REGISTRATION REPORT
Part A

Risk Management

Product code: BAS 500 06 F

Active Substance: Pyraclostrobin 200 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: BASF SE

Date: 2014-10-31

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of BAS 500 06 F containing pyraclostrobin in Germany. This evaluation is required subsequent to the approval of pyraclostrobin.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 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 registration by the EU review. It also includes assessment of data and information relating to BAS 500 06 F where that data has not been considered in the EU review. Otherwise assessments for the safe use of BAS 500 06 F have been made using endpoints agreed in the EU review of pyraclostrobin.

This document describes the specific conditions of use and labelling required for Germany for the re-registration/registration of BAS 500 06 F.

Appendix 1 of this document contains the final product authorisation for 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: Letters of access were not needed for evaluation of the formulation.

1 Details of the application

1.1 Application background

This application was submitted by BASF SE on 5th May 2012. It has been evaluated in line with the requirements of the zonal assessment under Regulation (EC) No. 1107/2009.

The application was for approval of BAS 500 06 F, an EC containing 200 g/L pyraclostrobin for use as a fungicide in cereals.

1.2 Annex I inclusion

The active substance pyraclostrobin was included into Annex I of Directive 91/414 EEC (see Commission Directive 2004/30/EC and 2009/25/EC), respectively is approved according to Commission Implementing Regulation (EU) No 540/2011 under the current regime Regulation (EC) No 1107/2009.

The Annex I Inclusion Directive for pyraclostrobin (2004/30/EC and 2009/25/EC) 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 the pyraclostrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28.November 2003, shall be taken into account. In this overall assessment:

Member States should pay particular attention to the:
- protection of aquatic organisms, especially fish
- protection of terrestrial arthropods and earthworms

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval the product BAS 500 06 F must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in Germany in order to allow the first approval of this product in the Central Zone in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BAS 500 06 F, 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.

2 Details of the authorisation

2.1 Product identity

Product Name	BAS 500 06 F
Authorization Number (for re-registration)	007643-00
Function	Fungicide
Applicant	BASF SE
Composition	200 g/L pyraclostrobin
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	High-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE Coex) in the range of 0.15 to 10 L bottles or containers.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 1999/45/EC

The following is proposed in accordance with Directive 99/45/EC in combination with the latest classification and labelling guidance under Directive 67/548/EEC:

Symbol(s)/Indication(s) of danger:	
N	Dangerous for the environment
Xn	Harmful
Risk phrases:	
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R20/22	Harmful by inhalation and if swallowed
R38	Irritating to skin
R43	May cause sensitisation by skin contact
Safety phrases:	
S2	Keep out of the reach of children
S13	Keep away from food, drink and animal feeding stuffs
S24	Avoid contact with skin
S35	This material and its container must be disposed of in a safe way.
S36/37	Wear suitable protective clothing and gloves.
S46	If swallowed, seek medical advice immediately and show this container or label
S57	Use appropriate container to avoid environmental contamination.
Specific labelling requirement:	
To avoid risks to man and the environment, comply with the instructions for use.	

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

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

Hazard classes and categories:	
Acute Tox. 4	
Asp. Tox. 1	
Skin Irrit. 2	
Skin Sens. 1	
Eye Irrit. 2	
Hazard pictograms:	

GHS 07	exclamation mark
GHS 08	health hazard
GHS 09	environment
Signal word:	
Danger	
Hazard statements:	
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H410	Very toxic to aquatic life with long lasting effects
H400	Very toxic to aquatic life.
Precautionary statemtents:	
EUH 401	To avoid risks to human health and the environment, comply with the instructions for use.

Special rule for labelling of PPP:	
Further labelling statements under Regulation (EC) No 1272/2008:	

2.2.3 R and S phrases under Regulation (EU) No 547/2011

None.

2.2.4 Other phrases

2.2.4.1 Restrictions linked to the PPP

The authorisation 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.
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.
SE110	Wear tight fitting eye protection when handling the undiluted product.

SE120	Wear tight fitting eye protection when applying/handling the product ready for application.
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.
SS610	Wear a rubber apron when handling the undiluted product.
ST1202	Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when applying/handling the product.
Integrated pest management (IPM)/sustainable use	
WMFC3	Mode of action (FRAC-Group): C3
NN3001	The product is classified as harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant predatory mites and spiders.
Ecosystem protection	
NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates
NW468	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 authorisation of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
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)

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 no. 003 and 004	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	
NW605-1	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 "*". 50 %: 10 m, 75 %: 5 m, 90 %: 5 m *Uses: 001 – 010*
NW606	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. 15 m *Uses: 001 – 010*

2.3 Product uses

GAP rev. , date: 2012-06-25

PPP (product name/code)	**BAS 500 06 F**	**Formulation type:**	**EC**
active substance	**Pyraclostrobin**	**Conc. of as :**	**0.2 kg/L**
Applicant:	**BASF SE**	**professional use**	☒
Zone(s):	**central**	**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		
1	DE	Wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)

2	DE	Wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
3	DE	Wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	WW7041 * F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
4	DE	Barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	WW7041 * F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
5	DE	Barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
6	DE	Barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	from spring at beginning of infestation and/or when first	a) 2 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk

						symptoms become visible BBCH 25 - 61	(21 days)					assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
7	DE	Barley HORVX	F	decrease of non-parasitic leaf spots YBFMI* no EPPO code	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 32 - 61	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
8	DE	Rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
9	DE	Rye SECCE	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 m)
10	DE	Triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments) NW605-1 (50 %: 10 m, 75 %: 5 m, 90 %: 5 m) NW606 (15 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:
BAS 500 06 F has not been the representative formulation for the Annex I inclusion of pyraclostrobin.
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 dark yellow clear liquid, with a moderate naphthalene-like odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 450°C. In aqueous solution, it has a pH value around 6-7. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for an EC formulation.
Regarding persistent foam and emulsifiability data at highest use rate after storage for 2 years at ambient temperature are missing. But the submitted studies indicate that there should be no problems also at the highest use rate.

Implications for labelling: Asp Tox 1 – H 304

Compliance with FAO specifications:
There are no published FAO specifications for pyraclostrobin.

Compliance with FAO guidelines:
The product BAS 500 06 F complies with the general requirements for EC formulations according to the FAO/WHO manual (2010).

Compatibility of mixtures:
No tank mixes are mentioned on the product label for BAS 500 06 F.

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 BAS 500 06 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 of BAS 500 06 F can be quantified using the analytical HPLC method CF-A 669. The method was developed for quantifying pyraclostrobin in BAS 500 06 F.
The active substance pyraclostrobin is dissolved in acetonitrile / water, chromatographed on a HPLC reversed phase system with UV-detection and external calibration. The method can be used in

emulsifiable concentration (EC). CIPAC method MT 657/EC/M/- is applicable for EC formulations containing pyraclostrobin.
The relevant impurity DMS of BAS 500 06 F can be quantified using a Headspace-GC/MS method. The method was developed for quantifying DMS in BAS 500 06 F.
The relevant impurity DMS is dissolved in toluene, chromatographed on a Headspace system with MS-detection and external calibration. The method can be used in emulsifiable concentration (EC).

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, i.e. pyraclostrobin, in food of plant and animal origin, soil, water, air, body fluids and tissue.
Pyraclostrobin residues can be determined by LC-MS/MS and HPLC/UV. Analytical methods used to meet the requirements of the Annex to Regulation (EU) No 544/2011, Part A, point 4.2 can be applied. The applicant is owner of the data package used for the approval of the active substance.
Additional LC-MS/MS methods for the determination of residues of pyraclostrobin in food of plant and animal origin, water and for body fluids and tissues were provided and were found acceptably validated.

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

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

BAS 500 06 F, containing 200 g/L Pyraclostrobin has a low toxicity in respect to dermal toxicity. Its acute oral toxicity is moderate resulting in a classification R22/H302. Its acute inhalation toxicity is moderate resulting in a classification R20/H332. It has sensitizing properties (R43/H317). It is irritating to skin (R38/H315) and eye (H319).

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

Operator exposure was assessed against the AOEL agreed in the EU review (Pyraclostrobin 0.015 mg/kg bw/d). Dermal absorption data of studies conducted with the formulation applied for have been used. The detailed evaluation is provided in Part B.
According to the German Model calculation, it can be concluded that the risk for the operator using BAS 500 06 F in cereals is acceptable with the use of personal protective equipment described in 2.2.3.1.
According to UK POEM an exceedance of the AOEL is predicted even with the use of PPE.

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

The bystander and/or resident exposure estimations indicated that the acceptable operator exposure level (AOEL) for Pyraclostrobin will not be exceeded under conditions of intended uses.

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

The worker exposure was estimated using the model “German model”. Even without any PPE the estimated consumption of AOEL was below 8 % for Pyraclostrobin.

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)

Fundamental residue data on Pyraclostrobin like metabolism are already evaluated previously and is described in detail in the respective DARs.

A sufficient number of residue trials are available to demonstrate that the MRLs set in Regulation (EC) No 396/2005 for Pyraclostrobin will not be exceeded for the intended uses in cereals.

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

An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the ADI below 100 %.

Substance	ADI	Model / Diet	ADI Consumption
Pyraclostrobin	0.03 mg/kg bw	TMDI, EFSA PRIMo, German children, aged 2-4 years	60 %

There is no acute risk for consumers to be expected.

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

A full exposure assessment for the plant protection product BAS 500 06 F in its intended uses in cereals according to use No 00-001 – 00-010is documented in detail in the core assessment of the plant protection product BAS 500 06 F dated from 16.07.2013 performed by zRMS Germany.
The following chapters summarise specific exposure assessments for soil and surface water and the specific risk assessment for groundwater for the authorization of BAS 500 06 F in Germany according to its intended use in cereals (use No 00-001 – 00-010).
No new environmental fate studies were performed. However, recalculations of previously reviewed study data were submitted by the applicant.
Based on the recalculated data provided in this submission, appropriate endpoints were used to calculate PEC values for BAS 500 06 F, pyraclostrobin and its metabolites in soil, surface water and ground water for the intended use patterns.

<u>Fate and behaviour summary of pyraclostrobin</u>:
In laboratory degradation studies pyraclostrobin showed a wide range of degradation times from 8 to 78 days. Under field conditions a maximum value of 37 days could be demonstrated. During degradation two metabolites occur in relevant amounts (BAS 500-6 and BAS 500-7) which are of more persistence in soil with DT_{50} values up to 166 days. The mineralization rate is low for pyraclostrobin, content of carbon dioxide is round 5 % after 90 days. To a higher degree bound residues could be detected with a level of 56 %. An accumulation in soil is not expected.
Adsorption values (Kfoc) for the active substance as well as the metabolites are high (> 3000) and should not be prone to translocation in the soil column.
In the water/sediment studies neither degradation nor dissipation values for the water phase are available. The degradation time in the whole system were measured with 25 days. In the water phase the metabolites BF 500-11, BF 500-13 and BF 500-14 could be detected. In the sediment the metabolites BF 500-3 and BF 500-6 occurred.

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

PEC_{Soil} calculations for pyraclostrobin and its metabolites for the intended use pattern of BAS 512 16 F were performed according to German requirements.

Table Summary PEC_{soil} calculation for the intended use in cereals used for German risk assessment

active substance/ formulation	soil relevant application rate (g/ha)	soil depth$_{act}$ (cm)	PEC_{act} (mg/kg)
active substance pyraclostrobin	2 x 125	1	1.3956
preparation BAS 500 06 F	2 x 625	1	7.2852

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 5.3.3 show that the active substance pyraclostrobin is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses in winter cereals in Germany.
For the soil metabolites BF 500-6 and BF 500-7 concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According modelling with EXPOSIT 3.01, groundwater contaminations at concentrations ≥ 0.1 µg/L by the active substance pyraclostrobin and its metabolites BF 500-6 and BF 500-7 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 (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

PEC_{sw} and PEC_{sed} calculations pyraclostrobin and its metabolites for the intended use pattern were performed according to German requirements.

Table Summary $PEC_{sw/sed}$ calculation for the intended use in cereals used for German risk assessment

active substance/ formulation	**PEC sw** Spray drift (1m – 82 Perc.) [µg/L]	**PEC sw** Run-off (0m-ditch) µg/L]	**PEC sw** Drainage (0m-ditch-autumn/winter/early spring)	**PEC sw** Drainage (0m-ditch-spring/summer) [µg/L]

			[µg/L]	
active substance pyraclostrobin	3.09	0.28	0.10	0.03
preparation BAS 500 06 F	15.47	-	-	-

3.1.5.1 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance pyraclostrobin is < 10^{-5} Pa (2.6 x 10^{-8} Pa). Hence the active substance is regarded as non-volatile. Therefore exposure of surface water by pyraclostrobin due to deposition following volatilisation does not need to be considered.

Implications for labelling resulting from environmental fate assessment:

Based on the data on the active substance pyraclostrobin the plant protection product BAS 500 06 F is considered to be not readily degradable in the sense of the CLP regulation.
The formulation BAS 500 06 F is regarded as a candidate for R53.

R and S phrases under Regulation (EU) No 547/2011
none

Other labels /conditions for use
Labelling
none

Conditions of use:
none

Further data requirements:
none

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

A full risk assessment according to Uniform Principles for the plant protection product BAS 500 06 F in its intended uses in winter and spring cereals (use No 00-001 – 00-010) is documented in detail in the core assessment of the plant protection product BAS 500 06 F dated from 16.07.2013 performed by Germany. The intended use of BAS 500 06 F in Germany is generally covered by the uses evaluated in the course of the core assessment by Germany.
The following chapters summarises specific risk assessment for non-target organisms and hence risk mitigation measures for the authorisation of BAS 500 06 F in Germany according to its intended use in winter and spring cereals (use No 00-001 – 00-010).

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

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).
For the risk assessment the following endpoints were used:
Active substance:
LD_{50} birds: > 2000 mg/kg bw/d
NOEC birds 105 mg/kg bw/d

LD_{50} mammals: > 5000 mg/kg bw/d
NOEC mammals: 3 mg/kg bw/d

Preparation BAS 500 06 F:
LD_{50} birds: > 2000 mg/kg bw/d
LD_{50} mammals: > 500 mg/kg bw/d

An increased toxicity by the formulation towards mammals can not be ruled out according to the presented data.

For birds acute and long-term TER values for BAS 500 06 F were calculated to be in excess of the accepted trigger (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. at the screening level.

For mammals acute TER values for BAS 500 06 F were calculated to be in excess of the accepted trigger (TER ≥ 5 modified German approach) according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. at the screening level respectively Tier 1 assessment. Based on Tier 1/ Tier 2 assessment, the calculated TER values for the long-term risk resulting from an exposure of mammals to pyraclostrobin according to the GAP of the formulation BAS 500 06 F achieve the modified acceptability criteria TER ≥ 2 according to the German adaptation of Guidance Document on Risk Assessment for Birds and Mammals.
Based on a Tier 1 assessment according to EFSA Journal 2009, the TER_{lt} values for earthworm-eating and fish-eating birds exceed the trigger value set by Regulation (EC) 1107/2009, Annex IV, uniform principles, point 2.5.2.1, indicating that the application of BAS 500 06 F in cereals does not provide reason for concern regarding a potential accumulation of the active substance pyraclostrobin in the food chain or for concern of secondary poisoning.
Overall, it can be concluded that the application of BAS 500 06 F according to good agricultural practice will not adversely affect birds and mammals under natural conditions.

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 BAS 500 06 F in winter and spring cereals based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
For authorisation 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.

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 pyraclostrobin is < 10^{-5} Pa. Therefore, exposure of surface water by the active substances pyraclostrobin due to deposition following volatilization was not considered.
The aquatic risk assessment of spray drift entries in surface water by the use of BAS 500 06 F in cereals is based on the HC5 of 5.9 µg pyraclostrobin/L to fish species.

According to this data a RAC of 0.295 µg/L for the aquatic environment can be established considering a margin of safety of 20.

Based on the relevant toxicity of the active substance pyraclostrobin the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to BAS 500 06 F according to all uses (use No 00-001 – 00-010) achieve the acceptability criteria of TER ≥ 20, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2 if appropriate risk mitigation are applied (see below).

2. Exposure by surface run-off and drainage
The concentration of the active substance pyraclostrobin in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.0.
The calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by the active substance pyraclostrobin due to runoff an drainage according to the all use No 00-001 to 00-010 achieve the acceptability criteria of TER ≥ 20, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

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

Effects on bees
Due to the results of laboratory tests BAS 500 06 F 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. Bee brood testing is not required since the test item is not an IGR.
It is concluded that BAS 500 06 F will not adversely affect bees or bee colonies when used as recommended.

Effects on other arthropod species
Extended laboratory studies with BAS 500 06 F, and the indicator species *T. pyri, A.* rhopalosiphi*, A. bilineata* and *C. carnea* were conducted (relevant endpoint EC_{50} 2500 g prep./ha, 3D test design). The off-field TER values are above the trigger value of 5, indicating low risk to terrestrial non-target arthropods off-field, from applications of BAS 500 06 F at the proposed use pattern.

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

Based on the predicted concentrations of pyraclostrobin in soils, the TER values describing the acute risk for earthworms following exposure to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria TER ≥ 10. However, the TER value describing the long term risk for earthworms (based on standard laboratory data) fails the acceptability criterion TER ≥ 5 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. This can be attributed to the low chronic endpoint of the formulation study with BAS 500 06 F resulting in a NOEC of 30 mg/kg. Since a field study with BAS 500 06 F and earthworms is available, which showed no significant effects, it can be concluded that the long-term risk to soil biocenosis, especially earthworms, from the intended use pattern of BAS 500 06 F can be considered low.
Noticeable is again the increased toxicity of the formulation compared to the test on the technical active substance. Expressed in active substance equivalents the LC_{50} is 38.56 mg/kg soil for the formulation compared to 283 mg as/kg soil for the technical substance.

For BAS 500 06 F a laboratory study with collembola is available. According to the results, as there were no significant effects observable (NOEC 25 mg/kg soil), it can be concluded, that risk to organic matter and other soil macro-organisms after exposure to BAS 500 06 F according to the GAP is acceptable.

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

Results from litter bag studies with pyraclostrobin did not cover the maximum PECsoil value of 1.3957 mg pyraclostrobin/kg dry soil. However in the view of the UBA and other involved European agencies as well as according to scientific opinions (e.g. "Scientific Panel on Plant protection products and their Residues", EFSA panel) the litter bag study endpoint and the subsequent use in the assessment are of concern. Since the litter bag test is a functional test, it has not the ability to unburden potential adverse effects on structural level. Hence litter bag studies are not suitable to unburden an identified risk. Thus to address risk to other non-target soil organisms, testing on other non-target macro-organism (IIIA 10.6.6) is required. Since a study with *Folsomia candida* is available, which shows an acceptable risk (TER = 17.2), regarding this specific application no further data to assess risk to other non-target macro-organism are required in the opinion of the MS.

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

For the active ingredient in BAS 500 06 F the soil concentrations which caused no deviations greater than ±25% in the micro-organism studies are at least 2.4 times higher the corresponding maximum PEC in soil. It may be concluded that there will be no unacceptable risk to soil micro-organisms following the use of BAS 500 06 F.

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

Non-Target Terrestrial Plants
Vegetative vigour and seedling emergence studies were conducted for BAS 500 06 F, testing ten terrestrial plant species in each study. EC50 values were 1.25 L product/ha for all species tested.
Based on the EC50 = 1.25L/ha for seedling emergence and vegetative vigour, treatment of BAS 500 06 F causes an acceptable risk without consideration of risk mitigation measures to terrestrial non-target plants for the intended uses cereals and sugar beet.
For details please refer to the core assessment Part B, section 6, chapter 6.8.

Implications for labelling resulting from ecotoxicological assessment:

Classification and labelling of the formulation

Relevant toxicity	LC_{50} = 0.046 mg/L (O. *mykiss)*
Classification and labelling according to Directive 67/548/EC, 78/631/EC and 1999/45/EC	
Hazard symbol	N, Dangerous for the environment
Risk phrases	R50/53
Classification and labelling according to Regulation (EC) No 1272/2008	
Hazard symbol	GHS09
Signal word	Warning
Hazard statement	H400, H410

Other labels /conditions for use
Labelling

NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW468	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.

Conditions of use for all uses (00-001 – 00-010):

NW605-1 NW606	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 "*". 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. Drift reduction by 90% 5 m 75 % 5 m 50 % 10 m No drift reduction 0 % 15 m

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

The proposed application rate is 1.25 L/ha which delivers 250 g/ha pyraclostrobin. BAS 500 06 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 1.25 L/ha of BAS 500 06 F provided the optimum overall level of activity and was effective against all the major cereal diseases for which activity of BAS 500 06 F is claimed. As a result, the proposed rate of 1.25 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 500 06 F, when applied at the proposed rate of 1.25 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 hectolitre weight confirmed the response in terms of grain quality to applications of BAS 500 06 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. No phytotoxicity or other adverse effects on crop plants, plant products, adjacent or succeeding crops were observed.

In conclusion, the results support the claim made in the introduction that BAS 500 06 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 applied for. However, resistance management is necessary for *Pyrenophora teres* (PYRNTE) in barley and *Pyrenophora tritici-repentis* (PYRNTR) in wheat.

The product is classified as harmful for populations of relevant beneficial insects and predatory mites and spiders.

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

3.2 Conclusions

Physical-chemical properties: With respect to the identity, physical, chemical and technical data and analysis of the product an authorisation can be granted.

Analytical methods for residues: An authorisation can be granted.

Toxicology and residues: The intended use in cereals will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food with these residues is not expected.

There is no unacceptable risk for operators (according German model only), workers and bystanders predicted which result from the intended use of BAS 500 06 F.

Concerning toxicology and residues an authorisation can be granted.

Environmental fate and ecotoxicology: Considering an application of the product in accordance with the intended and evaluated use pattern and good agricultural practice as well as compliance with imposed risk mitigation measures no harmful effects on groundwater or unacceptable effects on non-target organisms are to be expected.

Efficacy: BAS 500 06 F showed for all uses applied for a sufficient effect against the diseases and no unacceptable effects on the plants or plant products occur. All uses applied for can be authorised from the efficacy point of view.

In summary: an authorisation for the applied uses can be granted.

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

None.

Appendix 1 – Copy of the product authorisation

See below

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 made by the competent authority. The final version of the label has to fulfil the requirements according to Article 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

Letters of access were not needed for evaluation of the formulation.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007643-00/00.66892
(bitte bei Antwort angeben)

DATUM 31. Oktober 2014

ZV1 007643-00/00

BAS 500 06 F

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	200 g/l	Pyraclostrobin
Zulassungsnummer:	007643-00	
Versuchsbezeichnung:	BAS-50006-FW-0-EC	
Antrag vom:	9. Mai 2012	

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 31. Januar 2018.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungs-nummer	**Schadorganismus/ Zweckbestimmung**	**Pflanzen/-erzeugnisse/ Objekte**	**Verwendungszweck**
007643-00/00-005	Blattfleckenkrankheit (Rhynchosporium secalis)	Gerste	
007643-00/00-008	Blattfleckenkrankheit (Rhynchosporium secalis)	Roggen	
007643-00/00-009	Braunrost (Puccinia recondita)	Roggen	
007643-00/00-010	Braunrost (Puccinia recondita)	Triticale	
007643-00/00-001	Braunrost (Puccinia recondita)	Weizen	
007643-00/00-003	DTR-Blattdürre (Drechslera tritici-re-pentis)	Weizen	
007643-00/00-002	Gelbrost (Puccinia striiformis)	Weizen	
007643-00/00-007	Minderung nichtpa-rasitärer Blattflecken	Gerste	
007643-00/00-004	Netzfleckenkrankheit (Pyrenophora teres)	Gerste	
007643-00/00-006	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 87 des Gesetzes vom 7. August 2013 (BGBl. I S. 3154) 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 des Wirkstoffes Pyraclostrobin gegenüber aquatischen Organis-

men (Pyraclostrobin z.B. Fisch-akut-Tests HC5 5,9 µg/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 BAS 500 06 F 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 Deutsch-land, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlußbericht zum DBU-Projekt 09931, April 1998), ist es im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes (§ 1 Nr. 3 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281)) unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Anwendungsbestimmung 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**
Flasche	Coex	1		150,00	1000,00	ml
Kanister	Coex	1		3,00	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:

(NN3001)
Das Mittel wird als schädigend für Populationen relevanter Nutzinsekten eingestuft.

(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.

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

(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.

(SE110)
Dicht abschließende Schutzbrille tragen beim Umgang mit dem unverdünnten Mittel.

(SE120)
Dicht abschließende Schutzbrille tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(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.

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

(ST1203)
Partikelfiltrierende Halbmaske FFP2 oder Halbmaske mit Partikelfilter P2 (Kennfarbe: weiß) gemäß BVL-Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz, in der jeweils geltenden Fassung, tragen bei der Ausbringung/Handhabung des anwendungsfertigen Mittels.

(WMFC3)
Wirkungsmechanismus (FRAC-Gruppe): C3

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

Vorbehalt

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

Angaben zur Einstufung und Kennzeichnung gemäß § 4 Gefahrstoffverordnung

Gefahrensymbole:	N, Xn
Gefahrenbezeichnungen:	Umweltgefährlich, Gesundheitsschädlich

Gefahrenhinweise (R-Sätze):

R 20/22 : Gesundheitsschädlich beim Einatmen und Verschlucken

R 50/53: Sehr giftig für Wasserorganismen, kann in Gewässern längerfristig schädliche Wirkungen haben.

R 38 : Reizt die Haut

R 43 : Sensibilisierung durch Hautkontakt möglich

Sicherheitshinweise (S-Sätze):

S 36/37 : Bei der Arbeit geeignete Schutzkleidung und Schutzhandschuhe tragen

S 2 : Darf nicht in die Hände von Kindern gelangen

S 13 : Von Nahrungsmitteln, Getränken und Futtermitteln fernhalten

S 24 : Berührung mit der Haut vermeiden

S 35 : Abfälle und Behälter müssen in gesicherter Weise beseitigt werden

S 46 : Bei Verschlucken sofort ärztlichen Rat einholen und Verpackung oder Etikett vorzeigen

S 57 : Zur Vermeidung einer Kontamination der Umwelt geeigneten Behälter verwenden

Zur Vermeidung von Risiken für Mensch und Umwelt ist die Gebrauchsanleitung einzuhalten.

