances as presented in Table 5.5-1.

Table 5.5-1: Input parameters for BAS 701 00F for PEC_{soil} calculation

Active substance	**DT50**
Fluxapyroxad	370 d (alpha:0.2056, beta: 13.1342) (field, worst case, non-normalised, see Table 5.4.-2 in CA)
Metabolite M700F001	10 d (non-normalised worst case laboratory studies)
Metabolite M700F002	39.2 d (field, worst case, non-normalised, see Table 5.4.-3)
Epoxiconazole	226d (field, worst case, non-normalised, see Table 5.4.-7 in CA)
Metabolite 1,2,4-Triazole	parameters for DFOP 28.1d:: k1=0.0632. k2=0.0020 g =0.5732 (field, worst case s, non-normalised)
BAS 701 00F/ Adexar	226 d

Additional $PEC_{soil,act}$ was calculated for the formulation BAS 701 00F for a soil depth of 1 cm.

No short-term and long-term PEC_{soil} were calculated since $PEC_{soil,act}$ is considered sufficient for German risk assessment.

The calculated PEC_{soil} used for German risk assessment for the active substances and for the formulation BAS 701 00F are summarized in Table 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

plant protection product:		BAS 701 00F				
use:		A				
Number of applications/intervall		2/ 21				
application rate:		125				
crop interception:		70%/ 90%				
active substance/ formulation		**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Fluxapyroxad		1	0.288 on d21	20	0.0148	0.3036
Metabolite M700F001	Ff=100%	2.5	0.0046	20	0.0006	0.0052
Metabolite M700F002	Ff=100%	2.5	0.0091 on d49	20	0.0013	0.0104
Epoxiconazole		1	0.3177 on d21	20	0.0077	0.3254
Metabolite 1,2,4-Triazole	Ff=100%	2.5	0.0056 on d383	20	0.0015	0.0071
BAS 701 00F/ Adexar	2.072 kg/ha	1	4.1440	20	0.0379	4.1819

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of Fluxapyroxad and Epoxiconazole for the intended for uses of BAS 701 00F in cereals using FOCUS Surface Water are given in the core assessment (2013), part B, section 5, chapter 5.6.

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the models EVA 2.1. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0.

The German surface water exposure assessment is outlined in the following chapters.

5.6.1 PEC_{SW} after exposure by spraydrift and deposition following volatilization

5.6.1.1 Fluxapyroxad

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Fluxapyroxad is < 10^{-5} Pa. Hence the active substance Fluxapyroxad is regarded as non-volatile. Therefore no exposure of surface water by the active substance Fluxapyroxad due to deposition following volatilization needs to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of Fluxapyroxad used for the PEC_{SW} calculations with EVA 2.1

Parameter	Active substance Fluxapyroxad	Reference
vapour pressure at 20 °C (Pa)	2.7 x 10^{-9}	See core assessment, section 5, point 5.3.1.1
Solubility in water (mg/L)	3.44	
$DissT_{50}$ water (d)	79.5	
DT_{50} hydrolysis/photolysis (d)	1000 (default)	

The calculated PECsw values after exposure via spray drift for the active substance Fluxapyroxad for the intended use in cereals (worst case application rate) are summarized in Table 5.6-2.

Table 5.6-2 PEC_{SW} for the active substance Fluxapyroxad after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance	Fluxapyroxad
use pattern/gap:	A
application rate/number of applications / interval	125 g/ha/ 2 applications/ 21d (worst case)

DissT50 (SFO) in water	79.5							
relevant PEC if applicable twa-interval	…							
scenario/percentile:	agriculture/ 82.							
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	76.36	-	-	76.36	7.64	19.09	38.18
1	2.38	1.82	-	-	1.817	0.18	0.45	0.91
5	0.47	0.36	-	-	0.359	0.04	0.09	0.18
10	0.24	0.18	-	-	0.183	0.02	0.05	0.09
15	0.16	0.12	-	-	0.122	0.01	0.03	0.06
20	0.12	0.09	-	-	0.092	0.01	0.02	0.05

5.6.1.2 Accumulation in sediment of Fluxapyroxad

The accumulation of Fluxapyroxad in sediment has to be considered. After 100 days 76% Fluxapyroxad was detected in the sediment in the water sediment study.

The factor for multiplying the maximum concentration in sediment to reach the plateau concentration of BAS 701 00 F in sediment at steady state (PECsed,plateau) is:

factor for accumulation (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	3.47 (DT50 = 1000)

where

k Degradation rate in sediment (ln(2)/DT50) $[d^{-1}]$

t Time interval between growing seasons (365 days)

PECsed was calculated from the PECsw value using the following equation assuming a water volume of 300 L, a sediment volume of 10 L and a density of the sediment of 1.3 kg/L:

$$PEC_{sed,max} = \frac{PEC_{sw} \times V_{sw} \times f_{sed,max}}{V_{sed} \times bd_{sed}}$$

$PEC_{sed,\,max}$	Maximum concentration in the sediment (µg/kg)
PEC_{sw}	Initial concentration in the surface water (µg/L)
V_{sw}	Water volume (300 L)
$f_{sed,max}$	Maximum amount of the active substance in the sediment [-]
V_{sed}	Sediment volume for a sediment depth of 1 cm for a Koc > 500
bd_{sed}	Density of the moist sediment (bulk density)

The concentrations of 76% Fluxapyroxad in a sediment layer with 1 cm depth (koc>500) and 1.3 g/cm^3 sediment density) are given in the table below.

The overall accumulation PEC in sediment (PECsed,accu,overall) after multi-year use of of BAS 701 00 F is the sum of the concentration in sediment and the plateau concentration at steady state.

Table 5.6-3 Accumulation in sediment of Fluxapyroxad

	PECsw via drift	Pec sed	PEC sed plateau (3.47x PEC sed)	PEC overall accumulation= Pec sed plateau +Pec sed
	(µg/L)	µg/kg	µg/kg	µg/kg
1	1.82	31.92	110.76	142.68
5	0.36	6.31	21.89	28.21
10	0.18	3.15	10.93	14.08
15	0.12	2.1	7.29	9.39
20	0.09	1.57	5.45	7.02

5.6.1.3 Epoxiconazole

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Epoxiconazole is < 10^{-5} Pa. Hence the active substance Fluxapyroxad is regarded as non-volatile. Therefore no exposure of surface water by the active substance Fluxapyroxad due to deposition following volatilization needs to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

The endpoints used for modelling surface water exposure via spray drift and volatilization with subsequent deposition with EVA 2.1 are summarized in Table 5.6-4.

Table 5.6-4 Endpoints of Epoxiconazole used for the PEC_{SW} calculations with EVA 2.1

Parameter	Active substance Epoxiconazole	Reference
vapour pressure at 20 °C (Pa)	<10-5	See core assessment, section 5, point 5.3.1.1
Solubility in water (mg/L)	7.1	
DT_{50} water (d)	93,1	
DT_{50} hydrolysis/photolysis (d)	1000 (default)	

The calculated PECsw values after exposure via spray drift for the active substance Epoxiconazole for the intended use in cereals (worst case application rate) are summarized in Table 5.6-5.

Table 5.6-5 PEC_{SW} for the active substance Epoxiconazole after exposure via spray drift and volatilization with subsequent deposition modelled with EVA 2.1

active substance			Epoxiconazole					
use pattern/gap:			A					
application rate/number of applications / interval			125 g/ha/ 2 applications/ 21d (worst case)					
DissT50 (SFO) in water								
relevant PEC if applicable twa-interval			…					
scenario/percentile:			agriculture/ 82.					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	74.33	-	-	74.33	7.43	18.58	37.17
1	2.38	1.77	-	-	1.769	0.18	0.44	0.88
5	0.47	0.35	-	-	0.349	0.03	0.09	0.17
10	0.24	0.18	-	-	0.178	0.02	0.04	0.09
15	0.16	0.12	-	-	0.119	0.01	0.03	0.06
20	0.12	0.09	-	-	0.089	0.01	0.02	0.04

5.6.1.4 Accumulation in sediment of Epoxiconazole

The accumulation of Epoxiconazole in sediment has to be considered. After 100 days 61% Epoxiconazole was detected in the sediment in the water sediment study.

The factor for multiplying the maximum concentration in sediment to reach the plateau concentration of BAS 701 00 F in sediment at steady state (PECsed,plateau) is:

factor for accumulation (SFO) $f_{accu} = e^{-kt}/(1 - e^{-kt})$	0.3 (DT50 = 172.4)

where

k Degradation rate in sediment (ln(2)/DT50) $[d^{-1}]$

t Time interval between growing seasons (365 days)

PECsed was calculated from the PECsw value using the following equation assuming a water volume of 300 L, a sediment volume of 10 L and a density of the sediment of 1.3 kg/L:

$$PEC_{sed,max} = \frac{PEC_{sw} \times V_{sw} \times f_{sed,max}}{V_{sed} \times bd_{sed}}$$

$PEC_{sed,\ max}$ Maximum concentration in the sediment (µg/kg)

$PECs_w$	Initial concentration in the surface water (µg/L)
V_{sw}	Water volume (300 L)
$f_{sed,max}$	Maximum amount of the active substance in the sediment [-]
V_{sed}	Sediment volume for a sediment depth of 1 cm for a Koc > 500
bd_{sed}	Density of the moist sediment (bulk density)

The concentrations of 61% Epoxiconazole in a sediment layer with 1 cm depth (koc>500) and 1.3 g/cm^3 sediment density) are given in the table below.

The overall accumulation PEC in sediment (PECsed,accu,overall) after multi-year use of of BAS 701 00 F is the sum of the concentration in sediment and the plateau concentration at steady state.

Table 5.6-6 Accumulation in sediment of Epoxiconazole

distance (m)	PECsw via drift	PEC sed	PEC sed plateau (0.3x PEC sed)	PEC overall accumulation= Pec sed plateau +Pec sed
	(µg/L)	µg/kg	µg/kg	µg/kg
1	1.77	24.91	7.473	32.383
5	0.35	4.9	1.47	6.37
10	0.18	2.5	0.75	3.25
15	0.12	1.68	0.504	2.184
20	0.09	1.26	0.378	1.638

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

5.6.2.1 Fluxapyroxad

The concentration of the active substance Fluxapyroxad in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.

The parameters for Fluxapyroxad used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3. are summarized in Table 5.6-7.

Table 5.6-7 Input parameters for Fluxapyroxad used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Fluxapyroxad	Reference
$K_{foc,\ Runoff}$	729	arithm. mean (see CA, section 5, chapter 5.4.2)
$K_{foc,\ mobility\ class}$	729	
DT_{50} soil (d)	370	
Solubility in water (mg/L)	3.44	see CA, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Fluxapyroxad for the intended for use in cereals (worst case application rate) are summarized in Table 5.6-8.

Table 5.6-8 PEC_{SW} of Fluxapyroxad in an adjacent ditch due to surface run-off and drainage

Active substance:	Fluxapyroxad	
Use pattern/GAP:	A	
Application rate:	2x 125 g/ha (worst case), Interception: 70% and 90%	
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.34	0.38
5	0.30	0.33
10	0.25	0.26
20	0.18	0.18
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.02	
Spring/summer	0.01	

5.6.2.2 Epoxiconazole

The concentration of the active substance Epoxiconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.

The parameters for Epoxiconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3 are summarized inTable 5.6-9.

Table 5.6-9 Input parameters for Epoxiconazole used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	Epoxiconazole	Reference
$K_{foc,\ Runoff}$	1093	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc,\ mobility\ class}$	1093	
DT_{50} soil (d)	226	
Solubility in water (mg/L)	7.1	see core assessment, section 5, point 5.3.1.1
Reduction by bank filtration (only relevant for PECgw see 5.7.2)	100%	

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance Epoxiconazole for the intended for use in cereals (worst case application rate) are summarized in Table 5.6-10.

Table 5.6-10 PEC_{SW} of Epoxiconazole in an adjacent ditch due to surface run-off and drainage

Active substance: Epoxiconazole		
Use pattern/GAP: A		
Application rate: 2x 125 g/ha (worst case), Interception: 70% and 90%		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch ($PEC_{ini\ Runoff}$) (µg/L)**	**PECsw in adjacent ditch ($PEC_{ini\ Gesamtaustrag}$) (µg/L)**
0	0.24	0.32
5	0.21	0.28
10	0.18	0.20
20	0.13	0.14
Exposure by drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	
autuum/winter/early spring	0.02	
Spring/summer	0.01	

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of Fluxapyroxad for the intended uses of BAS 701 00F in cereals according to EU assessment using FOCUS PELMO are given in the core assessment (2013) part B, section 5, chapter 5.7.

For authorization in Germany, risk assessment for groundwater considers two pathways, (i) direct leaching of the active substance into the groundwater after soil passage and (ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

Direct leaching after soil passage is assessed following the recommendations of the publication of Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011) for tier 1 and tier 2 risk assessment. According to Hold et al, 2011, endpoints for groundwater modelling are derived with the program INPUT DECISION 3.1 and subsequent simulations are performed for the groundwater scenarios "Hamburg" or with the scenarios "Hamburg" and "Kremsmünster" of FOCUS PELMO 4.4.3.

In tier 3 risk assessment, results of experimental studies (lysimeter studies and/or field leaching studies) can also be considered in German groundwater risk assessment.

Surface run-off and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.

The German risk assessment for groundwater is given in the following chapters.

5.7.1 Direct leaching into groundwater

5.7.1.1 PEC_{GW} modelling

The worst case scenario used for PECgw modelling is summarized in Table 5.7-1. It covers the intended uses of BAS 700 05 F according to Table 5.2-1 (see also Appendix 4).

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 4.4.3

use evaluated	Group A
application rate (kg as/ha)	0.0375 and 0.0125, (interception considered)
crop (crop rotation)	Cereals spring, winter cereals
date of application	27 d and 48d after emergence (spring cereals), 169 d and 190 d after emergence (winter cereals)
application depth (cm)	5
interception (%)	0
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Fluxapyroxad

The endpoints used for groundwater modelling for Fluxapyroxad and its metabolites M700F001 and M700F002 according to INPUT DECISION 3.1 are summarized in Table 5.7-2.

Table 5.7-2 Input parameters for PEC_{GW} modelling

Parent	Fluxapyroxad	Remarks/Reference to CA, part B, section 5
molecular weight (g/mol)	381.3	
DT_{50} in soil (d)	151 d / 59.5 d	
K_{foc}	729	
1/n	0.914	
metabolite	**M700F001**	
molecular weight (g/mol)	176.1	
Formation fraction	1	
DT_{50} in soil (d)	5.4	
K_f	Horizon 1-3: 0	
1/n	0.954	
metabolite	**M700F002**	
molecular weight (g/mol)	175.1	
Formation fraction	1	
DT_{50} in soil (d)	25.9	
K_f	Horizon 1-3: 0.07	
1/n	0.964	

The results of the groundwater simulation are presented in Table 5.7-3.

Table 5.7-3 PEC_{GW} at 1 m soil depth of Fluxapyroxad and its metabolites M700F001 and M700F002considered relevant for German exposure assessment

crop.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3**		
		Fluxapyroxad	**M700F001 Max. residues of slow/ fast DT50 of ai**	**M700F002 Max. residues of slow/ fast DT50 of ai**
Winter cereals	**Hamburg**	**0.001**	**0.295**	**2.462**
Spring cereals	**Hamburg**	**0.001**	**0.288**	**2.336**

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance Fluxapyroxad in concentrations of ≥ 0.1 µg/L is not expected for the intended uses.

For the metabolite M700F001 of Fluxapyroxad a groundwater concentration of ≥ 0.1µg/L cannot be excluded for spring and winter cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

For the metabolite M700F002 of Fluxapyroxad a groundwater concentration of ≥ 0.75 µg/L cannot be excluded for the application in both winter cereals and spring cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3

Epoxiconazole

The PEC of Epoxiconazole and the metabolite 1,2,4-Triazole in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO.

The DT_{50} values of the metabolite 1,2,4-Triazole are calculated with DFOP kinetics.

If degradation follows a bi-phasic kinetic FOCUS (2006) recommends splitting the application rate according to the factor g of the DFOP kinetic of the metabolite. Afterwards two separate simulations according to the split application rate for the fast and slow degradation are performed. Breaking the pesticide into two fractions introduces a small error when the Freundlich exponent is not one. However, a conservative estimate can be made when the Freundlich exponent is not one by doubling the application rate and then dividing the final answer by two (FOCUS, 2006).

plant protection product	BAS 701 00 F
application rate (kg as/ha)	0.0375 and 0.0125 (interception considered) After Duplication : 0.075 and 0.025 Fast: (0.075 and 0.025) x g= 0.037 and 0.012 Slow: (0.075 and 0.025) x (1-g)= 0.038 and 0.013
crop (crop rotation)	Cereals spring, winter cereals
relative application date	27 d and 48d after emergence (spring cereals), 169 d and 190 d after emergence (winter cereals)

The endpoints used for groundwater modelling for Epoxiconazole and 1,2,4-Triazole according to INPUT DECISION 3.1 are summarized in Table 5.7-4 **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Table 5.7-4 Input parameters related to Epoxiconazole for PEC_{GW} modelling

Parent	**Epoxiconazole**	**Remarks/Reference to CA, part B, section 5**
molecular weight (g/mol)	329.8	
DT_{50} in soil (d)	78.7	
K_{foc}	1093	
1/n	0.845	
plant uptake factor	0	With deviation from CA
metabolite	1,2,4-Triazole	
molecular weight (g/mol)	69.1	
Formation fraction	1	
DT_{50} in soil (d)	1.7 (fast) / 60.5 (slow), g= 0.489, 1-g= 0.511	
K_{foc}	89	
1/n	0.916	

The results of the groundwater simulation are presented in Table 5.7-5**Fehler! Verweisquelle konnte nicht gefunden werden.**.

Table 5.7-5 PEC_{GW} at 1 m soil depth of Epoxiconazole and 1,2,4-Triazole considered relevant for German exposure assessment

crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3		
		Epoxiconazole	Metabolite 1,2,4-Triazole	
Winter cereals	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.088 0.044
Spring cereals	Hamburg	<0.01	Fast: Slow: (fast+slow) / 2:	<0.01 0.083 0.0415

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance Epoxiconazole an concentrations of ≥ 0.1 µg/L is not expected for the intended use in cereals.

For the metabolite 1,2,4-Triazole of Epoxiconazole a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in cereals according to the results of the groundwater simulation with FOCUS-PELMO.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO show that the active substances Fluxapyroxad and Epoxiconazole are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in cereals.

For the metabolite M700F001 of Fluxapyroxad a groundwater concentration of ≥ 0.1µg/L cannot be excluded. For the metabolite M700F002 of Fluxapyroxad a groundwater concentration of ≥ 0.75 µg/L cannot be excluded

For the metabolite 1,2,4-Triazole of Epoxiconazole concentrations of ≥ 0.1µg/L in groundwater can be excluded.

5.7.2 Ground water contamination by bank filtration due to surface water exposure via run-off and drainage

5.7.2.1 Fluxapyroxad

The input parameters for Fluxapyroxad used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-6.

Table 5.7-6 Input parameters for Fluxapyroxad used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	Fluxapyroxad	Reference
$K_{foc, Runoff}$	729	arithm. mean (see core assessment, section 5, chapter 5.4.2)
$K_{foc, mobility class}$	729	arithm. mean (see core assessment, section 5, chapter 5.4.2)
DT_{50} soil (d)	370	Worst case field studies
Solubility in water (mg/L)	3.44	see core assessment, section 5, point 5.3.1.2
Mobility class	1	
Reduction by bank filtration	100%	

The calculated PECgw for Fluxapyroxad after surface run-off and drainage with subsequent bank filtration are summarized inTable 5.7-7.

Table 5.7-7 PEC_{gw} for Fluxapyroxad after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

<table>
<tr><td colspan="2">Active substance</td><td colspan="4">Fluxapyroxad</td></tr>
<tr><td rowspan="3">Use No.</td><td rowspan="3">application rate interception</td><td colspan="4">PECgw due to</td></tr>
<tr><td colspan="2">run-off</td><td colspan="2">drainage</td></tr>
<tr><td>vegetated buffer strip
(m)</td><td>bank filtrate
(µg/L)</td><td>Time of application</td><td>bank filtrate
(µg/L)</td></tr>
<tr><td rowspan="4">Group A</td><td rowspan="4">2x 125 g/ha, 21d, 70% and 90%</td><td>0</td><td><0.001</td><td rowspan="2">autumn/winter/ early spring</td><td rowspan="2"><0.001</td></tr>
<tr><td>5</td><td><0.001</td></tr>
<tr><td>10</td><td><0.001</td><td rowspan="2">spring/summer</td><td rowspan="2"><0.001</td></tr>
<tr><td>20</td><td><0.001</td></tr>
<tr><td colspan="2">required labelling</td><td colspan="4">no</td></tr>
</table>

According modelling with EXPOSIT 3.01 groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Fluxapyroxad due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites

The soil metabolites of Fluxapyroxad (see core assessment, part B, section 5, point 5.3.1.3) are formed > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameter for the model EXPOSIT 3.01 are taken from the EU assessment and summarized in , the results are given in Table 5.7-8.

Table 5.7-8: Input parameter for soil metabolites of Fluxapyroxad for EXPOSIT 3.01

Parameter	Metabolite M700F001
Molecular weight (g/mol)	176.1
Correction factor molecular weight	176.1/ 381.3
Maximum occurrence in soil (%)	12.1
$K_{foc, Runoff}$	2.6
$K_{foc, mobility class}$	0
DT_{50} soil (d)[1)]	10
Solubility in water (mg/L)	39990
Mobility class	4
Parameter	**Metabolite M700F002**
Molecular weight (g/mol)	162.1
Correction factor molecular weight	162.1/ 381.3
Maximum occurrence in soil (%)	70.5(plus remaining parent and M700F001 in soil as still increasing at study termination)
K foc, Runoff	7.6
Kfoc, mobility class	3 (10. Perc.)
DT50 soil (d)1)	39.2
Solubility in water (mg/L)	31850
Mobility class	3

[1)] only relevant for mobility class

Table 5.7-9: PEC_{gw} for soil metabolites of Fluxapyroxad after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite M700F001					
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A	2x 7 g/ha, 70% and 90%	0	< 0.001	autumn/winter/ early spring	< 0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		none			
Metabolite M700F002					
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
A	2x 37.5, 70% and 90%	0	< 0.001	autumn/winter/ early spring	0.001
		5	< 0.001		
		10	< 0.001	spring/summer	< 0.001
		20	< 0.001		
required labelling		none			

According to modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of Fluxapyroxad due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

5.7.2.2 Epoxiconazole

The input parameters for Epoxiconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.01 are summarized in Table 5.7-10..

Table 5.7-10 Input parameters for Epoxiconazole used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	**Epoxiconazole**	**Reference**
$K_{foc,\ Runoff}$	1093	arithm. mean (see CA, section 5, chapter 5.4.2)
$K_{foc,\ mobility\ class}$	1093	arithm. mean (see CA, section 5, chapter 5.4.2)
DT_{50} soil (d)	226	Worst case field studies
Solubility in water (mg/L)	7.1	see CA, section 5, point 5.3.1.2
Mobility class	1	
Reduction by bank filtration	100%	

The calculated PECgw for Epoxiconazole after surface run-off and drainage with subsequent bank filtration are summarized inTable 5.7-11.

Table 5.7-11 PEC_{gw} for Epoxiconazole after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		Epoxiconazole			
Use No.	application rate interception	PECgw due to			
		run-off		drainage	
		vegetated buffer strip (m)	bank filtrate (µg/L)	Time of application	bank filtrate (µg/L)
Group A	2x 125 g/ha, 21d, 70% and 90%	0	<0.001	autumn/winter/ early spring	<0.001
		5	<0.001		
		10	<0.001	spring/summer	<0.001
		20	<0.001		
required labelling		no			

According modelling with EXPOSIT 3 groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Epoxiconazole due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

The authorization of the plant protection product BAS 701 00F is linked with following labeling:

Use No. - NG: -

Appendix 2 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 3 Detailed evaluation of studies relied upon

Report only studies, which have not previously been evaluated within a peer reviewed process at EU level (Annex I inclusion of active substance).

Appendix 4 Table of Intended Uses in Germany (according to BVL)

GAP-Table of intended uses for Germany

GAP rev. (1), date: 2013-05-14

PPP (product name/code) **Adexar**
active substance 1 **Epoxiconazole**
active substance 2 **Fluxapyroxad**

Formulation type: **EC**
Conc. of as 1: **62.5 g/L**
Conc. of as 2: **62.5 g/L**

Applicant: **BASF**
Zone(s): **centralEU**

professional use ☒
non professional use ☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

002	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
003	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
004	DE	wheat TRZSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PYRNTR	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
005	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
006	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of	a) 2	a) 2 L/ha	a) as1: 0.125 kg as/ha	100 - 400	F	

						infestation and/or when first symptoms become visible	b) 2 (21 d)	b) 4 L/ha	as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha			
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
010	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha	100 - 400	F	

						symptoms become visible			b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha			
012	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
013	DE	barley HORVX	F	Ramularia leaf spot disease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 32 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	for susceptible varieties and at increasing global radiation
015	DE	rye SECCE	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha	100 - 400	F	

									as2: 0.25 kg as/ha			
017	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
018	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
019	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
020	DE	triticale TTLSS	F	stem break of cereals *Pseudocercosporella herpotrichoides* PYRNTR	spraying	BBCH 30 - 32 from spring at beginning of infestation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

021	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
022	DE	triticale TTLSS	F	septoria-species *Septoria* spp. SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

81655 81655 **REGISTRATION REPORT**
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code:	**BAS-701000-FW-0-EC (ADEXAR)**
Active Substances:	**Fluxapyroxad: 62.5 g/l** **Epoxiconazole: 62.5 g/l**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant:	**BASF**
Date:	**02 June 2017**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product ADEXAR (BAS-70100-FW-0-EC) containing the active substances fluxapyroxad and epoxiconazole which are currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfils the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

The product ADEXAR (BAS-70100-FW-0-EC) contains the active substances fluxapyroxad and epoxiconazole, which are currently approved under Reg. (EC) No 1107/2009 (repealing Directive 91/414/EEC) and fulfills the criteria according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2.

Where appropriate, this document refers to the EFSA conclusions of fluxapyroxad and epoxiconazole (EFSA Journal 2012;10(1):2522 and EFSA Scientific Report 2008, 138, 1-80, respectively), especially when data on the active substances are relied upon in the risk assessment of the formulation. Each section will begin with a table providing the EU endpoints used in this evaluation.

ADEXAR (BAS-70100-FW-0-EC) was not the representative formulation considered in the EU review process as part of the approval of the active substances fluxapyroxad and epoxiconazole.

A full risk assessment according Commission Regulation (EU) No 546/2011 is provided.

Addenda are included containing country specific assessments for some annex points. In those cases this document should be read in conjunction with the relevant addenda.

Appendix 1 of this document contains the list of references included in this document in support of the evaluation.

Appendix 2 of this document reports the detailed evaluation of studies relied upon.

Appendix 3 of this document is the table of intended uses for ADEXAR (BAS-70100-FW-0-EC).

Information on the detailed composition of ADEXAR (BAS-70100-FW-0-EC) can be found in the confidential dossier of this submission (Registration Report - Part C).

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation ADEXAR (BAS-70100-FW-0-EC) containing the active substances fluxapyroxad and epoxiconazole and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarised below. Moreover, an overview of the metabolites of fluxapyroxad and epoxiconazole that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical GAP used for exposure assessment are presented in Table 6.1-1 that reports also a classification of intended uses for ADEXAR (BAS-70100-FW-0-EC) (see also Section 5). A list of all intended uses within the zone is given in Appendix 3.

Table 6.1-1: Critical use pattern of ADEXAR (BAS-701 00-FW-0-EC)

Group/ use No	Crop/growth stage	Application method Drift scenario	Number of applications, Minimum application interval, application time, interception	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
A/ 00-001 – 00-021	Wheat, barley, rye, triticale / BBCH 30-69	spraying	2 x, 21 d, spring 1. 70 % 2. 90 %	fluxapyroxad: 2 x 125 = 250 epoxiconazole: 2 x 125 = 250	fluxapyroxad: 1. 37.5 2. 12.5 = 50 epoxiconazole: 1. 37.5 2. 12.5 = 50

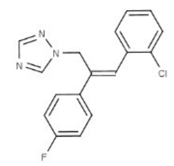
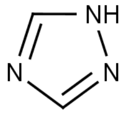
6.1.2 Consideration of metabolites

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU review of fluxapyroxad (EFSA Journal 2012;10(1):2522) and epoxiconazole (EFSA Scientific Report 2008, 138, 1-80).

The metabolites M700F001 and M700F002 of fluxapyroxad have been regarded as ecotoxicologically not relevant. Further information is provided in Part B, Section 5. Environmental occurring metabolites of fluxapyroxad requiring further assessment according to the results of the assessment of fluxapyroxad for EU approval are summarized in Table 6.1-2.

Further information is provided in Part B, Section 5. Environmental occurring metabolites of epoxiconazole requiring further assessment according to the results of the assessment of epoxiconazole for EU approval are summarized in Table 6.1-2.

Table 6.1-2: Metabolites of fluxapyroxad and epoxiconazole potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolites of fluxapyroxad	**Structural formula/ Molecular formula**	**occurence in compartments (Max. at day/)**	**Satus of Relevance (EFSA Journal 2012;10(1):2522)**
M700F001	C6H6F2N2O2	Soil: Max. 12.1 % (mean value) on day 30 Irradiated Water: Max. 10.9 % at day 43	Aquatic organisms: Water: low risk Sediment: low risk Terrestrial organisms: low risk Groundwater: risk assessed as low to the aquatic environment
M700F002	C5H4F2N2O2	Soil: Max. 38.5 % (mean value) on day 120	Aquatic organisms: Water: low risk Sediment: low risk Terrestrial organisms: low risk Groundwater: risk assessed as low to the aquatic environment
M700F007	C6H7F2N3O	Irradiated Water: Max. 7.5 % at day 57	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: not relevant Groundwater: not relevant
Metabolites of epoxiconazole	**Structural formula/ Molecular formula**	**occurence in compartments (Max. at day/)**	**(SANCO/136/08 – 11/07/2008, revised 28/09/2010)**
BF 480-entriazole	C17H13ClFN3 313.76 g/mol 	Sediment: Max. 32.3 at day 59	Aquatic organisms: not relevant Terrestrial organisms: not relevant Groundwater: not relevant (Step 2)
1,2,4-triazole	C2H3N3 69.1g/mol 	Soil: Max. 6.6 % at day 175 (increasing at end of study)	Aquatic organisms: not relevant Terrestrial organisms: not relevant Groundwater: relevant (Step 3-4)

6.2 Effects on Birds

6.2.1 Overview and summary

Effects on birds of ADEXAR (BAS-70100-FW-0-EC) were not evaluated as part of the EU review of either fluxapyroxad or epoxiconazole. For the acute risk assessment the notifier submitted a study on the bobwhite quail performed with the formulated product BAS 701 00 F.

For the long-term risk assessment, the provision of further data on the formulation ADEXAR (BAS-70100-FW-0-EC) is not considered essential as the available data on fluxapyroxad and epoxiconazole are deemed to be sufficient to assess the risk of birds exposed to ADEXAR (BAS-70100-FW-0-EC).

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table.

Table 6.2-1: Toxicity of fluxapyroxad and epoxiconazole to birds with reference to agreed endpoints

Study type	Test substance	Species	Results	Reference Author Date Report No.	ICS-No.
Acute oral toxicity	fluxapyroxad (BAS700F)	*Colinus virginianus*	LD_{50} > 2000 mg a.s /kg bw/d[1)]	XXX 2008 2007/1054365 11W0683/055077	73648
		Anas platyrhynchos	LD_{50} > 2000 mg a.s./kg bw/ d[1)]	XXX 2008 2008/1003797 13W0683/055082	73649
Short-term dietary toxicity		*Anas platyrhynchos*	> 1716 mg a.s./kg bw/d[1)]	XXX 2008 2008/1037447 32W0683/055091	73652
Long-term toxicity and reproduction		*Anas platyrhynchos*	NOEC = 33.6 mg a.s./kg bw/d[1)]	XXX 2008 2008/1055153	73687

				72W0683/055081	
Acute oral toxicity	epoxiconazole	*Colinus virginianus*	LD_{50} > 2 000 mg a.s./kg b.w. 1)	XXX 1990 11W0959/88071	26140
Short-term dietary toxicity		*Colinus virginianus*	LC_{50} > 907 mg a.s./kg b.w./day 2,1)	XXX 1990 31W0959/88083C	26141
Long-term toxicity and reproduction		*Colinus virginianus*	NOEL = 1.0 mg a.s./kg b.w./day 2;1)	XXX 1994 71W0195/91043	32757
Acute oral toxicity	BAS 70 100-F (ADEXAR)	*Colinus virginianus*	LD_{50} > 2 000 mg product/kg b.w*)	XXX 2009 2009/1075269 11W0497/075072	73805

Fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522

Epoxiconalzole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Daily Dose [mg/kg b.w./day] calculated based on study data for food consumption and body weight.

BAS 70 100-F: *) new study submitted by the notifier

As indicated above, an acute oral study with the formulated product has been conducted. Consequently, the toxicity of ADEXAR (BAS-70100-FW-0-EC) has not been assessed considering data generated on the individual active substances and assuming dose additivity of the single active substances in the formulation (see 'Mixture toxicity' chapter below).

For the active substance fluxapyroxad, an acute oral toxicity study was not only run for the bobwhite quail but also for the duck. Both studies provide the same ecotoxicological endpoint and are therefore equivalent. Concerning bird reproduction, the study conducted by Zok (2008/1055153; 72W0683/055081) resulted in a NOEL of 33.6 mg a.s./kg b.w./d. This endpoint is used for the risk assessment.

For the active substance epoxiconazole, the lowest endpoints resulted from studies performed on the bobwhite quail (LD_{50} > 2 000 mg a.s./kg b.w. (ICS 26140) and NOEL = 1 mg a.s./kg b.w./d (ICS 32757), respectively). These endpoints are used for the risk assessment.

6.2.1.2 Exposure

ADEXAR (BAS-70100-FW-0-EC) is a fungicide formulation containing fluxapyroxad and epoxiconazole as active substances. The product is formulated as an emulsifiable concentrate (EC) to control fungal diseases in cereal crops.

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$\mathrm{DDD} = \sum_i \frac{\mathrm{PD}_i \times \mathrm{FIR}_{total}}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$
$$= \sum_i \frac{\mathrm{FIR}_i}{\mathrm{bw}} \times \mathrm{RUD} \times \mathrm{AR} \times \mathrm{PT}$$

where:

DDD = Daily dietary dose (mg/kg bw/day)
PDi = composition of diet obtained from treated area
FIRi = Food intake rate of indicator species i (g fresh weight/d)
bw = Body weight (g)
RUD = Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR = Application rate (kg/ha)
PT = Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a "reasonable worst case". If a potential risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

Mixture toxicity

According to Appendix B to the Guidance Document on the Risk assessment for birds and mammals (EFSA, 1438/2009), the basic concept of the risk assessment is that animals are exposed to residues of the active substances in the environment. Thus, the assessment of ADEXAR (BAS-70100-FW-0-EC) is not an assessment of the formulation toxicity as such, but an assessment of the effects of an exposure to a mixture of active substances in the environment, resulting from the use of the formulation. Toxicity studies for birds with formulated products are typically not available. For the assessment of acute effects, a surrogate LD50 is calculated. Sublethal effects and effects on reproduction are assessed on a case-by-case basis. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney 1948 and 1971).

The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as e.g.:
0.5 (fluxapyroxad) = 62.5 g fluxapyroxad /kg / (62.5 g fluxapyroxad /kg + 62.5 g epoxiconazole /kg)

0.5 (epoxiconazole) = 62.5 g epoxiconazole /kg / (62.5 g fluxapyroxad /kg + 62.5 g epoxiconazole /kg)

LD_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Because of the direct proportionality of the calculated TER to the LD_{50}, it is possible to calculate a TER(mix) with the following formula:

$$\text{TER(mix)} = \left(\sum_i \frac{1}{\text{TER(a.s.}_i)} \right)^{-1}$$

where:

$\text{TER}_{(\text{a.s.}i)}$= calculated TER for the active substance *i*

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, a risk envelope approach was used to cover highest risk for birds from intended use of the group A (see also Table 6.1-1, page6).

The results of the acute and reproductive risk assessments are summarized in the following table.

Table 6.2-2: TER for birds

Compound	**Risk assessment level**	**Indicator species**	**Time scale**	**TER**	**TER trigger**
ADEXAR (BAS-70100-FW-0-EC)	Screening	Small omnivorous bird	Acute	> 4.9	10
	Tier 1	Small omnivorous bird “lark“ BBCH 30 -39		> 65	
		Small omnivorous bird “lark“ BBCH > 40		> 108	
Epoxiconazole	Tier 2	Skylark	Long-term	8.3	5
		Yellow wagtail		17.6	5
TER shown in bold are below the relevant trigger					

Based on the presumptions of a screening step and higher Tier, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

Drinking water risk assessment

Drinking water assessment is required as the ratio of effective treatment rate to toxicological endpoint does exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is required due to log P_{OW} values of fluxapyroxad and epoxiconazole being above the trigger. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TERA)

Screening step

In the screening step, the risk to indicator bird species from an exposure to ADEXAR (BAS-70100-FW-0-EC) is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

To estimate the daily dietary doses, following equations were used:

Daily dietary dose (DDD):

$DDD_{\text{single application}}$ = application rate [kg a.s./ha] × shortcut value[1]

[1] see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438). A specific MAF_{90} may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$DDD_{\text{multiple application}} = DDD_{\text{single application}} \times MAF_{90}$[1]

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ (\text{mg/kg bw/day})}{\text{Acute DDD}\ (\text{mg/kg bw/day})}$$

The resulting TER_A values are summarised in the following table, with the indicator species and the respective shortcut values.

Table 6.2-3: Acute screening risk assessment (TER_A) for birds. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
ADEXAR (BAS-70100-FW-0-EC)	Small omnivorous bird	2.08	158.8	1.23	406.3	> 2000	> 4.9
TERs shown in bold fall below the relevant trigger.							

* Density ADEXAR: 1.04 g/mL

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an unacceptable risk for birds, further refinement is necessary.

Tier 1

In the Tier 1 risk assessment step, the defined daily dietary doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009, Annex I). As for the indicator species, the generic focal species are considered to be representative for all species potentially at risk. In the Tier 1 assessment, a mixed diet approach is followed when appropriate and interception of the spray by the crop is taken into account for the calculation of residue levels for different food types.

If more than one generic focal species is relevant for the crop, the one that is relevant in terms of time of application or growth stage should be selected. If more than one generic focal species is relevant in terms of application time and growth stage, then the potential risk should be assessed for all relevant generic focal species. If the same generic focal species is relevant for several application times according to the BBCH growth stages, the risk assessment for this generic focal species is conducted once using the highest mean short-cut value, since this mirrows a realistic worst case scenario.

For the plant protection product "ADEXAR" (BAS-70100-FW-0-EC), the TER_A was below the trigger of 10 in the screening step for the intended uses in cereals. Therefore, a Tier 1 risk assessment step will be performed for these uses. Based on an application rate of ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30-69), the risk was assessed for the following generic focal species: Small omnivorous bird "lark".

The relevant short-cut values for these scenarios are summarized in the following table:

Table 6.2-4: Avian generic focal species for the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30-69) and relevant shortcut values

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (90th percentile RUD)
Group A	Cereals BBCH 30 to 69	Small omnivorous bird "lark" BBCH 30 -39	12.0
		Small omnivorous bird "lark BBCH ≥ 40	7.2

The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.2-5: Assessment of the acute risk to birds from ADEXAR (BAS-70100-FW-0-EC) in the intended uses in cereals (BBCH 30-69) (Tier 1)

Substance	Crop / Stage	Generic Focal Species	Application Rate (kg a.s./ha)	MAF	Short cut Value (90th percentile)	DDD (mg a.s./kg bw/d)	LD_{50} (mg a.s./kg bw/d)	TER
ADEXAR (BAS-70100-FW-0-EC)	cereals	Small omnivorous bird "lark" BBCH 30 -39	2.08	1.23	12	30.70	> 2000	> 65
		Small omnivorous bird "lark" BBCH > 40			7.2	18.42		> 108
TERs shown in bold fall below the relevant trigger.								

Based on refined Tier 1 assessment step, the calculated TER values for the acute risk resulting from an exposure of birds to epoxiconazol and fluxapyroxad according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals (BBCH 30-69) according to the label.

6.2.2.2 Short -term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.2-6: Avian generic focal species for the intended uses of ADEXAR (BAS-70100-FW-0-EC) and relevant shortcut values for long-term exposure

Crop	**Indicator species**	**Shortcut value (mean RUD)**
cereals	Small omnivorous bird	64.8

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{\text{single application}} = \text{application rate [kg/ha]} \times \text{shortcut value} \times \text{TWA*}$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{\text{NOEL (mg/kg bw/day)}}{\text{Long - term DDD (mg/kg bw/day)}}$$

As the active substances fluxapyroxad and epoxiconazole have different modes of actions, no TERmix will be calculated for the long-term risk assessment. The long –term risk assessment for birds exposed to ADEXAR (BAS-70100-FW-0-EC) will be calculated based of the toxicity study of the active substance epoxiconazole. In long-term toxicity studies on birds, the relevant lowest NOEL for the reproduction exposure scenario for epoxiconazole is 1 mg a.s./kg bw/d. The active substance epoxiconazole appears 30 time more toxic than the acitve substance fluxapyroxad, and will thus cover the long-term risk caused by fluxapyroxad. Full details of the avian toxicity studies are provided in the respective EU DAR as well as in appendix 2 of this document (new studies). The relevant long-term endpoint is provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to epoxiconazole following applications of ADEXAR (BAS-70100-FW-0-EC).

Table 6.2-7: Long-term screening risk assessment (TER_{LT}) for birds exposed to ADEXAR (BAS-70100-FW-0-EC) according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
epoxiconazole	Small omnivorous bird	0.125	64.8	0.53	1.14	4.9	1	**0.20**
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER values for the long-term risk resulting from an exposure of birds to the active substance epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for birds, further refinement is necessary.

Tier 1

For a general description of the followed approach in the Tier1 risk assessment step, please consult chapter 6.2.2.1 (acute toxicity).

For epoxiconazole, the TER_A was below the trigger of 5 in the screening step for the intended uses in cereals (BBCH 30 -69). Based on an application rate of 2 x 2L ADEXAR /ha (corresponding to 2 x 125 g epoxiconazole /ha) with a minimum of 21 days interval, the risk was assessed for the following generic focal species in cereals from BBCH 30 to BBCH 69: a small omnivorous bird (woodlark).

The relevant short-cut values for these scenarios are summarized in the following table:

Table 6.2-8: Avian generic focal species for the spraying of epoxiconazole and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
00-01 to 00-022	Winter and spring cereals BBCH 30 to 69	Small omnivorous bird “lark” (BBCH 30 to 39)	5.4
		Small omnivorous bird “lark” BBCH ≥ 40	3.3

Table 6.2-9 Refined long term risk assessment (TER_{LT}) for birds from ADEXAR (BAS-70100-FW-0-EC); Crop: cereals

Birds, Reproductive Exposure		
Crop	**Cereals**	
Generic focal species	Small omnivorous bird "lark"	
Scenario	BBCH 30 to 39	BBCH BBCH ≥ 40
Shortcut value for mean RUDs	5.4	3.3
Application rate [kg a.s./ha]	0.125	0.125
MAF_m for mean residue data	1.14	1.14
TWA	0.53	0.53
DDD	0.41	0.25
NOED [mg/kg b.w./d]	1.0	1.0
TER	**2.4**	**4**
Comment	**Refinement required**	**Refinement required**

Under the conservative assumptions of a Tier 1 assessment, for all relevant scenarios, the long-term (reproductive) TER values for birds following application of ADEXAR (BAS-70100-FW-0-EC) in cereals are below the trigger set by Annex VI of Directive 91/414/EEC, i.e. ≥ 5 for long-term exposure, and have therefore been refined in the following Higher Tier (Tier 2) risk assessment.

Tier 2

Further refinement options were considered in Tier 2.

Choice of the relevant focal species:

The notifier mentioned a study by Dietzen *et al.* (2006, BASF DoclD 2006/1039415). The generic bird monitoring study, in which the qualitative and quantitative composition of the bird community in cereal fields was studied between March and July 2005 in 3 countries of northern Europe (Germany, France and Poland) covers the main cereal growth stages from BBCH 10 (early leaf development) to BBCH 83 (ripening). This study indicates the **skylark (*Alauda arvensis*)** as being the relevant omnivorous focal species for the applied use scenario. Additionally to the skylark, the insectivorous **yellow wagtail (*Motacilla flava*)** shows high spatial and temporal occurrence values in the field monitoring study, and will be also considered as appropriate focal species in cereal fields with regard to the relevant application time for epoxiconazole (i.e. BBCH 30-69).

The zRMS agrees with the proposal of the notifier to use the skylark and the yellow wagtail for the refined risk assessment.

Composition of diet of the skylark (PD)

PD values for the skylark in arable land are available from a proprietary generic study conducted in Austria by Wolf (2005a). Data from this study are also included in EU risk assessment report (Final addendum to the Draft Assessment Report of epoxiconazole, 2008) as following:

UK scenario (April – June diet) 25.7 % grasses and cereal shoots, 15.1% dicotyl weeds, 32.4 % weed seeds and 26.9 % arthropods

Austrian scenario (April/May diet): 2 % grasses and cereal shoots, 9 % dicotyl weeds, 14 % weed seeds and 75 % arthropods

For details please refer to the final addendum of epoxiconazole (2008).

Beside these data, the notifier submitted a new generic field study (Giessing & Städtler 2011, BASF DocID 2010/1044221, ICS 26958) conducted in ten winter cereal fields in Brandenburg (Germany) and covering the growth stages BBCH 25 – 39. According to this study based on the analysis of 37 faecal samples, the diet composition of the skylark in cereal fields at BBCH 30-39 is

Giessing & Städtler 2011 (April/June diet): 0.3 % grasses and cereal shoots, 2.3 % dicotyl weeds, 26.2 % weed seeds and 71.2 % arthropods.

This diet composition is in accordance with the "Austrian scenario" of the generic study from Wolf (2005) and will be used by the zRMS to refine the composition of diet of the skylark (PD).

<u>Composition of diet of the yellow wagtail (PD)</u>

The yellow wagtail is a fully insectivorous species. To refine the diet composition of the yellow wagtail, the notifier cited 2 studies from public literature in which the foraging behaviour of yellow wagtails was studied in Germany (Stiebel 1997) and in Britain (Davies 1977)[1]. According to Davies (1977), there are three types of foraging techniques:

1. Picking (84%): The bird walks and picks up prey items from the ground surface.
2. Run-picking (9%): The wagtails make quick darting runs at a prey item and pick it up either from the ground or as it takes off.
3. Fly-catching (7%): The birds make a short sally up off the ground and catch prey mid-air.

These results are in accordance to those from Stiebel (1997)[2], who observed that the most common foraging technique of the yellow wagtail was picking arthropod prey from the soil while running on the ground. Therefore, as a simple approach, the zRMS agrees to the proposition of the notifier to set in the refined risk assessment the following diet composition for the yellow wagtail:

- Ground-dwelling arthropods PD = 0.93 (picking and run-picking, 84% + 9% = 93%)
- Non-ground-dwelling arthropods PD = 0.07

<u>Normalised mean residues of epoxiconazole in cereal plants:</u>

[1] Davies, N.B. 1977. Prey selection and social behavior in wagtails. Journal of Animal Ecology 46: 37-57
[2] Stiebel, H. 1997. Habitatwahl, Habitatnutzung und Bruterfolg der Schafstelze *Motacilla flava* in einer Agrarlandschaft. Die Vogelwelt 118: 257-268.

The notifier proposed to use a mean RUD of **22.86 mg a.s./kg** for the initial foliar residues of epoxiconazole in cereal plants. This value based on 24 field trials measuring epoxiconazole residues in cereal foliage, showed that the residue values are lower than the first tier default RUD value for plant feed items (see Table B.9.1-1 of the DAR for details). This mean RUD was accepted in the EFSA conclusion for epoxiconazole (EFSA, 2008; page 25) and is judged acceptable by the zRMS to refine the risk assessment. The zRMS also agrees to set the **MAF at 1** provided that the interval used in the trials is equal to or lower than the interval according to GAP (21 days)' (EFSA, 2008) and to set the twa to 0.53.

<u>Residues of epoxiconazole in arthropods:</u>

The notifier submitted a field study to specifically determine initial residue levels of epoxiconazole and the time course of epoxiconazole residues in ground-dwelling and foliage-dwelling arthropods in cereals after spray application (Schneider 2011, BASF DocID 2011/1102461, see Appendix 2 for a detailed study summary). The field part of the study was conducted in April / May 2010 in a winter wheat field located north-west of Berlin (Brandenburg, Germany), a typical area of winter wheat cultivation in Europe. Three test plots (replicates) were set up within the winter wheat field. The size of each plot was approximately 1.8 ha and was therefore large enough to prevent immigration of non-contaminated arthropods. An epoxiconazole-containing formulation (OPUS TOP®) was applied in similar application patterns as the intended uses of ADEXAR (2 spray applications with a nominal application rate of 125 g epoxiconazole/ha and an interval of 21 days at BBCH growth stages 29 and 32). The worst case time-weighted average (TWA) residue values of epoxiconazole in ground- and foliage dwelling arthropods were determined for 21-day periods (moving window) as following: [**0.141 mg a.s/kg fresh weight] for ground-dwelling arthropods** and **0.586 [mg a.s/kg fresh weight] for foliage-dwelling arthropods** (see Schneider 2011 for details). These measured residue values will be used to refine the risk assessment.

<u>Exposure in the treated area of the skylark</u>

In the refined risk assessment for epoxiconazole on EU level a PT value of 0.29 for skylark is used. This value is derived from a study by Wolf (2005a; see also above refinement of PD value) based on 29 radio-tracking sessions with skylarks, which gives a mean PT of 0.29 (all birds) and 0.352 (consumers) in maize and beet fields in Austria. As the birds were not necessarily trapped within cereal fields or in their close vicinity, the notifier propose to use the more conservative **PT value of 0.352** (consumers) in the refined risk assessment for the skylark in cereal fields. The zRMS agrees to this approach.

<u>Exposure in the treated area of the yellow wagtail</u>

To refine the proportion of diet of the yellow wagtail obtained from the treated area, the notifier cited a generic field study (Wolf 2005b, BASF DocID 2007/1042664) conducted in mixed arable land in Lower Saxony, Germany. In this study a total of 20 yellow wagtails were radio-tracked. The mean PT values, based on the pooled data for the crops barley, wheat and rye were 0.398 (all birds) and 0.419 (consumers). As the birds were not necessarily trapped within cereal fields or in their close vicinity, the notifier proposes to use the more conservative **PT value of 0.419 (consumers)** in the refined risk assessment for the yellow wagtail. This PT value is in accordance with the results of a study conducted by

Anthes *et al.* (2002)[3] in a agricultural landscape mainly composed of cereals (38-67%), sugar beets (6-45%) and maize (5-27%) in southern Germany. In Anthes *et al.* (2002), the yellow wagtails clearly show a preference for potato and cereal cultures and rather avoid cereal fields. Therefore the zRMS agrees to the use of a PT value of 0.419 to refine the exposure in the treated area of the yellow wagtail.

The outcome of the Tier 2 risk assessment steps is presented in the following tables:

Table 6.2-10: Refined long term risk assessment (TER_{LT}) for the skylark from ADEXAR (BAS-70100-FW-0-EC); Crop: cereals (TIER 2)

Birds, Reproductive Risk Assessment				
Crop	**Cereals**			
Scenario	BBCH 30-69			
Focal species a)	skylark			
Application rate [kg a.s./ha] b)	0.125			
FIR/b.w. c)	0.66			
PT d)	0.352			
Diet	Grass and cereals	Non grass weeds	Ground dwelling	Weed seeds
PD e)	0.023	0.003	0.712	0.262
Mean RUD /Measured residues	22.86 f)	22.86 f)	7.5 f)	40.2 g)
MAF_m for mean residue data	1 h)	1 h)	1	1.2 i)
TWA j)	0.53	0.53	1	0.53
DDD k)	0.005	0.001	0.014	0.1
DDDsum	0.12			
NOED [mg/kg b.w./d] l)	1.0			
TER_{RE} m)	8.33			
Comment	Risk acceptable			

a) Based on generic field study in cereal fields (Dietzen *et al*. 2006)
b) Intended maximum application rate according to GAP expressed as kg a.s./ha
c) Food intake rate for mixed diet calculated according to the 'Guidance Document', Appendix G (EFSA, 2009)
d) Portion of diet obtained from the treated area according to radio-tracking data of skylarks (Wolf, 2005a)
e) Portion of diet according to faeces samples from skylarks
f) epoxiconazole-specific residue data (arthropods) or RUD (plants) from supervised field trials in cereals
g) Mean RUDs for seeds according to the 'Guidance Document', Appendix F (EFSA, 2009)
h) Multiple application factor is included in risk assessment
i) Multiple application factor for 2 applications with 21 days interval according to the 'Guidance Document', (EFSA, 2009)
j) Time-weighted average factor based on default DT_{50} = 10 days according to the 'Guidance Document' (EFSA, 2009)
k) Daily Dietary Dose calculated according to the 'Guidance Document' (EFSA, 2009)
l) Lowest reproductive endpoint
m) Reproductive 'Toxicity-Exposure-Ratio' with TER = NOED/DDD according to the 'Guidance Document' (EFSA, 2009)

[3] Anthes, N., Gastel, R. and Quetz, P.C. (2002): Die Schafstelze im Landkreis Ludwigsburg. Orn. Jh.Bad.-Wurtt. 18: 347 - 361.

Table 6.2-11: Refined long term risk assessment (TER_{LT}) for the yellow wagtail from ADEXAR (BAS-70100-FW-0-EC); Crop: cereals (TIER 2)

Birds, Reproductive Risk Assessment		
Crop	**Cereals**	
Scenario	BBCH 30-69	
Focal species [a)]	Yellow wagtail	
Application rate [kg a.s./ha] [b)]	0.125	
FIR/b.w. [c)]	0.66	
PT [d)]	0.419	
Diet	Ground dwelling invertebrates	foliar dwelling invertebrates
PD [e)]	0.93	0.07
Residues [mg a.s./kg]	0.141 [f)]	0.586 [g)]
DDD [g)]	0.043	0.014
DDDsum	0.057	
NOED [mg/kg b.w./d] [h)]	1.0	
TER_{RE} [i)]	17.6	
Comment	Risk acceptable	

a) Based on generic field study in cereal fields (Dietzen *et al.* 2006)
b) Intended maximum application rate according to GAP expressed as kg a.s./ha
c) Food intake rate for mixed diet calculated according to the 'Guidance Document', Appendix G (EFSA, 2009)
d) Portion of diet obtained from the treated area according to Wolf (2005b)
e) Portion of diet according to Davies (1977) and Stiebel (1997)
f) epoxiconazole-specific residue data from supervised field trials in cereals (Schneider, 2011)
g) Daily Dietary Dose calculated according to the 'Guidance Document' (EFSA, 2009)
h) Lowest reproductive endpoint
i) Reproductive 'Toxicity-Exposure-Ratio' with TER = NOED/DDD according to the 'Guidance Document' (EFSA, 2009)

Based on refined Tier 2 assessment step, the calculated TER values for the long-term risk resulting from an exposure of birds to epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for birds due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.2.3 Drinking water exposure

In case of early post-emergence uses as intended for ADEXAR (BAS-70100-FW-0-EC) birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of fluxapyroxad and epoxiconazole formed on a field after rainfall. The ratios do not exceed the value of 3000 for fluxapyroxad (Koc = 728 L/kg) and epoxiconazole (Koc = 1073 L/kg), thus it is not necessary to conduct a drinking water risk assessment for birds.

Table 6.2-12 Ratios of effective application rate to endpoints for fluxapyroxad and epoxiconazole following the use of ADEXAR (BAS-70100-FW-0-EC) in cereals

Test substance	KOC	Application rate (g/ha)	Acute endpoint	Ratio of application rate to acute endpoint	Long-term endpoint	Ratio of application rate to long-term endpoint	Ratio trigger
fluxapyroxad	729	250	> 2000	< 0.125	33.6	7.44	≤ 3000
epoxiconazole	1073	250	> 2000	< 0.125	1	250	≤ 3000

6.2.4 Details on formulation type in proportion per item

6.2.4.1 Baits: Concentration of active substance in bait in mg/kg

ADEXAR (BAS-70100-FW-0-EC) is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.4.2 Pellets, granules, prills or treated seed

ADEXAR (BAS-70100-FW-0-EC) is not formulated as pellets, granules, prills or treated seeds. ADEXAR (BAS-70100-FW-0-EC) is intended for use as a foliar spray, and therefore this information is not required.

Amount of active substance in or on each item

Not applicable.

Proportion of active substance LD50 per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.5 Acute toxicity of the formulation

Please refer to section 6.2.1.1 and 6.2.2 for an overview of the submitted data on the toxicity of ADEXAR (BAS-70100-FW-0-EC) to birds and the outcome of the risk assessment for birds.

6.2.6 Metabolites

Avian toxicity tests with metabolites of fluxapyroxad were not performed and are not considered necessary.

According to the EFSA Scientific Report (2008) on epoxiconazole Triazolyl alanine (TA) and Triazolyl acetic acid (TAA) were identified as major residues in wheat grain for wheat which was grown on soil containing residues aged for 30 days. Residues for TA and TAA in wheat grain were 54 % total radioactivity residues (TRR) and 26 % TRR respectively. In contrast, straw contained a high percentage of unchanged parent (36 % TRR). Other major metabolites were TAA (10 % TRR) and triazoly hydroxyl propionic acid (THPA) with 16 % TRR. The most sensitive endpoints for investigated metabolites TA and TAA indicate low acute toxicity to mammals (LD_{50} > 5000 mg/kg bw in rats) and to birds (LD_{50} > 1354 mg/kg bw for TA and an LD50/NOEL of ≥ 2000 mg/kg bw for TAA). For the structural analogues TPHA no toxicity data is given but on the basis of the strong structural similarity with the metabolites TA and TAA no indication exists for an increased toxicity to mammals and birds. Given the low acute and short-term toxicity of the tested metabolites it is concluded that the risk from the major plant metabolites is covered by the risk assessment for epoxiconazole

6.2.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of ADEXAR (BAS-70100-FW-0-EC) pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.8 Acceptance of bait, granules or treated seeds (palatability testing)

ADEXAR (BAS-70100-FW-0-EC) is intended for use as a foliar spray, and therefore this information is not required.

6.2.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of fluxapyroxad and epoxiconazole are 3.13 (pH=7) and 3.3 (pH=7), respectively, these active substances are deemed to have a potential to bioaccumulate in animal tissues.

The assessment of the risk for bird through secondary poisoning is based on the evaluation of an earthworm eating bird (100 g bw, food intake rate, FIR = 104.6 g fresh weight /d). The calculation is performed for the worst case intended use with the maximal soil relevant amount of the formulation ADEXAR (BAS-70100-FW-0-EC).

Table 6.2-13: Assessment of the risk for earthworm eating birds from an exposure to fluxapyroxad and epoxiconazole through secondary poisoning

Parameter	fluxapyroxad	comments
PEC_{soil}, act [mg/kg soil]	0.098	2 × 125 g/ha, interception 70%, soil layer depth 5 cm, DT_{50} = 370 d
log Pow	3.13	Pow=1349
K_{oc}	729	-
F_{oc}	0.02	Default
BCF_{worm}	1.168	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.115	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.12	DDD = $PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	33.6	*Anas platyrhynchos*
TER_{lt}	279	≥ 5, acceptable risk
Parameter	**epoxiconazole**	**comments**
PEC_{soil}, act [mg/kg soil]	0.097	2 × 125 g/ha, interception 70%, soil layer depth 5 cm, DT_{50} = 226 d
log Pow	3.3	Pow=1995
K_{oc}	1093	-
F_{oc}	0.02	Default
BCF_{worm}	1.134	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.110	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietara dose (mg/kg bw/d)	0.115	DDD = $PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	1	*Colinus virginianus*
TER_{lt}	8.7	≥ 5, acceptable risk

The risk assessment for fish eating mammals according to the Guidance Document EFSA/2009/1438 is performed for a bird with 1000 g bw and a FIR (Food intake rate) of 4159 g (fresh weight) fish.

Table 6.2-14: Assessment of the risk for fish eating birds from an exposure from an exposure to fluxapyroxad and epoxiconazole through secondary poisoning

Parameter	**fluxapyroxad**	**comments**
RAC-aq [mg/L]	0.002900	LC_{50} = 0.29 mg/L with SF 100 for *O. mykiss*
BCF_{fish}	119	-
PEC_{fish}	0.345	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietara dose (mg/kg bw/d)	0.055	DDD = PEC_{fish} x 0.159
NOEL (mg/kg bw/d)	33.6	*Anas platyrhynchos*
TER_{lt}	612	≥ 5, acceptable risk
Parameter	**epoxiconazole**	**comments**
RAC aq [mg/L]	0.000430	EC_{50} = 0.0043 mg/L with SF 10 for *lemna gibba*
BCF_{fish}	70	-
PEC_{fish}	0.030	$PEC_{fish} = PEC_{water}$ x BCF_{fish}
Daily dietara dose (mg/kg bw/d)	0.005	DDD = PEC_{fish} x 0.159
NOEL (mg/kg bw/d)	1	*Colinus virginianus*
TER_{lt}	209	≥ 5, acceptable risk

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the actives substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

The risk assessment for effects on mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of fluxapyroxad and epoxiconazole to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	fluxapyroxad (BAS700F)	Acute oral toxicity	LD_{50} >2000 mg a.i./kg bw/d[1)]	XXX 2008 2008/1002441	73635
Rat		Multigeneration	NOAEL = 10 mg a.i./kg bw/d[1)] Impaired body weight development in F1 offspring	XXX 2009 2009/1072491	73636
Rat	Metabolite M700F007	Acute oral toxicity	LD_{50} >500 < 2000 mg a.i./kg bw/d[1]	XXX 2009 1084176 10A0432/099058	74038
Rat	epoxiconazole	Acute oral toxicity	LD_{50} > 3160 mg a.s./kg bw [1]	XXX 1988 10A0035/871003	73199
Rat		Long-term toxicity and reproduction	NOAEC = 25 mg a.s./kg diet NOAEL = 2.3 mg a.s./kg bw/day [1]	XXX 1992 70R0959/88098	73200
Rat	Metabolite 1,2,4-triazole (= BF 480-16)	Acute oral toxicity	LD_{50} = 1648 mg a.s./kg bw [1]	XXX 2006	74104
Rat		Long-term toxicity and reproduction	NOAEL = 15 mg a.s./kg bw/day [1]	XXX 2006	74104

fluxapyroxad: 1) Endpoints from EFSA Journal 2012;10(1):2522

M700F007: 1) Endpoints from EFSA Journal 2012;10(1):2522

epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Daily Dose [mg/kg bw/day] calculated based on study data for food consumption and body weight.

1,2,4-triazole : 1) EU agreed endpoint EFSA Scientific report No. 138 (2008)

6.3.1.2 *Exposure*

Exposure to standard generic indicator species was estimated according to the 'EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438). Please see chapter 6.2.1.2, page 9 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

6.3.1.3 *Risk assessment –overall conclusions*

The overall conclusion on the risk assessment for mammals and the calculated TER-values are shown in the following table.

Table 6.3-2: Minimum TER values for mammals after uses of ADEXAR (BAS-70100-FW-0-EC) in the intended uses

Substance	Risk assessment level	Indicator mammal	Time scale	TER	TER trigger
fluxapyroxad	Screening	Small herbivorous mammal	Acute	> 109	10
epoxiconazole	Screening	Small herbivorous mammal	Acute	> 173	10
	Screening	Small herbivorous mammals	Long-term	**0.6**	5
	Tier 1	BBCH ≥ 20 - small insectivore (*Sorex araneus*)		15.33	5
		BBCH 30-39 - small omnivore (*Apodemus sylvaticus*)		7.2	5
		BBCH ≥ 40 - small omnivore (*Apodemus sylvaticus*)		12	5
		BBCH ≥ 40 - small herbivore (*Microtus arvalis*)		**1.3**	5
	Tier 2	BBCH ≥ 40 - small herbivore (*Microtus arvalis*)		11.4	5
TER Mix	Screening	Small herbivorous mammal	Acute	> 41	10
TERs shown in bold fall below the relevant trigger.					

Based on the presumptions of the screening step and higher Tiers, the calculated TER values for the acute and long-term risk resulting from an exposure of mammals to the active substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3

Food chain behaviour

An assessment of the risk from secondary poisoning is required due to log P_{OW} values of the active substances fluxapyroxad and epoxiconazole being above the trigger. Please refer to chapter 6.2.9.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER$_A$)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

The indicator mammal species for the intended uses are listed in the following table.

Table 6.3-3: Indicator species for mammals according to intended use of ADEXAR (BAS-70100-FW-0-EC) and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
cereals	small herbivorous mammals	118.4

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1

Table 6.3-4: Acute screening risk assessment (TERA) for mammals. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
fluxapyroxad	small herbivorous mammals	0.125	118.4	1.23	18.2	> 2000	> 109
epoxiconazole						> 3160	> 173
TERmix > 41							
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the active substances fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-5: Mammal generic focal species for the intended uses of ADEXAR (BAS-70100-FW-0-EC) and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
cereals	small herbivorous mammals	48.3

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

As the active substances fluxapyroxad and epoxiconazole have different modes of actions, no TERmix will be calculated for the long-term risk assessment. The long –term risk assessment for mammals exposed to ADEXAR (BAS-70100-FW-0-EC) will be calculated based of the toxicity study of the active substance epoxiconazole. In long-term toxicity studies on rats, the active substance epoxiconazole appears 5 time more toxic than the acitve substance fluxapyroxad, and will thus cover the long-term risk caused by fluxapyroxad.

The relevant lowest NOEL for the reproduction exposure scenario for epoxiconazole is 2.3 mg a.s./kg bw/d. Full details of the toxicity studies are provided in the respective EU DAR. The following table reports the calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to epoxiconazole following applications of ADEXAR (BAS-70100-FW-0-EC).

Table 6.3-6: Long-term screening risk assessment (TER_{LT}) for mammals exposed to epoxiconazole according to the intended uses

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg/kg bw/day)	TER_{LT}
epoxiconazole	small herbivorous mammals	0.125	48.3	0.53	1.2	3.84	2.3	**0.6**
TERs shown in bold fall below the relevant trigger.								

Based on the highly conservative presumptions of the screening step, the calculated TER value for the long-term risk resulting from an exposure of mammals to the active substance epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for mammals due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label, further refinement is necessary.

Tier 1 risk assessment

For the Tier 1 risk assessment, the defined daily doses and TER values were calculated for so-called generic focal species (see EFSA 1438/2009. Annex I). Please refer to section 6.2.2 for general consideration in the choice of generic focal species in risk assessment procedures.

The relevant short-cut values for scenarios evaluated are summarized in the following table.

Table 6.3-7: Mammal generic focal species for the intended uses of ADEXAR (BAS-70100-FW-0-EC) and relevant shortcut values for long-term risk assessment

Intended use	Crop Growth Stage	Generic Focal Species	Shortcut value (mean RUD)
groupA	BBCH 30-39	Small omnivorous mammal “mouse”	3.9
	BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3

The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.3-8: Reproductive mammal risk assessment of ADEXAR (BAS-70100-FW-0-EC) uses in cereals (Tier 1)

Substance	Generic Focal Species	Application Rate (kg a.s./ha)	MAF x twa	Short cut Value (Mean RUD)	PT value	DDD (mg a.s./kg bw/d)	NOEL (mg a.s./ kg bw/d)	TER
epoxiconazole	BBCH ≥ 20 small insectivore (*Sorex araneus*)	0.125	0.65	1.9	1	0.15	2.3	15.33
	BBCH 30-39 small omnivore (*Apodemus sylvaticus*)	0.125	0.65	3.9	1	0.32	2.3	7.2
	BBCH ≥ 40 small omnivore (*Apodemus sylvaticus*)	0.125	0.65	2.3	1	0.19	2.3	12
	BBCH ≥ 40 small herbivore (*Microtus arvalis*)	0.125	0.65	21.7	1	1.76	2.3	**1.3**
TERs shown in bold fall below the relevant trigger.								

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of the small herbivore "*Microtus arvalis*" in BBCH growth stages ≥ 40 to epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for mammals for the scenario "BBCH ≥ 40, small herbivore (*Microtus arvalis*) due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label. Further refinement is necessary.

Further refinement options considered in Tier 2

<u>Normalised mean residues of epoxiconazole in cereal plants:</u>

A mean RUD of **22.86 mg a.s./kg** for the initial foliar residues of epoxiconazole in cereal plants will be used in the refined risk assessment. This value based on 24 field trials measuring epoxiconazole residues in cereal foliage, showed that the residue values are lower than the first tier default RUD value for plant feed items (see Table B.9.1-1 of the DAR for details). This mean RUD was accepted in the EFSA conclusion for epoxiconazole (EFSA, 2008; page 25) and is judged acceptable by the zRMS to refine the risk assessment. The zRMS also agrees to set the **MAF at 1** provided that the interval used in the trials is equal to or lower than the interval according to GAP (21 days)' (EFSA, 2008) and to set the twa to 0.53.

<u>Interception of the crop canopy (Deposition factor, DF)</u>

According to the Appendix A of Guidance Document (EFSA, 2009), in the scenario "Cereals, BBCH ≥ 40", the diet of the common vole (*Microtus arvalis*) is composed of 100% grass. Therefore, an interception of 90% can be included in the calculation of the residues in food items of this generic focal species. This corresponds to a deposition factor (DF) of 0.1.

Table 6.3-9: Refinement of reproductive risk assessment according to EFSA Journal (2009) for *Microtus arvalis* exposed to epoxiconazole in cereals at BBCH growth stages ≥ 40 (TIER 2)

Application rate (kg/ha)	**Species / Diet**	**MAF**	**FIR/ bw**	**DF**	**RUD**	**PT**	**DDD**	**Endpoint (mg/kg bw/day)**	**TER (10)**
Cereals, BBCH ≥ 40									
epoxiconazole	Vole, *Microtus arvalis* 100% grass	0.53	1.33	0.1	22.86	1	0.202	2.3	11.4
TERs shown in bold fall below the relevant trigger.									

Based on refined Tier 2 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.3.3 Drinking water exposure

In case of early post-emergence uses as intended for ADEXAR (BAS-70100-FW-0-EC) mammals might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by mammals (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of fluxapyroxad and epoxiconazole formed on a field after rainfall. The ratios do not exceed the value of 50 for fluxapyroxad (Koc = 729 L/kg) and epoxiconazole (Koc = 1073 L/kg), thus it is not necessary to conduct a drinking water risk assessment for mammals.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of ADEXAR (BAS-70100-FW-0-EC).

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

6.3.5 Acute toxicity of the formulation

Mammal toxicity tests with the formulation were not performed and are not considered necessary.

6.3.6 Metabolites

Please refer to section 6.3.1 for an overview of the risk assessment for mammals.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of ADEXAR (BAS-70100-FW-0-EC) pose no unacceptable acute or long-term risks to mammals, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

ADEXAR (BAS-70100-FW-0-EC) is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of fluxapyroxad and epoxiconazole are 3.13 (pH=7) and 3.3 (pH=7), respectively, these active substances are deemed to have a potential to bioaccumulate in animal tissues. A formal risk assessment from secondary poisoning is therefore required.

The assessment of the risk to mammals exposed to ADEXAR (BAS-70100-FW-0-EC) through secondary poisoning is based on the evaluation of an earthworm eating mammal (10 g bw, food intake rate, FIR =

12.8 g fresh weight/d). The calculation is performed for the worst case intended use with the maximal soil relevant amount of the formulation.

Table 6.3-10: Assessment of the risk for earthworm eating mammal from an exposure to fluxapyroxad and epoxiconazole through secondary poisoning

Parameter	**fluxapyroxad**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.098	2 × 125 g/ha, interception 70%, soil layer depth 5 cm, DT_{50} = 370 d
K_{ow}	3.13	-
K_{oc}	729	-
F_{oc}	0.02	Default
BCF_{worm}	1.168	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.115	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.147	DDD = PEC_{worm} x 1.28
NOEL (mg/kg bw/d)	10	rats
TER_{lt}	68	≥ 5, acceptable risk
Parameter	**epoxiconazole**	**comments**
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.097	2 × 125 g/ha, interception 70%, soil layer depth 5 cm, DT_{50} = 370 d
K_{ow}	3.3	Pow=1993
K_{oc}	1093	
F_{oc}	0.02	Default
BCF_{worm}	1.134	$BDF_{worm} = (PEC_{worm}/PEC_{soil})$ $= (0.84 + 0.12 \times K_{ow}) / f_{oc} \times K_{oc}$
PEC_{worm}	0.11	$PEC_{worm} = PEC_{soil} \times BCF$
Daily dietary dose (mg/kg bw/d)	0.141	DDD = PEC_{worm} x 1.28
NOEL (mg/kg bw/d)	2.3	rats
TER_{lt}	16	≥ 5, acceptable risk

The risk assessment for fish eating mammals according to the Guidance Document EFSA/2009/1438 is performed for a mammal with 3000 g bw and a food intake rate FIR =425 g fresh weight fish/ d.

Table 6.3-11: Assessment of the risk for fish eating mammal from an exposure to fluxapyroxad and epoxiconazole through secondary poisoning

Parameter	**fluxapyroxad**	**comments**
RAC-aq [mg/L]	0.002900	LC_{50} = 0.29 mg/L with SF 100 for *O. mykiss*
BCF_{fish}	119	
PEC_{fish}	0.345	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.049	DDD = PEC_{fish} x 0.142
NOEL (mg/kg bw/d)	10	rats
TER_{lt}	204	≥ 5, acceptable risk
Parameter	**epoxiconazole**	**comments**
RAC-aq [mg/L]	0.000430	EC_{50} = 0.0043 mg/L with SF 10 for *lemna gibba*
BCF_{fish}	70	-
PEC_{fish}	0.030	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.004	DDD = PEC_{fish} x 0.142
NOEL (mg/kg bw/d)	2.3	rats
TER_{lt}	538	≥ 5, acceptable risk

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for mammals exposed through secondary poisoning to the active substance fluxapyroxad according to the GAP of the formulation achieve the acceptability criteria TER ≥ 5, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

The following EU agreed endpoints for aquatic organisms exposed to the active substances fluxapyroxad and epoxiconazole are reported in the lists of endpoints of the Conclusion on the Peer review of fluxapyroxad (EFSA Journal 2012;10(1):2522) and epoxiconazole (EFSA Scientific Report 2008, 138, 1-80) (see table below).

The applicant provides further studies on the risk for aquatic organisms with the formulation ADEXAR (BAS-70100-FW-0-EC) and for the active substances fluxapyroxad and epoxiconazole and their major metabolites. Detailed study summaries for the studies performed with the formulated product ADEXAR (BAS-70100-F) as well as the Annex II data are presented in Appendix 2.

6.4.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to fluxapyroxad and epoxiconazole and ADEXAR (BAS-70100-F) with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Date author Report No.**	**ICS-No.**
Acute toxicity to fish					
Cyprinus carpio	fluxapyroxad (BAS700F)	4 d semi-static	**LC_{50} = 0.29 mg a.s./L**[1] (mean measured)	XXX 2008 5094351	73697
Oncorhynchus mykiss	BAS700F001 (fluxapyroxad-Metabolite)	4 d static	LC_{50} > 100 mg/L[1]	XXX 2009 2009/1021591	73769
Oncorhynchus mykiss	BAS700F002 (fluxapyroxad-Metabolite)	4 d static	LC_{50} > 100 mg/L[1]	XXX 2009 2009/1021595 W/15/09	73770
Oncorhynchus mykiss	BAS700F007 (fluxapyroxad-Metabolite)	4 d static	LC_{50} > 100 mg/L[1]	XXX 2009 W/12/09	73773
Oncorhynchus mykiss	epoxiconazole	4 d static	**96 h LC_{50} = 3.14 mg/L**	XXX 1989 12F0959/885095	26135

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Oncorhynchus mykiss	1,2,4-triazole (= BF 480-16)	4 d static	96 h LC_{50} = 498 mg/L (measured conc.)	XXX 1983 821418	41737
Oncorhynchus mykiss	ADEXAR (BAS 701 00 F)	4 d	LC_{50}= 10.6 mg Prod./L[2]	XXX 2009 075065	73838
Chronic toxicity to fish					
Pimephales promelas	fluxapyroxad (BAS700F)	ELS flow-through 33 d	**NOEC = 0.0359 mg a.s./L[1]** (mean measured)	XXX 2009 51F0683/055085	73738
Pimephales promelas	epoxiconazole	FLC flow-through 54 d	**NOEC = 0.003 mg/L** (growth F1) NOEAEC = 0.01 mg/L (growth F2)	XXX 2003 81F0307/005085	24111
Danio rerio	epoxiconazole	FLC 133 d with sediment static	EC_{10} = 0.030 mg/L [1] (reduced vitellogenin levels in females)	XXX 2003 BAS-014/4-61	33404
Oncorhynchus mykiss	1,2,4-triazole (= BF 480-16)	28 d	NOEC = 3.2 mg/L	XXX 2002 DOM 21060	45802
Invertebrates, acute toxicity					
Crassostrea virginia	fluxapyroxad (BAS700F)	4 d static	**EC_{50} = 1.1 mg/L[1]**	Gallagher *et al.* 2009 7000165 / 147A-233	73891
Daphnia magna	M700F001 (fluxapyroxad-Metabolite)	2 d static	EC_{50} > 100 mg/L[1]	Nierzedska E 2009 BASF DocID 2009/1021592	73775
Daphnia magna	M700F002 (fluxapyroxad-Metabolite)	2 d static	EC_{50} > 100 mg/L[1]	Zmijowski, G. 2009 2009/1021596!W16/09	73776
Daphnia magna	M700F007 (fluxapyroxad-Metabolite)	2 d static	EC_{50} > 100 mg/L[1]	Rzodeczko, H. 2009 2009/1026002!W/13/09	73777
Daphnia magna	epoxiconazole	2 d static	**EC_{50} = 8.69 mg/L**	Jatzek, J 1990 1/0691/2/89-1890691	26131
Daphnia magna	1,2,4-triazole (= BF 480-16)	2 d static	EC_{50} > 100 mg/L	Bell, 1995 AGV 50(b)/952181	48025

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Daphnia magna	ADEXAR (BAS 701 00F) batch 204437	2 d static	EC_{50} = 28.9 mg/L	Janson, G.-M. 2008 2008/1028244 314134	73839
Chronic toxicity to aquatic invertebrates					
Daphnia magna	fluxapyroxad (BAS700F)	21 d semi-static	NOEC = 0.5 mg/L[1]	Janson, G.-M. 2009 312500	73743
Daphnia magna	epoxiconazole	21 d static	**NOEC = 0.63 mg/L**	Elendt-Schneider, B.1992 1/89/0691/51/1	26132
Sediment dwelling organisms					
Chironomus riparius	fluxapyroxad (BAS700F)	28 d static	NOEC = 75.9 mg/kg dry sediment[1]	Backfisch, K. 2009 319818	73746
Chironomus riparius	epoxiconazole	21 d	NOEC = 0.0625 mg/L[1]	Dohmen, G.P. 1995 P93-E099	31360
Chironomus riparius	BF 480-entriazole	28d	NOEC = 0.03 mg/L[1]	Funk, 2003 154861	48031
Algae					
P. subcapitata	fluxapyroxad	4 d semi-static LoEP Static 72 h	ErC_{50} = 0.66 mg/L[1] **EyC_{50} = 0.37 mg/L[1]** ErC_{50} = 0.7 mg/L[1] EyC_{50} = 0.4 mg/L[1]	Hoffmann, F. 2008 2008/1022788	73744
P. subcapitata	M700F001 (fluxapyroxad-Metabolite)	3 d static	ErC_{50} = 36.31 mg/L[1] Growth rate EyC_{50} = 26.42 mg/L Biomasse	Nierzedska, E. 2009 2009/1021593!W/35/07	73783
P. subcapitata	M700F002 (fluxapyroxad-Metabolite)	3 d Static	ErC_{50} = 26.52 mg/L[1] Growth rate EyC_{50} = 22.44 mg/L Biomasse	Zmijowski, G. 2009 2009/1021597!W/17/09	73784
P. subcapitata	M700F007 (fluxapyroxad-Metabolite)	3 d static	ErC_{50} > 100 mg/L[1] Growth rate EyC_{50} = 100 mg/L[1] Biomasse	Rzodeczko, H. *et al.* 2009 2009/1026003!W/14/09	73787
P. subcapitata	epoxiconazole	3 d static	E_rC_{50} > 10 mg/L[1] **E_bC_{50} = 1.19 mg/L[1]**	Dohmen, G.P. 1991 3163	26130

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
P. subcapitata	1,2,4-triazole (= BF 480-16)	3 d static	E_rC_{50} = 22.5 mg/L [1] E_bC_{50} = 8.2 mg/L[1]	Bell, G. 1995 AGV 50(b)/952196	74250
P. subcapitata	ADEXAR (BAS 701 00F) batch 204437	3 d static	ErC_{50} = 5.38 mg/L Growth rate	Hoffmann, F. 2008 2008/1037030!314133	73828
Toxicity to aquatic plants					
Lemna gibba	fluxapyroxad (BAS700F)	7 d static	ErC_{50} > 3.425 mg/L[1] **EyC_{50} = 2.19 mg/L**[1]	Hoffmann F. 2009 BASF DocID 2009/1086122	79904
Lemna gibba	epoxiconazole	7 d static	E_rC_{50} = 0.0138 mg/L **EyC_{50} = 0.0043 mg/L**[1] (ini. meas.)	Hoffmann, F. 2006 269698	59124
Lemna gibba	ADEXAR (BAS 701 00F) batch 204438	7 d	ErC_{50} = 0.215 mg/L **EbC_{50} = 0.063 mg/L** EbC_{50} = 0.078 mg/L	Hoffmann, F. 2009 2009/1098713 319805	73843

ELS = early life stage; FLC = full life cycle

fluxapyroxad: 1) Endpoints from EFSA Journal 2012;10(1):2522

epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Daily Dose [mg/kg b.w./day] calculated based on study data for food consumption and body weight.

1,2,4-triazole : EU agreed endpoint EFSA Scientific report No. 138 (2008)

Mixture Toxicity

The active substance epoxiconazole in the formulation ADEXAR (BAS-70100-FW-0-EC) can be considered to drive the toxicity of the formulation for aquatic organisms. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney, D.J., 1948 and 1971).

Toxicity studies on acute and chronic effects of the active substances and ADEXAR (BAS-70100-FW-0-EC) to aquatic organisms are available. For a more detailed assessment of mixture toxicity, a surrogate LC_{50} or EC_{50} can be calculated. However, reliable results can only be expected for combinations of EC_X values for the same biological endpoint. Moreover, the use of NOEC values, which are strongly depending on dose-spacing, would introduce additional bias in the calculations.

The following formula is used to derive a surrogate LC_{50} or EC_{50} for the mixture of active substances with known toxicity assuming concentration additivity:

$$LC_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(a.s. *i*) = fraction of active substance (i) in the mixture expressed as e.g.:

X(fluxapyroxad) = 62.5 g fluxapyroxad /kg / (62.5 g fluxapyroxad / kg + 62.5 g epoxiconazole /kg)

X(epoxiconazole) = 62.5 g epoxiconazole /kg / (62.5 g epoxiconazole / kg + 62.5 g fluxapyroxad /kg)

LC_{50}(a.s. *i*) = acute toxicity value for active substance (*i*)

Because of the direct proportionality of the calculated TER to the LC_{50}, it is possible to calculate a TER(mix) with the following formula:

$$\mathrm{TER(mix)} = \left(\sum_i \frac{1}{\mathrm{TER(a.s.}_i)} \right)^{-1}$$

where:

$TER_{(a.s.i)}$= calculated TER for the active substance *i*

6.4.1.2 Exposure

ADEXAR (BAS-70100-FW-0-EC) is an EC formulation containing fluxapyroxad and epoxiconazole as active substances. The product is formulated as spray application according to the GAP table of intended uses (Appendix 3). The applications are considered to take place at BBCH 30 to 69 in spring and winter cereals with a minimum 21 days between applications. It will be used as fungicide.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When ADEXAR (BAS-70100-FW-0-EC) is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spray drift during application, by run-off and drainage.

The predicted environmental concentrations in surface water (PEC_{SW}) have been calculated based on the application rates of 2x 125 fluxapyroxad g/ha and 2x 125 epoxiconazole g/ha. For details on the FOCUS modelling, see dRR CA Part B, Section 5.7.

The relevant global maximum FOCUS Step 1 and 2 PEC_{SW} for risk assessments covering the proposed use patterns are summarized for the metabolites of fluxapyroxad and epoxiconazole in the following table.

Table 6.4-2: Summary of highest global maximum FOCUS surface water PECsw and PECsed values for the metabolites of fluxapyroxad and epoxiconazole - Step 1 and 2

Plant protection product:	BAS 701 00 F	
Use No evaluated	A	
Crop	Spring and winter cereals	
Application method (-)	spraying	
Growth stage at first application (BBCH)	30-69	
Crop interception:	Average crop cover	
Number of applications/interval	2 / 21	
Application rate:	2x 125 g/ha	
FOCUS STEP Scenario	**PECsw (µg/L)**	**PECsed (µg/L)**
Metabolite M700F001		
STEP 1	4.76	0.12
STEP 2, Northern Europe, Mar.-May	0.25 (0.20 single application)	0.01 (0.01 single application)
STEP 2, Southern Europe, Mar.-May	0.4 (0.34 single application)	0.01 (0.01 single application)
Metabolite M700F002		
STEP 1	24.71	1.88
STEP 2, Northern Europe, Mar.-May	1.74 (1.11 single application)	0.13 (0.08 single application)
STEP 2, Southern Europe, Mar.-May	3.49 (2.22 single application)	0.26 (017 single application)
Metabolite M700F007		
STEP 1	0.19	0.00
STEP 2, Northern Europe, Mar.-May	0.16 (0.09single application)	0.00 (0.00single application)
STEP 2, Southern Europe, Mar.-May	0.16 (0.09single application)	0.00 (0.00single application)
Metabolite BF480 entriazole		
STEP 1	0.71	3.06
STEP 2, Northern Europe, Mar.-May	0.46 (0.35 single application)	2.46 (1.47 single application)
STEP 2, Southern Europe, Mar.-May	0.4 (0.34 single application)	2.46 (1.47 single application)
Metabolite 1,2,4-triazole		
STEP 1	15.61	13.89
STEP 2, Northern Europe, Mar.-May	1.33	1.19
STEP 2, Southern Europe, Mar.-May	2.66	2.37

For refined risk assessments, the FOCUS Step 3 PECsw values for the different scenarios are presented in the table below for the active substances fluxapyroxad and epoxiconazole. The scenarios relevant for the risk assessments in the central zone are highlighted.

Table 6.4-3 Predicted environmental concentrations of fluxapyroxad in surface water – FOCUS Step 3

fluxapyroxad				
Spring cereals	**FOCUS STEP 3** Scenario	**PEC_{sw} global max (µg/L)**	**Application dates**	**PEC_{SED}, accu, overall= PEC_{SED} + PEC_{SED} plateau**
	D1, ditch	2.515	17.6/ 8.7.	119.42
	D1, stream	1.585	17.6/ 8.7.	64.24
	D3, ditch	0.693	4.5. / 27.5.	2.22
	D4, pond	0.567	26.4./ 30.5	20.58
	D4, stream	0.846	26.4./ 30.5	6.94
	D5, pond	0.294	8.4./ 1-5.	16.60
	D5, stream	0.607	8.4./ 1-5.	2.91
	R4, stream	3.516	21.3./ 4.5.	11.86
Winter cereals	D1, ditch	4.000	29.3./ 25.4	153.74
	D1, stream	2.550	29.3./ 25.4	84.95
	D2, ditch	3.001	7.5./ 2.6.	92.18
	D2, stream	1.875	7.5./ 2.6.	53.90
	D3, ditch	0.693	15.5./ 21.6.	2.28
	D4, pond	0.616	19.3./ 18.4.	22.00
	D4, stream	0.936	19.3./ 18.4.	7.99
	D5, pond	0.201	11.5./ 9.6.	10.48
	D5, stream	0.639	11.5./ 9.6.	1.96
	D6, ditch	0.718	18.5./ 8.6.	7.46
	R1, pond	0.288	30.4./ 13.6.	10.19
	R1, stream	1.856	30.4./ 13.6.	11.09
	R3, stream	2.061	1.6./ 22.6	5.60
	R4, stream	2.131	4.5./ 27.5.	7.94

Table 6.4-4: Predicted environmental concentrations of epoxiconazole in surface water – FOCUS Step 3

epoxiconazole				
Spring cereals	**FOCUS STEP 3** Scenario	**PEC_{sw} global max (µg/L)**	**Application dates**	**PEC_{SED}, accu, overall= PEC_{SED} + PEC_{SED} plateau**
	D1, ditch	1.067	17.6/ 8.7.	8.8374
	D1, stream	0.607	17.6/ 8.7.	4.225
	D3, ditch	0.692	4.5. / 27.5.	0.8567
	D4, pond	0.0493	26.4./ 30.5	0.8983
	D4, stream	0.566	26.4./ 30.5	0.2873
	D5, pond	0.0378	8.4./ 1-5.	0.4303
	D5, stream	0.591	8.4./ 1-5.	0.05876
	R4, stream	2.211	21.3./ 4.5.	4.3043
Winter cereals	D1, ditch	1.000	29.3./ 25.4	9.1052
	D1, stream	0.739	29.3./ 25.4	5.1155
	D2, ditch	0.802	7.5./ 2.6.	5.9696
	D2, stream	0.670	7.5./ 2.6.	4.4395
	D3, ditch	0.693	15.5./ 21.6.	0.8723
	D4, pond	0.0434	19.3./ 18.4.	0.8151
	D4, stream	0.542	19.3./ 18.4.	0.273
	D5, pond	0.0252	11.5./ 9.6.	0.39
	D5, stream	0.638	11.5./ 9.6.	0.2652
	D6, ditch	0.720	18.5./ 8.6.	2.8873
	R1, pond	0.176	30.4./ 13.6.	2.093
	R1, stream	1.154	30.4./ 13.6.	4.2874
	R3, stream	0.973	1.6./ 22.6	1.7901
	R4, stream	1.241	4.5./ 27.5.	3.029

6.4.1.3 Risk assessment –overall conclusions

Based on the FOCUS Step 3 PECs, the aquatic TER values for fluxapyroxad and epoxiconazole are above the trigger of 10, indicating a low and acceptable acute risk for aquatic organisms from fluxapyroxad and epoxiconazole and their water metabolites in 5 out of 22 relevant FOCUS Surface Water Scenarios following application of ADEXAR (BAS-70100-FW-0-EC) at the proposed application rates.

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-5: Aquatic TER values for fluxapyroxad and epoxiconazole after applications of ADEXAR (BAS-70100-FW-0-EC).

	Endpoint (µg/L) **Test organism**	**FOCUS STEP 3** Scenario	**PEC_{sw} global max (µg/L)**	**TER**	**Trigger value**
fluxapyroxad					
Spring cereals	290 (LC_{50}) *Cyprinus carpio*	D1, ditch	2.515	115	100
		D1, stream	1.585	183	
		D3, ditch	0.693	418	
		D4, pond	0.567	511	
		D4, stream	0.846	343	
		D5, pond	0.294	986	
		D5, stream	0.607	478	
		R4, stream	3.516	**82**	
Winter cereals		D1, ditch	4.000	**73**	
		D1, stream	2.550	114	
		D2, ditch	3.001	**97**	
		D2, stream	1.875	155	
		D3, ditch	0.693	418	
		D4, pond	0.616	471	
		D4, stream	0.936	310	
		D5, pond	0.201	1443	
		D5, stream	0.639	454	
		D6, ditch	0.718	404	
		R1, pond	0.288	1007	
		R1, stream	1.856	156	
		R3, stream	2.061	141	
		R4, stream	2.131	136	
epoxiconazole					
Spring cereals	4.3 (EbC_{50}) *Lemna gibba*	D1, ditch	1.067	**4**	10
		D1, stream	0.607	**7**	
		D3, ditch	0.692	**6**	
		D4, pond	0.049	87	
		D4, stream	0.566	**8**	
		D5, pond	0.038	114	

		D5, stream	0.591	**7**	
		R4, stream	2.211	**2**	
Winter cereals		D1, ditch	1.000	**4**	
		D1, stream	0.739	**6**	
		D2, ditch	0.802	**5**	
		D2, stream	0.670	**6**	
		D3, ditch	0.693	**6**	
		D4, pond	0.043	99	
		D4, stream	0.542	**8**	
		D5, pond	0.025	171	
		D5, stream	0.638	**7**	
		D6, ditch	0.720	**6**	
		R1, pond	0.176	24	
		R1, stream	1.154	**4**	
		R3, stream	0.973	**4**	
		R4, stream	1.241	**3**	

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to fluxapyroxad and epoxiconazole and their metabolites was assessed according to the intended uses.

As first step, the initial maximum PEC_{SW} values (Step 3) were compared to the relevant acute and long-term toxicity endpoints available for fluxapyroxad and epoxiconazole. Based on all studies on aquatic toxicity as well as the corresponding safety factors, the relevant endpoint for fluxapyroxad is LC_{50} = 0.29 mg fluxapyroxad /L (*Cyprinus carpio*). For epoxiconazole, the relevant endpoint is E_bC_{50} = 0.0043 mg epoxiconazole /L (*Lemna gibba*). Risk assessment is driven by these endpoints; the ratio endpoint/corresponding safety factor is higher for all other organisms.
Since the applicant (BASF) submitted additional data on aquatic plants (a second test with *Lemna gibba* and a toxicity test on *Myrioplyllum aquaticum*) the safety factor can be revised to 8 instead on 10.

In the table below, the TER values relative to the most sensitive endpoint of each organisms' group are given.

Table 6.4-6: Aquatic organisms: PECsw for fluxapyroxad and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic Plants	PEC_{SED} accu	Sed. dweller prolonged
		O. mykiss	*D. rerio*	*C. virginica*	*D. magna*	*P. subcapitata*	*L. gibba*	(µg/kg)	*C. riparius*
FOCUS	(µg/L)	LC_{50} (µg/L)	NOEC (µg/L)	EC_{50} (µg/L)	NOEC (µg/L)	E_bC_{50} (µg/L)	E_bC_{50} (µg/L)		NOEC (µg/kg)
STEP 3		**290**	**35.9**	**1100**	**500**	**370**	**2190**		**75900**
Spring cereals									
D1/ditch	2.515	115	14	437	199	147	871	119.42	635.6
D1/stream	1.585	183	23	694	315	233	1382	64.24	1181.5
D3/ditch	0.693	418	52	1587	722	534	3160	2.22	34164.7
D4/pond	0.567	511	63	1940	882	653	3862	20.58	3687.3
D4/stream	0.846	343	42	1300	591	437	2589	6.94	10940.6
D5/pond	0.294	986	122	3741	1701	1259	7449	16.60	4573.1
D5/stream	0.607	478	59	1812	824	610	3608	2.91	26122.9
R4/stream	3.516	**82**	10	313	142	105	623	11.86	6397.8
Winter cereals									
D1/ditch	4.000	**73**	**9**	275	125	93	548	153.74	493.7
D1/stream	2.550	114	14	431	196	145	859	84.95	893.4
D2/ditch	3.001	97	12	367	167	123	730	92.18	823.3
D2/stream	1.875	155	19	587	267	197	1168	53.90	1408.2
D3/ditch	0.693	418	52	1587	722	534	3160	2.28	33359.3
D4/pond	0.616	471	58	1786	812	601	3555	22.00	3449.8
D4/stream	0.936	310	38	1175	534	395	2340	7.99	9501.9
D5/pond	0.201	1443	179	5473	2488	1841	10896	10.48	7244.0
D5/stream	0.639	454	56	1721	782	579	3427	1.96	38678.5
D6/ditch	0.718	404	50	1532	696	515	3050	7.46	10173.7
R1/pond	0.288	1007	125	3819	1736	1285	7604	10.19	7447.3
R1/stream	1.856	156	19	593	269	199	1180	11.09	6846.7
R3/stream	2.061	141	17	534	243	180	1063	5.60	13562.2
R4/stream	2.131	136	17	516	235	174	1028	7.94	9555.4
TER criterion		**100**	**10**	**100**	**10**	**10**	**10**		**10**

Table 6.4-7: Aquatic organisms: PECsw for fluxapyroxad metabolites and relevant ecotoxicological endpoints for each organism' group

Scenario	PEC global max (µg/L)	Fish acute	Invertebrates acute	Algae
Metabolite M700F001		***Cyprinus carpio*** **LC_{50} (µg/L)**	***Daphnia magna*** **EC_{50} (µg/L)**	***Pseudokirchn. Subcapitata*** **EyC_{50} (µg/L)**
		> 100000	**> 100000**	**26420**
FOCUS Step 1	4.76	> 21000	> 21000	5550
FOCUS Step 2				
North Europe	0.25	> 400000	> 400000	105680
South Europe	0.4	> 250000	> 250000	66050
Metabolite M700F002		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchn. subcapitata***
		LC_{50} (µg/L)	**EC_{50} (µg/L)**	**EyC_{50} (µg/L)**
		> 100000	**> 100000**	**22440**
FOCUS Step 1	24.71	4047	25	908
FOCUS Step 2				
North Europe	1.74	57471	2	12897
South Europe	3.49	28653	3	6430
Metabolite M700F007		***Cyprinus carpio***	***Daphnia magna***	***Pseudokirchn. subcapitata***
		LC_{50} (µg/L)	**EC_{50} (µg/L)**	**EyC_{50} (µg/L)**
		> 100000	**> 100000**	**> 100000**
FOCUS Step 1	0.19	> 526315	> 526315	> 526315
FOCUS Step 2				
North Europe	0.16	> 625000	> 625000	> 625000
South Europe	0.16	> 625000	> 625000	> 625000
TER criterion		**100**	**100**	**10**

Table 6.4-8: Aquatic organisms: PECsw for epoxiconazole and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Aquatic Plants	PEC_{SED} accu	Sed. dweller prolonged
		O. mykiss	*D. rerio*	*D. magna*	*D. magna*	*P. subcapitata*	*L. gibba*	(µg/kg)	*C. riparius*
FOCUS STEP 3	**(µg/L)**	**LC_{50} (µg/L) 3140**	**NOEC (µg/L) 30**	**EC_{50} (µg/L) 8690**	**NOEC (µg/L) 630**	**E_bC_{50} (µg/L) 1190**	**E_bC_{50} (µg/L) 4.3**		**NOEC (µg/kg) 62.5**
Spring cereals									
D1/ditch	1.067	2942.8	28	8144.3	590.4	1115.3	**4**	8.8374	**7.1**
D1/stream	0.607	5173	49	14316.3	1037.9	1960.5	**7.1**	4.225	14.8
D3/ditch	0.692	4537.6	43	12557.8	910.4	1719.7	**6.2**	0.8567	73.0
D4/pond	0.0493	63691.7	609	176267.7	12778.9	24137.9	87.2	0.8983	69.6
D4/stream	0.566	5547.7	53	15353.4	1113.1	2102.5	**7.6**	0.2873	217.5
D5/pond	0.0378	83068.8	794	229894.2	16666.7	31481.5	113.8	0.4303	145.2
D5/stream	0.591	5313	51	14703.9	1066	2013.5	**7.3**	0.05876	1063.6
R4/stream	2.211	1420.2	14	3930.3	284.9	538.2	**1.9**	4.3043	14.5
Winter cereals									
D1/ditch	1.0	3140	30	8690	630	1190	**4.3**	9.1052	**6.9**
D1/stream	0.739	4249	41	11759.1	852.5	1610.3	**5.8**	5.1155	12.2
D2/ditch	0.802	3915.2	37	10835.4	785.5	1483.8	**5.4**	5.9696	10.5
D2/stream	0.67	4686.6	45	12970.1	940.3	1776.1	**6.4**	4.4395	14.1
D3/ditch	0.693	4531	43	12539.7	909.1	1717.2	**6.2**	0.8723	71.6
D4/pond	0.0434	72350.2	691	200230.4	14516.1	27419.4	99.1	0.8151	76.7
D4/stream	0.542	5793.4	55	16033.2	1162.4	2195.6	**7.9**	0.273	228.9
D5/pond	0.0252	124603.2	1190	344841.3	25000	47222.2	170.6	0.39	160.3
D5/stream	0.638	4921.6	47	13620.7	987.5	1865.2	**6.7**	0.2652	235.7
D6/ditch	0.72	4361.1	42	12069.4	875	1652.8	**6**	2.8873	21.6
R1/pond	0.176	17840.9	170	49375	3579.5	6761.4	24.4	2.093	29.9
R1/stream	1.154	2721	26	7530.3	545.9	1031.2	**3.7**	4.2874	14.6
R3/stream	0.973	3227.1	31	8931.1	647.5	1223	**4.4**	1.7901	34.9
R4/stream	1.241	2530.2	24	7002.4	507.7	958.9	**3.5**	3.029	20.6
TER criterion		**100**	**10**	**100**	**10**	**10**	**8**		**10**

Table 6.4-9: Aquatic organisms: PECsw for epoxiconazole metabolites 1,2,4-triazole and BF480 entriazole and relevant ecotoxicological endpoints.

Scenario	**PEC global max (µg/L)**	**Fish acute**	**Fish prolonged**	**Invertebrates acute**	**Algae**	**PEC_{SED} global max (µg/kg)**	**Sed. dweller prolonged**
		O. mykiss	***O. mykiss***	***D. magna***	***P. subcapitata***		***C. riparius***
		LC_{50} (µg/L) 498000	**NOEC (µg/L) 3200**	**EC_{50} (µg/L) > 100000**	**E_bC_{50} (µg/L) 8200**		
Metabolite 1,2,4-triazole							
Focus Step 1	15.61	31903	205	> 6406	525	13.89	_
Focus Step 2							
North Europe	1.33	374436	2406	> 75188	6165	1.19	_
South Europe	2.33	187218	1203	> 37594	3083	2.37	_
							NOEC (µg/kg) 30
Metabolite BF480 entriazole							
Focus Step 1	0.71	_	_	_	_	3.06	10
Focus Step 2							
North Europe	0.46	_	_	_	_	2.46	12.2
South Europe	0.46	_	_	_	_	2.46	12.2
TER criterion		**100**	**1**	**100**	**10**		**10**

Based on the calculated concentrations of fluxapyroxad and epoxiconazole and their metabolites in surface water (PEC_{SW} FOCUS Step 1, 2 and 3), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 100 and TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an unacceptable risk for aquatic organisms for 5 scenarios out of 22 due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in spring and winter cereals according to the label.

For the intended use in spring and winter cereals, further refinement is necessary for some scenarios.

According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 3 PEC values for the intended use in spring and winter cereals, the implementation of management practices will be necessary to reduce the exposure of aquatic organisms to ADEXAR (BAS-70100-FW-0-EC). Management practices relevant for Germany are given in the respective Addendum.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of ADEXAR (BAS-70100-FW-0-EC) on aquatic organisms. Section 6.4.2, page 45, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of fluxapyroxad and epoxiconazole

Assessment of the metabolites of fluxapyroxad:

Please refer to section 6.1.2, page 6 for the assessment of the metabolites of fluxapyroxad that was performed during peer review of the active substance in view of its approval.

Please refer to section 6.4.1.1 for a summary of the provided studies on the effects of fluxapyroxad metabolites on aquatic organisms. Section 6.4.2, page 45, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

Fluxapyroxad forms 2 major metabolites in surface water. Fluxapyroxad metabolites M700F001 and M700F007 are formed in irradiated water with 10.9 % and 7.5 % on day 43 and 57, respectively. The fluxapyroxad metabolites M700F001 and M700F002 are formed in soil with 12.1 % and 38.5 %, respectively. Contamination via run-off and drainage cannot be excluded.

Ecotoxicological studies are available for metabolites M700F001, M700F002 and M700F007 for *Dapnia magna*, *Pseudokirchneriella subcapitata* and *Oncorhynchus mykiss*. The comparison of the study results for the metabolites M700F001, M700F002 and M700F007 with the results of studies performed with fluxapyroxad shows that fluxapyroxad is more toxic for aquatic organisms than the metabolite. It is predicted that the risk for aquatic organisms exposed to fluxapyroxad metabolites according to the intended use of BAS 700 00 F will be low.

Assessment of the metabolites of epoxiconazole:

Aquatic organisms may be exposed to residues of the metabolites BF 480-16 F (1,2,4-triazole) and BF 480-entriazole (see part B, section 5), therefore, the risk to aquatic organisms also needs to be addressed. The results from toxicity tests with representative freshwater species conducted with the metabolites found in aquatic systems are summarized in Table 6.4-1. Study summaries were provided in the DAR of epoxiconazole, Vol. 3, B.9.

An entry of BF 480-16 F (1,2,4-triazole) in surface water cannot be excluded. Ecotoxicological endpoints for aquatic species are available. According to these data the parent compound epoxiconazole is a multiple more toxic than the metabolite. Therefore the metabolite BF 480-16 F (1,2,4-triazole) is considered to be not relevant regarding the ecotoxicity.

A sediment study with *Chironomus riparius* and epoxiconazole as well as BF 480-entriazole (NOEC = 0.03 mg/L) was carried out. The study with the active substance epoxiconazole results in a NOEC of 0.0625 mg/L indicating that sediment organism react more sensitive against the metabolite.

6.4.5 Accumulation in aquatic non-target organisms

Since the log K_{ow} values of fluxapyroxad is 3.13 (pH=7), this active substance is deemed to have a potential to bioaccumulate in animal tissues. Data to evaluate the residues of fluxapyroxad in fish have been submitted by the applicant, and the following BCF values were estimated: a BCF-value of 119 calculated for the total radioactivity residues (TRR) and a BCF-value of 46 calculated for the unchanged parent compound fluxapyroxad. Both values were measured in the whole fish and were normalized on a lipid content of 5%.

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

Since the log K_{ow} values of epoxiconazole is 3.33 (pH=7), this active substance is deemed to have a potential to bioaccumulate in animal tissues. Data to evaluate the residues of epoxiconazole in fish have been submitted by the applicant, and the following BCF values were estimated: a BCF-value of 70 was calculated.

Bioaccumulation of any of the active substances under natural conditions is not expected to occur and a study is not necessary to determine bioaccumulation in aquatic non-target organisms.

6.5 Effects on Bees

Effects on bees of Adexar (BAS 701 00 F) were not evaluated as part of the EU review of fluxapyroxad or epoxiconazole. Therefore all relevant data and assessments are provided here and are considered adequate.

Toxicity

Table 6.5-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in section KCP 10.3.2. For the sake of completeness the table also presents results of laboratory bee toxicity studies with the active substance. Other data submitted in support of the evaluation are not considered adequate and are not reported here.

Table 6.5-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
BAS 701 00 F (Adexar)	oral 48 h	690.4 µg product/bee	Barth, M (2008) Report 08 10 48 020 B
	contact 48 h	830.4 µg product/bee	
fluxapyroxad tech.	oral 48 h	> 110.9 µg as/bee *	EFSA Journal (2012) 10(1):2522
	contact 48 h	> 100 µg as/bee *	
epoxiconazole tech.	oral 48 h	> 83 µg as/bee *	EFSA Scientific Report (2008) 138, 1-80
	contact 48 h	> 100 µg as/bee *	

* EU agreed endpoint

Exposure

The recommended use pattern for Adexar includes application in cereals at a maximum application rate of up to 2 L product/ha. This maximum single application rate is equivalent to 2072 g product/ha.

Bees may be exposed to Adexar by direct spraying while bees are foraging on flowers and weeds, through contact with fresh or dried residues or by oral uptake of contaminated pollen, nectar and honey dew.

Hazard quotients

Hazard quotients for oral and contact exposure according to EPPO (2003) Environmental risk assessment scheme for plant protection products (Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145) were calculated as follows:

Hazard Quotient = max. application rate [g product/ha] / LD_{50} [µg product/bee]

Table 6.5-2 Hazard quotients for honeybees

Test substance	Max. single application rate [g product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
BAS 701 00 F (Adexar)	2072	oral	690.4 µg	3.0	50
		contact	830.4 µg	2.4	

Semi-field tests

Schmitzer, S., 2009; project 43871031:
In a tunnel test according to EPPO Guideline 170 Adexar was applied at the maximum single application rate of 2.0 L/ha during active foraging of the honeybees onto flowering *Phacelia*.
The test item caused no effects on bee survival and foraging activity. Also, no impact on the behaviour of the bees was found. The condition of the colonies, colony strength and brood development did not differ between the test item and the control.

Risk assessment

Due to the results of laboratory tests Adexar is considered to be practically non-toxic to bees. All hazard quotients are clearly below the trigger of 50, indicating that the intended use poses a low risk to bees in the field. In addition, no effects on bee survival and foraging activity on honeybee colonies and no sublethal effects up to 2.0 L/ha product were observed in a tunnel test according to EPPO Guideline 170.

Overall conclusion:
It is concluded that Adexar (BAS 701 00 F) will not adversely affect bees or bee colonies when used as recommended.

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for ADEXAR (BAS-70100-FW-0-EC) were not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. Data on ADEXAR (BAS-70100-F) have been submitted by the applicant and are evaluated here. They are considered adequate to assess the risk for non-target arthropods following the use of ADEXAR (BAS-70100-F) according to the intended uses.

6.6.1.1 Toxicity

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 6.6-1: Toxicity of fluxapyroxad and epoxiconazole / ADEXAR (BAS-70100-F) to non-target arthropods with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
A. rhopalosiphi	BAS 701 00 F batch 204438	14 d Extended laboratory 2D	LR_{50} > 6 L/ha[1)] ER_{50} > 6 L/ha	Sipos, K. 2009 2008/1046577 08/649-351FD	73853
T. pyri	ADEXAR (BAS 701 00 F) batch 204438	14 d Extended laboratory 2D	LR_{50} > 6 L/ha[1)] ER_{50} > 0.5 < 1 L/ha	Sipos, K. 2009 2008/1046576 08/649-351RA	73852
T. pyri	ADEXAR (BAS 701 00 F) batch 204437	14 d Extended laboratory 3D	LR_{50} > 4 L/ha[1)] ER_{50} > 4 L/ha	Mayer, C.J. 2009 2009/1069104 314141	73855
C. carnea	ADEXAR (BAS 701 00 F) batch 204438	8 d Extended laboratory 2D	LR_{50} > 6 L/ha[1)] ER_{50} > 6 L/ha	Spincer, D. 2009 2008/1042192 314136	73851

1) New study submitted by the applicant

6.6.1.2 Exposure

In field

Non-target arthropods living in the crop can be exposed to residues from ADEXAR (BAS-70100-FW-0-EC) by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. ADEXAR (BAS-70100-FW-0-EC) is applied at a maximum rate of 2 x 2 L with a minimum 21-day application interval. The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling or soil-dwelling organisms is therefore 4L (equivalent to 250 g a.s./ha), assuming the worst-case of 100% crop interception and 0% crop interception, respectively.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of ADEXAR (BAS-70100-FW-0-EC) is calculated according to published agreement after ESCORT 2 workshop (Candolfi *et al.* 2001[4] -hereafter referred to as 'Guidance Document') using the following equation:

$$PER_{in-field} = \text{Application rate (g a.s./ha)} \times \text{MAF}$$

where:

MAF = generic multiple application factor used to take into account the potential build-up of applied substances between applications. This factor integrates number of applications, application interval and degradation kinetics of the active substance

Default foliar and soil MAF values are listed in the Guidance Document and are the following for ADEXAR (BAS-70100-FW-0-EC) and its application scheme:

MAF (leaf substrate) = 1.7
MAF (soil) = 1.9

The maximum predicted environmental rate (PER) occurring in the field after application of ADEXAR (BAS-70100-FW-0-EC) at the maximum application rate is presented in the following table.

Table 6.6-2: In-field predicted environmental rates (PER) for ADEXAR (BAS-70100-FW-0-EC), intended use in cereals BBCH 30- 69

Substance	**Application rate**	**in-field PER (foliar) (MAF = 1.7)**	**in-field PER (soil) (MAF = 1.9)**
ADEXAR (BAS-70100-FW-0-EC)	2 L Product/ha 2080 g Product/ha*	3.4 L Product/ha 3536 g Product/ha*	3.8 L Product/ha 3952 g Product/ha*

* density ADEXAR: 1.04 g/mL

[4] Candolfi, M.P.; Barrett, K.L.; Campbell, P.; Forster, R.; Grandy, N.; Huet, M.C.; Lewis. G.; Oomen, P.A.; Schmuck, R.; Vogt, H. (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods. ESCORT2 Workshop European Standard Characteristics of Non-Target Arthropod Regulatory Testing. Wageningen, The Netherlands, 46 pp.

Off-field

Exposure of non-target arthropods living in non-target off-field areas to ADEXAR (BAS-70100-FW-0-EC) will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by the BBA (2000[5]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x \left({drift\ percentile}/{100} \right)}{vegetation\ distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

The drift rate at 1 m distance is 2.38% of the application rate (82th percentile drift).

Regarding the results of the study with *T. pyri* exposed to ADEXAR (BAS-70100-FW-0-EC), the vegetation distribution factor does not have to be considered since it was conducted in 3D environment.

The resulting PERoff-field values are shown in the following table.

Table 6.6-3: Off-field predicted environmental rates (PER) resulting from the intended uses of ADEXAR (BAS-70100-FW-0-EC)

Study type	Max. rate (ml Prod./ha)	MAF (Foliar)	Maximum in-field PER (ml Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (ml Prod./ha)
3-dimensional (foliar)	2000	1.7	3400	2.38%	1	80.92

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to ADEXAR (BAS-70100-FW-0-EC) is given in the table below.

[5] BBA (Biologische Bundesanstalt für Land- und Forstwirtschaft) (2000): Abtrifteckwerte für Flächen- und Raumkulturen sowie für den gewerblichen Gemüse-, Zierpflanzen- und Beerenobstanbau. Bundesanzeiger 100, 26. Mai 2000, Köln, pp. 9879.

Table 6.6-4: Maximum HQ and minimum TER values for arthropod species other than bees after uses of ADEXAR (BAS-70100-FW-0-EC) in cereals BBCH 30- 69.

Test substance	Species	Test type	Endpoint ER50 (ml Prod./ha)	Worst-case PER in-field (ml Prod./ha)	HQ In-field	PER off-field (1 m) (ml Prod./ha)	HQ Off-field	TER Off-field
ADEXAR (BAS-70100-FW-0-EC)	*Typhlodromus pyri*	Lab. 3D	ER_{50} > 4000	3400	< 0.85	80.92	< 0.021	> 49
HQ and TER values in bold are below the trigger								

Based on the calculated rates of ADEXAR (BAS-70100-FW-0-EC) in-field and off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria HQ ≤ 2 resp. TER ≥ 10 (Tier 1) or of less than 50% effects at calculated drift rates resp. TER ≥ 5 (higher Tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 In-field

Tier 1

The potential risk for non-target arthropods exposed in-field to ADEXAR (BAS-70100-FW-0-EC) was assessed by calculating the hazard quotient (HQ = exposure/toxicity) as the ratio of the predicted environmental rate (PER) and the lowest lethal rate (LR50) estimated in standard toxicity tests with non-target arthropods according to the formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{LR_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table.

Table 6.6-5: Tier 1 in-field HQ values for non-target arthropods other than bees and acceptability criteria for Tier 1 data

Species	LR50 (mL Product/ha)	PER (mL Product/ha)	In-field HQ	Trigger value
Aphidius rhopalosiphi (2D)	> 6000	3400	< 0.57	2
Typhlodromus pyri (3D)	> 4000	3400	< 0.85	2
HQ values in bold are above the trigger				

The in-field HQ values for exposure to maximum residues for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi* are lower than the trigger value of 2 (Candolfi *et al*, 2001).

The results indicate that ADEXAR (BAS-70100-FW-0-EC) poses low risk to non-target arthropods in-field following application according to the intended uses.

6.6.2.2 Off field

HQ approach

In order to assess the potential risk of ADEXAR (BAS-70100-FW-0-EC) to non-target arthropods in off-field areas, the predicted environmental rate in the Off-field (see chapter 6.6.1.2) is compared to the toxicity endpoints according to the following formula:

$$Off-field\ \ HQ = \frac{Off-field\ \ PER}{LR_{50}} \times correction\ \ factor$$

where:

Correction factor (also 'safety factor') = amounts to 10 in conjunction with Tier I data from tests on glass plates; amounts to 5 for Tier II data from extended laboratory tests/field tests. The factor accounts for extrapolation from testing few representative species to the species diversity expected in off-crop areas.

Tier 1

Calculated HQ off-field values are given in the following table.

Table 6.6-6: Calculated off-field HQs for non-target arthropods and acceptability criteria for Tier 1 data

Species	Test type	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PER off-field	PER off-field x correction factor (mL product/ha)	HQ	HQ trigger
Aphidius rhopalosiphi	2 D glass plate	> 6000	3400	1	80.92	809.2	< 0.14	2
Typhlodromus pyri	3D	> 4000		1	80.92	404.6	< 0.11	2

The off-field HQ values for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value, indicating that ADEXAR (BAS-70100-FW-0-EC) does not pose an unacceptable risk to non-target arthropods in off-field areas.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to ADEXAR (BAS-70100-FW-0-EC) was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\ (L\ product/ha)}{Off-field\ \ PER\ (L\ product/ha)}$$

The risk is considered acceptable if the values obtained are TER off-field > 10 when the ecotoxicological data resulted from Tier 1 tests on glass plates or TER off-field > 5 when the data were obtained in higher tier test (extended lab or field tests).

The resulting TER off-field values are given in the following table. Since the calculated TER values for *Aphidius rhopalosiphi* and *Typhlodromus pyri* were above the trigger of 10, no risk mitigation measures have to be implemented.

Table 6.6-7: Calculated TER values for non-target arthropods exposed to ADEXAR (BAS-70100-FW-0-EC) in off-field areas according to intended uses

Species	Test type	Correction factor	L/ER50 (mL product/ha)	PER in-field (mL product/ha)	Distance (m)	PERoff-field (mL product/ha)	TER
Aphidius rhopalosiphi	2D	5	> 6000	3400	1	16.18	> 370
					-	-	-
					-	-	-
Typhlodromus pyri	3D	1	> 4000		1	80.92	> 49
					-	-	-
					-	-	-
TER values in bold are below the trigger							

Based on the calculated rates of ADEXAR (BAS-70100-FW-0-EC) in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Overview and summary

Earthworms, other soil non-target macro and mesofauna as well as soil organisms involved in the breakdown of dead organic matter will be exposed to plant protection products containing fluxapyroxad and epoxiconazole whenever contamination of soil may occur as a result of the intended uses of ADEXAR (BAS-70100-FW-0-EC).

Effects on earthworms and other soil non-target organisms resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) were not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the intended uses of ADEXAR (BAS-70100-FW-0-EC) are provided here. New data are listed in Appendix 12 and summarized in Table 6.7-1.