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

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 401)

Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

(H302)

Gesundheitsschädlich bei Verschlucken.

(H304)

Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

(H315)

Verursacht Hautreizungen.

(H317)

Kann allergische Hautreaktionen verursachen.

(H319)

Verursacht schwere Augenreizung.

(H332)
Gesundheitsschädlich bei Einatmen.

(H400)
Sehr giftig für Wasserorganismen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

Sicherheitshinweise (P-Sätze):
- keine -

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).

Weitere Hinweise und Bemerkungen
Zu KIIIA1 6.2.8:
Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkmechanismus (WMFC3: Pyraclostrobin):
Die FRAC-Klassifizierung ist als neutrale Information dem Wirkstoff zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkmechanismus von Fungiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

Momentan gibt es seitens des BVL keinen Vorschlag für P-Sätze gemäß Verordnung (EG) Nr. 1272/2008 (CLP-Verordnung).

KIIA 8.16
Vorhandene Daten zu Auswirkungen auf Salz- bzw. Brackwasserarten sind von Ihnen vorzulegen:
Es existieren Daten zur Toxizität des Wirkstoffs Pyraclostrobin gegenüber marinen Organismen (z.B. Americamysis bahia), die für US-amerikanische Zulassungsprüfungen erarbeitet wurden, jedoch von Ihnen weder für die europäische Wirkstoffprüfung noch für die aktuelle Zulassungsprüfung für das Mittel "BAS 500 06 F" eingereicht wurden. Folglich konnten diese Daten auch im Rahmen dieser Bewertung nicht berücksichtigt werden.
Antragsteller müssen alle ihnen vorliegenden relevanten biologischen Daten, die für die Bewertung des ökotoxikologischen Profils eines Wirkstoffs/ Produkt von Bedeutung sind, vorlegen (siehe Artikel 8 Absatz 1 der Verordnung (EG) Nr. 1107/2009 in Verbindung mit Punkt 8. i) des Anhangs der VO (EU) Nr. 544/2011 und Punkt 10. iii) des Anhangs der VO (EU) Nr. 545/2011). Diese im Rahmen der nordamerikanischen Zulassung erzeugten Studien zu marinen bzw. Brackwasser-Arten stellen eine für die Bewertung des ökotoxikologischen Profils einer Substanz relevante Information dar.

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. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 007643-00/00-001

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
<u>Begründung:</u>
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
<u>Begründung:</u>
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-002

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
<u>Begründung:</u>
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
<u>Begründung:</u>
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-003

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:	25 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:	
-	1,25 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: 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% 10 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
Begründung:
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-004

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
Begründung:
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Blattfleckenkrankheit (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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
Begründung:
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-006

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
<u>Begründung:</u>
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
<u>Begründung:</u>
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-007

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
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	2
Anwendungstechnik:	spritzen
Aufwand:	
-	1,25 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 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% 10 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
Begründung:
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-008

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Blattfleckenkrankheit (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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
<u>Begründung:</u>
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
<u>Begründung:</u>
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-009

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
<u>Begründung:</u>
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
<u>Begründung:</u>
Siehe unter Begründung zu NW605-1.

Anlage 1 zugelassene Anwendung: 007643-00/00-010

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:	25 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:	
-	1,25 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% 10 m, 75% 5 m, 90% 5 m
Begründung:
Das Pflanzenschutzmittel BAS 500 06 F bzw. der darin enthaltene Wirkstoff Pyraclostrobin weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bewertungsbestimmend ist hier die HC5 für Fische von 5,9 µg/L. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 20 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 605-1/606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BAS 500 06 F in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Registration Report 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.
15 m
Begründung:
Siehe unter Begründung zu NW605-1.

REGISTRATION REPORT
Part B

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

Product code: **BAS 500 06 F**

Active Substance: **Pyraclostrobin 200 g/L**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **BASF SE**

Date : **2014-10-31**

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 BAS 500 06 F containing the active substance Pyraclostrobin which was approved according to Regulation (EC) No 1107/2009.

The product BAS 500 06 F was not the representative formulation. However, it has been evaluated by many European authorities, since it is already registered for the use in cereals in Denmark, Estonia, Finland, Lithuania, Norway, Latvia, Ireland, United Kingdom and France. In Spain, Greece and Portugal, a mutual recognition application is currently under evaluation for the use in cereals which is based on the French authorisation and GAP.

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

Agreed EU End-points

End-Point	**Pyraclostrobin** (Reg. (EU) No. 540/2011)
Purity of active substance	min 975 g/kg
Maximum content of the impurity dimethyl sulfate (DMS)	0.001 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 BAS 500 06 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

Agricultural Center

P.O. Box 120

D-67114 Limburgerhof

Contact person:	Cordula Nieslony
Tel.No.:	+49 (0)621 60 519 16
Fax No:	+49 (0)621 60 277 01
e-mail:	cordula.nieslony @basf.com

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)

Pyraclostrobin:	min. 975 g/kg
Relevant impurity:	dimethyl sulfate (DMS) max. 1 mg/kg

Further information/justification is provided in Part C.

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

Trade name:	BAS 500 06 F
Company code number:	BAS 500 06 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 pyraclostrobin:	200 g/L
limits pyraclostrobin:	188.0 - 212.0 g/L

Technical active substance:

content of technical pyraclostrobin at minimum purity (97.5 %):	205.13 g/L	(19.65 % w/w)

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	Pyraclostrobin
1.4.3.2	CAS No.	175013-18-0
1.4.3.2	EINECS No.	–
1.4.3.2	CIPAC No.	657
1.4.3.2	ELINCS	–
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.

Confodential 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

Pyraclostrobin contains < 1mg/kg Dimethylsulfate. The origin of this impurity has been discussed in the document JM II for Annex I inclusion of pyraclostrobin. This impurity is proportionally diluted during the formulation process.

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

None.

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

BAS 500 06 F has not been the representative formulation for the Annex I inclusion of pyraclostrobin.

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 dark yellow clear liquid, with a moderate naphthalene-like odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 450 °C. In aqueous solution, it has a pH value around 6-7. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for an EC formulation.

Tabelle 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	BAS 500 06 F, batch No. 8241 205.04 g/L	The preparation is a dark yellow liquid with a moderate naphthalene-like odour.	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable
Explosive properties (IIIA 2.2.1)	OECD 113 (DSC)	BAS 500 06 F, batch No. 8241	The exothermic decomposition energy is less than 500 J/g.	Y	Loeffler, U., 2004a, 2004/1004104	Acceptable.
Oxidizing properties (IIIA 2.2.2)	UN test O.2	BAS 500 06 F, batch No. 8241	The substance is not considered an oxidizing substance.	Y	Loeffler, U., 2004a, 2004/1004104	Acceptable.
Flash point (IIIA 2.3.1)	EEC A 9	batch No. 8241	The flash point of the formulation is 104 °C.	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.
Flammability (IIIA 2.3.2)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Auto-flammability (IIIA 2.3.3)	EEC A 15	batch No. 8241	Auto-ignition at 450 °C.	Y	Loeffler, U., 2004a, 2004/1004104	Acceptable.
Acidity or alkalinity and pH (IIIA 2.4.1)			The test was not conducted, because the measured pH value at 1 % are clearly in the neutral range and for the neat formulation it can be assumed the pH would be between 4 and 10.			Acceptable.
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75	batch No. 8241	Before storage: CIPAC water D, 20 °C: 0.06 % 6.3 0.8 % 6.5 1.0 % 6.5 Pure water, 20 °C: 0.06 % 6.0 0.8 % 6.0 1.0 % 6.1 After 2 weeks, 54 °C: CIPAC water D, 20 °C: 0.06 % 6.3 0.8 % 6.4 1.0 % 6.5 Pure water, 20 °C: 0.06 % 6.7 0.8 % 6.0 1.0 % 5.9 After 7 days, 0 °C:	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			CIPAC water D, 20 °C: 0.06 % 6.5 0.8 % 6.6 1.0 % 6.6 Pure water, 20 °C: 0.06 % 5.9 0.8 % 6.0 1.0 % 6.1			
	CIPAC MT 75.3	BAS 500 06 F batch No. 8265	Before storage: CIPAC water D, 20 °C: 1.25 % 6.0 Pure water, 20 °C: 1.25 % 5.3 After 2 weeks, 54 °C: CIPAC water D, 20 °C: 1.25 % 6.0 Pure water, 20 °C: 1.25 % 5.2 After 7 days, 0 °C: CIPAC water D, 20 °C: 1.25 % 6.2 Pure water, 20 °C: 1.25 % 5.3	Y	Kroehl, T., 2008a, 2008/1086283	Acceptable.
	CIPAC MT 75	batch No. 8241	Before storage: CIPAC water D, 20 °C: 0.06°% 6.3 0.8°% 6.5	Y	Kroehl, T., 2006a, 2006/1019717	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			Pure water, 20 °C: 0.06°% 6.0 0.8°% 6.0 After 2 years, ambient temperature: CIPAC water D, 20 °C: 0.06°% 6.8 0.8°% 6.8 Pure water, 20 °C: 0.06°% 5.9 0.8°% 5.7			
Kinematic viscosity (IIIA 2.5.1)	OECD 114 (calculated from dynamic viscosity)	batch No. 8241	40 °C: 12.9×10^{-6} m²/s R 65 is not triggered. Asp. Tox 1, H 304 is triggered!	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable. Viscosity does not trigger R 65, but Asp. Tox. 1, H304 according to CLP regulation
Dynamic viscosity (IIIA 2.5.2)	OECD 114	batch No. 8241	20 °C, shear rate = 100 s^{-1}: 31.4 mPa s 40 °C, shear rate = 100 s^{-1}: 13.3 mPa s	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.
		batch No. 8241	20 °C, shear rate = 100 s^{-1}: 31.7 mPa s	Y	Kroehl, T., 2006a, 2006/1019717	Acceptable. Table with single values is missing.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		batch 8241	20 °C: 31.4 mPa s at 10 s^{-1} 31.4 mPa s at 100 s^{-1} 31.4 mPa s at 400 s^{-1} 40 °C: 13.3 mPa s at 10 s^{-1} 13.3 mPa s at 100 s^{-1} 13.3 mPa s at 400 s^{-1} Newtonian liquid.	N	Arago, L. 2014 2014/1046553	Acceptable; formulation is a Newtonian liquid
Surface tension (IIIA 2.5.3)	EEC A.5	batch No. 8241	0.06 %, pure water, 20 °C: 36.3 mN/m 0.8 %, pure water, 20 °C: 33.4 mN/m neat, 25 °C: 36.3 mN/m	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable. The surface tension does not trigger R 65.
Relative density (IIIA 2.6.1)	EEC A.3	batch No. 8241	Before storage: $d_4^{20} = 1.044$ After 2 weeks, 54 °C: $d_4^{20} = 1.042$	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.
Bulk or tap density (IIIA 2.6.2)			Not required by regulation (EU) 2011/545.			Acceptable
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	CIPAC MT 46.3	batch No. 8241	Storage material: glass bottle The content of the active substance does not decrease > 5 %. The changes of the physical and chem-	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			ical properties are negligible. Content of pyraclostrobin: before storage: 205.4 g/L after storage: 204.4 g/L			
		batch No. 8265	Storage material: PE/PA coextruded pack The changes of the physical and chemical properties are negligible. Content of pyraclostrobin: before storage: not determined after storage: not determined	Y	Kroehl, T., 2008a, 2008/1086283	Acceptable. Content of as was not determined.
		batch No. 8265	Batch 8265 was re-analysed after 4 years of storage; the content of pyraclostrobin was 202.7 g/L.	Y	Kreucher, R., 2008 2008/1101718	The determined value suggests stability, but no information on storage material is given. Additional information
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	-		Not necessary, since the decrease of the active substance did not exceed 5 %.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
(IIIA 2.7.3)						
Effect of low temperatures on stability (IIIA 2.7.4)	CIPAC MT 39.3	batch No. 8241	No separated material, homogeneous liquid.	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.
		batch No. 8265	No separated material, homogeneous liquid.	Y	Kroehl, T., 2008a, 2008/1086283	Acceptable.
Ambient temperature shelf life (IIIA 2.7.5)	GIFAP Technical Monograph No. 17 (May 1993), EEC 91/414	batch No. 8241	Storage material: PE/PA coextruded Average temperature: 23 °C The content of the active substance does not decrease > 5 %. The changes of the physical and chemical properties are negligible. Content of pyraclostrobin: before storage: 203.9 g/L after storage: 200.9 g/L	Y	Kroehl, T., 2006a, 2006/1019717	Acceptable.
Shelf life in months (if less than 2 years) (IIIA 2.7.6)	-		Please refer to 2.7.5			Acceptable.
Wettability (IIIA 2.8.1)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	batch No. 8241	CIPAC water D, 0.06 %: Before storage 10s: 10 mL 1 min: 8 mL 3 min: 8 mL 12 min: 0 mL CIPAC water D, 0.8 %: Before Storage 10s: 20 mL 1 min: 14 mL 3 min: 10 mL 12 min: 4 mL	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 47.2	batch No. 8265	CIPAC water D, 0.06 %: Before Storage 10s: 6 mL 1 min: <1 mL 3 min: <1 mL 12 min: <1 mL 2 weeks, 54 °C 10s: 10 mL 1 min: 8 mL 3 min: 8 mL 12 min: 8 mL CIPAC water D, 1.25 %: Before Storage 10s: 16 mL 1 min: 16 mL 3 min: 16 mL 12 min: 16 mL 2 weeks, 54 °C 10s: 22 mL 1 min: 20 mL 3 min: 20 mL 12 min: 20 mL	Y	Kroehl, T., 2008a, 2008/1086283	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		batch No. 8241	CIPAC water D, 0.06 %: Before Storage 10s: 10 mL 1 min: 8 mL 3 min: 8 mL 12 min: 0 mL 2 years, ambient 10s: 6 mL 1 min: 4 mL 3 min: 2 mL 12 min: 0 mL CIPAC water D, 0.8 %: Before Storage 10s: 20 mL 1 min: 14 mL 3 min: 10 mL 12 min: 4 mL 2 years, ambient 10s: 18 mL 1 min: 18 mL 3 min: 16 mL 12 min: 16 mL	Y	Kroehl, T., 2006a, 2006/1019717	Acceptable. Data at highest use rate (1.25 %) are missing.
Suspensibility (IIIA 2.8.3.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Spontaneity of dispersion (IIIA 2.8.3.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dilution stability (IIIA 2.8.4)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Dry sieve test (IIIA 2.8.5.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Wet sieve test (IIIA 2.8.5.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Particle size distribution (IIIA 2.8.6.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Nominal size range of granules (IIIA 2.8.6.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dust content (IIIA 2.8.6.3)			Not required by regulation (EU) 2011/545.			Acceptable.
Particle size of dust (IIIA 2.8.6.4)			Not required by regulation (EU) 2011/545.			Acceptable.
Friability and attrition (IIIA 2.8.6.5)			Not required by regulation (EU) 2011/545.			Acceptable.
Emulsifiability (IIIA 2.8.7.1)	CIPAC MT 36.3	batch No. 8241	CIPAC water D, 0.06 % and 0.8 %: Before storage, after 2 weeks, 54 °C and after 7 days, 0 °C 0 h: spontan emulsifiable 0.5 h: 0 mL cream 0 mL oil 0 mL sediment/cream 2 h: 0 mL cream	Y	Kaestel, R., 2004a, 2004/1010381	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			0 mL oil 0 mL sediment/cream 24 h: spontan re-emulsifiable 24.5 h: 0 mL cream 0 mL oil 0 mL sediment/cream Almost the same results for CIPAC water A, 0.06 % and 0.8 %.			
		batch No. 8265	CIPAC water D, 1.25 %: Before storage, after 2 weeks, 54 °C and after 7 days, 0 °C 0 h: spontan emulsifiable 0.5 h: < 1 mL cream 0 mL oil 0 mL sediment 2 h: <1 mL cream 0 mL oil 0 mL sediment 24 h: spontan re-emulsifiable 24.5 h: <1 mL cream 0 mL oil 0 mL sediment Similar results for CIPAC water A, 1.25 %.	Y	Kroehl, T., 2008a, 2008/1086283	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
		batch No. 8241	CIPAC water D, 0.06 % and 0.8 %: Before storage and after 2 years, ambient temperature 0 h: spontan emulsifiable 0.5 h: 0 mL cream 0 mL oil 0 to <1 mL sediment 2 h: 0 mL cream 0 mL oil 0 mL sediment 24 h: spontan re-emulsifiable 24.5 h: 0 to <1 mL mL cream 0 mL oil 0 mL sediment Similar results for CIPAC water A, 0.06 % and 0.8 %.	Y	Kroehl, T., 2006a, 2006/1019717	Acceptable. Data at highest use rate (1.25 %) are missing.
Dispersibility (IIIA 2.8.7.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Flowability (IIIA 2.8.8.1)			Not required by regulation (EU) 2011/545.			Acceptable.
Pourability (including rinsed residue) (IIIA 2.8.8.2)			Not required by regulation (EU) 2011/545.			Acceptable.
Dustability following accelerated storage (IIIA 2.8.8.3)			Not required by regulation (EU) 2011/545.			Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Physical compatibility of tank mixes (IIIA 2.9.1)	ASTM 1518-93 - mixing by hand - evaluation after standing for different times - additional characterizations	batch No. 8241	BAS 500 06 F was tested for physical compatibility with 9 formulations of the types SC, SE, SL, EC, OL, and WG. All mixtures were 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 preparing some of them. The mixtures appeared to be homogeneous. No tank mixture is envisaged in the instructions for use.	N	Rudoll, B., Schneider, K-H., 2004, 2004/1008462	Acceptable.
Chemical compatibility of tank mixes (IIIA 2.9.2)	ASTM 1518-93 - mixing by hand - evaluation after standing for different times - additional characterizations	batch No. 8241	Pyraclostrobin, the active substances of BAS 500 06 F, is stable in diluted aqueous conditions. Therefore none of the functional groups are likely to react under normal tank mix conditions. BAS 500 06 F was tested for physical compatibility with 9 formulations of the types SC, SE, SL, EC, OL, and WG.. No indication of any chemical reaction between the mixed products was observed. Therefore BAS 500 06 F is apparently chemically compatible with the tested products.	N	Rudoll, B., Schneider, K-H., 2004, 2004/1008462	Acceptable.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
			No tank mixture is envisaged in the instructions for use.			
Distribution to seed (IIIA 2.10.1)	CIPAC MT 147		Not required by regulation (EU) 2011/545.			
Adhesion to seeds (IIIA 2.10.2)	CIPAC MT 175		Not required by regulation (EU) 2011/545.			
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)	Statement		During the manufacture, handling or storage of BAS 500 06 F, corrosiveness on apparatus, containers, or packing material was not observed.	N	Kaltz, G., 2004, 2004/1016185	Acceptable.
Container material (IIIA 2.14)	ADR/RID regulations		BAS 500 06 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 polypropylene or polyethylene.	N	Schreiner, B., 2005, 2005/1025057	Acceptable.
Other/special studies (IIIA 2.15)			Not required by regulation (EU) 2011/545.			Acceptable.

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

BAS 500 06 F has not been the representative formulation for the Annex I inclusion of pyraclostrobin.

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 dark yellow clear liquid, with a moderate naphthalene-like odour. It is not explosive, has no oxidising properties. It has a self ignition temperature of 450°C. In aqueous solution, it has a pH value around 6-7. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for an EC formulation. Regarding persistent foam and emulsifiability data at highest use rate after storage for 2 years at ambient temperature are missing. But the submitted studies indicate that there should be no problems also at the highest use rate.

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

See Appendix 3

Implications for labelling:

Asp Tox 1 – H 304

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

Agriculture

IIIA 3.2 Nature of the Effects on Harmful Organisms

According to FRAC: C3 (QoI-fungicide)

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

BAS 500 06 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 or by polyamide laminated PE-foam gaskets, 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 185.5 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:	42 mm inner diameter
	closure:	Polypropylene/Polyethylene screw cap
	seal:	Induction sealed

1 litre eco-bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	54 mm 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:	54 mm inner diameter
	closure:	polypropylene screw cap
	seal:	Induction sealed

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:	54mm 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 sealed

10 litre eco-container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 230 mm x 187 mm x 358 mm
	opening:	54mm inner diameter
	closure:	polypropylene screw cap
	seal:	gasket

IIIA 4.1.2 Suitability of the packaging and closures

Report:	Schreiner, B. , 2005a
Title:	EU performance tests of BAS 500 06 F (Standard-Coex-Bottle, 1L, Spec.-No. 775 5108)
Document No:	BASF DocID 2005/1025057
Guidelines:	None
GLP	No

The packaging complies with ADR 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.

IIIA 4.1.3 Resistance of the packaging material to its contents

Report:	Kroehl T., 2006a
Title:	Shelf life at 23 °C in original containers of the formulation BAS 500 06 F, 24 month storage, analytical results and physical properties
Document No:	BASF DocID 2006/1019717
Guidelines:	OECD Principles of Good Laboratory Practice, GLP Principles of the German Chemikaliengesetz (Chemicals Act), GIFAP Technical Monograph No. 17 (May 1993), EEC 91/414 Annex III 2.7.3
GLP	Yes

The study results prove, that the original container material and the closure/seal resists to the product BAS 500 06 F. No corrosion of the container could be observed during the storage time.

IIIA 4.2 Procedures for Cleaning Application Equipment

IIIA 4.2.1 Procedures for cleaning application equipment and protective clothing

Report:	Nolte M., 2010a
Title:	BAS 500 06 F: Effectiveness of procedures for cleaning application equipment and protective clothing
Document No:	BASF DocID 2010/1048392
Guidelines:	None
GLP	No, not subject to GLP regulations

Any surplus spray mix is to be diluted at the ratio of 1:10 with water and to be sprayed onto the previously treated area, according to the use instructions.
Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of product have been removed.

Protective clothing for applicators of agrochemicals is usually made of cotton. The polar surface of the fiber presents little affinity to the unpolar active ingredients. Therefore, usual laundering with detergents will either suspend or dissolve any contamination efficiently.

IIIA 4.2.2 Effectiveness of the cleaning procedures

Report:	Nolte M., 2010a
Title:	BAS 500 06 F: Effectiveness of procedures for cleaning application equipment and protective clothing
Document No:	BASF DocID 2010/1048392
Guidelines:	None
GLP	No, not subject to GLP regulations

Common agricultural practice implies cleaning of application equipment with water. This will remove any remainders of BAS 500 06 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 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

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

See Part B section 4.

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

See Part B section 4.

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

See Part B section 4.

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

See Part B section 4.

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

See Part B section 4.

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

See Part B section 4.

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

See Part B section 4.

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

IIIA 4.4.1 Warehouse storage

Report:	Anonymous, 2012a
Title:	Safety data sheet Retengo (BAS 500 06 F)
Document No:	-
Guidelines:	EEC 1907/2006
GLP	No, not subject to GLP regulations

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

IIIA 4.4.2 User level storage

Please refer to 4.4.1.

IIIA 4.4.3 Transport

Please refer to 4.4.1.

IIIA 4.4.4 Fire

Please refer to 4.4.1.

IIIA 4.4.5 Nature of protective clothing proposed

Please refer to 4.4.1.

IIIA 4.4.6 Characteristics of protective clothing proposed

Please refer to 4.4.1.

IIIA 4.4.7 Suitability and effectiveness of protective clothing and equipment

Please refer to 4.4.1.

IIIA 4.4.8 Procedures to minimise the generation of waste

Please refer to 4.4.1.

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

Please refer to 4.4.1.

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

Report:	Anonymous, 2012a
Title:	Safety data sheet Retengo (BAS 500 06 F)
Document No:	-
Guidelines:	EEC 1907/2006
GLP	No, not subject to GLP regulations

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

Please refer to 4.5.

IIIA 4.5.2 Decontamination of areas, vehicles and buildings

Please refer to 4.5.

IIIA 4.5.3 Disposal of damaged packaging, adsorbents and other materials

Please refer to 4.5.

IIIA 4.5.4 Protection of emergency workers and bystanders

Please refer to 4.5.

IIIA 4.5.5 First aid measures

Please refer to 4.5.

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

For BAS 500 06 F, no neutralization procedures can be proposed.

IIIA 4.6.1 Details of proposed procedures for small quantities

Please refer to 4.6.

IIIA 4.6.2 Evaluation of products of neutralization (small quantities)

Please refer to 4.6

IIIA 4.6.3 Procedures for disposal of small quantities of neutralized waste

Please refer to 4.6

IIIA 4.6.4 Details of proposed procedures for large quantities

Please refer to 4.6

IIIA 4.6.5 Evaluation of products of neutralization (large quantities)

Please refer to 4.6

IIIA 4.6.6 Procedures for disposal of large quantities of neutralized waste

Please refer to 4.6

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 500 06 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 500 06 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 approximately 1100°C with a residence time of about 2 seconds is advised.

By doing so, i.e., operating the incinerator according to the conditions laid down in council directive 94/67/EEC resp. 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 rinsing water must be added to the spray liquid.

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

IIIA 4.8.2 Methods other than controlled incineration for disposal

No other methods for disposal of BAS 500 06 F than those described in chapter 4.8.1 are available.

IIIA 4.9 Other/Special Studies

No additional studies were performed.