6.7.1.1 Toxicity

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to fluxapyroxad and epoxiconazole and ADEXAR (BAS-70100-FW-0-EC) with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Acute toxicity					
Eisenia fetida	BAS 700 F / fluxapyroxad	14 d Acute	LC_{50} > 1000 mg/kg soil dw[1]	Friedrich, S. 2009 2009/1072245 091048061S	73797
Eisenia fetida	M 700 F 001, metabolite of fluxapyroxad		LC_{50} > 1000 mg/kg soil dw[1]	Witte, B. 2009 1050216 50651021	73799
Eisenia fetida	M 700 F 002, Metabolite of fluxapyroxad		LC_{50} > 1000 mg/kg soil dw[1]	Witte, B. 2009 1072244 51491021	73800
Eisenia fetida	epoxiconazole		LC_{50}, corr > 500 mg/kg soil dw [1, 2]	Dohmen, G. P. 1991 P90-E043	43074
Eisenia fetida	1,2,4-Triazole Metabolite of epoxiconazole		LC_{50} > 1000 mg/kg soil dw [1]	Heimbach, F. 1986 HBF/Rg 59	41735
Eisenia fetida	ADEXAR (BAS-70100-F)		LC_{50} = 341.7 mg/kg soil dw[3]	Friedrich, S. 2009 2009/1072246 091048060S	73860
Chronic toxicity					

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Eisenia fetida	M 700 F 002, Metabolite of fluxapyroxad	56 d chronic	NOEC ≥ 2.56 mg/kg soil dw[1]	Wolf, A. 2008 2008/1017010 314075	73803
	M 700 F 001, Metabolite of fluxapyroxad		NOEC ≥ 5.33 mg/kg soil dw[1]	Wolf, A. 2008 2008/1033932 314079	73804
	epoxiconazole (BAS 480 28 F) Formulated product (125 g/L)		NOEC = 0.167 mg/kg dry soil NOEC corr = 0.084 mg as/kg dry soil (depth 5 cm) [1, 2]	Dohmen, G. P. 1997 44176	48051
	1,2,4-Triazole Metabolite of epoxiconazole		NOEC = 0.0708 mg/kg dry soil [1]	Ehlers, H. A. 2000 7781022	43621
	ADEXAR (BAS 70 100 F) batch 204437		NOEC= 87,9 mg Product/kg soil dw[3] Equivalent to: NOEC = 5.33 mg fluxapyroxad/ kg soil dw NOEC = 5.33 mg epoxiconazole/ kg soil dw	Lührs, U. 2008 2008/1000701 39461022	73857
Folsomia candida	M 700 F 002, Metabolite of fluxapyroxad	28 d chronic	NOEC ≥ 1000 mg/kg soil dw[1]	Royer, S. 2009 2009/1045472 365782	73802
	1,2,4-Triazole Metabolite of epoxiconazole		NOEC = 1.8 mg/kg dry soil [1]	Moser, T. & Scheffczyk, A. 2002 P31CR	48035
	ADEXAR (BAS 70100 F) batch 204438		NOEC = 12.5 mg/kg soil dw[3] EC_{50} = 22.84 mg/kg soil dw	Lührs, U. 2009 2009/1002761 43872016	73854
		42 d chronic Multi-generation study	NOEC = 30 mg/kg soil dw[3 *] (28 d) EC_{50} = 67.4 mg/kg soil dw[3 *] (28 d)	Royer, S. 2013 2013/1040568 413921	85293
Hypoaspis aculeifer	ADEXAR (BAS 70100 F) batch 204438	14 d	NOEC ≥ 500 mg/kg soil dw[3] ER_{50} > 500 mg/kg soil dw	Schulz, L. 2009 2009/1089814 091048075S	73856
Field studies					
Lumbricus sp.	ADEXAR (BAS 70100 F) batch 204438		NOEC ≥ 10 L Product /ha [3] (applied twice at intervals of 14 days; first application BBCH 27)	Krück,S. 2009 1000121 081048005F	73859

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Collembola	Pyraclostrobin (81.4 g/L) Fluxapyroxad (50.2 g/L) Epoxiconazole (49.0 g/L) (analysed)	85 days	NOEC > 10 L BAS70200 F /ha3)	Schabio & Eichler 2013 BASF DocID 2012/1143242	85292
Organic matter breakdown					
Litter bag (all organisms)	ADEXAR BAS 70100 F	12.5 months	Effects below 10 % after 12months exposure to total application rate of 5 L product/ha.	Royer, S., Obermann, M. 2009 2009/1067172 314115	73862
	BAS 701 00 F	183 days	Effects between 10-25 % after 12 months exposure to total application rates of 8 and 10 L product/ha. 3	Lührs, U. 2010 2010/1000084 43873081	73863

fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522

epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)
2) Toxicity endpoint is re-adjusted by a soil factor of 2 to address the organic content of the soil, since the log P_{ow} for the active substance is >2.

3) New study submitted by the applicant

*Since the design and the relevance of collembolan multi-generation-study is not discussed and accepted at the moment in the EU, the study of Royer (2013) cannot be accepted for the current risk assessment. Only the endpoints from the 1st generation (28d) are documented as additional information.

The log KOW values for fluxapyroxad and epoxiconazole are above the agreed trigger value of 2. Therefore, a correction of the endpoints is required in order to account for the relatively high organic matter content of the artificial test soil compared to agricultural soils and a resulting lower bioavailability of the active substance to soil organisms.

6.7.1.2 Exposure

According to the GAP, ADEXAR (BAS-70100-FW-0-EC) is intended to be applied 2 times in spring and winter with a maximum application rate of 2 x 2 L formulation/ha (i.e. 125 g fluxapyroxad /ha and 125 g epoxiconazole /ha). It will be used as fungicide.

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances fluxapyroxad and epoxiconazole and the major soil degradation products are presented in the table below. Calculations considered the maximum application rate of 2x 2 L formulation/ha, a minimum of 21 days between applications and 70% and 90 % foliar interception for applications to cereals at BBCH growth stage 30-40 and 40-69 respectively. PEC values for the soil metabolites were calculated considering the maximum percentage of their formation observed in either the aerobic or anaerobic soil degradation studies and correcting for molecular weight.

All calculations assumed an even distribution of the substances in the top 5 cm horizon with a soil bulk density of 1.5 g/mL. Accumulation in the soil profile due to the persistence of fluxapyroxad and epoxiconazole was considered.

Table 6.7-2: Maximum predicted environmental concentrations in soil PECs[1)] fluxapyroxad and epoxiconazole / ADEXAR (BAS-70100-FW-0-EC) and major soil degradation products of fluxapyroxad and epoxiconazole following application in the intended use in cereals.

plant protection product:		ADEXAR (BAS-70100-FW-0-EC)				
use:		Cereals BBCH 30- 69				
Number of applications/intervall		2/21d				
application rate:		2L product / ha (125g a.i./ha per active substance)				
crop interception:		1. Appl.: 70% 2. Appl.: 90%				
Active substance / Preparation	**soil relevant application rate (g/ha)**	**PEC_{act} (mg/kg)**	**PEC_{twa} 21 d (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
fluxapyroxad		0.0578 on d21	0.0539	20	0.0148	0.0726
Metabolite M700F001	Ff=100%	0.0023 on d29	0.002220	20	0.0006	0.0029
Metabolite M700F002	Ff=100%	0.0046 on d49	0.0045	20	0.0013	0.0059
epoxiconazole		0.0635 on d21	0.0615	20	0.0077	0.0712
Metabolite 1,2,4-triazole	Ff=100%	0.0028 on d383	0.0028	20	0.0015	0.0043
Adexar / BAS 701 00F	2.072 kg/ha	0.8228		20	0.0379	0.8667

1) PEC_{act} = maximum annual soil concentration for a soil depth of 5 cm

PEC_{bkgd}= background concentration in soil considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops)

PEC_{accu} = accumulated soil concentration

The fluxapyroxad metabolite M700F001 and fluxapyroxad metabolite M700F002 were formed in soil in concentrations >10 % total AR at day 30 and 120 respectively. For details please see Section 5, Part 9.1 of this submission and Table 6.1-2, page 7.

The epoxiconazole metabolite 1,2,4-triazole was formed in soil in concentrations < 10 % total AR at day 175. For details please see Section 5, Part 9.1 of this submission and Table 6.1-2, page 7.

6.7.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.7-3: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of ADEXAR (BAS-70100-FW-0-EC) according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PECaccu (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Acute	LC_{50} = 341.7 mg Product/kg soil dw3)	0.8667	= 394	10
		Long-term	NOEC= 87,9 mg Product/kg soil dw3)		= 101	5
fluxapyroxad Metabolite M700F001	Formation fraction 100%	Acute	LC_{50} > 1000 1)	0.0029	> 1000	10
		Long-term	NOEC ≥ 5.33 1)		> 1000	5
fluxapyroxad Metabolite M700F002	Formation fraction 100%	Acute	LC_{50} > 1000 1)	0.0059	> 1000	10
		Long-term	NOEC ≥ 2.56 1)		> 400	5
epoxiconazole Metabolite 1,2,4-Triazole	Formation fraction 100%	Acute	LC_{50} > 1000	0.0043	> 1000	10
		Long-term	NOEC = 0.0708 1)		16.5	5
Other soil meso-and macrofauna						
Collembola (*Folsomia candida*)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Acute	-	0.8667	-	10
		Long-term	NOEC = 12.5 3) *Folsomia candida*		14.4	5
fluxapyroxad Metabolite M700F002	Formation fraction 100%	Acute	-	0.0059	-	10
		Long-term	NOEC ≥ 1000 1)		> 1000	5
epoxiconazole Metabolite 1,2,4-Triazole	Formation fraction 100%	Acute	-	0.0043	-	10
		Long-term	NOEC = 1.8 1)		419	5
Mites (*Hypoaspis aculeifer*)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Acute	-	0.8667		10
		Long-term	NOEC > 500 3)		> 500	5
Organic matter breakdown (all organisms)						
Adexar / BAS 70100F	2x 2L product/ha (2 x 2.072 kg/ha)	Long-term	10 L formulation 3) (625 g a.s): < 25 % effect	0.8667	> 700	5
TER values in bold are below the trigger						

fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522

epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)

2) Toxicity endpoint is re-adjusted by a soil factor of 2 to address the organic content of the soil, since the log P_{ow} for the active substance is >2.

3) New study submitted by the applicant

Based on the predicted concentrations of ADEXAR (BAS-70100-FW-0-EC) in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.7.2 Toxicity to Exposure Ratio

6.7.2.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) as well as the major soil degradation products of fluxapyroxad and epoxiconazole was assessed by comparing the maximum PECsoil with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The resulting TER_A values are shown in Table 6.7-3 above.

6.7.2.2 Chronic risk

There is a need to address the long term risk of the active substance fluxapyroxad for earthworms and other soil macro- and mesofauna, since its degradation in soil (DT90 > 365 d, Kinetic, laboratory/field data, Guidance Document on Terrestrial Ecotoxicology SANCO/10329/2002 rev2 final) is relatively slow.

According to the Guidance Document on Terrestrial Ecotoxicology, a test for assessing effects on organic matter breakdown (litterbag) is required where:

- DT_{90fiel}d of the active substance is > 365 days or
- $DT_{90field}$ of the active substance is between 100 and 365 days and
- Effects on soil microflora > 25 % or TER_{LT} earthworm < 5
- or Collembola TER_{LT} < 5

None of these criteria is met for epoxiconazole ($DT_{90field}$= 226 d) and the soil metabolite 1,2,4-Triazole ($DT_{90field}$= 28.1 d), since $DT_{90field}$ values are less than 365 days and no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of ADEXAR (BAS-70100-FW-0-EC).

One of these criteria is met fluxapyroxad ($DT_{90field}$= 370 d). Submitted data are reported in Table 6.7-1.

The potential chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) was assessed by comparing the maximum PECsoil with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\,(mg/kg)}$$

The resulting TER_{LT} values are shown in Table 6.7-3 above.

6.7.3 Residue content of earthworms

The log K_{ow} values of fluxapyroxad and epoxiconazole are > 3. Thus, a field study was conducted to investigate effects of ADEXAR (BAS-70100-FW-0-EC) on natural earthworm populations and abundance. During the trial samples of earthworms were collected and analysed for residues of epoxiconazole. A summary of the residue analysis work is presented in appendix 2.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing fluxapyroxad and epoxiconazole whenever contamination of soil may occur as a result of the intended uses of ADEXAR (BAS-70100-FW-0-EC).

Effects on soil microorganisms resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) were not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of ADEXAR (BAS-70100-FW-0-EC) are provided here. New studies are listed in Appendix 1 and summarized in (Table 6.8-1).

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for soil microbial activity following exposure to fluxapyroxad and epoxiconazole and ADEXAR (BAS-70100-FW-0-EC) with indication to agreed endpoints

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-tranformation	Adexar / BAS 70100F	28 d	Effects < 25 % compared to the control after exposure of 2.77 und 27.65 mg Product/kg soil dry weight[3)]	Schulz, L. 2009 1004146 091048009C	73864
C-transformation				Schulz, L. 2009 1004147 091048009N	73865
C-Mineralisation	fluxapyroxad Metabolite M700F002	42 d	Effects < 25 % compared to the control after exposure of 6.9 and 69.6 mg Prod/kg soil[1)] (*equi*: 2.3 und 23 mg a.i./kg soil)	Schulz, L. 2010 2010/1043638	79908
N-Mineralisation			Effects < 25 % compared to the control after exposure of 6.9 and 69.6 mg Prod/kg soil[1)] (*equi*: 2.3 und 23 mg a.i./kg soil)	Schulz, L. 2010 2010/1043639	79909

fluxapyroxad: 1)Endpoints from EFSA Journal 2012;10(1):2522

epoxiconazole: 1) Endpoint from EFSA Scientific Report 138 (2008)

3) New study submitted by the applicant

6.8.1.2 Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PECsoil) of fluxapyroxad and epoxiconazole.

6.8.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation ADEXAR (BAS-70100-FW-0-EC), the active substances fluxapyroxad and epoxiconazole and the major soil degradation product M700F002 are below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.8-2: Summary of risk assessment for soil micro-organisms exposed to ADEXAR (BAS-70100-FW-0-EC)/ and metabolites

Substance	Test type	PECaccu (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Adexar / BAS 70100F	N transformation	0.8667	27.65	32
	C transformation			
fluxapyroxad Metabolite M700F002	N transformation	0.0059	69.6	> 1000
	C transformation			

For the active ingredients in ADEXAR (BAS-70100-FW-0-EC), fluxapyroxad and epoxiconazole and their metabolites, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 10-times higher than the corresponding maximum PEC in soil. Considering concurrent exposure to both the active ingredients in ADEXAR (BAS-70100-FW-0-EC) at the time of application, a low risk to soil microflora is also concluded.

Based on the predicted concentrations of ADEXAR (BAS-70100-FW-0-EC) in soils, the risk to soil microbial processes following exposure to fluxapyroxad and epoxiconazole according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

6.9 Effects on Non-Target Plants

6.9.1 Overview and summary

Effects on non-target plants resulting from an exposure to ADEXAR (BAS-70100-FW-0-EC) were not evaluated as part of the EU review of fluxapyroxad and epoxiconazole. Therefore, all relevant study data for the assessment of the risk to non-target plants from the intended uses of ADEXAR (BAS-70100-FW-0-EC) are provided here, listed in Appendix 1 and summarized in appendix 2 (new studies).

6.9.1.1 Toxicity

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure ADEXAR (BAS-70100-FW-0-EC) with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Seedling emergence					
Carrot *(Daucus carota)* Sunflower *(Helianthus annuus)* Rape *(Brassica napus)* Soya bean *(Glycine max)* Onion *(Allium cepa)* Oats *(Avena sativa)*	ADEXAR BAS 70100 F (batch 204437)	Seedling emergence 21 d	ER_{50} > 2000 mL BAS 701 00 F /ha	Strömel, C. & Teresiak, H. 2009 2009/1089827 AC/09/185	73867
Vegetative vigour					
Carrot *(Daucus carota)* Sunflower *(Helianthus annuus)* Rape *(Brassica napus)* Soya bean *(Glycine max)* Onion *(Allium cepa)* Oats *(Avena sativa)*	ADEXAR BAS 701 00 F (batch 204520)	Vegetative vigour 20 d	ER_{50} > 2000 mL BAS 701 00 F /ha	Dutillie, H., Sack, D. 2009 2009/1067188 314165	73866

6.9.1.2 Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the BBA (2000) from the spray-drift predictions of Ganzelmeier & Rautmann (2000). Any dilution over the 3-dimensional vegetation surface is accounted for in the study design. Therefore, in contrast to the assessment of risks to arthropods from standard laboratory tests, no vegetation distribution factor is considered here.

PER off-field= Maximum in-field PER (including MAF) x %drift

For calculation of PER in-field, please refer to section 6.6.1.2, page 54.

The resulting maximum off-field predicted environmental rates (PER off-field) are summarized in the following table:

Table 6.9-2: Maximum off-field predicted environmental rates of ADEXAR (BAS-70100-FW-0-EC) following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.38% drift)	Maximum PERoff-field at 5m (0.47% drift)	Maximum PERoff-field at 10m (0.24% drift)
(mL ADEXAR (BAS-70100-FW-0-EC)/ha)			
2000	80.92	-	-

6.9.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.9-3: Summary of risk assessment for non-target terrestrial plants exposed (BAS-70100-FW-0-EC)

Endpoint	ER50 (mL product/ha)	PERin-field (mL product/ha)	Distance (m)	Exposure PERoff-field (mL product/ha)	TER
Seedling emergence	ER_{50} > 2000 mL	3400	1	80.92	> 24
			-	-	-
			-	-	-
Vegetative vigour	ER_{50} > 2000 mL		1	80.92	> 24
			-	-	-
			-	-	-

Based on the predicted rates of ADEXAR (BAS-70100-FW-0-EC) in off-field areas, the TER values describing the risk for non-target plants following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation of ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label.

6.10 Other Non-Target Species (Flora and Fauna)

6.10.1 Overview and summary

6.10.1.1 Toxicity

6.10.1.2 Exposure

6.10.1.3 Risk assessment –overall conclusions

6.10.2 Toxicity to Exposure Ratio

6.11 Other/Special Studies

6.11.1 Laboratory studies

6.11.2 Field studies

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source Report-No. Published or not	Data protection claimed	Owner	How considered in dRR Study-Status
KIIA 8.7	Schur, A.	1999	Assessment of side effects of Epoxiconazole technical to the honey bee, Apis mellifera L. in the laboratory 1999/11547!99345/01-BLEU 312726	Yes	BASF	1
KIIA 8.7.1	Schmitzer, S.	2008	Effects of BAS 700 F (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory 2008/1010703!41711035 312727 312728	Yes	BASF	1
KIIA 8.7.2	Schmitzer, S.	2009	Study on the effect of BAS 700 00 F on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel test 2009/1037123!48141031 312729	Yes	BASF	1
KIIIA 10.1.6/1	XXX	2009	BAS 701 00 F - Acute toxicity in the bobwhite quail (*Colinus virginianus*) after single oral administration (LD_{50}) BASFDocID 2009/1075269	Yes	BASF	1
KIIIA 10.10/1	Dietzen C. *et al.*	2006	Bird species in cereal fields in Germany, Poland, France and Italy: Field data for the determination of focal species BASF DocID 2006/1039415	Yes	BASF	1
KIIIA 10.10/2	Wolf C.	2005a	Generic field monitoring of birds and mammals on maize and beet fields in Austria BASF DocID 2005/1031348	Yes	BASF	1
KIIIA 10.10/3	Wolf C.	2005b	Generic field monitoring of birds in potato cultivation in Northern Germany BASF DocID 2007/1042664	Yes	BASF	1
KIIIA 10.10/4	Staedtler &Giessing	2011	Diet composition of skylarks (Alauda arvensis) in cereal fields during spring in Germany BASF DocID 2010/1044221	Yes	BASF	1
KIIIA 10.10/5	Schneider	2011	Time course of epoxiconazole residues in arthropods after spray application starting at early growth stages in cereal	Yes	BASF	1

			fields in Germany BASF DocID 2011/1102461			
KIIIA 10.2.2.1	XXX	2009 a	BAS 701 00 F - Acute toxicity study with the rainbow trout (*Oncorhynchus mykiss*) BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2009/1048372 Unpublished	Yes	BASF	1
KIIIA 10.2.2.2	Janson G.-M.	2008 a	Acute toxicity of BAS 701 00 F to *Daphnia magna* STRAUS in a 48 hour static test BASF SE, Limburgerhof, Germany Fed.Rep. 2008/1028244 Unpublished	Yes	BASF	1
KIIIA 10.2.2.3/1	Hoffmann F.	2008 a	Effect of BAS 701 00 F on the growth of the green alga *Pseudokirchneriella subcapitata* BASF SE, Limburgerhof, Germany Fed.Rep. 2008/1037030 Unpublished	Yes	BASF	1
KIIIA 10.2.2.3/2	Hoffmann F.	2009 a	Effect of BAS 701 00 F on the growth of *Lemna gibba* BASF SE, Limburgerhof, Germany Fed.Rep. 2009/1098713 Unpublished	Yes	BASF	1
KIIIA1 10.4.2.1	Barth, M.	2008	Acute toxicity of BAS 701 00 F to the honeybee Apis mellifera L. under laboratory conditions 2008/1034508 ! 081048020B 312512 312513	Yes	BASF	1
KIIIA1 10.4.2.2	Barth, M.	2008	Acute toxicity of BAS 701 00 F to the honeybee Apis mellifera L. under laboratory conditions 2008/1034508!081048020B 312513	Yes	BASF	1
KIIIA1 10.4.2.2	Schmitzer, S.	2009	Study on the effect of BAS 701 00 F on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel test	Yes	BASF	1
KIIIA 10.5.1/1	Sipos K.	2008	Effect of BAS 701 00 F on the predatory mite (*Typhlodromus pyri*) in a laboratory trial	Yes	BASF	1

			LAB Research Ltd., Veszprem, Hungary 2008/1010765 Unpublished			
KIIIA 10.5.2/1	Mayer C.J.	2009 a	Evaluation of the duration of effects of BAS 701 00 F on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) - Aged residue trial BASF SE, Limburgerhof, Germany Fed.Rep. 2009/1069104 Unpublished	Yes	BASF	1
KIIIA 10.5.2/2	Spincer D.	2009 a	A rate-response extended laboratory test to determine the effects of BAS 701 00 F on the green lacewing, *Chrysoperla carnea* (Neuroptera, Chrysopidae) Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom 2008/1042192 Unpublished	Yes		1
KIIIA 10.6.2	Friedrich S.	2009 a	Acute toxicity of BAS 701 00 F to the earthworm *Eisenia fetida* in artificial soil with 5% peat BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1072246 Unpublished	Yes	BASF	1
KIIIA 10.6.3/1	Luehrs U.	2008 a	Effects of BAS 701 00 F on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2008/1000701 Unpublished	Yes	BASF	1
KIIIA 10.6.4/1	Krueck S.	2009 a	Field study to evaluate effects of BAS 701 00 F on earthworms BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1000121 Unpublished	Yes	BASF	1
KIIIA 10.6.6/1	Luehrs U.	2009 a	Effects of BAS 701 00 F on the reproduction of the collembola *Folsomia candida* in artificial soil with 5% peat Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2009/1002761 Unpublished	Yes	BASF	1

KIIIA 10.6.6/2	Schulz L.	2009 a	Effects of BAS 701 00 F on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1089814 Unpublished	Yes	BASF	1
KIIIA 10.6.6/3	Royer S.	2013	Effect of BAS 701 00 F on the reproduction of different generations of the Collembola *Folsomia candida* (multi generation study) BASF DocID 2013/1040568	Yes	BASF	3/5
KIIIA 10.6.6	Schabio & Eichler	2013	Effects of BAS 702 00 F on Soil Collembola under field conditions BASF DoclD 2012/1143242	Yes	BASF	3/5
KIIIA 10.6.7/1	Royer S., Obermann M.	2009 a	Effect of BAS 701 00 F on the organic matter decomposition under field conditions (litter bag method) BASF SE, Limburgerhof, Germany Fed.Rep. 2009/1067172 Yes Unpublished	Yes	BASF	1
KIIIA 10.6.7/2	Luehrs U.	2010 a	Effects of BAS 701 00 F on the breakdown of organic matter in litter bags in the field Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2010/1000084 Yes Unpublished	Yes	BASF	1
KIIIA 10.7.1/1	Schulz L.	2009 b	Effects of BAS 701 00 F on the activity of soil microflora (carbon transformation test) BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1004146 Unpublished	Yes	BASF	1
KIIIA 10.7.1/2	Schulz L.	2009 c	Effects of BAS 701 00 F on the activity of soil microflora (nitrogen transformation test) BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1004147 Unpublished	Yes	BASF	1
KIIIA 10.8.1.2/1	Dutillie H., Sack D.	2009 a	BAS 701 00 F: Effects on non-target plants in the greenhouse - A multiple dose test	No	BASF	1

			BASF SE, Limburgerhof, Germany Fed.Rep. 2009/1067188 Unpublished			
KIIIA 10.8.1.3/1	Stroemel C., Teresiak H.	2009 a	Effect of BAS 701 00 F on seedling emergence and seedling growth of six species of terrestrial plants Agro-Check, Lentzke, Germany Fed.Rep. 2009/1089827 Unpublished	No	BASF	1

1) accepted (study valid and considered for evaluation)

2) not accepted (study not valid and not considered for evaluation)

3) not considered (study not relevant for evaluation)

4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)

5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of the new studies according to Commission regulation (EU) No 284/2013

Present the authority's comment on the study in a box above each individual study. If there is more than one toxicity study available, list them separately, i.e., KPC.2.1.1 Study 1, KPC .2.1.2 Study 2 etc.

KPC 10.1 Effects on birds and other terrestrial vertebrates

KPC 10.1.1 Effects on birds

KPC 10.1.1.1 Acute oral toxicity

Report:	**10.1.6/1, Zok S.,2009a**
Title:	BAS 701 00 F - Acute toxicity in the bobwhite quail (*Colinus virginianus*) after single oral administration (LD_{50})
Document No:	BASFDocID 2009/1075269
Guidelines:	EPA 71-1, EPA 850.2100, EPA 540/9-82-024, EPA 540/9-85-007, EPA 712-C-96-139
GLP	Yes

Executive Summary

An avian acute oral toxicity test with the formulation BAS 701 00 F, containing the active substances fluxapyroxad and epoxiconazole, was conducted. The objective of the study was to test the acute toxicity of BAS 701 00 F on the bobwhite quail (*Colinus virginianus*) and to determine the oral LD_{50} and the no observed effect level (NOEL).

The formulation was administered via a single-dose of 500, 1000 or 2000 mg /kg body weight to approximately 5-month old northern bobwhite quails. Ten birds (5 males and 5 females) were used in each group. The doses were suspended in drinking water. Birds that have been fasted for about 19 to 21 hours were administered the test item.

All groups were observed for mortality, signs of clinical toxicity, impact on food consumption and body weight for 14 consecutive days post dosing. Birds of all groups received food and water *ad libitum* throughout the test. The test was terminated after 14 days.

Biological results: No mortality occurred throughout the duration of the study in the control and in all test item groups. The highest dose causing no mortality was 2000 mg/kg body weight for males and females. No toxic signs were observed in the control and in all test item concentration groups. There was no test item-related impairment of feed uptake in comparison to the control observed in any of the dose groups. There was no statistically significant test item-related reduction of the body weights in any of the dose groups at day 7 and day 14 (sacrifice) and the body weight development was not impaired in comparison to the control group. No test item-related macroscopic abnormalities were detected in the gross-pathological post-mortem examination.

In an acute oral toxicity test with the bobwhite quail (*Colinus virginianus*), the LD_{50} of BAS 701 00 F was found to be greater than 2000 mg/kg b.w. The NOEL was ≥ 2000 mg/kg b.w.

MATERIAL AND METHODS

Test item:	BAS 701 00 F, batch no. 204438, containing BAS 700 (Reg. No. 5094351) with nominal 62.5 ga.s./L (62.4 g a.s./L analyzed) and epoxiconazole (Reg. No. 205259) with nominal 62.5 g a.s./L (62.7 g a.s./L analyzed)
Test species:	Bobwhite quail (*Colinus virginianus*); indistinguishable from wild birds; age: approx. 5 months at dosing (before their first egg-laying season); source: Geflügelzucht Küberich, D-97353 Geesdorf/Wiesentheid, Germany.
Test design:	Birds were administered single doses of 500, 1000 or 2000 mg/kg body weight of the test item BAS 701 00 F in drinking water by gavage into the crop in a total amount of 10 g preparation per kg body weight; 5 males and 5 females per dose group were used; observation period of 14 days; assessment of mortality and signs of clinical toxicity was carried out four times on day of dosing and daily thereafter; assessment of body weight was carried out on the day of dosing and on day 7 and 14; mean food consumption (g/bird/day) was calculated from the weekly food consumption/cage separately for male and female birds for the first and second week after dosing. Gross-pathological post-mortem examinations of all birds that died during the study and all birds sacrificed at study termination on day 14 after dosing.
Endpoints:	Mortality, clinical signs, feed consumption, body weight (b.w.), and gross-pathological examinations were conducted on all birds sacrificed at the termination of the test. Calculation of LD_{50} and NOEL.
Test concentrations:	0 (Control), 500, 1000 and 2000 mg a.s./kg body weight (nominal).
Test conditions:	Birds fasted for 19 h to 21 h before administration of the test item; temperature: 20.0 °C - 24.7 °C; relative humidity: 45% - 70% (limits); photoperiod: 8 hours light: 16 hours dark during the test period, light intensity: 4 lux - 9 lux.
Analytics:	The test substance concentrations were analyzed using HPLC.
Statistics:	Descriptive statistics, Dunnett test for body weight data.

RESULTS AND DISCUSSION

Analytical measurements: The results of the analytical verification of the test item concentration in the diet were within a range of 94% to 98% of the nominal concentrations during the test. The biological results are therefore based on the nominal values.

Biological results: No mortality occurred throughout the duration of the study in the control and in all test item groups. The highest dose causing no mortality was 2000 mg/kg body weight for males and females. No toxic signs were observed in the control and in all test item concentration groups. There was no test item-related impairment of feed uptake in comparison to the control observed in any of the dose groups. There was no statistically significant test item-related reduction of the body weights in any of the dose groups at day 7 and day 14 (sacrifice) and the body weight development was not impaired in comparison to the control group (Dunnett test). No test item-related macroscopic abnormalities were detected in the gross-pathological post-mortem examination. The relevant endpoints are summarized in Table 10.1.6-1.

Table 10.1.6-1: Acute toxicity of BAS 701 00 F to the bobwhite quail (*Colinus virginianus*)

Endpoints	Dose [mg/kg b.w.]
Highest dose causing no substance-related mortality	2000
LD_{50} (14 d)	> 2000
NOEL	≥ 2000

b.w. = body weight

CONCLUSION

In an acute oral toxicity test with the bobwhite quail (*Colinus virginianus*), the LD_{50} of BAS 701 00 F was found to be greater than 2000 mg/kg b.w. The NOEL was ≥ 2000 mg/kg b.w.

KPC 10.1.1.2 Higher tier data on birds

The results of the following 5 studies are used for the refinement of the long-term risk of birds and mammals as detailed in chapters 10.1 and 10.3.

Study 1

Report:	**10.10/1, Dietzen C. et al., 2006a,**
Title:	Bird species in cereal fields in Germany, Poland, France and Italy: Field data for the determination of focal species
Document No:	BASF DocID 2006/1039415
Guidelines:	EEC 91/414, EEC 96/68, SANCO/4145/2000
GLP	No, not subject to GLP regulations

The selection of focal species for the refined risk assessment is based on the results of a generic bird monitoring study (Dietzen at al. 2006; BASF DocID 2006/1039415) conducted in cereal fields of main growing regions in France, Germany and Poland. Note that the report by Dietzen at al. 2006 (BASF DocID 2006/1039415) also includes results from Italy (Apulia), which are not included in this analysis for Northern Europe.
The field part of this monitoring study was carried out in 70 cereal fields between March and July. Field surveys were conducted at three periods of crop development (survey periods), covering the growth stages from BBCH 10 (leaf development) to BBCH 83 (ripening). The data were collected using standard line transects comprising of 50 m band to each side of the observer moving along a longitudinal in-crop line (field transect). Using this method all bird individuals in a 100 m wide ‘in-crop transect band’ were recorded.

Focal species selection criteria
The criteria to select focal bird species for PPP risk assessments are outlined below. These criteria are consistent with recent EFSA recommendations (Anonymous 2008, Appendix 27).

The focal species candidates are selected by analyzing the species' frequency of occurrence (FO). In a two-step analysis, first spatial and thereafter temporal aspects in the species' occurrence pattern are evaluated.
The spatial frequency of occurrence is given by the **FO_{field}.** This value denotes the number of fields in which a defined species was recorded, given as percentage of the total number of fields, regardless in which survey period the species was observed.
Temporal aspects in a species' frequency of occurrence can be assessed by analyzing the data of each of the three survey periods independently. **FO (survey period)** values are calculated for each of the three survey periods. These values also denote the number of fields in which a defined species was recorded, given as percentage of the total number of fields, but for a single survey period only.

The FO data are used sequentially as follows. First, birds with a $FO_{field} \geq 20\%$ are considered to occur at high enough spatial frequency to be candidate focal species. Second, FO (survey period) values ≥20% are used to identify birds at high enough temporal frequency of occurrence. Thus, species fulfilling both these spatiotemporal criteria (*i.e.* $FO_{field} \geq 20\%$ and FO (survey period) ≥20% in at least one survey period) are considered to be candidate focal species.

The candidate focal species are further allocated to diet guilds (i.e. insectivorous, herbivorous, omnivorous, and granivorous). Then, before defining the focal species of the respective diet guilds it is

necessary to consider issues such as feeding strata and body weight of potential focal species to ensure that the selected species is protective for the whole guild.
In most cases this approach will allow deducing the focal species. However, there might be cases where the data are ambiguous and the clear definition of a focal species is difficult. In such cases a weight of evidence approach may be applied, using additional information from literature and / or expert judgment.

Evaluation of study data
The bird monitoring data are analyzed for France, Germany and Poland separately. The first step of the analysis is to select those bird species with a $FO_{field} \geq 20\%$ (Table 10.10-1).

Table 10.10-1 Focal species candidates in cereal fields in northern Europe - Spatial criterion FO_{field}

Seasonal period	BBCH at survey	Number of transects / Method	Diet guild (Size of species)	Species with $FO_{field} \geq 20\%$	Stratum	FO_{field} [%]	Mean body weight [g] [1]
France							
March April June	10-29 30-39 73-77	n = 21 / transect counts	insectivore (small)	yellow wagtail	ground	85.7	17.6
			herbivore	No finding	--	--	--
			omnivore (small)	skylark	ground	81	37.2
				corn bunting		38.1	46
			omnivore (medium)	quail	ground	52.4	90
				grey partridge		23.8	381
			granivore (small)	No finding	--	--	--
Germany							
Mar(-April) April May-July	10-29 30-39 59-83	n = 25 / transect counts	insectivore (small)	white wagtail	ground	28	21.0
				yellow wagtail		20	16.7
			herbivore	No finding	--	--	--
			omnivore (small)	skylark	ground	96	37.2
				tree sparrow	ground / foliage	32	22
				carrion crow	ground	20	570
			granivore (small)	No finding	--	--	--
Poland							
April-May May June	10-29 30-39 58-83	n = 24 / transect counts	insectivore (small)	yellow wagtail	ground	66.7	17.6
			herbivore	No finding	--	--	--
			omnivore (small)	skylark	ground	95.8	37.2
				corn bunting		37.5	46
			granivore (small)	No finding	--	--	--

1) Bodyweight data according to Dunning et al. 1993

From the above list (Table 10.10-1) the focal bird species of the respective diet guilds (i.e. insectivorous, herbivorous, omnivorous, and granivorous) are determined in the following paragraphs.

In the next step those species given in Table 10.10-1 (hence fulfilling the spatial criterion of $FO_{field} \geq 20\%$) are examined closer guild by guild. This closer examination takes into account the FO (survey period) values from all three survey periods (Table 10.10-2 and Table 10.10-3).

Insectivorous diet guild

The results for the insectivorous diet guild are summarized in Table 10.10-2.

Table 10.10-2 Insectivorous focal species candidates for cereals in northern Europe - Temporal criterion FO (survey period)

<table>
<tr><th rowspan="2">Species</th><th rowspan="2">Stratum</th><th colspan="3">FO_{field}[1] [%]
$FO_{survey\ period}$ [%] for each period between parentheses</th><th rowspan="2">Mean body weight [g] [2]</th></tr>
<tr><th>France
(March / April /June)
BBCH 10-29 / 30-39 / 73-77</th><th>Germany
(Mar(-Apr) / Apr / May-July)
BBCH 10-29 / 30-39 / 59-83</th><th>Poland
(Apr(-May) / May / June)
BBCH 10-29 / 30-39 / 58-83</th></tr>
<tr><td>Yellow wagtail</td><td rowspan="2">ground</td><td>85.7
(0.0 / 66.7 / 61.9)</td><td>20.0
(0.0 / 4.0 / 20.0)</td><td>66.7
(12.5 / 58.3 / 54.2)</td><td>17.6</td></tr>
<tr><td>White wagtail</td><td>No finding</td><td>28.0
(8.0 / 12.0 / 8.0)</td><td>No finding</td><td>21.0</td></tr>
</table>

1) This table includes only those species with $FO_{field} \geq 20\%$
2) Bodyweight data according to Dunning et al. 1993

The two wagtail species, i.e. yellow wagtail and white wagtail are candidates for the insectivorous focal species.
The yellow wagtail (*Motacilla flava*) fulfills the relevance criteria for spatial ($FO_{field} \geq 20\%$) and temporal distribution (at least one FO (survey period) ≥ 20%) in all three countries. The species' first occurrence was in April at relatively low FO (survey period) values. The yellow wagtail is a summer visitor to Europe, returning during April (Cramp 1988), which explains the low numbers recorded during the surveys in March. Concordantly, it is noted that the yellow wagtail consistently occurred at all surveys conducted between April and July.
The white wagtail (*Motacilla alba*) was found only in one of the three countries (Germany) and fulfills the relevance criterion for spatial occurrence ($FO_{field} \geq 20\%$), however, not for temporal distribution (at least one FO (survey period) ≥ 20%). Therefore, the white wagtail will not be taken into account as a candidate focal species.
In conclusion, the **insectivorous yellow wagtail** is the focal species for cereals in northern Europe.

Herbivorous diet guild

For the herbivorous diet guild no representatives fulfilling the focal species relevance criteria were found suggesting that herbivorous species are of low relevance in cereals in northern Europe. As a result, for the herbivorous diet guild no focal species can be defined. Nevertheless, the potential exposure through plant feed items can also be addressed through the focal species selected for the omnivorous guild (see below). This is due to the reason that omnivorous species feed on a mixed diet including green plant matter, seeds, arthropods etc.

Omnivorous diet guild

The results for the omnivorous diet guild are summarized in Table 10.10-3.

Table 10.10-3 Omnivorous focal species candidates for cereals in northern Europe - Temporal criterion FO (survey period)

Species	Stratum	FO_{field}[1] [%] $FO_{survey\ period}$ [%] for each period between parentheses			Mean body weight [g] [2)]
		France March / April /June BBCH 10-29 / 30-39 / 73-77	**Germany** Mar(-Apr) / Apr / May-July BBCH 10-29 / 30-39 / 59-83	**Poland** Apr(-May) / May / June BBCH 10-29 / 30-39 / 58-83	
Small-sized species					
Skylark	ground	81 (66.7 / 47.6 / 52.4)	96 (80 / 84 / 88)	95.8 (95.8 / 91.7 / 95.8)	27.2
Tree sparrow		No finding	32 (8.0 / 16 / 16)	No finding	22.0
Corn bunting		38.1 (9.5 / 9.5 / 28.6)	No finding	37.5 (25 / 20.8 / 16.7)	46
Medium-sized species					
Quail	ground	52.4 (0.0 / 0.0 / 52.4)	No finding	No finding	90
Grey partridge		23.8 (4.8 / 9.5 / 9.5)	No finding	No finding	381
Large-sized species					
Carrion crow	ground	No finding	20 (16 / 0.0 / 4.0)	No finding	570

1) This table includes only those species with $FO_{field} \geq 20\%$
2) Bodyweight data according to Dunning et al. 1993

The small-sized skylark (*Alauda arvensis*) is the omnivorous focal species for cereals in northern Europe. The skylark was found in all three countries showing both high spatial and temporal occurrence values, the latter ranging between 47.6% and 95.8%. Hence, regarding the even geographic distribution and temporal consistency of occurrence, the skylark appears as the most widespread small omnivorous species in cereal fields in northern Europe.
The remaining small-sized (*i.e.* tree sparrow and corn bunting), medium-sized (quail, grey partridge) and large sized (carrion crow) species were mostly observed in a single country only. The temporal selection criterion (at least one FO (survey period) ≥ 20%) was met only for the quail and the corn bunting. However, both species corn bunting and quail are clearly heavier than the skylark (Table 10.10-3), which ensures that the skylark is protective for those species.
Therefore, the **omnivorous skylark** is selected as focal species in cereal fields in northern Europe.

<ins>Granivorous diet guild</ins>
For the granivorous diet guild no representative candidate species was identified in cereal fields. Therefore, a focal species for the granivorous diet guild can not be defined. Nevertheless, the potential exposure through seeds can also be addressed through the focal species selected for the omnivorous guild. This is due to the reason that omnivorous species feed on a mixed diet including green plant matter, seeds, arthropods etc.

To summarize, the focal species selected in the previous sections for cereals in northern Europe are summarized in Table 10.10-4.

Table 10.10-4 Focal species for cereals in northern Europe

Diet guild	Focal species for refined risk assessment
Insectivorous	**Yellow wagtail**
Herbivorous	No finding
Omnivorous	**Skylark**
Granivorous	No finding

References to Dietzen et al. 2006

Anonymous (2008). Scientific Opinion of the Panel on Plant protection products and their residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. The EFSA Journal (2008) 734, 1-181

Cramp S (1998). The complete birds of the western Palearctic. CD-ROM edition. Oxford University Press.

Dunning, J.B. (1993). CRC Handbook of Avian Body Mass. CRC press, Boca Raton.

Study 2

Report:	**10.10/2, Wolf C., 2005a,**
Title:	Generic field monitoring of birds and mammals on maize and beet fields in Austria
Document No:	BASF DocID 2005/1031348
Guidelines:	EEC 91/414, EEC 96/46, SANCO/4145/2000
GLP	Yes

Report:	**10.10/3, Placke F.-J.,Koehler J., 2007d,**
Title:	Letter of access for generic behavioural ecology data - Study report Bayer CropScience AG DocID WFC/FS017 - Grouping: Maize, pre-emergence (seed treatments) and early post-emergence
Document No:	BASF DocID 2007/1044669
Guidelines:	-
GLP	No, not subject to GLP regulations

The objective of this study was to obtain information on crop use and diet of farmland birds and mammals in an agricultural environment in Austria. This study was carried out to generate information for use in the assessment of risks from plant protection products to terrestrial vertebrates in the frame of EU directive 91/414/EEC and the guidance document SANCO/4145/2000. The study focused on one bird (skylark) and one mammal (wood mouse) but information on other species were also collected. In the present summary, only results of the skylark are included.

MATERIAL AND METHODS

The study was conducted in mixed arable land in the 'Tullner Feld' to the west of Vienna in Austria. This region is a typical area of maize and sugar beet cultivation in Europe, but also comprises a significant amount of cereal fields. 5 maize and 5 sugar beet fields were chosen as primary study plots. The study plots for bird radio-tracking (apart from study plot 3 and 9) were surrounded by several adjacent cereal fields (mainly winter wheat).

The experimental phase of the study started some weeks before drilling of maize and sugar beet (19.03.2004) and was completed approximately 2 months later (19.05.2004).

To quantify the proportion of potential foraging time (PT), 16 skylarks were trapped, tagged with radio-transmitters and tracked for one to four daylight periods, respectively. During each session the skylark was tracked continuously so that location, habitat and behavior could be recorded in order to get information on the home range, habitat selection and time budget of individuals living in arable landscape. The radio-tracking of skylarks was carried out between 6 April and 19 May.

RESULTS AND DISCUSSION

The outcome of the 29 radio-tracking sessions conducted with skylarks is summarized below. The table includes the results for cereals (relevant crop for this submission) and for maize and sugar beets (primary target crops of the study). These results are taken from Table 10 on page 75 of the study report.

PORTION OF TIME potentially foraging (PT) per habitat used by radio-tracked skylarks					
	Habitat	**Mean PT (all birds)**	**Mean PT (consumers)** [1)]	**90%tile PT**	**No. of tracking sessions**
potential foraging time (PT) 16 skylarks spent per habitat based on 29 tracking sessions (Table 10, page 75)	plain fields	19.9 %	--	59.3 %	15
	drilled maize fields	4.1 %	--	14.4 %	7
	germinated maize fields	42.1 %	--	95.4 %	10
	drilled sugar beet fields	8.1 %	--	21.2 %	9
	germinated sugar beet fields	19.7 %	--	58.7 %	14
	winter cereals	29.2 %	35.2%	94.1 %	29

1) The mean PT (consumers) is not given in the study report, but was re-calculated based on study data for the purpose of the avian refined risk assessment.

The mean portion skylarks spent "potentially foraging" in germinated maize and sugar beet fields were 42.1% and 19.7% respectively. Within the drilling stage the corresponding values were 4.1% for maize and 8.1% for sugar beet fields. The mean (all birds) portion of time potentially foraging in winter cereals was 29.2%, the mean (consumers) portion of time potentially foraging in winter cereals was 35.2%

CONCLUSION

Radio-tracking of 16 individual skylarks (each for a minimum of 24 and a maximum of 96 hours) in an arable landscape with maize, sugar beet and cereal fields prevailing in the west of Vienna (Austria) showed that these field types were frequently used as feeding habitats by these birds.

For risk assessment purposes a value for portion of time spent foraging in cereal fields (PT) can be derived for skylarks from the results of this study: Skylarks breeding in or in close vicinity to cereal fields spent on the average 29.2% (all birds) and 35.2% (consumers) of their potential foraging time in winter cereal fields.

Study 3

Report:	**10.10/4, Wolf C., 2005b,**
Title:	Generic field monitoring of birds in potato cultivation in Northern Germany
Document No:	BASF DocID 2007/1042664
Guidelines:	EEC 96/46, EEC 91/414, SANCO/4145/2000
GLP	Yes

Report:	**10.10/5, Placke F.-J.,Koehler J., 2007b,**
Title:	Letter of access from Bayer DE Grouping for generic behavioural ecology data - Study report Bayer CropScience AG DocID WFC/FS019 - Grouping: Potato, post-emergence (foliar stages)
Document No:	BASF DocID 2007/1044666
Guidelines:	-
GLP	No, not subject to GLP regulations

The objective of this study was to obtain information on crop use of yellow wagtails in an agricultural environment in Lower Saxony (Germany). This study was carried out to generate information for use in the assessment of risks from plant protection products to terrestrial vertebrates in the frame of EU directive 91/414/EEC and the guidance document SANCO/4145/2000. The study focused on one bird species (yellow wagtail).

MATERIAL AND METHODS

The study was conducted in mixed arable land in Northern Germany, specifically in and around six different potato fields in the "Wildeshauser Geest" region near the village Dötlingen between the towns of Wildeshausen and Oldenburg, in Lower Saxony, Germany. This region is a typical area of potato cultivation in Europe, and known to hold a population of yellow wagtails. The study plots for bird radio-tracking were chosen to be typical sites for potato cultivation in a quite open landscape, providing the typical habitat for the yellow wagtail in an agrarian landscape. All sites were commercially cultivated fields and treated according to the good agricultural practice (GAP).

The experimental phase of the study started at the end of may (28.05.2004) and was completed approximately 4 months later (17.09.2004).

To quantify the proportion of potential foraging time (PT), 20 yellow wagtails were trapped, tagged with radio-transmitters and tracked for one to five daylight periods, respectively. During each session the yellow wagtails were tracked continuously so that location, habitat and behavior could be recorded in order to get information on the home range, habitat selection and time budget of individuals living in arable landscape. The radio-tracking of yellow wagtails was carried out between 2 June and 14 July 2004.

Additionally, the diet composition of yellow wagtails was determined by analyzing samples of faeces collected in the field or obtained during the handling of birds. In the present summary, only results of the radio-tracking are included.

RESULTS AND DISCUSSION

The outcome of the radio-tracking sessions conducted with yellow wagtails is summarized below. Concerning arable crops, the table includes the results for potato, cereals and oilseed rape. These results are taken from the table on page 9 of the study report. The radio-tracking results for potatoes and cereals are relevant for the risk assessment in this submission.

PORTION OF TIME potentially foraging (PT) per habitat used by radio-tracked yellow wagtails				
	Habitat	**Mean PT (all birds)**	**Mean PT (consumers)** [1)]	**90%tile PT**
potential foraging time (PT) 20 yellow wagtails spent per habitat based on 1-5 tracking sessions (Table on page 9)	Potato fields	38.4%	--	72.3%
	Cereal fields	39.8%	41.9%	44.1%
	Oilseed rape fields	6.8%	--	22.2%
	Streets and field paths	3.7%	--	10.7%
	Other habitats	11.3%	--	16.0%

1) The mean PT (consumers) is not given in the study report, but was re-calculated based on study data for the purpose of the avian refined risk assessment.

CONCLUSION

Radio-tracking of 20 individual yellow wagtails (each for a minimum of 24 and a maximum of 120 hours) in an arable landscape with a high number of potato fields in the north-western of Lower Saxony (Germany) showed that this field type was used as a main feeding habitat by this bird species.

However, cereal fields (barley, wheat and rye) have been used as well to a (in summary) similar high proportion by yellow wagtails, which foraged for chick provisioning or the bird's own use. Only one individual fed almost exclusively on potato fields while tracking, while one individual did not use potato fields as feeding habitat at all.

For risk assessment purposes a value for portion of time spent foraging in potato fields and cereal fields (PT) can be derived for yellow wagtails from the results of this study: yellow wagtails settling in or in close vicinity to potato fields have spent on average 38.4% of their potentially foraging time in potato fields. The arithmetic mean PT value (all birds) for yellow wagtails in cereal fields is 39.8%. The arithmetic mean PT value (consumers) for yellow wagtails in cereal fields is 41.9%

Study 4

Report:	**10.10/6, Staedtler T.,Giessing B., 2011**
Title:	Diet composition of skylarks (*Alauda arvensis*) in cereal fields during spring in Germany
Document No:	BASF DocID 2010/1044221
Guidelines:	EFSA Guidance Document: Risk assessment for birds and mammals (2009)
GLP	Yes

The objective of this study was to obtain information on the diet of a farmland bird species in an agricultural environment in Germany and to generate information for use in the assessment of risks from plant protection products to terrestrial vertebrates in the frame of EU Regulation No 1107/2011 and EFSA/2009/1438. The aim of this generic study was to collect faeces samples of skylarks (*Alauda arvensis*), which utilize winter cereal fields as foraging habitat, and to estimate the proportion of different food types (e.g. arthropods, cereal leaves, seeds) in their diet for improvement of higher tier risk assessments.

MATERIAL AND METHODS

The study was conducted in ten winter cereal fields in the area of the administrative districts Ostprignitz-Ruppin and Havelland, Brandenburg / Germany, a typical area for winter cereal cultivation in Europe.

The experimental phase of this study, i.e. the sampling of faeces was carried out during spring (April to June) 2010 correlating to BBCH 25 to 39 in winter cereal fields.

To estimate the proportion of different food types in their diet (PD), 56 faeces samples of skylarks collected in winter cereal fields were analyzed. For this purpose the area proportion of the remains per food item category found in each faeces sample was measured. In order to account for differences in digestibility and recognizability between the food types, correction factors as published by Green (1978) were applied and subsequently the dry weight proportion of originally ingested food items was calculated.

Faeces were sampled during three different growth stage periods: (1) BBCH 25-29 ('five tillers detectable' to 'end of tillering'), (2) BBCH 30-34 (early 'stem elongation') and BBCH 35- 39 (late 'stem elongation').

RESULTS AND DISCUSSION

PD values were calculated for individual faeces samples and as overall PD values per BBCH growth stage periods (expressed as mean, 50%tile and 90%tile percentages). The PD values for skylarks utilizing winter cereals are presented in the table below for four different growth stage periods (sampling period I, II and III and combined for period II - III).

PORTION OF DIET of skylarks in cereal fields in Central Europe (Germany) [1)]					
Food category		**Period I BBCH stage 25-29**	**Period II BBCH stage 30-34**	**Period III BBCH stage 35-39**	**Period II to III BBCH 30-39**
Invertebrates	**Mean**	**0.633**	**0.768**	**0.654**	**0.712**
	50%tile	0.682	0.865	0.612	0.770
	90%tile	0.936	0.988	0.973	0.986
Cereal grain	**Mean**	**0.005**	**0.039**	**0**	**0.020**
	50%tile	0	0	0	0.000
	90%tile	0	0.065	0	0.000
Weed and grass seeds	**Mean**	**0.051**	**0.127**	**0.272**	**0.198**
	50%tile	0.017	0.058	0.314	0.140
	90%tile	0.119	0.214	0.432	0.406
Grass flowers	**Mean**	**0**	**0.016**	**0.073**	**0.044**
	50%tile	0	0	0.059	0.000
	90%tile	0	0.069	0.171	0.151
Green plant material (monocotyledonous)	**Mean**	**0.004**	**0.006**	**0**	**0.003**
	50%tile	0	0	0	0.000
	90%tile	0.007	0	0	0.000
Green plant material (dicotyledonous)	**Mean**	**0.306**	**0.044**	**0.001**	**0.023**
	50%tile	0.262	0	0	0.000
	90%tile	0.792	0.089	0.002	0.032

1 Given as proportions of the dry weight of the total diet ingested per period

For the relevant time period, from BBCH 30 to 39, the mean percentage values of total dry weight for the portion of diet were highest for invertebrates with 71.2%, followed by weed and grass seeds (19.8%), grass flowers (4.4%), dicotyledonous plant material (2.3%), cereal grains (2.0%) and monocotyledonous plant material (0.3%).

CONCLUSION

This study provides a reliable refinement for skylark PD to be used in higher tier risk assessments.

References to Giessing & Städtler 2011

Green, R.E. 1978. Factors affecting the diet of farmland skylarks, *Alauda arvensis*. Journal of Animal Ecology 47: 913-928.

Study 5

Report:	**10.10/7, Schneider K., 2011**
Title:	Time course of epoxiconazole residues in arthropods after spray application starting at early growth stages in cereal fields in Germany
Document No:	BASF DocID 2011/1102461
Guidelines:	EEC 91/414, EFSA Guidance Document: Risk assessment for birds and mammals (2009)
GLP	Yes

The aim of this study was to determine residue levels of epoxiconazole in ground-dwelling and foliage-dwelling arthropods in a winter wheat field, after spray application of the fungicidal product BAS 481 08 F (containing a.s. epoxiconazole and fenpropimorph). These data can be used in the assessment of risks from plant protection products to terrestrial vertebrates in the frame of EU Regulation No 1107/2011 and EFSA/2009/1438.

MATERIAL AND METHODS

The field study was conducted to measure residues of epoxiconazole on arthropods after spray application in a winter wheat field. The study site, located north-west of Berlin ((Brandenburg, Germany), is a typical area of winter wheat cultivation in Europe. Three test plots (replicates) were set up within the winter wheat field. The size of each plot was approximately 1.8 ha.

Application
The experimental phase of this study was carried out during April to July 2010. The test item BAS 481 08 F was applied twice. The first application was conducted on 13th, April 2010 (DAT 0) at BBCH 29 and the second application was conducted on 4th, May 2010 at BBCH 32 in accordance with 'Good Agricultural Practice' (GAP). The nominal single application rate for epoxiconazole was 125 g a.s./ha.

Arthropod sampling
Samples of the natural populations of ground- dwelling and foliage-dwelling arthropods were collected for residue analysis by pitfall trapping and inventory spray (using the knock-down insecticide AquaPy containing 30 g/L natural pyrethrum. The traps were activated (opened) approximately 24h before sampling. Three replicates were collected over a period of 45 days at -2, 1, 2, 3, 5, 7, 10, 14, 15, 18, 21 (before 2nd application), 22, 23, 24, 26, 28, 31, 35, 39 and 43. Following each sampling event, arthropods were recovered from all pitfall traps on each plot and the individual samples pooled to provide a single sample per plot.

For collection of foliage-dwelling arthropods fifty gutters (14 m^2) per plot were used to provide a minimum of foliage-dwelling arthropod matrix of 1 g. All foliage-dwellers sampled from all gutters on each plot at each sampling event were pooled to provide a single sample per plot. Inventory spraying was performed on DAT -3, 0 (after first application), 1, 2, 3, 5, 7, 10, 14, 18, 21 (after 2nd application), 22, 25, 26, 28, 31, 35, 39, and 43.
After determination of the main taxonomic groups the arthropod samples were weighed. If the sample mass was ≥ 2 g fresh weight the sample was split into two sub-samples of approximately equal weights and stored in two separate containers. One of the sub-samples served as retain sample. Furthermore, disproportional large numbers of aphids or collembola and disproportional large/heavy insects were sampled and bagged separately. All samples were stored at a temperature of at least -11.7°C until residue analysis.

Residue analysis
The arthropod specimens were analysed for epoxiconazole with BASF-method No. L0076/04, which has a limit of quantification of 0.01 mg/kg. Procedural recoveries averaged at about 79% for epoxiconazole at fortification levels between 0.01 and 10 mg/kg.

Calculations
Initial and maximum epoxiconazole concentrations in ground-dwelling and foliage-dwelling arthropods were determined. For ground-dwellers they were calculated as the arithmetic mean of three replicates (n=3). For foliage dwellers to give sufficient matrix for analysis, the samples of study plots 1 to 3 had to be pooled at each sampling date. A mean value could therefore not be calculated.
Where possible, also the 90th percentiles of epoxiconazole concentrations in arthropods were calculated.

RESULTS AND DISCUSSION

Ground-dwelling arthropods
The initial concentration after first application (DAT 1) of epoxiconazole was 0.334 mg a.s./kg fresh weight. The initial concentration after second application (DAT 22) of epoxiconazole was 0.885 mg a.s./kg fresh weight.

Foliage-dwelling arthropods
The initial concentration after first application of epoxiconazole could not be determined since the arthropod matrix obtained per sampling date for the entire study field, i.e. sum of all three plots, was far below the required minimum amount of 1 g for analysis. The initial concentration after second application (DAT 22) of epoxiconazole was 3.250 mg a.s./kg fresh weight.

The initial concentrations for ground-dwelling and foliage-dwelling arthropods are summarized in the table below.

epoxiconazole residues in arthropods		
Characteristic	**Ground-dwelling arthropods** epoxiconazole residues [mg a.s/kg fresh weight]	**Foliage-dwelling arthropods** epoxiconazole residues [mg a.s/kg fresh weight]
Initial concentration (after *first* application, DAT 1)	0.334 1) (DAT 1)	n.d. 2)
Initial concentration (after *second* application, DAT 22)	0.885 1) (DAT 22)	3.250 2) (DAT 21)

1 arithmetic mean (n=3)
2 n.d.: not determined, due to insufficient arthropod matrix
3 based on pooled samples from replicates 1 to 3 (n=1)

CONCLUSION

In conclusion, based on the results shown in the table above, the worst case initial residue values for epoxiconazole are 0.885 mg/kg for ground-dwellers and 3.250 mg/kg foliage-dwellers.

KPC 10.2 Effects on aquatic organisms

KPC 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Report:	**10.2.2.1/1,** XXX**, 2009(a)**
Title:	BAS 701 00 F - Acute toxicity study with the rainbow trout (Oncorhynchus mykiss)
Document No:	BASF DocID 2009/1048372
Guidelines:	OECD 203, EPA 72-1, EPA 540/9-82-024, (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to (EC) No 1907/2006 of European Parliament and of Council on the REACH
GLP	Yes

Executive Summary

In a static acute toxicity laboratory study, juvenile rainbow trout were exposed to nominal concentrations of 3.2, 5.6, 10, 18, 32 and 56 mg BAS 701 00 F/L in groups of 10 animals in glass aquaria containing 50 L water. Fish were observed for survival and symptoms of toxicity within 1 hour after start of exposure and 6, 24, 48, 72 and 96 hours after start of exposure.

The biological results are based on the nominal concentrations. After 96 hours of exposure no mortality was observed in the control and at concentrations of up to and including 5.6 mg BAS 701 00 F/L, whereas 100% mortality was observed at the three highest test item concentrations of 18, 32 and 56 mg/L within the first day of the test. Sub-lethal effects (i.e. apathy and swimming at the surface) were found at 5.6 and 10 mg BAS 701 00 F/L after 96 hours.

In a static acute toxicity study with rainbow trout the LC_{50} (96 h) of BAS 701 00 F was 10.6 mg/L based on nominal concentrations. The NOEC (96 h) was determined to be 3.2 mg/L (nominal).

I. MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s. BAS 700 F (fluxapyroxad, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: Rainbow trout (*Oncorhynchus mykiss*), approx. 5 months old; mean body length 4.6 cm (4.3 - 4.9 cm); mean body weight 0.76 g (0.66 - 0.92 g); supplied by Forellenzucht Trostadt GbR, Trostadt, Germany.

Test design: Static system (96 hours); 10 fish per aquarium (loading 0.15 g fish/L) and per concentration; assessment of mortality and symptoms of toxicity within 1 hour after start of exposure and 6, 24, 48, 72 and 96 hours after start of exposure.

Endpoints: LC_{50}, NOEC, mortality and sub-lethal effects.

Test concentrations: Control, 3.2, 5.6, 10, 18, 32 and 56 mg BAS 701 00 F/L (nominal).

Test conditions: Glass aquaria with stainless steel frame (60 x 35 x 40 cm), test volume: 50 L, non-chlorinated, filtered tap water; temperature: 12 - 13 °C; pH 8.0 - 8.1; oxygen content: 6.8 mg/L - 10.6 mg/L; total hardness: about 100 mg $CaCO_3$/L; conductivity: approx. 250 µS/cm; photoperiod 16 h light : 8 h dark; light intensity: approx. 100 lux - 490 lux; no aeration over the first 72 hours, afterward slight aeration due to decreased oxygen content; no feeding.

Analytics: Analytical verification of test item concentrations was conducted using a HPLC-method with MS detection.

Statistics: Descriptive statistics; Probit analysis for calculation of LC_{50}.

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and except for the two highest concentrations tested at the end of the test. The analyzed contents of fluxapyroxad ranged from 90.6% - 103.7% of nominal at test initiation and from 88.4% to 100.7% of nominal at test termination. Measured concentrations of epoxiconazole were between 97.0% and 109.8% of nominal in samples taken at test initiation and between 97.8% and 108.3% at test termination. As measured concentrations confirmed correct application of the test substance, the following biological results are based on nominal concentrations.

Biological results: After 96 hours of exposure no mortality was observed in the control and at concentrations of up to and including 5.6 mg BAS 701 00 F/L, whereas 100% mortality was observed at the three highest test item concentrations of 18, 32 and 56 mg/L within the first day of the test. Sub-lethal effects (i.e. apathy and swimming at the surface) were found at 5.6 and 10 mg BAS 701 00 F/L after 96 hours. The results are summarized in Table 10.2.2.1-1.

Table 10.2.2.1-1: Acute toxicity (96 h) of BAS 701 00 F on rainbow trout (*O. mykiss*)

Concentration [mg/L] nominal	**Control**	**3.2**	**5.6**	**10**	**18**	**32**	**56**
Mortality [%]	0	0	0	20	100	100	100
Symptoms*	none	none	A, C	A	n.d.	n.d.	n.d.
Endpoints [mg BAS 701 00 F/L] nominal							
LC_{50} (96 h)	10.6						
NOEC (96 h)	3.2						

* Symptoms: A = apathy, C = swimming at the surface
n.d. = not determined; all fish dead

III. CONCLUSION

In a static acute toxicity study with rainbow trout the LC_{50} (96 h) of BAS 701 00 F was 10.6 mg/L based on nominal concentrations. The NOEC (96 h) was determined to be 3.2 mg/L (nominal).

Report:	**10.2.2.2/1, Janson G.-M., 2008(a)**
Title:	Acute toxicity of BAS 701 00 F to Daphnia magna STRAUS in a 48 hour static test
Document No:	BASF DocID 2008/1028244
Guidelines:	OECD 202, EPA 850.1010
GLP	Yes

Executive Summary

In a static acute toxicity laboratory study, water flea neonates were exposed to BAS 701 00 F at nominal concentrations of 3.13, 6.25, 12.5, 25 and 50 mg/L in 4 replicates per concentration, containing 5 daphnids each. Daphnids were observed for immobility 24 hours and 48 hours after start of exposure.

The biological results are based on nominal concentrations. After 24 and 48 hours of exposure statistically significant effects on mobility of daphnids were observed at the two highest tested concentrations of 25 and 50 mg BAS 701 00 F/L. At the highest tested concentration of 50 mg BAS 701 00 F/L all daphnids were immobile after 24 and 48 hours of exposure.

In a 48-hour static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 701 00 F was 28.9 mg/L based on nominal concentrations. The NOEC was determined to be 12.5 mg/L (nominal).

I. MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204437; content of a.s. fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.9 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 63.5 g/L (nominal: 62.5 g/L).

Test species: Water flea (*Daphnia magna* STRAUS), neonates collected from in-house culture (originally obtained from Institute National de Recherché Chimique Appliquée, France), > 2 < 24 hours old at test initiation.

Test design: Static system (48 hours), 5 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility after 24 and 48 hours.

Endpoints: NOEC, EC_{50} based on immobility of daphnids.

Test concentrations: Control, 3.13, 6.25, 12.5, 25 and 50 mg BAS 701 00 F/L (nominal).

Test conditions: Glass vessels, test volume 50 mL, dilution water "M4" (Elendt medium); pH 7.92 - 8.02; oxygen content: 8.4 mg/L - 8.9 mg/L; total hardness: 2.39 mmol/L at test initiation; conductivity: 611 µS/cm at test initiation; temperature: 20.3 °C - 20.8 °C; light intensity 318 lux - 718 lux; photoperiod: 16 h light : 8 h dark, no feeding, no aeration.

Analytics: Analytical verification of test item concentrations was conducted using a HPLC-method with MS detection.

Statistics: Descriptive statistics; Linear maximum likelihood regression and William`s t-test for EC_{50} and NOEC calculation, $p < 0.05$).

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and at the end of the test. The analyzed contents of fluxapyroxad ranged from 96.0% - 105.7% of nominal at test initiation and from 98.8% to 103.6% of nominal at test termination. Measured concentrations of epoxiconazole were between 95.1% and 100.2% of nominal in samples taken at test initiation and between 96.3% and 99.6% at test termination. As measured concentrations confirmed correct application of the test substance, the following biological results are based on nominal concentrations.

Biological results: After 24 and 48 hours of exposure statistically significant effects on mobility of daphnids were observed at the two highest tested concentrations of 25 and 50 mg BAS 701 00 F/L (William`s t-test, $p < 0.05$). At the highest tested concentration of 50 mg BAS 701 00 F/L all daphnids were immobile after 24 and 48 hours of exposure. No other sub-lethal effects were observed during the test. For results see Table 10.2.2.2-1.

Table 10.2.2.2-1: Effects of BAS 701 00 F on *Daphnia magna* immobility

Concentration [mg/L] nominal	**Control**	**3.13**	**6.25**	**12.5**	**25**	**50**
Immobility (24 h) [%]	0	0	0	5	15*	100*
Immobility (48 h) [%]	0	0	5	5	25*	100*
	Endpoints [mg BAS 701 00 F/L] nominal					
EC_{50} (48 h)	28.9 (95% confidence limits: 23.1 - 36.3)					
NOEC (48 h)	12.5					

* Statistically significant different compared to the control (William's t-test, $p < 0.05$).

III. CONCLUSION

In a 48-hour static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 701 00 F was 28.9 mg/L based on nominal concentrations. The NOEC was determined to be 12.5 mg/L (nominal).

Report:	**10.2.2.3/1, Hoffmann F., 2008(a)**
Title:	Effect of BAS 701 00 F on the growth of the green alga Pseudokirchneriella subcapitata
Document No:	BASF DocID 2008/1037030
Guidelines:	OECD 201
GLP	Yes

Executive Summary

In a 72-hour static acute toxicity laboratory study, the effect of BAS 701 00 F on the growth of the green alga *Pseudokirchneriella subcapitata* was investigated. The following concentrations were applied: 0.010, 0.032, 0.102, 0.328, 1.05, 3.36 and 10.74 mg BAS 701 00 F/L (nominal). Assessment of growth was conducted 0 h, 24 h, 48 h and 72 h after test initiation.

The biological results are based on nominal concentrations. No morphological effects on algae were observed in the control and at concentrations up to 0.102 mg BAS 701 00 F/L. At 0.328 mg/L about 10%, at 1.05 and 3.36 mg/L about one third and at 10.74 mg/L all cells appeared smaller than those in the control.

In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_rC_{50} for BAS 701 00 F was determined to be 5.38 mg/L, the E_yC_{50} was 0.38 mg/L based on nominal concentrations.

I. MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204437; content of a.s. fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.9 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 63.5 g/L (nominal: 62.5 g/L).

Test species: Unicellular fresh water green alga, *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. *Selenastrum capricornutum* Prinz), SAG 61.81; stock obtained from the "Sammlung von Algenkulturen" Göttingen, Germany.

Test design: Static system; test duration 72 hours; 7 test concentrations, each with 5 replicates per treatment plus a control with 10 replicates; daily assessment of growth.

Endpoints: EC_{10} and EC_{50} with respect to growth rate and yield after exposure over 72 hours.

Test concentrations: Control, 0.010, 0.032, 0.102, 0.328, 1.05, 3.36 and 10.74 mg BAS 701 00 F/L (nominal).

Test conditions: 100 mL Erlenmeyer dimple flasks; test volume 60 mL; nutrient solution according to OECD 201; pH 8.1 at test initiation, pH 7.48 - 7.92 at test termination; temperature: 22 ± 1 °C; initial cell densities 1 x 10^4 cells/mL; continuous light at about 8000 lux; continuous shaking.

Analytics: Analytical verification of test item concentrations was conducted using a HPLC-method with MS detection.

Statistics: Descriptive statistics; log-log and probit analysis for determination of EC_x values for growth rate and yield.

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and at the end of the test. The analyzed contents of fluxapyroxad ranged from 103.3% - 116.8% of nominal at test initiation and from 104.5% to 113.3% of nominal at test termination. Measured concentrations of epoxiconazole were between 103.1% and 111.9% of nominal in samples taken at test initiation and between 103.2% and 115.3% at test termination. As measured concentrations confirmed correct application of the test substance, the following biological results are based on nominal concentrations.

Biological results: No morphological effects on algae were observed in the control and at concentrations up to 0.102 mg BAS 701 00 F/L. At 0.328 mg/L about 10%, at 1.05 and 3.36 mg/L about one third and at 10.74 mg/L all cells appeared smaller than those in the control. The effects on algal growth rate and yield are summarized in Table 10.2.2.3-1.

Table 10.2.2.3-1: Effect of BAS 701 00 F on the growth of green alga *P. subcapitata*

Concentration [mg/L] nominal	**Control**	**0.010**	**0.032**	**0.102**	**0.328**	**1.05**	**3.36**	**10.74**
Inhibition in 72 h (growth rate) [%] *	--	0.5	3.0	8.3	11.6	21.2	29.1	72.4
Inhibition in 72 h (yield) [%] *	--	2.4	14.3	34.5	44.8	66.3	77.6	98.0
Endpoints [mg BAS 701 00 F/L] nominal								
E_rC_{50} (72 h)	5.38 (95% confidence limits: 4.92 - 5.87)							
E_rC_{10} (72 h)	0.29 (95% confidence limits: 0.25 - 0.34)							
E_YC_{50} (72 h)	0.38 (95% confidence limits: 0.35 - 0.41)							
E_YC_{10} (72 h)	0.023 (95% confidence limits: 0.020 - 0.026)							

III. CONCLUSION

In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_rC_{50} for BAS 701 00 F was determined to be 5.38 mg/L, the E_yC_{50} was 0.38 mg/L based on nominal concentrations.

Report:	10.2.2.3/2, Hoffmann F., 2009(a)
Title:	Effect of BAS 701 00 F on the growth of *Lemna gibba*
Document No:	BASF DocID 2009/1098713
Guidelines:	OECD 221, EPA 850.4400, ASTM E 1415-91
GLP	Yes

Executive Summary

In a 7-day static toxicity laboratory study, the effect of BAS 701 00 F on the growth of the duckweed *Lemna gibba* was investigated. The following nominal concentrations were applied: 0.010, 0.032, 0.102, 0.328, 1.05 and 3.36 mg BAS 701 00 F/L. Assessment of growth and other effects was conducted 3, 5 and 7 days after test initiation. The percentage growth inhibition, relative to the control, was calculated for each test concentration based on growth rates and final yield for the parameters frond number and plant dry weight (biomass).

The biological results are based on geometric mean measured concentrations. The duckweed population in the control vessels showed sufficient growth, increasing from 10 fronds per vessel to an average of 125 fronds per vessel, corresponding to a 12.5 x multiplication. The dry weight increased from 1.8 mg at test initiation to an average of 19.8 mg per vessel in the control at test termination. At the geometric mean measured concentrations of 0.085, 0.267, 0.840 and 2.77 mg BAS 701 00 F/L the roots were shorter at the end of the test. At 0.840 mg/L about 50% of the fronds and at 2.77 mg/L all fronds were smaller than those in the control at test termination.

In a 7-day aquatic plant test with *Lemna gibba* the E_rC_{50} of BAS 701 00 F was determined to be 0.265 mg/L based on frond no. and 0.215 mg/L based on dry weight (geometric mean measured). The E_yC_{50} was 0.078 mg/L based on frond no. and 0.063 mg/L based on dry weight (geometric mean measured).

I. MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s. fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L).

Test species: Duckweed (*Lemna gibba* G3), inocula 7 - 10 days old cultures; cultures maintained in-house; stock obtained from "ÖkoTox Moser & Pickl GbR", Stuttgart, Germany.

Test design: Static system (7 days); 7 treatment groups (6 test item concentrations, control) with 3 replicates for the test item treatments and 6 replicates for the control; 2 plants with 3 fronds and 1 plant with 4 fronds, total number of fronds at test initiation: 10 per replicate; assessment of growth and other effects on days 3, 5 and 7.

Endpoints: EC_{10} and EC_{50} with respect to growth rate and yield after exposure over 7 days.

Test concentrations:	Control, 0.010, 0.032, 0.102, 0.328, 1.05 and 3.36 mg BAS 701 00 F/L (nominal), corresponding to geometric mean measured test concentrations of 0.009, 0.028, 0.085, 0.267, 0.84 and 2.77 mg BAS 701 00 F/L.
Test conditions:	400 mL glass beakers, test volume: 160 mL, 20x-AAP nutrient medium, pH 7.50 - 7.53 at test initiation and pH 8.67 - 8.74 at test termination; temperature 24 °C - 25 °C, continuous light, average light intensity: about 8200 lux.
Analytics:	Analytical verification of test item concentrations was conducted using a HPLC-method with MS detection.
Statistics:	Descriptive statistics; probit analysis for determination of ECx values for growth rate and yield.

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentrations was conducted in each concentration at the beginning and at the end of the test. The analyzed contents of fluxapyroxad ranged from 89.1% - 97.0% of nominal at test initiation and from 73.9% to 83.5% of nominal at test termination. Measured concentrations of epoxiconazole were between 87.8% and 92.1% of nominal in samples taken at test initiation and between 70.2% and 76.9% at test termination. The following biological results are based on geometric mean measured concentrations.

Biological results: The duckweed population in the control vessels showed sufficient growth, increasing from 10 fronds per vessel to an average of 125 fronds per vessel, corresponding to a 12.5 x multiplication. The dry weight increased from 1.8 mg at test initiation to an average of 19.8 mg per vessel in the control at test termination. At the geometric mean measured concentrations of 0.085, 0.267, 0.840 and 2.77 mg BAS 701 00 F/L the roots were shorter at the end of the test. At 0.840 mg/L about 50% of the fronds and at 2.77 mg/L all fronds were smaller than those in the control at test termination. Effects on growth rate and yield are summarized below (see Table 10.2.2.3-2).

Table 10.2.2.3-2: Effect of BAS 701 00 F on the growth of duckweed *Lemna gibba*

Concentration (geom. mean measured) [mg/L]	0.009	0.028	0.085	0.267	0.840	2.77
Inhibition after 7 d [%] (growth rate based on frond no.)	0.0	8.9	27.2	58.7	73.2	77.7
Inhibition after 7 d [%] (growth rate based on dry weight)	0.0	14.8	34.5	53.4	75.2	91.7
Inhibition after 7 d [%] (yield based on frond no.)	0.0	22.0	54.0	84.0	91.6	93.3
Inhibition after 7 d [%] (yield based on dry weight)	0.0	32.8	62.0	79.5	91.9	97.8
	Endpoints [mg BAS 701 00 F/L] (geom. mean measured)					
E_rC_{50} (7 d) based on frond no.	0.265 (95% limits: 0.138 - 0.526)					
E_rC_{10} (7 d) based on frond no.	0.020 (95% limits: 0.002 - 0.050)					
E_yC_{50} (7 d) based on frond no.	0.078 (95% limits: 0.056 - 0.107)					
E_yC_{10} (7 d) based on frond no.	0.015 (95% limits: 0.006 - 0.025)					
E_rC_{50} (7 d) based on dry weight	0.215 (95% limits: 0.169 - 0.273)					
E_rC_{10} (7 d) based on dry weight	0.018 (95% limits: 0.010 - 0.028)					
E_yC_{50} (7 d) based on dry weight	0.063 (95% limits: 0.040 - 0.101)					
E_yC_{10} (7 d) based on dry weight	0.010 (95% limits: 0.002 - 0.019)					

III. CONCLUSION

In a 7-day aquatic plant test with *Lemna gibba* the E_rC_{50} of BAS 701 00 F was determined to be 0.265 mg/L based on frond no. and 0.215 mg/L based on dry weight (geometric mean measured). The E_yC_{50} was 0.078 mg/L based on frond no. and 0.063 mg/L based on dry weight (geometric mean measured).

KPC 10.3 Effects on bees

KCP 10.3.1 Hazard quotients for bees

Refer to table 6.5-2.

KCP 10.3.1.1 Oral exposure QHO

Refer to IIIA 10.3.1.

KCP 10.3.1.2 Contact exposure QHC

Refer to IIIA 10.3.1.

KCP 10.3.2 Acute toxicity of the formulation to bees

The following bee acute toxicity study performed on Adexar (BAS 701 00 F) is provided in support of the assessment and has been previously evaluated for the initial registration of Adexar. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KCP 10.3.2.1/01**
	Barth, M. (2008) Acute toxicity of BAS 701 00 F to the honeybee Apis mellifera L. under laboratory conditions. BioChem agrar, Gerichshain, Germany, Final report 08 10 48 020 B
Document No:	BASF DocID 2008/1034508
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

In a test under laboratory conditions BAS 701 00 F was offered to worker honey bees (*Apis mellifera* L.) in oral and contact route. Treatments with the test substance, the control and the reference item (dimethoate) were carried out in three replicates containing 10 bees each.

Test species:	Worker honey bees *Apis mellifera*
Test substance:	BAS 701 00 F: fluxapyroxad (BAS 700 F): 62.4 g/L (nominal: 62.5 g/L) epoxiconazole (BAS 480 F): 62.7 g/L (nominal: 62.5 g/L) density: 1.037 g/cm^3
Control:	oral: 50% (w/v) aqueous sucrose solution contact: deionized water, tween control (Tween® 80)

Toxic standard: Dimethoate EC 400 (dimethoate, 395.9 g/L analyzed)
oral: 0.0625, 0.125, 0.25, 0.5 µg as/bee
contact: 0.0625, 0.125, 0.25, 0.5 µg as/bee dissolved in 1.0% (v/v) tween solution
Doses: oral (BAS 701 00 F sucrose solution):
103.7, 207.4, 414.8, 829.6, 1659.2 µg product/bee
contact (BAS 701 00 F dissolved in 1.0% (v/v) Tween solution):
103.7, 207.4, 414.8, 829.6, 1659.2 µg product/bee

Bees per dose: 10

Replicates: 3

Oral toxicity study:
In a dose response, three replicates of 10 bees were fed with a sugar/water solution containing BAS 700 F. The tested concentration was 103.7, 207.4, 414.8, 829.6, 1659.2 µg product/bee. An untreated sugar/water solution was used as water control. Dimethoate was used as toxic standard. The test was conducted at darkness and a temperature of 24.2 - 25.9 °C and humidity between 69 and 71%. Biological observations including mortality and behavioural changes were recorded at 4, 24 and 48 hours after dosing. Results are based on nominal concentrations of the product per bee.

Contact toxicity study:
In a dose response, three replicates of 10 bees were exposed to BAS 701 00 F dissolved in 1.0% (v/v) tween solution, administered topically in a small droplet to the thorax of each bee. The tested concentration was 103.7, 207.4, 414.8, 829.6, 1659.2 µg product/bee. A group of bees treated with an equivalent volume of deionized water or tween control was used as control. Dimethoate solved in a tween solution was used as toxic standard. The test was conducted at darkness and a temperature of 24.2 - 25.9 °C and humidity between 69 and 71%. Biological observations, including mortality and behavioural changes were recorded at 4, 24 and 48 hours after application.

Findings

Oral toxicity study:
After 48 hours of oral exposure, no mortality was observed in the control. In the different treatment groups, mortalities between 0% and 83.3% were observed. At the two highest tested concentrations of 652.7 and 1305.3 µg BAS 701 00 F/bee the effects on survival were statistically significant different compared to the control (Fisher's Exact Binomial test, α = 0.05). No behavioural abnormalities of the surviving bees were observed after 48 hours of exposure. The results are summarized in Table 10.4.2.1.
The LD_{50} value (24 h) for the toxic standard in the oral toxicity test was determined to be 0.143 µg as/bee (95% confidence limits: 0.122 - 0.168).

Table 10.3.2-1 Toxicity of BAS 701 00 F to *Apis mellifera* in an oral toxicity test

Treatment [µg as/bee]	Uptake of test item [µg as/bee]	Uptake of test item [µg BAS 701 00 F / bee]	Mean mortality [%]	
			24 h	48 h
control	--	--	0.0	0.0
12.5	11.8	97.5	0.0	0.0
25.0	21.7	179.9	0.0	0.0
50.0	39.4	326.9	10.0	13.3
100.0	78.7	652.7	46.7*	46.7*
200.0	157.3	1305.3	80.0*	83.3*
Endpoint [µg / bee]				
LD_{50} (95% CL) [1)] (48 h)	based on active substance		based on BAS 701 00 F	
	83.2 (68.8 - 100.6)		690.4 (571.0 - 834.8)	

[1)] Median lethal dose after 48 hours of exposure calculated by Probit analysis (with 95% Confidence Limits).
* = Statistically significant differences compared to the control (Fisher's Exact Binomial test, one-sided greater, α = 0.05)

Contact toxicity study:
After 48 hours of contact exposure, no mortality was observed in the control. In the different treatment groups, mortalities between 0% and 93.3% were observed. At the two highest tested concentrations of 829.6 and 1659.2 µg BAS 701 00 F/bee the effects on survival were statistically significant different compared to the control (Fisher`s Exact Binomial test, α = 0.05). No behavioural abnormalities of the surviving bees were observed after 48 hours of exposure. The LD_{50} was determined to be 830.4 µg BAS 701 00 F/bee. The results are summarized in Table 10.4.2.2.
The LD_{50} value (24 h) for the toxic standard in the contact toxicity test was determined to be 0.177 µg as/bee (95% confidence limits: 0.140 - 0.225).

Table 10.3.2-2 Toxicity of BAS 701 00 F to *Apis mellifera carnica* in a contact toxicity test

Treatment [µg as/bee]	Treatment [µg BAS 701 00 F / bee]	Corrected mortality [%] [1]	
		24 h	48 h
Water control	--	0	0
Tween control	--	0	0
12.5	103.7	0	0
25.0	207.4	10.0	10.0
50.0	414.8	13.3	13.3
100.0	829.6	20.0*	20.0*
200.0	1659.2	93.3*	93.3*
		Endpoint [µg / bee]	
LD_{50} (95% CL) [2] (48 h)		based on active substance	based on BAS 701 00 F
		100.1 (46.2 - 216.9)	830.4 (383.2 - 1799.5)

[1] Re-calculated from mean mortality data according to the formula of Abbott (1925).
[2] Median lethal dose after 48 hours of exposure calculated by Probit analysis (with 95% Confidence Limits).
* = Statistically significant differences compared to the control (Fisher's Exact Binomial test, one-sided greater, $\alpha = 0.05$).

Conclusions

In an acute contact toxicity study with BAS 701 00 F, the LD_{50} (48 h) was determined to be 830.4 µg BAS 701 00 F/bee (equivalent to 100.1 µg as/bee).

In a 48-hour acute oral and contact toxicity test, honeybees (*Apis mellifera*) were exposed to BAS 701 00 F. Under the conditions of this study, the acute oral LD_{50} (48 h) was 690.4 µg product/bee (equivalent to 83.2 µg as/bee) and the contact LD_{50} (48 h) was 830.4 µg product/bee (equivalent to 100.1 µg as/bee).

KCP 10.3.2.1 Oral

Refer to KCP 10.3.2.

KCP 10.3.2.2 Contact

Refer to KCP 10.3.2.

KCP 10.3.3 Effects on bees of residues on crops

Not required.

KCP 10.3.4 Cage tests

The following tunnel test performed on Adexar (BAS 701 00 F) is provided in support of the assessment and has been previously evaluated for the initial registration of Adexar. Since no major deviations from the guideline were reported which could have influenced the results of the study only a brief summary and the endpoints are presented below.

Report:	**KCP 10.3.4/01** Schmitzer, S. (2009) Study on the effect of BAS 701 00 F on honey bee brood (*Apis mellifera* L.) under semi-field conditions - Tunnel test-. Project 43871031. IBACON GmbH, Rossdorf, Germany.
Document No:	BASF DocID 2008/1035915
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and methods

Test species:	*Apis mellifera* L. (honeybees), small healthy bee colonies, containing 4 honeycombs with honey, pollen and all brood stages present The preliminary brood check indicated healthy colonies with all brood stages present and a sufficient supply with nectar and pollen. The mean number of bees per colony in the three treatment groups one day before application was similar.
Test substance:	BAS 701 00 F: fluxapyroxad (BAS 700 F): 62.4 g/L (nominal: 62.5 g/L) epoxiconazole (BAS 480 F): 62.7 g/L (nominal: 62.5 g/L) density: 1.037 g/cm^3
Control:	For the control group, water (400 L/ha) was used.
Toxic standard:	Insegar (Fenoxycarb: 250 g/kg nominal).
Doses:	BAS 701 00 F: 2.0 L product/ha (corresponding to 0.125 kg/ha fluxapyroxad, 0.125 kg/ha epoxiconazole) Reference item: 1.20 kg/ha Insegar (corresponding to 300 g/ha Fenoxycarb) All substances were applied in 400 L/ha water.
Test plots:	The test site was located in 64380 Rossdorf, Germany; Separate tunnels for the different groups and replicates; size of the tunnels: 14 m length x 5.5 m width x 2.5 m height, set up on a *ca.* 40 m² plot of full flowering *Phacelia tanacetifolia* (2 x 20 m²).
Test conditions:	Natural field conditions

Before application: temperature: 12.7 °C - 28.5 °C; 0.2 mm rain

During application: 20 - 22 °C, humidity: 39% - 42%; wind speed: 0 m/s (applications were conducted during absolutely calm), no rain

Exposure phase in the tunnels: temperature: 12.7 °C - 32.6 °C; 2.0, 0.8 and 2.2 mm rain on day +1, +4 and day +6

Phase outside the tunnels: 10.4 °C - 29.0 °C, 0.4, 3.0, 0.6, 14.2, 1.2, 0.4 and 2.6 mm rain on days +10, +11, +12, +14, +19, +20 and +21

Statistics: Descriptive statistics; Student-t or Welch t-test (pairwise or multiple) for mortality, foraging activity and the brood termination ($\alpha = 0.05$)

Test design:
In order to assess potential effects of BAS 701 00 F to honeybee colonies including brood development under semi-field conditions, a tunnel test was conducted. Tunnels were set up on a ca. 40 m² plot of *Phacelia tanacetifolia* and small bee colonies were introduced 7 days before application. A water control and a toxic reference were included in the study. The application was carried out during full foraging activity of the bees. The trial was carried out using three tunnels (i.e. replicates) for each treatment group, with one bee hive per tunnel. The exposure period of the bees to the water, test item and reference item treated crops in the tunnels was 7 days. On day 7 the hives were removed from the tunnels and placed besides them until DAT 21 to an area with no main flowering, bee attractive crops.
Mortality of adult bees and pupae was assessed 4 days before to 21 days after application; foraging activity of the bees was assessed 4 days before to 7 days after application; condition of the colonies (food stores, brood status and colony strength) was assessed 1 day before and 3, 10, 14 and 21 days after application. Ontogenesis for the bees from egg to adult workers was observed for a period of 21or 14 days. This was done by marking 120 eggs at the brood area fixing day (BFD 0) one day before application and investigating the further progress of their development 3 (= BFD 4), 10 (= BFD 11), 14 (= BFD 15) and 21 (= BFD 22) days after the application.

Results and discussion

After application of BAS 701 00 F, no behavioural abnormalities occurred at any time during the whole assessment period (up to day 7). No behavioural abnormalities were observed in the control group and in the reference item group.

Table 10.3.4-1 Effects of BAS 701 00 F on bee mortality, foraging activity and bee brood under semi-field conditions (tunnel test).

	Control	BAS 701 00 F	Reference Item
Mean mortality of worker bees/colony/day [%]			
pre-application phase 1)	18.0	14.9 n.s.	20.9 n.s.
exposure phase in the tunnels 1)	31.3	21.2 n.s.	32.9 n.s.
phase outside the tunnels 2)	0.5	0.6 n.s.	0.9*
overall after application	12.2	8.4 n.s.	13.1 n.s.
Total mortality of larvae and pupae [n]			
pre-application phase	1	0 n.s.	2 n.s.
exposure phase in the tunnels	0	0 n.s.	3 n.s.
phase outside the tunnels 2)	0	0 n.s.	10*
overall after application	0	0 n.s.	13*
Mean foraging activity/ m²/ colony/day [n]			
pre-application phase	23.9	18.3 n.s.	22.6 n.s.
exposure phase in the tunnels	22.6	18.3 n.s.	21.1 n.s.
Mean brood termination rate of the eggs [%]			
	39.4	30.3 n.s.	93.1 *
Mean brood termination rate of the larvae [%]			
	11.1	9.7 n.s.	25.6 n.s.

1) mean number of dead honeybees per day and colony found in dead bee traps and on gauze strips in the tunnels
2) mean number of dead honeybees per day and colony found in dead bee traps, only
Statistic: Student or Welch t-test, α=0.05, one-sided greater
n.s. = no statistically significant differences compared to the control compared to the control
* = statistically significant differences compared to the control

Condition of the Colonies:
The brood check one day before the application indicated healthy colonies with all brood stages present and a sufficient supply with nectar and pollen. After application, no indication of a test item related effect on the condition of the colonies was observed. All test item treated colonies survived the trial with increasing bee numbers and healthy brood. There was no indication of any hazard of the test item on the condition of the bee colonies.

Colony Strength:
The mean number of bees per colony in the three treatment groups one day before application was similar (2625 to 3660 mean bees per colony).

Considering the initial mean number of bees per treatment group before the application as 100%, the following relative mean numbers of bees were determined:

	Day -1	Day +3	Day +10	Day +14	Day 21
Control	100%	102%	120%	139%	131%
BAS 701 00 F	100%	119%	153%	167%	179%
Reference Item	100%	129%	136%	161%	146%

There was no decrease of colony size after application of the test item to the bees. During exposure of the bees to the treated crop in the tunnels, the colony strength increased in all treatment groups. After free access to other food sources the colony size increase was even more in all treatment groups.

Brood Compensation Index:
Looking at the brood compensation index, which shows the development of the brood at each assessment, a continuous brood development was observed in the test item as well as in the control group. The brood compensation indices following the labelling of the egg stage were similar or even higher to the control values during all assessments up to day 21 following the application (BFD +22).

Compensation index of the eggs:

	BFD +4	BFD +11	BFD +15	BFD +22
Control	1.9	2.9	3.2	4.0
BAS 701 00 F	2.0	3.1	3.3	4.0
Reference Item	0.4	0.3	0.4	1.5

The brood indices of the marked larvae were slightly lower for the first assessment following the application, but thereafter higher compared to the control:

Compensation index of the larvae:

	BFD +4	BFD +11	BFD +15
Control	3.5	3.6	4.5
BAS 701 00 F	3.2	3.9	4.8
Reference Item	2.8	3.0	3.8

Accordingly, no effect on the brood development was identifiable following the labelling of the egg or larvae stage. The high termination rate of the marked cells after treatment with the reference item was also reflected by the brood compensation indices.

Conclusion

No effects of BAS 701 00 F were observed after direct application and exposure to 2.0 L/ha BAS 701 00 F on survival of adult bees, foraging activity and behaviour. Furthermore, no effects on bee brood comprising its development, colony strength or colony development were observed. Overall, based on the results of this study, BAS 701 00 F does not adversely affect honeybee colonies.

KCP 10.3.5 Field tests

Not required.

KCP 10.4.6 Investigation into special effects

Not required.

KCP 10.4.6.1 Larval toxicity

Not required since the test item is not an IGR.

KCP 10.4.6.2 Long residual effects

Not required.

KCP 10.4.6.3 Disorienting effects on bees

Not required.

KCP 10.4.7 Tunnel tests

Not required.

KPC 10.4 Effects on non-target soil meso- and macrofauna

KPC 10.4.1 Earthworms

Report:	**10.6.2/1, Friedrich S., 2009(a)**
Title:	Acute toxicity of BAS 701 00 F to the earthworm *Eisenia fetida* in artificial soil with 5% peat
Document No:	BASF DocID 2009/1072246
Guidelines:	ISO 11268-1 (1993), OECD 207 (1984)
GLP	Yes

Executive Summary

In an acute toxicity laboratory study, adults of *Eisenia fetida* (Annelida: Oligochaeta), were exposed to BAS 701 00 F. The test item was mixed into artificial soil at concentrations of 62.5, 125, 250, 500 and 1000 mg BAS 701 00 F/kg dry soil. For the control treatment the soil was left untreated. The artificial test soil had an organic content of 5% (as sphagnum peat).

After 14 days of exposure, no mortality was observed in the control and at 62.5 and 125 mg BAS 701 00 F/kg dry soil. A mortality of 2.5% was observed at 250 mg BAS 701 00 F/kg dry soil. At higher test item concentrations (500 and 1000 mg BAS 701 00 F/kg dry soil) all animals died, which was statistically significant different compared to the control. The biomass development was not statistically significant different compared to the control up to 250 mg BAS 701 00 F/kg dry soil. The biomass change could not be determined at the treatments with 500 and 1000 mg BAS 701 00 F/kg dry soil, because all worms died within the first 7 days. Behavioral abnormalities were observed at 1000 mg BAS 701 00 F/kg dry soil, where the worms did not bury promptly into the substrate surface or in the upper soil.

In a 14-d acute toxicity study with BAS 701 00 F on earthworms (*Eisenia fetida)* the LC_{50} was 341.7 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: *Eisenia fetida* (earthworm), adult worms (with clitellum and weight 306 - 468 mg), approx. 3 months old, source: in-house culture.

Test design: In a 14-day test, adults of *Eisenia fetida* were exposed to five soil concentrations of BAS 701 00 F. The test substrate was artificial soil according to OECD 207 with only 5% peat. In total, 6 treatment groups were set up (5 test item concentrations and control) with 4 replicates per treatment group and 10 worms each. The artificial soil was treated and filled into glass vessels, before the earthworms were introduced on the top of the soil.
Assessment of earthworm mortality and behavioral effects was done after 7 and 14 d; weight change as sub-lethal parameter after 14 d.

Endpoints: LC_{50} (NOEC).

Reference item: 2-Chloroacetamide. The effects of the reference item were investigated in a separate study.

Test concentrations:

BAS 701 00 F [mg/kg dry soil]	fluxapyroxad [mg a.s./kg dry soil]	epoxiconazole [mg a.s./kg dry soil]
62.5	3.77	3.77
125	7.53	7.53
250	15.07	15.07
500	30.14	30.14
1000	60.27	60.27

The amount of fluxapyroxad and epoxiconazole is calculated based on the nominal content of a.s.

Test conditions: Artificial soil according to OECD 207 (with a reduced content of peat of 5%); pH 6.0 - 6.1 at test initiation; pH 5.8 - 5.9 at test termination; water content at test initiation 57.8% - 58.3% of its water holding capacity (WHC) and 57.1% -

58.1% WHC at test termination; temperature: 20 °C - 21 °C; constant illumination of 590 lux.

Statistics: Descriptive statistics; Fisher exact test for mortality data and Dunnett test for weight change data (α = 0.05), probit analysis for determination of the LC_{50}.

RESULTS AND DISCUSSION

The LC_{50} was determined to be 341.7 mg BAS 701 00 F/kg dry soil (95% confidence limits: 248.1 - 470.6 mg BAS 701 00 F/kg dry soil).

After 14 days of exposure, no mortality was observed in the control and at 62.5 and 125 mg BAS 701 00 F/kg dry soil. A mortality of 2.5% was observed at 250 mg BAS 701 00 F/kg dry soil. At higher test item concentrations (500 and 1000 mg BAS 701 00 F/kg dry soil) all animals died, which was statistically significant different compared to the control (Fisher exact test, α = 0.05).
The biomass development was not statistically significant different compared to the control up to 250 mg BAS 701 00 F/kg dry soil (Dunnett test, α = 0.05). The biomass change could not be determined at the treatments with 500 and 1000 mg BAS 701 00 F/kg dry soil, because all worms died within the first 7 days. Behavioral abnormalities were observed at 1000 mg BAS 701 00 F/kg dry soil, where the worms did not bury promptly into the substrate surface or in the upper soil. The results are summarized in **Table 10.6.2-1**.

Table 10.6.2-1 Effect of BAS 701 00 F on mortality and biomass of *Eisenia fetida* (14 d)

BAS 701 00 F [mg/kg dry soil]	**Control**	**62.5**	**125**	**250**	**500**	**1000**
fluxapyroxad [mg a.s./kg dry soil]		**3.77**	**7.53**	**15.07**	**30.14**	**60.27**

Appendix 3 epoxiconazole [mg a.s./kg dry soil]		**3.77**	**7.53**	**15.07**	**30.14**	**60.27**
Mortality [%]	0	0 n.s.	0 n.s.	2.5 n.s.	100 *	100 *
Weight change [%]	-9.6	-8.6 n.s.	-9.4 n.s.	-9.8 n.s.	--	--
	Endpoints [mg BAS 701 00 F/kg dry soil]					
NOEC	250					
LC_{50} (95% confidence limits)	341.7 (248.1 - 470.6)					

n.s. = no statistically significant differences compared to the control (Fisher exact test for mortality, Dunnett test for weight change data; α = 0.05).
* = statistically significant differences compared to the control (Fisher exact test for mortality, Dunnett test for weight change data; α = 0.05).

CONCLUSION

In a 14-d acute toxicity study with BAS 701 00 F on earthworms (*Eisenia fetida)* the **LC_{50} was 341.7 mg BAS 701 00 F/kg dry soil**.

KPC 10.4.1.1 Earthworms - sub-lethal effects

Report:	**10.6.3/1, Luehrs U., 2008(a)**
Title:	Effects of BAS 701 00 F on reproduction and growth of earthworms *Eisenia fetida* in artificial soil with 5% peat
Document No:	BASF DocID 2008/1000701
Guidelines:	ISO 11268-2 (1998), OECD 222 (2004)
GLP	Yes

Executive Summary

In a chronic toxicity study, adults of adults of *Eisenia fetida* (Annelida: Oligochaeta), were exposed to BAS 701 00 F. The test item was mixed into artificial soil at concentrations of 11.06, 22.12, 44.24, 88.49, 176.98 and 353.95 mg BAS 701 00 F/kg dry soil. For the control treatment, the soil was left untreated. The artificial test soil had an organic content of 5% (as sphagnum peat). Assessment of adult earthworm mortality, behavioral effects, body weight and feeding activity was carried out after 28 days; assessment of reproduction (number of juveniles) was carried out after 56 days.

No mortality was observed in the control and any of the treatment groups. No statistically significant effects on body weight change up to the highest test concentration of 353.95 mg/kg dry soil were observed. In the control, a mean of 205 juveniles was counted. In the treatment groups, a mean number of juveniles between 84 and 218 was counted. This is corresponding to a reproduction relative to the control between 41.1% and 106.4%. The number of juveniles was statistically significantly reduced at the two highest test item concentrations of 176.98 and 353.95 mg BAS 701 00 F/kg dry soil. No behavioral abnormalities were observed in any of the treatment groups. The feeding activity in all test item treated groups was comparable to the control.

In a 56-day reproduction study with BAS 701 00 F, the NOEC was 88.49 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204437; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.9 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 63.5 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: *Eisenia fetida andrei* (earthworm), adult worms with clitellum and weight of 300 - 588 mg, age: approx. 8 months, source: in-house culture.

Test design: In a 56-day test, adults of *Eisenia fetida andrei* were exposed to six soil concentrations of BAS 701 00 F. The test substrate was artificial soil according to OECD 222 with only 5% peat. In total, 7 treatment groups (6 test item concentrations, control) were set up with 4 replicates for the test item treatments and 8 replicates for the control and 10 worms per replicate. The artificial soil was treated and filled into glass vessels, before the earthworms were introduced on the top of the soil.
Assessment of adult worm mortality, behavioral effects, weight change and feeding activity after 28 days of exposure; after additional 28 days (56 days after application) the number of offspring was assessed.

Endpoints: NOEC.

Reference item: Brabant Carbendazim Flowable (carbendazim, 500 g/L nominal). The effects of the reference item were investigated in a separate study.

Test concentrations:

BAS 701 00 F [mg/kg dry soil]	fluxapyroxad [mg a.s./kg dry soil]	epoxiconazole [mg a.s./kg dry soil]
11.06	0.67	0.67
22.12	1.33	1.33
44.24	2.67	2.67
88.49	5.33	5.33
176.98	10.67	10.67
353.95	21.33	21.33

The amount of fluxapyroxad and epoxiconazole is calculated based on the nominal content of a.s.

Test conditions: Artificial soil according to OECD 222 with a reduced content of peat: (5%); pH 6.3 - 6.5 at test initiation; pH 6.2 - 6.4 at test termination; water content at test initiation 52.9% - 54.1% of its water holding capacity (WHC) and 49.0% - 58.5% WHC at test termination; temperature: 19 °C - 21 °C; photoperiod: 16 hours light : 8 hours dark; light intensity: 400 lux- 640 lux; feeding with cattle manure.

Statistics: Descriptive statistics; Dunnett`s test, two-sided for weight change data and one-sided smaller for reproduction data (α = 0.05).

RESULTS AND DISCUSSION

No mortality was observed in the control and any of the treatment groups. No statistically significant effects on body weight change up to the highest test concentration of 353.95 mg/kg dry soil were observed (Dunnett`s test, two-sided, α = 0.05).
In the control, a mean of 205 juveniles was counted. In the treatment groups, a mean number of juveniles between 84 and 218 was counted. This is corresponding to a reproduction relative to the control between 41.1% and 106.4%. The number of juveniles was statistically significantly reduced at the two highest test item concentrations of 176.98 and 353.95 mg BAS 701 00 F/kg dry soil (Dunnett`s test, one-sided smaller, α = 0.05). No behavioral abnormalities were observed in any of the treatment groups. The feeding activity in all test item treated groups was comparable to the control. The results are summarized in Table 10.6.3-1.

Table 10.6.3-1 Effect of BAS 701 00 F on *Eisenia fetida andrei* in a 56-day reproduction study

BAS 701 00 F [mg/kg dry soil]	**Control**	**11.06**	**22.12**	**44.24**	**88.49**	**176.98**	**353.95**
fluxapyroxad [mg a.s./kg dry soil]		**0.67**	**1.33**	**2.67**	**5.33**	**10.67**	**21.33**
epoxiconazole [mg a.s./kg dry soil]		**0.67**	**1.33**	**2.67**	**5.33**	**10.67**	**21.33**
Mortality (28 d) [%]	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Weight change (28 d) [%]	53.1	50.6 n.s.	51.5 n.s.	50.5 n.s.	52.9 n.s.	55.2 n.s.	44.3 n.s.
Number of juveniles (56 d)	205	218 n.s.	178 n.s.	205 n.s.	156 n.s.	105*	84*
Reproduction (56 d) [% of control]	--	106.4	87.1	100.3	76.0	51.1	41.1
	Endpoints [mg BAS 701 00 F/kg dry soil]						
NOEC	88.49						

n.s. = no statistically significant differences compared to the control (Dunnett`s test, α = 0.05, two-sided for weight change and one-sided smaller for reproduction data).
* = statistically significant differences compared to the control (Dunnett`s test, α = 0.05, two-sided for weight change and one-sided smaller for reproduction data).

CONCLUSION

In a 56-day reproduction study with BAS 701 00 F, the NOEC was 88.49 mg BAS 701 00 F/kg dry soil.

KPC 10.4.1.2 Earthworms - field studies

Report:	**10.6.4/1, Krueck S., 2009(a)**
Title:	Field study to evaluate effects of BAS 701 00 F on earthworms
Document No:	BASF DocID 2009/1000121
Guidelines:	ISO 11268-3 (1999)
GLP	Yes

Executive Summary

The objective of this study was to assess potential effects of field populations of earthworms after application of the test item BAS 701 00 F in a winter barley crop.
An arable field site was chosen as a natural habitat of earthworms. Five different test item treatment groups were set up. In an early application scenario (1st application BBCH 27, 2nd application two weeks later) the following rates were tested: 2.0 L/ha + 2.0 L/ha, 6.0 L/ha (only one application at BBCH 27), 4.0 L/ha + 2.0 L/ha and 8.0 L/ha + 2.0 L/ha BAS 701 00 F. In a late application scenario (1st application BBCH 30, 2nd application two weeks later) 2.0 L/ha + 2.0 L/ha BAS 701 00 F were tested. The effects of the test item were compared to a tap water treated control and to a reference item (Nutdazim 50 FLOW® as toxic standard). Over the experimental period, four earthworm samplings were evaluated. Earthworm extraction was achieved by hand sorting in combination with formalin extraction.

All of the test item application regimes tested up to a total application rate of 8.0 + 2.0 L/ha BAS 701 00 F, did not reduce earthworm total number or earthworm total biomass at any of the post-treatment sampling dates. Also, no effects were observed on the age stages total adult or total juvenile. *A. caliginosa*, *A. chlorotica*, and *A. rosea*, were the three endogeic species present on the test field.
For all endogeic species, as well as for the ecological group endogeic, no effects of any of the test item application regimes tested were observed for totals throughout the assessment period. Only endogeic adult biomass showed statistically significant reductions in the treatment groups 2.0 + 2.0 L/ha BAS 701 00 F in the early application scenario and 8.0 + 2.0 L/ha BAS 701 00 F in the early application scenario at 2nd sampling. Reductions as compared to the control amounted to 38.6% and 36.6%, respectively. Recovery was assessed at the end of the study at the 3rd sampling date. Furthermore, for both anecic species present, *A. longa* and *L. terrestris*, no effect of the test item was observed.

The results of this field study showed that low risk to earthworm populations can be concluded for the use of BAS 701 00 F applied twice at intervals of 14 days in four different early exposure scenarios (1st application at BBCH 27) and one late exposure scenario (1st application BBCH 30) up to 10 L/ha.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: Naturally occurring population of earthworms comprising all ontogenetic stages (juveniles and adult worms) dependent on the species life cycles.

Test site:	Arable field side (crop: winter barley) in Gerichshain near Leipzig, Saxony, Eastern Germany. Winter barley was seeded prior to the experimental starting and harvested on 10.07.2008 by combine harvester and the straw was left on the field. The fodder crop "Landsberger Gemenge" followed as aftercrop and was seeded on 18.08.2008. The fodder mixture was grown on the field till the end of the study. The site had not received chemical applications and none were applied during the study apart from the test and toxic reference item.
Test design:	Randomized block design; the study area was divided into plots with an area of 100 m^2 (10 m x 10 m). The test item treatments were set up to represent two scenarios: early scenario (1st application at BBCH 27, followed by a 2nd 2 weeks later) and late scenario (1st application at BBCH 30, followed by a 2nd 2 weeks later). 7 treatment groups (5 test item groups, control, reference item) each with 4 replicates; the substances in all treatments were applied in a water volume equivalent to 600 L/ha. Application was performed using a Plot sprayer (PL 1, agrotop GmbH, Obertraubling) with Lechler DG Teejet 8004 VS nozzles.
Endpoints:	Total abundance and biomass of earthworms.
Reference item:	Nutdazim 50 FLOW (Carbendazim, 500 g/L).
Test rates:	Control (tap water in the early application scenario and left untreated in the late application scenario) BAS 701 00 F applied at 2.0 + 2.0 L/ha (equivalent to 125 + 125 g BAS 700 F/ha), early application. BAS 701 00 F applied at 6.0 L/ha (equivalent to 375 g BAS 700 F/ha), early application. BAS 701 00 F applied at 4.0 + 2.0 L/ha (equivalent to 250 + 125 g BAS 700 F/ha), early application. BAS 701 00 F applied at 8.0 + 2.0 L/ha (equivalent to 500 + 125 g BAS 700 F/ha), early application. BAS 701 00 F applied at 2.0 + 2.0 L/ha (equivalent to 125 + 125 g BAS 700 F/ha), late application. Nutdazim 50 FLOW applied at 16 L/ha at 1st application of the early application scenario, untreated on all other application dates.
Application date:	Early scenario: 1st application: BBCH 27 2nd application: BBCH 30, 14 days after 1st application Late scenario: 1st application: BBCH 30 2nd application: BBCH 33/34, 14 days after 1st application
Method of extraction:	Earthworm extraction was achieved by hand sorting in combination with formalin extraction. 4 samples per plot were taken from the inner area of the plots at each sampling date.
Sampling dates:	1st sampling: 2 weeks prior to 1st application early scenario; 2nd sampling: approx. 1 month after 1st application early scenario;

3rd sampling: approx. 6 months after 1st application early scenario;
4th sampling: approx. 12 months after 1st application early scenario.

Test conditions: Natural field conditions; silty loam sand (according to DIN 4220), pH 6.0, 1.24% total organic carbon, water holding capacity 20.6%.
Mean air temperature during 1st application early: 13.3 °C - 20.0 °C, 2nd application early: 18.8 °C - 21.0 °C, 1st application late: 15.3 °C - 19.3 °C, 2nd application late: 19.9 °C - 21.0 °C.
Mean relative soil moisture (w/w) during 1st application early: 17.9% - 25.1%, 2nd application early: 14.2% - 18.2%, 1st application late: 16.6% - 19.9%, 2nd application late: 15.6% - 12.1%.
Mean soil temperature during sampling: 1st sampling: 7.1 °C - 9.1 °C, 2nd sampling: 14.7 °C - 20.2 °C, 3rd sampling: 10.5 °C - 13.1 °C, 4th sampling: 5.0 °C - 6.0 °C.

Statistics: Descriptive statistics; ANOVA, Dunnett-test (one-sided) ($\alpha = 0.05$).

RESULTS AND DISCUSSION

All of the test item application regimes tested up to a total application rate of 10.0 L/ha BAS 701 00 F, did not reduce earthworm total number or earthworm total biomass at any of the post-treatment sampling dates. Also, no effects were observed on the age stages total adult or total juvenile.

A. caliginosa, *A. chlorotica*, and *A. rosea*, were the three endogeic species present on the test field. For all endogeic species, as well as for the ecological group endogeic, no effects of any of the test item application regimes tested were observed for totals throughout the assessment period. Only endogeic adult biomass showed statistically significant reductions in the treatment groups 2.0 + 2.0 L/ha BAS 701 00 F in the early application scenario and 8.0 + 2.0 L/ha BAS 701 00 F in the early application scenario at 2nd sampling (Dunnett-test, one-sided, $\alpha = 0.05$). Reductions as compared to the control amounted to 38.6% and 36.6%, respectively. Recovery was assessed at the end of the study at the 3rd sampling date.
Furthermore, for both anecic species present, *A. longa* and *L. terrestris*, no effect of the test item was observed. The results are summarized in Table 10.6.4-1.

Table 10.6.4-1 Summary of total earthworm abundance and biomass in a field study with BAS 701 00 F

Treatment	First sampling 1) 01. - 02.04.2008	Second sampling 13. - 14.05.2008	Third sampling 13. - 14.10.2008	Fourth sampling 23. - 24.03.2009
Earthworm abundance [Ind./m²]				
Control	322.0	217.5	193.5	244.5
2.0 + 2.0 L/ha early (125+125 g fluxapyroxad/ha)	315.5 n.s.	180.5 n.s.	186.0 n.s.	232.5 n.s.
% deviation from control	97.4	83.0	96.1	95.1
6.0 L/ha early (375 g a.s./ha)	303.5 n.s.	193.5 n.s.	207.0 n.s.	222.0 n.s.
% deviation from control	94.3	89.0	107.0	90.8
4.0 + 2.0 L/ha early (250+125 g fluxapyroxad/ha)	364.5 n.s.	247.0 n.s.	202.0 n.s.	253.0 n.s.
% deviation from control	113.2	113.6	104.4	103.5
8.0 + 2.0 L/ha early (500+125 g fluxapyroxad/ha)	375.0 n.s.	208.5 n.s.	188.5 n.s.	250.0 n.s.
% deviation from control	116.5	95.9	97.4	102.3
2.0 + 2.0 L/ha late (125+125 g fluxapyroxad/ha)	316.0 n.s.	261.0 n.s.	239.5 n.s.	274.0 n.s.
% deviation from control	98.1	120.0	123.8	112.1

1) Prior to application
n.s. = no statistically significant differences compared to the control (Dunnett-test, $\alpha = 0.05$)

CONCLUSION

The results of this field study showed that low risk to earthworm populations can be concluded for the use of BAS 701 00 F applied twice at intervals of 14 days in four different early exposure scenarios (1st application at BBCH 27) and one late exposure scenario (1st application BBCH 30) up to 10 L/ha.

KPC 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Report:	**10.6.6/1, Luehrs U., 2009(a)**
Title:	Effects of BAS 701 00 F on the reproduction of the collembola *Folsomia candida* in artificial soil with 5% peat
Document No:	BASF DocID 2009/1002761
Guidelines:	ISO 11267 (1999)
GLP	Yes

Executive Summary

The effects of BAS 701 00 F on survival and reproduction of the collembolan *Folsomia candida* were investigated in a laboratory study over 28 days. The test item was incorporated into the soil at concentrations of 3.125, 6.25, 12.5, 25.0 and 50.0 mg BAS 701 00 F/kg dry soil with 5 replicates per treatment. Each replicate contained 10 juvenile collembolans. An untreated control with 5 replicates was included. Assessment of mortality of the adults and reproduction (number of juveniles) was carried out after 28 days. The artificial test soil had an organic content of 5% (as sphagnum peat).

In the test item treatments mortalities of 20% to 82% were observed, compared to 12% in the control. At the tested concentrations of 25.0 and 50.0 mg BAS 701 00 F/kg dry soil statistically significant effects on survival were recorded.
In the control, a mean of 418 juveniles was counted. In the treatment groups, a mean number of juveniles between 28 to 408 was counted. This is corresponding to a reproduction relative to the control between 7% and 98%. At 25.0 and 50.0 mg BAS 701 00 F/kg dry soil statistically significant effects on reproduction were recorded.
No abnormal behavior or conditions of the surviving Collembola were observed at any tested concentration.

In a 28-day collembolan reproduction study with BAS 701 00 F the NOEC was 12.5 mg BAS 701 00 F/kg dry soil. The EC_{50} was 22.84 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: *Folsomia candida* (springtails), juveniles, 10 - 12 days old; source: in-house culture.

Test design: In a 28-day test, adults of Folsomia candida were exposed to five soil concentrations of BAS 701 00 F. The test substrate was artificial soil according to ISO 11267 with only 5% peat. In total, 6 treatment groups were set up (5 concentrations of the test item and an untreated control group) with 5 replicates per treatment and 10 juvenile collembolans per replicate. The artificial soil was treated and filled into glass vessels, before the collembolans were introduced on the top of the soil.

Assessment of adult collembolans mortality, behavioral effects and reproduction (number of juveniles) was done after 28 days.

Endpoints: NOEC (LC_{50}, EC_{50}).
.
Reference item: Betosip (Phenmedipham, 157 g/L). The effects of the reference item were investigated in a separate study.

Test concentrations:

BAS 701 00 F [mg/kg dry soil]	fluxapyroxad [mg a.s./kg dry soil]	epoxiconazole [mg a.s./kg dry soil]
3.125	0.19	0.19
6.25	0.38	0.38
12.5	0.75	0.75
25.0	1.51	1.51
50.0	3.01	3.01

The amount of fluxapyroxad and epoxiconazole is calculated based on the nominal content of a.s.

Test conditions: Artificial soil according to ISO 11267 (with reduced content of peat: 5%); pH 6.4 - 6.5 at test initiation and test termination; water content at study initiation 52.6% - 54.1% of maximum water holding capacity and 48.2% - 49.8% of maximum WHC at test termination; temperature: 18 °C - 20 °C; photoperiod: 16 h light : 8 h dark, light intensity: 410 lux - 790 lux; food: 2 mg granulated dry yeast at the start of the test and after 14 days.

Statistics: Descriptive statistics, Fisher`s exact test for mortality data, Dunnett`s test for reproduction data ($\alpha = 0.05$); probit analysis for determination of the EC_{50} and LC_{50}.

RESULTS AND DISCUSSION

In the test item treatments mortalities of 20% to 82% were observed, compared to 12% in the control. At the tested concentrations of 25.0 and 50.0 mg BAS 701 00 F/kg dry soil statistically significant effects on survival (Fisher`s exact test, $\alpha = 0.05$) were recorded.
In the control, a mean of 418 juveniles was counted. In the treatment groups, a mean number of juveniles between 28 to 408 was counted. This is corresponding to a reproduction relative to the control between 7% and 98%. At 25.0 and 50.0 mg BAS 701 00 F/kg dry soil statistically significant effects on reproduction (Dunnett`s test for reproduction data, $\alpha = 0.05$) were recorded.
No abnormal behavior or conditions of the surviving Collembola were observed at any tested concentration. The results are summarized in Table 10.6.6-3.

Table 10.6.6-3 Effect of BAS 701 00 F on *Folsomia candida* in a 28-day reproduction study

BAS 701 00 F [mg/kg dry soil]	**Control**	**3.125**	**6.25**	**12.5**	**25.0**	**50.0**
fluxapyroxad [mg a.s./kg dry soil]		**0.19**	**0.38**	**0.75**	**1.51**	**3.01**
epoxiconazole [mg a.s./kg dry soil]		**0.19**	**0.38**	**0.75**	**1.51**	**3.01**
Mortality (day 28) [%]	12	20 n.s.	28 n.s.	26 n.s.	52*	82*
No. of juveniles (day 28)	418	408 n.s.	400 n.s.	330 n.s.	207*	28*
Reproduction in [%] of control (day 28)	--	98	96	79	49	7
	Endpoints [mg BAS 701 00 F/kg dry soil]					
LC_{50} (95% confidence limits)	24.95 (19.05 - 32.69)					
$EC_{50\ reproduction}$ (95% confidence limits)	22.84 (18.54 - 28.21)					
NOEC	12.5					

* = statistically significant differences compared to the control (Fisher`s exact test for mortality data, Dunnett`s test for reproduction data (α = 0.05).
n.s. = no statistically significant differences compared to the control (Fisher`s exact test for mortality data, Dunnett`s test for reproduction data (α = 0.05).