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 labelling of BAS 512 16 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 (-)	Loeffler, U., 2004a, 2004/1004104
Oxidizing properties	Not oxidizing (-)	Loeffler, U., 2004a, 2004/1004104
Flammability	Auto-ignition temperature is 460°C	Loeffler, U., 2004a, 2004/1004104
Content of hydrocarbon	< 10 % (w/w)	Composition see part C
Viscosity (dynamic)	31.4 mPas (at a shear rate of 100 s^{-1} at 20°C)	Kaestel, R., 2004a, 2004/1010381
Surface tension	neat product: 36.3 mN/m 36.6 mN/m at 0.06 % w/w and 33.4 mN/m at 0.8%	Kaestel, R., 2004a, 2004/1010381

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	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, KIIIA1 2.3.1, KIIIA1 2.4.2, KIIIA1 2.5.1, KIIIA1 2.5.2, KIIIA1 2.5.3, KIIIA1 2.6.1, KIIIA1 2.7.1, KIIIA1 2.7.4, KIIIA1 2.8.2, KIIIA1 2.8.7.1, KIIIA1 2.8.7.2	Kaestel, R.	2004a	Physical and chemical properties of the formulation BAS 500 06 F, 2004/1010381, GLP, unpublished	Y	BAS	1
KIIIA1 2.2.1, KIIIA1 2.2.2, KIIIA1 2.3.3	Loeffler, U.	2004a	Evaluation of physical and chemical properties according to Directive 92/69/EC, Annex A9-A17, 2004/1004104 GLP, unpublished	Y	BAS	1
KIIIA1 2.4.2, KIIIA1 2.7.1, KIIIA1 2.7.4, KIIIA1 2.8.2, KIIIA1 2.8.7.1, KIIIA1 2.8.7.3	Kroehl, T.	2008a	Emulsion stability, persistent foaming and pH value of Pyraclostrobin 200 g/L EC (BAS 500 06 F), 2008/1086283, GLP, unpublished	Y	BAS	1
KIIIA1 2.4.2, KIIIA1 2.5.2, KIIIA1 2.7.5, KIIIA1 2.8.2, KIIIA1 2.8.7.1	Kroehl, T.	2006a	Shelf life at 23°C in original container of the formulation BAS 500 06 F, 24 month storage, analytical results and physical properties, 2006/1019717, GLP, unpublished	Y	BAS	1

Annex point/ reference No	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 2.5.2	Arago, L.	2014	BAS 500 06 F – supplementary information to the viscosity test 2014/1046553 non GLP, unpublished	Y	BAS	1
KIIIA1 2.7.1	Kreucher, R.	2008	Certificate of analysis BAS 500 06 F, batch 8265 2008/1101718 GLP, unpublished	Y	BAS	1
KIIIA1 2.9.1	Rudoll B., Schneider K.-H.	2004a	Physical and chemical compatibility in aqueous tank mixtures of BAS 500 06 F, 2004/1008462, Not GLP, unpublished	Y	BAS	1
KIIIA1 2.13	Kltz, G.	2004a	Corrosiveness of the formulation BAS 500 06 F, 2004/1016185, Not GLP, unpublished	Y	BAS	1
KIIIA1 2.14, 4.1.2	Schreiner, B.	2005a	EU performance tests of BAS 500 06 F (Standard-Coex-Bottle, 1 L, Spec.-No. 775 5108), 2005/1025057, Not GLP, unpublished	Y	BAS	1
KIIIA1 4.1.3	Kroehl, T.	2006a	Shelf life at 23°C in original container of the formulation BAS 500 06 F, 24 month storage, analytical results and physical properties, 2006/1019717, GLP, unpublished	Y	BAS	1
KIIIA1 4.2.1, 4.2.2	Nolte, M.	2010a	BAS 500 06 F: Effectiveness of Procedures for cleaning application equipment and protective clothing, 2010/1048392, Not GLP, unpublished	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)

Appendix 2: Critical Uses – Justification and GAP tables

GAP-Table for Germany

GAP rev. , date: 2012-06-25

PPP (product name/code)	**BAS 500 06 F**	**Formulation type:**	**EC**
active substance	**Pyraclostrobin**	**Conc. of as :**	**0.2 kg/L**

Applicant:	**BASF SE**	**professional use**	☒
Zone(s): central		**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		
1	DE	Wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

						BBCH 25 - 69					
2	DE	Wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
3	DE	Wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
4	DE	Barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
5	DE	Barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
6	DE	Barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	from spring at beginning of infestation and/or when first symptoms become visible	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

						BBCH 25 - 61						
7	DE	Barley HORVX	F	decrease of non-parasitic leaf spots YBFMI* no EPPO code	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 32 - 61	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
8	DE	Rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
9	DE	Rye SECCE	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
10	DE	Triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

GAP-Table for CMS

GAP rev. 1, date: 2013-07-09

PPP (product name/code)	**BAS 500 06 F**	**Formulation type:**	**EC**
active substance	**Pyraclostrobin**	**Conc. of as :**	**0.2 kg/L**
Applicant:	**BASF SE**	**professional use**	☒
Zone(s): central		**non professional use**	☐
Verified by MS:	**no**		

Crop and/ or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days)	**Remarks:**
					Type	Conc. of as kg/L	Method Kind	Growth stage & season	number min max	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)						(l)	(m)

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation: Type (d-f)	Formulation: Conc. of as kg/L (i)	Application: Method Kind (f-h)	Application: Growth stage & season (j)	Application: number min max (k)	Application: interval between applications (min)	Application rate per treatment: kg as/hL min max	Application rate per treatment: water L/ha min max	Application rate per treatment: kg as/ha min max	Application rate per treatment: Product (L/ha) min max	PHI (days) (l)	Remarks: (m)
Cereals	**Central zone**		F	*As detailed below*	EC	0.2	SP	25-69	2	21 days	0.0625 – 0.25	100-400	0.25	0.8-1.25*	35	*As discussed during the pre-submission meeting with the German zRMS, a range of 0.8-1.25 L product/ha will be applied for in Eastern European countries
Wheat (spring, winter, durum, spelt)	**AT**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-61 (*P. recondita*: 25-69)	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Barley (spring, winter)	**AT**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**				**PHI (days)**	**Remarks:**
(a)			(b)	(c)	Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max	(l)	(m)
Rye	**AT**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**AT**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**BE, LU**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Barley (spring, winter)	**BE, LU**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Rye	**BE, LU**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**BE, LU**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Oat	**BE, LU**		F	*Puccinia coronata*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**NL**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**NL**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* *Sunburn injury*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Rye	**NL**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**NL**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**CZ**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**CZ**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Rye	**CZ**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**CZ**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**SK**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation Type (d-f)	Formulation Conc. of as kg/L (i)	Application Method Kind (f-h)	Application Growth stage & season (j)	Application number min max (k)	Application interval between applications (min)	Application rate per treatment kg as/hL min max	Application rate per treatment water L/ha min max	Application rate per treatment kg as/ha min max	Application rate per treatment Product (L/ha) min max	PHI (days) (l)	Remarks: (m)
Barley (spring, winter)	**SK**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**SK**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**SK**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**SI**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**SI**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**SI**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**SI**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**RO**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**RO**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**RO**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**RO**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**HU**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation Type (d-f)	Formulation Conc. of as kg/L (i)	Application Method Kind (f-h)	Application Growth stage & season (j)	Application number min max (k)	Application interval between applications (min)	Application rate per treatment kg as/hL min max	Application rate per treatment water L/ha min max	Application rate per treatment kg as/ha min max	Application rate per treatment Product (L/ha) min max	PHI (days) (l)	Remarks: (m)
Barley (spring, winter)	**HU**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**HU**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**HU**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**PL**		F	*Septoria tritici* *Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**PL**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**PL**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**PL**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter)	**UK, IE**		F	*P. recondita* *P. striiformis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**UK, IE**		F	*P. triticina* *P. striiformis* *P. teres,* *R. secalis*	EC	0,2	SP	25-59	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Oat (winter, spring)	**UK, IE**		F	*P. coronata*	EC	0,2	SP	25-59	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Triticale	**IE**		F	*P. triticina* *P. striiformis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Rye	**IE**		F	*P. triticina* *P. striiformis* *R. secalis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered

(a) For crops, the EU and Codex classifications (both) should be used; where

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of 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

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) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix 3: Experimental testing of the product's physico-chemical and technical characteristics:

The following physical, chemical and technical properties of the plant protection product were experimentally tested:

density, colour, pH, surface tension, storage stability at high temperatures (14 d at 54 °C), low temperature stability (7 d at 0 °C), persistent foaming and the emulsion chracteristics.

No significant deviations from the data submitted by the applicant were detected.

The formulation complies with the chemical, physical and technical criteria which are stated for this type of formulation in the FAO/WHO manual (2010).

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code: BAS 500 06 F

Active Substance: Pyraclostrobin 200 g/L

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE

Date: 2014-10-31

Table of Contents

IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product BAS 500 06 F containing the active substance pyraclostrobin which was 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.

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 BAS 500 06 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 provided by the applicant but no analysis of the contents of the active substances or the relevant impurity dimethyl sulfate was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of pyraclostrobin 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 pyraclostrobin and its 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 BAS 500 06 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

The following analytical method for the determination of the active substances in the plant protection product performed on BAS 500 06 F has not previously been reviewed.

Report:	5.2.1/1 Ziegler, H., Machauer, B., 2003a
Title:	Analytical method CF-A 669: Quantitative determination of the active ingredient Pyraclostrobon in BAS 500 06 F by HPLC
Document No:	BASFDocID 2003/1022228
Guidelines:	None
GLP	No

Report:	5.2.1/2 Ziegler, H., 2004a
Title:	Validation of the analytical method CF-A 669. Determination of the active ingredient Pyaclostrobin in BAS 500 06 F by HPLC
Document No:	BASFDocID 2004/1004041
Guidelines:	SANCO 3030/99 rev. 4
GLP	Yes

Method description

The analytes are determined by reversed-phase HPLC on a J'sphere ODS-H80 column (250 x 4.6 mm, dp = 4 µm) at approximately 23 °C (room temperature), using external calibration.
Injection volume is 5 µL. The separation is achieved by using a gradient with a flow of 1- 2 mL/min.
Detection is performed with a UV detector at a wavelength of 230 nm.
The mobile phases consist of:
A: 660 mL acetonitrile, 340 mL water and 5 mL sulfuric acid 0.5 mol/L.
B: 900 mL acetonitrile, 100 mL water and 5 mL sulfuric acid 0.5 mol/L.
The retention times of the peaks of pyraclostrobin in BAS 500 06 F and the reference items are observed of the same value.
Identical UV-spectra of the compound peaks in the preparation and the reference items were measured.
The chromatogram of the blank formulation showed no interference with the active ingredient peak.

Method validation

The validation data of method CF-A 669 were determined for the formulation BAS 500 06 F. It was with respect to precision, accuracy, linearity and specificity proved that the method is suitable for the determination of pyraclostrobin in the EC-formulation.

Table containing the methods and validation of the methods (formulation BAS 500 06 F)

Analyte	Linearity n = 5	Accuracy n = 6 Mean [%]	Repeatability n = 6 [%RSD]	Specificity/Inteferences
Pyraclostrobin	0.5, 0.75, 1.0, 1.25 and 1.5 times of expected concentration $r^2 = 1.0000$	100.27	0.194 (mean content 19.19 %)	No interferences were noted. Chromatograms of formulation with and without active ingredients present were submitted.

Summary

The active substance of BAS 500 06 F can be quantified using the analytical HPLC method CF-A 669. The method was developed for quantifying pyraclostrobin in BAS 500 06 F.

The active substance pyraclostrobin is dissolved in acetonitrile / water, chromatographed on a HPLC reversed phase system with UV-detection and external calibration. The method can be used in emulsifiable concentration (EC).

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

Please refer to chapter 5.2.1 as BAS 500 06 F contains only one active substance.

IIIA 5.2.3 Applicability of existing CIPAC methods

CIPAC method MT 657/EC/M/- is applicable for EC formulations containing pyraclostrobin. As this method was not used for the quantification of the active substance in the evaluation of BAS 500 06 F, no specific chromatograms proving its applicability were necessary.

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

Pyraclostrobin contains dimethyl sulfate as relevant impurity. The content must not exceed 1 mg/kg in the technical material. That means that for the product BAS 500 06 F the content must not exceed 0.2 mg/L. The analysis of this impurity in the technical grade active substance has been discussed in the document JM II for Annex I inclusion of pyraclostrobin. This impurity is proportionally diluted during the formulation process, the method of analysis in BAS 500 06 F is described below.

Report:	5.2.4/01, Stegmaier W., 2011a
Title:	Validation of an analytical method for the determination of dimethyl sulfate in BAS 500 06 F
Document No:	BASF DocID 2011/1009064
Guidelines:	SANCO 3030/99 rev. 4
GLP	Yes

The method of analysis was developed in order to determinate dimethyl sulphate in BAS 500 06 F. The method applied is a Headspace GC method with quantification by means of standard addition.

Method description

The principle of the method is Headspace gas chromatography with mass spectrometer.
The sample is dissolved in toluene directly in a headspace vial and the vial is sealed. For the separation a: fused silica capillary column Rtx-1701 from Restek (length: 30 m, internal diameter: 0.25 mm, film thickness 0.25 µm) is used. The carrier gas is helium, a splitless injection is used and the oven is heated as following:
50°C for 1 min, 50°C -> 160°C, 15 C/min, 160°C -> 270 °C, 35 °C/min, 270°C for 22 min.
Detection of selected ions: m/z = 95.0, m/z = 96.0, m/z = 125.0,
External calibration is used for quantification.

Method validation

Specificity:
Peaks in the gas chromatogram are assigned to the analyte dimethyl sulfate by comparison of retention times and by the selection of characteristic ions in MS-detection.

Table containing the methods and validation of the methods (formulation BAS 500 06 F)

Analyte	**Linearity* n = 6**	**Accuracy n = 6 Mean [%]**	**Repeatability n = 6 [%RSD]**	**Specificity/Inteferences**
dimethyl sulfate	0.189 mg/kg to 4.425 mg/kg r^2= 0.9989	99 (0.2 mg/kg) 102 (0.8 mg/kg)	7.6 (0.2 mg/kg) 4.3 (0.8 mg/kg)	No interferences were noted. Chromatograms of formulation with and without impurity present were submitted.

* Fortification of test item (fortification of blank sample is also possible)

The Limit of Quantification (LOQ) was determined to be 0.2 mg/kg (see table). The Limit of Determination (LOD) was calculated as 0.3 * LOQ = 0.06 mg/kg.

Summary

The relevant impurity DMS of BAS 500 06 F can be quantified using a Headspace-GC/MS method. The method was developed for quantifying DMS in BAS 500 06 F.
The relevant impurity DMS is dissolved in toluene, chromatographed on a Headspace system with MS-detection and external calibration. The method can be used in emulsifiable concentration (EC).

IIIA 5.2.5 Description of analytical methods for the determination of formulants

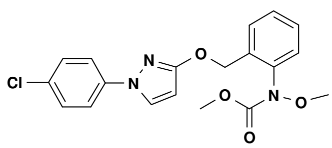
No formulants with toxicological or ecotoxicological relevant compounds are present in the formulation. Therefore, no analytical methods for the determination of formulants are necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of Pyraclostrobin

The conclusion regarding the peer review of the analytical methods for residues of Pyraclostrobin is summarized in SANCO/1420/2001-Final (2004).

Table 5.3-1: Information on the active substance Pyraclostrobin

Name of component of residue definiton **substance code** **IUPAC name** **formula**	**Structural formula**
Pyraclostrobin BAS 500 F Methyl-N-(2-{[1-(4-chlorphenyl)-1H-pyrazol-3-yl] oxymethyl}phenyl)-N-methoxy-carbamate $C_{19}H_{18}ClN_3O_4$	

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	pyraclostrobin	Regulation (EU) No 293/2013, annex II, Regulation (EU) No 978/2011 annex III part B
foodstuff of animal origin	pyraclostrobin	
soil ecotoxicology	pyraclostrobin	DAR, vol 1 chap. 2.5.1 ASB2010-10576
water ecotoxicology	pyraclostrobin	DAR, vol 1 chap. 2.5.1 ASB2010-10576
human toxicology	pyraclostrobin	DAR, vol 1 chap. 2.5.1 ASB2010-10576
air	pyraclostrobin	generally defined
body fluids/tissue	pyraclostrobin	classified as T generally defined

Table 5.3-3: Levels for which compliance is required

Matrix	**MRL**	**Reference for MRL/level** **Remarks**
Plant, high water content	0.02 mg/kg	Regulation (EU) No 293/2013, annex II, Regulation (EU) No 978/2011 annex III part B
Plant, acidic commodities	0.02 mg/kg	
Plant, dry commodities	0.02 mg/kg	

Matrix	MRL	Reference for MRL/level Remarks
Plant, high oil content	0.02 mg/kg	
Plant, difficult matrices hops coffee beans	 10 mg/kg 0.2 mg/kg	
meat	0.05 mg/kg	
milk	0.01 mg/kg	
eggs	0.05 mg/kg	
fat	0.05 mg/kg	
liver, kidney	0.05 mg/kg	
soil	0.05 mg/kg	common limit
drinking water	0.1 µg/L	general limit for drinking water
surface water	2.3 µg/L	NOEC *Oncorhynchus mykiss*; SANCO/1420/2001-Final 2004
air	4.5 µg/m^3	AOEL sys/AOEL inhal: 0.015 mg/kg bw/d
tissue (meat or liver)	0.1 mg/kg	classified as T
blood	0.05 mg/kg	classified as T

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin in plant matrices is given in the following tables. New studies were provided. For the detailed evaluation of new studies refer to **Fehler! Verweisquelle konnte nicht gefunden werden.**.

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	Reinhard and Mackenroth, 1999*	Devine, 2002	Lehmann and Mackenroth, 2007
acidic	Reinhard and Mackenroth, 1999*	Devine, 2002	Lehmann and Mackenroth, 2007
fatty	Reinhard and Mackenroth, 1999*	Devine, 2002	Lehmann and Mackenroth, 2007
dry	Reinhard and Mackenroth, 1999*	Devine, 2002	Lehmann and Mackenroth, 2007
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:	Reinhard and Mackenroth, 1999* (RIP2001-72)

*EU agreed method (see Draft Assessment Report)

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
Reinhard and Mackenroth, 1999 MET2000-273	high water content, dry, acidic, fatty	0.02 mg/kg	LC-MS/MS, Phenyl column, m/z 388→194	no confirmation	Vol. 3, section B.5.2.1 of the DAR ASB2010-10576
Devine, 2002 ASB2008-4973	high water content, acidic, dry, fatty, difficult (hops)	0.02 mg/kg	LC-MS/MS, Phenyl column, m/z 388→194	ILV of Reinhard and Mackenroth, 1999	Appendix 2
Lehmann and Mackenroth, 2007 RIP2007-463	high water content, acidic, dry, fatty	0.01 mg/kg	LC-MS/MS, C18 column, ESI+, m/z 388→194; 388→163	confirmation included	Appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin in animal matrices is given in the following tables. New studies were provided. For the detailed evaluation of new studies refer to **Fehler! Verweisquelle konnte nicht gefunden werden.**.

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	Hopf, 2010	Schacherl, 2010	Hopf, 2010
eggs	Hopf, 2010	Schacherl, 2010	Hopf, 2010
meat	Hopf, 2010	Schacherl, 2010	Hopf, 2010
fat	Hopf, 2010	Schacherl, 2010	Hopf, 2010
kidney, liver	Hopf, 2010	Schacherl, 2010	Hopf, 2010

Table 5.3-8: Statement on extraction efficiency

	Method for products of animal origin

Required, available from:	Bross and Tilting, 2000* (RIP2000-1020) Hafemann and Knoell, 1999* (RIP2000-1022)

*EU agreed method (see Draft Assessment Report)

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
Hopf, 2010 ASB2012-10307	milk, eggs, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 388→194, 388→163	confirmation included	Appendix 2
Schacherl, 2010 ASB2012-10308	milk, eggs, meat, fat, liver, kidney	0.01 mg/kg	LC-MS/MS, C18, ESI+, m/z 388→194, 388→163	confirmation included, ILV of Hopf, 2010	Appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin 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
pyraclostrobin	Ziegler, 1998*	Zangmeister, 1999*

*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
Ziegler, 1998 MET2000-282	0.01 mg/kg	LC-UV, 270 nm, Spherisorb column	no confirmation	Vol. 3, section B.5.3.1 of the DAR ASB2010-10576
Zangmeister, 1999 MET2000-283	0.01 mg/kg	LC-MS, m/z 388	no confirmation	Vol. 3, section B.5.3.1 of the DAR ASB2010-10576

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin in surface and drinking water is given in the following table. A new study was provided. A detailed evaluation of the new study is given in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

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

Component(s) of residue definition	Matrix	Primary method	Confirmatory method
pyraclostrobin	drinking water surface water	Zangmeister, 1999*	Tilting, 2012

*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
Zangmeister, 1999 MET2000-285	0.05 µg/L	LC-MS/MS hypersil green ENV column, m/z 388→194	no confirmation	Vol. 3, section B.5.3.2 of the DAR ASB2010-10576
Tilting, 2012 ASB2012-10310	0.003 µg/L	LC-MS/MS, C18, ESI+, m/z 388→194, 388→163	confirmation included	Appendix 2

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin in air is given in the following table.

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

Component(s) of residue definition	Primary method	Confirmatory method
pyraclostrobin	Zangmeister, 1999*	not required

*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 MET2000-287	0.3 µg/m^3	HPLC-UV , 276 nm, Supelcosil ABZ plus		Vol. 3, section B.5.3.3 of the DAR ASB2010-10576

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

An overview of the acceptable methods and possible data gaps for analysis of pyraclostrobin in body fluids and tissues is given in the following table. A new study was provided. A detailed evaluation of the new study is given in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

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
pyraclostrobin	Hopf, 2010	Hopf, 2010

Table 5.3-17: Methods for body fluids and tissues

Author(s), year	Method LOQ	Principle of method	Comment	Evaluated in
Hopf, 2010 ASB2012-10307	0.01 mg/kg (meat, liver, kidney) 0.01mg/L (blood)	LC-MS/MS, C18, ESI+, m/z 388→194, 388→163	confirmation included	Appendix 2

IIIA 5.3.1.8 Other Studies/ Information

Other studies were not provided.

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 definition.

Appendix 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*
KIIIA1 5.2.1	Ziegler, H., Machauer, B.	2003	Analytical method CF-A 669: Quantitative determination of the active ingredient Pyraclostrobin in BAS 500 06 F by HPLC, 2003/1022228, Not GLP, unpublished	Y	BAS	1
KIIIA1 5.2.1	Ziegler, H	2004	Validation of the analytical method CF-A 669: Determination of the active ingredient Pyraclostrobin in BAS 500 06 F by HPLC, 2004/1004041, GLP, unpublished	Y	BAS	1
KIIIA1 5.2.4	Stegmaier, W.	2012	Validation of an analytical method for the determination of dimethyl sulfate in BAS 500 06 F, 2011/1009064, GLP, unpublished	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	Data protection claimed	Owner	How considered in dRR *
	Rapporteur Member State: Germany	2001	Pyraclostrobin (Monograph) ASB2010-10576			Add
OECD: KIIA 4.3	Abdel-Baky, S.; Riley, M.	2000	Validation of BASF analytical method D9904, method for determination of BAS 500 F and its metabolite BF 500-3 residues in plant matrices using HPLC-UV 63770 ! 1999/5179 BVL-2298290, MET2000-275			N
OECD: KIIA 4.3	Burkey, J. D.; Huntsinger, D.	2000	Statement to: Independent method validation of BASF analytical method DD9904 entitled "Method for the determination of BAS 500F and its metabolits BF 500-3 residues om plant matrices using HPLC-UV" 2000/1003597 BVL-2298297, MET2004-747			N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD: KIIA 4.3	Jordan, J.	2000	Independent method validation of BASF analytical method D9904 entitled "Method for determination of BAS 500 F and its metabolite BF 500-3 residues in plant matrices using HPLC-UV" - Revised report for study number change and revised study completion date 63832 revised to 64058 ! 1999/5184 BVL-2298291, MET2000-276			N
OECD: KIIA 4.3	Kampke-Thiel, K.	1999	Validation of BASF method 439/0 for the determination of BAS 500 F (as parent compound) in matrices of animal origin 53018 ! 99/11079 BVL-2298294, MET2000-279			N
OECD: KIIA 4.3	Levsen, K.	1999	Independent validation of BASF method 439/0 for the determination of BAS 500 F (as parent compound) in matrices of animal origin 15 G 99015 ! 1999/11369 BVL-2298295, MET2000-280			N
OECD: KIIA 4.3	Perez, R.; Perez, S.	2000	Independent method validation of BASF method numbers D9808 (USA) and 421/0 (Germany) entitled "Method for determination of BAS 500 F and its metabolite BF 500-3 residues in plant matrices using LC/MS/MS" 63832 ! 1999/5187 BVL-2298289, MET2000-274			N
OECD: KIIA 4.3	Reinhard, K.; Mackenroth, C.	1999	Validation of BASF method no. 453/0: Determination of BAS 500 F and its metabolite BF 500-3 in matrices / fractions of the processing of barley 35513 ! 1999/11135 BVL-2298292, MET2000-277			N
OECD: KIIA 4.3	Reinhard, K.; Mackenroth, Ch.	1999	Validation of BASF method No. 421/0 (Germany) / D9808 (USA): Determination of BAS 500 F and its metabolite BF 500-3 in wheat, grape, peanut and orange matrices 35509 ! 1999/11134 ! method 421/0 BVL-2298288, MET2000-273			Y
OECD: KIIA 4.3	Tilting, N.; Lehmann, W.	2000	Validation of analytical method 446 for the determination of BAS 500 F (reg. no. 304428) in sample material of animal origin 35636 ! 1999/11075 BVL-2298296, MET2000-281			N
OECD: KIIA 4.3	Weeren, R. D.; Pelz, S.	1999	Examination of the applicability of DFG Method S 19 for the determination of BAS 500 F Az. M5894/99 ! BASF 99/10833 ! BAS-9901V BVL-2298293, MET2000-278			N
OECD: KIIA 4.3, OECD: KIIA 6.2.1	Reinhard, K.; Mackenroth, C.	1999	Extractabilitiy of 14C-BAS 500 F residues from wheat and grape matrices with aqueous methanol (according to method No. 421/0) - Report amendment no.1, 35512 ! 1999/11700 BVL-2296800, BVL-2298299, RIP2001-73			N
OECD: KIIA 4.3, OECD: KIIA 6.2.1	Reinhard, K.; Mackenroth, C.	1999	Extractabilitiy of 14C-BAS 500 F residues from wheat and grape matrices with aqueous methanol (according to method no. 421/0) 35512 ! 1999/11138 BVL-2296799, BVL-2298298, RIP2001-72			Y