CONCLUSION

In a 28-day collembolan reproduction study with BAS 701 00 F the NOEC was 12.5 mg BAS 701 00 F/kg dry soil. The EC_{50} was 22.84 mg BAS 701 00 F/kg dry soil.

Report:	**10.6.6/2, Schulz L., 2009(a)**
Title:	Effects of BAS 701 00 F on the reproduction of the predatory mite *Hypoaspis aculeifer*
Document No:	BASF DocID 2009/1089814
Guidelines:	OECD 226 (2008)
GLP	Yes

Executive Summary

The effects of BAS 701 00 F on survival and reproduction of the soil mite *Hypoaspis aculeifer* were investigated in a laboratory study over 14 days. The test item was incorporated into the soil at concentrations of 31.3, 62.5, 125, 250 and 500 mg BAS 701 00 F per kg dry soil with 4 replicates per treatment. An untreated control with 8 replicates was included. Each replicate contained 10 adult mites. Assessment of mortality of the adults and reproduction (number of juveniles) was carried out after 14 days. The artificial test soil had an organic content of 5% (as sphagnum peat).

In the test item treatments, mortalities of 22.5% to 2.5% were observed, compared to 15.0% in the control. No statistically significant effects on survival were recorded. In the control, a mean of 152.3 juveniles was counted. In the treatment groups, mean numbers of juveniles between 121.0 and 146.5 were counted. This is corresponding to a reproduction relative to the control between 80% and 96%. No statistically significant effects on reproduction were observed.

In a 14-day soil mite reproduction study with BAS 701 00 F the NOEC was 500 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: *Hypoaspis aculeifer* (soil mite), adult females from a synchronised culture with an age difference of 3 days, from in- house culture.

Test design: In a 14-day test, adults of *Hypoaspis aculeifer* were exposed to five soil concentrations of BAS 701 00 F. The test substrate was artificial soil according to OECD 226 with only 5% peat. In total, 6 treatment groups were set up (5 concentrations of the test item and untreated control) with 8 replicates for the control and 4 replicates for the test item treatments and 10 adult soil mites per replicate. The artificial soil was treated and filled into glass vessels, before the soil mites were introduced on the top of the soil.
Assessment of adult soil mite mortality and reproduction (number of juveniles) was done after 14 days.

Endpoints: NOEC (LC_{50}, EC_{50})

Reference item: Perfekthion (Dimethoate 422.4 g/L analyzed). The effects of the reference item were investigated in a separate study.

Test concentrations:

BAS 701 00 F [mg/kg dry soil]	fluxapyroxad [mg a.s./kg dry soil]	epoxiconazole [mg a.s./kg dry soil]
31.3	1.9	1.9
62.5	3.8	3.8
125	7.5	7.5
250	15.0	15.0
500	30.1	30.1

* The amount of fluxapyroxad is calculated based on the nominal content of a.s.

Test conditions: Artificial soil according to OECD 226 with a reduced content of peat (5%); pH 5.6 - 6.2 at test initiation, pH 5.5 - 6.1 at test termination; water content at study initiation 53.1% - 55.2% of the max. WHC and 52.9% - 53.5% of the max. WHC at test termination; temperature: 19.7 °C - 21.9 °C; photoperiod: 16 h light : 8 h dark, light intensity: 476 lux; food: Mold mite *Tyrophagus putrescentiae* at the beginning and *ad libitum* in the course of the test.

Statistics: Descriptive statistics. Dunnett-test for reproduction and Fishers exact-test for mortality data (α = 0.05).

RESULTS AND DISCUSSION

In the test item treatments, mortalities of 22.5% to 2.5% were observed, compared to 15.0% in the control. No statistically significant effects on survival (Fishers-exact-test, one-sided greater, α = 0.05) were recorded. In the control, a mean of 152.3 juveniles was counted. In the treatment groups, mean numbers of juveniles between 121.0 and 146.5 were counted. This is corresponding to a reproduction relative to the control between 80% and 96%. No statistically significant effects on reproduction (Dunnett-test, one-sided smaller, α = 0.05) were observed. The results are summarized in Table 10.6.6-4.

Table 10.6.6-4 Effect of BAS 701 00 F on *Hypoaspis aculeifer* in a 14-day reproduction study

BAS 701 00 F [mg/kg dry soil]	**Control**	**31.3**	**62.5**	**125**	**250**	**500**
fluxapyroxad [mg a.s./kg dry soil]		**1.9**	**3.8**	**7.5**	**15.0**	**30.1**
epoxiconazole [mg a.s./kg dry soil]		**1.9**	**3.8**	**7.5**	**15.0**	**30.1**
Mortality (day 14) [%]	15.0	22.5 n.s.	25.0 n.s.	25.0 n.s.	27.5 n.s.	22.5 n.s.
No. of juveniles (day 14)	152.3	146.5 n.s.	141.3 n.s.	138.8 n.s.	138.0 n.s.	121.0 n.s.
Reproduction (day 14) [% of control]	--	96	93	91	91	80
	Endpoints [mg BAS 701 00 F/kg dry soil]					
NOEC	≥ 500					
EC_{50}	> 500					
LC_{50}	> 500					

n.s. = no statistically significant differences compared to the control (Dunnett-test for reproduction, Fishers exact-test for mortality; α = 0.05)

CONCLUSION

In a 14-day soil mite reproduction study with BAS 701 00 F the NOEC was 500 mg BAS 701 00 F/kg dry soil.

Report:	**10.6.6/3, Royer, S (2013)**
Title:	**Effect of BAS 701 00 F on the reproduction of different generations of the Collembola *Folsomia candida* (multi generation study)**
Document No:	BASF DocID 2013/1040568
Guidelines:	No guideline available, but test design based on ISO 11267 (1999) and OECD 232
GLP	Yes
Validity	No guideline for this multi-generation test at the moment

Executive Summary

The effects of the test item BAS 701 00 F on survival and reproduction of different generations of the Collembola *Folsomia candida* were investigated in two consecutive chronic laboratory experiments, each over a time period of 28 days according to ISO 11267 and OECD 232. Test soil was prepared and treated with the test item for both experiments at the same time before the first reproduction test. While the first experiment (reproduction test 1, 1st generation) was conducted with freshly prepared test soil, the residue aged soil was used for the second experiment (reproduction test 2, 2nd generation). Both - freshly prepared and residue aged soil - were treated with the same concentrations of the test item. After the evaluation of reproduction test 1, the extracted juveniles from the test were stored in residue aged test soil for 14 days (interim storage in order to ensure a sufficient synchronized timing for the second test) and then used as starting population for the second experiment (reproduction test 2) with aged soil. The goal of this test setup was to examine the recovery potential of a collembola population exposed to relevant residues of BAS 701 00 F over a period of two generations.

At the beginning of the study, the test item was mixed into artificial soil at concentrations of 20.0, 30.0, 45.0, 67.5 and 101.3 mg BAS 701 00 F *I* kg soil dry weight. For the control treatment the soil was left untreated. For the first reproduction test 8 replicates were prepared for the control and 4 replicates for the other treatment groups, each containing 10 springtails. Additional test soil was prepared and treated at the same time but was stored under greenhouse conditions in order to let it age. The aged test soil was then used for the interim storage (ageing time 28 days) of collembola and the second reproduction test (ageing time 42 days). For both reproduction tests assessment of mortality, reproduction and behaviour was carried out 28 days after treatment and/or introduction of the collembola, respectively.

Reproduction test 1 (1st generation): In reproduction test 1 (1st generation), no mortality was observed in the control. In the groups treated with 20.0 and 30.0 mg/kg soil dry weight, mortalities of 2.5% and 5.0%, respectively, were recorded which were not statistically significantly different compared to control (Fisher's Exact Binomial Test with Bonferroni Correction, one-sided greater, $\alpha = 0.05$). In the groups treated with 45.0, 67.5 and 101.3 mg/kg soil dry weight, mortalities of 30.0%, 42.5% and 80.0%, respectively, were recorded, which were all statistically significantly different compared to control (Fisher's Exact Binomial Test with Bonferroni Correction, one-sided greater, $\alpha = 0.05$).
The LC50 of the first generation test was determined to be 67.1 mg/kg soil dry weight.

The mean reproduction in the control reached 803.6 juveniles per replicate. Mean reproduction in the groups treated with 20.0 and 30.0 mg/kg soil dry weight were 820.1 and 754.0 juveniles per replicate (corresponding to 102.1 % and 93.8% of control), respectively, which were not statistically significantly different compared to control (Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, one-sided smaller, $\alpha = 0.05$). The mean reproduction rates in the groups treated with 45.0, 67.5 and 101.3 mg/kg soil dry weight were 498.6, 397.6 and 141.1 juveniles per replicate (corresponding to 62.0%, 49.5% and 17.6% of control), respectively. The decreased reproduction rates in the 45.0 and 101.3 mg/kg treatments were statistically significant effects compared to the control, the one in the group treated with 67.5 mg/kg soil dry weight was - despite of the strong differences compared to control - not statistically significantly different from the control (Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, one-sided smaller, $\alpha = 0.05$).
The EC50 of the first generation test was determined to be **61.4 mg/kg soil dry weight**.
The NOEC of the first generation test was determined to be **30 mg/kg soil dry weight**.
No behavioural abnormalities were observed in any of the test item treatment groups.

Reproduction test 2 (2nd generation)
In reproduction test 2 (2nd generation), a mortality of 18.8% was observed in the control. In the treatment groups mortalities of 20.0%, 30.0%, 10.0%, 17.5% and 32.5%, respectively, were recorded which were all not statistically significantly different compared to control (Fisher's Exact Binomial Test with Bonferroni correction, one-sided greater, $\alpha = 0.05$). The LC50 of the second generation test was estimated to be >101.3 mg/kg soil dry weight. Mean reproduction in the control of test 2 reached 374.3 juveniles per replicate and hence, the reproduction performance was less than 50% in comparison to the control in test 1. Furthermore, a higher variability could be observed in the control of test 2 (variation coefficient of 39.2%). In contrast, mean reproduction in the treatment groups was at 756.4, 524.6, 835.8, 815.5 and 865.4 juveniles per replicate. This corresponds to 202.1%, 140.2%, 223.3%, 217.9% and 231.2% of the control from test 2 but was well in the range of the better performing control from test 1. No clear dose response relation was observed. The reproductive performance in all treatments were clearly higher than the moderately performing control group of test 2. Tested for reduction of reproduction success compared to the control, no statistically significant differences were (Williams Multiple Sequential Hest Procedure, one-sided smaller, $\alpha = 0.05$).

The EC50 of the second generation test was estimated to be >101.3 mg/kg soil dry weight.
The NOAEC of the second generation test was determined to be 101.3 mg/kg soil dry weight.
No behavioural abnormalities were observed in any of the test item treatment groups.

As a result of two consecutive 28-day Collembola reproduction studies which were conducted as a multi generation study with BAS 701 00 F, a NOAEC of 101.3 mg/kg soil dry weight, the highest tested concentration, could be determined. The LC50 and the EC50 were estimated to be >101.3 mg/kg soil dry weight.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: Collembola (*Folsomia candida*), source: in-house culture (non-GLP) Age: reproduction test 1: 9 - 12 days, reproduction test 2: unknown (about 2 to maximal 6 weeks)

Test design: The effects of the test item BAS 701 00 F on survival and reproduction of different generations of the Collembola *Folsomia candida* were investigated in two consecutive chronic laboratory experiments, each over a time period of 28 days according to ISO 11267 and OECD 232. The first experiment (reproduction test 1, 1st generation) was conducted with freshly prepared test soil. After the evaluation of reproduction test 1, the juveniles extracted from this test were stored in residue aged test soil for 14 days (interim storage).
Finally a second experiment (reproduction test 2, 2nd generation) with residue aged soil was carried out, where the juveniles of the first test were introduced. Both - the freshly concentrations of the test item. The test soil contained 5% peat.

In both reproduction tests, 7 treatment groups (control, 5 test item concentrations, reference item in reproduction test 1) or 6 treatment groups (control, 5 test item concentrations in reproduction test 2), respectively, were set up. Each treatment group had 8 replicates (controls) or 4 replicates (test item and reference item treated groups), respectively for exposure of the test organisms (10 per replicate) and 1 additional replicate without test organisms for analytical purposes.
The different test item concentrations were homogeneously mixed into the soil. For reproduction test 1, the soil was distributed over the replicate test units (glass vessels), afterwards ten 9 - 12 days old Collembola were introduced on the top of the soil. For reproduction test 2, aged soil was used and juvenile collembola extracted from the first reproduction test were introduced on the top of the soil. The Collembola of both tests were fed twice during the test (day 0 and day 14) with approximately 2 mg dry yeast per test unit.

Assessment of adult mortality, reproduction and behavioral effects was carried out 28 days after introduction of the collembola.

Endpoints: NOEC, LC_{50}, EC_{50} at day 28 and NOAEC, LC_{50}, EC_{50} at day 70

Reference item: Reg. No. 4321735 (boric acid), Charge A0150365, The effects of the reference item were investigated in this study only in reproduction test 1 at a rate of 120 mg Reg. No. 4321735 Ikg soil dry weight

Test concentrations:

BAS 701 00 F [mg/kg dry soil]	mg BAS 480 F (nominal) / kg soil dw	mg BAS 700 F (nominal) / kg soil dw
20.0	1.2	1.2
30.0	1.8	1.8
45.0	2.7	2.7
67.5	4.1	4.1
101.3	6.1	6.1

Test conditions: Reproduction test 1

	Artificial soil according to OECD 232, pH 5.50 - 5.72 at test initiation, pH 5.34 - 5.60 at test termination; maximum water holding capacity was 39 g/100 g dry soil, the moisture was maintained at about 55% of the maximum water holding capacity; temperature was 20°C ± 2 °C (measured: 19 - 21°C); photoperiod: 16 h light: 8 h dark; light intensity: 430 lux - 690 lux.
	Reproduction test 2
	Artificial soil according to OECD 232, pH 5.18 - 5.40 at test initiation, pH 5.15 - 6.08 at test termination; maximum water holding capacity was 39 g/100g dry soil, the moisture was maintained at about 55% of the maximum water holding capacity; temperature was 20 cC ± 2 cC (measured: 19 - 21 CC); photoperiod: 16 h light: 8 h dark; light intensity: 460 lux - 680 lux.
Statistics:	Shapiro-Wilk's Test on Normal Distribution, Levene's Test on Variance Homogeneity (with Residuals), Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, Williams Multiple Sequential t-test Procedure, Fisher's Exact Binomial Test with Bonferroni Correction, STUDENT-t test for Homogeneous Variances, Probit Analysis. (ToxRatPro Version 2.10)
Validity criteria	Mean mortality of the adults in control: should be ≤ 20% Mean number of juveniles per control container: should be ≥ 100 Coefficient of variance of reproduction in control: should be ≤30%
	Validity criteria set by the ISO 11267 (1999) and OECD 232 (2009) guidelines were only applicable for reproduction test 1. In general, reproduction test 2 was carried out following the principles of the guidelines. However, since the results of reproduction test 2 rely on additional intermediate processing steps between tests 1 and 2, which resulted in introduced juveniles with a wider range of ages, a higher variability then specified in the guidelines, can be anticipated for reproduction test 2. Hence, the validity criteria of the standard test cannot be applied for reproduction test 2.

RESULTS AND DISCUSSION

In reproduction test 1, at a concentration of 120 mg per kg soil dry weight, the toxic reference item Reg. No. 4321735 (boric acid) inhibited the reproduction statistically significant (mean: 136.9 juveniles per container) to 17.0% compared to the control.

Table 1: Effect of BAS 701 00 F on Collembola (*Folsomia candida*) mortality and reproduction (day 28, reproduction tests 1 and 2)

Reproduction test 1 (1st generation)						
BAS 701 00 F [mg/kg soil dry weight]	Control	**20.0**	**30.0**	**45.0**	**67.5**	**101.3**
Mortality [%] (day 28) 1)	0	2.5 n.s.	5.0 n.s.	30.0 *	42.5 *	80.0 *
Mean number of juveniles per container (day 28) 2)	803.6	820.1 n.s.	754.0 n.s	498.6 *	397.6 n.s	141.1 *
Reproduction in [%] of control (day 28)	--	102.1	93.8	62.0	49.5	17.6
Reproduction test 2 (2nd generation)						
BAS 701 00 F [mg/kg soil dry weight]	Control	**20.0**	**30.0**	**45.0**	**67.5**	**101.3**
Mortality [%] (day 28) 1)	18.8	20.0 n.s.	30.0 n.s.	10.0 n.s.	17.5 n.s.	32.5 n.s.
Mean number of juveniles per container (day 28) 3)	374.3	756.4 n.s.	524.6 n.s.	835.8 n.s.	815.5 n.s.	865.4 n.s.
Reproduction in [%] of control (day 28)	--	202.1	140.2	223.3	217.9	231.2
	Endpoints (based on reproduction test 2 (2nd generation)) [mg BAS 701 00 F / kg soil dry weight]					
NOAEC	101.3					
LOEAC	>101.3					
LC_{50} 4)	>101.3					
EC_{50} 4)	>101.3					

n.s. = statistically not significant compared to the control / * = statistically significant compared to the control
(ToxRatPro Version 2.10, 1) Fisher's Exact Binomial Test with Bonferroni Correction, one-sided greater, α = 0.05
2) Welch-t test for Inhomogeneous Variances with Bonferroni-Holm Adjustment, one-sided smaller, α = 0.05)
3) Williams Multiple Sequential t-test Procedure, one-sided smaller, α = 0.05)
4) based on estimation of the data

CONCLUSION

As a result of two consecutive 28-day Collembola reproduction studies which were conducted as a multi generation study with SAS 701 00 F a NOAEC of 101.3 mg/kg soil dry weight, the highest tested concentration, was determined by the applicant. The LC_{50} and the EC_{50} were estimated to be >101.3 mg/kg soil dry weight.

Comments of zRMS	Since the design and the relevance of collembolan multi-generation-study is still not discussed and accepted at the moment in the EU, the study of Royer (2013) cannot be accepted for current risk assessment. Only the endpoints of the 1st generation (21d) appear at the moment as relevant (additional information) for the current dossier LC_{50} 1st generation (28d) = 67.1 mg/ kg soil dw NOEC 1st generation (28d) = 30 mg/ kg soil dw **zRMS DE: Preliminary evaluation of the multi-generation study with collembolan exposed to fresh and aged soil residues of PPP** In the process of the authorization of the plant protection product Adexar (BAS 701 00 F), the company seeking for authorization (BASF) has provided the German National Authorities with a study assessing the effects of the PPP on soil organisms in a multi- generation approach. The submitted test is novel in the general approach, since it is performed with the aim of assessing the impact of fresh as well as aged PPP residues on soil organisms, in this case on collembolans. A test in such a design has not been submitted to European Authorities before. Since it has not been jointly peer-reviewed by Member States in the European Union, the present evaluation has to be considered as preliminary. European Member States believe that the assessment of novel testing approaches -and consequently of novel endpoint derivation- is best addressed in the framework of relevant guidance document development or, alternatively, during the peer-reviewed process of active substance evaluated at EU level. We strongly feel that the submission of studies presenting novel testing strategies during the process of the authorization of single products at Member State level is unfortunate for the achievement of harmonized PPP risk assessment in the European Union. A preliminary general assessment of the study regarding the pertinence of the chosen set up for the achievement of the assessment goals is provided below by the German Authorities. The study design consists in principle of two subsequent chronic tests with *Folsomia candida*. The reproductive success of the collembolan exposed to PPP is assessed in an artificial soil matrix according to guideline OECD 232. The whole study according to the new design lasts 70 days, the single experiments 28 day each. The artificial soil employed in the tests is contaminated prior to the first test, and is therefore slightly ‘aged’ at the start of the second chronic tests (42 days). Between the two chronic tests, two

	weeks are foreseen to rear and synchronize the retrieved organisms from the first test and to select the starting animals for the second tests. The endpoints given at test termination concern survival and reproductive success of *F. candida* in the first chronic test and of *F. candida* F1 generation in the second test with 'aged residues', respectively. In the opinion of MS DE, two main issues are to be discussed regarding the submitted study. The first issue concerns the test strategy in the ecotoxicological effect assessment is performed, the second regards how the test environments might influence the fate and behavior of the active substances in the present study. Both concerns centre on the fact that the results of the submitted experiment intend to address in a higher tier approach unacceptable effects of PPP on soil organisms (here: mesofauna, collembolan) that had been previously identified in a first tier assessment step. The study is designed to assess the risk of non-target-organisms exposed to PPP residues in the long term, after initial effects due to the toxicity of fresh residues. Since the aim is to demonstrate an acceptable risk to soil organisms after a certain time following PPP application, the assessment includes necessarily population recovery and/or recolonization processes. Regarding the ecotoxicological effect assessment, the first point of concern regards in our opinion the species that has been chosen to address the risk to soil organisms in a higher tier approach. The chosen collembolan *Folsomia candida* is a soil dwelling organisms, generally employed in ecotoxicological laboratory testing. It has been shown to be fairly sensitive to toxicants, is easily reared and has a short reproductive cycle (21 days) with a high number of offspring per cycle (e.g. Krogh et al. 2008). In our opinion, the life history traits displayed by *F. candida* are not representative for ecologically sensitive, vulnerable species of the soil organisms' community in the field. Such vulnerable species (e.g. species with long life cycles) are however those that should be particularly considered when addressing long term effects on non-target organisms communities after initial effects due to PPP use. Please refer for further details on which species' traits should be addressed when considering recovery and/ or recolonization processes to the EFSA Report "Biodiversity as Protection Goal in Environmental Risk Assessment for EU agro-ecosystems" (EFSA 2013) and chapter 'Recovery' therein. Since *F. candida* has a short reproductive cycle and reproduces mostly partenogenetically, it does not represent the species' traits that are suitable to address the recovery of soil organisms under field condition in a higher tier

	risk assessment approach. The uncertainty on the relevance of the test results should therefore be addressed in the risk assessment outcome. The test design does not assess the reproductive success of the first adult generation after 28 days. Since these animals contribute further to the population size development and are also still exposed to the PPP, it cannot be stated that there are no effect on the population of collembolan in the long term if the second reproduction test delivers toxicity thresholds above the acceptability criterion. The second matter of concern relates to the employed soil in the submitted test. The standard soil that is used in this test –and commonly in almost all tests according to OECS 232- is an artificial soil built up with sand (74%), kaolin clay (20% ; with a kaolinite content above 30%) and sphagnum peat (commonly 10 to 5%, here 5%). The pH of the soil is adjusted to 6 ± 0.5 with calcium carbonate (<1%) (OECD 232). This soil substrate has the evident advantage of being reproducible and standardized. Deviations are nevertheless to be expected regarding the quality of the peat employed as organic matter substrate. Compared to the range of natural soils under agricultural use, the standard soil with 10% peat has to be considered outside the upper range for organic matter content (e.g. Jones et al. 2004). Even with the reduced amount of organic matter added to the standard soil as in the present study (5%), the quality of the added organic matter deviates from natural organic particles usually present in agricultural field soils. Degraded peat bog soils under agricultural use represent only a minority of agricultural soils in Europe. The bioavailability of freshly added PPP –and even to higher extend of aged PPP residues- is greatly reduced by the sorption of the active substances to the artificial soil. The sorption to the organic matter and the decrease of the bioavailability of the active substance to the tested organisms are deemed to be much higher in the artificial soil compared to natural agricultural soils. Concluding, the submitted two generation collembola test with the standard test organisms *Folsomia candida* is seen as a combination of a prolonged reproduction test (with specimen of F1 generation) and a modified exposure test design (with ageing PPP in artificial soil). At present, it is not possible to link the outcome of the submitted *F. candida* two generation test with the response of other collembolan species with longer generation times in natural agricultural soils under intended PPP uses. It is acknowledged that no reduction of the assessment factor – current acceptability criterion is 5- was foreseen for the risk assessment. Nevertheless, the achievement of a Toxicity to Exposure Ratio of 5 with the

	outcome of the reproductive success of the second generation of *F. candida* in the artificial soil after slight ageing of the PPP might be of low relevance for the field situation. If the test set up is to address the risk for soil organisms at higher tier, further improvement of the ecological realisms of the test environments would be necessary. Alternatively, the assessment of the protectivity of the outcome of this novel tests compared to the response of soil organisms field communities should be quantified. At present, the outcome of the *F. candida* two generation test cannot be employed to refine an unacceptable risk that was determined at lower tier assessment step and to demonstrate an acceptable long-term risk for soil organisms after exposure to PPP in the field. Krogh, P.H., M. Amorim, P. Andrés, G. Bakonyi, K. Becker van Slooten, X. Domene, I. Geujin, N. Kaneko, S. Knäbe, V.Kocí, J. Lana, T. Moser, J. Princz, M. Schaefer, J.J. Scott-Fordsmand, H. Stubberud and B.-M. Wilke (2008): Toxicity testing with the collembolans Folsomia fimetaria and Folsomia candida and the results of a ringtest. Environmental Project No. 1256, Danish Environmental Protection Agency Miljøministeriet Miljøstyrelsen. EFSA Scientific Colloquium XIX, Parma, 27 - 28 November 2013, ISBN 978-92-9199-588-2, doi: 10.2805/57358. Jones, R.J.A., R. Hiederer, E. Rusco, P.J. Loveland and Montanarella, L. (2004). The map of organic carbon in topsoils in Europe, Version 1.2, September 2003: Explanation of Special Publication Ispra 2004 No.72 (S.P.I.04.72). European Soil Bureau Research Report No.17, EUR 21209 EN, 26pp. and 1 map in ISO B1 format. Office for Official Publications of the European Communities, Luxembourg.

Report:	**10.6.6/3, Royer,S (2013)**
Title:	**Effects of BAS 702 00 F on Soil Collembola under Field Conditions**
Document No:	BASF DocID 2012/1143242
Guidelines:	GLP compliant study based on ESCORT 2 and Guidance for summarising and evaluating field studies with non-target arthropods (de J ong *et af.* 20 I 0) for the hazard assessment of plant protection products
GLP	Yes
Validity	Yes, with restrictions

The notifier submitted a higher tier study on Collembola (Schabio & Eichler, 2013).
In their report “BASF DoclD 2012/1143242”, Schabio and Eichler present the results of a survey designed in 2013 to investigate the effects of BAS 702 00 F on soil Collembola under field conditions. The trial was run in Groß Zimmern, near Dieburg Germany. The test item BAS 702 00 F (81.4 g/L Pyraclostrobin (BAS 500 F), 50.2 g/L Fluxapyroxad (BAS 700 F) and 49.0 g/L Epoxiconazole (BAS 480 F) was applied at two rates of 5.0 and 10.0 L/ha, corresponding to 407.0 and 814.0 g/ha Pyraclostrobin, 251.0 and 502.0 g/ha Fluxapyroxad and 245.0 and 490.0 g/ha Epoxiconazole on the soil surface. The correct application was confirmed by the residue analysis in soil samples taken after the application.

The test item is not “ADEXAR”, which is the product of the current dossier, but the rates applied in the study actually cover the intended use of ADEXAR in Germany (i.e. 2x2L/ha; i.e.250 g/ha Fluxapyroxad and 250 g/ha Epoxiconazole).

The study was set up as randomized block design with 4 treatment groups (control, rate 1, rate 2 and toxic reference). Sixteen plots, each 10 m x 10 m, were arranged in a 4 x 4 formation, each plot surrounded by at least a 3 m guard row between the plots. The treatments were randomly assigned to the plots within each replicate (4 replicates each).

The sampling dates were the following:

The authors investigated pitfall traps (activity of soil surface dwelling arthropods) and core soil samples (endogeic species), the endpoints were the abundance and the community composition of Collembolan population and the abundance of individual species.

The authors discussed the results as following:

- Total Collembolan abundance from the pitfall traps
Pitfall traps were used to investigate the activity of soil surface dwelling arthropods. Collembolan abundance of the BAS 702 00 F treated plots was not statistically significantly different compared to the control. In the toxic reference group, the Collembolan abundance was statistically significantly reduced to 3.3 %, 3.7% and 6.2% of the control level at the 1st, 2nd and 3rd sampling after application.

- Collembolan abundance in the soil cores:
Based on the results of this study, no statistically significant effect on Collembolan abundance was seen as a result of BAS 702 00 F groups during 82 days after application in the soil cores.

- Community composition of Collembolan populations:
There were no relevant treatment-related effects caused by the test item according to the test on the first PRC. The only major effects were caused by the toxic reference. For the raw abundance data sets, the results of the permutation tests per sampling date indicated that the treatment regime had significant effect (p-value<0.05) on the community on the first sampling after application. In all other datasets for the later samplings, the treatment regime had no significant effect on all post treatment samplings.
NOECcommunity is rate 2 (10 L/ha) for all datasets.
Collembolan community structure was not affected in the soil cores and 85 days after application in the pitfall traps.

The authors conclude that: "... exposure of Collembolan populations to a concentration of 10 L/ha BAS 702 00 F has no significant or ecologically relevant effects on Collembolan abundance during an 85 days trial".

Comments of zRMS	The main concern of the zRMS DE about the study of Schabio & Eichler (2013) is the low abundance of Collembola recorded in the study. This moderate abundance might be related to the choice of the sampling dates (i.e. late starting point of the study), or to the choice of study place and/or to the duration of the study. All these factors are of main importance in evaluating the reliability of the study addressing the risk of Collembola exposed to BAS 702 00 F. The value of abundance of 31.476.6 ind./m² recorded in the control soil cores at the pre-treatment sampling date is lower but in the range of the normal mean values of abundance given for Central European crop sites (41.000 ind./m2 and 4 species, e.g. Römbke et al. 2012) . However, from the 1st post-treatment sampling date on until the end of the study, the abundance recorded in the control strongly decrease and strongly deviate from the "normal mean values of abundance" expected for central Europe (cf Table 8, page 46 of the report). For example, 1263 and 1565 animals were counted in June and July and only 214 and 182 were counted in August and September in the pitfall traps. This represents in average a decrease of about 85% of the soil surface -dwelling arthropods. A similar pattern was observed for the endogeic species counted in the core soil samples: 31476 and 23609 invidious per m² were counted in June and July and only 17261 and 18025 individuals per m² were counted in August and September (decrease of about 25%). The authors argue that "this pattern confirms the results found in literature regarding the temporal and special dynamics of Collembolan populations", which is correct. We agree with the authors that the temporal pattern of decrease of abundance in summer confirms some results found in literature regarding the temporal and spacial dynamics of Collembolan populations. For example, decrease of abundance correlates with the increasing soil temperature at the same sampling dates (cf figure 3, page 38 of the study) and mirrows the annual phenology of many collembolan species. However, since it was to be expected that the diversity and abundance of the soil arthropods will decrease over the summer month, the relevance of the choice of the starting point to conduct the study (early summer, 1st application on the 28th of June) is strongly questionable. Independently of its origin, such a decrease in abundance poses a problem for further statistical analysis. Indeed, a reduction of the sampling size (i.e. number of Collembola recorded) might interfere with the power of the statistic

	tests to demonstrate significant effects, since effects are harder to detect in smaller samples with high natural variability of the enpoints. The first sampling date might be of satisfactory statistical accuracy in order to detect potential effects in the treated plots compared to the control. However, this 1st sampling date occurs already 9 days after application, and is therefore not relevant to address the time course of effects of the test item on the collembolan populations. The last concern of the UBA is about the short duration of the study. The test item was applied on the 28th of June and the last sample was taken on the 18th of September, which represents only 3 months. It is regrettable that the study has been stopped before the second activity peak of Collembola usually occurring in autumn. Under these conditions, it is questionable if effects occurring on arthropods having a longer life-span could be address in this study design. There are however of most importance since the aim of this study was to address putative long-term effects of the test item on collembolan populations. On the basis of the data presented in the report of Schabio & Eichler (2013) no effect of BAS 702 00 F on collembolan populations could be detected. However, (i) mainly because of the late start of the study, effects of BAS 702 00 F had to be expected in summer where populations of Collembola are at their minimal abundance, and (ii) because of the short duration of the study, which did not have taken into account the autumnal activity peak of the Collembola, the number of individuals recorded in the study was low. It is therefore questionable if the statics power of the tests used in the study and their suitability to determine significant effects from the control were justified. It would have been more pertinent for the higher tier study and powerful for the statistics to design the survey earlier in the year (like in the intended use of the product, i.e. from BBCH stages 30) and to record the autumnal activity peak of Collembola to ensure that effects of BAS 702 00 F on juveniles of animals that have reproduced in the year after application were also assessed, which was actually the aim of this higher tier study. However, in a weight of evidence approach it is considered that, – the dosing in the study displayed much higher application rates as the intended uses of ‘Adexar’ (application rates approx doubled in the field study); – the individual numbers in the first sampling date were fairly high, so that statistically significant effects on collembola abundance and on abundance of dominant species could in principle be detected;

	– effects on single species were detected at the first and second sampling date. One species was reduced at the third sampling date, but only in the lower application rate and not in the higher application rate; – the toxic reference had a statistically significant effects on collembola abundance and on single species (for some species detectable differences were found till the end of the experiment); – the application pattern of 'Adexar' according to the intended uses in the GAP of this application might well spam from beginning of April till Mai. Therefore, irrespective of the examination of new information whenever these will become available, the risk for collembola community in the field after application of 'Adexar' according to the intended uses in the GAP of this application is considered acceptable in a weight of evidence approach. Römbke *et al.* (2012) Erfassung und Analyse des Bodenzustands im Hinblick auf die Umsetzung und Weiterentwicklung der Nationalen Biodiversitätsstrategie. Report 33/2012 for the Federal Environmental Agency Dessau-Roßlau. http://www.uba.de/uba-info-medien/4312.html

KPC 10.4.2.1 Species level testing

KPC 10.4.2.2 Higher tier testing

Report:	**10.6.7/1, Royer S., Obermann M., 2009(a)**
Title:	Effect of BAS 701 00 F on the organic matter decomposition under field conditions (litter bag method)
Document No:	BASF DocID 2009/1067172
Guidelines:	OECD-ENV/JM/MONO(2002)/9, OECD-ENV/JM/MONO(2006)23, OECD 56
GLP	Yes

Executive Summary

The test item BAS 701 00 F was studied for its potential effects on the degradation of buried organic wheat straw compared to a water control after exposure of about 1, 3, 6, 11 and 12.5 months. The study was set up as randomized block design with three incorporated long-term plateau concentrations in the upper 10 cm of soil (1.0, 2.0 and 4.0 L/ha) + application of the annual rate on the soil surface (*i.e*. 4.0 L/ha). The treatments were randomly assigned to the plots within each replicate (6 replicates each).

The mass loss of the straw material in the untreated control was 77.6% at the end of the experiment after 385 days. In treatment group exposing the soil to 1.0 + 4.0 L BAS 701 00 F/ha, the mean mass losses after the exposure phases of about 1, 3, 6, 11 and 12.5 months were only slightly different from those in the control, resulting in effects of +9.2%, +12.7%, +11.4%, +9.1% and +7.2%. There were no statistically significant differences between this treatment group and the water treated control.
In treatment group exposing the soil to 2.0 + 4.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1 month was only slightly different from that in the untreated control, resulting in an effect of 7.4%. The mean mass losses after the exposure phases of about 3, 6, 11 and 12.5 months showed differences (inhibition) to those in the control with effects of +14.2%, +15.4%, +14.2% and +14.2%. However, only the mean mass loss after about 12.5 months was statistically significant compared to the control.
In treatment group exposing the soil to 4.0 + 4.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1 month was only slightly different from those in the untreated control, resulting in an effect of +9.6%. The mean mass losses after the exposure phases of about 3, 6, 11 and 12.5 months showed differences (inhibition) to those in the control with effects of +23.6%, +23.2%, +19.1% and +21.0%. All that were all statistically significant compared to the control.

The results of this field study with BAS 701 00 F in a one year monitoring program on an arable field site emphasize that BAS 701 00 F proved to have no treatment-related ecologically relevant effects on the organic matter breakdown at the application scenario of 1.0 L BAS 701 00 F/ha as simulated plateau concentration (1st application) and 4.0 L BAS 701 00 F/ha as the annual application rate (2nd application).

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: Naturally occurring non-target soil organisms.

Test site: Arable crop site in Waldsee (Rheinland-Pfalz), Germany; total size about 0.27 hectare, the site had not received chemical application since 2007 and none was applied during the study apart from the test item.

Test design: Randomized block design with four treatments (3 test item groups, water treated control) and six replicates each treatment. Exposure via an incorporated long-term plateau concentration in the upper 10 cm of soil and an application of the annual rate on the soil surface. Within the plots (6 x 6 m plot size) the litter bags were randomly distributed in the upper soil layer (depth of about 5 cm). The treatments were assigned randomly to the plots within each replicate. The substances in all treatments were applied in a water volume equivalent to 300 L/ha. Application was performed using a movable single-tank-sprayer with a distance between nozzles and plants of 0.5 m.

Endpoints: Mean weight loss based on ash-free dry weight per plot per treatment.

Test rates: Treatment group 1: Untreated control
Treatment group 2: 1.0 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 4.0 L BAS 701 00 F/ha
Treatment group 3: 2.0 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 4.0 L BAS 701 00 F/ha
Treatment group 4: 4.0 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 4.0 L BAS 701 00 F/ha

Treatment group	BAS 701 00 F [L/ha]	fluxapyroxad* [mg a.s./kg dry soil]	epoxiconazole * [mg a.s./kg dry soil]
1st application			
2	1.0	0.042	0.042
3	2.0	0.083	0.083
4	4.0	0.167	0.167

* considering a soil depth of 10 cm and a default soil density of 1.5 g/cm³.

Treatment group	BAS 701 00 F [L/ha]	fluxapyroxad [g/ha]	epoxiconazole [g/ha]
2nd application			
2	4.0	250	250
3	4.0	250	250
4	4.0	250	250

The amount of fluxapyroxad is calculated based on the nominal content of a.s.

Application dates: 1st application: 26.04.2008
Burying of litter bags: 8./ 9.05.2008
2nd application: 13.05.2008

Test conditions:	Natural field conditions; clay loam/sandy loam according to DIN 4220, 1.64% - 2.29% total organic carbon, 0.18% - 0.23% total nitrogen; pH 7.4 - 7.5. Air temperature: -11.1 to 26.1 °C, soil temperature: -2.9 - 25.0 °C, air humidity: 40% - 99.1%.
Litter bags:	Litter bags consisted of curtain material with a mesh size of about 8 x 8 mm. The size of a bag was about 12 x 20 cm. Bags were filled with about 4.0 g (dry weight) of untreated dried wheat straw. Litter-bags were horizontally buried at a depth of about 5 cm, shortly after incorporation of the plateau concentration and before application of the annual rate of BAS 701 00 F at 08./09.05.2008.
Sampling dates:	1st sampling: 24.06.2008 (after 46/47 days after burying) 2nd sampling: 22.08.2008 (after 105/106 days after burying) 3rd sampling: 17.11.2008 (after 192/193 days after burying) 4th sampling: 20.04.2009 (after 346/347 days after burying) 5th sampling: 28.05.2009 (after 384/385 days after burying)
Sample processing:	Sampling was done at five different time intervals (46/47, 105/106, 192/193, 346/347 and 384/385 days after burying of the litter bags). 8 bags were sampled per replicate per sampling date (48 bags per treatment), immediately transported to the laboratory and stored deep frozen until further processing. The enclosed straw material was cleaned and the bag content was oven-dried at 50 °C for 24 hours and weighted. Finally, the straw was ashed at 600 °C for 2 hours and ash-free weight was determined.
Analytics:	Soil samples were analyzed for the active substance fluxapyroxad according to the analytical method L0092/01.
Statistics:	Descriptive statistics; Dunnett multiple t-test or multiple sequentially rejective U-test after Bonferroni-Holm ($\alpha = 0.05$).

RESULTS AND DISCUSSION

Recovery rates for the active substance fluxapyroxad after the 1st application ranged from 120.4% - 140.5% of the expected soil concentration, and from 108.2% and 123.2% after the 2nd application.

The mass loss of the straw material in the untreated control was 77.6% at the end of the experiment after 385 days. In treatment group exposing the soil to 1.0 + 4.0 L BAS 701 00 F/ha, the mean mass losses after the exposure phases of about 1, 3, 6, 11 and 12.5 months were only slightly different from those in the control, resulting in effects of +9.2%, +12.7%, +11.4%, +9.1% and +7.2%. There were no statistically significant differences between this treatment group and the water treated control (Dunnett Multiple t-test or Bonferroni-Holm Multiple sequentially rejective U-test, $\alpha = 0.05$).

In treatment group exposing the soil to 2.0 + 4.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1 month was only slightly different from that in the untreated control, resulting in an effect of 7.4%. The mean mass losses after the exposure phases of about 3, 6, 11 and 12.5 months showed differences (inhibition) to those in the control with effects of +14.2%, +15.4%, +14.2% and +14.2%. However, only the mean mass loss after about 12.5 months was statistically significant compared to the control (Dunnett Multiple t-test or Bonferroni-Holm Multiple sequentially rejective U-test, $\alpha = 0.05$).

In treatment group exposing the soil to 4.0 + 4.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1 month was only slightly different from those in the untreated control, resulting in an effect of +9.6%. The mean mass losses after the exposure phases of about 3, 6, 11 and 12.5 months showed differences (inhibition) to those in the control with effects of +23.6%, +23.2%, +19.1% and +21.0%. All that were all statistically significant compared to the control (Dunnett Multiple t-test or Bonferroni-Holm Multiple sequentially rejective U-test, $\alpha = 0.05$).

Effects of the treatments on the degradation of buried wheat straw are summarized in Table 10.6.7-4.

Table 10.6.7-3 Mass loss [%] of wheat straw following exposure to BAS 701 00 F

Treatment	Mean mass loss [%]				
	Sampling 1	**Sampling 2**	**Sampling 3**	**Sampling 4**	**Sampling 5**
Control	28.2	56.9	71.2	72.7	77.6
1.0 + 4.0 L BAS 701 00 F/ha, % effect (mass loss)	25.6 (+9.2 n.s.)	49.7 (+12.7 n.s.)	63.1 (+11.4 n.s.)	66.1 (+9.1 n.s.)	72.0 (+7.2 n.s.)
2.0 + 4.0 L BAS 701 00 F/ha % effect (mass loss)	26.1 (+7.4 n.s.)	48.8 (+14.2 n.s.)	60.2 (+15.4 n.s.)	62.4 (+14.2 n.s.)	66.6 (+14.2 *)
4.0 + 4.0 L BAS 701 00 F/ha % effect (mass loss)	25.5 (+9.6 n.s.)	43.5 (+23.6 *)	54.7 (+23.2 *)	58.8 (+19.1 *)	61.3 (+21.0 *)

* = statistically significant differences compared to the control (Dunnett multiple t-test or Bonferroni-Holm multiple sequentially rejective U-test, $\alpha = 0.05$)
n.s. = not statistically significant differences compared to the control (Dunnett multiple t-test or Bonferroni-Holm multiple sequentially rejective U-test, $\alpha = 0.05$)

CONCLUSION

The results of this field study with BAS 701 00 F in a one year monitoring program on an arable field site emphasize that BAS 701 00 F proved to have no treatment-related ecologically relevant effects on the organic matter breakdown at the application scenario of 1.0 L BAS 701 00 F/ha as simulated plateau concentration (1st application) and 4.0 L BAS 701 00 F/ha as the annual application rate (2nd application).

Report:	**10.6.7/2, Luehrs U., 2010(a)**
Title:	Effects of BAS 701 00 F on the breakdown of organic matter in litter bags in the field
Document No:	BASF DocID 2010/1000084
Guidelines:	OECD 56 (2006), Roembke et al. (2003)
GLP	Yes

Executive Summary

The test item BAS 701 00 F was studied for its potential effects on the degradation of buried organic wheat straw compared to a water control after exposure of about 1, 3 and 6 months. The study was set up as randomized block design with three incorporated long-term plateau concentrations in the upper 10 cm of soil (1.15, 1.15 and 2.30 L/ha) + application of three annual rates on the soil surface (*i.e.* 1.6, 2.00 and 2.00 L/ha).

The mass loss of the straw material in the untreated control was 75.5% at the end of the experiment after 183 days. In treatment group exposing the soil to 1.15 + 1.60 L BAS 701 00 F/ha, the mean mass losses after the exposure phases of about 1, 3 and 6 months were only slightly different from those in the control, resulting in effects of -4.1%, -7.2% and -2.0%. There were no statistically significant differences between this treatment group and the water treated control. In treatment group exposing the soil to 1.15 + 2.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1, 3 and 6 months were only slightly different from those in the control resulting in effects of -10.7%, -4.5% and -3.3%. There were no statistically significant differences between this treatment group and the water treated control. In treatment group exposing the soil to 2.0 + 2.3 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1, 3 and 6 months were only slightly different from those in the control resulting in effects of +0.7%, -7.9% and -0.9%. There were no statistically significant differences between this treatment group and the water treated control.

The results of this field study with BAS 701 00 F in a 183-day monitoring program on an arable field site emphasize that BAS 701 00 F proved to have no treatment-related ecologically relevant effects on the organic matter breakdown at the application scenario of 1.15, 1.15 and 2.3 L BAS 701 00 F/ha as simulated plateau concentration (1st application) and 1.60, 2.0 and 2.0 L BAS 701 00 F/ha as the annual application rate (2nd application).

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test species: Naturally occurring non-target soil organisms.

Test site: Arable crop site in Rossdorf (Darmstadt-Dieburg), Germany; total size about 2500 m^2, the site had not received chemical application since May 2008 and none was applied during the study apart from the test item.

Test design: Randomized block design with four treatments (3 test item groups, water treated control) and six replicates each treatment. Exposure via an incorporated long-term plateau concentration in the upper 10 cm of soil and an application of the annual rate on the soil surface. Within the plots (5 x 6 m plot size) the litter bags were randomly distributed in the upper soil layer (depth of about 5 cm). The treatments were assigned randomly to the plots within each replicate. The substances in all treatments were applied in a water volume equivalent to 400 L/ha. Application was performed using a movable single-tank-sprayer with a distance between nozzles and plants of 0.5 m. Immediately after the 2nd application the test site was irrigated with 10.5 mm.

Endpoints: Mean weight loss based on ash-free dry weight per plot per treatment.

Test rates: Treatment group 1: Untreated control
Treatment group 2: 1.15 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 1.6 L BAS 701 00 F/ha
Treatment group 3: 1.15 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 2.0 L BAS 701 00 F/ha
Treatment group 4: 2.30 L BAS 701 00 F/ha (incorporated in the soil at 10 cm) + 2.0 L BAS 701 00 F/ha

Treatment group	BAS 701 00 F [L/ha]	fluxapyroxad* [mg a.s./kg dry soil]	epoxiconazole * [mg a.s./kg dry soil]
1st application			
2	1.15	0.048	0.048
3	1.15	0.048	0.048
4	2.30	0.096	0.096

* considering a soil depth of 10 cm and a default soil density of 1.5 g/cm³.

Treatment group	BAS 701 00 F [L/ha]	fluxapyroxad [g/ha]	epoxiconazole [g/ha]
2nd application			
2	1.6	100	100
3	2.0	125	125
4	2.0	125	125

The amount of fluxapyroxad is calculated based on the nominal content of a.s.

Application dates: 1st application: 23.04.2009
Burying of litter bags: 06.05.2009
2nd application: 08.05.2009

Test conditions: Natural field conditions; clayey silt/silty loam according to DIN 4220, 1.1% - 1.2% total organic carbon, pH 6.4 - 7.1. Air temperature: 9.6 to 19.6 °C, soil temperature: -11.3 - 19.8 °C, total precipitation per month: 12.6 - 110.2 L/m².

Litter bags: Litter bags consisted of mesh material (100% polyester) with a mesh size of about 8 mm. The size of a bag was about 12 x 20 cm. Bags were filled with about 4.0 g (dry weight) of untreated dried wheat straw. Litter-bags were horizontally buried at a depth of about 5 cm, 13 days after incorporation of the plateau concentration and 1 day before application of the annual rate of BAS 701 00 F at 08.05.2009.

Sampling dates: 1st sampling: 05.06.2009 (after 30 days of exposure)
2nd sampling: 07.08.2009 (after 93 days of exposure)
3rd sampling: 05.11.2009 (after 183 days of exposure)

Sample processing: Sampling was done at three different time intervals (30, 93 and 183 days of exposure). 8 bags were sampled per replicate per sampling date (48 bags per treatment), immediately transported to the laboratory and stored deep frozen until further processing. The enclosed straw material was cleaned and the bag content was oven-dried at 35 °C for 12 hours and weighted. Finally, the straw was ashed at 600 °C for 0.5 hours and ash-free weight was determined.

Analytics: Soil samples were only analyzed for the active substance fluxapyroxad according to the analytical method L0092/02.

Statistics: Descriptive statistics, Dunnett-t test ($\alpha = 0.05$).

RESULTS AND DISCUSSION

Recovery rates for the active substance fluxapyroxad after the 1st application ranged from 81% - 91% of the expected soil concentration, and from 80% and 85% after the 2nd application.

The mass loss of the straw material in the untreated control was 75.5% at the end of the experiment after 183 days.

In treatment group exposing the soil to 1.15 + 1.60 L BAS 701 00 F/ha, the mean mass losses after the exposure phases of about 1, 3 and 6 months were only slightly different from those in the control, resulting in effects of -4.1%, -7.2% and -2.0%. There were no statistically significant differences between this treatment group and the water treated control (Dunnett t-test, $\alpha = 0.05$).

In treatment group exposing the soil to 1.15 + 2.0 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1, 3 and 6 months were only slightly different from those in the control resulting in effects of -10.7%, -4.5% and -3.3%. There were no statistically significant differences between this treatment group and the water treated control (Dunnett t-test, $\alpha = 0.05$).

In treatment group exposing the soil to 2.0 + 2.3 L BAS 701 00 F/ha, the mean mass loss after the exposure phase of about 1, 3 and 6 months were only slightly different from those in the control resulting in effects of +0.7%, -7.9% and -0.9%. There were no statistically significant differences between this treatment group and the water treated control (Dunnett t-test, $\alpha = 0.05$).

Effects of the treatments on the degradation of buried wheat straw are summarized in Table 10.6.7-5.

Table 10.6.7-4 Mass loss [%] of wheat straw following exposure to BAS 701 00 F

Treatment	Mean mass loss [%]		
	Sampling 1	Sampling 2	Sampling 3
Control	20.8	57.0	75.5
1.15 + 1.60 L BAS 701 00 F/ha, % effect (mass loss)	19.9 (-4.1 n.s.)	52.9 (-7.2 n.s.)	74.0 (-2.0 n.s.)
1.15 + 2.0 L BAS 701 00 F/ha % effect (mass loss)	18.6 (-10.7 n.s.)	54.4 (-4.5 n.s.)	73.0 (-3.3 n.s.)
2.30 + 2.0 L BAS 701 00 F/ha % effect (mass loss)	20.9 (+0.7 n.s.)	52.5 (-7.9 n.s.)	74.8 (-0.9 n.s.)

n.s. = not statistically significant differences compared to the control (Dunnett t-test, $\alpha = 0.05$)

CONCLUSION

The results of this field study with BAS 701 00 F in a 183-day monitoring program on an arable field site emphasize that BAS 701 00 F proved to have no treatment-related ecologically relevant effects on the organic matter breakdown at the application scenario of 1.15, 1.15 and 2.3 L BAS 701 00 F/ha as simulated plateau concentration (1st application) and 1.60, 2.0 and 2.0 L BAS 701 00 F/ha as the annual application rate (2nd application).

KPC 10.5 Effects on soil nitrogen transformation

Report:	**10.7.1/1, Schulz L., 2009(b)**
Title:	Effects of BAS 701 00 F on the activity of soil microflora (Carbon transformation test)
Document No:	BASF DocID 2009/1004146
Guidelines:	OECD 217 (2000)
GLP	Yes

Executive Summary

In a soil microbial activity study, the effects of BAS 701 00 F on the carbon transformation were investigated in a loamy sand soil. BAS 701 00 F was applied to samples of the soil at nominal concentrations of 2.77 and 27.65 mg/kg dry soil. Triplicate samples of each treatment were removed for analysis of carbon transformation (oxygen consumption) 7, 14 and 28 days after application.

No significant influences of BAS 701 00 F on the carbon transformation were observed after 28 days, only slight deviations from the control of +1.9% and +4.1% were measured at the concentrations of 2.77 and 27.65 mg/kg dry soil.

Based on the results of this study, BAS 701 00 F caused no short-term and no long-term effects on the carbon transformation (measured as oxygen consumption) in a loamy sand field soil tested up to a concentration of 27.65 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm^3.

Test soil: Biologically active agricultural soil: loamy sand soil (according to DIN 4220); pH 6.8, 1.44% Corg and 38.41% WHC.

Test design: Determination of carbon-transformation (O_2-consumption) in soil after addition of glucose resulting in a soil concentration of 0.6%. Three treatment groups were set up (one untreated control group and two concentrations of the test item) with three replicates per treatment. The O_2-consumption was measured using a "BSB-digi" respirometer system over a period of 12 hours at different sampling intervals. Sampling scheme: 0, 7, 14 and 28 days after treatment, sub-samples were withdrawn from the bulk batches and subjected to measurement.

Endpoints: Effects on O_2 consumption after 28 days of exposure.

Test concentrations: Control, 2.77 mg BAS 701 00 F/kg dry soil (corresponding to 0.17 mg fluxapyroxad/kg dry soil and 0.17 mg epoxiconazole/kg dry soil) and 27.65 mg BAS 701 00 F/kg dry soil (corresponding to 1.67 mg fluxapyroxad/kg dry soil and 1.67 mg epoxiconazole/kg dry soil). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm^3.

Reference item: Dinoterb (purity: 98% ± 0.5%). The reference item was tested in a separate study at rates of 6.8, 16.0 and 27.0 mg Dinoterb/kg dry soil.

Test conditions: Soil moisture: 42.27% - 44.78% of its water holding capacity; corresponding to a water content of 16.24%- 17.20%, pH 6.8. Soil samples were incubated at 19.4 °C - 21.5 °C during the study.

Statistics: Descriptive statistics.

RESULTS AND DISCUSSION

No significant influences of BAS 701 00 F on the carbon transformation were observed after 28 days, only slight deviations from the control of +1.9% and +4.1% were measured at the concentrations of 2.77 and 27.65 mg/kg dry soil. The results are summarized in Table 10.7.1-1.

Table 10.7.1-1: Effects of BAS 701 00 F on soil micro-organisms (carbon transformation)

Soil (days)	Control	2.77 mg BAS 701 00 F per kg dry soil		27.65 mg BAS 701 00 F per kg dry soil	
	O_2 Consumption [mg/kg dry soil/h]	O_2 Consumption [mg/kg dry soil/h]	% Deviation from the Control [1)]	O_2 Consumption [mg/kg dry soil/h]	% Deviation from the Control [1)]
Loamy sand soil (7 d)	8.76	8.84	+0.9	9.12	+4.1
Loamy sand soil (14 d)	8.64	8.83	+2.1	9.13	+5.6
Loamy sand soil (28 d)	8.01	8.16	+1.9	8.34	+4.1

[1)] Based on O_2 consumption - = inhibition; + = stimulation

In a separate study the reference item Dinoterb caused effects on the C-transformation of -28.8%, -42.1% and -46.9% at test concentrations of 6.8, 16.0 and 27.0 mg Dinoterb/kg dry soil, respectively.

CONCLUSION

Based on the results of this study, BAS 701 00 F caused no short-term and no long-term effects on the carbon transformation (measured as oxygen consumption) in a loamy sand field soil tested up to a concentration of 27.65 mg BAS 701 00 F/kg dry soil.

Report:	10.7.1/2, Schulz L., 2009(c)
Title:	Effects of BAS 701 00 F on the activity of soil microflora (Nitrogen transformation test)
Document No:	BASF DocID 2009/1004147
Guidelines:	OECD 216 (2000)
GLP	Yes

Executive Summary

In a soil microbial activity study, the effects of BAS 701 00 F on the nitrogen transformation were investigated in a loamy sand soil. BAS 701 00 F was applied to samples of the soil at nominal concentrations of 2.77 and 27.65 mg/kg dry soil. Triplicate samples of each treatment were removed for analysis of nitrogen content 0, 7, 14 and 28 days after application.

No significant influences of BAS 701 00 F on the nitrogen transformation were observed after 28 days, only slight deviations from the control of +1.6% and +1.6% were measured at the concentrations of 2.77 and 27.65 mg/kg dry soil.

Based on the results of this study, BAS 701 00 F caused no short-term and no long-term effects on the soil nitrogen transformation (measured as NO_3-N production) in a loamy sand field soil tested up to a concentration of 27.65 mg BAS 701 00 F/kg dry soil.

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch no. 204438; content of a.s.: fluxapyroxad (BAS 700 F, Reg. no. 5 094 351): 62.4 g/L (nominal: 62.5 g/L); epoxiconazole (BAS 480 F, Reg. no. 205 259): 62.7 g/L (nominal: 62.5 g/L); density: 1.037 g/cm3.

Test soil: Biologically active agricultural soil: loamy sand soil (according to DIN 4220); pH 6.8, 1.44% Corg and 38.41% WHC.

Test design: Determination of the N-transformation (NO_3-nitrogen production) in soil enriched with lucerne meal resulting in a soil concentration of 0.5%. Three treatment groups were set up (one untreated control group and two concentrations of the test item) with three replicates per treatment. NH4-nitrogen formed from organically bound nitrogen in the soil and NO_3-nitrogen from the nitrification process was determined using an Autoanalyzer II (Bran and Luebbe). Sampling scheme: 0, 7, 14 and 28 days after treatment. Sub-samples were withdrawn from the bulk batches and subjected to measurement.

Endpoints: Effects on NO_3-nitrogen production after 28 days of exposure.

Reference item: Dinoterb (purity: 98% ± 0.5%). The reference item was tested in a separate study at rates of 6.8, 16.0 and 27.0 mg Dinoterb/kg dry soil.

Test concentrations: Control, 2.77 mg BAS 701 00 F/kg dry soil (corresponding to 0.17 mg fluxapyroxad/kg dry soil and 0.17 mg epoxiconazole/kg dry soil) and 27.65 mg BAS 701 00 F/kg dry soil (corresponding to 1.67 mg fluxapyroxad/kg dry soil and 1.67 mg epoxiconazole/kg dry soil). Test concentrations related to a soil depth of 5 cm and a soil density of 1.5 g/cm3.

Test conditions: Soil moisture: 41.22% - 43.08% of its water holding capacity; corresponding to a water content of 15.83% - 16.55%, pH 6.7 - 6.8. Soil samples were incubated at 19.4 °C - 21.5 °C during the study.

Statistics: Descriptive statistics.

RESULTS AND DISCUSSION

No significant influences of BAS 701 00 F on the nitrogen transformation were observed after 28 days, only slight deviations from the control of +1.6% and +1.6% were measured at the concentrations of 2.77 and 27.65 mg/kg dry soil. The results are summarized in Table 10.7.1-2.

Table 10.7.1-2: Effects of BAS 701 00 F on soil micro-organisms (nitrogen transformation)

Soil (days)	Control	2.77 mg BAS 701 00 F per kg dry soil		27.65 mg BAS 701 00 F per kg dry soil	
	NO_3-N [mg/kg dry soil]	NO_3-N [mg/kg dry soil]	% Deviation from the Control [1)]	NO_3-N [mg/kg dry soil]	% Deviation from the Control [1)]
Loamy sand soil (7 d)	21.1	21.5	+1.9	26.3	+24.5
Loamy sand soil (14 d)	23.6	24.1	+2.1	27.3	+16.0
Loamy sand soil (28 d)	33.0	33.5	+1.6	33.5	+1.6

[1)] Based on NO_3-nitrogen production; - = inhibition; + = stimulation

In a separate study the reference item Dinoterb caused effects on the N-transformation of +18.8%, +37.9% and +48.3% at test concentrations of 6.8, 16.0 and 27.0 mg Dinoterb/kg dry soil, respectively.

CONCLUSION

Based on the results of this study, BAS 701 00 F caused no short-term and no long-term effects on the soil nitrogen transformation (measured as NO_3-N production) in a loamy sand field soil tested up to a concentration of 27.65 mg BAS 701 00 F/kg dry soil.

KPC 10.6 Effects on terrestrial non-target higher plants

Report:	**10.8.1.3/1, Stroemel C., Teresiak H., 2009(a)**
Title:	Effect of BAS 701 00 F on seedling emergence and seedling growth of six species of terrestrial plants
Document No:	BASF DocID 2009/1089827
Guidelines:	OECD 208 (2006) - Seedling Emergence and Seedling Growth Test
GLP	No

Executive Summary

In a multiple dose test the phytotoxic potential of BAS 701 00 F on six terrestrial plant species (non-target plants) was evaluated. BAS 701 00 F was applied pre-emergence at test rates of 0.5, 1.0 and 2.0 L/ha. The application was done using a laboratory spray cabin, which simulated an application in agricultural practice.
Following the application the plants were cultivated for 21 days (for carrot and onion: 28 ays) under greenhouse conditions. Assessments for phytotoxicity were done 7 and 21 days (for carrot and onion: 14 and 28 days) after application (DAA). Fresh weight was determined at study termination 21 DAA (for carrot and onion: 28 DAA).
After treatment with BAS 701 00 F, all plant species had reached the 50% emergence rate after 7 days except carrots and onion (14 days). In none of the tested plant species seedling emergence was adversely affected by the application of BAS 701 00 F up to 2.0 L/ha. None of the tested plant species showed phytotoxic symptoms after use of up to 2.0 L/ha pre-emergence. After treatment with BAS 701 00 F, no influence on plant fresh weight was observed in all tested plant species up to the highest tested rate of 2.0 L/ha.

The NOER based on fresh weight results was 2.0 L/ha BAS 701 00 F (250.0 g a.s./ha) for all tested species. For all tested species the ER_{50} (median effect rate) based on fresh weight results was higher than 2.0 L/ha (the highest rate tested).

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch No. 204437, content of a.s.: fluxapyroxad (BAS 700 F, Reg. No. 5094351): 62.5 g/L (nominal), epoxiconazole (BAS 480 F, Reg. No. 205259): 62.5 g/L (nominal).

Test species: Onion (*Allium cepa*), oats (*Avena sativa*), pea (*Pisum sativum*), carrot (*Daucus carota*), oilseed rape (*Brassica napus*), sunflower (*Helianthus annuus*).

Test design: Dose-response design; 4 treatments (3 test item rates, control); 4-6 replicates/ treatment, each replicate comprised one pot with 7 to 12 seeds each; greenhouse cultivation; BAS 701 00 F was applied pre-emergence shortly after seeding using a laboratory spray cabin at a water rate of 225 L/ha; assessments for plant damage were done 7 and 21 days (for carrot and onion: 14 and 28 days) after application (DAA);

fresh weight was determined at study termination 21 DAA (for carrot and onion: 28 DAA).

Endpoints: ER_{50}.

Test rates: Control, 0.5, 1.0 and 2.0 L/ha BAS 701 00 F (equivalent to 62.5, 125 and 250 g a.s./ha).

Test conditions: Temperatures between 19.7 °C and maximum 23.8 °C; humidity: 50.7% to 64.3%; photoperiod: 16 h light, 8 h dark.

Statistics: Descriptive statistics, ANOVA for plant biomass, survival, emergence.

RESULTS AND DISCUSSION

After treatment with BAS 701 00 F, all plant species had reached the 50% emergence rate after 7 days except carrots and onion (14 days). In none of the tested plant species seedling emergence was adversely affected by the application of BAS 701 00 F up to 2.0 L/ha.
None of the tested plant species showed phytotoxic symptoms after use of up to 2.0 L/ha pre-emergence. After treatment with BAS 701 00 F, no influence on plant fresh weight was observed in all tested plant species up to the highest tested rate of 2.0 L/ha. The results are summarized in Table 10.8.1.3-1.

Table 10.8.1.3-1: Effect of BAS 701 00 F on plant biomass and plant condition 21 DAA (28 DAA for carrot and onion)

Treatment [L/ha]	onion	oats	pea	carrot	rapeseed	sunflower
	Seedling emergence rate [%]					
control	73	100	97	90	98	97
0.5	81	100	97	77	94	97
1.0	79	100	94	81	96	100
2.0	75	100	94	83	90	100
	Mean plant weight [% of control]					
control	100	100	100	100	100	100
0.5	124.3	102.9	99.4	98.4	101.8	98.4
1.0	108.4	94.6	91.0	107.5	102.8	100.1
2.0	100.7	95.6	103.3	107.3	106.5	102.3
	Mean visible damage [% damage compared to control]					
control	0	0	0	0	0	0
0.5	0	0	0	0	0	0
1.0	0	0	0	0	0	0
2.0	0	0	0	0	0	0

No statistically significant differences compared to the control.

CONCLUSION

The NOER based on fresh weight results was 2.0 L/ha BAS 701 00 F (250.0 g a.s./ha) for all tested species. For all tested species the ER_{50} (median effect rate) based on fresh weight results was higher than 2.0 L/ha (the highest rate tested).

Report:	**10.8.1.2/1, Dutillie H., Sack D., 2009(a)**
Title:	BAS 701 00 F: Effects on non-target plants in the greenhouse - A multiple dose test
Document No:	BASF DocID 2009/1067188
Guidelines:	OECD 227 July 2006
GLP	No

Executive Summary

In a multiple dose test the phytotoxic potential of BAS 701 00 F on six terrestrial plant species (non-target plants) was evaluated. BAS 701 00 F was applied post-emergence at growth stage BBCH 12 – 14 at test rates of 0.5, 1.0 and 2.0 L/ha. The application was done using a laboratory spray cabin, which simulated an application in agricultural practice. Following the application the plants were cultivated for 20 days under greenhouse conditions. Assessments for phytotoxicity were done 7 and 20 days after application (DAA). Fresh weight was determined at study termination (20 DAA).

After treatment with BAS 701 00 F, no visible damage on plants was found in onion and oats. Slight visible damage was seen in carrot following treatment with 2.0 L BAS 701 00 F/ha. Pea, oilseed rape and sunflower showed visible damage in all treatment rates with a maximum of 35% in sunflower.
After treatment with BAS 701 00 F, statistically significant reductions in plant biomass were only observed in sunflower with a maximum reduction of 31%.

The NOAER based on visible damages was 2.0 L/ha BAS 701 00 F (250 g a.s./ha) for onion and oats, 1.0 L/ha BAS 701 00 F (125 g a.s./ha) for carrot and 0.5 L/ha BAS 701 00 F (62.5 g a.s./ha) for rapeseed. For pea and sunflower a NOAER could not be determined.
The NOAER based on fresh weight results was 2.0 L/ha BAS 701 00 F (250.0 g a.s./ha) for onion, oats, pea, carrot and rapeseed and 1.0 L/ha for sunflower.
For all tested species the ER_{50} (median effect rate) based on fresh weight results was higher than 2.0 L/ha (the highest rate tested).

MATERIAL AND METHODS

Test item: BAS 701 00 F, batch No. 204520, content of a.s.: fluxapyroxad (BAS 700 F, Reg. No. 5094351): 62.5 g/L (nominal), epoxiconazole (BAS 480 F, Reg. No. 205259): 62.5 g/L (nominal).

Test species: Onion (*Allium cepa*), oats (*Avena sativa*), pea (*Pisum sativum*), carrot (*Daucus carota*), oilseed rape (*Brassica napus*), sunflower (*Helianthus annuus*).

Test design: Dose-response design; 4 treatments (3 test item rates, control); 6 replicates/ treatment, 24 replicates/ control, each replicate comprised one pot with 1 to 5 plants each; greenhouse cultivation; BAS 701 00 F was applied post-emergence at growth stage BBCH 12 - 14 using a laboratory spray cabin at a water rate of 375 L/ha; assessments for plant damage were done 7 and 20 days after application (DAA); fresh weight was determined at study termination 20 DAA.

Endpoints: ER_{50}.

Test rates: Control, 0.5, 1.0 and 2.0 L/ha BAS 701 00 F (equivalent to 62.5, 125 and 250 g a.s./ha).

Test conditions: Temperatures between 14 °C and maximum 31 °C; humidity: about 80%; photoperiod: 16 h light, 8 h dark; additional light when outdoor illumination was less than 4500 lux.

Statistics: Calculation of mean values and standard deviations, ANOVA followed by Bonferroni t-Test for plant biomass.

RESULTS AND DISCUSSION

After treatment with BAS 701 00 F, no visible damage on plants was found in onion and oats. Slight visible damage was seen in carrot following treatment with 2.0 L BAS 701 00 F/ha. Pea, oilseed rape and sunflower showed visible damage in all treatment rates with a maximum of 35% in sunflower.
After treatment with BAS 701 00 F, statistically significant reductions in plant biomass were only observed in sunflower with a maximum reduction of 31% (Bonferroni t-Test; $\alpha = 0.05$). The results are summarized in Table 10.8.1.2-1.

Table 10.8.1.2-1: Effect of BAS 701 00 F on plant biomass and plant condition 20 DAA

Treatment [L/ha]	onion	oats	pea	carrot	rapeseed	sunflower
	Mean plant weight [% of control]					
control	100	100	100	100	100	100
0.5	99	101	93	98	97	75 *
1.0	103	104	108	89	104	88
2.0	86	95	95	84	97	69 *
	Mean visible damage [% damage compared to control]					
control	0	0	0	0	0	0
0.5	0	0	3	0	3	6
1.0	0	0	6	0	11	17
2.0	3	0	20	7	25	35

* Statistically significant differences compared to the control (Bonferroni t-Test, $\alpha = 0.05$)

CONCLUSION

The NOAER based on visible damages was 2.0 L/ha BAS 701 00 F (250 g a.s./ha) for onion and oats, 1.0 L/ha BAS 701 00 F (125 g a.s./ha) for carrot and 0.5 L/ha BAS 701 00 F (62.5 g a.s./ha) for rapeseed. For pea and sunflower a NOAER could not be determined.
The NOAER based on fresh weight results was 2.0 L/ha BAS 701 00 F (250.0 g a.s./ha) for onion, oats, pea, carrot and rapeseed and 1.0 L/ha for sunflower.

For all tested species the ER_{50} (median effect rate) based on fresh weight results was higher than 2.0 L/ha (the highest rate tested).

KPC 10.6.1 Summary of screening data

KPC 10.6.2 Testing on non-target plants

KPC 10.6.3 Extended laboratory studies on non-target plantsKPC 10.6.4

KPC 10.7 Effects on other terrestrial organisms (flora and fauna)

KPC 10.8 Monitoring data

Appendix 3: Table of Intended Uses justification and GAP tables

1	2	3	4	5	6	7	8	10	11
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application**	
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. ra per appl b) max. to rate per crop/seas
1	AT	Wheat, barley, rye, triticale	F	*Erysiphe graminis, Septoria spp. (only wheat and triticale), Puccinia spp., Drechslera tritici-repentis (only wheat), Pyrenophora teres (only barley), Rhynchosporium secalis (only barley and rye) Ramularia collo-cygni (only barley,) Decrease of non-parasitic leaf spots (only barley)*	spraying	spring BBCH 30 - 61	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**
2	AT	Wheat, barley, rye, triticale	F	*Pseudocercosporella herpotrichoides*	spraying	spring BBCH 30 - 32	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**
3	AT	Wheat, rye, triticale	F	*Puccinia recondita*	spraying	spring BBCH 30 – 69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**

4	BE	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**
5	CZ	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* (not triticale) *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-61	a) 1 b) 2 (21 days)	**a)** 2.0 **b)** 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**
7	IE, UK	Wheat, barley, rye, triticale, oats	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69 (malting barley 49)	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**
8	NL	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	31-69	a) 1 b) 2 (21 days)	a) 2.0 b) 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**

9	PL, SK	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	a) 1 b) 2 (21 days)	a) 1.33-2.0 b) 2.66-4.0	a) **0.166-0.250** 0.083-0.125* 0.083-0.125** b) **0.332-0.500** 0.166-0.250* 0.166-0.250**

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BE Blackwell, ISBN 3-8263-3152-4), in application
(k) The minimum and maximum num must be provided
(l) PHI - minimum pre-harvest interva
(m) Remarks may include: Extent of us

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **BAS-701000-FW-0-EC (ADEXAR)**
Active Substances: **Fluxapyroxad: 62.5 g/l**
Epoxiconazole: 62.5 g/l

Central Zone
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM

Applicant: **BASF**
Date: **02 June 2017**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

Please refer to the core assessment part B section 6 for the central zone.

6.1 Effects on Birds

Please refer to the core assessment part B section 6 for the central zone.

6.2 Effects on Terrestrial Vertebrates Other Than Birds

Please refer to the core assessment part B section 6 for the central zone.

6.3 Effects on Aquatic Organisms

6.3.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.3.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.3-1: Ecotoxicological endpoints for aquatic species exposed to fluxapyroxad, epoxiconazole and ADEXAR (BAS 701 00F) with indication to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Lemna gibba	Fluxapyroxad (BAS700F)	7 d static	ErC_{50} > 3.425 mg/L **EyC_{50} = 2.19 mg/L**	Hoffmann F. 2009 BASF DocID 2009/1086122	79904
Lemna gibba	Epoxiconazole	7 d Static without sediment	E_rC_{50} = 0.0138 mg/L **E_yC_{50} = 0.0043 mg/** (biomass)	Hoffmann, F. 2006 269698	59124
		7 d Static with sediment	E_rC_{50} = 0.0663 mg/L **E_yC_{50} = 0.0252 mg/** (biomasse)		
Lemna gibba	ADEXAR (BAS 701 00F) batch 204438	7 d	ErC_{50} = 0.215 mg/L (dw) **EyC_{50} = 0.063 mg/L (dw)** (m.m of the test concentrations)	Hoffmann, F. 2009 2009/1098713 319805	73843

Mixture Toxicity

In the results of the ecotoxicological studies performed on aquatic plants the product ADEXAR (BAS-70100-F) show that the formulation does not cause any significant, unexpected (additional) toxicity. Therefore, it can be considered that the active substance epoxiconazole drives the toxicity of the formulated product ADEXAR (BAS-70100-F) for aquatic plants. The risk assessment will then be based on the endpoint of the active substance epoxiconazole (EyC_{50} = 4.3 µg/L; *Lemna gibba*) and its corresponding exposure.

6.3.1.2 Exposure

For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model DRIFTOX 4.0_a. Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.0. For details of the calculated PEC_{sw} values (i.a. input parameters for EXPOSIT and DRIFTOX) please refer to the national addendum part B, section 5.

6.3.1.3 Risk assessment –overall conclusions

6.3.2 Toxicity to Exposure ratio

The risk assessment for ADEXAR (BAS-70100-FW-0-EC), epoxiconazole and their metabolites was carried out following application according to the proposed uses. The initial risk assessments were carried out by comparing the initial maximum PEC_{SW} values with the acute and long-term toxicity endpoints. Based on all aquatic studies as well as the corresponding safety factors the relevant endpoint for the active ingredient epoxiconazole is E_bC_{50} = 0.0043 mg/L (*Lemna gibba).* Risk assessment is done only for those organisms because the endpoints devided by the corresponding safety factor for the other organisms are higher.

Since the applicant (BASF) submitted additional data on aquatic plants (a second test with *Lemna gibba* and a toxicity test with *Myrioplyllum aquaticum*), for the active substance epoxiconazole the safety factor for aquatic plants can be revised from 10 to 8.

An entry of the metabolite BF 480-entriazole into sediment cannot be excluded.
A sediment study with *Chironomus riparius* and epoxiconazole as well as BF 480-entriazole (NOEC = 0.03 mg/L) was carried out. The study with the active substance epoxiconazole results in a NOEC of 0.0625 mg/L indicating that sediment organism react more sensitive against the metabolite. Therefore a risk assessment will be conducted for sediment organisms with the metabolite BF 480-entriazole.
The maximal occurrence of the metabolite BF 480-entriazole in sediment is 32.3% at day 59.
A DT_{50} sediment of 65.2 days was used to calculate the accumulation factor of BF 480-entriazole in sediment.

6.3.2.1 TER: Entry pathway spray drift and volatilization/deposition (IIIA1 10.2.1)

The vapour pressures at 20 °C of the active substances fluxapyroxad and epoxiconazole are < 10^{-5} Pa. Hence the active substances fluxapyroxad and epoxiconazole are regarded as non-volatile. Therefore exposure of surface water by the active substances fluxapyroxad and epoxiconazole due to deposition following volatilization does not need to be considered.

The calculation of PECsw and TER after exposure via spray drift is performed using the model DRIFTOX 4.0. Results are summarized in the following table (TER values in bold are above the trigger).

active substance		epoxiconazole					
use pattern/gap:		A					
application rate/number of applications / interval		2 x 125 g a.i./ha, 21 d					
$DissT_{50}$ (SFO) in water		59.8 d					
relevant PEC		PECact					
scenario/percentile:		Agriculture/82th					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	90% red.	75% red.	50% red.
0	100.00	74.331	-	-	74.33	-	-	-
1	2.38	1.769	-	-	1.840	0.18	0.46	0.92
5	0.47	0.349	-	-	0.363	0.04	0.09	0.18
10	0.24	0.178	-	-	0.186	0.02	0.05	0.09
15	0.16	0.119	-	-	0.124	0.01	0.03	0.06
20	0.12	0.089	-	-	0.093	0.01	0.02	0.05
Endpoint:		E_bC_{50} = 0.0043 mg/L						
TER risk assessment trigger:		8						
Buffer zone [m]					TER			
0					0.1	-	-	-
1					**2**	23	9	**5**
5					12	118	47	24
10					23	232	93	46
15					35	348	139	70
20					46	464	185	93
Risk mitigation measures :		NW 605-1 (50%; 5m) NW 606 (5m)						

The TER values are greater than the Annex VI trigger value of 8 for all intended uses under consideration of risk mitigation measures (drift reduction and/or buffer zone). This indicates that the active substance epoxiconazole contained in ADEXAR (BAS-70100-FW-0-EC) poses an acceptable long-term risk to aquatic organisms following application of ADEXAR (BAS-70100-FW-0-EC) at the proposed application rates.

6.3.2.1 TER: Entry pathway run-off and drainage

Surface water exposure via surface run-off and drainage is estimated using the model EXPOSIT 3.01. (see also section 5 NA chapter 5.6.2). The parameters for epoxiconazole used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01, as well as the calculated PECsw and TER values after exposure via run-off and drainage for the intended uses of ADEXAR (BAS-70100-FW-0-EC) are summarized in the following tables (TER values in bold are below the trigger).

Table 6.3-2: TER values of epoxiconazole in an adjacent ditch due to surface run-off and drainage for spring and winter cereals

Active substance:	Epoxiconazole	
Use pattern/GAP:	A	
Application rate/Interval/Interception:	2 x 125 g a.s./ha, 70 % and 90% interception	
Endpoint:	E_yC_{50} = 0.0043 mg/L	
TER risk assessment trigger:	8	
Entry pathway run-off		
Buffer zone [m]	PECsw [µg/L]	TER
0	0.24	18
5	0.21	21
10	0.18	24
20	0.13	34
Entry pathway drainage		
Time of application	PECsw [µg/L]	TER
autumn/winter/early spring	0.45	10
Spring/summer	0.15	29
Risk mitigation measures :	none	

The TER values are greater than the Annex VI trigger value of 10 for all intended uses. This indicates that the active substance epoxiconazole contained in ADEXAR (BAS-70100-FW-0-EC) poses an acceptable long-term risk to aquatic organisms following application of ADEXAR (BAS-70100-FW-0-EC) at the proposed application rates.

6.3.2.2 TER: Entry pathway into sediment

An entry of the metabolite BF 480-entriazole into sediment cannot be excluded. Therefore, in order to assess the potential risk of ADEXAR (BAS-70100-FW-0-EC) to sediment organism, the predicted environmental concentration of the metabolite BF 480-entriazole in sediment is compared to the toxicity endpoint according to the following formula:

$$PEC_{sed}(t) = \frac{PEC_{ini,SW} \times V_{OFG} \times P_{sed}(t)}{V_{sed} \times bd_{sed}}$$

PECini,SW	initial concentration in SW (in µg/L)
VOFG	water volume (300 L)
Psed (t) %	accumulation of the a.s. in sediment
Vsed	volume of the sediment for a sediment depth of 1 cm and a Koc > 500 (10 L)
bdsed	density of the humid sediment (bulk density) (1.3 kg/L)

The maximal plateau concentration PECsed,accu,max has been calculated with a Single First Order model according to the following formula:

$$PEC_{sed,accu,max} = PEC_{sed,max} + PEC_{sed,max} \times \frac{e^{-kt}}{1 - e^{-kt}}$$

PECsed,accu, max	Plateau concentration in sediment
PECsed,max	maximal annual concentration in sediment
k	$k = \ln(2)/DT_{50}$ with DT_{50},Sed. = 65.2 d
t	nominal interval between the single applications (365 d)

The factor for multiplying the maximum concentration in sediment to reach the plateau concentration of BF 480-entriazole in sediment at steady state is 0.02 (DT_{50} = 62.5 d).
The sediment study conducted with *Chironomus riparius* and the sediment metabolite BF 480-entriazole results in a NOEC = 30µg/kg.

The resulting TER values are summarized in the following table showing the results from EVA3_rev1 (TER values in bold are above the trigger)

active substance	BF 480-entriazole			
use pattern/gap:	A			
$DissT_{50}$ (SFO) in sediment	62.5 d			
Accumulation factor	-			
Distance (m)	PECsed,accu,max (µg/kg) depending on application technique (drift reduction)			
	common	50% red.	75% red.	90% red.
1	3.286	1.643	0.822	0.329
5	0.649	0.324	0.162	0.065
10	0.331	0.166	0.083	0.033
15	0.221	0.110	0.055	0.022
20	0.166	0.083	0.041	0.017
Endpoint:	NOEC = 0.03 mg/L (*Chironomus riparius)*			
TER risk assessment trigger:	10			
Buffer zone [m]	TER_{sed}			
0	0			
1	9	**18**	**37**	**91**
5	**46**	**93**	**185**	**462**
10	**91**	**181**	**362**	**905**
15	**136**	**272**	**543**	**1358**
20	**181**	**362**	**724**	**1811**
Risk mitigation measures:	**NW 609 (0% red. - 5m buffer zone)**			

The TER_{sed} values are greater than the Annex VI trigger value of 10 for all intended uses under consideration of risk mitigation measures (NW609). This indicates that the active substance epoxiconazole contained in ADEXAR (BAS-70100-FW-0-EC) poses an acceptable long-term risk to aquatic organisms following application of ADEXAR (BAS-70100-FW-0-EC) at the proposed application rates.

6.3.3 Acute toxicity and chronic toxicity of the formulation

Please refer to the core assessment part B section 6 for the central zone.

6.3.4 Metabolites of fluxapyroxad and epoxiconazole

Please refer to the core assessment part B section 6 for the central zone.

6.3.5 Accumulation in aquatic non-target organisms

Please refer to the core assessment part B section 6 for the central zone.

6.4 Effects on Bees

- Please refer to the core assessment.

6.5 Effects on Arthropods Other Than Bees

Please refer to the core assessment part B section 6 for the central zone (section 6.6.2.2, TER approach).

6.6 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.6.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.6.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

Species	**Substance**	**Duration**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Chronic toxicity (Field study)					
Collembola	Pyraclostrobin (81.4 g/L) Fluxapyroxad (50.2 g/L) Epoxiconazole (49.0 g/L) (analysed)	85 days	NOEC > 10 L BAS70200 F /ha	Schabio & Eichler 2013 BASF DoclD 2012/1143242	Appendi 5292

6.6.1.2 Exposure

In accordance with national guidance (Füll, 2003)1 a reduced thickness of the soil layer of 2.5 cm may be considered for substances with Koc-values below 500 mL/g. A soil depth of 1 cm is considered additionally for substances with Koc-values above 500 mL/g.

The average Koc-values of fluxapyroxad and epoxiconazole are above 500 mL/g. Thus, PECsoil of fluxapyroxad and epoxiconazole are calculated for a soil layer of 1 cm (see Part B, Section 5 of the Part B, National Addendum Germany).

Due to the slow degradation of the active substances fluxapyroxad and epoxiconazole in soil (DT_{90} > 365 d, SFO, laboratory and field data) their accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}).

[1] Füll, C.; Schulte, C.; Kula C. (2003): *Assessment of effects of plant protection products on earthworms.* Umweltwissenschaften und Schadstoff-Forschung 15.2: 78-84

For full details of the calculation see Part B, Section 5 of the National Addendum. The resulting initial PECsoil value is given in the table below.

Table 6.6-1: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

plant protection product:	BAS 701 00F					
use:	A					
Number of applications/intervall	2/ 21					
application rate:	125 g a.i./ha					
crop interception:	70%/ 90%					
active substance/ formulation		**soil depth$_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Fluxapyroxad		1	0.288 on d21	20	0.0148	0.3028
Metabolite M700F001	Ff=100%	2.5	0.0046	20	0.0006	0.0052
Metabolite M700F002	Ff=100%	2.5	0.0091 on d49	20	0.0013	0.0104
Epoxiconazole		1	0.3177 on d21	20	0.0077	0.3254
Metabolite 1,2,4-Triazole	Ff=100%	2.5	0.0056 on d383	20	0.0015	0.0071
BAS 701 00F/ Adexar	2.072 kg/ha	1	4.1440	20	0.0379 0.0225 (sum of a.s.)	4.1819 0.6282 (sum of a.s.)

The epoxiconazole metabolite 1,2,4-triazole was formed in concentrations <10 % TAR at the end of the study in the soil (see although section 5, Part 9.1).

6.6.1.3 Risk assessment –TER values and overall conclusions

The risk assessment according to the German Federal Environment Agency (Füll et al. 2003) is presented below. Due to the slow degradation of the active substances fluxapyroxad and epoxiconazole in soil (DT_{90} > 365 d, SFO, laboratory and field data) the accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}).

The risk assessment results are summarized in the following table:

Table 6.6-2: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of ADEXAR (BAS-70100-FW-0-EC) according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PECaccu (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Acute	LC_{50} = 341.7 mg Product/kg soil dw (= 41.07 sum of a.s.)	4.1819 0.6282	= 82 = 65	10
		Long-term	NOEC= 87.9 mg Product/kg soil dw (= 10.56 sum of a.s.)		= 21 =17	5
Fluxapyroxad Metabolite M700F001	Formation fraction 100%	Acute	LC_{50} > 1000	0.0052	> 1000	10
		Long-term	NOEC ≥ 5.33		> 1000	5
Fluxapyroxad Metabolite M700F002	Formation fraction 100%	Acute	LC_{50} > 1000	0.0104	> 1000	10
		Long-term	NOEC ≥ 2.56		> 246	5
Epoxiconazol Metabolite 1,2,4-Triazole	Formation fraction 100%	Acute	LC_{50} > 1000	0.0071	> 1000	10
		Long-term	NOEC = 0.0708		9.97	5
Other soil meso-and macrofauna						
Collembola (*Folsomia candida*)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Acute	-	4.1819 0.6282	-	10
		Long-term	NOEC = 12.5 (1.6 mg sum of a.s.) *Folsomia candida*		**2.99 2.5**	5
Fluxapyroxad Metabolite M700F002	Formation fraction 100%	Acute	-	0.0104	-	10
		Long-term	NOEC ≥ 1000		> 1000	5
Epoxiconazol Metabolite 1,2,4-Triazole	Formation fraction 100%	Acute	-	0.0071	-	10
		Long-term	NOEC = 1.8		254	5
Field study (collembola)						

BAS 70200 F Pyraclostrobin (81.4 g/L) Fluxapyroxad (50.2 g/L) Epoxiconazole (49.0 g/L) (analysed	2x 2L Adexar/ha (2 x 2.072 kg/ha; 2x 2x 62.5 g =250 g Epoxiconazole/ha and 2 x 2x 62.5 g = 250 g Fluxapyroxad/ha)	Long-term	NOEC > 10 L BAS 70200 F /ha (10 x 49.0 = 490 g Epoxiconazole/ha and 10 x 50.2 =502 g Pyraclostrobin/ha)	2x 2L Adexar/ha (2 x 2.072 kg/ha; 2x 2x 62.5 g =250 g Epoxiconazole/ ha and 2 x 2x 62.5 g = 250 g Fluxapyroxad/ ha)	> 1	1
Mites (*Hypoaspis aculeifer*)						
Adexar / BAS 701 00F	2x 2L product/ha	Acute	-	4.1819 0.6282		10
	(2 x 2.072 kg/ha)	Long-term	NOEC > 500 (>60.2 sum a.s.)		> 119 > 95	5
Organic matter breakdown (all organisms)						
Adexar / BAS 701 00F	2x 2L product/ha (2 x 2.072 kg/ha)	Long-term	10 L formulation (625 g a.s): < 25 % effect	2x 2L product/ha	> 1	
TER values in bold are below the trigger						

Based on the predicted concentrations of ADEXAR (BAS-70100-FW-0-EC) in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) achieve the acceptability criteria TER ≥ 10, but the longterm risk for other non-target soil organisms following exposure to ADEXAR (BAS-70100-FW-0-EC) according to the GAP of the formulation ADEXAR (BAS-70100-FW-0-EC) does not achieve the acceptability criteria TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an unacceptable longterm risk for not-target soil organisms due to the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label. Further refinement is required.

Litter Bag

To assess potential effects of the exposure of ADEXAR (BAS-70100-FW-0-EC) on the breakdown of organic matter by soil organisms, two litter bag studies were carried out with ADEXAR (BAS 701 00 F). The first study (ICS-Nr 73862) was reported in the DAR and the EFSA Journal. The second study (ICS-Nr. 73863) was performed after submission of the EU Dossier for BAS 700 F for Annex I inclusion. For a summary, please refer to the core assessment.

The application rates applied in these studies reflected the worst-case recommended GAP in cereals, however, in the study performed with the higher application rates, clear increases in litter bags

degradation were observed. Although these biological effects were significantly smaller than 25%, they were clearly concentration dependant.
In agreement with current risk assessment according to the European Guidance Document on Terrestrial Ecotoxicology, the risk to soil macro-organisms following the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals according to the label can be considered as acceptable.

However, according to the concept developed by the federal environmental agency UBA and other European assessment authorities, as well as according to other scientific opinions (e.g. “Panel on Pesticides and their Residues” of the European Food Safety Authority EFSA), it is questionable whether ecotoxicological endpoints resulting from tests performed on ecological functions/processes (e.g. organic matter breakdown) can address adverse effects occurring at the structural level (e.g. biological effects observed at the species level).

Following a request of the zRMS DE, a higher assessment was submitted by the applicant, in order to address the possible long-term effects on soil macro-organisms populations (especially Collembola) at the expected plateau concentrations of epoxiconazole and fluxapyroxad in soils following the intended use of ADEXAR (BAS-70100-FW-0-EC) in cereals.

Two generation study with Collembola

Please refer to the Annex II of the Core Assessment for the detailed evaluation of the presented study in novel design (10.6.6/3, Royer, S (2013): Effect of BAS 701 00 F on the reproduction of different generations of the Collembola Folsomia candida (multi generation study).

Field Study with Collembola

The notifier submitted a higher tier study on Collembola (Schabio & Eichler, 2013).
In their report “BASF DoclD 2012/1143242”, Schabio and Eichler present the results of a survey designed in 2013 to investigate the effects of BAS 702 00 F on soil Collembola under field conditions. The trial was run in Groß Zimmern, near Dieburg Germany. The test item BAS 702 00 F (81.4 g/*L* Pyraclostrobin (BAS 500 F), 50.2 g/L Fluxapyroxad (BAS 700 F) and 49.0 g/L Epoxiconazole (BAS 480 F) was applied at two rates of 5.0 and 10.0 L/ha, corresponding to 407.0 and 814.0 g/ha Pyraclostrobin, 251.0 and 502.0 g/ha Fluxapyroxad and 245.0 and 490.0 g/ha Epoxiconazole on the soil surface. The correct application was confirmed by the residue analysis in soil samples taken after the application.

The test item is not “ADEXAR”, which is the product of the current dossier, but the rates applied in the study actually cover the intended use of ADEXAR in Germany (i.e. 2x2L/ha; i.e.250 g/ha Fluxapyroxad and 250 g/ha Epoxiconazole).

The study was set up as randomized block design with 4 treatment groups (control, rate 1, rate 2 and toxic reference). Sixteen plots, each 10 m x 10 m, were arranged in a 4 x 4 formation, each plot surrounded by at least a 3 m guard row between the plots. The treatments were randomly assigned to the plots within each replicate (4 replicates each).

The sampling dates were the following:

pre-treatment sampling	June 22 – June 23, 2012	performed 5-6 days before application
1st post treatment sampling	July 09, 2012	performed 11 days after application
2nd post treatment sampling	August 03, 2012	performed 1 month after application
3rd post treatment sampling	September 18 and 21, 2012	performed 2 months after application

The authors investigated pitfall traps (activity of soil surface dwelling arthropods) and core soil samples (endogeic species), the endpoints were the abundance and the community composition of Collembolan population and the abundance of individual species.

The authors discussed the results as following:

- <u>Total Collembolan abundance from the pitfall traps</u>
Pitfall traps were used to investigate the activity of soil surface dwelling arthropods. Collembolan abundance of the BAS 702 00 F treated plots was not statistically significantly different compared to the control. In the toxic reference group, the Collembolan abundance was statistically significantly reduced to 3.3 %, 3.7% and 6.2% of the control level at the 1st, 2nd and 3rd sampling after application.

- <u>Collembolan abundance in the soil cores:</u>
Based on the results of this study, no statistically significant effect on Collembolan abundance was seen as a result of BAS 702 00 F groups during 82 days after application in the soil cores.

- <u>Community composition of Collembolan populations:</u>
There were no relevant treatment-related effects caused by the test item according to the test on the first PRC. The only major effects were caused by the toxic reference. For the raw abundance data sets, the results of the permutation tests per sampling date indicated that the treatment regime had significant effect (p-value<0.05) on the community on the first sampling after application. In all other datasets for the later samplings, the treatment regime had no significant effect on all post treatment samplings. $NOEC_{community}$ is rate 2 (10 L/ha) for all datasets.

Collembolan community structure was not affected in the soil cores and 85 days after application in the pitfall traps.

The authors conclude that: "... exposure of Collembolan populations to a concentration of 10 L/ha BAS 702 00 F has no significant or ecologically relevant effects on Collembolan abundance during an 85 days trial".

Evaluation of the zRMS DE:

The main concern of the zRMS DE about the study of Schabio & Eichler (2013) is the **low abundance** of Collembola recorded in the study. This moderate abundance might be related to the choice of the sampling dates (i.e. late starting point of the study), or to the choice of study place and/or to the duration of the study. All these factors are of main importance in evaluating the reliability of the study addressing the risk of Collembola exposed to BAS 702 00 F.

The value of abundance of 31.476.6 ind./m² recorded in the control soil cores at the pre-treatment sampling date is lower but in the range of the normal mean values of abundance given for Central European crop sites (41.000 ind./m^2 and 4 species)[2]. However, from the 1st post-treatment sampling date on until the end of the study, the abundance recorded in the control strongly decrease and strongly deviate from the "normal mean values of abundance" expected for central Europe (cf Table 8, page 46 of the report).

For example, 1263 and 1565 animals were counted in June and July and only 214 and 182 were counted in August and September in the pitfall traps. This represents in average a decrease of about 85% of the soil surface -dwelling arthropods. A similar pattern was observed for the endogeic species counted in the core soil samples: 31476 and 23609 invidious per m² were counted in June and July and only 17261 and 18025 individuals per m² were counted in August and September (decrease of about 25%).

The authors argue that "this pattern confirms the results found in literature regarding the temporal and special dynamics of Collembolan populations", which is correct.
We agree with the authors that the temporal pattern of decrease of abundance in summer confirms some results found in literature regarding the temporal and spacial dynamics of Collembolan populations. For example, decrease of abundance correlates with the increasing soil temperature at the same sampling dates (cf figure 3, page 38 of the study) and mirrows the annual phenology of many collembolan species. However, since it was to be expected that the diversity and abundance of the soil arthropods will decrease

[2] Römbke *et al.* (2012) Erfassung und Analyse des Bodenzustands im Hinblick auf die Umsetzung und Weiterentwicklung der Nationalen Biodiversitätsstrategie. Report 33/2012 for the Federal Environmental Agency Dessau-Roßlau. http://www.uba.de/uba-info-medien/4312.html

over the summer month, the relevance of the choice of **the starting point** to conduct the study (early summer, 1st application on the 28th of June) is strongly questionable.

Independently of its origin, such a decrease in abundance poses a problem for further statistical analysis. Indeed, a reduction of the sampling size (i.e. number of Collembola recorded) might interfere with the **power of the statistic tests** to demonstrate significant effects, since effects are harder to detect in smaller samples with high natural variability of the enpoints. The first sampling date might be of satisfactory statistical accuracy in order to detect potential effects in the treated plots compared to the control. However, this 1st sampling date occurs already 9 days after application, and is therefore not relevant to address the time course of effects of the test item on the collembolan populations.

The last concern of the UBA is about the **short duration of the study**. The test item was applied on the 28th of June and the last sample was taken on the 18th of September, which represents only 3 months. It is regrettable that the study has been stopped before the second activity peak of Collembola usually occurring in autumn. Under these conditions, it is questionable if effects occurring on arthropods having a longer life-span could be address in this study design. There are however of most importance since the aim of this study was to address putative long-term effects of the test item on collembolan populations.

On the basis of the data presented in the report of Schabio & Eichler (2013) no effect of BAS 702 00 F on collembolan populations could be detected. However, (i) mainly because of the late start of the study, effects of BAS 702 00 F had to be expected in summer where populations of Collembola are at their minimal abundance, and (ii) because of the short duration of the study, which did not have taken into account the autumnal activity peak of the Collembola, the number of individuals recorded in the study was low. It is therefore questionable if the statics power of the tests used in the study and their suitability to determine significant effects from the control were justified.

It would have been more pertinent for the higher tier study and powerful for the statistics to design the survey earlier in the year (like in the intended use of the product, i.e. from BBCH stages 30) and to record the autumnal activity peak of Collembola to ensure that effects of BAS 702 00 F on juveniles of animals that have reproduced in the year after application were also assessed, which was actually the aim of this higher tier study.
However, in a weight of evidence approach it is considered that,

- firstly, the dosing in the study displayed much higher application rates as the intended uses of ‘Adexar’ (application rates approx doubled in the field study);
- secondly, the individual numbers in the first sampling date were fairly high, so that statistically significant effects on collembola abundance and on abundance of dominant species could in principle be detected;

- thirdly, effects on single species were detected at the first and second sampling date. One species was reduced at the third sampling date, but only in the lower application rate and not in the higher application rate;
- fourthly, the toxic reference had a statistically significant effects on collembola abundance and on single species (for some species detectable differences were found till the end of the experiment);
- fifthly, the application pattern of 'Adexar' according to the intended uses in the GAP of this application might well spam from beginning of April till Mai.

Therefore, irrespective of the examination of new information whenever these will become available, the risk for collembola community in the field after application of 'Adexar' according to the intended uses in the GAP of this application is considered acceptable in a weight of evidence approach.

6.7 Effects on Non-Target Plants

Please refer to the core assessment part B section 6 for the central zone

6.8 Other Non-Target Species (Flora and Fauna)

Not relevant.

6.9 Other/Special Studies

Not relevant.

REGISTRATION REPORT
Part B
Section 7: Efficacy Data and Information
Detailed Summary

Product Code: Adexar

Reg. No.: ZN1 026958-00/00

Active Substance:

Epoxiconazole (BAS 480 F) 62.5 g/L

Fluxapyroxad (BAS 700 F) 62.5 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF

2017

Date 02 June 2017

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

IIIA1 6.0 General information

The present Registration Report (RR) is prepared to support the registration of the fungicide Adexar for the control of fungal diseases in cereals in the Central Registration Zone (Zone B). Adexar is formulated as an emulsifiable concentrate (EC) and contains 62.5 g/L fluxapyroxad and 62.5 g/L epoxiconazole.

The application is a request for the first authorisation according to Art. 29 Reg. (EC) No 1107/2009. Germany (DE) is zonal rapporteur Member State (zRMS). Other member states are not concerned (Table 6.0-1).

Current document indicates the information related to the efficacy data of the plant protection product BAS 701 00 F containing the active substances fluxapyroxad and epoxiconazole. DE acts as the zonal rapporteur member state (Table 6.0-1).

Table 6.0-1: Zonal rapporteur member state (zRMS)

zRMS	Germany	DE

Recent registration situation/history of the PPP

BAS 701 00 F is a cereal fungicide. It is formulated as an emulsifiable concentrate (EC) and contains 62.5 g/L fluxapyroxad and 62.5 g/L epoxiconazole. The envisaged maximum individual application rate is 2.0 L/ha which would deliver 125 g/ha fluxapyroxad and epoxiconazole. BAS 701 00 F is a fungicide with a broad spectrum of activity against important leaf and ear diseases in wheat, barley, rye and triticale. It is already registered in several countries in Europe (Table 6-2).

Table 6.0-2: Existing registrations for BAS 701 00 F in cereal crops in Europe

Country	Trade name	Formulation		Authorisation No.	Registered rate	Crops
		Type	Conc.			
FRANCE	ADEXAR	EC	125.0 g/L	2110170	2.0 L/ha	Cereals
ITALY	ADEXAR	EC	125.0 g/L	015137	2.0 L/ha	Cereals
U.KINGDOM	ADEXAR	EC	125.0 g/L	15474	2.0 L/ha	Cereals
IRELAND	ADEXAR	EC	125.0 g/L	4324	2.0 L/ha	Cereals
AUSTRIA	ADEXAR	EC	125.0 g/L	3151/0	2.0 L/ha	Cereals
GERMANY	ADEXAR	EC	125.0 g/L	006958-00	2.0 L/ha	Cereals
BELGIUM	ADEXAR	EC	125.0 g/L	10119/B	2.0 L/ha	Cereals
NETHERLANDS	ADEXAR	EC	125.0 g/L	13978N	2.0 L/ha	Cereals
LUXEMBOURG	ADEXAR	EC	125.0 g/L	LO1886-042	2.0 L/ha	Cereals

Information on the active ingredients (Uptake and mode of action)

Fluxapyroxad (BAS 700 F)

Fluxapyroxad is a novel fungicidal active ingredient from the fungicidal group of succinate dehydrogenase inhibitors (SDHI). The biochemical mechanism of action of fluxapyroxad at the molecular level is based on inhibition of mitochondrial succinate dehydrogenase (SDH). The enzyme SDH forms part of the citric acid cycle, also known as the Krebs cycle. This enzyme, as so-called Complex II, also conducts electrons into the mitochondrial respiratory chain. During the process, the SDH oxidizes succinate to fumarate.

Fluxapyroxad acts against fungal stages both on and in the plant. After application to the plant (preferably by spraying), the active ingredient is taken up via the leaf and then translocated acropetally. In some crops, a systemic translocation of the active ingredient from lower to upper parts of the plant has been observed. After application, a part of the active ingredient taken up by the leaves moves to the opposite site of the leaf by translaminar translocation.

The main protective action of fluxapyroxad is to prevent not only the germination of spores landing on the leaves but also re-infection, since during these extremely energy-consuming phases fungi react very sensitively to disturbances of their mitochondrial respiratory chain. In addition, fluxapyroxad blocks germ tube elongation. Due to its ability to penetrate into the leaf and its good systemic translocation, it can also control fungal stages which have already become established in deeper tissue layers. Even later fungal stages can also be controlled by fluxapyroxad, which means that it has good curative efficacy. Fluxapyroxad also inhibits sporulation. With this mechanism of action is also puts a stop to the reproduction of pathogenic fungi.

Epoxiconazole (BAS 480 F)

Epoxiconazole is a triazole fungicide. A characteristic feature of epoxiconazole is its broad fungicidal efficacy against numerous cereal pathogens. The fungicidal action of epoxiconazole is based on an extremely effective inhibition of cytochrome P450-dependent sterol 14α-demethylase, an enzyme which takes part in the biosynthesis of ergosterol, an indispensable component of the fungal cell membrane. Among the direct consequences of the action of epoxiconazole on ergosterol biosynthesis are abnormal formation of fungal infection structures and strong inhibition of mycelium growth both on and in the leaf. Epoxiconazole is notable both for its excellent curative/eradicative performance and its excellent protective action.

The fungicidal action of epoxiconazole is backed up by its special biokinetic property. The active ingredient is taken up rapidly from the leaf surface and uniformly distributed throughout the plant by acropetal (systemic) translocation.

Information on crops and pests

Aim of this report is to present the efficacy and crop safety data in support of an application for the approval of BAS 701 00 F containing the active substance epoxiconazole and fluxapyroxad for use as a fungicide for the control of a broad spectrum of activity against the major fungal pathogens in wheat, barley, rye and triticale.

Wheat

Cereal eyespot (*Pseudocercosporella herpotrichoides* – TRZSS/PSDCHE)

Cereal eyespot is economically the most important stem-base disease in winter wheat and is a typical disease in crop rotations (predominantly rotations with high percentages of cereals), occurring in all cereal growing areas with mild weather in winter and cool, damp weather in spring. Depending on the severity of infestation, yield depressions of up to 30 percent are possible either directly (through damage to vascular tissues) and indirectly (through disease-induced lodging). Economic losses are likely if, at the milk ripeness stage, most of the plants show browning on 50 percent of the stem circumference, or one third of the stems is rotting. The relevance of cereal eyespot for yield has decreased in recent years in Central Europe due to weather conditions. Insufficiently incorporated debris of straw and stubble, on which the fungus can retain its ability to sporulate and spread infection for up to three and a half years (in the form of a tough mycelium). Straw debris decomposes less rapidly when colonized by the pathogens, which act to prevent further colonization by microorganisms. Conditions favourable for sporulation are cool, damp weather between 5 °C and 15 °C, the optimum temperature being 10 °C. Sufficient moisture is often available at these temperatures. Spores are spread over shorter distances by rain and wind.

Powdery mildew (*Erysiphe graminis f.sp. tritici* – TRZSS/ERYSGR)

The yield losses caused by mildew vary depending on the start, progress and intensity of the epidemic and can amount to over 25 percent. Early infestation leads to reductions in stand density. Severe yield losses can be shown to have occurred resulting from high infestation pressure on the leaf positions on the stem which are essential for yield. Adverse effects came about here through lower yields of individual ears due to reductions in the numbers of grains per ear and in the TGW. There is no sound evidence of yield losses from infestation of leaf positions on the stem lower down. However, this infestation constitutes a lasting source of infection. As an obligate parasite, powdery mildew forms black coloured fruiting bodies (cleistothecia) on older leaves in order to bridge the summer dormancy. Ascospores ripening inside them can be a source of infection in volunteer wheat and after early sowing in autumn. Of greater importance for the over summering are probably mildew pustules on volunteer cereals (“green bridge”), the spores from which can infect newly sown crops when dispersed by the wind. The pathogen overwinters in a dormant form as a mycelium on infested plants. Epidemics in spring start out from this asexual spore form. In this way spring wheat is infected by the infestation in winter wheat. The infection units (conidia) are released by wind turbulences and dispersed. The conidia are formed in a temperature range from 5-28 °C. The ideal temperature is 20 °C. High relative humidity favours spore production, when powdery mildew can proliferate explosively. On the other hand, rain and wet leaves inhibit sporulation and pustule growth. Depending on the intensity of the weather conditions, the epidemic outbreak can even stagnate. The conidia can survive for only a few days. Early sown crops favour strong population growth in spring, and high sowing densities promote pathogen development at the beginning of the main growth phase. Higher shoot densities and increased elongation growth alter the microclimate of the crop in favour of pathogen development. The time between the start of infection and conidia formation is about 5 days at 15 °C. Powdery mildew of wheat with resistance to strobilurins was isolated for the first time in Germany in 1998. Further details on this can be found in Section 6.3, “Information on actual or potential resistance development”.

***Septoria tritici* blotch** (*Septoria tritici* – TRZSS/SEPTTR)

It has been observed in recent years that *Septoria tritici*, which occurred up to now mainly in the marshland areas of Northern Germany, has also become established in regions with a continental climate. Early and severe infestation by *Septoria tritici* can lead to yield losses of up to 30%. The pathogen largely colonizes only the leaves. Infestation occurs rarely on glumes. The yield losses result from a loss of assimilating plant matter and from a shift of the source/sink relationships in the plant, leading to retention of assimilates and nitrogen compounds in the leaves. TGW is the yield parameter reacting most markedly to infestation. The pathogen survives for several months on post-harvest debris on the surface of the soil. If the fungus is ploughed in with the debris it will quickly die off. Not only asexually produced pycnospores, which can infect new plants by rain splash, form on post-harvest debris during late summer rainfalls, but also black, sexually produced pseudothecia, which release their wind-borne ascospores from about the beginning of October. These still continue to infect the newly sown wheat in autumn and winter. Persistent high moisture is necessary for sporulation on post-harvest debris. The number of ascospores produced increases continuously during the autumn, remains at a high level during the winter and declines sharply in spring. With help from the wind, the ascospores can be transported over fairly long distances, thus serving to bring about widely dispersed primary infection of young wheat crops. The epidemic spread in crops is due to pycnidia, spherical fruiting bodies which develop by asexual proliferation and which turn darker with increasing maturity. The pycnidiospores emerge from the pycnidia in the form of whitish slime tendrils. Their dispersal depends on the moisture conditions (rain and dew). Abundant rainfall, followed by long-lasting leaf wetness, is necessary for the formation of the spores, the emergence of the spores from the pycnidia, their dispersal, the course of infection and the formation of necrosis. The ideal temperatures here are between 15 and 25 °C. Even at these temperatures the fungus requires at least 20 hours for an infection. The probability of infection is high if these favourable temperatures are followed by 35 hours with continuous leaf wetness and another 48 hours with a relative humidity of over 90 percent. The pycnospores are conveyed sideways or upwards to other leaf positions on the stem by the kinetic energy of raindrops hitting the leaves. Since the pathogen is very aggressive even at lower temperatures, it will already spread in mild winter weather. Under cultivation conditions in Central Europe, a latency period of about 4 weeks must be reckoned with, i.e. four weeks go by between infection and recognizable new symptoms. For this reason *Septoria tritici* is a problem during temperate weather when slow but continuous plant growth predominates. In wheat there are marked varietal differences with regard to *Septoria tritici* (differences in pycnidia density, also in the size of leaf blotches).

Septoria **leaf and glume blotch** (*Septoria nodorum* – TRZSS/LEPTNO)

Infestation by *Septoria nodorum* (leaf and glume blotch) during the course of vegetation does not become visible in many cases until after the start of panicle emergence, with the appearance of necrotized leaves and afterwards of chocolate-coloured glumes. Because of the rapid succession of generations in locations with summer moisture, reductions in grain number per ear and TGW can lead to yield losses of up to 30 percent. Infestation on leaf organs can bring about considerable yield depressions by reducing the assimilation surfaces and interfering with nutrient transport processes; assimilates are also retained in the infested plant organs. *Septoria nodorum* is one of the most important pathogens in wheat growing, and when infestation spreads it can still lead to marked losses even after the start of milk ripeness. Pycnidiospores from pathogens surviving in mycelium form in post-harvest debris on the surface of the soil are dispersed over short distances by rain splash. Thus wheat as preceding crop increases the infestation risk. Moreover, from autumn till spring, ascospores from sexually formed fruiting bodies on post-harvest debris are dispersed by the wind over longer distances. As a result, the entire stand can be uniformly infected even on fields not directly contaminated by inoculums. Transmission by infected seed is generally possible, but in cultivation methods using treated seed this is likely to be only a very minor inoculum source. *Septoria nodorum* can spread in warm, humid weather as early as the start of stem elongation and cause secondary infections in the crop. The pathway of epidemiological importance is via pycnidiospores, which form in pitcher-shaped fruiting bodies (pycnidia) on necrotized leaf tissue. The pycnospores oozing in slime tendrils from the pycnidia are transported by the impact of rain drops to neighbouring higher leaf positions on the stem and also to the ear. On the basis of meteorological data it could be concluded that a minimum rain intensity of 0.5 mm/h is sufficient for spreading. Violent gusts of wind during thunderstorms enable the pathogen to colonize several leaf positions on the stem in a single infection attack. The rain splash pathway also accounts for the successive upward colonization of the leaf positions on the stem as far as the ear. Infections require minimum temperatures of > 10 °C. For an explosive spread it is necessary to have temperatures of around 20 °C accompanied by continual rainfalls. Under these conditions, new symptoms with renewed pycnidia formation will become visible in the field 8-12 days after infection.

Brown rust (*Puccinia recondita* f.sp. *tritici* – TRZSS/PUCCRE)

Brown rust in wheat occurs mainly in warm locations and years. There are signs that it is becoming more important as a result of increasingly intensive and large-area cultivation of susceptible and late ripening varieties. Even late infections at growth stage 71 can lead to considerable yield losses. Brown rust has an adverse effect not only on yield but also on grain quality (protein content). Grain number per ear and thousand grain weights are the yield factors most particularly affected. Rust fungi reduce photosynthesis and enhance respiration and evaporation, thus greatly damaging the development of cereal plants. Besides of wheat, brown rust attacks also barley, rye and grass.
After overcoming the main brown rust resistance gene in wheat (LR 37) in 2006/2007 in Germany, the susceptibility of many varieties increased dramatically. Yield depressions of 10-15% have been recorded as a result of early infections in the eastern regions of Germany.
In Poland, the losses due to leaf rust are usually less than 10%, but can be more severe in single cases (30% or more in the southern and northern parts of the country).
Brown rust in wheat occurs regularly in all areas of Czech Republic, mainly in South of Moravia. Yield can be reduced by 50% or more, depending on the variety.
In warmer regions in Slovakia, brown rust can cause big damages especially when the infection starts in early spring.
In the last 14 years, brown rust caused 10.7% yield damage on average in winter wheat in Hungary. The development of brown rust epidemic is most frequent in the southern and the middle part of the country.
In Romania the frequency and the intensity of attack depends on the climatic conditions and cultivation measurements. Yield losses are reported with 3-4% in average and with 20-25% in exceptional years.

Yellow rust (*Puccinia striiformis* TRZSS/PUCCST)

Yellow rust on wheat is a disease adapted primarily to cool, damp weather. If these weather conditions are fulfilled in some years at early growth stages, the damage is likely to be severe. Yellow rust is of economic importance mainly in wheat and to an increasing extent also in triticale. The greatest threat is to the uppermost leaves and the ears. Infestations of flag leaf and glumes during milk ripeness have particular serious effects on yield. Massive infestations lead to a reduction of thousand grain weight. Yield depressions of 40-50% have been recorded as a result of disturbed assimilation and increased respiration.

In the last four to five years, infections could be found also under higher temperatures and more continental weather conditions in all parts of Germany, Sweden and other Scandinavian countries. Moreover, the aggressiveness of these strains seems to have increased. The scientific analysis of these strains is ongoing - but this new strains of stripe rust will have a strong influence on the wheat production after expansion in adjacent regions.
In Poland, yellow rust occurs mainly in the north-western regions. Yellow rust in wheat in Czech Republic occurs only rarely. This pathogen was important in old varieties from Ex-Yugoslavia 30 years ago.
In Slovakia, this pathogen can cause yield reduction up to 20 – 40%; in years with higher disease pressure even more. Yellow rust epidemic in winter wheat is very rare in Hungary. In the last 14 years only 2001 was one infectious year with severe yield damage up to 30%.

Previous studies on yellow rust indicated that yellow rust epidemics can develop transboundary and build up over years. As in the case of Bulgaria, this could lead to severe outbreaks in countries where yellow rust has not be considered as a problem at all.

DTR tan spot (*Pyrenophora tritici-repentis* – TRZSS/PYRNTR)

A high proportion of wheat and minimum tillage are favourable for *Drechslera tritici-repentis* (DTR). Depending on pathogen progression, grain yield losses can be 10-50%. The yield parameter most severely affected is the thousand grain weight. Because of favourable weather conditions for the pathogen, the occurrence and damage potential of this disease has increased considerably over the last years in Europe. Tan spot is known for a very quick disease development and breakdown of the plant.
In Poland the rapid increase of tan spot has been reported since the late 1980s. In the early 1990s the spread of DTR decreased to a few percent in Hungary, but has increased again in the late 1990s.
In Latvia and Lithuania tan spot is known since the early 1990s when an increase of the wheat proportion in the crop rotation caused rapid spread of the disease. In some cases, the incidence of tan spot approached 100% and the severity reached 70% in these countries. In Estonia tan spot has not been reported as an important wheat disease. Prior to 2000, tan spot was regarded as rare or not present in Danish winter wheat crops. However, since 2000 the disease has become more common in Denmark and non-inversion tillage and intensive winter wheat production were found to be the major factors influencing its severity.

Barley

Powdery mildew (*Erysiphe graminis f. sp. hordei* – HORVX/ERYSGR)

Early infestation in winter and spring barley serves mainly to reduce crop density and grain number per ear. Later infections tend rather to reduce the TGW. During severe epidemics yield losses of up to 25 percent can occur. Infections disturb the sink/source relationships in the plant’s metabolism, with the result that the plant is often unable to compensate the assimilates drawn off by the pathogen. In addition, mildew infestation speeds up chlorosis and necrosis of leaf surfaces. Brewer’s barley reacts with a reduction of the thousand grain weight accompanied by higher protein content in the grains, i.e. with poorer malting characteristics. To bridge the summer dormancy, powdery mildew forms blackish cleistothecia in older mildew pustules. Ascospores ripen in these, and are then able to infect volunteer cereals and winter crops in autumn. However, the epidemic spreads from the asexual spore form. By infesting late shoots and volunteer cereals (“green bridge”), powdery mildew can cause direct infestation of winter cereals also in its asexual multiplication form by forming mildew pustules with conidia. Early sown crops favour strong population growth in spring. High sowing densities promote pathogen development at the beginning of the main growth phase. Higher shoot densities and increased elongation growth alter the microclimate of the crop in favour of pathogen development. High temperatures, low relative humidity, strong air turbulences and the absence of leaf wetness help to detach the conidia from the carriers and to disperse them. Sporulation is possible in the temperature range from 5-28 °C, the ideal being 20 °C. The incubation period at 20 °C is about 66 hours. A relative humidity of 95 percent is ideal for spore germination.

Barley brown rust (*Puccinia hordei* – HORVX/PUCCHD)

Puccinia hordei occurs regularly in all barley cultivation areas, especially in warm and dry years. The damage potential for spring barley growing under warmer conditions is mostly higher than for winter barley. Severe infestation leads to a reduction of the thousand grain weight (up to 30 percent) and the corn number per ear. Adverse effects are also reported for the malting quality in brewing barley.
In the Czech Republic brown rust is mainly important for barley varieties, which have a resistance gene against *Erysiphe graminis*. In some regions in Europe, like in Romania, this disease appears frequently without major impact to crop. Whereas *Puccinia hordei* is more widely spread than net blotch in Bulgaria.

Net blotch of barley (*Pyrenophora teres* – HORVX/PYRNTE)

Infestation by net blotch of barley occurs in winter and spring barley. Yield losses can be very considerable particularly in years with heavy rainfall. Yield losses are due to the destruction of the assimilation surfaces of the three uppermost leaf positions on the stem (hence the reduction of thousand grain weight). It has been shown that a reduction of grain number per ear was caused by an infestation at the time of panicle emergence.

European-wide, net blotch is the most important disease on barley with a high influence on yield every year. In some regions in Europe like in Romania, the disease occurs every year but without important crop losses.

Due to a lack of satisfactory resistance in the current barley cultivars, the relative importance of net blotch has increased in the past decade in Slovakia. In Czech Republic, yield losses due to net blotch attack range from 10-40%.

***Rhynchosporium* leaf blotch** (*Rhynchosporium secalis* – HORVX/RHYNSE)

In temperate regions (e.g. the south west of Germany, Poland, cold areas of Czech Republic, in Muntenia and Oltenia regions of Romania) this pathogen is one of the major diseases in barley, together with net blotch.
In Bulgaria, *Rhynchosporium secalis* is more widely spread than net blotch. The symptoms are found mainly on the leaf blades, though also on stems and ears. Occurrence on an epidemic scale can result in considerable economic damage. The yield losses caused by the pathogen through reduction of grain number per ear and thousand grain weights can amount to 30% and more.