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD: KIIA 4.3, OECD: KIIA 6.2.3	Ohnsorge, U.	2000	Volatility from water:300355 and air 2000/1001011 BVL-2298167, BVL-2298752, MET2001-81			N
OECD: KIIA 4.3, OECD: KIIA 6.2.3	Tilting, N.; Knoell, H.-E.	2000	14C-validation of method 446 for the determination of BAS 500 F (Reg. No. 304428) and its metabolites in matrices of animal origin 35907 ! 2000/1000001 BVL-2296805, BVL-2298300, MET2003-163			N
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Benz, A.; Mackenroth, C.	2001	Validation of BASF method no. 445/0: Determination of BAS 500 F and BF 500-3 in various plant matrices 78593 ! 2000/1012405 BVL-2291069, BVL-2298301, MET2001-278			N
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Devine, H. C.	2002	Independent laboratory validation of BASF method number D9808 (USA), 421/0 (Germany), an analytical method for the determination of residues of BAS 500 F and its metabolite BF 500-3 2002/1007082 ! CEMR-1655 ! CEMS-1655 ! method 421/0 BVL-2291067, BVL-2298302, ASB2008-4973			Y
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Devine, H. C.	2002	Independent laboratory validation of BASF method D9904, an analytical method for the determination of residues of BAS 500 F and its metabolite BF 500-3 2002/1007083 ! CEMR-1656 ! CEMS-1656 ! method D9904 BVL-2291068, BVL-2298303, ASB2008-4974			N
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Hopf, B.	2010	Validation of the analytical method L0151/01: Method for the determination of BAS 500 F (Reg. No. 304428) in animal matrices 2010/1018944 BVL-2304442, BVL-2307292, ASB2012-10307			Y
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Hopf, B.	2011	Technical procedure: Method for the determination of BAS 500 F (Reg. No. 304428) in animal matrices 2011/1018046 BVL-2304444, BVL-2307293, ASB2012-10309			N
OECD: KIIA 4.3, OECD: 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 BVL-2291070, BVL-2298678, RIP2007-463			Y
OECD: KIIA 4.3, OECD: KIIIA1 5.3.1	Schacherl, A.	2010	Independent laboratory validation (ILV) of an analytical method for the determination of BAS 500 F (Reg. No. 304428) in animal matrices 2010/1123694 BVL-2304445, BVL-2307295, ASB2012-10308			Y
OECD: KIIA 4.3, OECD: KIIIA1 5.3.2	Reinhard, K.; Mackenroth, Ch.	1999	Determination of the stability of BAS 500 F and of relevant metabolites and derivatives thereof in different solutions 35511 ! 99/11136 BVL-2291071, BVL-2298679, ASB2010-15584			N

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
OECD: KIIA 4.4	Zangmeister, W.	1999	Validation of analytical method no. 432, Determination of BAS 500 F, Reg. no. 340266, Reg. no. 369315 and Reg. no 364380 in soil. 1999/10076; 37275 BVL-2298277, MET2000-283			Y
OECD: KIIA 4.4	Ziegler, G.	1998	Validation of analytical method no. 409, Determination of BAS 500 F (parent) in soil. 35646 ! 1998/10657 BVL-2298276, MET2000-282			Y
OECD: KIIA 4.5	Staab, G.	1998	Validation of analytical method no. 415, determination of BAS 500 F (parent) in tap and leachate water 35886 ! 1998/11182 BVL-2298279, MET2000-284			N
OECD: KIIA 4.5	Zangmeister, W.	1999	Validation of analytical method 455 - Determination of BAS 500 F, BF 500-11, BF 500-12, BF 500-13, BF 500-14 and BF 500-15 residues in water (tap water and surface water) 35888 ! 1999/10701 BVL-2298282, MET2000-285			Y
OECD: KIIA 4.5	Zangmeister, W.	2000	Determination of BAS 500 F in water by HPLC/UV 2000/1000133 BVL-2298286, MET2000-286			N
OECD: KIIA 4.5, OECD: KIIIA1 5.6	Tilting, N.	2012	Validation of method L0182/01: Determination of BAS 500 F and its metabolites Reg.No. 412053 (500M59), Reg.No. 411847 (500M60), Reg.No. 412785 (500M62), Reg.No. 413038, and Reg.No. 377613 in ground- surface- and tapwater using LC-MS/MS 2012/1009641 BVL-2291072, BVL-2298680, ASB2012-10310			Y
OECD: KIIA 4.7	Zangmeister, W.	1999	Validation of analytical method 447: Determination of BAS 500 F (reg. no 304428) in air by HPLC/UV 35892 ! 1999/10694 BVL-2298283, MET2000-287			Y
OECD: KIIA 4.7	Zangmeister, W.	1999	Report amendment no.1 to validation of analytical method 447: Determination of BAS 500 F (Reg. no 304428) in air by HPLC/UV 35892 ! 1999/11104 BVL-2298287, MET2007-242			N
OECD: KIIA 4.8	Grosshans, F.; Gruetzmacher, M.	2001	Validation of BASF method 439/0: The determination of BAS 500 F in body fluids (blood) 110517 ! 2001/1009037 BVL-2298304, MET2001-276			N
OECD: KIIA 6.2.2	Hafemann, C.; Knoell, H.-E.	1999	Metabolism of (14C) BAS 500 F in laying hens BASF 99/11480 ! 35635 BVL-2296802, RIP2000-1022			Y
OECD: KIIA 6.2.3	Bross, M.; Tilting, T.	2000	Investigation of the metabolism of 14C-BAS 500 F in the goat 2000/1000004 ! 35634 BVL-2296804, RIP2000-1020			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 1.1 Analytical methods for Pyraclostrobin

A 1.1.1 Methods for enforcement of residues in food and feed of plant origin

A 1.1.1.1 Independent laboratory validation

Reference:	OECD KIII A 5.3.1
Report	Independent laboratory validation of BASF method Number D9808 (USA), 421/0 (Germany), an analytical method for the determination of residues of BAS 500 F and its metabolite BF 500-3 Devine H.C., 2002, Study No. 2002/1007082, Report No. CEMR-1655; ASB2008-4973
Guideline(s):	Yes, EEC 91/414, EEC 96/68, Guidance Document on Residue Analytical Methods (SANCO/825/00rev.6)
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Residues of pyraclostrobin are extracted from cabbage, onion, orange, hops and grain specimens with methanol/water (70/30, v/v) and then filtered. An aliquot of the extract is concentrated to dryness and then re-dissolved in methanol/water (70/30, v/v).
Rape seed is homogenized with acetonitrile followed by addition of hexane. The homogenate is filtered and the filtrate is transferred to a separating flask and shaken. The hexane layer is discarded and the acetonitrile layer is washed with hexane again. An aliquot of the acetonitrile extract is concentrated to dryness and then re-dissolved in methanol/water (70/30, v/v).
The extracts are purified by SPE on cartridges filled with Bakerbond C18-polar plus. Residues are eluted with dichloromethane. The eluates are concentrated to dryness.
For onion, orange, rape seed and hops specimens an additional cleanup stage using micro silica columns is necessary. The eluates of C18 polar plus SPE are re-dissolved in 20 % dichloromethane/hexane and transferred to SPE cartridges filled with silica for flash chromatography. Residues are eluted with 2 % ethyl acetate in dichloromethane. The eluates are concentrated to dryness.
All SPE eluates are re-dissolved in methanol/aqueous 4 mM ammonium formate/formic acid (80/20/0.02, v/v/v).
Final determination is done by LC-MS/MS using Inertsil Phenyl column and APCI ionization in positive mode: m/z 388→194. Quantification is done by standards in solvent. The method validation is also performed for the metabolite BF 500-3. Validation data for the metabolite are not reported here because the metabolite is not included in the residue definition.

Results and discussions

Table A 1: Recovery results from the independent laboratory validation of cabbage, onion, orange flesh, wheat grain, hops and rape seed using the analytical method. Standards were prepared in methanol.

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
cabbage	0.02 1.0	5 5	82 86	3.4 3.4	m/z 388→194
onion	0.02 1.0	5 5	86 88	6.3 5.0	m/z 388→194
orange flesh	0.02 1.0	4 5	74 86	4.3 8.3	m/z 388→194
wheat grain	0.02 0.5	4 5	83 90	1.5 2.6	m/z 388→194
hops	0.02 10.0	5 5	71 92	7.1 3.4	m/z 388→194
rape seed	0.02 0.5	5 5	89 84	8.9 7.2	m/z 388→194

Table A 2: Characteristics for the analytical method used for the independent laboratory validation of pyraclostrobin residues in methanol/buffer solution (99.9% 4mM ammonium formate in water and 0.1 % formic acid) (80/20, v/v)

	Pyraclostrobin m/z 388→194
Calibration function	Y = 16392.44*X+310.66, R^2=0.9998
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.5 to 5.0 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.005 to 0.05 mg/kg (without dilution)*
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes, 4 levels in duplicate
Assessment of matrix effects is presented (yes/no)	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes

* A dilution factor for the higher fortification levels is not reported.

Conclusion

The method is acceptable for the quantification of residues of pyraclostrobin according to the current residue definition in Reg. (EC) No. 396/2005. The method is successfully validated for the quantification of pyraclostrobin residues in cabbage, onion, orange flesh, wheat grain, hops and rape seed at the limit of quantification of 0.02 mg/kg. A confirmation by validation of a second MS/MS transition is not included. The study of Devine, 2002 is accepted as an independent laboratory validation of the method of Reinhard and Mackenroth, 1999 (MET2000-273).

Comments of zRMS:	Acceptable.

A 1.1.1.2 Confirmatory method

Reference: OECD KIII A 5.3.1

Report: Validation of BASF method No. 535/1 in plant matrices

Lehmann A. and Mackenroth C., 2007, Study No. 246631, Document No. BASF DocID 2006/1039427; RIP2007-463

Guideline(s): Yes, EPA 860.1340, SANCO/825/00 rev. 6 (20 June 2000), SANCO/3029/99 rev. 4 (11 July 2000), EEC 6/46, EEC 91/414 Annex III (Part A Section 5)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The plant material is extracted with methanol/water/2 N hydrochloric acid (70/25/5, v/v/v). After centrifugation, the pH of the supernatant is adjusted to >12 by addition of sodium hydroxide solution. For purification, liquid/liquid partitioning is performed into cyclohexane. The cyclohexane layer is evaporated to dryness and the residue is dissolved in methanol/water (50/50, v/v). The sample concentration in the final extract is 0.02 g/mL at LOQ respective 0.002 g/mL at >LOQ. Final determination is done by LC-MS/MS using C18 column and electrospray ionization in positive mode: m/z 388→194 and 388→163. Quantification is done by standards in solvent. The method validation is also performed for the metabolite BF 500-3. Validation data for the metabolite are not reported because the metabolite is not included in the residue definition.

Results and discussions

Table A 3: Recovery results from the confirmatory method validation of wheat (plant, grain, straw), lemon (fruit), lettuce, oilseed rape (seed), tomato (fruit) and onion (bulb) using the confirmatory method. Standards were prepared in methanol

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
wheat plant	0.01 0.1	5 5	101 86	7.7 4.8	m/z 388→194
wheat grain	0.01 0.1	5 5	95 98	4.2 5.0	m/z 388→194
wheat straw	0.01 0.1	5 5	92 86	5.0 4.8	m/z 388→194

Matrix	Fortification level (mg/kg)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
lemon fruit	0.01 0.1	5 5	97 88	7.0 6.1	m/z 388→194
lettuce	0.01 0.1	5 5	93 87	4.1 4.8	m/z 388→194
oilseed rape seed	0.01 0.1	5 5	96 90	6.4 5.6	m/z 388→194
tomato fruit	0.01 0.1	5 5	92 90	5.0 3.5	m/z 388→194
onion bulb	0.01 0.1	5 5	99 93	3.5 3.8	m/z 388→194
wheat plant	0.01 0.1	5 5	103 88	9.6 6.4	m/z 388→163
wheat grain	0.01 0.1	5 5	101 96	3.8 7.4	m/z 388→163
wheat straw	0.01 0.1	5 5	95 80	7.7 4.7	m/z 388→163
lemon fruit	0.01 0.1	5 5	97 89	4.7 5.4	m/z 388→163
lettuce	0.01 0.1	5 5	92 88	6.2 6.0	m/z 388→163
oilseed rape seed	0.01 0.1	5 5	94 91	2.4 3.3	m/z 388→163
tomato fruit	0.01 0.1	5 5	92 87	4.2 3.3	m/z 388→163
onion bulb	0.01 0.1	5 5	96 85	2.7 6.7	m/z 388→163

Table A 4: Characteristics for the confirmatory method used for the quantitation of pyraclostrobin residues in methanol/water (50/50, v/v)

	Pyraclostrobin (primary method)	Pyraclostrobin (confirmatory transition)
Calibration function	m/z 388→194 Y = 68080.6770*X-145.6775, R^2=0.9991	m/z 388→163 Y = 35173.0301*X-25.0858, R^2=0.9989
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.05 to 0.5 ng/mL	0.05 to 0.5 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0025 to 0.025 mg/kg and 0.0250 to 0.250 mg/kg*	0.0025 to 0.025 mg/kg and 0.0250 to 0.250 mg/kg*
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)?	yes, 4 levels in triplicate	yes, 4 levels in triplicate

(yes/ no)		
Assessment of matrix effects is presented (yes/no)	no	no
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

* A dilution by a factor of 10 is used for all samples > LOQ.

Conclusion

The method is acceptable for the quantification of residues of pyraclostrobin in plant matrices according to the current residue definition in Reg. (EC) No. 396/2005.
The method is successfully validated for the quantification of pyraclostrobin residues in wheat (plant, grain, straw), lemon (fruit), lettuce, oilseed rape (seed), tomato (fruit) and onion (bulb) at the limit of quantification of 0.01 mg/kg. A confirmation by validation of second MS/MS transition is included. Chromatograms (both transitions) are shown only for pyraclostrobin in tomato.

Comments of zRMS:	Acceptable.

A 1.1.2 Methods for enforcement of residues in food and feed of animal origin

A 1.1.2.1 Analytical method 1

Reference: OECD KIII A 5.3.1

Report: Validation of the analytical method L0151/01: Method for the determination of BAS 500 F (Reg. No. 304428) in animal matrices Hopf, B., 2010; Study No. 2010/1018944; ASB2012-10307

Guideline(s): Yes; SANCO/825/00 rev. 7; SANCO/3029/99 rev. 4: OPPTS 860.1340

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Residues of pyraclostrobin are extracted from sample material by homogenisation with acetonitrile. After centrifugation the sample extract is partitioned into cyclohexane under alkaline conditions (0.2 N NaOH). An aliquot of the cyclohexane layer is evaporated to dryness and reconstituted in acetonitrile/water (50/50; v/v). The sample concentration in the final extract is 0.02 g/mL at LOQ respective 0.002 g/mL at 10xLOQ. Final determination is done by LC-MS/MS using Betasil C18 column. Two MS/MS transitions are monitored after electrospray ionization in positive mode: m/z 388→194 and 388→163. Quantification is done by standards in solvent.

Results and discussions

Table A 5: Recovery results from method validation of cow meat, kidney, liver, fat, milk, skim milk, cream, hen egg and swine blood using the analytical method. Standards were prepared in acetonitrile (primary method).

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
meat	0.01 0.1	5 5	101.1 97.0	1.6 1.7	m/z 388→194
kidney	0.01 0.1	5 5	105.8 97.3	1.4 1.8	m/z 388→194
liver	0.01 0.1	5 5	98.4 96.7	4.2 2.1	m/z 388→194
fat	0.01 0.1	5 5	102.7 99.7	1.5 1.3	m/z 388→194
milk	0.01 0.1	5 5	102.7 96.1	1.8 1.4	m/z 388→194
skim milk	0.01 0.1	5 5	94.4 90.9	1.4 2.3	m/z 388→194

cream	0.01 0.1	5 5	99.3 95.5	5.0 3.8	m/z 388→194
egg	0.01 0.1	5 5	94.4 98.5	7.7 1.8	m/z 388→194
blood	0.01 0.1	5 5	81.4 76.5	3.7 1.6	m/z 388→194

Table A 6: Recovery results from method validation of cow meat, kidney, liver, fat, milk, skim milk, cream, hen egg and swine blood using the analytical method. Standards were prepared in acetonitrile (confirmatory transition).

meat	0.01 0.1	5 5	101.6 95.8	1.2 1.5	m/z 388→163
kidney	0.01 0.1	5 5	105.2 97.0	1.6 0.8	m/z 388→163
liver	0.01 0.1	5 5	99.3 95.1	4.0 1.4	m/z 388→163
fat	0.01 0.1	5 5	102.4 98.7	1.3 1.1	m/z 388→163
milk	0.01 0.1	5 5	101.1 96.4	1.6 1.6	m/z 388→163
skim milk	0.01 0.1	5 5	95.2 90.6	1.0 1.5	m/z 388→163
cream	0.01 0.1	5 5	99.8 94.9	3.5 3.1	m/z 388→163
egg	0.01 0.1	5 5	93.6 98.0	8.9 1.6	m/z 388→163
blood	0.01 0.1	5 5	81.9 77.6	3.5 2.5	m/z 388→163

Table A 7: Characteristics for the analytical method used for the quantitation of pyraclostrobin residues in acetonitrile/water (50/50, v/v)

	Pyraclostrobin (primary method)	**Pyraclostrobin (confirmatory transition)**
Calibration function	m/z 388→194 Y = 255000*X+1810, R^2=0.9994	m/z 388→163 Y = 185000*X+879, R^2=0.9995
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.025 – 1 ng/mL	0.025 – 1 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.00125 – 0.5 mg/kg	0.00125 – 0.5 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes, 6 levels in duplicate	yes, 6 levels in duplicate
Assessment of matrix effects is presented (yes/no)	no	no

Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of residues of pyraclostrobin according to the current residue definition in Reg. (EC) No. 396/2005.
The method is successfully validated for the quantification of pyraclostrobin residues in milk, meat, fat, eggs, liver, kidney at LOQ of 0.01 mg/kg and in blood at LOQ of 0.01 mg/L. A confirmation by validation of a second MS/MS transition is included.

Comments of zRMS:	Acceptable.

A 1.1.2.2 Independent laboratory validation

Reference: OECD KIII A 5.3.1

Report: Independent laboratory validation (ILV) of an analytical method for the determination of BAS 500 F (Reg. No. 304428) in animal matrices
Schacherl, A., 2010; Study No. 2010/1123694; ASB2012-10308

Guideline(s): Yes; SANCO/825/00; OECD ENV/JM/MONO (2007) 17

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

Residues of pyraclostrobin are extracted from sample material by homogenisation with acetonitrile. After centrifugation the sample extract is partitioned into cyclohexane under alkaline conditions. An aliquot of the cyclohexane layer is evaporated to dryness and reconstituted in acetonitrile/water (50/50; v/v). The sample concentration in the final extract is 0.02 g/mL at LOQ. Final determination is done by LC-MS/MS using Phenomenex Luna C18 column. Two MS/MS transitions are monitored after electrospray ionization in positive mode: m/z 388→194 and 388→163. Quantification is done by matrix-matched standards for eggs and by standards in solvent for meat, kidney, fat, milk and blood.

Results and discussions

Table A 8: Recovery results from the independent laboratory validation of meat, kidney, liver, fat, milk, egg and blood using the analytical method. Standards were prepared in matrix for eggs and in acetonitrile for the other matrices (primary method).

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
meat	0.01 0.1	5 5	70 73	2 5	m/z 388→194

kidney	0.01 0.1	5 5	71 72	6 2	m/z 388→194
fat	0.01 0.1	5 5	71 73	4 3	m/z 388→194
milk	0.01 0.1	5 5	77 82	4 2	m/z 388→194
egg	0.01 0.1	5 5	104 105	3 3	m/z 388→194
blood	0.01 0.1	5 5	71 73	4 4	m/z 388→194

Table A 9: Recovery results from the independent laboratory validation of meat, kidney, liver, fat, milk, egg and blood using the analytical method. Standards were prepared in matrix for eggs and in acetonitrile for the other matrices (confirmatory transition).

Matrix	Fortification level (mg/kg)	No of samples per fortifica-tion level	Mean recovery	RSD (%)	Comments
meat	0.01 0.1	5 5	76 72	4 3	m/z 388→163
kidney	0.01 0.1	5 5	73 73	1 2	m/z 388→163
fat	0.01 0.1	5 5	71 72	4 3	m/z 388→163
milk	0.01 0.1	5 5	77 83	3 3	m/z 388→163
egg	0.01 0.1	5 5	104 105	4 3	m/z 388→163
blood	0.01 0.1	5 5	72 73	2 5	m/z 388→163

Table A 10: Characteristics for the analytical method used for the independent laboratory validation of pyraclostrobin residues in acetonitrile/water (50/50, v/v)

	Pyraclostrobin (primary method)	Pyraclostrobin (confirmatory transition)
Calibration function	m/z 388→194 Y = 46900*X+28, R^2=0.9993	m/z 388→163 Y = 16800*X+20.8 R^2=0.9995
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.02 – 100 ng/mL	0.02 – 100 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.001 – 5 mg/kg	0.001 – 5 mg/kg
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes, 12 levels (single points)	yes, 12 levels (single points)
Assessment of matrix effects is presented (yes/no)	yes, supression 28-37 % for	yes, supression 28-37 % for

	eggs	eggs
Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is acceptable for the quantification of residues of pyraclostrobin according to the current residue definition in Reg. (EC) No. 396/2005. The method is successfully validated for the quantification of pyraclostrobin residues in milk, meat, fat, eggs, kidney at the limit of quantification of 0.01 mg/kg and in blood at a LOQ of 0.01 mg/L. A confirmation by validation of a second MS/MS transition is included. The study of Schacherl, 2010 is accepted as an independent laboratory validation of the method of Hopf, 2010.

Comments of zRMS:	Acceptable.

A 1.1.3 Description of Methods for the Analysis of Water

A 1.1.3.1 Analytical method 1

Reference: OECD KIII A 5.6

Report: Validation of method L0182/01: Determination of BAS 500 F and its metabolites Reg.No. 412053 (500M59), Reg.No. 411847 (500M60), Reg.No. 412785 (500M62), Reg.No. 413038, and Reg.No. 377613 in ground- surface- and tapwater using LC-MS/MS

Tilting, N., 2012, Document No. BASF DocID 2012/1009641, Study No. 2012/1009641; ASB2012-10310

Guideline(s): Yes (SANCO/3029/99 rev. 4 (11 July 2000), SANCO/825/00 rev. 8 (30 June 2010)

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The water samples (tap water, ground water, surface water) are acidified by addition of formic acid and and residues are enriched on a C18 SPE column. The elution is performed by ethyl acetate. The eluate is evaporated to dryness and dissolved in acetonitrile/water (2/8, v/v). The sample concentration in the final extract is 0.0083 L/mL at LOQ respective 0.00083 L/mL at 10xLOQ. Final quantification is done by LC-MS/MS using a Waters Atlantis T3 (C18) column and monitoring two MS/MS transition m/z 388→194, m/z 388→163 after electrospray ionization in positive mode. Quantification is performed by matrix-matched standards. The method validation is also performed for the metabolites 500M59, 500M60, 500M62, 500M76, and 500M78. Validation data for metabolites are not reported here because the metabolites are not included in the residue definition.

Results and discussions

Table A 11: Recovery results from method validation of tap water, ground water, surface water using the analytical method. Standards were prepared in acetonitrile (primary transition).

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
ground water	0.003 0.03	5 5	87.9 94.2	7.4 2.6	m/z 388→194
surface water	0.003 0.03	5 5	89.3 97.5	4.1 4.6	m/z 388→194
tap water	0.003 0.03	5 5	89.6 103.0	4.9 5.2	m/z 388→194

Table A 12: Recovery results from method validation of tap water, ground water, surface water using the analytical method. Standards were prepared in acetonitrile (confirmatory transition).

Matrix	Fortification level (µg/L)	No of samples per fortification level	Mean recovery	RSD (%)	Comments
ground water	0.003 0.03	5 5	92.6 99.0	7.4 5.3	m/z 388→163
surface water	0.003 0.03	5 5	93.8 100.4	6.1 2.6	m/z 388→163
tap water	0.003 0.03	5 5	92.1 104.4	3.1 9.4	m/z 388→163

Table A 13: Characteristics for the analytical method used for the quantitation of pyraclostrobin residues in water

	Pyraclostrobin (primary transition)	**Pyraclostrobin (confirmatory transition)**
Calibration function	surface water : m/z 388→194 Y = 1110000*X+1260, R^2=0.9997	surface water : m/z 388→163 Y = 609000*X+542 R^2=0.9990
Accepted calibration range in concentration units (e.g. in µg/ml or ng/µl)	0.005 – 0.1 ng/mL	0.005 – 0.1 ng/mL
Corresponding calibration range in mass ratio units for the sample (e.g.in mg/kg or µg/L)	0.0006 – 0.12 µg/L	0.0006 – 0.12 µg/L
Does the calibration consist of at least 3 levels (duplicated points) or 5 levels (single points)? (yes/ no)	yes, 6 levels in duplicate	yes, 6 levels in duplicate
Assessment of matrix effects is presented (yes/no)	yes	yes

Interference >30% of LOQ in blank sample is absent (yes/no)	yes	yes

Conclusion

The method is successfully validated for the quantification of pyraclostrobin residues in drinking water, groundwater and surface water. Type and origin of the water samples are given, but they are not characterized. The limit of quantification is 0.003 µg/L. A confirmation by validation of a second MS/MS transition is included.

Comments of zRMS:	Acceptable.

A 1.1.4 Description of Methods for the Analysis of Body Fluids and Tissues

For the detailed evaluation of the methods for the analysis of pyraclostrobin in body fluids and tissues it is referred to chapter A 2.1.2.1. The described analytical method (Hopf, B., 2010, ASB2012-10307) is acceptable for the quantification of residues of pyraclostrobin in body fluids and tissues. The method is successfully validated for the quantification of pyraclostrobin residues in meat, liver, kidney at a limit of quantification of 0.01 mg/kg and in blood at LOQ of 0.01 mg/L. A confirmation by validation of a second MS/MS transition is included.