***Ramularia* leaf spot** (*Ramularia collo-cygni* – HORVX/RAMUCC)

Ramularia leaf spot has become increasingly evident in Germany since the middle of the nineties. Infestation is more severe in the south than in the north, the yield losses being estimated at 11-20 percent. Browning of the leaves and toxin production are followed by a reduction of the assimilating leaf surface and by a deterioration of grain quality and thousand grain mass. The economic importance of Ramularia leaf spot has been increasing over recent years particularly in the southern parts of the country. Possible effects on brewer's barley and its suitability for brewing are still unclear. The pathogen responsible for Ramularia leaf spot disease is the fungus *Ramularia collo-cygni*, which was first described in 1893. This fungus infests all varieties of barley, though also other graminaceous crops such as wheat and triticale. The first infections in winter barley can already take place on the young plants on warm, damp autumn days. The fungus survives on standing plants (winter and spring barley, other cereal species and wild grasses) and can possibly also maintain itself for a time on straw. *R. collo-cygni* occurs more frequently with rising temperatures and damp weather in spring, but in most cases does not cause the typical spots until after panicle emergence, first on the lower leaf positions on the stem, later also on the ear including the awns. *R. collo-cygni* forms a substomatal hyaline mycelium. When relative humidity is high, the typical clusters of conidia carriers, strung out like pearls, emerge from the stomata on the underside of the leaf. The conidia carriers are septate and curved like a swan's neck (*"collo-cygni"* = swan's neck). The curved conidia carrier apparently serves to discharge the conidia with a certain momentum. *R. collo-cygni* can cause massive infestation of intact, vital and green leaf tissue. For ripening, the fungus on the dead leaves can go over to a saprophytic form of life, where it can make itself particularly evident. The fungus prefers higher temperatures for growth. Mycelium growth and spore germination proceed most rapidly at 20-28 °C. Marked differences between day and night temperatures with heavy dew are especially favourable for infection.

Non-parasitic leaf spots (HORVX/YBFMI)

Browning of the assimilating organs of cereals, resulting in premature ripening, has been observed for a fairly long time in south Germany and increasingly also in north Germany during the last years. Barley is most particularly affected. The damage pattern starts with light-coloured dots on the leaves. Within few days small, closely circumscribed brown spots appear. The initial symptoms can be mistaken for net blotch. Since it has not been possible to isolate any pathogens, the phenomenon is described as "non-parasitic leaf spots".
Non-parasitic leaf spots belong to the less important diseases of barley in countries like Poland, Czech Republic, Slovakia, Hungary, Romania and Slovenia, despite its occurrence from time to time.
Non-specific leaf spots are caused by an unfavourable interplay of genetic factors and environmental conditions. In susceptible varieties, a set of different stress factors trigger oxidative stress in the plants, resulting in dead cells which become apparent in the form of leaf spots. The involved stress factors originate both from the environment and the plants themselves.
A change from a cool, very cloudy and rainy weather period to high irradiation, associated with high temperatures, UVB intensities and ozone levels is assumed to play a role in the symptom development. Symptoms usually are starting at the leaf tips depending on the inclination and the angle of the leaves. Leaves intensively exposed to sunlight are more severely affected.

Rye

Powdery mildew (*Erysiphe graminis f. sp. Secalis* – SECCE/ERYSGR)

Rye is regularly parasitized by the special form *Erysiphe graminis* f. sp. *secalis*. Yield depressions would appear to occur only locally and in intensive farming. Here, again, serious epidemics can cause yield losses of up to 25 percent. Survives over the warm, dry summer months in the form of cleistothecia on plants and stubble debris; cool, rainy weather in autumn induces the spread of ascospores. These are able in autumn to infect volunteer cereals and newly sown winter crops. However, transmission of infestation via the “green bridge” provided by late shoots and volunteer cereals is likely to be the more important inoculum source for winter rye also and the cause of primary infections in newly sown crops. Overwintering takes place on live host tissue. Layers of snow are of advantage for survival. High sowing densities promote pathogen development at the beginning of the main growth phase. The optimum temperature range for strong sporulation with an epidemic spread of powdery mildew in rye is similar to that in wheat.

Brown rust (*Puccinia recondita f.sp. recondita* – SECCE/PUCCRE)

In spite of its regular occurrence, the importance of brown rust in Central and Eastern Europe is usually underestimated. Higher N-fertilizer rates in more stable varieties and fodder rye, together with early sowing dates, have led to increasing incidences of infections in autumn, which might also be connected with adverse effects on winter hardiness. The denser crops that are common today provide a more favourable microclimate for the development of the disease. The increasing cultivation of hybrid rye varieties, which are generally very susceptible to brown rust, has enormously increased the impact of this disease on yields. At the present time, brown rust is probably the most important disease in rye under cultivation conditions in Central Europe.

***Rhynchosporium* leaf blotch** (*Rhynchosporium secalis* – SECCE/RHYNSE)

The economic importance of this pathogen in rye is less than in barley. Evidence of infestation can be found almost every year in spring on the lower leaves. The spreading of infestation to upper leaf organs, that are essential for yield generally takes longer than in barley, since rye, with its enormous growth potential, creates unfavourable conditions for the pathogen, which is spread by rain splash. Since rye crop are often thinner than barley, the upper leaves dry more quickly after rain or dew. The infection conditions are unfavourable for spores landing on the upper leaves.
With the increase of the area of hybrid varieties in Germany and other European countries with a higher susceptibility against this disease like Czech Republic, Slovakia, Poland, Hungary, Romania and Slovenia, the importance of Rhynchosporium in rye is growing in agricultural practice.

<u>Triticale</u>

Cereal eyespot (*Pseudocercosporella herpotrichoides* – TTLSS/PSDCHE)

Cereal eyespot is economically the most important stem-base disease in triticale and is a typical disease in crop rotations (predominantly rotations with high percentages of cereals), occurring in all cereal growing areas with mild weather in winter and cool, damp weather in spring. Depending on the severity of infestation, yield depressions of up to 30 percent are possible either directly (through damage to vascular tissues) and indirectly (through disease-induced lodging). Economic losses are likely if, at the milk ripeness stage, most of the plants show browning on 50 percent of the stem circumference, or one third of the stems are rotting. The relevance of cereal eyespot for yield has decreased in recent years in Central Europe due to weather conditions, variety selection and changes in cultivation methods. Insufficiently incorporated debris of straw and stubble, on which the fungus can retain its ability to sporulate and spread infection for up to three and a half years (in the form of a tough mycelium). Straw debris decomposes less rapidly when colonized by the pathogens, which act to prevent further colonization by microorganisms. Conditions favourable for sporulation are cool, damp weather between 5 °C and 15 °C, the optimum temperature being 10 °C. Sufficient moisture is often available at these temperatures. Spores are spread over shorter distances by rain and wind.

Powdery mildew (*Erysiphe graminis* – TTLSS/ERYSGR)

Because triticale is now being more widely cultivated, adaptation of the pathogen populations has made it more susceptible to the disease. Infestation of triticale by Erysiphe graminis (powdery mildew) is occasionally observed to be relatively slight compared to other cereal species. Although infestation is seldom sufficient to cause heavy yield losses, individual varieties can be very heavily infested by powdery mildew in years with high infection pressure. A detailed description of the inoculum source and spreading of infestation for powdery mildew can be found in the section Erysiphe graminis f. sp. tritici in wheat.

Brown rust (*Puccinia recondita* – TTLSS/PUCCRE)

Infection of triticale has been increasing for several years because the originally complex resistance genes to foliar diseases have been disrupted in most varieties. Slight infestation of triticale by *Puccinia recondita* (brown rust) is occasionally observed. Although infestation is seldom, it is sufficient to cause heavy yield losses. Individual varieties can be very heavily infested by rust in years with high infection pressure. Detailed information on inoculum source and spreading of infestation by brown rust is given in the section on *Puccinia recondita* in wheat.

***Septoria* species** (*Septoria* ssp. – TTLSS/SEPTSP)

The present spectrum of triticale varieties appears to have only medium resistance to the pathogen of leaf and glume blotch (*Septoria nodorum*). The pathogen has been described in detail in the section on wheat. *Septoria nodorum* can bring about considerable leaf losses in triticale, and infection of glumes also occurs. Under favourable weather conditions for the pathogen, small, spindle-shaped blotches start to become visible during the late shooting stage, and then expand to form irregular necrotic areas. Isolated leaf axil infestations can be observed. Particularly in the case of triticale, the symptoms on the leaves are scarcely specific, and reliable evidence of the presence of the pathogen is given only by 20 to 30-fold magnification of the typically honey yellow to honey brown coloured fruiting bodies. The key data for an epidemic build-up and its control are the same as for infestation in wheat. Fungicidal effects in triticale are most likely to come about through reduction of *Septoria nodorum* infestation. The targeted control strategy is the same as for the situation in wheat. The emergence of *Septoria tritici* is observed in years with infestation, though pathogen progression takes place with greater delay than in wheat, resulting in less extensive damage. The biological requirements of the fungus are set out in detail in the chapter on wheat. The black pigmented pycnidia (20 to 30-fold magnification) in leaf necroses can be used as a criterion for differential diagnosis. The fruiting bodies are frequently arranged in rows alongside the leaf veins, and in cases of more severe infestation can be discerned as small black dots. The fungicides authorized for the control of *Septoria nodorum* – which experience has shown to be very effective – can be used for containing infestations with *Septoria tritici* if the application is timed as carefully as possible in relation to infestation and infection. The pathogen survives for several months on post-harvest debris on the surface of the soil. If the fungus is ploughed in with the debris it will quickly die off. Not only asexually produced pycnospores, which can infect new plants by rain splash, form on post-harvest debris during late summer rainfalls, but also black, sexually produced pseudothecia, which release their wind-borne ascospores from about the beginning of October. These still continue to infect the newly sown wheat in autumn and winter. Persistent high moisture is necessary for sporulation on post-harvest debris. The number of ascospores produced increases continuously during the autumn, remains at a high level during the winter and declines sharply in spring. With help from the wind, the ascospores can be transported over fairly long distances, thus serving to bring about widely dispersed primary infection of young wheat crops. The epidemic spread in crops is due to pycnidia, spherical fruiting bodies which develop by asexual proliferation and which turn darker with increasing maturity. The pycnidiospores emerge from the pycnidia in the form of whitish slime tendrils. Their dispersal depends on the moisture conditions (rain and dew). Abundant rainfall, followed by long-lasting leaf wetness, is necessary for the formation of the spores, the emergence of the spores from the pycnidia, their dispersal, the course of infection and the formation of necrosis. The ideal temperatures here are between 15 and 25 °C. Even at these temperatures the fungus requires at least 20 hours for an infection. The probability of infection is high if these favourable temperatures are followed by 35 hours with continuous leaf wetness and another 48 hours with a relative humidity of over 90 percent. The pycnospores are conveyed sideways or upwards to other leaf stages by the kinetic energy of raindrops hitting the leaves. Since the pathogen is very aggressive even at lower temperatures, it will already spread in mild winter weather. Under cultivation conditions in Central Europe, a latency period of about 4 weeks must be reckoned with, i.e. four weeks go by between infection and recognizable new symptoms.

Table 6.0-3: Classification of crop and disease (including abiotic damage) in the zRMS

Crop/ utilisation	**EPPO-Code**	**Classification of crop**		**Classification of disease**	
		major	**minor**	**major**	**minor**
1	2	3		4	
Wheat / *Puccinia recondita*	TRZSS / PUCCRE	DE		DE	
Wheat / *Puccinia striiformis*	TRZSS / PUCCST	DE		DE	
Wheat / *Drechslera tritici-repentis*	TRZSS / PYRNTR	DE		DE	
Wheat / *Pseudocercosporella herpotrichoides*	TRZSS / PSDCHE	DE		DE	
Wheat / *Erysiphe graminis*	TRZSS / ERYSGR	DE		DE	
Wheat / *Septoria tritici*	TRZSS / SEPTTR	DE		DE	
Wheat / *Septoria nodorum*	TRZSS / LEPTNO	DE		DE	
Barley / *Erysiphe graminis*	HORVX / ERYSGR	DE		DE	
Barley / *Puccinia hordei*	HORVX / PUCCHD	DE		DE	
Barley / *Pyrenophora teres*	HORVX / PYRNTE	DE		DE	
Barley / *Rhynchosporium secalis*	HOVRX / RHYNSE	DE		DE	

Barley / *Ramularia collo-cygni*	HORVX / RAMUCC	DE		DE	
Barley / decrease of non-parasitic leaf spots	HORVX / YBFMI	DE		DE	
Rye / *Erysiphe graminis*	SECCE / ER-YSGR	DE		DE	
Rye / *Puccinia re-condita*	SECCE / PUCCRE	DE		DE	
Rye / *Rhyncho-sporium secalis*	SECCE / RHYNSE	DE		DE	
Triticale / *Erysiphe graminis*	TTLSS / ER-YSGR	DE		DE	
Triticale / *Pseudo-cercosporella herpo-trichoides*	TTLSS / PSDCHE	DE		DE	
Triticale / *Puccinia recondita*	TTLSS / PUCCRE	DE		DE	
Triticale / *Septoria spp.*	TTLSS / SEPTSP	DE		DE	

1 = common name (see field of use), 2 = EPPO-Code, 3 = classification of crop/situation (major/minor) in zRMS, if is renamed, 4 = classification of pest/disease (major/minor) in zRMS, if is renamed

Information on the intended uses

Date: 2013-07-03

Use No.	**026958-00/00-001**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-002**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	stripe rust of grasses (*Puccinia striiformis*) (PUCCST)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-003**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	tan spot of cereals (*Drechslera tritici-repentis*) (PYRNTR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-004**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 32
Pest(s)/target(s)	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	1
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
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Use No.	**026958-00/00-005**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	powdery mildew (*Erysiphe graminis*) (ERYSGR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-006**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	leaf spot of wheat (SEPTTR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-007**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	wheat (TRZSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	septoria leaf spot of wheat (LEPTNO)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first

	symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-009**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	powdery mildew (*Erysiphe graminis*) (ERYSGR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-010**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	brown rust of barley (*Puccinia hordei*) (PUCCHD)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-011**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	net blotch (*Pyrenophora teres*) (PYRNTE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-012**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-013**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	Ramularia leaf spot disease (*Ramularia collo-cygni*) (RAMUCC)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-014**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	barley (HORVX)
Crop stage(s) (BBCH)	32 to 61
Pest(s)/target(s)	decrease of non-parasitic leaf spots (YBFMI)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Notes on time of treatment	for vulnerable varieties and an increase in global radiation
Max. number of treatments for the use	1
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
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Use No.	**026958-00/00-015**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	rye (SECCE)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	powdery mildew (*Erysiphe graminis*) (ERYSGR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-017**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	rye (SECCE)
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-018**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	rye (SECCE)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)

Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-019**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	triticale (TTLSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	powdery mildew (*Erysiphe graminis*) (ERYSGR)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
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Use No.	**026958-00/00-020**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	triticale (TTLSS)
Crop stage(s) (BBCH)	30 to 32
Pest(s)/target(s)	stem break of cereals (*Pseudocercosporella herpotrichoides*) (PSDCHE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	1
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
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Use No.	**026958-00/00-021**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	triticale (TTLSS)
Crop stage(s) (BBCH)	30 to 69
Pest(s)/target(s)	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha
Rate App. comment	treatments must be at least 21 days apart
----------------------------	----------------------------
Use No.	**026958-00/00-022**
Field of use	Agriculture (field crops)
Crop(s)/object(s)	triticale (TTLSS)
Crop stage(s) (BBCH)	30 to 61
Pest(s)/target(s)	septoria-species (*Septoria spp.*) (SEPTSP)
Area of application	Outdoors
Timing of application	From spring at beginning of infestation and/or when first symptoms become visible
Max. number of treatments for the use	2
Max. number of treatments per crop or season	2
Application method/kind of treatment	spraying
Application rate(s) in amount of water to be used	2 L/ha in 100 to 400 L water/ha

Rate App. comment	treatments must be at least 21 days apart
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IIIA1 6.1 Efficacy data

The applicant stated that the product BAS 701 00 F was developed to stop relevant leaf and ear diseases in wheat, barley, rye and triticale and which retains its efficacy over a particularly long period. At the same time exacting demands are made on the protective and curative performance and the long-lasting action of the new fungicide.

The aim of this report is to secure authorization for use in the cereal species wheat, barley, rye and triticale.

IIIA1 6.1.1 Preliminary range-finding tests

To determine the optimum application rate and the best combination of the active ingredients fluxapyroxad and epoxiconazole for the control various fungal diseases in cereals, testing was carried out with wheat and barley in field and greenhouse trials in the years 2002 to 2007. The following pathogens were used in the investigations:

Erysiphe graminis:	trials in wheat, n=2
Septoria tritici:	trials in wheat, n=11
Puccinia recondita:	trials in wheat, n=3
Puccinia striiformis:	trials in wheat, n=2
Drechslera tritici repentis:	trials in wheat, n=3
Pseudocercosporella herpotrichoides:	trials in wheat, n=2
Pyrenophora teres:	trials in barley, n=3
Rhynchosporium secalis:	trials in barley, n=2
Ramularia collo-cygni :	trials in barley, n=3

The tested active ingredients were shown to differ in efficacy:

Fluxapyroxad showed outstanding and very long-lasting efficacy against a broad spectrum of diseases such as *Septoria tritici* and *Puccinia recondita* in wheat, and at the same time especially good efficacy against *Pyrenophora teres, Rhynchosporium secalis* and *Ramularia collo-cygni* in barley and rye. Very good efficacy is obtained against *Puccinia striiformis* and *Pseudocercosporella herpotrichoides* and good efficacy against *Erysiphe graminis* and *Pyrenophora tritici-repentis.* Epoxiconazole showed outstanding efficacy against a broad spectrum of diseases such as *Septoria tritici, Septoria nodorum, Puccinia recondita* und *Puccinia striiformis* in wheat, also moderate efficacy against *Pyrenophora teres* and *Rhynchosporium secalis* in barley, and moderate efficacy in rye and triticale. The combination of the two active ingredients improved yet further the excellent efficacy of fluxapyroxad against the relevant pathogens referred to above. The combination product BAS 701 00 F shows a broader performance profile including excellent activity against important pathogens in the area of the ears.

Different mixing ratios of the active ingredients were evaluated. Results for the tested mixing ratios – evaluated over the various pathogens – showed the following combination to possess above-average efficacy:

Fluxapyroxad	Epoxiconazole
1	1
62.5 g/L	62.5 g/L

At an application rate of 2.0 L/ha this combination outperformed the efficacy of the full application rate of each separate active ingredient and made it possible to obtain a highly reliable preventive and curative action together with particularly long-lasting action.

Application timing

The application date depends on the pathogen and the start of infection or re-infection. BAS 701 00 F can be used in wheat, barley, rye and triticale for the control of *Erysiphe graminis, Septoria tritici, Septoria nodorum, Puccinia recondita, Puccinia striiformis, Pyrenophora tritici-repentis, Puccinia hordei, Pyrenophora teres, Rhynchosporium secalis* and *Ramularia collo-cygni* from growth stages 30 to 61. Application for reduction of non-parasitic leaf spots in barley is performed from growth stages 32 to 61 and for the control of *Pseudocercosporella herpotrichoides* from growth stages 30 to 32. For control of brown rust it is recommended to apply from growth stages 30 to 69, since brown rust can still have marked effects on yield under conditions in Germany even if infestation starts late.

For control of the above leaf pathogens, the first application must be carried out in spring at the start of infestation or as soon as the first symptoms become visible. If re-infection occurs, it will be necessary to spray a second time.

IIIA1 6.1.2 Minimum effective dose tests

The applicant mentions that in 2008 to 2009, the minimum effective dose for BAS 701 00 F was tested in several field trials conducted throughout Europe. Data as a summary table for each tested intended uses are presented at Table 6.1.2-1.

Table 6.1.2-1: Location and number of BAS 701 00 F minimum effective dose trials

Country	Year		Total
	2008	2009	
AT	1	0	1
BE	2	0	2
CZ	1	2	3
DE	9	23	32
FR	6	16	22
HU	2	1	3

IE	1	1	2
NL	0	1	1
PL	1	7	8
UK	2	1	3
Total	25	52	77

Table 6.1.2-1: Efficacy (%) in minimum effective dose trials of BAS 701 00 F

Crop	Disease (EPPO)	# trials	disease level in % (UTC)	Efficacy of BAS 701 00 F in %					
				full rate 2.0 L/ha			reduced rate 1.33 L/ha		
				mean	min	max	mean	min	max
Wheat	*Puccinia recondite* (PUCCRE)	9	38.4	**94.8**	81,9	100.0	**90.4**	75.8	100.0
	Drechslera tritici-repentis (PYRNTR)	6	15.9	**80.5**	76.6	89.2	**70.6**	61.7	83.0
	Erysiphe graminis (ERYSGR)	3	22.9	**85.1**	84.6	85.6	**81.8**	81.3	82.2
	Septoria tritici (SEPTTR)	16	63.1	**95.4**	91.7	99.6	**90.7**	85.2	98.9
Barley	*Puccinia hordei* (PUCCHD)	3	20.1	**93.8**	86.1	100.0	**83.4**	75.0	88.1
		5 *	85.2 *	**96.1 ***	83.8 *	100.0 *	**94.9 ***	80.3 *	99.3 *
	Pyrenophora teres (PYRNTE)	9	25.5	**96.5**	82.6	100.0	**93.5**	79.7	100.0
	Rhynchosporium secalis (RHYNSE)	12	41.1	**91.6**	70.5	100.0	**86.4**	62.9	98.8
	Ramularia collo-cygni (RAMUCC)	4	50.0	**93.6**	58.8	98.6	**88.8**	58.8	98.4
Rye	*Puccinia recondita* (PUCCRE)	11	40.8	**97.4**	88.6	100.0	**94.3**	78.6	99.1
	Rhynchosporium secalis (RHYNSE)	10	19.0	**89.2**	76.0	100.0	**84.8**	68.0	100.0
Triticale	*Puccinia recondita* (PUCCRE)	5	23.4	**94.2**	87.5	100.0	**90.8**	81.3	100.0
	Septoria spp. (SEPTSP)	6	20.5	**88.8**	83.8	100.0	**84.3**	76.2	91.1

Figures and values marked with an asterisk were assessed according to Numbers of pustules.

The results can be summarized as following:

Wheat: Fungicidal performance at the 33% lower application rate was markedly lower in all tested uses (powdery mildew, *Septoria tritici* blotch, brown rust und DTR tan spot). For powdery mildew, *Septoria tritici* blotch and brown rust the biological efficacy was reduced by about 4% - 5% - for DTR 10%. In wheat, this reduction of fungicidal performance due to the lower application rate resulted in a yield depression.

Barley: In the efficacy trials with the different application rates for control barley brown rust, net blotch, Rhynchosporium leaf blotch and Ramularia leaf spot the lowering of the application rate showed a similar reduction of disease control as for the wheat pathogens. Here, again, the degree of efficacy was reduced by 3% - 5% compared with the full application rate. The reduction of the application rate brought about a marked yield loss (2-4 dt/ha) in all tested uses.

Rye: In the 21 trials to test the efficacy of the different application rates in brown rust and Rhynchosporium leaf blotch, the 33% lowering of the application rate also led to a reduction of efficacy, particularly where infestation pressure was more strongly marked. The average degrees of disease control efficacy were also reduced by 3% - 5% in rye and a yield loss of 1-2 dt/ha.

Triticale: Similar results were obtained from testing of the two application rates in triticale. Testing for control of brown rust and the *Septoria* species also confirmed that the lower application rates resulted in reduced disease control. The degrees of disease control efficacy were reduced by 3-5% and a yield loss of 2 dt/ha.

Since pathogens normally emerge in associated form, it is important in all conceivable constellations to achieve not only reliable and long-lasting control of the pathogens but also at the same time the greatest possible safeguarding of yield. This justifies the proposed application rate of 2.0 L/ha.

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/225. The applicant showed a decrease of efficacy as a result of dose reduction by 33%. The justification of the proposed application rate of 2.0 L/ha will be accepted.

It can be concluded to accept the data provided by the applicant to demonstrate the minimum effective dose.

IIIA1 6.1.3 Efficacy tests

At the present study, efficacy data of BAS 701 00 F against diseases are presented from totally 250 efficacy trials with 317 comparisons within the different Indications assessed between 2008 and 2009.

Table 6.1.3-1: Location and number of BAS 701 00 F efficacy trials

Country	Year		Total
	2008	2009	
AT	2	0	2
BE	2	5	7

CZ	1	2	3
DE	67	79	146
DK	6	2	8
FR	17	24	41
IE	2	5	7
NL	0	3	3
PL	1	2	3
UK	10	20	30
Total	108	142	**250**

The applicant claims that all trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organizations. Efficacy of BAS 701 00 F in these trials was compared to the commercial standards.

Table 6.1.3-2: Guidelines and trial design

GEP	Yes (all trials)		
Standards	PP 1/26(3), PP 1/28(2), PP 1/28(3), PP 1/79(3), PP 1/152(2), PP 1/181(3), PP 1/135(3), PP 1/214(1), PP 1/223(1), CEB N°189 REVISEE 1999		
Number of replications	4		
Plot design, plot size	RB, minimum 10 m² (*)		
Trials per crop	wheat: 111; barley: 110; rye: 41; triticale: 44		
Trials per intended use	Wheat	Brown rust of cereals (*Puccinia recondita*)	16 trial results
		Stripe rust of grasses *(Puccinia striiformis)*	16 trial results
		DTR tan spot (*Pyrenophora tritici-repentis*)	12 trial results
		Stem break of cereals (*Pseudocercosporella herpotrichoides*)	16 trial results
		Powdery mildew (*Erysiphe graminis*)	16 trial results
		Leaf spot of wheat (*Septoria tritici*)	25 trial results

		Septoria leaf spot (*Septoria nodorum*)	10 trial results
	Barley	Powdery mildew (*Erysiphe graminis*)	16 trial results
		Brown rust of barley (*Puccinia hordei*)	15 trial results
		Net blotch (*Pyrenophora teres*)	22 trial results
		Leaf blotch of cereals (*Rhynchosporium secalis*)	18 trial results
		Ramularia leaf spot disease (*Ramularia collo-cygni*)	23 trial results
		Decrease of non-parasitic leaf spots	16 trial results
	Rye	Powdery mildew (*Erysiphe graminis*)	5 trial results
		Brown rust of cereals (*Puccinia recondita*)	20 trial results
		Leaf blotch of cereals (*Rhynchosporium secalis*)	16 trial results
	Triticale	Powdery mildew (*Erysiphe graminis*)	13 trial results
		Stem break of cereals (*Pseudocercosporella herpotrichoides*)	7 trial results
		Brown rust of cereals (*Puccinia recondita*)	12 trial results
		Septoria species (*Septoria spp.*)	12 trial results
Crop stage (BBCH) at application	BBCH 30-69		
Reference product(s) (dosage), act. subst	Unix (1.0 kg/ha)	Cyprodinil	
	Opus Top (1.5 L/ha)	Epoxiconazole, fenpropimorph	
	Champion (1.5 L/ha)	Epoxiconazole, boscalid	
	Corbel (1.0 L/ha)	Fenpropimorph	
	Caramba (1.5 L/ha)	Metconazole	
	Capalo (2.0 L/ha)	Epoxiconazole, fenpropimorph, metrafenone	
	Talius (0.25 L/ha)	Proquinazid	
	Input (1.25 L/ha)	Prothioconazole, spiroxamine	
	Opus (1.0 L/ha)	Epoxiconazole	

	Amistar Opti (2.5 L/ha)	Azoxystrobin, chlorthalonil
	Osiris (3.0 L/ha)	Epoxiconazole, metconazole
	Fandango (1.25 L/ha)	Fluoxastrobin, prothioconazole

* The plot size was 9.9 m² in four (French study reports) - 2x SEPTR and PUCCST in wheat.

Conclusion:

The presented information about used test method, trial number, crop stage and reference product correspond with the requirements of the EPPO standards PP1/26, PP1/152, PP1/181 and PP1/226. The trials are carried out in the maritime zone.

It can be concluded to accept the data provided by the applicant to perform efficacy trials.

Efficacy results in details for each group are presented at Table 6.1.3-3.

Table 6.1.3-3: Mean efficacy (%) against various diseases taken from trials in 2008 and 2009

Crop	Disease (EPPO)	Assessed variable/ part	# trials	Disease level in % (UTC)	BAS 701 00 F			Standard		
					mean	min	max	mean	min	max
Wheat	*Puccinia recondita* (PUCCRE)	P%INF	16	32.4	**95.9**	81.6	100.0	**83.4**	43.2	98.7
	Puccinia striiformis (PUCCST)	P%INF	16	24.9	**98.8**	94.0	100.0	**97.0**	74.0	100.0
	Drechslera tritici-repentis (PYRNTR)	P%INF	12	25.0	**85.8**	75.0	96.5	**76.5**	53.2	98.8
	Pseudocercosporella herpotrichoides (PSDCHE)	BEFWER	11	28.1	**67.5**	45.8	100.0	**50.9**	14.8	100.0
		BEFHKT	11	60.3	**47.1**	23.9	100.0	**29.8**	-2.9	100.0
		P%INF	5	49.5	**65.3**	54.2	90.7	**44.4**	17.4	71.4
		P%FREQ	5	82.9	**40.3**	19.7	89.7	**22.7**	5.4	68.4
	Erysiphe graminis (ERYSGR)	P%INF	16	19.4	**81.1**	62.7	99.4	**73.4**	44.1	95.3
	Septoria tritici (SEPTTR)	P%INF	25	64.3	**95.4**	83.0	99.9	**83.3**	51.3	96.3
	Septoria nodorum (LEPTNO)	P%INF	10	27.4	**78.7**	36.8	100.0	**72.1**	21.1	100.0
Barley	*Erysiphe graminis* (ERYSGR)	P%INF	16	18.8	**90.4**	59.1	100.0	**85.2**	47.6	100.0

	*Puccinia hordei (*PUCCHD*)*	P%INF	15	24.2	**98.7**	80.6	100.0	**96.4**	50.0	100.0
	*Pyrenophora teres (*PYRNTE*)*	P%INF	22	37.8	**97.8**	90.0	100.0	**68.5**	18.2	100.0
	*Rhyncho-sporium secalis (*RHYNSE*)*	P%INF	18	38.2	**91.9**	83.9	100.0	**59.7**	27.8	97.6
	*Ramularia col-lo-cygni (*RAMUCC*)*	P%INF	23	47.1	**90.0**	58.8	99.5	**72.0**	25.8	96.6
	Non-parasitic leaf spots *(*YBFMI*)*	P%INF	16	43.6	**91.7**	80.0	100.0	**73.3**	37.3	95.6
Rye	*Erysiphe gram-inis (*ERYSGR*)*	P%INF	5	11.7	**100.0**	99.8	100.0	**93.5**	70.0	100.0
	Puccinia re-condita (PUCCRE)	P%INF	20	36.9	**97.7**	83.9	100.0	**78.8**	12.2	97.2
	*Rhyncho-sporium secalis (*RHYNSE*)*	P%INF	16	22.4	**88.6**	66.3	100.0	**70.4**	45.2	100.0
Triticale	*Erysiphe gram-inis (*ERYSGR*)*	P%INF Leaves	12	14.7	**89.1**	74.1	100.0	**81.2**	42.6	100.0
		P%INF Plant	1	15.0	**100.0**	100.0	100.0	**66.7**	66.7	66.7
	Pseudocerco-sporella herpo-trichoides (PSDCHE*)*	BEFWER	7	31.8	**64.2**	33.8	95.6	**63.0**	35.0	100.0
		BEFHKT	7	67.4	**53.9**	21.7	92.5	**55.4**	25.0	100.0
	*Puccinia re-condita (*PUCCRE*)*	P%INF Leaves	10	24.3	**99.0**	87.5	100.0	**96.8**	77.8	100.0
		P%INF Plant	2	11.3	**98.4**	98.0	99.0	**90.7**	84.0	99.0
	Septoria spp. *(*SEPTSP*)*	P%INF Leaves	11	19.8	**88.9**	72.4	100.0	**81.6**	46.7	100.0
		P%INF Plant	1	18.8	**93.3**	93.3	93.3	**73.3**	73.3	73.3

Brown rust in wheat

The efficacy of BAS 701 00 F against *Puccinia recondita* in wheat was tested in 16 trials.

The reference products selected were Input with an application rate of 1.25 L/ha and Opus with an application rate of 1.0 L/ha.

In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 95.9%. The standards shows a degree of efficacy of 83.4%

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 95.9% (exceptional achievement) for the control of *Puccinia recondita* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Puccinia recondita* in wheat.

Stripe rust in wheat

The efficacy of BAS 701 00 F against *Puccinia striiformis* in wheat was tested in 16 trials.

The reference products selected was Opus with an application rate of 1.0 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference product.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 98.8%. The standard shows a degree of efficacy of 97.0%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 98.8% (exceptional achievement) for the control of *Puccinia striiformis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Puccinia striiformis* in wheat.

DTR tan spot in wheat

The efficacy of BAS 701 00 F against *Pyrenophora tritici repentis* in wheat was tested in 12 trials.

The reference products selected were Input with an application rate of 1.25 L/ha, Opus Team with an application rate of 1.5 L/ha and Opus with an application rate of 1.0 L/ha.
In 10 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – two trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 85.8%. The standards show a degree of efficacy of 76.5%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed a good efficacy of 85.8% (extensive achievement) for the control of *Pyrenophora tritici-repentis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Pyrenophora tritici-repentis* in wheat.

Eyespot in wheat

The efficacy of BAS 701 00 F against *Pseudocercosporella herpotrichoides* in wheat was tested in 16 trials.

The reference products selected were Champion with an application rate of 1.5 L/ha, and Unix with an application rate of 1.0 kg/ha.
In 15 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – one trial show a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F in the trials where the disease values where estimated with the degree of efficacy of 67.5% (65.3% with P%INF). The standards show a degree of efficacy of 50.9% (44.4% with P%INF). In the trials with the estimation of the percentage of infection the degree of efficacy was 65.3% (40.3% with P%FREQ). The standards show a degree of efficacy of 44.4% (22.7% with P%FREQ) in these trials.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/28, PP1/214 and PP1/223. The applicant showed a satisfactory efficacy of 65.3% to 67.5 % (acceptable achievement) for the control of *Pseudocercosporella herpotrichoides (new: Oculimacula herpotrichoides)* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Pseudocercosporella herpotrichoides (new: Oculimacula herpotrichoides)*. in wheat.

Powdery mildew in wheat

The efficacy of BAS 701 00 F against *Erysiphe graminis* in wheat was tested in 16 trials.

The reference products selected were Corbel with an application rate of 1.0 L/ha, Capalo with an application rate of 2.0 L/ha and Talius with an application rate of 0.25 L/ha.
In 13 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – three trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 81.1%. The standards show a degree of efficacy of 73.4%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed a satisfactory efficacy of 81.1 % (acceptable achievement) for the control of *Erysiphe graminis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Erysiphe graminis* in wheat.

Leaf spot in wheat

The efficacy of BAS 701 00 F against *Septoria tritici* in wheat was tested in 25 trials.

The reference products selected were Input with an application rate of 1.25 L/ha and Opus with an application rate of 1.0 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 95.4%. The standards show a degree of efficacy of 83.3%.

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 95.4 % (exceptional achievement) for the control of *Septoria tritici* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Septoria tritici* in wheat.

***Septoria* leaf spot in wheat**

The efficacy of BAS 701 00 F against *Septoria nodorum* in wheat was tested in 10 trials.

The reference products selected were Caramba with an application rate of 1.5 L/ha, Opus with an application rate of 1.0 L/ha and Opus Team with an application rate of 1.5 L/ha.
In 8 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – two trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 78.7%. The standards show a degree of efficacy of 72.1%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed a satisfactory efficacy of 78.7 % (acceptable achievement) for the control of *Septoria nodorum* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Septoria nodorum* in wheat.

Powdery mildew in barley

The efficacy of BAS 701 00 F against *Erysiphe graminis* in barley was tested in 16 trials.

The reference products selected were Corbel with an application rate of 1.0 L/ha, Opus with an application rate of 1.0 L/ha and Opus Team with an application rate of 1.5 L/ha.
In 9 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the ref-

erence products – seven trials show a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 90.4%. The standards show a degree of efficacy of 85.2%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 90.4 % (exceptional achievement) for the control of *Erysiphe graminis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Erysiphe graminis* in barley.

Brown rust in barley

The efficacy of BAS 701 00 F against *Puccinia hordei* in barley was tested in 15 trials.

The reference products selected were Champion with an application rate of 1.5 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 98.7%. The standards show a degree of efficacy of 96.4%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 98.7 % (exceptional achievement) for the control of *Puccinia hordei* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Puccinia hordei* in barley.

Net blotch in barley

The efficacy of BAS 701 00 F against *Pyrenophora teres* in barley was tested in 22 trials.

The reference products selected were Champion with an application rate of 1.5 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 97.8%. The standards show a degree of efficacy of 68.5%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 98.7 % (exceptional achievement) for the control of *Pyrenophora teres* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Pyrenophora teres* in barley.

Based on the current findings of resistant isolates of *Pyrenophora teres* following resistance support WW7041 is suggested for this application:

For the active substance, or an active substance of this product resistance was detected. Application only within the framework of appropriate resistance management.

Leaf blotch in barley

The efficacy of BAS 701 00 F against *Rhynchosporium secalis* in barley was tested in 18 trials.

The reference products selected were Opus with an application rate of 1.0 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 91.9%. The standards show a degree of efficacy of 59.7%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 91.9 % (exceptional achievement) for the control of *Rhynchosporium secalis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Rhynchosporium secalis* in barley.

***Ramularia* leaf spot in barley**

The efficacy of BAS 701 00 F against *Ramularia collo cygni* in barley was tested in 23 trials.

The reference products selected were Amistar Opti with an application rate of 2.5 L/ha, Osiris with an application rate of 3.0 l/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 90.0%. The standards show a degree of efficacy of 72.0%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 90.0 % (exceptional achievement) for the control of *Ramularia collo-cygni* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Ramularia collo-cygni* in barley.

Decrease of non-parasitic leaf spots in barley

The efficacy of BAS 701 00 F against *Non parasitic leaf spots* in barley was tested in 16 trials.

The reference products selected were Champion with an application rate of 1.5 L/ha and Fandango with an application rate of 1.25 L/ha.
In 15 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products– one trial show a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 91.7%. The standards show a degree of efficacy of 73.3%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 91.7 % (exceptional achievement) for the control of *non parasitic leaf spots* based on trials from 2008 and 2009. It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *non parasitic leaf spots* in barley.

Powdery mildew in rye

The efficacy of BAS 701 00 F against *Erysiphe graminis* in rye was tested in 5 trials.

The reference products selected were Corbel with an application rate of 1.0 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 100%. The standards show a degree of efficacy of 93.5%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 100.0 % (exceptional achievement) for the control of *Erysiphe graminis* based on trials from 2008 and 2009. It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Erysiphe graminis* in rye.

Brown rust in rye

The efficacy of BAS 701 00 F against *Puccinia recondita* in rye was tested in 20 trials.

The reference products selected were Opus with an application rate of 1.0 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 97.7%. The standards show a degree of efficacy of 78.8%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 97.7 % (exceptional achievement) for the control of *Puccinia recondita* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Puccinia recondita* in rye.

Leaf blotch in rye

The efficacy of BAS 701 00 F against *Rhynchosporium secalis* in rye was tested in 16 trials.

The reference products selected was Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 88.6%. The standards show a degree of efficacy of 70.4%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed a good efficacy of 88.6 % (extensive achievement) for the control of *Rhynchosporium secalis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Rhynchosporium secalis* in rye.

Powdery mildew in triticale

The efficacy of BAS 701 00 F against *Erysiphe graminis* in triticale was tested in 13 trials.

The reference products selected were Input with an application rate of 1.25 L/ha and Opus Team with an application rate of 1.5 L/ha.
In 6 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – seven trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 89.1%. The standards show a degree of efficacy of 81.2%. In the trial with the reported P%INF for the whole Plant BAS 701 00 F shows 100% efficacy, the standards 66.7%

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 89.1 % (exceptional achievement) for the control of *Erysiphe graminis* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Erysiphe graminis* in triticale.

Eyespot in triticale

The efficacy of BAS 701 00 F against *Pseudocercosporella herpotrichoides* in triticale was tested in 7 trials.

The reference product selected was Unix with an application rate of 1.0 KG/ha.
In 15 trials it was confirmed that BAS 701 00 F generally reduced infestation even than the reference products – all trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F in the trials where the disease values where estimated with the degree of efficacy of 64.2%. The standards show a degree of efficacy of 63.0%. In the trials with the estimation of the percentage of infection the degree of efficacy was 53.9%. The standards show a degree of efficacy of 55.4% in these trials.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/28, PP1/214 and PP1/223. The applicant showed a satisfactory efficacy of 53.9% to 64.2 % (acceptable achievement) for the control of *Pseudocercosporella herpotrichoides (new: Oculimacula herpotrichoides)* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Pseudocercosporella herpotrichoides (new: Oculimacula herpotrichoides)*. in triticale.

Brown rust in triticale

The efficacy of BAS 701 00 F against *Puccinia recondita* in triticale was tested in 12 trials.

The reference products selected were Input with an application rate of 1.25 L/ha and Opus Team with an application rate of 1.5 L/ha.
In all trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 99.0%. The standards show a degree of efficacy of 96.8%. For the trials with the evaluation of the disease level of the whole plant shows BAS 701 00 F the degree of efficacy of 98.4%. The standards show a degree of efficacy of 90.7%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 99.0 % (exceptional achievement) for the control of *Puccinia recondita* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Puccinia recondita* in triticale.

***Septoria* species in triticale**

The efficacy of BAS 701 00 F against *Septoria ssp.* in triticale was tested in 12 trials.

The reference products selected were Input with an application rate of 1.25 L/ha and Opus

Team with an application rate of 1.5 L/ha.
In 9 trials it was confirmed that BAS 701 00 F generally reduced infestation better than the reference products – three trials shows a comparable disease control.
The disease level in the UTC was reduced by BAS 701 00 F with the degree of efficacy of 88.9%. The standards show a degree of efficacy of 81.6%. For the trials with the evaluation of the disease level of the whole plant shows BAS 701 00 F the degree of efficacy of 93.3%. The standards show a degree of efficacy of 73.3%.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an excellent efficacy of 93.3 % (exceptional achievement) for the control of *Septoria spp.* based on trials from 2008 and 2009.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness against *Septoria spp.* in triticale.

In conclusion, the applicant describes that the results show that BAS 701 00 F provided very good to excellent fungicidal activity against the target pathogens. The fungicidal performance of BAS 701 00 F against all diseases was at least equivalent to that of the standard; although as a rule the efficacy of BAS 701 00 F often significantly exceeded that of the standards. Thus documentary evidence is provided to support the spectrum of activity of BAS 701 00 F against important and relevant leaf and ear diseases of cereal crops.

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

The applicant just submitted a summary of the grain quality data from the efficacy trials. The applicant mentions that a total of 250 efficacy trials were carried out between 2008 and 2009. Measurements of the thousand grain mass (TGM) and hectolitre weight (HLW) were made in 208 and 204 trials, respectively. The objective was to confirm the response in terms of grain quality to applications of BAS 701 00 F in the presence of fungal diseases. A positive response in grain quality is demonstrated for the individual pathogens of all the cereal crops tested.

Table 6.1.4.1-1: Quality parameters (TGM and HLW in g) measured in the efficacy trials

Variety	Disease (EPPO)	n		Untreated con-		BAS 701 00 F		Standard	
		TGM	HLW	TGM	HLW	TGM	HLW	TGM	HLW
Wheat	*Puccinia recondita* (PUCCRE)	11	10	38.8	75.2	**43.7**	**77.7**	42.1	77.0
	Puccinia striiformis (PUCCST)	8	11	37.5	74.1	**44.9**	**75.7**	43.7	75.5
	Drechslera tritici-repentis (PYRNTR)	9	7	41.3	76.5	**44.4**	**77.8**	43.5	77.6

	Pseudocercosporella herpotrichoides (PSDCHE)	13	11	42.8	75.3	**45.2**	**76.4**	44.0	75.7
	Erysiphe graminis (ERYSGR)	11	11	42.0	76.3	**44.2**	**76.9**	42.6	76.6
	Septoria tritici (SEPTTR)	15	16	39.4	71.9	**46.7**	**75.2**	44.9	74.6
	Septoria nodorum (LEPTNO)	6	8	46.0	70.2	**48.8**	**72.7**	46.9	72.0
Barley	*Erysiphe graminis* (ERYSGR)	10	10	48.5	64.9	**50.5**	**65.3**	49.9	65.3
	Puccinia hordei (PUCCHD)	12	8	45.9	62.7	**48.3**	**64.8**	48.4	64.0
	Pyrenophora teres (PYRNTE)	10	12	38.2	61.3	**42.3**	**63.7**	40.2	62.9
	Rhynchosporium secalis (RHYNSE)	11	13	39.2	63.3	**44.8**	**66.0**	42.6	64.9
	Ramularia collo-cygni (RAMUCC)	16	19	46.2	62.8	**48.7**	**64.1**	49.0	64.6
	Non-parasitic leaf spots (YBFMI)	8	11	48.5	61.8	**49.8**	**63.4**	49.6	63.1
Rye	*Erysiphe graminis* (ERYSGR)	4	3	34.0	72.6	**35.6**	**73.3**	34.8	73.4
	Puccinia recondita (PUCCRE)	13	10	35.0	74.2	**37.9**	**75.3**	36.5	74.8
	Rhynchosporium secalis (RHYNSE)	13	11	35.7	74.7	**38.5**	**75.3**	36.6	75.1
Triticale	*Erysiphe graminis* (ERYSGR)	11	8	47.7	72.7	**51.2**	**73.5**	51.0	73.7
	Pseudocercosporella herpotrichoides (PSDCHE)	6	5	45.8	77.0	**47.1**	**77.4**	47.7	77.6
	Puccinia recondita (PUCCRE)	11	11	48.2	75.7	**50.9**	**76.3**	50.1	76.6
	Septoria spp. (SEPTSP)	10	9	48.5	74.4	**50.6**	**75.2**	49.9	75.3

Altogether, BAS 701 00 F had a positive effect on thousand grain mass (TGM). The effect on TGM was at least up to the standard. The influence of the fungicide variants on hectolitre weight (HLW) was lower, but the tendency was always positive.

Conclusion:

he presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. The applicant showed an increase of thousand grain mass and hectolitre weight for intended uses in wheat, barley, rye and triticale.

It can be concluded to accept the data provided by the applicant to demonstrate positive fungicide on thousand grain mass and hectolitre weight.

IIIA1 6.1.4.2 Effects on the processing procedure

According to knowledge currently available, there is no reason to expect that application of BAS 701 00 F at the proposed rates will have adverse effects on the processing procedure.

The applicant believes that BAS 701 00 F has been formulated in a similar way to other fungicides, containing this active ingredients and so it is therefore considered reasonable to conclude that BAS 701 00 F will have no effect on the malting and brewing process of the cereal crops to which it is applied.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

At the present study the applicant submitted a summary of the grain yield data from all the efficacy trials (Table 6.1.4.3-1).
In general, the applicant mentions that a total of 311 efficacy results were obtained between 2008 and 2009. Although the applicant presented any statistical analysis for the results but he is convinced that BAS 701 00 F, applied at the proposed label rate of 2.0 L/ha, showed a markedly positive influence on grain yield compared to the untreated control in all crop species. The yield-enhancing effect of BAS 701 00 F was at least equivalent to the standard products and in many cases even exceeded it.

Table 6.1.4.3-1: Summary of yield data in the presence of disease (mean yield relative to the untreated)

Crop	Disease	# trials	yield (dt/ha) Untreated	% yield relative to the untreated at target dose rate					
				BAS 701 00 F			Standard		
				mean	min	max	mean	min	max
Wheat	*Puccinia recondita* (PUCCRE)	16	86.6	**122.7**	102.1	156.4	**117.3**	101.8	142.1
	Puccinia striiformis (PUCCST)	16	87.1	**130.5**	104.8	186.7	**125.6**	104.2	180.5
	Drechslera tritici-repentis (PYRNTR)	12	75.0	**115.8**	103.6	135.2	**113.7**	102.3	132.3
	Pseudocercosporella herpotrichoides (PSDCHE)	16	90.6	**107.9**	95.5	116.4	**104.3**	98.8	112.8
	Erysiphe graminis (ERYSGR)	15	82.5	**111.5**	97.9	129.1	**104.8**	97.7	111.3

	Septoria tritici (SEPTTR)	25	74.2	**140.5**	102.4	206.7	**131.4**	101.3	190.4
	Septoria nodorum (LEPTNO)	10	79.2	**112.7**	97.9	129.9	**110.9**	99.9	123.8
Barley	*Erysiphe graminis (*ERYSGR*)*	16	68.9	**118.2**	99.2	155.6	**109.4**	101.8	116.0
	*Puccinia hordei (*PUCCHD*)*	14	75.2	**120.8**	102.0	235.3	**114.6**	98.2	213.1
	*Pyrenophora teres (*PYRNTE*)*	22	72.9	**128.9**	104.9	167.1	**117.1**	96.7	137.6
	*Rhynchosporium secalis (*RHYNSE*)*	18	67.1	**137.6**	104.0	227.1	**118.4**	101.6	213.1
	*Ramularia collo-cygni (*RAMUCC*)*	23	72.3	**118.2**	101.0	148.4	**112.7**	97.4	137.4
	Non-parasitic leaf spots *(*YBFMI*)*	16	79.5	**115.9**	104.9	133.1	**112.0**	103.5	119.1
Rye	*Erysiphe graminis (*ERYSGR*)*	5	85.1	**113.3**	108.0	118.7	**109.1**	102.5	119.4
	Puccinia recondita (PUCCRE)	18	80.6	**118.4**	107.8	139.3	**109.8**	102.5	118.4
	*Rhynchosporium secalis (*RHYNSE*)*	16	80.7	**113.8**	104.5	139.3	**107.9**	99.0	118.4
Triticale	*Erysiphe graminis (*ERYSGR*)*	13	85.2	**109.6**	101.7	122.5	**107.6**	100.9	117.6
	Pseudocerco-sporella herpo-trichoides (PSDCHE*)*	7	81.0	**110.5**	101.5	124.4	**107.4**	101.8	115.5
	*Puccinia recondita (*PUCCRE*)*	12	88.7	**110.8**	102.9	124.7	**109.3**	104.4	121.6
	Septoria spp. *(*SEPTSP*)*	12	87.8	**113.2**	105.0	124.7	**111.4**	104.4	122.6

In conclusion the applicant demonstrated that BAS 701 00 F had a good to very good influence on yield in all crop species. The effect was at least up to the standard and in most cases even exceeded it.

Conclusion:

The presented data correspond with the requirements of the EPPO standards PP1/26, PP1/214 and PP1/223. Additional a mean grain yield increase of 20 % in wheat uses, 23 % in barely uses, 15 % in rye uses and 11 % in triticale uses could also be achieved by applying the fungicide.

It can be concluded to accept the data provided by the applicant to demonstrate of the effectiveness in crops.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

The requirements for evaluation of potential phytotoxicity on cereals, by using of BAS 701 00 F, were determined by applicant in accordance with the EPPO standard PP1/135(3) - Phytotoxicity Assessment. In all of the field trials carried out, there were no significant symptoms of phytotoxicity observed following treatment with BAS 701 00 F at the proposed use rate of 2.0 L/ha. Trials were carried out on cereal crops from 2008 to 2009 on a wide range of commercially grown varieties. According to him all of the available data clearly demonstrates the excellent crop safety of BAS 701 00 F in all cereal species.
The applicant also mentions that in the vast majority of the trials, treatment with BAS 701 00 F resulted in a greater yield in comparison to the untreated control. This cannot be fully explained by the observed levels of fungicidal activity and so underlines the crop safety of BAS 701 00 F. The well documented and recognized physiological effects of pyraclostrobin may well have contributed to this increase in yield. This trend is apparent for both the western European and eastern European trials.

Table 6.2.1-1: Location and number of BAS 701 00 F phytotoxicity trials

Country	Year		Total
	2008	2009	
AT	2	1	3
BE	2	5	7
CZ	2	2	4
DE	72	77	151
DK	1	2	8
FR	16	25	42
IE	2	5	7
NL	0	1	1
PL	1	2	3
UK	10	18	30

Total	108	138	**246**

Table 6.2.1-2: Guidelines and trial design

GEP	Yes (all trials)		
Standards	PP 1/26(3), PP 1/28(2), PP 1/28(3), PP 1/79(3), PP 1/152(2), PP 1/181(3), PP 1/135(3), PP 1/214(1), 1/223(1), CEB N°189 REVISEE 1999		
Number of replications	4		
Plot design, plot size	RB, minimum 10 m² (*)		
Trials per crop	wheat: 108; barley: 99; rye: 41; triticale: 43		
Trials per intended use	Wheat	Brown rust of cereals (*Puccinia recondita*)	15 trial results
		Stripe rust of grasses *(Puccinia striiformis)*	14 trial results
		DTR tan spot (*Pyrenophora tritici-repentis*)	12 trial results
		Stem break of cereals (*Pseudocercosporella herpo-trichoides*)	16 trial results
		Powdery mildew (*Erysiphe graminis*)	16 trial results
		Leaf spot of wheat (*Septoria tritici*)	25 trial results
		Septoria leaf spot (*Septoria nodorum*)	10 trial results
	Barley	Powdery mildew (*Erysiphe graminis*)	15 trial results
		Brown rust of barley (*Puccinia hordei*)	9 trial results
		Net blotch (*Pyrenophora teres*)	20 trial results
		Leaf blotch of cereals (*Rhynchosporium secalis*)	18 trial results
		Ramularia leaf spot disease (*Ramularia collo-cygni*)	23 trial results
		Decrease of non-parasitic leaf spots	14 trial results
	Rye	Powdery mildew (*Erysiphe graminis*)	5 trial results

		Brown rust of cereals (*Puccinia recondita*)	20 trial results
		Leaf blotch of cereals (*Rhynchosporium secalis*)	16 trial results
	Triticale	Powdery mildew (*Erysiphe graminis*)	12 trial results
		Stem break of cereals (*Pseudocercosporella herpotrichoides*)	7 trial results
		Brown rust of cereals (*Puccinia recondita*)	12 trial results
		Septoria species (*Septoria spp.)*	12 trial results
Crop stage (BBCH) at application	BBCH 30-69		
Reference product(s) (dosage), act. subst	Unix (1.0 kg/ha)	Cyprodinil	
	Opus Top (1.5 L/ha)	Epoxiconazole, fenpropimorph	
	Champion (1.5 L/ha)	Epoxiconazole, boscalid	
	Corbel (1.0 L/ha)	Fenpropimorph	
	Capalo (2.0 L/ha)	Epoxiconazole, fenpropimorph, metrafenone	
	Talius (0.25 L/ha)	Proquinazid	
	Input (1.25 L/ha)	Prothioconazole, spiroxamine	
	Opus (1.0 L/ha)	Epoxiconazole	
	Amistar Opti (2.5 L/ha)	Azoxystrobin, chlorthalonil	
	Osiris (3.0 L/ha)	Epoxiconazole, metconazole	
	Fandango (1.25 L/ha)	Fluoxastrobin, prothioconazole	

* The plot size was 9.9 m² in four (French study reports) - 2x SEPTR and PUCCST in wheat.

Table 6.2.1-3: Effect on phytotoxicity in efficacy trials of BAS 701 00 F

Crop	**Disease (EPPO)**	**# trials***	**Untreated control (UTC) in %**			**2.0 L/ha BAS 701 00 F in %rel.**			**Type of loss/ damage**
			mean	**min**	**max**	**mean**	**min**	**max**	
Wheat	*Puccinia recondita* (PUCCRE)	14	**0.0**	0.0	0.0	**0.3**	0.0	3.0	Yellowing
	Puccinia striiformis (PUCCST)	14	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-

	Drechslera tritici-repentis (PYRNTR)	12	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Pseudocercosporella herpotrichoides (PSDCHE)	16	**0.0**	0.0	0.0	**0.0**	0.0	1.3	Yellowing
	Erysiphe graminis (ERYSGR)	15	**0.0**	0.0	0.0	**0.0**	0.0	2.5	Yellowing
	Septoria tritici (SEPTTR)	25	**0.0**	0.0	0.0	**0.4**	0.0	4.0	Yellowing
	Septoria nodorum (LEPTNO)	10	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
Barley	*Erysiphe graminis* (ERYSGR)	15	**0.0**	0.0	0.0	**0.3**	0.0	4.0	Yellowing
	Puccinia hordei (PUCCHD)	9	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Pyrenophora teres (PYRNTE)	20	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Rhynchosporium secalis (RHYNSE)	18	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Ramularia collo-cygni (RAMUCC)	23	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Non-parasitic leaf spots (YBFMI)	14	**0.0**	0.0	0.0	**0.1**	0.0	0.8	Yellowing
Rye	*Erysiphe graminis* (ERYSGR)	5	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Puccinia recondita (PUCCRE)	20	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Rhynchosporium secalis (RHYNSE)	16	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
Triticale	*Erysiphe graminis* (ERYSGR)	12	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-

	Pseudocercosporella herpotrichoides (PSDCHE)	7	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Puccinia recondita (PUCCRE)	12	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-
	Septoria spp. (SEPTSP)	12	**0.0**	0.0	0.0	**0.0**	0.0	0.0	-

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/135. The applicant submitted 106 wheat trials, 9 barley trails, 44 rye trials and 43 triticale trials of the year 2008 and 2009. A negative impact on the plant compatibility, even for different cultivars, was not given by the fungicide applied in the requested dose rate.

Based on this submitted data and on the expert knowledge about fluxyparoxad and epoxiconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The toxicity of Adexar (= BAS 701 00 F) on beneficial organisms has been investigated by carrying out tests under different laboratory conditions on *Aphidius rhopalosiphi*, *Typhlodromus pyri* and *Chrysoperla carnea*. The results are presented in Table 6.2.4-1 to Table 6.2.4-3.
On the basis of the results in the higher tier tests no unacceptable effects (≥ 25%) are expected for populations of *Aphidius rhopalosiphi*, *Chrysoperla carnea* and *Typhlodromus pyri*, when Adexar is applied according to the recommended use pattern, i.e. maximal 2 applications of 2.0 L/ha to wheat, barley, rye and triticale.
Typhlodromus pyri is not relevant antagonist in fields with cereals. With today's level of knowledge, the results for *Typhlodromus pyri* indicate that 2 applications of Adexar to cereals should not reduce populations of relevant predatory mites and spiders ≥ 25%.

Table 6.2.4-1: Effects of BAS 701 00 F on *Aphidius rhopalosiphi* (exposed stage: male and female) in different laboratory tests

Application rate [L/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
1 Laboratory test using glass			Sipos, K., 2008
0.375	2.5	-	2008/1010766
0.750	7.5	-	
1.500	20.0	-	
3.000	47.5	-	

6.000	92.5	-	
LR_{50}: 3.23 L/ha (95% Confidence limits: 2.79 L/ha – 3.68 L/ha)			
2 Extended laboratory test using barley plants			Sipos, K., 2009 2008/10465577
0.5	0	-	
1.0	0	-	
2.0	0	3.5	
4.0	10.0	16.1	
6.0	13.3	25.9	

Table 6.2.4-2: Effects of BAS 701 00 F on *Chrysoperla carnea* (exposed stage: larva) in an extended laboratory test (substrate: bean leaves)

Application rate [L/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
0.500	4.0	21.7	Spincer, D., 2009 2008/1042192
1.000	2.0	12.3	
2.000	6.0	13.1	
4.000	0	20.7	
6.000	4.0	8.8	

Table 6.2.4-3: Effects of BAS 701 00 F on *Typhlodromus pyri* (exposed stage: protonymph) in different laboratory tests

Application rate [L/ha]	Corrected mortality [%]	Effect on reproduction [%]	Reference
1 Laboratory test using glass			Sipos, K., 2008 2008/1010765
0.096	20.3	-	
0.240	20.3	-	
0.600	40.2	-	
1.500	38.4	-	
3.000	42.0	-	
6.000	54.7		
2 Extended laboratory test using bean leaves			
0.5	20.1	26.5	Sipos, K., 2009 2008/1046576
1.0	26.9	76.3	
2.0	32.0	59.4	
4.0	32.0	82.6	
6.0	38.8	86.6	
3 Extended laboratory test using leaves from treated bean plants			
2.0	18.9	-12.3	Mayer, C.J., 2009 2009/1069104
4.0	22.3	-33.6	

Conclusions

Adexar is classified as not harmful for populations of *Aphidius rhopalosiphi* and *Chrysoperla carnea*.
Adexar is classified as not harmful for populations of relevant predatory mites and spiders.

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

A series of greenhouse trials were performed by the applicant to test the germination capacity of wheat, barley, rye and triticale. The results demonstrated that there were no adverse effects on the germination behaviour of the tested cereal species, even after double application or after very late application of BAS 701 00 F.
The applicant also mentions that trials which done with the earlier formulation BAS 701 00 F has no detrimental effect on the germination of cereal grain harvested from treated crops.

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/248. Any negative effect of fungicide application with the active ingredients fluxapyroxad and epoxiconazole has been found on the process or on the treated plants and plant products used for propagation.

Based on this submitted data and on the expert knowledge about fluxapyroxad and epoxiconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.6 Impact on succeeding crops

The applicant claims that the evaluation given below of the influence of BAS 701 00 F on succeeding crops is according to EPPO standard PP 1/207 'Effects on succeeding crops'.
At the present study, in a greenhouse trial using a relatively light soil, the formulation (= double the application rate) was applied at a rate of 4.0 L/ha to the bare soil and incorporated in the soil to a depth of about 10 cm. Immediately after this the following crop species were sown or planted: bean, field bean, cabbage, lettuce, carrot, sun flower, barley, rape seed, sugar beet, wheat, corn, potatoes, grasses, pea, clover and rye grass.
After sowing or planting, the percentages of normally emerged plants and of abnormal and non-germinated seeds were determined in accordance with ISTA guidelines (ISTA Methods, Chapter 5, The Germination Test, 2004). Any cases of damage to plant were recorded on a scale from 0 to 100 (0 = without symptoms of damage, 100 = total damage). In addition, plant height was measured. All assessments were performed at growth stage 12.
The results demonstrated that there were no adverse effects on any of the succeeding crops tested. This is also confirmed by a seedling emergence test. This indicates that BAS 701 00 F presents a low risk of damage to the most of the following crops.
It may therefore be concluded that the application of BAS 701 00 F provides no risk of damage to following crops and the applicant believes that there is no necessity for any restrictions in the choice of following crops, even in the event of crop failure, on a field which has been treated

with BAS 701 00 F.

Table 6.2.6-1: Effect on germination, height, crop injury and weight on plants at pre-emergence application of BAS 701 00 F (sowing five weeks after soil preparation) – greenhouse trials

Crop	EPPO	Untreated control (UTC)				Effect on germination, height, crop injury and weight on plants at pre-emergence of 4.0 L BAS 701 00 F/ ha			
		Germination [%]	Crop Injury [%]	Height [cm]	Weight [g/plant]	Germination [%]	Crop Injury [%]	Height [cm]	Weight [g/plant]
Onion	ALLCE	88.0	0.0	13.0	-	92.0	0.0	13.0	-
Oat	AVESA	89.0	0.0	15.1	-	91.0	0.0	16.3	-
Sugar beet	BEAVA	95.0	0.0	-	1.5	95.0	8.0	-	1.6
Oilseed rape	BRSNN	71.0	0.0	-	0.6	67.0	0.0	-	0.8
Cabbage	BRSOX	82.0	0.0	-	1.5	92.0	0.0	-	1.9
Carrot	DAUCS	91.0	0.0	-	0.1	87.0	0.0	-	0.1
Sunflower	HELAN	96.0	0.0	-	0.9	96.0	0.0	-	1.2
Winter barley	HORVW	90.0	0.0	14.8	-	88.0	0.0	15.2	-
Lettuce	LACSA	98.0	0.0	-	1.5	100.0	0.0	-	2.2
Ryegrass	LOLPE	66.0	0.0	15.1	-	73.0	0.0	15.5	-
Bean	PHSVX	75.0	0.0	-	4.1	71.0	0.0	-	4.3
Pea	PIBSA	87.0	0.0	-	1.4	94.0	0.0	-	1.4
Potato	SOLTU	88.0	0.0	-	1.3	100.0	0.0	-	2.2
Clover	TRFRE	87.0	0.0	-	3.0	78.0	0.0	-	2.8
Winter wheat	TRZAW	94.0	0.0	16.0	-	92.0	0.0	15.9	-
Field bean	VICFX	94.0	0.0	-	2.9	94.0	0.0	-	3.0
Corn	ZEAMX	95.0	0.0	29.2	-	98.0	0.0	30.6	-

Table 6.2.6-2: Effect on emergence and crop injury after an application of 2.0 L BAS 701 00 F /ha – field trials

Crop	EPPO	Untreated control (UTC)					Effect on emergence and crop injury at treated soil with 2.0 L BAS 701 00 F/ ha				
		Emergence [plants/plot]		Crop Injury [%]			Emergence [plants/plot]		Crop Injury [%]		
		20 DAS	41 DAS	20 DAS	41 DAS	20 DAS	41 DAS	20 DAS	20 DAS	41 DAS	20 DAS
Sugar beet	BEAVA	236.5	193.5	0.0	0.0	0.0	222.0	204.0	0.0	0.0	0.0
		288.5	302.8	0.0	0.0	0.0	268.0	252.0	0.0	0.0	0.0

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/207. Results from greenhouse experiments were presented by the applicant. They show no negative effect of fluxapyroxad and epoxiconazole on germination and plant growth of succeeding crops.

Based on this submitted data and expert knowledge about fluxapyroxad and epoxiconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.7 Impact on other plants including adjacent crops

The applicant mentions that according to the corresponding EPPO standard PP 1/256(1) for testing of effects on adjacent crops, results generated with one formulation are normally applicable to other formulations of the active substance. Therefore, reference is made to results obtained with BAS 701 00 F. Vegetative vigour evaluations were made for a range of indicator crops (corn, cabbage, sugar beet, lettuce, bean and potato) for BAS 701 00 F.
ER 50 values were > 1.25 L/ha for BAS 701 00 F for all tested crops (Table 6.2.7-1 and 6.2.7-2). The equivalent dose rate for BAS 701 00 F would be 6 L/ha, which is three times the target dose rate for the intended use.

Table 6.2.7-1: Effect of BAS 701 00 F on vegetative vigour - biomass production dry weight (% to untreated control) and phytotoxicity (% plant damage compared to control) – 21 DAT for all plant species

Treatment	Mean plant weight [% of untreated control]		Mean visible damage [% damage compared to control]	
	Untreated control	0.2 L/ha BAS 701 00 F	Untreated control	0.2 L/ha BAS 701 00 F
Corn	100.0	102.0	0.0	0.0
Cabbage	100.0	115.0	0.0	0.0
Sugar beet	100.0	101.0	0.0	5.0
Lettuce	100.0	114.0	0.0	0.0
Bean	100.0	83.0	0.0	5.0
Potato	100.0	93.0	0.0	0.0

No significant differences compared to the control (2-Sample t-Test; $\alpha = 0.05$)

The applicant is convinced that since a safe use of BAS 701 00 F on non-target plants was shown with three times the target dose rate in a 1st vegetative vigour study, a calculation of the Toxicity Exposure Ratio is not required. The data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops after the application of BAS 701 00 F.

Table 6.2.7-2: PEC-values* (g/ha) (drift)

distance [m]	%	drift test product [g/ha]
1	2.00	3.00
1	2.77	35.91
3	0.95	12.31
5	0.57	7.39
10	0.29	3.76
15	0.20	2.59

1 distance to adjacent crop (m)
2 percentage drift (%) according to Ganzelmeier, BBA 1995
3 drift test product (g/ha; considering density of BAS 701 00 F of 1.037 g/cm³)
* Predicted Environmental Concentration

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/256. Results from vegetative vigour tests and PEC-values were submitted by the applicant. Slightly effects of fluxapyroxad and epoxiconazole on biomass production and visible damage could observed for beans, potatoes and sugar beets.

Based on this submitted data and expert knowledge about fluxapyroxad and epoxiconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

BAS 701 00 F is a fungicide mixture containing 62.5 g BAS 700 F and 62.5 g epoxiconazole per litre formulated product. It is intended for the control of powdery mildews (*Blumeria graminis*), *Septoria* leaf spot and glume blotch (*Septoria tritici, Stagonospora nodorum*), rusts (*Puccinia* spp.), leaf scald (*Rhynchosporium secalis*), net blotch (*Pyrenophora teres*), tan spot (*Pyrenophora tritici-repentis*), eye spot (*Oculimacula yallundae, Oculimacula acuformis*) and Ramularia leaf spot (*Ramularia collo-cygni*) in cereals.

Mode of action

BAS 700 F is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI) and the mode of action of BAS 700 F at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain (Kulka and von Schmeling 1995). Like other complexes of the respiratory chain, this enzyme is a component of the inner mitochondrial membrane. It consists of four nucleus-encoded sub-units (SDH A, B, C, D). Two of these polypeptides (SDH C, D) anchor the complex in the membrane whilst the others project into the mitochondrial matrix where they catalyse the oxidation of succinate to fumarate as part of the tricarboxylic acid (TCA) cycle. The electrons so released are channelled into the electron transport chain via the co-substrate ubiquinol. Complex II occupies a key function in fungal metabolism. Not only does it deliver high energy electrons for energy production, it also forms an essential junction where components of the TCA cycle can be diverted to become the building blocks for amino acids and lipids. Through its inhibition of complex II, BAS 700 F disrupts fungal growth by preventing energy production and also by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components.

Epoxiconazole belongs to the triazole group of fungicides and the primary mode of action is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol C14-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional C14-methyl sterols results in inhibition of growth and cell membrane disruption. Because of the mode of action triazoles belong to the demethylation inhibitors (DMI). DMIs and morpholines together are named sterolbiosynthesis inhibitors (SBI).

Mechanism of resistance

Fluxapyroxad belongs to the succinate dehydrogenase inhibitors (SDHI). The target enzyme is succinate dehydrogenase (SDH), which is a functional part of the tricarboxylic cycle and of the mitochondrial electron transport chain (Matsson and Hederstedt 2001, Keon et al. 1991). SDH consists of four subunits (A-D). Information about the putative mechanism of resistance to the SDHI carboxin has been reported for some plant pathogenic fungi (Keon et al. 1991, Ben-Yephet et al. 1975, Gunatilleke et al. 1976, Skinner et al. 1998, Stammler et al. 2007a,b, Stammler 2008, FRAC 2013) and it has been found that some specific mutations, which lead to amino acid substitutions in conserved regions in the B- (Keon et al. 1991, Skinner et al. 1998, Li et al. 2006, Stammler et al. 2007a, b, Stammler 2008), C- (Ito et al. 2004, Stammler 2008) or D-subunit (Matsson et al. 1998, Glättli et al. 2009), result in reduced sensitivity (Scalliet et al. 2012). Amino acid exchanges found in the SDH subunits of SDHI resistant mutants and their possible impact on SDH structure and SDHI binding are described in more detail by Glättli et al. (2009).

Epoxiconazole: Different resistance mechanisms have been reported for DMIs mainly based on work with yeast, *Ustilago* spp., *Mycosphaerella graminicola* and *Candida albicans*. These have been reviewed e.g. by Hollomon et al. 1990, Köller 1992, de Waard 1994, Stergiopoulos et al. 2003, Cools and Fraaije 2013). Three major mechanisms are associated with changes in DMI-sensitivity: Mutations in the target gene, cyp51 (Leroux et al. 2006, 2011, Stammler et al. 2008, 2011), elevation of intracellular CYP51 levels (Ma et al. 2006, Cools et al. 2012) and reduced intracellular accumulation of triazoles by overexpression of efflux-pumps (Leroux et al. 2011). It is assumed that these resistance mechanisms may be combined in an additive manner. Mutations of a single gene result in a low degree of resistance and resistance levels may increase by additional mutations in the same or in other genes. This results in a quantitative (directional) type of resistance and changes in the sensitivity of a population are gradual. Studies on resistance mechanisms have often involved laboratory mutants which have also been shown to have a considerably reduced pathogenicity (Fuchs and Viets-Verveij 1975, Fuchs et al. 1977) and/or fitness penalties due to reduced spore germination, spore production, mycelial growth or temperature tolerance (Fuchs and Drandarevsky 1976, Sherald and Sisler 1975, De Waard and Gieskes 1977, Kalamarakis et al. 1991, Köller et al. 1991, Karaoglanidis et al. 2001, Karaoglanidis and Thanassoupoulos 2002).

Evidence of resistance

Fluxapyroxad: Several mutations in the target protein at different positions in three SDH subunits B, C and D were detected in field isolates of some plant pathogens such as *Botrytis cinerea, Corynespora cassiicola, Alternaria alternata, Didymella bryoniae,* and *Sclerotinia sclerotiorum* and in laboratory mutants of *Mycosphaerella graminicola* (Skinner et al. 1998, Avenot

and Michaelidis 2007, Stammler 2008, Stammler et al. 2007a, b, Ishii 2007, Glättli 2009, Stammler et al. 2010, Veloukas et al. 2011, Scalliet et al. 2012). Even within a single species, different mutations were found at one location (e.g. B-P225L,F,T or B-H272Y,R,L in *Botrytis cinerea*), and in different locations in different subunits (e.g. B-H277Y, C-H134R, D-H133R in *Alternaria alternata*). Some mutations are part of the binding site with explainable effects on SDHI binding (e.g. in case of B-H272-exchanges in *B. cinerea*) or outside of the binding area which excludes a direct influence on SDHI binding. The impact of the mutation on the resistance level is not correlated with its proximity to the binding site and exchanges at one position can cause different resistance factors (e.g. H272Y,R,L in *Botrytis cinerea*). In most cases mutated SDH has a lower activity which might confer fitness penalties of SDHI resistant isolates (Scalliet et al. 2012).
In the last years extensive monitoring programmes were performed and results were shown in the annual FRAC meetings of the SDHI Working Group. One isolate with slightly increased EC50 value for *Mycosphaerella graminicola* from a trial site and 2 isolates for *Pyrenophora teres* with slightly increased EC50 values from the 2012 random monitoring had been found in BASF monitoring and reported in FRAC (FRAC 2013). Target gene analysis showed the mutations C-T79N for *Mycosphaerella graminicola* and B-H277Y in *Pyrenophora teres*. Newest data from the 2013 monitoring in Pyrenophora teres showed isolates with additional mutations (mainly C-G79R and also others, see chapter “Baseline sensitivity / Sensitivity studies”) which lead to lower SDHI sensitivity in such isolates.

Epoxiconazole: A current summary of the situation for some of the main indications where DMIs are used can be found in the FRAC SBI Working Group report (FRAC 2013). In summary, it can be said that some pathogens have shown a shift towards lower sensitivity in the period since their introduction, but that in most cases the situation has now stabilised (FRAC 2013). For the intensive cereal growing regions of Northern Europe, the sensitivity situation of *Mycosphaerella graminicola* towards DMIs was widely discussed in recent years. Since the early 2000s, a shift in *Mycosphaerella graminicola* to a reduced sensitivity towards different DMIs has been determined in microtitre assays with isolates taken from the most important cereal-growing regions in Europe (FRAC 2013). Molecular biological analyses have shown that mutations and mutation combinations in cyp51, and also other factors, such as the activity of efflux transporters, can be linked to the sensitivity changes observed (Cools and Fraaije 2006, Leroux et al. 2006, 2007, 2011, Brunner et al. 2008 Stammler et al. 2008, Cools et al. 2010, Walker et al. 2010, Stammler and Semar 2011). Isolates belonging to different CYP51-haplotypes showed variation in their sensitivity response to different DMIs (Glättli et al. 2009, Fraaije et al. 2007), that means, correlation of sensitivity between various DMIs can be low or even negative. This is confirmed by frequency analyses of cyp51-haplotypes in field trials after the application of DMI treatments, which showed that DMIs select cyp51-haplotypes differently (Fraaije et al. 2007, Stammler et al. 2008). Sensitivity changes observed in microtitre plates do not always correlate with DMI efficacy observed in the field (Mehl et al. 2010, Stammler et al. 2006, Stammler and Semar 2011, Strobel et al. 2010), because other factors such as application timing, weather conditions and disease pressure may influence fungicide efficacy. Despite sensitivity changes measured in microtiter plates, some DMIs (including epoxiconazole) at registered dose rates has shown reliable field performance against Mycosphaerella graminicola throughout the past decade (Stammler et al. 2006, Strobel et al. 2010), whereas the efficacy of some other DMIs has significantly decreased (Defra 2007, Strobel et al. 2010).

Cross-resistance

Fluxapyroxad: BASF internal studies showed that there is cross resistance between SDHI fungicides in different tested fungal species, which is also confirmed by modelling studies with different SDHIs (Glättli *et al.* 2009). The founding of a separate FRAC SDHI Working Group indicates the cross resistance of fungicides belonging to this mode of action group and is also specified on the webpage: *"The SDHI fungicides (benodanil, bixafen, boscalid, carboxin, fenfuram, fluopyram, flutolanil, furametpyr, isopyrazam, mepronil, oxycarboxin, penflufen, penthiopyrad, sedaxane, thifluzamide) are in the same crossresistance group".*

Baseline sensitivity / Sensitivity monitoring data

Fluxapyroxad:

Baseline sensitivity studies on *Mycosphaerella graminicola, Pyrenophora teres, Rhynchosporium secalis* and *Puccinia triticina* are attached to this Resistance Risk Analysis and show unimodal frequency distributions of the ED_{50} and ED_{90} values for fluxapyroxad and each pathogen. Resistance to benzimidazoles (mainly by the mutation E198A in β-tubulin) and QoIs (by G134A mutation in cytochrome *b*) is widespread in European populations of *Mycosphaerella graminicola*, and also QoI sensitivity changes in populations of *Pyrenophora teres* (by F129L or G137R mutation in cytochrome *b*) are common. Additionally, several *cyp51* (target of DMIs) haplotypes, which are correlated with different DMI-sensitivities, are known for *Mycosphaerella graminicola* (Stammler *et al.* 2008) and two *cyp51*-haplotypes are also described for *Puccinia triticina* (Stammler *et al.* 2009). However, the unimodal frequency distributions of ED_{50} and ED_{90} values for fluxapyroxad for these pathogens indicate that resistance to benzimidazoles, QoIs and adaptation to DMI fungicides by *cyp51* mutations do not influence the sensitivity to fluxapyroxad.

Epoxiconazole:

Within DMIs: Cross resistance studies over many years, different pathogens and with different DMI-fungicides indicated that a clear statement is not possible. There are DMIs which show a good correlation on the sensitivity in *Mycosphaerella graminicola* (Figure 1), but correlations for others are low, especially when sensitivities of imidazoles and triazoles are correlated (Figure 2, 3). Obviously there are mechanisms which affect all DMIs, such as target site (cyp51) overexpression, enhanced efflux or some target site mutations. It has been shown for *Mycosphaerella graminicola* in various studies that some target site mutations are more selective to the one than to another DMI. While R-types (classified by mutations in cyp51, Leroux et al. 2011, Stammler et al. 2008) containing I381V have higher EC50 values to some triazoles as tebuconazole and metconazole, EC50 values for prochloraz are on the wild type level or even lower (at least for the cases where I381V is not combined with V136A and/or S524T).

There exist several reports from various plant pathogens that complete cross resistance within DMI fungicides is not always present (Kendall et al. 1986, Leroux et al. 2000, 2006, Stammler and Semar 2011, Steva et al. 1990). However, the current recommendation of the FRAC SBI Working Group is to consider all DMIs as one product group in which general cross resistance exists.

Resistance risk assessment of unrestricted use pattern

Fungicide risk

FRAC describes the SDHI fungicides in general as *medium to high-risk* compounds (FRAC 2013) according to the principles described in FRAC Monographs 1 and 2 (Brent 1995, Brent and Hollomon 1998).

FRAC describes the DMI fungicides in general as *medium-risk* compounds (FRAC 2013) according to the principles described in FRAC Monographs 1 and 2 (Brent 1995, Brent and Hollomon 1998).

Pathogen risk

Table 5 shows a method for the risk classification of the target pathogens of this resistance risk analysis based on the biology of the fungus (generations, spore dispersal and spore production), its history of fungicide resistance development and the occurrence of the disease (frequency, control of disease).

The pathogen risk is assessed as follows:

Medium risk pathogens: *Mycosphaerella graminicola, Phaeosphaeria nodorum, Oculimacula* spp., *Puccinia* spp., *Pyrenophora tritici-repentis, Pyrenophora teres, Ramularia collo-cygni, Rhynchosporium secalis*,

High risk pathogens: *Blumeria graminis*

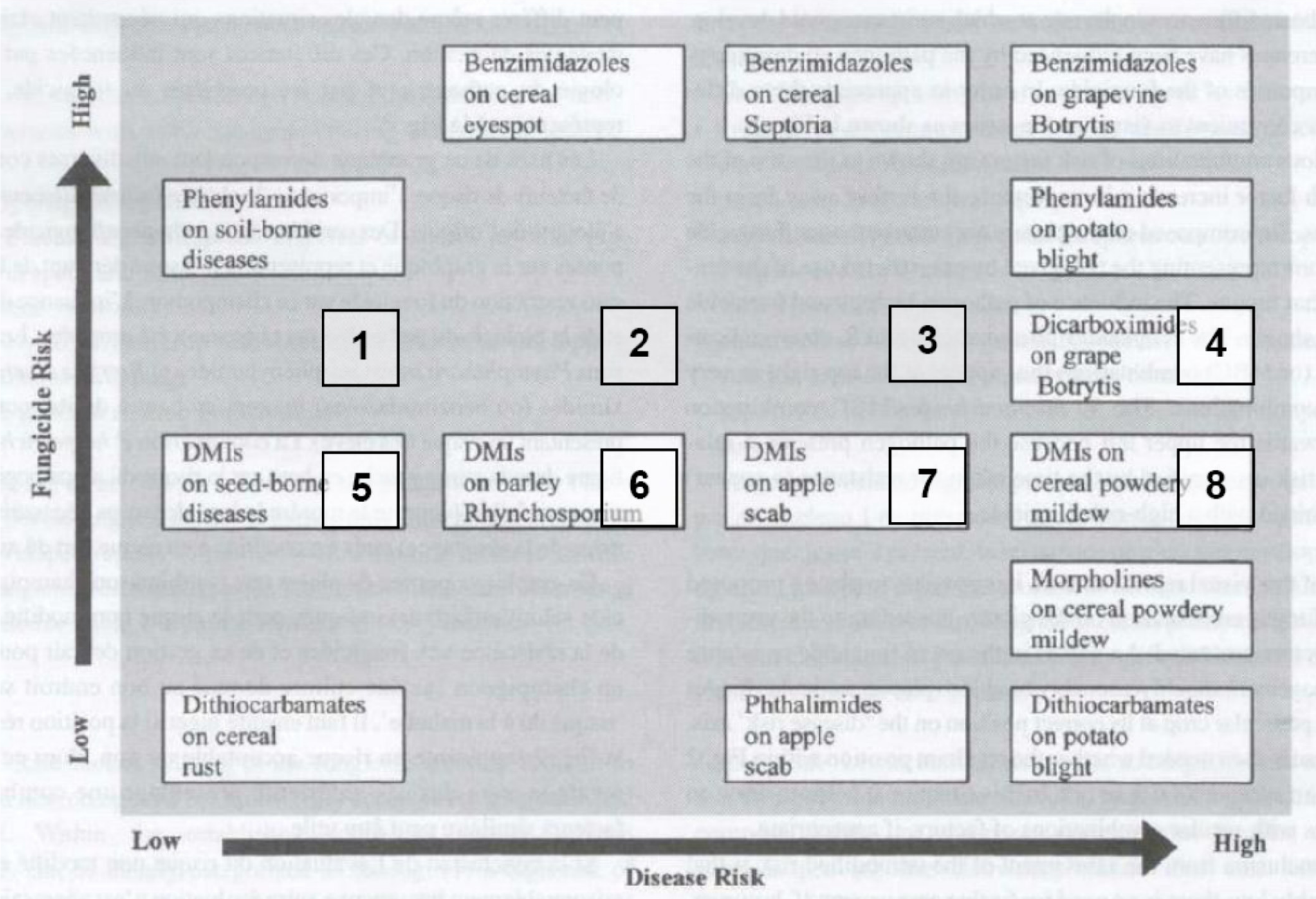
The classification of the target species with this method is in most cases in accordance with the risk classification of Brent and Hollomon (1998), EPPO (2003) and FRAC (2013). Please note: This method is an attempt for an estimation of the pathogen resistance risk. Depending on changes in the occurrence and importance of the disease and knowledge on development of resistance, it will be continually adapted.

The combined pathogen and fungicide risk is assessed as follows:

The combined resistance risk of pyraclostrobin and the different pathogens in the following scheme can be positioned as follows:

1: BAS 700 F on *Puccinia* spp.
2: BAS 700 F on *Oculimacula* spp.*, Rhynchosporium secalis*
3: BAS 700 F on *Pyrenophora teres, Pyrenophora tritici-repentis, Septoria tritici, Stagonospora nodorum, Ramularia collo-cygni*
4: BAS 700 F on *Blumeria graminis* f.sp. *tritici, Blumeria graminis* f.sp. *hordei*

5: Epoxiconazole on *Puccinia* spp.
6: Epoxiconazole on *Oculimacula* spp.*, Rhynchosporium secalis*
7: Epoxiconazole on *Pyrenophora teres, Pyrenophora tritici-repentis, Septoria tritici, Stagonospora nodorum, Ramularia collo-cygni*
8: Epoxiconazole on *Blumeria graminis* f.sp. *tritici, Blumeria graminis* f.sp. *hordei*



Scheme for visualizing the inherent combined resistance risk.

These diagrams exemplify interactions between inherent fungicide and pathogen risks of resistance development. The risk categorisation is approximate and the scores are arbitrary. Nevertheless, these are probably the best estimates that can be made in the light of current knowledge. They represent risks under conditions of unrestricted fungicide use and severe, sustained disease pressure.

Taken the results of both analyses together we classify the combined risks a follows:

Pathogen X SDHIs

*Puccini*a spp. x SDHI: low

Oculimacula spp., Rhynchosporium secalis X SDHI: low to medium

Mycosphaerella graminicola, Phaeosphaeria nodorum, Pyrenophora tritici-repentis, Pyrenophora teres, Ramularia collo-cygni X SDHI: medium

Blumeria graminis X SDHI: high

Pathogen X DMIs

Puccinia spp.x DMI: low

Oculimacula spp., *Rhynchosporium secalis* X DMI: low to medium

Mycosphaerella graminicola, Phaeosphaeria nodorum, Pyrenophora tritici-repentis, Pyrenopho-

ra teres, Ramularia collo-cygni X DMI: medium

Blumeria graminis X DMI: medium to high

Management strategy

The objective of anti-resistance management strategies is the reduction of selection pressure to avoid or delay the occurrence of resistance or to keep the frequency of resistant isolates in a population low. This can be achieved by good agricultural practice which leads to less infection pressure (e.g. phytosanitary measurements, cultivation of less susceptible varieties, appropriate crop cultivation unfavourable for the target pathogens).

A further tool is the use of fungicide mixtures. BAS 701 00 F is already a combination of two fungicides which are both active against the target pathogens.

Limiting the number of sprays is also an important factor in delaying the build-up of resistant pathogen populations. The number of BAS 701 00 F applications will be restricted to a maximum of 2 per crop cycle.

Since population size of pathogens is lower at disease onset than when already established in the field, selection pressure is less when using preventive applications rather than curative or eradicative spray schemes. Therefore, BAS 701 00 F should be applied in a preventive manner following the recommendations on the label.

Fungicide applications should be ensured to be well-timed and that the appropriate dose is used.

The applicant is a member of the FRAC SDHI and SBI Working Groups and will promote effective anti-resistance management strategies. The current FRAC recommendations for resistance management of SDHI and SBI-fungicides are:

General guidelines for using SDHI fungicides (all crops)

Strategies and General Guidelines for the 2009 season (foliar applications)

- Strategies for the management of SDHI fungicide resistance, in all crops are based on the statements listed below. These statements serve as a fundamental guide for the development of local resistance management programs.
- Resistance management strategies have been designed in order to be proactive and to prevent or delay the development of resistance to SDHI fungicides.
- A fundamental principle that must be adhered to when applying resistance management strategies for SDHI fungicides is that:
    - The SDHI fungicides (benodanil, bixafen, boscalid, carboxin, fenfuram, fluopyram, flutolanil, furametpyr, isopyrazam, mepronil, oxycarboxin, penthiopyrad, sedaxane, thifluzamide) are in the same cross-resistance group.
- Fungicide programs must deliver effective disease management. Apply SDHI fungicide based products at effective rates and intervals according to manufacturers' recommendations.
- Effective disease management is a critical component to delay the buildup of resistant pathogen populations.

- The number of applications of SDHI fungicide based products within a total disease management program must be limited.
- When mixtures are used for SDHI fungicide resistance management, applied as tank mix or as a co-formulated mixture, the mixture partner:
  - should provide satisfactory disease control when used alone on the target disease
  - must have a different mode of action
- SDHI fungicides should be used preventively or at the early stages of disease development.

Guidelines SDHI fungicides – Cereals 2009

- When mixtures are used for SDHI fungicide resistance management, applied as tank mix or as a co-formulated mixture, the mixture partner:
  - should provide satisfactory disease control when used alone on the target disease
  - must have a different mode of action
- Apply SDHI fungicides always in mixtures
- Apply a maximum of 2 SDHI fungicide containing sprays per cereal crop.
- Apply the SDHI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of SDHI fungicides.
- Strongly reduced rate programs including multiple applications must not be used. Refer to manufacturers' recommendations for rates.

General guidelines for using SBI fungicides (all crops)

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.
- Where alternation or the use of mixtures is not feasible because of lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If DMI's or "morpholine" performance should decline and sensitivity testing has con-

firmed the presence of less sensitive forms, SBI's should only be used in mixture or alternation with effective non cross-resistant partner fungicides.

- The introduction of the new classes of chemistry offers new opportunities for more effective resistance management. The use of different mode of actions should be maximised for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of “resistance" have, on investigation, been attributed to cutting recommended rates of use, or to poor or miss-timed application.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.

Guidelines SBI fungicides – Cereals 2009

- Repeated application of DMI or “morpholine“ fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- Reduced rates of DMIs have been shown to accelerate the shift to less sensitive populations. It is important to use effective rates of DMIs in order to ensure robust disease control. DMIs must provide effective disease control and be used at manufacturers recommended rates.
- When used in mixture recommended effective rates of the SBI should be maintained.
- Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance in situations of high disease pressure it is of importance to adhere to dosages and spray timings as recommended by manufacturers. Highly curative late applications should be avoided. Mixing with a non-DMI fungicide at effective dose rates may contribute to a higher level of disease control.
- The “morpholine” fungicides are effective non-cross-resistant partner fungicides for DMI's on cereals for the control of powdery mildew.

The fact that FRAC reports the sensitivity to SBI fungicides to be a stable situation for all medium and high-risk pathogens indicates that the present management strategies are effective and the risk is reduced to an acceptable level.

The responsible usage of all these different measurements provides under the current knowledge an effective anti-resistance management strategy.

Implementation of the management strategy

The applicant promotes an awareness of fungicide resistance management in product leaflets and training sessions to sales personnel, distributors and growers' associations. The latest issues relating to fungicide resistance are discussed with the applicant technical managers from all regions of the world so that the information from individual countries can be passed on as quickly as possible to the other countries. Anti-resistance management strategies will be included as a topic in product brochures, labels and training courses.
In addition the applicant actively participates in the FRAC Meetings for all presently established active ingredient Working Groups. In this way every attempt is made to formulate and promote resistance management strategies and the rational use of its fungicides.

Monitoring, reporting and reacting to changes in performance
The sensitivity of *Mycosphaerella graminicola, Blumeria graminis f.sp. tritici, Puccinia triticina, Pyrenophora teres* and *Rhynchosporium secalis* to SDHIs is monitored on an annual or biannual basis in extensive monitoring studies over all important European cereal growing areas.
The sensitivity of *Mycosphaerella graminicola, Puccinia triticina* and *Rhynchosporium secalis* to DMIs is monitored on an annual or biannual basis in extensive monitoring studies over all important European cereal growing areas.
In case of field failure which cannot be explained by other agronomic parameters, the sensitivity of the target pathogens of this Resistance Risk Analysis to fluxapyroxad and/or epoxiconazole will be analysed.
Regulatory authorities will be informed at an early stage about all cases of field failure known to be due to resistance. Changes in sensitivity will be communicated in the FRAC Working Groups and may result in modifications to the recommended resistant management strategies.

Conclusion:

The presented data correspond with the requirements of the EPPO standard PP1/213. The applicant addresses all points of the EPPO standard to evaluate the possible actual resistance risk of fluxapyroxad and epoxiconazole. Based on FRAC assessment the applicant stated the risk of resistance due to the mode of action:

for DMI fungicides (SBI-class I; Triazole) it will be assessed as low to medium depends on the pathogen (combined resistance risk = 2-4)

and the SDHI fungicides it will be assessed as medium to high depends on the pathogen (combined resistance risk = 4-6)

Despite on the current findings of resistant isolates of *Pyrenophora teres* that the applicant has not taken into account, will be proposed application restriction to minimize the resistance risk.

Based on further submitted data in the BAD and expert knowledge about fluxapyroxad and epoxiconazole it can be concluded to accept the data provided by the applicant.

IIIA1 6.3 Economics

This is not an EC data requirement.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA1 6.5 Other/special studies

This is not required by Regulation (EU) No 545/2011.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

This document summarizes the information related to the efficacy data of the plant protection product BAS 701 00 F containing 62.5 g fluxapyroxad and 62.5 g epoxiconazole per litre formulated product. It is formulated as an emulsifiable concentrate (EC). The proposed application rate is 2.0 L/ha which delivers 125 g/ha fluxapyroxad and 125 g/ha epoxiconazole. BAS 701 00 F is a fungicide with a broad spectrum of activity against important leaf and ear diseases in wheat, barley, rye and triticale.
According to the results presented, the dose of 2.0 L/ha of BAS 701 00 F provided the optimum overall level of activity and was effective against all the major cereal diseases for which activity of BAS 701 00 F is claimed. As a result, the proposed rate of 2.0 L/ha should be considered as the minimum effective dose to deliver broad spectrum control under a wide range of environmental conditions. The presented data also demonstrated that BAS 701 00 F, when applied at the proposed rate of 2.0 L/ha, gave at least an equivalent level of performance to the tested standard products against the different cereals diseases. Furthermore, measurements of the thousand grain mass (TGM) and hectolitre weight (HLW) confirmed the response in terms of grain quality to applications of BAS 701 00 F in the presence of fungal diseases. A positive response in grain quality is demonstrated for the individual pathogens of all the cereal crops tested.
In conclusion, the results support the claim made in the introduction that BAS 701 00 F is an efficient broad-spectrum fungicide which provides a positive control of important pathogens in cereals. The fungicide provides a rapid and particularly long-lasting fungicidal action against the pathogens listed.

Adexar is classified as not harmful for populations of *Aphidius rhopalosiphi* and *Chrysoperla carnea* as well as not harmful for populations of relevant predatory mites and spiders.

IIIA1 6.7 List of test facilities including the corresponding certificates

Test Centre	Officially recognized
BASF spol. s.r.o., **Czech Republic**	Yes
BASF **Germany** / **Austria**	Yes
BASF **Belgium**	Yes
BASF **France**	Yes
BASF **Ireland**	Yes
Agrostat GmbH In den Gruben 6 74572 Herrentierbach,**Germany**	Yes
Landesanstalt für Landwirtschaft, Forsten und Gartenbau, Dezernat Pflanzenschutz Bernburg, **Germany**	Yes
Landesamt für Ernährung und Landwirtschaft Amtlicher Pflanzenschutzdienst Frankfurt (Oder), **Germany**	Yes
Sächsische Landesanstalt für Landwirtschaft Referat Pflanzenschutz Dresden, **Germany**	Yes
BASF A/S, **Denmark**	Yes
U. A. S. Umwelt- und Agrarstudien GmbH, Jena, **Germany**	Yes
Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern Pflanzenschutzdienst Rostock, **Germany**	Yes
Landwirtschaftskammer Schleswig-Holstein, -Abteilung Pflanzenbau und Pflanzenschutz- Fachbereich Pflanzenschutz Kiel, **Germany**	Yes
Landwirtschaftskammer Niedersachsen - Pflanzenschutzamt - Hannover, **Germany**	Yes
Direktor der Landwirtschaftskammer Nordrhein- Westfalen als Landesbeauftragter - Pflanzenschutzdienst - Münster, **Germany**	Yes
Agrartest Aarbergen-Panrod, **Germany**	Yes

Test Centre	Officially recognized
Regierungspräsidium Stuttgart - Pflanzenschutzdienst - Stuttgart, **Germany**	Yes
Bayerische Landesanstalt für Landwirtschaft Institut für Pflanzenschutz Freising, **Germany**	Yes
Ingenieurbüro für landwirtschaftliche Feldversuche Schwarzach OT Düllstadt, **Germany**	Yes
SGS INSTITUT FRESENIUS GmbH Taunusstein, **Germany**	Yes
BASF, **Poland**	Yes
BASF plc, **United Kingdom**	Yes

Appendix 1: List of data submitted in support of the evaluation

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.5.1	Sipos, K.	Effect of BAS 701 00 F on the predatory mite (Typhlodromus pyri) in a laboratory trial	2008	2008/1010 765 ! 08/649-335RA 312515
KIIIA1 10.5.1	Sipos, K.	Effect of BAS 701 00 F on the parasitic wasp (Aphidius rhopalosiphi) in a laboratory trial	2008	2008/1010 766 ! 08/649-335FD 312516
KIIIA1 10.5.2	Sipos, K.	Effect of BAS 701 00 F on the predatory mite (Typhlodromus pyri) in a extended laboratory trial	2009	2008/1046 576 ! 08/649-351RA 312517
KIIIA1 10.5.2	Mayer, C.J.	Evaluation of the duration of effects of BAS 701 00 F on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) - Aged residue trial	2009	2009/1069 104 ! 314141 312518
KIIIA1 10.5.2	Sipos, K.	Effect of BAS 701 00 F on the parasitic wasp (Aphidius rhopalosiphi) in an extended laboratory trial	2009	2008/1046 577 ! 08/649-351FD 312519
KIIIA1 10.5.2	Spincer, D.	A rate-response extended laboratory test to determine the effects of BAS 701 00 F on the green lacewing, Chrysoperla carnea (Neuroptera, Chrysopidae)	2009	2008/1042 192 ! 314136 312520
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - Adexar - DE - Section 6 Ecotoxicology - Core assessment	2013	2012/1321 589 312554
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - Adexar - DE - Section 6 Ecotoxicology - Core assessment	2013	2012/1321 589 312557
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - Adexar - DE - Section 6 - Ecotoxicology - National addendum	2013	2012/1332 821 312560
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - Adexar - DE - Section 6 - Ecotoxicology - National addendum	2013	2012/1332 821 312562
MIIIA1 Sec 7	BASF	Draft Registration Report - Part B - Adexar - DE - Section 7 Efficacy Data and Information - Core assessment	2013	2012/1321 590 312564
MIIIA1 Sec 7	BASF	Draft Registration Report - Part B - Adexar - DE - Section 7 Efficacy Data and Information - Core assessment	2013	2012/1321 590 312566
KIIIA1 6.1.3	Strathmann, S.	Fungicidal efficacy of BAS 700 F metabolites: M700F001, M700F002, M700F007	2009	2009/1108 856 312572

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 3.9	Gall, A.	Adexar Entwurf der Gebrauchsanleitung	2013	312591
KIIIA1 3.9	Gall, A.	Attachment: Adexar_Rereg vorläufige GA	2013	312592
KIIIA1 6.1.1	Strobel D. et al.	Dose rate justification to the active ingredients of BAS 701 F (ratio justification) - According to guideline 91/414/EWG - Annex III A, 6.1	2010	2010/1009574 312593
KIIIA1 6.1.2	Strobel D. et al.	Dose rate justification to the active ingredients of BAS 701 F (ratio justification) - According to guideline 91/414/EWG - Annex III A, 6.1	2010	2010/1009574 312594
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Weizen - OECD-Antragspunkt III 6.1.2	2009	2009/1116740 312595
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Echter Mehltau in Weizen - OECD-Antragspunkt III 6.1.2	2009	2009/1116706 312596
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Septoria-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.2	2009	2009/1116707 312597
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Braunrost in Weizen - OECD-Antragspunkt III 6.1.2	2009	2009/1116708 312598
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: DTR-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.2	2009	2009/1116709 312599
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116741 312600
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Zwergrost in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116710 312601
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Netzflecken in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116711 312602
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Rhynchosporium-Blattflecken in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116712 312603
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Sprenkelkrankheit in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116713 312604
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Roggen - OECD-Antragspunkt III 6.1.2	2009	2009/1116742 312605
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Braunrost in Roggen - OECD-Antragspunkt III 6.1.2	2009	2009/1116714 312606
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Rhynchosporium-Blattflecken in Roggen - OECD-Antragspunkt III 6.1.2	2009	2009/1116715 312607

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KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Triticale - OECD-Antragspunkt III 6.1.2	2009	2009/1116743 312608
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Braunrost in Triticale - OECD-Antragspunkt III 6.1.2	2009	2009/1116716 312609
KIIIA1 6.1.2	Hanke W.	BAS 701 00 F: Daten zum Grenzaufwand in der Indikation: Septoria-Arten in Triticale - OECD-Antragspunkt III 6.1.2	2009	2009/1116717 312610
KIIIA1 6.1.3	Prochnow J.	BAS 701 00 F - Vergleichsmittel - OECD-Antragspunkt III 6.1.3, 6.1.4, 6.2.1	2010	2010/1009571 312611
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116718 312612
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116719 312613
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116720 312614
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Blatt- und Spelzenbraeune in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116721 312615
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116722 312616
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Gelbrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116723 312617
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: DTR-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116724 312618
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116725 312619
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116726 312620
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Induktion: Zwergrost in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116727 312621

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KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Netzflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116728 312622
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116729 312623
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Sprenkelkrankheit in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116730 312624
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Minderung nicht parasitaerer Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116731 312625
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116732 312626
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116733 312627
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116734 312628
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116735 312629
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116736 312630
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116737 312631
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116738 312632
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116739 312633
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Datenueberblick zur Wirksamkeit in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116744 312634
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Datenueberblick zur Wirksamkeit in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116745 312635

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KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Gerste - OECD-Antragspunkt III 6.1.2	2009	2009/1116741 312636
KIIIA1 6.1.3	Hanke W.	BAS 701 00 F: Datenueberblick zum Grenzaufwand in Roggen - OECD-Antragspunkt III 6.1.2	2009	2009/1116742 312637
KIIIA1 6.1.4.1	Prochnow J.	BAS 701 00 F - Vergleichsmittel - OECD-Antragspunkt III 6.1.3, 6.1.4, 6.2.1	2010	2010/1009571 312638
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116718 312639
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116719 312640
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116720 312641
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Blatt- und Spelzenbraeune in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116721 312642
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116722 312643
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Gelbrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116723 312644
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: DTR-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116724 312645
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116725 312646
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116726 312647
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Induktion: Zwergrost in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116727 312648
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Netzflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116728 312649

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KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 729 312650
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Sprenkelkrankheit in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 730 312651
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Minderung nicht parasitaerer Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 731 312652
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 732 312653
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 733 312654
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 734 312655
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 735 312656
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 736 312657
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 737 312658
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 738 312659
KIIIA1 6.1.4.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 739 312660
KIIIA1 6.1.4.3	Prochnow J.	BAS 701 00 F - Vergleichsmittel - OECD-Antragspunkt III 6.1.3, 6.1.4, 6.2.1	2010	2010/1009 571 312661
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 718 312662

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KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 719 312663
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 720 312664
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Blatt- und Spelzenbraeune in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 721 312665
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 722 312666
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Gelbrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 723 312667
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: DTR-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 724 312668
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 725 312669
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 726 312670
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Induktion: Zwergrost in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 727 312671
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Netzflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 728 312672
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 729 312673
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Sprenkelkrankheit in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 730 312674
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Minderung nicht parasitaerer Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 731 312675

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KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 732 312676
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 733 312677
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 734 312678
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 735 312679
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 736 312680
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 737 312681
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 738 312682
KIIIA1 6.1.4.3	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 739 312683
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 718 312684
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 719 312685
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 720 312686
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Blatt- und Spelzenbraeune in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 721 312687
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 722 312688

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Gelbrost in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 723 312689
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: DTR-Blattduerre in Weizen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 724 312690
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 725 312691
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 726 312692
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Induktion: Zwergrost in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 727 312693
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Netzflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 728 312694
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 729 312695
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Sprenkelkrankheit in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 730 312696
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Minderung nicht parasitaerer Blattflecken in Gerste - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 731 312697
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 732 312698
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 733 312699
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 734 312700
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Rhynchosporium-Blattflecken in Roggen - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 735 312701

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Halmbruch in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 736 312702
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Echter Mehltau in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 737 312703
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Braunrost in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 738 312704
KIIIA1 6.2.1	Hanke W.	BAS 701 00 F: Daten zur Wirksamkeit in der Indikation: Septoria-Blattduerre in Triticale - OECD-Antragspunkt III 6.1.3 (Wirksamkeit), III 6.1.4 (Qualitaet, Ertrag), III 6.2.1 (Phytotoxizitaet)	2009	2009/1116 739 312705
KIIIA1 6.2.5	Dunker S.	Germination trials with harvested grains from winter wheat, winter barley, winter rye and winter triticale treated with BAS 701 00 F	2009	2009/1075 071 312706
KIIIA1 6.2.6	Wuts M.	Cultivation of different crops in BAS 701 00 F treated soil	2010	2010/1009 573 312707
KIIIA1 6.2.7	Dutillie H.	BAS 701 00 F: Effects on non-target plants in the greenhouse ? A multiple dose test	2009	2009/1067 188 312708
KIIIA1 6.2.7	Dutillie H.	BAS 701 00 F: Effects on adjacent crops in the greenhouse	2009	2009/1075 140 312709
KIIIA1 6.2.8	Stammler G.	BAS 701 00 F - Resistance risk analysis	2009	2009/1110 721 312710
KIIIA1 6.6	Prochnow J.	BAS 701 00 F: Gebrauchsanleitung - OECD-Antragspunkt III 6.6	2010	2010/1009 570 312711
KIIIA1 6.6	Prochnow J.	BAS 701 00 F: Gebrauchsanleitung - OECD-Antragspunkt III 6.6	2010	2010/1009 570 312712
KIIIA1 6.6	Prochnow J.	BAS 701 00 F: Gebrauchsanleitung - OECD-Antragspunkt III 6.6	2010	2010/1009 570 312713
KIIIA1 6.7	Prochnow J.	BAS 701 00 F: Information zu den Versuchseinrichtungen und den jeweiligen Bescheinigungen - OECD-Antragspunkt III 6.1.3 und 6.7	2010	2010/1009 572 312714
KIIA 3.5.2	Strathmann S.	Fungicidal efficacy of BAS 700 F metabolites: M700F001, M700F002, M700F007	2009	2009/1108 856 312715
KIIA 8.10	Völkel, W.	The effects of CGA71019 on soil respiration and nitrification	2000	2000/1021 861!76336 7 312724

Appendix 2: GAP table

GAP-Table of intended uses for Germany

GAP rev. (1), date: 2013-05-14

PPP (product name/code)	**Adexar**	**Formulation type:**	**EC**
active substance 1	**Epoxiconazole**	**Conc. of as 1:**	**62.5 g/L**
active substance 2	**Fluxapyroxad**	**Conc. of as 2:**	**62.5 g/L**
Applicant:	**BASF**	**professional use**	☒
Zone(s):	**central EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

002	DE	wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	BBCH 30 - 61 from spring at beginning of infesta-tion and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
003	DE	wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	BBCH 30 - 61 from spring at beginning of infesta-tion and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
004	DE	wheat TRZSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infesta-tion and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
005	DE	wheat TRZSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

006	DE	wheat TRZSS	F	leaf spot of wheat *Septoria tritici* SEPTTR	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
007	DE	wheat TRZSS	F	septoria leaf spot *Septoria nodorum* LEPTNO	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
009	DE	barley HORVX	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
010	DE	barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

011	DE	barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
012	DE	barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
013	DE	barley HORVX	F	Ramularia leaf spot dis-ease *Ramularia collo-cygni* RAMUCC	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
014	DE	barley HORVX	F	decrease of non-parasitic leaf spots YBFMI	spraying	BBCH 32 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	for susceptible varieties and at increasing global radiation

015	DE	rye SECCE	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
017	DE	rye SECCE	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
018	DE	rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
019	DE	triticale TTLSS	F	powdery mildew *Erysiphe graminis* ERYSGR	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

020	DE	triticale TTLSS	F	eyespot of cereals *Pseudocercosporella herpotrichoides* PSDCHE	spraying	BBCH 30 - 32 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 1 b) 2	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
021	DE	triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	BBCH 30 - 69 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	
022	DE	triticale TTLSS	F	septoria-species *Septoria* spp. SEPTSP	spraying	BBCH 30 - 61 from spring at beginning of infes-tation and/or when first symptoms become visible	a) 2 b) 2 (21 d)	a) 2 L/ha b) 4 L/ha	a) as1: 0.125 kg as/ha as2: 0.125 kg as/ha b) as1: 0.25 kg as/ha as2: 0.25 kg as/ha	100 - 400	F	

Remarks:
(a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/L
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

REGISTRATION REPORT
Part B

Section 8 Assessment of the relevance of metabolites in groundwater
Detailed summary of the risk assessment

Product code: **BAS-701000-FW-0-EC (ADEXAR)**

Active Substance(s): **fluxapyroxad (BAS 700 F) 62.5 g/L**
epoxiconazole (BAS 480 F) 62.5 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT,
NATIONAL ADDENDUM – Germany

Applicant: **BASF**
Date: **02 June 2017**

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Sec 8 IIIA 12 ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER

8.1 Introduction

The active substance Fluxapyroxad has been approved according Regulation (EC) No 1107/2009.

Table 8.1-1: Identity, further information on fluxapyroxad

Active substance (ISO common name)	**Fluxapyroxad**
IUPAC	3-(difluoromethyl)-1-methyl-N-(3′,4′,5′-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide
Function (e.g. fungicide)	fungicide
Status under Reg. (EC) No 1107/2009	approved
Date of approval	01/01/2013
Conditions of approval	none
Confirmatory data	none
RMS	UK
Minimum purity of the active substance as manufactured (g/kg)	
Molecular formula	$C_{18}H_{12}F_5N_3O$
Molecular mass	381.31
Structural formula	

Environmental occurring metabolites of fluxapyroxad according to the results of the assessment of fluxapyroxad for EU approval are summarized in Part B, core assessment, Section 5,

Table 8.1-2: Metabolites of fluxapyroxad potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolites	**Structural formula/Molecular formula**	**Maximum occurence in compartements**	**Status of relevance (according to SANCO 7593/VI/97 final - 14/08/2000)**
M700F001	$C_6H_6F_2N_2O_2$	Soil: Max. 12.1 % (mean value) on day 30	Groundwater: risk assessed as low to the aquatic environment
M700F002	$C_5H_4F_2N_2O_2$	Soil: Max. 38.5 % (mean value) on day 120	Groundwater: risk assessed as low to the aquatic environment

[1)] According to Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

8.2 Quantification of potential groundwater contamination

Core Assessment:

According to the PECGW modelling with FOCUSPELMO 5.5.3 a groundwater contamination of the active substance fluxapyroxad at a concentration of ≥ 0.1 µg/L is not expected for all FOCUS groundwater scenarios in case of winter cereals (Châteaudun, Hamburg, Jokoinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva) and all the FOCUS groundwater scenarios with spring cereals (Châteaudun, Hamburg, Jokoinen, Kremsmünster, Okehampton, and Porto) respectively.

For the metabolite M700F001 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded in case of winter cereals and spring cereals for the FOCUS groundwater scenarios Hamburg, Jokoinen, Okehampton, and Porto.

For the metabolite M700F002 a groundwater concentration of ≥ 0.75 µg/L cannot be excluded for the FOCUS groundwater scenarios with spring and winter cereals except Châteaudun, for which however a groundwater concentration of ≥ 0.1 µg/L cannot be excluded.An assessment of the relevance of both metabolites is necessary.

Table 8.2-1: PEC_{GW} at 1 m soil depth for Fluxapyroxad and its metabolites

Crop/Group/use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 5.5.3**	
		Metabolite M700F001 (max . amount of slow/ fast DT50 of ai)	Metabolite M700F002 (max. amount of slow/ fast DT_{50} of ai)
Winter cereals	**Châteaudun**	0.015	**0.634**
	Hamburg	**0.231**	**2.106**
	Jokioinen	**0.375**	**2.678**
	Kremsmünster	0.068	**1.318**
	Okehampton	**0.121**	**1.362**
	Piacenza	0.091	**1.033**
	Porto	**0.138**	**0.923**
	Sevilla	0.021	**0.340**
	Thiva	0.025	**0.471**
spring cereals	**Châteaudun**	0.016	**0.538**
	Hamburg	**0.215**	**2.00**
	Jokioinen	**0.392**	**2.474**
	Kremsmünster	0.068	**1.283**
	Okehampton	**0.114**	**1.261**
	Porto	**0.126**	**0.839**

national Addendum Germany

Table 8.2-2: PEC_{GW} at 1 m soil depth of Fluxapyroxad and its metabolites considered relevant for German exposure assessment

crop.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 5.5.3	
		M700F001 Max. residues of slow/ fast DT50 of ai	M700F002 Max. residues of slow/ fast DT50 of ai
Winter cereals	Hamburg	0.295	2.462
Spring cereals	Hamburg	0.288	2.336

For the metabolite M700F001 of fluxapyroxad a groundwater concentration of ≥ 0.1µg/L cannot be excluded for spring and winter cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

For the metabolite M700F002 of fluxapyroxad a groundwater concentration of ≥ 0.75 µg/L cannot be excluded for the application in both winter cereals and spring cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3

8.3 Hazard Assessment: Identification of relevant metabolites

8.3.1 Screening for biological activity

The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU peer review of the risk assessment of fluxapyroxad (EFSA Journal 2012;10(1):2522).

The metabolites M700F001 and M700F002 of fluxapyroxad have been regarded as not pesticidal active. The risk for the aquatic environment was assessed as low.

8.3.2 Screening for genotoxicity

In the EU peer review of the risk assessment for fluxapyroxad the metabolites M700F001 and M700F002 were evaluated as not genotoxic (EFSA Journal 2012;10(1):2522).

Please refer also to 8.4.

8.3.3 Screening for toxicity

In the EU peer review of the risk assessment for fluxapyroxad the metabolites M700F001 and M700F002 were evaluated as not toxicological relevant (EFSA Journal 2012;10(1):2522).

Please refer also to 8.4.

8.4 Exposure assessment – threshold of concern approach

The metabolites M700F001 and M700F002 are predicted to occur in groundwater at concentrations above 0.1 µg/L by the competent authority in Germany (Federal Environment Agency/UBA). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required. General information on the metabolites is provided in the next table.

Table 8.4 General information on the metabolites

Metabolite name and code	Structural/molecular formula	Name of parent active substance	Trigger for relevance assessmnent	
M700F001	$C_6H_6F_2N_2O_2$	Fluxapyroxad	Max PECgw Based on:	0.392 µg/L FOCUS PELMO 5.5.3 Jokioinen Szenario spring cereals
M700F002	$C_5H_4F_2N_2O_2$	Fluxapyroxad	Max PECgw Based on:	2.678 µg/L FOCUS PELMO 5.5.3 Jokioinen Szenario winter cereals

8.4.1 Relevance assessment of M700F001

Summary:
The relevance of the groundwater metabolite M700F001 has already been assessed and accepted at EU level (see EFSA conclusion on fluxapyroxad, EFSA Journal 2012,10(1):2522, ASB2012-3723). M700F001 is not considered to be relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the next table.

Table 8-4.1 Summary of the relevance assessment for M700F001

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	No
Quantification of	STEP 2		Max PECgw Based on	0.392 µg/L FOCUS PELMO 5.5.3 Jokioinen Szenario spring cereals
Hazard assessment	STEP 3*	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified (Peer Review proposal: Xn, R40/H351; after legal classification further data are required)
			Classification of metabolite	Not classified
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	acceptable
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	n.a. n.a. n.a.

* Details of toxicological evaluation are presented in dRR, Part B, core assessment, Section 3; chapter 3.4
n.a., not applicable

8.4.2 Relevance assessment of M700F002

Summary:
The relevance of the groundwater metabolite M700F002 has already been assessed and accepted at EU level (see EFSA conclusion on fluxapyroxad, EFSA Journal 2012,10(1):2522, ASB2012-3723). M700F002 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the next table.

Table 8-3 Summary of the relevance assessment for M700F002

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwate	STEP 2		Max PECgw Based on	2.678 µg/L FOCUS PELMO 5.5.3 Jokioinen Szenario winter cereals
Hazard assessment	STEP 3*	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified (Peer Review proposal: Xn, R40/H351; after legal classification further data are required)
			Classification of metabolite	Not classified
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	acceptable < 0.1% ADI ADI for the metabolite (0.3mg/kg bw, based on the NOAEL of a developmental study on M700F002 and SF 1000)

* Details of toxicological evaluation are presented in dRR, Part B, core assessment, Section 3; chapter 3.4
n.a., not applicable

8.5 Refined risk assessment for non-relevant metabolites

Not applicable.

Appendix 1 Critical Uses – justification and GAP tables

1	2	3	4	5	6	7	8	10	11	12	13	14

Use-	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**	**Application rate**	**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures

					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	AT	Wheat, barley, rye, triticale	F	*Erysiphe graminis,* *Septoria spp. (only wheat and triticale),* *Puccinia spp.,* *Drechslera tritici-repentis (only wheat),* *Pyrenophora teres (only barley),* *Rhynchosporium secalis (only barley and rye)* *Ramularia collo-cygni (only barley,)* *Decrease of non-parasitic leaf spots (only barley)*	spraying	spring BBCH 30 - 61	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria
2	AT	Wheat, barley, rye, triticale	F	*Pseudocercosporella herpotrichoides*	spraying	spring BBCH 30 - 32	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria

3	AT	Wheat, rye, triticale	F	*Puccinia recondita*	spraying	spring BBCH 30 – 69	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	200 - 400	---	For the detailed GAP please refer to Part A, National Addendum - Austria
4	BE	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	35	

5	CZ	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* (not triticale) *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-61	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-400	35	
7	IE, UK	Wheat, barley, rye, triticale, oats	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69 (malting barley 49)	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	Defined by last application	

8	NL	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	31-69	1 2 (21 days)	2.0 4.0	a) **0.250** 0.125* 0.125** b) **0.500** 0.250* 0.250**	100-300	35	
9	PL, SK	Wheat, barley, rye, triticale	F	*P. herpotrichoides* *E. graminis* *Septoria spp.* *Puccinia spp.* *P. triticirepentis* *P. teres,* *R. secalis* *R. collo-cygni* MEHITE	spraying	30-69	1 2 (21 days)	1.33-2.0 2.66-4.0	a) **0.166-0.250** 0.083-0.125* 0.083-0.125** b) **0.332-0.500** 0.166-0.250* 0.166-0.250**	100-300	35	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix 2 Additional information provided by the applicant (e.g. detailed modelling data)

Additional appendices may be added to include further information such as the table of metabolites

This appendix can be deleted if not needed.