REGISTRATION REPORT
Part B

Section 3: Mammalian Toxicology
Detailed summary of the risk assessment

Product code/name: BAS 500 06 F
Active Substance: Pyraclostrobin 200 g/L

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE
Date: 2014-10-31

Table of Contents

3 Mammalian Toxicology (IIIA 7)

3.1 Summary

Table 3.1-1: Information on BAS 500 06 F *

Product name and code	BAS 500 06 F (BAS-50006-FW-0-EC)
Formulation type	Emulsifiable concentrate
Active substance (incl. content)	Pyraclostrobin 200 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	No

* Information on the detailed composition of BAS 500 06 F 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:	Xn
Indications of danger:	Harmful
Risk phrases:	R20-22-38-43
Safety phrases:	S2-13-24-36-37-46
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use.
C&L according to Regulation (EC) No 1272/2008	
Hazard classes, categories:	Acute Tox. 4, Asp. Tox. 1, Skin Irrit. 2, Skin Sens. 1, Eye Irrit. 2
Signal word:	Danger
Hazard statements:	H302-H304-315-317-319-332
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 3.1-3: Summary of risk assessment for operators, workers, bystanders and residents for BAS 500 06 F

	Result	PPE / Risk mitigation measures
Operators	Acceptable	- Avoid any unnecessary contact with the product. Misuse can lead to health damage (SB001). - 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 (SB110). - Wear tight fitting eye protection when handling the undiluted product (SE110). - Wear tight fitting eye protection when applying/handling the product ready for application (SE120). - Wear standard protective gloves (plant protection) when handling the undiluted product (SS110). - Wear standard protective gloves (plant protection) when handling/applying the product ready for application (SS120). - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product (SS2101). - Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application (SS2202). - Wear a rubber apron when handling the undiluted product (SS610). - Wear particle-filtering half mask FFP2 or half mask with particle filter P2 (identification colour: white) according to the BVL guideline "Personal protective equipment for handling plant protection products", current version, when applying/handling the product ready for application (ST1203).
Workers	Acceptable	- Treated areas/crops may not be entered until the spray coating has dried (SF245-01).
Bystanders	Acceptable	None
Residents	Acceptable	None

The risk assessment according to the German model has shown that the estimated exposure towards pyraclostrobin in BAS 500 06 F will not exceed the particular systemic AOEL for operators, workers, bystanders and residents.

The risk assessment according to the UK-POEM has shown that the estimated exposure towards pyraclostrobin in BAS 500 06 F does exceed the particular systemic AOEL for operators even if PPE is worn (possible refinement: when minimum water application volume is set to 150 L/ha, than the exposure towards pyraclostrobin in BAS 500 06 F will not exceed the particular systemic AOEL).

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

<table>
<tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td colspan="4">8</td></tr>
<tr><td rowspan="2">Crops [1] and situation (e.g. growth stage of crop)</td><td rowspan="2">F/G or I [2]</td><td colspan="2">Application</td><td colspan="2">Application rate</td><td rowspan="2">Remarks:

(e.g. surfactant (L /ha))

critical gap for operator, worker, bystander or resident exposure based on [Exposure model]</td><td colspan="4">Acceptability of exposure assessment</td></tr>
<tr><td>Method / Kind (incl. application technique [3])</td><td>Max. number (min. interval between applications)
a) per use
b) per crop/ season</td><td>kg as/ha

a) max. rate per appl.
b) max. total rate per crop/season</td><td>Water L/ha

min / max</td><td>Operator</td><td>Worker</td><td>Bystander</td><td>Residents</td></tr>
<tr><td rowspan="2">Cereals</td><td rowspan="2">F</td><td rowspan="2">Spraying</td><td rowspan="2">a) 2
b) 2</td><td rowspan="2">a) 0.25
b) 2 x 0.25</td><td rowspan="2">100 / 400</td><td>critical gap for operator (according to the German Model), worker, bystander or resident exposure</td><td></td><td></td><td></td><td></td></tr>
<tr><td>critical gap for operator exposure based on UK-POEM</td><td></td><td></td><td></td><td></td></tr>
</table>

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

[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] e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

3.2 Toxicological Information on Active Substance

Information regarding classification of the active substance and on EU endpoints are given in Table 3.2-1.

Table 3.2-1: Information on active substance

	Pyraclostrobin
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Dir. 67/548/EEC)	Regulation (EC) No 1272/2008 (Table 3.2): T - Toxic R23 - Toxic by inhalation R38 - Irritating to the skin
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008)	Regulation (EC) No 1272/2008 (Table 3.1): Acute toxicity, cat. 3* Skin irritation, cat. 2 H315 - Causes skin irritation H331 - Toxic if inhaled*
Additional C&L proposal	none additional
Agreed EU endpoints	
AOEL systemic	0.015 mg/kg bw/d
Reference	SANCO/1420/2001-Final (2004-09-08)

3.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for BAS 500 06 F is given in Table 3.3-1. Full summaries of studies on the product are presented in Appendix 2. MSDS on BAS 500 06 F 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 500 06 F

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)	300 < LD_{50} < 2000 mg/kg bw	Yes	R22	H302	[redacted]
LD_{50} dermal, rat (OECD 402)	> 5000 mg/kg bw	Yes	None	None	[redacted]
LC_{50} inhalation, rat (OECD 403)	2.02 < LC_{50} < 4.68 mg/L air	Yes	R20	H332	[redacted]
Skin irritation, rabbit (OECD 404)	Irritant	Yes	R38	H315	[redacted]
Eye irritation, rabbit (OECD 405)	Non-irritant / Irritant	Yes	None	H319	[redacted]
Skin sensitisation, mouse (OECD 429, LLNA)	Sensitising	Yes	R43	H317	[redacted]
Skin sensitisation, guinea pig (OECD 406, M&K)	Sensitising	Yes	R43	H317	[redacted]
Supplementary studies for combinations of plant protection products	Not required				

Table 3.3-2: Additional toxicological information relevant for classification/labelling of BAS 500 06 F

	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 substance(s) (relevant for classification of product)	None			
Toxicological properties of non-active substance(s) (relevant for classification of product)	Solvent naphtha (petroleum), heavy arom. (C9-C16) (CAS 64742-94-5) (54.01 % (w/w))	Xn; R65 (≥ 10 %, kinematic viscosity < 7 mm²/s (40 °C), surface tension ≤ 33 mN/m (25 °C)) H304 (≥ 10 %, kinematic viscosity ≤ 20.5 mm²/s (40 °C)) R66 (≥ 20 %) EUH066	SDS [1)] Based on BfR aggreement acc. to TRGS 200	- [2)] H304 [2)] (R66) [3)] (EUH066) [3)]
Further toxicological information	No data – not required			

[1)] Material safety data sheet by the applicant
[2)] See phys.-chem. properties: viscosity and surface tension of the product in Part B, section 1
[3)] Dispensable since R38/H315 has been allocated to the preparation

3.4 Dermal Absorption (IIIA 7.6)

The dermal absorption of pyraclostrobin formulated in BAS 500 06 F was not evaluated as part of the EU review of the active substance. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

No in-vivo dermal penetration study was submitted with pyraclostrobin formulated in BAS 500 06 F. The dermal absorption values of pyraclostrobin are derived from an in-vitro study with the formulation BAS 500 06 F using dermatomed human skin are summarised in the following tables.

Table 3.4-1: Dermal absorption endpoints for the risk assessment of pyraclostrobin in BAS 500 06 F

	Value	Reference
Concentrate	1.6 %	[redacted], 2010 ASB2012-10289 reported in Appendix 2
Dilution (field dilution)	4.8 %	[redacted], 2010 ASB2012-10289 reported in Appendix 2

Table 3.4-2: Summary of dermal absorption studies for pyraclostrobin

Test	**Concentrate**	**Dilution II (1:200)**	**Reference**
In-vivo (rat)	-		not submitted
In vitro (rat)	-		not submitted
In vitro (human)	1.6%	4.8%	2010/1059865 [redacted] 2010 ASB2012-10289

*indicates that a study was reviewed at EU level

3.5 Exposure Assessment of Plant Protection Product

Table 3.5-1: Product information and toxicological reference values used for exposure assessment

Product name and code	BAS 500 06 F (BAS-50006-FW-0-EC)
Formulation type	Emulsifiable concentrate
Category	Fungicide / growth regulator
Container sizes, short description	150 mL, 250 mL, 500 and 1000 mL high-density polyethylene bottles and 3 L, 5 L, 10 L high-density polyethylene container
Active substance(s) (incl. content)	**Pyraclostrobin** 200 g/L
AOEL systemic	0.015 mg/kg bw/d
Inhalative absorption	100 %
Oral absorption	50 %
Dermal absorption	Concentrate: 1.6 % Dilution: 4.8 % (Dilution rate: 1:200) (based on BAS 500 06 F)

3.5.1 Selection of critical uses and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 3.1-4 (see 3.1).

3.5.2 Operator exposure (IIIA 7.3)

3.5.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance during application of BAS 500 06 F according to the critical use is presented in Table 3.5-2. Outcome of the estimation is presented in Table 3.5-3. Detailed calculations are given in Appendix 3.

Table 3.5-2: Exposure models for intended uses

Critical uses	Cereals (max. 1.25 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	Cereals (max. 1.25 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 3.5-3: Estimated operator exposure

		Pyraclostrobin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 0.25 kg a.s./ha			
German Model Body weight: 70 kg	no PPE[1)]	0.00985	65.7
	with PPE: gloves during mixing/loading	0.00714	47.6
UK POEM Application volume: 100 L/ha Container: 10 L Body weight: 60 kg	no PPE[2)]	0.10427	695.1
	with PPE: gloves during mixing/loading and during application	0.01727	115.1
UK POEM Application volume: 150 L/ha Container: 10 L Body weight: 60 kg	with PPE: gloves during mixing/loading and during application	0.01213	80.9

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

3.5.2.2 Measurement of operator exposure

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

3.5.3 Worker exposure (IIIA 7.5)

3.5.3.1 Estimation of worker exposure

Table 3.5-4 shows the exposure model used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with BAS 500 06 F according to the critical use. Outcome of the estimation is presented in Table 3.5-5. Detailed calculations are in Appendix 3.

Table 3.5-4: Exposure models for intended uses

Critical uses	Cereals (max. 2 x 1.25 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 3.5-5: Estimated worker exposure

		Pyraclostrobin	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Number of applications and application rate: 2 x 0.25 kg a.s./ha			
2 hours/day [1], TC: 1500 cm^2/person/h [2] Body weight: 60 kg DFR: 1 µg/cm^2/kg a.s. [3]	no PPE [4]	0.00120	8.0
	with PPE [5]	0.00006	0.4
2 hours/day [1], TC: 1500 cm^2/person/h [2] Body weight: 60 kg DFR: 3 µg/cm^2/kg a.s. [3]	no PPE [4]	0.00360	24.0
	with PPE [5]	0.000180	1.2

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) 1 µg/cm^2/kg a.s. acc. to Hoernicke et al. (1998); 3 µg/cm^2/kg a.s.: EUROPOEM II database (2002)
4) no PPE: Worker wearing long sleeved shirt, long trousers (“permeable”) but no gloves
5) see 'Instructions for use'

3.5.3.2 Measurement of worker exposure

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

3.5.4 Bystander and resident exposure (IIIA 7.4)

3.5.4.1 Estimation of bystander and resident exposure

Table 3.5-6 shows the exposure model used for estimation of bystander and resident exposure to pyraclostrobin. Outcome of the estimation is presented in Table 3.5-7. Detailed calculations are presented in Appendix 3.

Table 3.5-6: Exposure models for intended uses

Critical uses	Cereals (max. 2 x 1.25 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 3.5-7: Estimated bystander and resident exposure

	Pyraclostrobin	
Model data	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Tractor mounted boom spray application outdoors to low crops Application rate: 2 x 0.25 kg a.s./ha		
Bystanders (adult) Drift rate: 2.77 % (1 m) Body weight: 60 kg	0.000555	3.70
Bystanders (children) Drift rate: 2.77 % (1 m) Body weight: 16.15 kg	0.000435	2.90
Residents (adult) Drift rate: 2.38 % (1 m) Body weight: 60 kg	0.000069	0.46
Residents (children) Drift rate: 2.38 % (1 m) Body weight: 16.15 kg	0.000184	1.23

3.5.4.2 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 pyraclostrobin 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.

3.5.5 Statement on combined exposure

Not relevant. The product contains only one active substance.

Appendix 1 Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	How considered in dRR *
OECD: KIIIA1 7.1.1	[redacted]	2008	BAS 500 06 F: Acute oral toxicity study in rats 2007/1053390 ! 10A0023/061140 BVL-2291074, ASB2012-10282	Y
OECD: KIIIA1 7.1.2	[redacted]	2009	BAS 500 06 F: Acute dermal toxicity study in rats 2009/1084157 ! 11A0023/069143 BVL-2291076, ASB2012-10283	Y
OECD: KIIIA1 7.1.3	[redacted]	2010	BAS 500 06 F: Acute inhalation toxicity study in Wistar rats - 4-Hour liquid aerosol (head-nose only) 2009/1122167 ! 13I0023/067027 BVL-2291078, ASB2012-10284	Y
OECD: KIIIA1 7.1.4	[redacted]	2010	BAS 500 06 F: Acute dermal irritation / corrosion in rabbits 2009/1100358 ! 18H0023/062338 BVL-2291080, ASB2012-10285	Y
OECD: KIIIA1 7.1.5	[redacted]	2010	BAS 500 06 F: Acute eye irritation in rabbits 2009/1100359 ! 11H0023/062339 BVL-2291082, ASB2012-10286	Y
OECD: KIIIA1 7.1.6/01	[redacted]	2008	BAS 500 06 F: Murine local lymph node assay (LLNA) 2007/1053391 ! 58H0023/062279 BVL-2291084, ASB2012-10287	Y
OECD: KIIIA1 7.1.6/02	[redacted]	2009	BAS 500 06 F: Maximization test in guinea pigs 2009/1018498 ! 30H0023/062327 BVL-2291086, ASB2012-10288	Y
OECD KIIIA1 7.6.2	[redacted]	2010	14C-BAS 500 F in BAS 500 06 F: Study of penetration through human skin in vitro 2010/1059865 ! 52H0364/962182 GLP: Yes Published: No BVL-2291088, ASB2012-10289	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 Acute oral toxicity (IIIA1 7.1.1)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

Reference: 7.1.1
Report: BAS 500 06 F: Acute oral toxicity study in rats; [redacted].; 2008; BASF DocID 2007/1053390, ASB2012-10282
Guidelines: OECD 423 (2001)
Commission Regulation (EC) No 440/2008, B.1 tris.
US EPA OPPTS 870.1100
Deviations: No
GLP: Yes
Acceptability: Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Rat, Wistar , HanRcc:WIST(SPF)
No. of animals (group size)	5 x 3 females
Doses	300 mg/kg bw , 500 mg/kg bw and 2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	Doubly destilled water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of BAS 500 06 F

Dose [mg/kg bw]	**Toxicological results [1)]**	**Duration of signs**	**Time of death**	**LD_{50} [mg/kg bw] (14 days)**
Female rats				
2000	3/3/3	h 1 - h 5	h 2 – d 1	< 2000
500	0/3/3	h 1 – h 5	-	> 500
300	0/3/3	h 1 – h 4	-	> 300
Female rats				
500	2/3/3	day 1	h 2 – d 1	< 500
300	0/0/3	-	-	> 300

[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 of BAS 500 06 F

Mortality:	All animals of the 2000 mg/kg administration group were found dead on study day 1 and two

	animals of the second 500 mg/kg administration group were found dead 2 hours after application.
Clinical signs:	Yes. Clinical observations in the 2000 mg/kg administration group revealed impaired general state, dyspnoea, staggering and piloerection and were reported from 1 hour to 5 hours after administration. Clinical observations in the 500 mg/kg administration groups revealed impaired or poor general state, dyspnoea, apathy, abdominal position, atonia and piloerection and were observed from 1 hour to 5 hours after administration. Clinical observations in the first 300 mg/kg administration group revealed impaired general state, dyspnoea and piloerection and were recorded from 2 hours to 4 hours after administration.
Body weight:	The body weight of the surviving animal of the second 500 mg/kg administration group and the mean body weights of all other administration groups increased throughout the study period.
Macroscopic examination:	The following macroscopic pathologic findings were observed in the animals that died:red and black discoloration of contents of the small intestine (2000 mg/kg, 3 females); oedema in all lobes of the lung (500 mg/kg, 2 females). No macroscopic pathologic abnormalities were noted in the surviving animal of the second 500 mg/kg administration group, in all animals of the first 500 mg/kg administration group and in 5 animals of the 300 mg/kg administration groups examined on the last day of observation. One animal of the 300 mg/kg administration group showed a red/beige mass of the mammary gland with a diameter of 30 mm in the left side region, full consistency and incrusted surface. Histopathological examination revealed an adenocarcinoma in the mammary gland which is considered to be a spontaneous finding.

Conclusion

Under the experimental conditions, the oral LD_{50} of BAS 500 06 F is 300 < LD_{50} < 2000 mg/kg bw in rats. Thus, classification as Xn and R 22 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H302 according to Regulation (EC) No. 1272/2008.

A 2.2 Acute percutaneous (dermal) toxicity (IIIA1 7.1.2)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

Reference:	7.1.2
Report	BAS 500 06 F: Acute dermal toxicity study in rats; [redacted].; 2009; BASF DocID 2009/10844157, ASB2012-10283
Guidelines:	OECD 402 (1987) Commission Regulation (EC) No 440/2008, B.3 US EPA OPPTS 870.1200 Japan MAFF 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Rat, Wistar , Crl:WI (Han) SPF
No. of animals (group size)	5 rats/sex
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 of BAS 500 06 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 of BAS 500 06 F

Mortality:	No mortality occurred.
Clinical signs:	No clinical signs of toxicity were observed.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD_{50} of BAS 500 06 F is higher than 5000 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 2.3 Acute inhalation toxicity (IIIA1 7.1.3)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

Reference: 7.1.3
Report: BAS 500 06 F: Acute inhalation toxicity study in Wistar rats – 4-Hour liquid aerosol (head-nose only); [redacted].; 2010; BASF DocID 2009/1122167, ASB2012-10284

Guidelines:	OECD 403 (2009) Commission Regulation (EC) No 440/2008, B.2 US EPA OPPTS 870.1300
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Rat, Wistar , RccHan:WIST (SPF)
No. of animals (group size)	3 x 5 males and 3 x 5 females
Concentrations	1.04 mg/L air, 2.02 mg/L air, 4.68 mg/L air
Exposure	4 hours (nose only)
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]	Actual conc. [mg/L air]	MMAD [1] [µm]	GSD [2]
8.8	1.04	2.9 (m)[3], 2.8 (f) [3]	2.3 (m) [3], 2.4 (f) [3]
20.9	2.02	2.9 (m) [3], 3.3 (f) [3]	2.3 (m) [3], 2.5 (f) [3]
100.9	4.68	3.1 (m) [3], 2.9 (f) [3]	2.5 (m) [3], 2.2 (f) [3]

[1] MMAD = Mass Median Aerodynamic Diameter
[2] GSD = Geometric Standard Deviation
[3] m: male, f: female

Table A 6: Results of acute inhalation toxicity study in rats of BAS 500 06 F

Concentration [mg/L air]	Toxicological results [1]	Duration of signs	Time of death	LC_{50} [mg/L air] (14 days)
Male rats				
1.04	1/5/5	h 2 –day 14	day 0	> 1.04
2.02	0/5/5	h 1 –day 11	-	> 2.02
4.68	3/5/5	h 1 –day 9	h 4, day 1 (2 x)	< 4.68
Female rats				
1.04	0/5/5	h 2 –day 8	-	> 1.04
2.02	0/5/5	h 1 –day 5	-	> 2.02
4.68	3/5/5	h 1 –day 14	h 3, day 1 (2 x)	< 4.68

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

Table A 7: Summary of findings of acute inhalation toxicity study in rats of BAS 500 06 F

Mortality:	Yes, one female died at 1.04 mg/L air on study day 0 after exposure and L three males and three females died at 4.68 mg/ or were sacrificed in a moribund state during exposure on study day 0 or on study day 1.
Clinical signs:	Yes, Clinical signs of toxicity in animals exposed to 1.04 mg/L air comprised impaired respiration, abdominal respiration, respiration sounds, red encrusted nose and eye, semiclosed eyelid, reduced attention, hunched posture, piloerection and substance contaminated fur. Findings were observed from 2 hours after exposure to the end of the post exposure observation period. Clinical signs of toxicity in animals exposed to 2.02 mg/L air comprised impaired respiration, labored respiration, abdominal respiration, gasping, respiration sounds, red encrusted nose, reduced nutritional condition, piloerection and substance contaminated fur. Findings were observed from 1 hour after exposure to study day 11. No clinical signs of toxicity were observed from study day 12 onwards. Clinical signs of toxicity in animals exposed to 4.68 mg/L air comprised impaired respiration, labored respiration, abdominal respiration, gasping, respiration sounds, red encrusted nose and eye, semiclosed eyelid, reduced attention, hunched posture, piloerection and substance contaminated fur. Findings were observed from 1 hour after exposure to the end of the post exposure observation period.
Body weight:	The mean body weight of the surviving animals decreased at 1.04 mg/L air and at 4.68 mg/L air during the first post exposure observation week but increased during the second week. The mean body weights of the animals did not increase adequately at 2.02 mg/L air during the first post exposure observation week but increased during the second week.
Macroscopic examination:	At 1.04 mg/L air necropsy of the one male animal that died on study day 0 after exposure revealed diffuse dark-red discoloration of the dexter cranial lobe, medialis lobe and the pulmo sinister. The following gross pathological abnormality was noted in one male animal necropsy at termination of the post exposure observation period, few red foci in all lung lobes At 4.68 mg/L air necropsy of one male and one female animal that died on study day 0 during exposure showed no gross pathological abnormality. The female animal that died on study day 1 after exposure showed partly sunken surface and focal dark-red discoloration of the lung and few black erosion/ulcer in the glandular stomach. From the animals which were sacrificed in a moribund state on study day 1 two of three animals showed the following findings: one male animal: focal dark-red discoloration in the dexter cranial lobe and the pulmo sinister, one female animal: several red foci in all lobes. Both animals showed a moderate dilation of the jejunum with gaseous content, additionally. The third animal (male) showed no grosspathological abnormality. The following gross pathological abnormality was noted in one female animal necropsy at termination of the post exposure observation period, few red foci in the dexter cranial lobe and the pulmo sinister. All other animals showed no gross pathological abnormalities.

Conclusion

Under the experimental conditions, the LC_{50} of BAS 500 06 F is 2.02 < LC_{50} < 4.68 mg/L air (for both sexes) in rats. Thus, classification as Xn and R20 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H332 according to Regulation (EC) No. 1272/2008.

A 2.4 Skin irritation (IIIA1 7.1.4)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

Reference:	7.1.4
Report	BAS 500 06 F: Acute dermal irritation / corrosion in rabbits; [redacted].; 2010; BASF DocID 2009/1100358, ASB2012-10285

Guidelines:	OECD 404 (2002) Commission Regulation (EC) No 440/2008, B.4 US EPA OPPTS 870.2500 Japan MAFF 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Rabbit, New Zealand White, A 1077 INRA (SPF)
No. of animals (group size)	2 males and 1 female
Initial test using one animal	No
Exposure	0.5 mL (4 hours, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 8: Skin irritation of BAS 500 06 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 2	3 2	2 1	2 1	2.3 1.3	>14 14
2	Erythema Oedema	2 2	3 1	3 1	3 0	3.0 0.7	>14 3
3	Erythema Oedema	2 2	3 1	3 1	3 1	3.0 1.0	>14 14

1) scores in the range of 0 to 4

Clinical signs:	Additional finding in some animals: scaling.

Conclusion

Under the experimental conditions, BAS 500 06 F is a skin irritant. Thus, classification as Xi and R38 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H315 according to Regulation (EC) No. 1272/2008.

A 2.5 Eye irritation (IIIA1 7.1.5)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

Reference:	7.1.5
Report	BAS 500 06 F: Acute dermal irritation / corrosion in rabbits; [redacted].; 2010; BASF DocID 2009/1100358, ASB2012-10286

Guideline(s):	OECD 405 (2002) Commission Regulation (EC) No 440/2008, B.5 US EPA OPPTS 870.2400 Japan MAFF 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
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 in conjunctival sac)
Irrigation (time point)	Yes (24 hours after application with tap water)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 9: Eye irritation of BAS 500 06 F

Animal No.		Scores after treatment [1)]				Mean scores (24-72 h)	Reversible [day]
		1 h	24 h	48 h	72 h		
1	Corneal opacity	0	1	2	2	1.7	7
	Iritis	0	1	1	1	1.0	7
	Redness conjunctivae	2	2	3	3	2.7	14
	Chemosis conjunctivae	2	3	2	2	2.3	7
2	Corneal opacity	0	1	1	1	1.0	7
	Iritis	0	1	1	0	0.7	3
	Redness conjunctivae	2	3	2	2	2.3	7
	Chemosis conjunctivae	2	2	2	1	1.7	7
3	Corneal opacity	0	1	1	1	1.0	7
	Iritis	0	0	0	1	0.3	7
	Redness conjunctivae	2	2	2	2	2.0	7
	Chemosis conjunctivae	2	2	1	1	1.3	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 finding in some animals: pupil contracted.

Conclusion

Under the experimental conditions, BAS 500 06 F is an eye irritant. No classification is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations, but H319 is required according to Regulation (EC) No. 1272/2008.

A 2.6 Skin sensitisation (IIIA1 7.1.6)

Comments of zRMS:	Acceptable (no deviations from below mentioned test guidelines), used for evaluation.

A 2.6.1 Study 1

Reference:	7.1.6/01
Report	BAS 500 06 F Murine Local Lymph Node Assay (LLNA[redacted].; 2008; BASF DocID 2007/1053391, ASB2012-10287
Guidelines:	OECD 429 (2002) Commission Regulation (EC) No 440/2008, B.42 US EPA OPPTS 870.2600
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Mouse, CBA/J strain
No. of animals (group size)	Test substance group: 3 x 5 female mice Vehicle control goup: 5 female mice
Range finding:	Yes
Exposure (concentrations), no. of applications)	3 %, 10 % and 30 % w/w
Vehicle	Aceton
Reliability check	Alpha-Hexylcinnamaldehyde (1%, 3 %, 10%) in acetone
Remarks	None

Results and discussions

Table A 10: Results of skin sensitisation study of BAS 500 06 F

	No. of animals	Concentration [%]	DPM / group	Stimulation index (SI)
BAS 500 06 F	5	3	2839.2	6.88
	5	10	6014.6	14.58
	5	30	6643.4	16.10
Test Vehicle Control Group	5	0	412.5	1.00
Positive control		1		1.81
		3		3.24
		10		3.74

Clinical signs:	Increase in lymph node weights and increase in ear weights as an indication of ear skin irritation.

Conclusion

Under the experimental conditions, BAS500 06 F is a skin sensitiser. Despite a certain skin irritating potential, classification as Xi and R43 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H317 according to Regulation (EC) No. 1272/2008.

A 2.6.2 Study 2

Reference:	7.1.6/02
Report	BAS 500 06 F Maximization test in guinea pigs; [redacted].; 2009; BASF DocID 2009/1018498, ASB2012-10288
Guidelines:	OECD 406 (1992) Commission Regulation (EC) No 440/2008, B.6 US EPA OPPTS 870.2600 Japan MAFF 8147
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

Test material (Lot/Batch No.)	BAS 500 06 F (Batch No.: 8265)
Species	Guinea pig, Dunkin Hartley, Crl:HA
No. of animals (group size)	Test substance group: 20 female guinea pigs Vehicle control goup: 10 male guinea pigs
Range finding:	Yes
Exposure (concentrations, no. of applications)	Intradermal induction: 5 % Topical induction: 50 % First challenge: 25 % Second challenge: 10 %
Vehicle	Isotonic saline solution and deionized water
Pretreatment prior to topical application	No
Reliability check	Alpha-Hexylcinnamaldehyde, techn. 85 % (5 % in paraffin oil intradermal induction, 10 % in Lutrol® E 400 topical induction and 5 % in Lutrol® E 400 challenge)
Remarks	None

Results and discussions

Table A 11: Results of skin sensitisation study of BAS 500 06 F

	24 hours	**48 hours**
	After first challenge	
BAS 500 06 F	14/20	8/20
Test Vehicle Control Group	3/10	1/10
	Historical Control	
Positive control	10/10	10/10
Negative Control	0/5	0/5

	After second challenge	
BAS 500 06 F	5/20	7/20
Test Vehicle Control Group	0/10	0/10

1) Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	None

Conclusion

Under the experimental conditions, BAS 500 06 F is a skin sensitiser. Thus, classification as Xn and R43 is required according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations as well as H317 according to Regulation (EC) No. 1272/2008.

A 2.7 Dermal Absorption (IIIA1 7.6)

A 2.7.1 Dermal absorption, in vivo in the rat

No in vivo dermal penetration studies were submitted with pyraclostrobin formulated in BAS 500 06 F.

A 2.7.2 Comparative dermal absorption, in vitro using rat and human skin

Report:	**7.6.2/1, [redacted]., 2010a**
Title:	14C-BAS 500 F in BAS 500 06 F - Study of penetration through human skin in vitro
Document No:	BASF DocID 2010/1059865
Guidelines:	OECD Guideline for testing of chemicals No. 428 (Skin absorption: In vitro method (2004)), OECD Guidance Document No. 28 for the conduct of skin absorption studies (March 2004)
GLP	Yes
BfR study number	ASB2012-10289

Materials and methods

^{14}C BAS 500 F (Pyraclostrobin; Batch 579-2301, Radiochemical purity 99.4%, Specific activity 4.38 MBq/mg), and the organic solvent based EC formulation BAS 500 06 F (Batch 8265, active ingredient content: 202.7 g/L) was used to prepare a homogenously labelled radioactive BAS 500 06 F formulation concentrate by spiking appropriate amounts of radioactive BAS 500 F to the non-radioactive formulation. The 1:200 spray dilution was prepared accordingly by mixing appropriate amounts of the formulation concentrate with radioactive BAS 500 F and adding tap water up to the final volume.
The penetration of BAS 500 F formulated as BAS 500 06 F through human skin was determined using a modified Franz cell under static conditions equipped with dermatomed human skin at a thickness of 390-420 µm. Skin from 2 donors were used in this study. Each 5 cells for the formulation concentrate and the 1:200 dilution were loaded with 10 µl of dosing solutions (treated skin area: 1 cm²). The test was performed under semiocclusive conditions. In order to guarantee sufficient solubility of the BAS 500 F in

the receptor fluid, ethanol/(tap) water (1+1; v+v) for the concentrate and ethanol/tap water (2+8; v+v) for the spray dilution were used as receptor medium. After 6 hours the surface was washed twice using approx. 250 µL Texapon® N70 diluted 1:140 (w/w) in highly deionized (HD) water and once with 250 µL pure water. The skin was then wiped dry using cotton swabs. Thereafter the semiocclusive cover of the cells was renewed and the penetration experiment continued for another 18 hours.

Samples of the receptor fluid were withdrawn 0.5, 1, 2, 4, 6, 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. 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 (first 2 tapes and the remaining 4 tapes) for analysis. The remaining skin and the tape strips were analyzed separately.

Results and discussions

Table A 12: In-vitro dermal penetration of BAS 500 F formulated as BAS 500 06 F through human skin - Recovery data

Dose group	**High dose[b] (Formulation concentrate)**		**Low dose (Spray dilution 1:200)**	
Application volume [µL/cm²]	10		10	
Target dose [µg/cm²]	2000		10.0	
Mean actual applied dose [µg/cm²]	2002		10.8	
	[µg]	[%]	[µg]	[%]
Unabsorbed dose[a]				
Tape strip (1st pool, strips 1 -2)	2.61	0.13	0.024	0.22
Donor chamber	107.0	5.35	0.240	2.24
Skin washing after 6 hours	1695	84.6	6.03	56.0
Skin washing after 24 hours	170.6	8.62	3.82	35.5
Sum unabsorbed[#]	**1975.21**	**98.7**	**10.11**	**93.96**
Absorbed dose[a]				
Tape strips (2nd pool; strips 3 - 6)	2.77	0.14	0.040	0.37
Skin preparation	25.44	1.28	0.300	2.79
Sum receptor samples incl. wash out	0.305	0.02	0.024	0.22
Receptor fluid	3.68	0.18	0.086	0.80
Receptor chamber wash	0.393	0.02	0.063	0.59
Sum absorbed[#]	**32.588**	**1.64**	**0.513**	**4.77**
Total recovery[#]	**2008**	**100.3**	**10.6**	**98.7**

[#] values may not calculate exactly due to rounding of figures
[a] Grouping is different than in the report: The radioactivity in the second tape-strip pool (3rd to 6th tape strip) as well as the skin preparation is considered potentially absorbable.
[b] Results of one cell not used for calculation due to aberrant test substance recovery in the 1st skin washe

- After 24 h solubility in ethanol/water (1+1, v+v) was 2.71 g/L and in ethanol/water (2+8, v+v) 0.0082 g/L.
- The mean total and individual recovery was in the range of 98.7 to 100.3% [see Table 7.6.2-1] and 96.5 to 103.1%, respectively.
- As indicated in Table 7.6.2-1 the majority of dose was recovered at the 6 and 24 hour skin washes (91.5 to 93.2%).

- At the high dose (formulation concentrate) 1.64% of the applied dose either penetrated the human skin or was considered potentially bioavailable (remaining skin). Substantial amounts of radioactivity penetrated only after the 6 hour skin wash. Thus the the determined absorption rate / flux of 0.140 µg/cm²·h reflects the artificial washing-in conditions after the removal of the majority of the formulation deposited on the skin at the 6-hour skin wash.
- At the 1:200 spray dilution 4.77% of the applied dose either penetrated the human skin or was considered potentially bioavailable (remaining skin). The absorption rate / flux was determined to be 0.007 µg/cm²·h.
- Absorption lag times were 8.6 hours or 1.8 hours for the high or low dose and demonstrate the presence of a functional barrier in the skin samples used.

Table A 13: In-vitro dermal penetration of BAS 500 F formulated as BAS 500 06 F through human skin - Penetration kinetics

Dose group	**High dose* (Formulation concentrate)**		**Low dose[c] (Spray dilution 1:200)**	
Application volume [µL/cm²]	10		10	
Target dose [µg/cm²]	2000		10.0	
Mean actual applied dose [µg/cm²]	2002		10.8	
	Mean cumulative absorption		Mean cumulative absorption	
	[µg]	[%]	[µg]	[%]
Sample time [h]				
0.5	0.000	0.00	0.000	0.00
1	0.000	0.00	0.000	0.00
2	0.000	0.00	0.002	0.02
4	0.000	0.00	0.016	0.15
6	0.000	0.00	0.025	0.23
10	0.174	0.01	0.042	0.39
24	2.13	0.11	0.073	0.68
Kp [$*10^{-5}$ cm/h]	0.069		0.662	
Absorption rate [µg/cm²·h]	0.140		0.007	
Lag time [h]	8.6		1.8	

[a] assuming a density of 1 g/ml
* Results of one cell not used for calculation due to aberrant test substance recovery in the 1st skin wash

Conclusion / endpoint

A very slow to slow penetration of BAS 500 F (pyraclostrobin) formulated as BAS 500 06 F through human dermatomed skin was observed in-vitro. The amount of applied dose penetrating within 24 hours was determined to be 1.64% for the formulation concentrate and 4.77% for the 1:200 aqueous spray dilution, respectively.

Study Comments: 7.6.2/1	The summary prepared by the applicant adequately represents the study conduct and study results as given in the study report. Some parts in the summary were clarified. The study is considered acceptable. The amount found in the receptor fluid/chamber, skin preparation and tape strips 3-6 are considered as absorbed (1.64 % or 4.77 % for the concentrate or the dilution, respectively). The results were rounded.
Agreed endpoint: 7.6.2/1	Under the study conditions, the dermal absorption rate was 1.6 % for the concentrate and 4.8 % for the dilution.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (IIIA1 7.3.1)

A 3.1.1 Calculations for pyraclostrobin

Table A 14: Input parameters considered for the estimation of operator exposure

Formulation type:	EC		**Application technique:**	Field Crop Tractor Mounted (FCTM)	
Application rate (AR):	0.25	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):	1.6	% (concentr.)	**Dermal hands appl. ($D_{A(H)}$):**	0.38	mg/person/kg a.s.
	4.8	% (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	0.015	mg/kg bw/d	**Inhalation appl. (I_A):**	0.001	mg/person/kg a.s.

Table A 15: Estimation of operator exposure towards pyraclostrobin using the German model

Without PPE			**With PPE**		
Operators: Systemic dermal exposure after application in					
Dermal exposure during mixing/loading					
Hands			Hands		
$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times DA) / BW$			$SDE_{OM(H)} = (D_{M(H)} \times AR \times A \times PPE^{1)} \times DA) / BW$		
(2.4 x 0.25 x 20 x 1.6%) / 70			(2.4 x 0.25 x 20 x 0.01 x 1.6%) / 70		
External dermal exposure	12	mg/person	External dermal exposure	0.12	mg/person
External dermal exposure	0.171429	mg/kg bw/d	External dermal exposure	0.001714	mg/kg bw/d
Systemic dermal exposure	**0.002743**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000027**	**mg/kg bw/d**
Dermal exposure during application					
Hands			Hands		
$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times DA) / BW$			$SDE_{OA(H)} = (D_{A(H)} \times AR \times A \times PPE \times DA) / BW$		
(0.38 x 0.25 x 20 x 4.8%) / 70			(0.38 x 0.25 x 20 x 1 x 4.8%) / 70		
External dermal exposure	1.9	mg/person	External dermal exposure	1.9	mg/person
External dermal exposure	0.027143	mg/kg bw/d	External dermal exposure	0.027143	mg/kg bw/d
Systemic dermal exposure	**0.001303**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.001303**	**mg/kg bw/d**
Body			Body		
$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times DA) / BW$			$SDE_{OA(B)} = (D_{A(B)} \times AR \times A \times PPE \times DA) / BW$		
(1.6 x 0.25 x 20 x 4.8%) / 70			(1.6 x 0.25 x 20 x 1 x 4.8%) / 70		
External dermal exposure	8	mg/person	External dermal exposure	8	mg/person
External dermal exposure	0.114286	mg/kg bw/d	External dermal exposure	0.114286	mg/kg bw/d
Systemic dermal exposure	**0.005486**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.005486**	**mg/kg bw/d**
Head			Head		
$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times DA) / BW$			$SDE_{OA(C)} = (D_{A(C)} \times AR \times A \times PPE \times DA) / BW$		
(0.06 x 0.25 x 20 x 4.8%) / 70			(0.06 x 0.25 x 20 x 1 x 4.8%) / 70		
External dermal exposure	0.3	mg/person	External dermal exposure	0.3	mg/person
External dermal exposure	0.004286	mg/kg bw/d	External dermal exposure	0.004286	mg/kg bw/d
Systemic dermal exposure	**0.000206**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000206**	**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	22.2	mg/person	Total external dermal exposure	10.32	mg/person
Total external dermal exposure	0.317143	mg/kg bw/d	Total external dermal exposure	0.147429	mg/kg bw/d
Total systemic dermal exposure	0.009737	mg/kg bw/d	Total systemic dermal exposure	0.007022	mg/kg bw/d
Operators: Systemic inhalation exposure after application in					
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 0.25 x 20 x 100%) / 70			(0.0006 x 0.25 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.003	mg/person	External inhalation exposure	0.003	mg/person
External inhalation exposure	0.000043	mg/kg bw/d	External inhalation exposure	0.000043	mg/kg bw/d
Systemic inhalation exposure	**0.000043**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000043**	**mg/kg bw/d**
<u>Inhalation exposure during application</u>					
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 0.25 x 20 x 100%) / 70			(0.001 x 0.25 x 20 x 1 x 100%) / 70		
External inhalation exposure	0.005	mg/person	External inhalation exposure	0.005	mg/person
External inhalation exposure	0.000071	mg/kg bw/d	External inhalation exposure	0.000071	mg/kg bw/d
Systemic inhalation exposure	**0.000071**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000071**	**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	0.008	mg/person	Total external inhalation exposure	0.008	mg/person
Total external inhalation exposure	0.000114	mg/kg bw/d	Total external inhalation exposure	0.000114	mg/kg bw/d
Total systemic inhalation exposure	**0.000114**	**mg/kg bw/d**	**Total systemic inhalation exposure**	**0.000114**	**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	0.6896	mg/person	Total systemic exposure	0.49952	mg/person
Total systemic exposure	**0.009851**	**mg/kg bw/d**	**Total systemic exposure**	**0.007136**	**mg/kg bw/d**
% of AOEL	**65.7**	**%**	**% of AOEL**	**47.6**	**%**

[1)] reduction factor for gloves is 0.01 (professional appl.)

Table A 16: Estimation of operator exposure towards pyraclostrobin using the UK-POEM (without PPE)

Active substance	**Pyraclostrobin**			
Product	BAS 500 06 F			
Formulation type	organic solvent-based			
Concentration of a.s.	200	mg/mL		
Dose	1,25	L preparation/ha	(0,25 kg a.s./ha)	
Application volume	100	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	1,6	%		
Dermal absorption from spray	4,8	%		
EXPOSURE DURING MIXING AND LOADING				
Container size	10	Litres		
Hand contamination/operation	0,05	mL		
Application dose	1,25	Litres product/ha		
Work rate	50	ha/day		
Number of operations	7	/day		
Hand contamination	0,3500	mL/day		
Protective clothing	None			
Transmission to skin	100	%		
Dermal exposure to formulation	0,3500	mL/day		
DERMAL EXPOSURE DURING SPRAY APPLICATION				
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	100	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		41,5500	mL/day			
ABSORBED DERMAL DOSE						
		Mix/load			Application	
Dermal exposure		0,3500	mL/day		41,5500	mL/day
Concen. of a.s. product or spray		200,0000	mg/mL		2,5000	mg/mL
Dermal exposure to a.s.		70,0000	mg/day		103,8750	mg/day
Percent absorbed	1,6		%	4,8		%
Absorbed dose		1,1200	mg/day		4,9860	mg/day
INHALATION EXPOSURE DURING SPRAYING						
Inhalation exposure		0,01	mL/h			
Duration of exposure		6	h			
Concentration of a.s. in spray		2,5000	mg/mL			
Inhalation exposure to a.s.		0,1500	mg/day			
Percent absorbed		100	%			
Absorbed dose		0,1500	mg/day			
PREDICTED EXPOSURE						
Total absorbed dose		6,2560	mg/day			
Operator body weight		60	kg			
Operator exposure		0,1043	mg/kg bw/day			
Amount of AOEL		695,1	%			

Table A 17: **Estimation of operator exposure towards pyraclostrobin using the UK-POEM (with PPE: gloves during mixing/loading and during application)**

Active substance	**Pyraclostrobin**		
Product	BAS 500 06 F		
Formulation type	organic solvent-based		
Concentration of a.s.	200	mg/mL	
Dose	1,25	L preparation/ha	(0,25 kg a.s./ha)
Application volume	100	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	1,6	%	
Dermal absorption from spray	4,8	%	
EXPOSURE DURING MIXING AND LOADING			
Container size	10	Litres	
Hand contamination/operation	0,05	mL	
Application dose	1,25	Litres product/ha	
Work rate	50	ha/day	
Number of operations	7	/day	
Hand contamination	0,3500	mL/day	
Protective clothing	Gloves		
Transmission to skin	10	%	
Dermal exposure to formulation	0,0350	mL/day	
DERMAL EXPOSURE DURING SPRAY APPLICATION			
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles		

Application volume		100	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		6,4500	mL/day		
ABSORBED DERMAL DOSE					
		Mix/load		Application	
Dermal exposure		0,0350	mL/day	6,4500	mL/day
Concen. of a.s. product or spray		200,0000	mg/mL	2,5000	mg/mL
Dermal exposure to a.s.		7,0000	mg/day	16,1250	mg/day
Percent absorbed	1,6		%	4,8	%
Absorbed dose		0,1120	mg/day	0,7740	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure		0,01	mL/h		
Duration of exposure		6	h		
Concentration of a.s. in spray		2,5000	mg/mL		
Inhalation exposure to a.s.		0,1500	mg/day		
Percent absorbed		100	%		
Absorbed dose		0,1500	mg/day		
PREDICTED EXPOSURE					
Total absorbed dose		1,0360	mg/day		
Operator body weight		60	kg		
Operator exposure		0,0173	mg/kg bw/day		
Amount of AOEL		115,1	%		

Table A 18: Estimation of operator exposure towards pyraclostrobin using the UK-POEM (with PPE: gloves during mixing/loading and during application and application volume of 150 L/ha)

Active substance	**Pyraclostrobin**		
Product	BAS 500 06 F		
Formulation type	organic solvent-based		
Concentration of a.s.		200	mg/mL
Dose		1,25	L preparation/ha (0,25 kg a.s./ha)
Application volume		150	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	1,6		%
Dermal absorption from spray	4,8		%
EXPOSURE DURING MIXING AND LOADING			
Container size		10	Litres
Hand contamination/operation		0,05	mL
Application dose		1,25	Litres product/ha
Work rate		50	ha/day
Number of operations		7	/day
Hand contamination		0,3500	mL/day
Protective clothing		Gloves	
Transmission to skin		10	%

Dermal exposure to formulation	0,0350	mL/day			
DERMAL EXPOSURE DURING SPRAY APPLICATION					
Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Application volume	150	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	6,4500	mL/day			
ABSORBED DERMAL DOSE					
	Mix/load			Application	
Dermal exposure	0,0350	mL/day		6,4500	mL/day
Concen. of a.s. product or spray	200,0000	mg/mL		1,6667	mg/mL
Dermal exposure to a.s.	7,0000	mg/day		10,7500	mg/day
Percent absorbed	1,6	%	4,8		%
Absorbed dose	0,1120	mg/day		0,5160	mg/day
INHALATION EXPOSURE DURING SPRAYING					
Inhalation exposure	0,01	mL/h			
Duration of exposure	6	h			
Concentration of a.s. in spray	1,6667	mg/mL			
Inhalation exposure to a.s.	0,1000	mg/day			
Percent absorbed	100	%			
Absorbed dose	0,1000	mg/day			
PREDICTED EXPOSURE					
Total absorbed dose	0,7280	mg/day			
Operator body weight	60	kg			
Operator exposure	0,0121	mg/kg bw/day			
Amount of AOEL	80,9	%			

A 3.2 Worker exposure calculations (IIIA1 7.5.1)

A 3.2.1 Calculations for pyraclostrobin

Table A 19: Input parameters considered for the estimation of worker exposure

Intended use(s):	Various cereals		**Dislodgeable foliar residues (DFR):**	1	µg/cm²/kg a.s.
Application rate (AR):	0.25	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):	4.8	% ('worst case')			
AOEL	0.015	mg/kg bw/d			

Table A 20: Estimation of worker exposure towards pyraclostrobin using the German re-entry model (DFR: 1 µg/cm²/kg a.s.)

Without PPE [1)]			**With PPE [2)]**		
Worker (re-entry): Systemic dermal exposure after application in Various 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 0.25 x 2 x 4.8%) / 60			(1 x 1500 x 2 x 0.25 x 2 x 5% x 4.8%) / 60		
External dermal exposure	1.5	mg/person	External dermal exposure	0.075	mg/person
External dermal exposure	0.025	mg/kg bw/d	External dermal exposure	0.00125	mg/kg bw/d
Total systemic exposure	0.072	mg/person	Total systemic exposure	0.0036	mg/person
Total systemic exposure	**0.00120**	**mg/kg bw/d**	**Total systemic exposure**	**0.00006**	**mg/kg bw/d**
% of AOEL	**8.0**	**%**	**% of AOEL**	**0.4**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)
2) see 'Instructions for use'

Table A 21: Input parameters considered for the estimation of worker exposure

Intended use(s):	Various cereals		**Dislodgeable foliar residues (DFR):**	3	µg/cm²/kg a.s.
Application rate (AR):	0.25	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):	4.8	% ('worst case')			
AOEL	0.015	mg/kg bw/d			

Table A 22: Estimation of worker exposure towards pyraclostrobin using the German re-entry model (DFR: 3 µg/cm²/kg a.s.)

Without PPE [1)]			**With PPE [2)]**		
Worker (re-entry): Systemic dermal exposure after application in Various 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		
(3 x 1500 x 2 x 0.25 x 2 x 4.8%) / 60			(3 x 1500 x 2 x 0.25 x 2 x 5% x 4.8%) / 60		
External dermal exposure	4.5	mg/person	External dermal exposure	0.225	mg/person
External dermal exposure	0.075	mg/kg bw/d	External dermal exposure	0.00375	mg/kg bw/d
Total systemic exposure	0.216	mg/person	Total systemic exposure	0.0108	mg/person
Total systemic exposure	**0.0036**	**mg/kg bw/d**	**Total systemic exposure**	**0.00018**	**mg/kg bw/d**
% of AOEL	**24.0**	**%**	**% of AOEL**	**1.2**	**%**

1) acceptable without PPE: Worker wearing long sleeved shirt, long trousers ("permeable") but no gloves (allocation of BVL code SF245-01 for spray applications)
2) see 'Instructions for use'

A 3.3 Bystander and resident exposure calculations (IIIA1 7.4.1)

A 3.3.1 Calculations for pyraclostrobin

Table A 23: Input parameters considered for the estimation of bystander exposure

Intended uses:	Various cereals		**Drift (D):**	2.77	% (FC, 1 m)
Application rate (AR):	0.25	kg a.s./ha	**Exposed body surface area (BSA):**	1	m² (adults)
	25	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):	4.8	% ('worst case')	**Area Treated (A):**	20	ha/d (based on FCTM)
Inhalation absorption (IA):	100	%			
AOEL:	0.015	mg/kg bw/d	**Exposure duration (T):**	5	min

Table A 24: Estimation of bystander exposure towards pyraclostrobin

Adults			**Children**		
Bystander: Systemic dermal exposure during/after application in various cereals (via spray drift)					
SDE$_B$ = (AR x D x BSA x DA) / BW			SDE$_B$ = (AR x D x BSA x DA) / BW		
(25 x 2.77% x 1 x 4.8%) / 60			(25 x 2.77% x 0.21 x 4.8%) / 16.15		
External dermal exposure	0.6925	mg/person	External dermal exposure	0.145425	mg/person
External dermal exposure	0.011542	mg/kg bw/d	External dermal exposure	0.009005	mg/kg bw/d
Systemic dermal exposure	**0.000554**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000432**	**mg/kg bw/d**
Bystander: Systemic inhalation exposure during/after application in various 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 0.25 x 20 x 5 x 100%) / 60			(0.000575 / 360 x 0.25 x 20 x 5 x 100%) / 16.15		
External inhalation exposure	0.000069	mg/person	External inhalation exposure	0.00004	mg/person
External inhalation exposure	0.000001	mg/kg bw/d	External inhalation exposure	0.000002	mg/kg bw/d
Systemic inhalation exposure	**0.000001**	**mg/kg bw/d**	**Systemic inhalation exposure**	**0.000002**	**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	0.033309	mg/person	Total systemic exposure	0.00702	mg/person
Total systemic exposure	**0.000555**	**mg/kg bw/d**	**Total systemic exposure**	**0.000435**	**mg/kg bw/d**
% of AOEL	**3.7**	**%**	**% of AOEL**	**2.9**	**%**

Table A 25: Input parameters considered for the estimation of resident exposure

Intended use(s):	Various cereals		**Drift (D):**	2.38	% (FC, 1 m)
Application rate (AR):	0.25	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm²/h (adults)
	0.0025	mg/cm²		2600	cm²/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/m³
Dermal absorption (DA):	4.8	% ('worst case')	**Inhalation Rate (IR):**	16.57	m³/d (adults)
Inhalation absorption (IA):	100	%		8.31	m³/d (children)
Oral absorption (OA):	50	%	**Saliva Extraction Factor (SE):**	50	%
AOEL:	0.015	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm²
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm²/d

Table A 26: Estimation of resident exposure towards pyraclostrobin

Adults			**Children**		
Residents: Systemic dermal exposure after application in various 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		
(0.0025 x 2 x 2.38% x 5% x 7300 x 2 x 4.8%) / 60			(0.0025 x 2 x 2.38% x 5% x 2600 x 2 x 4.8%) / 16.15		
External dermal exposure	0.08687	mg/person	External dermal exposure	0.03094	mg/person
External dermal exposure	0.001448	mg/kg bw/d	External dermal exposure	0.001916	mg/kg bw/d
Systemic dermal exposure	**0.000069**	**mg/kg bw/d**	**Systemic dermal exposure**	**0.000092**	**mg/kg bw/d**
Residents: Systemic inhalation exposure after application in various 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		
			(0.0025 x 2 x % x 5% x 50% x 20 x 20 x 2 x 50%) / 16.15		
			External oral exposure	0.00238	mg/person
			External oral exposure	0.000147	mg/kg bw/d
			Systemic oral exposure	**0.000074**	**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		
			(0.0025 x 2 x % x 20% x 25 x 50%) / 16.15		
			External oral exposure	0.000595	mg/person
			External oral exposure	0.000037	mg/kg bw/d
			Systemic oral exposure	**0.000018**	**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	0.00417	mg/person	Total systemic exposure	0.002973	mg/person
Total systemic exposure	**0.000069**	**mg/kg bw/d**	**Total systemic exposure**	**0.000184**	**mg/kg bw/d**
% of AOEL	**0.46**	**%**	**% of AOEL**	**1.23**	**%**

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 500 06 F

Active Substance: 200 g/L Pyraclostrobin

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE

Finalized: 2014-10-31

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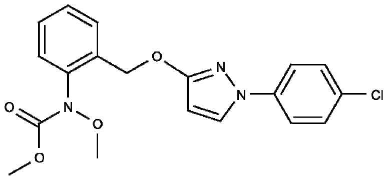
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

4.1.1 Pyraclostrobin

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Pyraclostrobin
CAS number	175013-18-0

4.1.1.1 Storage stability

A brief summary of the storage stability data on pyraclostrobin is given in the following table. Data has been previously evaluated at EU level and is described in detail in the DAR (DE 2001, ASB2010-10576) and in EFSA's Reasoned Opinion on the review of the existing maximum residue levels for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (ASB2012-16035).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of pyraclostrobin, BF 500-3 and BF 500-10 (animal matrices only)	Storage stability of pyraclostrobin and its metabolite BF 500-3 was investigated in peanut matrices (oil, nutmeat), wheat matrices (grain, straw), sugar beet tops and roots, tomatoes and grape juice (interim reports RIP2000-2043 and RIP2000-1074, final report ASB2008-4987). Residues of pyraclostrobin and BF 500-3 were stable over a period of 19 (peanut nutmeat and oil) or 25 months (other commodities). Pyraclostrobin residues were stable in bovine liver, muscle and milk for at least 240 days when stored at <-18°C (interim report RIP2000-1077; final report RIP2000-2042). Losses of the metabolite B500-10 (2-hydroxy-phenyl metabolite), which was used as a model for hydroxylated metabolites, were 29% (liver), 12% (muscle) and 36% (milk) after that period.

4.1.1.2 Metabolism in plants and plant residue definitions

A brief summary of the metabolism of pyraclostrobin in plants is given in the following table. Data has been previously evaluated at EU level and is described in detail in the DAR (ASB2010-10576) and in EFSA's Reasoned Opinion on the review of the existing maximum residue levels for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (ASB2012-16035).

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	Grapes (fruit, RIP2000-1050, RIP2000-1275), wheat (cereals, RIP2000-1009) and potatoes (root and tuber vegetables, RIP2000-1051, RIP2000-1041), all as foliar application with [tolyl-U-^{14}C]-and [chlorophenyl-U-^{14}C]-pyraclostrobin The relevant residue in grapes consisted of parent pyraclostrobin (56–66% TRR) and its desmethoxy metabolite BF 500-3 (11–15 % TRR). Pyraclostrobin was also the main component in forage and potato tubers in the chlorophenyl study, amounting to 55 % and 29 % of the TRR, respectively. In forage, metabolite BF 500-3 was identified at a level of 20 % TRR in both studies. In the tolyl study the major component of the residue in potato tubers was the natural amino acid L-tryptophan (29% TRR). In cereal grain, residues ranged from 0.098 mg/kg (chlorophenyl label) to 0.441 mg/kg (tolyl label). The cereal matrix with highest residues was wheat straw, amounting to 40 mg/kg in both studies. The major component of residues in straw and grain in the chlorophenyl study was parent pyraclostrobin and its metabolite BF 500-3. In the tolyl study the major component in grain was L-tryptophan (23 % TRR). All other metabolites were clearly below 10 % TRR.
Rotational crops	Treatment of bare soil with [tolyl-U-^{14}C] and [chloro-phenyl-U-^{14}C] pyraclostrobin at an application rate of 0.9 kg as/ha, planting of rotational crops lettuce (leafy vegeta-bles), wheat (cereals) and radish (root and tuber vegeta-bles) after PBIs of 30, 120 and 365 days (RIP2000-1085) TRR in edible parts of succeeding crops were very low for all PBIs: radish roots, lettuce ≤0.04 mg/kg and wheat grain ≤0.089 mg/kg. After a PBI of 30 days, TRR was highest in wheat straw: 0.11 mg/kg (both labels). In all crop samples the residue levels decreased with longer PBI except for lettuce where residue levels remained the same throughout various plant back intervals. No accumulation of parent compound or its metabolites was observed. No metabolites were found in significant amounts in addition to those already found in primary crop metabolism studies.
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	yes
Distribution of the residue in peel/ pulp	No information
Processed commodities (nature of residue)	Pyraclostrobin is stable under standard conditions representing pasteurisation, baking, brewing, boiling and sterilisation (RIP2000-1078).
Residue pattern in raw and processed commodities similar? (yes/no)	yes
Plant residue definition for monitoring	Pyraclostrobin This is in line with Reg. (EC) No. 396/2005.
Plant residue definition for risk assessment	Pyraclostrobin
Conversion factor(s) (monitoring to risk assessment)	none

4.1.1.3 Metabolism in livestock and animal residue definitions

A brief summary of the metabolism of pyraclostrobin in livestock is given in the following table. Data has been previously evaluated at EU level and is described in detail in the DAR (ASB2010-10576) and in EFSA's Reasoned Opinion on the review of the existing maximum residue levels for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (ASB2012-16035).

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 (RIP2000-1018, RIP2000-1020): tolyl and chlorophenyl label, 12 and 50 mg/kg feed DM, 5 days Pyraclostrobin was extensively metabolised, with the majority of the administered radioactivity being excreted via the faeces. 0.1–0.5 % of the applied dose was recovered in milk. No accumulation of pyraclostrobin was seen in tissues. Pyraclostrobin was present in all tissues and in milk and was the main residue component in muscle and in fat. Metabolites are formed (mainly in liver and kidney) by oxidation of the aromatic rings to several hydroxylated compounds and by cleavage of the molecule which led to further metabolites. As these transformations occurred in matrices with small amounts of parent or little extractability, it was suggested to apply a total residue method to obtain residue data representting reasonable worst case estimates for risk assessment. Laying hens (RIP2000-1021, RIP2000-1022): tolyl and chlorophenyl label, 12 and 13 mg/kg feed DM, 7 days Only 0.05 and 0.19 % of the applied dose were recovered in eggs and poultry tissues. Residues were low in all matrices. The parent compound was found in fat and eggs but not in liver. BF 500-3 was also present in fat and eggs (main residue; 30–40 % of the extractable residue in fat). The main metabolite in liver was the glucuronic acid conjugate which was bound to the tolyl ring of the demethoxylated parent structure.
Time needed to reach a plateau concentration in milk and eggs	Milk: 7 days Eggs: not concluded
Animal residue definition for monitoring	Pyraclostrobin This is in line with Reg. (EC) No. 396/2005.
Animal residue definition for risk assessment	Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin (see ASB2012-16035).
Conversion factor(s) (monitoring to risk assessment)	Ruminant liver: 4 Other commodities: 1
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	Yes (log $P_{O/W}$ = 3.9)

4.1.1.4 Residues in rotational crops

No respective studies are available. This is commented on in the following table.

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	No data available. From the outcome of a confined study, no significant residues of parent compound or its metabolites are expected to occur in rotational crops.

4.1.1.5 Residues in livestock

An actual calculation of the dietary burden (based on all relevant uses authorized in the EU according to EFSA, 2011, ASB2012-16035) is provided in Table 4.1-6. The silage residue is not obtained from EFSA's RO. It was obtained from a later application procedure of a pyraclostrobin-containing product on maize (evaluated in DE).

Table 4.1-6: Calculation of the dietary burden (based on all relevant uses authorized 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
Cabbage	14	5	–	–	–	0.090 [a]	0.032	–	–	–
Sugar Beet leaves and tops	16	–	–	–	25	0.180 [b]	–	–	–	0.281
Silage	20	–	80	–	–	0.160 [c]	–	0.640	–	–
Fruit Pomace	23	–	–	30	–	0.490 [d]	–	–	0.639	–
Grains except Maize	86	70	–	–	–	0.070 [e]	0.057	–	–	–
Bran (Wheat and Rye)	89	–	–	–	15	0.160 [f]	–	–	–	0.027
Straw (Cereals)	86	–	20	50	–	6.920 [g]	–	1.609	4.023	–
Sugar and Fodder Beet	20	20	–	20	60	0.110 [h]	0.110	–	0.110	0.330
Oil seed	86	5	–	–	–	0.070 [i]	0.004	–	–	–
Intake (mg/kg dry weight feed)							**0.203**	**2.249**	**4.772**	**0.638**
Intake (mg/kg bw/d)							**0.013**	**0.082**	**0.205**	**0.026**
Intake (mg/animal/d)							**0.024**	**44.986**	**71.586**	**1.915**

[a] HR, based on the following cGAP: 3x 0.07 kg as/ha, PHI: 14 d (EFSA, 2011, ASB2012-16035)
[b] HR, based on the following cGAP: 2x 0.13 kg as/ha, PHI: 28 d (EFSA, 2011, ASB2012-16035)
[c] HR, based on the following cGAP: 1x 0.2 kg as/ha, PHI: 28 d
[d] STMR, based on the following cGAP: 4x 0.28 kg as/ha, PHI: 14 d (EFSA, 2011, ASB2012-16035)
[e] STMR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 35 d (EFSA, 2011, ASB2012-16035)
[f] STMR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 35 d, PF 8 (EFSA, 2011, ASB2012-16035)
[g] HR, based on the following cGAP: 2x 0.25 kg as/ha, PHI: 35 d (EFSA, 2011, ASB2012-16035)
[h] HR, based on the following cGAP: 4x 0.22 kg as/ha, PHI: 7 d (EFSA, 2011, ASB2012-16035)
[i] STMR, based on the following cGAP: 2x 0.22 kg as/ha, PHI: 21 d, PF 2 (EFSA, 2011, ASB2012-16035)

Table 4.1-7: Conditions of requirement of livestock feeding studies on pyraclostrobin

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	yes 2.2 (dairy) 4.8 (beef)	yes 0.2	yes 0.6
Potential for accumulation (yes/no):	yes	no	yes
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	yes	no	see ruminant

A brief summary of the available livestock feeding study is given in the following table. Data has been previously evaluated at EU level and is described in detail in the DAR (ASB2010-10576) and in EFSA's Reasoned Opinion on the review of the existing MRLs for pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 (ASB2012-16035).

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	Dairy cattle: 7, 21, 70 (RIP2000-1075, RIP2000-1076)	No data; metabolism studies indicate residues <0.01 mg/kg in edible tissues	see ruminant
Relevant dosing levels in feeding study:	7	--	7
	Expected residue levels in animal matrices (mg/kg), parent only/total residue:		
Muscle	<0.05/<0.1	<0.01	<0.05/<0.1
Liver	<0.05/0.20	<0.01	<0.05/0.20
Kidney	<0.05/<0.1	<0.01	<0.05/<0.1
Fat	<0.05/<0.1	<0.01	<0.05/<0.1
Milk	<0.01/<0.02	–	–
Eggs	–	<0.01	–

4.2 Evaluation of the intended uses

4.2.1 Selection of critical use and justification

The GAPs for wheat, rye, barley and triticale used for consumer intake and risk assessment are presented in Table 4.2-1.

Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
					Application			**Application rate**				
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)**	**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 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**	**PHI (days) (i)**	**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)**
1	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL, UK, IE	wheat (spring, winter, durum, spelt)	F	brown leaf rust of cereals, *Puccinia recondite*	spraying	from spring, BBCH 25-69	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
2	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL, UK, IE	wheat (spring, winter, durum, spelt)	F	stripe rust of grasses, *Puccinia striiformis, P. triticana*	spraying	from spring, BBCH 25-61 (BE, LU, NL, CZ, SK, SI, UK, IE: BBCH 25-69)	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
3	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL	wheat (spring, winter, durum, spelt)	F	tan spot of cereals, *Drechslera (Pyrenophora) tritici-repentis*	spraying	from spring, BBCH 25-61 (BE, LU, NL, CZ, SK, SI: BBCH 25-69)	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
4	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL, UK, IE	barley (spring, winter)	F	net blotch, *Pyrenophora teres, P. triticana, P. striiformis, P. teres*	spraying	from spring, BBCH 25-61 (AT, BE, LU, NL; CZ, SK, SI, UK, IE: BBCH 25-69)	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
5	DE, AT,BE, LU, NL, CZ, SK,	barley (spring, winter)	F	leaf blotch of cereals, *Rhynchosporium secalis*	spraying	from spring, BBCH 25-61 (AT, BE, LU, NL, CZ, SK, SI, UK, IE:	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	

1	2	3	4	5	6	7	8	9	10	11	12	13
					Application			**Application rate**				
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)**	**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 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**	**PHI (days) (i)**	**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (j)**
	SI; RO, HU, PL, UK, IE					BBCH 25-69)						
6	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL	barley (spring, winter)	F	brown rust of barley, *Puccinia hordei*	spraying	from spring, BBCH 25-61 (AT, BE, LU, NL, CZ, SK, SI: BBCH 25-69)	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
7	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL	barley (spring, winter)	F	decrease of non-parasitic leaf spots	spraying	from spring, BBCH 25-61 (AT, BE, LU, NL,CZ , SK, SI: BBCH 25-69)	a) 1 b) 2	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
8	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL, IE	rye	F	leaf blotch of cereals, *Rhynchosporium secalis, P. triticina, Puccinia striiformis*	spraying	from spring, BBCH 25-61 (AT, BE, LU, NL , CZ, SK, SI, IE: BBCH 25-69)	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
9	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL	rye	F	brown leaf rust of cereals, *Puccinia recondite*	spraying	from spring, BBCH 25-69	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	

1	2	3	4	5	6	7	8	9	10	11	12	13
					Application			**Application rate**				
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)**	**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 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**	**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
10	DE, AT,BE, LU, NL, CZ, SK, SI; RO, HU, PL, IE	triticale	F	brown leaf rust of cereals, *Puccinia recondite, P. triticina, Puccinia striiformis*	spraying	from spring, BBCH 25-69	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	35	
11	BE, LU, UK, IE	oats	F	brown leaf rust of cereals, *Puccinia recondite, P. coronata*	spraying	from spring, BBCH 25-69	a) 2 b) 2 (21 days)	a) 1.25 b) 2.5	a) 0.25 b) 0.50	100 / 400	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) 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 (incl. durum, spelt), barley, rye, triticale, oats

4.2.2.1 Residues in primary crops

The following table summarizes the results of the supervised residue trials selected for the assessment of pyraclostrobin in wheat (incl. durum, spelt). The data may also serve for evaluating residues resulting from the GAPs on triticale and rye according to Guidance Document SANCO 7525/VI/95-rev. 9.
The data have already been evaluated at EU level for the critical GAP of 2 applications of 0.233 kg as/ha (last treatment at BBCH 69, PHI 35 days). This is comparable to the intended uses. The EU evaluation is described in more detail in the DAR (ASB2010-10576).

Table 4.2-2: Overview of the selected supervised residue trials for pyraclostrobin in wheat

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	Median CF (d)
			Enforcement (pyraclostrobin)	Risk assessment (pyraclostrobin)			
wheat grain	NEU	Outdoor	7 x <0.02; 0.03; 0.04; 0.04	7 x <0.02; 0.03; 0.04; 0.04	0.02	0.04	1
wheat straw	NEU	Outdoor	0.87; 1.10; 1.19; 1.31; 1.96; 2.23; 2.34; 2.50; 3.14	0.87; 1.10; 1.19; 1.31; 1.96; 2.23; 2.34; 2.50; 3.14	1.96	3.14	1

(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.

The results of storage stability experiments reported in the DAR show that residues of pyraclostrobin (BAS 500 F) and its metabolite BF 500-3 are stable in cereal grain and straw under storage conditions of -20°C over a period of 25 months.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant for wheat commodities.

4.2.2.3 Residues in processed commodities

Processing studies on wheat have been previously evaluated at EU level and are described in the DAR (ASB2010-10576).

4.2.2.4 Proposed pre-harvest intervals, withholding periods

The suggested PHI of 35 days is deemed appropriate.

4.2.3 Barley

The following table summarizes the results of the supervised residue trials selected for the assessment of pyraclostrobin in barley. The data may also serve for evaluating residues resulting from the GAPs on oats according to Guidance Document SANCO 7525/VI/95-rev. 9.
The data has already been evaluated at EU level for the critical GAP of 2 applications of 0.233 kg as/ha (last treatment at BBCH 69, PHI 35 days). This is comparable to the intended uses. The EU evaluation is described in more detail in the DAR (ASB2010-10576).

Table 4.2-3: Overview of the selected supervised residue trials for pyraclostrobin in wheat

Commodity	Region (a)	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	Median CF (d)
			Enforcement (pyraclostrobin)	Risk assessment (pyraclostrobin)			
barley grain	NEU	Outdoor	2 x <0.02, 0.03; 3 x 0.04; 0.05; 2 x 0.07; 0.09; 0.29	2 x <0.02, 0.03; 3 x 0.04; 0.05; 2 x 0.07; 0.09; 0.29	0.04	0.29	1
barley straw	NEU	Outdoor	0.78; 0.78; 0.82; 1.72; 1.81; 2.15; 2.23; 2.77; 3.83; 4.38; 5.68	0.78; 0.78; 0.82; 1.72; 1.81; 2.15; 2.23; 2.77; 3.83; 4.38; 5.68	2.15	5.68	1

(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.

The results of storage stability experiments reported in the DAR show that residues of pyraclostrobin (BAS 500 F) and its metabolite BF 500-3 are stable in cereal grain and straw under storage conditions of -20°C over a period of 25 months.

4.2.3.1 Distribution of the residue in peel/pulp

Not relevant for barley commodities.

4.2.3.2 Residues in processed commodities

Processing studies on barley have been previously evaluated at EU level and are described in the DAR (ASB2010-10576).

4.2.3.3 Proposed pre-harvest intervals, withholding periods

The suggested PHI of 35 days is deemed appropriate.

4.3 Consumer intake and risk assessment

The consumer intake and risk assessment is based on the appropriate input values given in Table 4.3-1 and the toxicological reference values stated in Table 4.3-2. Detailed calculation results are presented in 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
wheat grain	0.2	MRL	0.02	STMR
rye grain	0.2	MRL	0.02	STMR
barley grain	1	MRL	0.04	STMR
oat grain	1	MRL	0.04	STMR
All other commodities	various	MRL	--	not calculated

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.03 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	77 % (based on DE children, aged 2-4 years, mean body weight)
NTMDI (% ADI) according to NVS II	83 % (based on DE children, aged 2-4 years, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo	not performed
NEDI (% ADI) according to NVS II	not performed
Factors included in IEDI and NEDI	not applicable
ARfD	0.03 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo	Wheat: 1 % (based on UK children, 4-6 years) Rye: <1 % (based on UK infants) Barley: 1 % (based on NL adults) Oats: <1 % (based on DE children, 2-4 years)
NESTI (% ARfD) according to NVS II	Wheat: 1 % (based on DE children, 2-4 years) Rye: <1 % (based on DE children, 2-4 years, and DE general population) Barley: 1 % (based on DE general population) Oat, bran: 1 % (based on DE children, 2-4 years)
Factors included in IESTI and NESTI	none

4.4 Proposed maximum residue levels (MRLs)

The MRLs of 1 mg/kg and 0.2 mg/kg presently being established in EU residue legislation (Commission Reg. (EU) No 51/2014) for pyraclostrobin in barley/oats and wheat/spelt/triticale/rye, respectively, are sufficient. No new MRLs are required to cover residues from the intended uses.

4.5 Conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of pyraclostrobin as laid down in EU Commission Reg. (EU) No 51/2014 for barley, oats, wheat (including spelt, triticale) and rye grain is not expected.

Based on the consumption figures contained in EFSA PRIMo and NVS II, the chronic and the short-term intake of pyraclostrobin residues in barley, wheat (including triticale) and rye grain is unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended uses.

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*
	Germany	2001	pyraclostrobin (Monograph) ASB2010-10576			Add
	EFSA	2011	Reasoned opinion - Review of the existing maximum residue levels (MRLs) for Pyraclostrobin according to Article 12 of Regulation (EC) No 396/2005 EFSA Journal 2011;9(8):2344 ! EFSA-Q-2008-620 ASB2012-16035			Add
KIIA 6.1.1	Abdel-Baky, S.	2000	Storage stability of BAS 500 F and BF 500-3 in various plant matrices including processed commodities for up to 19 months of frozen storage 2000/5248 ! 90001419 GLP: Yes Published: No BVL-2296789, RIP2000-2043	Yes	BAS	Y
KIIA 6.1.1	Abdel-Baky, S.; Riley M. E.	1999	Freezer storage stability of BAS 500 F and BF 500-3 in various plant matrices including processed commodities 1999/5064 ! 90001419 GLP: Yes Published: No BVL-2296792, RIP2000-1074	Yes	BAS	Y
KIIA 6.1.1	Tilting, N.	2000	Investigation of the stability of residues of BAS 500 F (Reg. No. 304428) in sample materials of animal origin under usual storage conditions 2000/1017116 ! 35913 GLP: Yes Published: No BVL-2296790, RIP2000-2042	Yes	BAS	Y
KIIA 6.1.1	Tilting, N.; Knoell, H.-E.	2000	Investigation of the stability of residues of BAS 500 F (Reg. No. 304428) in sample materials of animal origin under usual storage conditions 2000/1000002 ! 35913 GLP: Yes Published: No BVL-2296791, RIP2000-1077	Yes	BAS	Y
KIIA 6.1.1, KIIIA1 8.1.1	Abdel-Baky, S.	2001	Freezer storage stability of BAS 500 F and BF 500-3 in plant matrices including processed commodities 2001/5000232 ! 66414 GLP: Yes Published: No BVL-2291089, BVL-2296793, ASB2008-4987	Yes	BAS	Y
KIIA 6.2.1	Bross, M.; Mackenroth, C.	1999	The metabolism of 14C-BAS 500 F (14C-Reg.No.304428) in potato 1999/11419 ! 35751 GLP: Yes Published: No BVL-2296796, RIP2000-1051	Yes	BAS	Y
KIIA 6.2.1	Bross, M.; Mackenroth, C.	2000	The metabolism of 14C-BAS 500 F (14C-Reg.No. 304428) in potato - Report amendment no. 1 2000/1000048 ! 35751 GLP: Yes Published: No BVL-2296797, RIP2000-1041	Yes	BAS	Y
KIIA 6.2.1	Hamm, R. T.	1998	Metabolism of BAS 500 F in grapes BASF 98/10988 ! 35507 GLP: Yes Published: No BVL-2296794, RIP2000-1050	Yes	BAS	Y

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 6.2.1	Hamm, R. T.	2000	Metabolism of BAS 500 F in grapes - Report amendment no. 1 BASF 2000/1000201 ! 35507 GLP: Yes Published: No BVL-2296795, RIP2000-1275	Yes	BAS	Y
KIIA 6.2.1	Reinhard, K.	1999	Metabolism of 14C-BAS 500 F in wheat 1999/11137 ! 38203 GLP: Yes Published: No BVL-2296798, RIP2000-1009	Yes	BAS	Y
KIIA 6.2.2	[redacted]	1999	Metabolism of (14C) BAS 500 F in laying hens BASF 99/11480 ! 35635 GLP: Yes Published: No BVL-2296802, RIP2000-1022	Yes	BAS	Y
KIIA 6.2.2	[redacted]	1998	14C-BAS 500 F - Study of the absorption, distribution and excretion after repeated oral administration to laying hens BASF 98/10637 ! 1b104 GLP: Yes Published: No BVL-2296801, RIP2000-1021	Yes	BAS	Y
KIIA 6.2.3	[redacted]	2000	Investigation of the metabolism of 14C-BAS 500 F in the goat 2000/1000004 ! 35634 GLP: Yes Published: No BVL-2296804, RIP2000-1020	Yes	BAS	Y
KIIA 6.2.3	[redacted]	1998	14C-BAS 500 F - Absorbtion, distribution and excretion after repeated oral adminstration in lactating goats BASF 98/10636 ! 1b0094 GLP: Yes Published: No BVL-2296803, RIP2000-1018	Yes	BAS	Y
KIIA 6.4.2	[redacted]	1999	Feeding study with BAS 500 F (Reg. no. 304428) in lactating dairy cows 1999/11895 ! V99.037 ! 806 GLP: Yes Published: No BVL-2296817, RIP2000-1075	Yes	BAS	Y
KIIA 6.4.2	[redacted]	2000	Investigation of residues of BAS 500 F (Reg. No. 304428) in tissues and milk of dairy cows 2000/1000003 ! 35639 GLP: Yes Published: No BVL-2296818, RIP2000-1076	Yes	BAS	Y
KIIA 6.5.1	Scharf, J.	1998	Hydrolysis of BAS 500 F at 90°C, 100°C, and 120°C BASF 98/10840 ! 42127 GLP: Yes Published: No BVL-2296819, RIP2000-1078	Yes	BAS	Y
KIIA 6.6.2	Veit, P.	2000	Confined rotational crop study with 14C-BAS 500 F 1999/11829 ! 35510 GLP: Yes Published: No BVL-2296827, RIP2000-1085	Yes	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

No further studies submitted/needed.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Pyraclostrobin (F)

Status of the active substance:		Code no.	1013
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,03**
Source of ADI:	**EU Comm.**	Source of ARfD:	**EU Comm.**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

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
10 77

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 ADI)
77,0	DE child	25,4	Oranges	21,2	Pome fruit	4,2	Table grapes	
59,9	NL child	20,8	Oranges	11,3	Pome fruit	3,2	Wheat	
55,6	WHO Cluster diet B	11,9	Wine grapes	5,7	Wheat	5,7	Oranges	
49,4	IE adult	8,3	Wine grapes	7,0	Oranges	4,1	Barley	
46,2	UK Toddler	15,2	Sugar beet (root)	13,2	Oranges	3,1	Pome fruit	
45,9	FR all population	26,7	Wine grapes	6,3	Other lettuce and other salad plants	2,2	Wheat	
37,7	FR toddler	13,3	Oranges	4,8	Pome fruit	4,1	Carrots	
35,2	WHO cluster diet E	10,7	Wine grapes	3,0	Oranges	2,7	Barley	
33,8	PT General population	16,6	Wine grapes	4,1	Oranges	2,6	Wheat	
31,6	ES child	14,4	Oranges	3,0	Wheat	2,8	Lettuce	
31,4	UK Infant	8,7	Oranges	6,7	Sugar beet (root)	3,0	Pome fruit	
29,2	NL general	9,9	Oranges	4,2	Wine grapes	2,3	Pome fruit	
27,7	WHO Cluster diet F	5,8	Oranges	4,0	Wine grapes	2,4	Wheat	
26,9	ES adult	8,6	Oranges	3,6	Lettuce	2,8	Wine grapes	
26,7	DK child	5,0	Pome fruit	3,7	Wheat	2,9	Rye	
26,4	WHO cluster diet D	4,3	Wheat	2,5	Onions	2,4	Wine grapes	
24,7	SE general population 90th percentile	5,0	Oranges	2,4	Pome fruit	2,3	Onions	
24,5	FR infant	6,1	Oranges	4,7	Pome fruit	4,4	Carrots	
24,5	WHO regional European diet	3,3	Oranges	2,5	Lettuce	2,2	Onions	
23,4	UK vegetarian	5,8	Oranges	5,4	Wine grapes	2,5	Sugar beet (root)	
23,3	IT kids/toddler	4,4	Wheat	3,7	Other lettuce and other salad plants	3,2	Oranges	
22,1	IT adult	5,3	Other lettuce and other salad	2,8	Wheat	2,5	Lettuce	
20,9	UK Adult	7,2	Wine grapes	3,7	Oranges	2,7	Sugar beet (root)	
19,0	DK adult	9,3	Wine grapes	1,7	Pome fruit	1,3	Wheat	
17,2	FI adult	6,5	Oranges	2,0	Wine grapes	0,8	Currants (red, black and white)	
12,0	PL general population	3,9	Pome fruit	1,6	Onions	1,1	Table grapes	
9,9	LT adult	3,4	Pome fruit	0,7	Rye	0,7	Wheat	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Pyraclostrobin (F) 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 500 06 F**
Active Substance(s): **Pyraclostrobin 200 g/L**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: **BASF**
Date: **2014-10-31**

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 BAS 500 06 F containing the active substance pyraclostrobin in its intended uses in cereals according to Appendix 3.

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 500 06 F

Code	BAS 500 06 F
plant protection product	-
applicant	BASF
date of application	09.05.2012
Formulation type (WP, EC, SC, …; density)	EC
active substance	Pyraclostrobin
Concentration of as	200 g L^{-1}

5.2 Proposed use pattern

The critical GAP used for exposure assessment is presented in Table 5.2-1. It has been selected from the individual GAPs in the zone for cereals (winter and spring wheat, winter and spring barley, rye, oat). A list of all intended uses within the zone is given in Appendix 3.

Table 5.2-1: Critical use pattern of BAS 500 06 F

Group / use No	Crop/ growth stage (BBCH)	Application method, Drift scenario	Number of applications	Minimum application interval	Application rate, cumulative (g as/ha)	Interception (%)	Soil effective application rate (g as/ha)
A/ 00-001 to 00-010	Cereals (winter and spring) 25-69	Spray	2 x	21 d	2 x 250 = 500	2 x 50[1]	2 x 125 = 250

[1] applicant proposed to use interception values of 1 x 50% and 1 x 70 % in the risk assessment, zRMS decided to use 2 x 50% (as a more conservetive assumption)

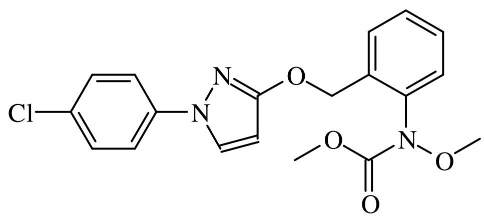
5.3 Information on the active substances

5.3.1 Pyraclostrobin

5.3.1.1 Identity, further information of pyraclostrobin

Table 5.3-1: Identity, further information on pyraclostrobin

Active substance (ISO common name)	pyraclostrobin

IUPAC	Methyl-N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl] oxymethyl} phenyl) N methoxy carbamate
Function (e.g. fungicide)	Fungicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01.06.2004
Conditions of approval	Only uses as fungicide or plant growth regulator may be authorised. Me mber States should pay particular attention to - the protection of aquatic organisms, especially fish, - the protection of terrestrial arthropods and earthwor ms, Risk mitigation measures should be applied where appro-priate.
Confirmatory data	-
RMS	Germany
Minimum purity of the active substance as manufactured (g/kg)	975
Molecular formula	$C_{19}H_{18}ClN_3O_4$
Molecular mass	387.82
Structural formula	

5.3.1.2 Physical and chemical properties of pyraclostrobin

Physical and chemical properties of pyraclostrobin as agreed at EU level (see SANCO/1420/2001–08/09/2004) and considered relevant for the exposure assessment are listed in Table 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of pyraclostrobin relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	2.6×10^{-8}	SANCO/1420/2001– 08/09/2004
Henry's law constant (Pa × m³ × mol⁻¹)	5.307×10^{-6}	SANCO/1420/2001– 08/09/2004
Solubility in water (at 25 °C in mg/L)	1.9 ± 0.17 (20°C, deionized H_2O, pH 5.8)	SANCO/1420/2001– 08/09/2004
Partition co-efficient (at 25 °), log Pow	3.99 (20°C, purity 99.8%)	SANCO/1420/2001– 08/09/2004
Dissociation constant, pKa	not applicable: no indication of dissociation in water	SANCO/1420/2001– 08/09/2004

Hydrolytic degradation	pH 7: stable	SANCO/1420/2001– 08/09/2004
Photolytic degradation	DT_{50} = 1.7 d (12h-days, April)	SANCO/1420/2001– 08/09/2004
Quantum yield of direct phototransformation in water > 290 nm	Φ = 2.17 x 10-1	SANCO/1420/2001– 08/09/2004
Photochemical oxidative degradation in air (calculation according to Atkinson)	DT_{50} = 0.155 d (AOP version: 1.91, 1.5×10^6 radicals/cm³, 12 h day)	SANCO/1420/2001– 08/09/2004

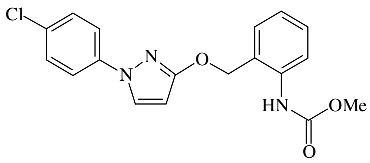
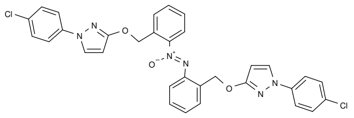
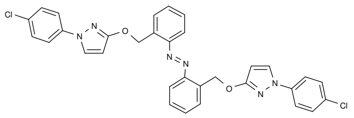
5.3.1.3 Metabolites of pyraclostrobin

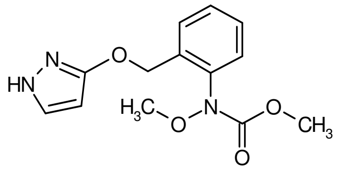
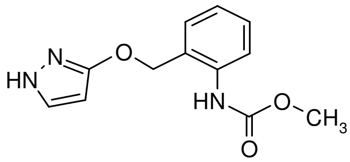
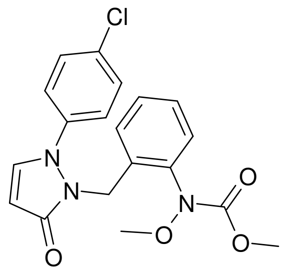
Environmental occurring metabolites of pyraclostrobin requiring further assessment according to the results of the assessment of pyraclostrobin for EU approval are summarized in

Table 5.3-3.

No new study on the fate and behaviour of pyraclostrobin or BAS 500 06 F has been performed. Hence no potentially new metabolites need to be considered.

Table 5.3-3: Metabolites of pyraclostrobin 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)

Metabolit	Structural formula/ Molecular formula	Molecular weight (g mol^{-1})	occurence in compartements (Max. at day)	Status of Relevance (SANCO/1420/2001– 08/09/2004)
BF 500-3 (500M07)	 $C_{19}H_{18}ClN_3O_4$	357.80	Sediment: Max. 66 % at day 14	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: : not applicable Groundwater: not relevant (Step 2)[1)]
BF 500-6 (500M01)	 $C_{32}H_{24}Cl_2N_6O_3$	611.5	Soil: Max. 30.9 % at day 120 Sediment: 2 x > 5%	Aquatic organisms: Water: not applicable Sediment: not relevant Terrestrial organisms: : not relevant Groundwater: not relevant (Step 1)[1)]
BF 500-7 (500M02)		595.49	Soil: Max 12.5 % at day 62	Aquatic organisms: Water: not relevant Sediment: not applicable

	$C_{32}H_{24}Cl_2N_6O_2$			Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]
BF 500-11 (500M60)	 $C_{13}H_{15}N_3O_4$	277.28	Water: Max. 16.3%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]
BF 500-13 (500M62)	 $C_{12}H_{13}N_3O_3$	247.26	Water: Max. 15.7%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]
BF 500-14 (500M76)	 $C_{19}H_{18}ClN_3O_4$	387.82	Water: Max. 11.4%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]

[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 Inputparameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Pyraclostrobin

No new studies have been submitted regarding route and rate of degradation in soil of pyraclostrobin and its metabolites BF 500-6 and BF 500-7. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory as summarized in Table 5.4-1 to Table 5.4-3.

Table 5.4-1: Summary of aerobic degradation rates for pyraclostrobin - laboratory studies

Soil type	pH	T (°C)	Moisture (% MWHC)	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa		Kinetic, Fit	Reference
Bruch West, loamy sand (tolyl-label)	7.3	20	40	12	143	8.1	8.7[1]	1st order, n.a.	Ebert (1999) / Monograph (2001)
Bruch West, loamy sand (chlorophenyl-label)	7.5	20	40	14	152	9.4		1st order, n.a.	Ebert (1999) / Monograph (2001)
Lufa 2.2, loamy sand	5.4	20	40	101	n.a.	77.6		1st order, n.a.	Ebert (1999) / Monograph (2001)
Li 35 b, loamy sand	6.5	20	40	50	163	38.4		1st order, n.a.	Ebert (1999) / Monograph (2001)
US 771-15, loamy sand	5.6	20	40	38	n.a	29.2		1st order, n.a.	Ebert (1999) / Monograph (2001)
Canada, loam	7.7	20	40	85	n.a.	52.0		1st order, n.a.	Ebert (1999) / Monograph (2001)
Aggregated DT_{50} (n=6)	**Coefficient of variation (%)**					63			
	Geometric mean (d)					33.0			

[1] – geometric mean
n.a. – not available

Table 5.4-2: Summary of aerobic degradation rates for metabolite BF 500-6 - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa		Kinetic, Fit	Reference
Bruch West, loamy sand (tolyl-label)	7.3	20	40	129 / 428	n.a.	86.8	98.5[1]	1st order, n.a.	Ebert (1999) / Monograph (2001)
Bruch West, loamy sand (chlorophenyl-label)	7.5	20	40	166 / 552	n.a.	111.7		1st order, n.a.	Ebert (1999) / Monograph (2001)
Lufa 2.2, loamy sand	5.4	20	40	131/ n.a.	n.a.	100.6		1st order, r2=0.98	Ebert (1999) / Monograph (2001)
US 771-15, loamy sand	5.6	20	40	70/ 231	n.a.	53.8		1st order, r2=0.98	Ebert (1999) / Monograph (2001)
Aggregated DT_{50} (n=3)		**Coefficient of variation (%)**				31			

	Geomean (d)	81.1	

[1] – geometric mean
n.a. = not available

Table 5.4-3: Summary of aerobic degradation rates for metabolite BF 500-7 - laboratory studies

Soil type	pH	T (°C)	Moisture	DT_{50}/ DT_{90} (d)	f.f.	DT_{50} (d) 20 °C pF2/10kPa		Kinetic, Fit	Reference
Bruch West, loamy sand (tolyl-label)	7.3	20	40	112/ 372	n.a.	75.4	89.8[1]	1st order, n.a.	Ebert (1999) / Monograph (2001)
Bruch West, loamy sand (chlorophenyl-label)	7.5	20	40	159/ 529	n.a.	107		1st order, n.a.	Ebert (1999) / Monograph (2001)
US 771-15, loamy sand	5.6	20	40	38/ 129	n.a.	29.2		1st order, r2=0.98	Ebert (1999) / Monograph (2001)
Aggregated DT_{50} (n=2)	**Coefficient of variation (%)**					72			
	Geomean (d)					51.2			
	Maximum (d)					89.8			

[1] – geometric mean
n.a. = not available

5.4.1.2 Field studies

Pyraclostrobin

The field dissipation rates of pyraclostrobin and its metabolites BF 500-6 and BF 500-7 were evaluated during EU assessment. No additional studies have been performed.

The field dissipation studies with pyraclostrobin are discussed in detail in the monograph 12945/ECCO/BBA/01 and the addendum 16316/EPCO/BVL/04 of the EU review where the study references can be found. A brief summary of the studies together with re-calculated and/or normalized dissipation DT_{50} values is given

However, a new study for normalisation of the degradation rates against a reference temperature of 20°C and a soil moisture at pF2 as needed for current European environmental exposure assessment was submitted that has not been previously reviewed. The study is described and evaluated in detail in Appendix 2 (Horn, 2006). Besides, the applicant calculated new DT_{50} and DT_{90} values after kinetic evaluation for two field studies (Manzanilla, Alcala del Rio) with biphasic degradation behavior (a detailed summary is documented in Appendix 2). The recalculated or normalized DT_{50} values for pyraclostrobin are summarized in Table 5.4-4.

The relevant endpoints concerning degradation of pyraclostrobin and its metabolites in soil used for exposure assessment are presented in the respective PEC-chapter.

Table 5.4-4: Field degradation studies of pyraclostrobin

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Fit, Kinetic Parameters	DT_{50} (d) 20 °C, pF2	Reference

Germany, Großharrie, loamy sand	6.2	0-10	25	83	$r^2 = 0.997$, 1st order	26.5[2]	Kellner and Zangmeister, (1999a), Horn (2006)
Germany, Bad Sassendorf Lohne, loamy silt	6.8	0-10	37	122	$r^2 = 0.999$, 1st order	12.5[2]	Kellner and Zangmeister, (1999a), Horn (2006)
Germany, Meckenheim, loamy sand	5.6	0-10	26	85	$r^2 = 0.91$, 1st order	15.5[2]	Kellner and Zangmeister, (1999a), Horn (2006)
Spain, Manzanilla, sandy loam/loamy sand	7.6	0-10	*6.92*[1] 7.99[1]	*153.77*[1] 136.26[1]	*$chi^2 = 8.38$*[1], *FOMC*[1] $chi^2 = 6.582$, DFOP[1]	-	Kellner and Zangmeister (1999)
Spain, Alcala del Rio , sandy loam	7.6	0-10	*3.78*[1] 1.25[1]	*698.55*[1] 253.34[1]	*$chi^2 = 14.60$*, *FOMC*[1] $chi^2 = 7.78$, DFOP[1]	-	Kellner and Zangmeister (1999)
Sweden, Bjärred,loamy sand	5.8	0-10	31[1]	103[1]	$r^2 = 0.92$, 1st order	20.6[2]	Kellner and Zangmeister (1999) Horn (2006)

[1] recalculated by the applicant according to FOCUS degradation kinetics, 2006 (the DFOP fits are used for risk assessment due to the better quality of the fits))
[2] from Horn, 2006

At some locations field dissipation studies are fulfilling ctgb criteria, so that $DegT_{50}$ values can be used for PEC_{GW} modeling. The respective $DegT_{50}$ values are summarized in Table 5.4-5.

Table 5.4-5: Field degradation studies of pyraclostrobin fulfilling ctgb criteria (applicable for PEC_{GW})

soil / location	pH	depth (cm)	DT_{50} (d)	DT_{90} (d)	Kinetic, Fit	DT_{50} (d) 20 °C, pF2	Reference
Germany, Großharrie, loamy sand	6.2	0-10	25	83	r^2 = 0.997, 1st order	26.5[1]	Kellner and Zangmeister, (1999a), Horn (2006)
Germany, Bad Sassendorf Lohne, loamy silt	6.8	0-10	37	122	r^2 = 0.999, 1st order	12.5[1]	Kellner and Zangmeister, (1999a), Horn (2006)
Germany, Meckenheim, loamy sand	5.6	0-10	26	85	r^2 = 0.91, 1st order	15.5[1]	Kellner and Zangmeister, (1999a), Horn (2006)
Sweden, Bjärred,loamy sand	5.8	0-10	31[1]	103	r^2 = 0.92, 1st order	20.6[1]	Kellner and Zangmeister (1999) Horn (2006)
Geometric Mean						18.0	

[1] from Horn, 2006

The DT_{50} values of pyraclostrobin do not show any pH dependency.

Metabolites BF 500-6 and BF 500-7

The soil levels of metabolites BF 500-6 and BF 500-7 are negligible (expected to be < 0.01 mg kg^{-1}), based on the rare detection in the field degradation studies where pyraclostrobin was applied to bare soil with a distinctly higher rate than the expected soil load after application of BAS 500 06 F (BF 500-6 found only rarely at a single trial site, BF 500-7 not detected; see also chapter 9.5.1, section on metabolites of pyraclostrobin).

During the pyraclostrobin field dissipation trials, samples were also analyzed for the metabolites BF 500-6 and BF 500-7. Despite the rapid dissipation of the parent compound, BF 500-6 was found only rarely at a single trial site, and BF 500-7 was not detected (limit of quantification 0.01 mg kg^{-1}). The application rate of pyraclostrobin used in the field studies was 250 g a.s. ha^{-1} in a single treatment to bare soil.

Due to these results, it can be concluded that the occurrence of both metabolites in the soil is negligible and is expected to be < 0.01 mg kg^{-1}.

Therefore BF 500-6 and BF 500-7 were not considered in the risk assessment.

5.4.2 Adsorption/desorption

Pyraclostrobin

No new studies have been submitted regarding adsorption/desorption in soil of pyraclostrobin. The exposure modeling is based on the EU K_{foc} values as summarized in Table 5.4-6.

Table 5.4-6: K_f, K_{foc} and 1/n (Freundlich exponent) values for pyraclostrobin

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Li 35 b, sandy loam	0.8	6.4	7500	7500	0.896	Ziegler (1998) / Monograph (2001)
LUFA 2.2, loamy sand	1.9	5.6	16000	16000	1.025	
Bruch West, sandy loam	1.8	7.3	7889	7889	1.012	
USA 538-30-5, loamy sand	0.5	5.9	6000	6000	0.861	
USA 538-31-2, sandy loam	0.6	5.3	9000	9000	0.873	
CAN-95024, sandy loam	3.9	7.6	9436	9436	1.005	
Arithmetic mean				**9304**	**0.945**	

The K_{foc}/K_f values of pyraclostrobin do not show any pH dependence.

Metabolites BF 500-3, BF 500-6 and BF 500-7

The K_{oc}-values for pyraclostrobin metabolites BF 500-3, BF 500-6 and BF 500-7 are summarized in Table 5.4-7 to Table 5.4-9.

Even under worst case laboratory leaching conditions (unaged as well as aged soil column leaching studies by Ziegler, 1998), all radioactivity remained in the upper soil layer and no radioactivity could be found in the leachates.

These metabolites were therefore classified as non-mobile in soil.

Table 5.4-7: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite BF 500-3

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{foc} (mL g^{-1})	1/n (-)	Reference
Li 35 b loamy sand	1.1	6.5	n.a.	6750	0.802	Seher (1999) / Monograph (2001)
LUFA 2.2 sand/ loamy sand	2.5	5.8	n.a.	10700	0.942	
Bruch West sandy loam	1.5	7.5	n.a.	4240	0.688	
USA (538-30-5) loamy sand	0.4	5.8	n.a.	11800	0.942	
USA (538-31-2) loam	0.5	5.2	n.a.	12000	0.773	
CAN-95024/ RCN 95012 sandy clayey loam	3.4	7.5	n.a.	10400	0.831	
Arithmetic mean				**9315**	**0.830**	

n.a. – not available

Table 5.4-8: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite BF 500-6

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{oc} (mL g^{-1})	1/n (-)	Reference
Li 35 b loamy sand	1.1	6.5	n.a.	31830	n.a.	Seher (1999) / Monograph (2001)
LUFA 2.2 sand/ loamy sand	2.5	5.8	n.a.	3360	n.a.	
Bruch West sandy loam	1.5	7.5	n.a.	16550	n.a.	
USA (538-30-5) loamy sand	0.4	5.8	n.a.	91650	n.a.	
USA (538-31-2) loam	0.5	5.2	n.a.	126800	n.a.	
CAN-95024/ RCN 95012 sandy clayey loam	3.4	7.5	n.a.	18500	n.a.	
Arithmetic mean				**48115**	**-**	

n.a. – not available

Table 5.4-9: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite BF 500-7

Soil Type	OC (%)	pH (-)	K_f (mL g^{-1})	K_{oc} (mL g^{-1})	1/n (-)	Reference
Li 35 b loamy sand	1.1	6.5	n.a.	37950	n.a.	Seher (1999) / Monograph (2001)
LUFA 2.2 sand/ loamy sand	2.5	5.8	n.a.	4020	n.a.	
Bruch West sandy loam	1.5	7.5	n.a.	29950	n.a.	
USA (538-30-5) loamy sand	0.4	5.8	n.a.	135900	n.a.	
USA (538-31-2) loam	0.5	5.2	n.a.	149900	n.a.	
CAN-95024/ RCN 95012 sandy clay loam	3.4	7.5	n.a.	15950	n.a.	
Arithmetic mean				**62278**	**-**	

n.a. – not available

5.4.3 Rate of degradation in water

Pyraclostrobin

No new water/sediment study has been submitted. The exposure modeling is based on the results of the water/sediment studies of pyraclostrobin under dark conditions (Staudenmaier, 1999) reviewed in the Monograph (2001).

However, since no DT_{50} values for the whole system were available as required for deriving PEC_{SW} values for pyraclostrobin, they were calculated according to FOCUS Degradation Kinetics, 2006. The recalculation of the DT_{50} values is described in detail in Appendix 2 (KIIA 7.8.3).

$DegT_{50}$ and $DegT_{90}$ values of pyraclostrobin from the water sediment studies under dark (Staudenmaier, 1999) and irradiated conditions (Ebert, 1999) are summarized in Table 5.4-10.

Table 5.4-10: Degradation in water/sediment of pyraclostrobin

Water/ sediment system	**pH water**	**pH sed**	**T (°C)**	**whole system**			**water**			**sediment**			**Reference**
				$DegT_{50}$	**$DegT_{90}$**	**Kinetic, Fit**	**$DegT_{50}$**	**$DegT_{90}$**	**Kinetic, Fit**	**$DissT_{50}$**	**$DegT_{50}$**	**Kinetic, Fit**	
dark conditions													
Pond (system A)	8.4	7.1	20	25.1*	83.3*	SFO*	n.c.	n.c.	-	n.c.	n.c.	-	Staudenmaier (1999)/ Monograph (2001)
River (System B)	8.1	7.3	20	7.3*	24.4*	SFO*	n.c.	n.c.	-	n.c.	n.c.	-	
irradiated conditions													
Kell-metsch-weiher	n.a.	n.a.		7.4*	24.4*	SFO*	n.c.	n.c.	-	n.c.	n.c.	-	Ebert (1999)/ Monograph (2001)
Geometric mean (dark conditions)				**13.5**	**45.1**		n.c.	n.c.		n.c.	n.c.		

n.a. - not available
n.c. - not recalculated by zRMS
* recalculated by zRMS according to FOCUS degradation kinetics [FOCUS, 2006]

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 for pyraclostrobin as presented in Table 5.5-1.

Table 5.5-1: Input parameter for active substance for PEC_{soil} calculation

Active substance	DT_{50}
pyraclostrobin	37 d (SFO, Maximum, field studies, see Table 5.4-4)

Due to the fast degradation of pyraclostrobin in soil (DT_{90} < 365 d, DFOP, field data) the accumulation potential of pyraclostrobin does not need to be considered.

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 5.5-2.

Table 5.5-2: Results of PEC_{soil} calculation (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm)

plant protection product:		BAS 500 06 F				
use:		00-001 to 00-010 cereals (winter/spring)				
Number of applications/intervall		2 x, 21 d				
application rate:		active substance pyraclostrobin: 250 g ai ha^{-1} preparation BAS 500 06 F: (1.25 L ha^{-1} * density: 1044 g L^{-1}) = 1305 g ha^{-1}				
crop interception:		2 x 50				
active substance/ preparation	**soil relevant application rate (g ha^{-1})**	**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)**
active substance pyraclostrobin	2 x 125	0.2791	-	-	-	-
preparation BAS 500 06 F	2 x 652.5	1.4570	-	-	-	-

5.6 Estimation of concentrations in surface water and sediment (PEC_{sw}/PEC_{sed}) (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.

The relevant input parameters for the pyraclostrobin used for PEC calculation are summarized in Table 5.6-1

Table 5.6-1: Input parameters for active substance for $PEC_{SW/sed}$ calculations

Parameter	Endpoint used for $PEC_{SW/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance Pyraclostrobin			
$DT_{50,soil}$ (d)	18.0	no	Geometric mean (normalized field studies, n=4, see Table 5.4-5)

$DT_{50,wholesystem}$ (d)	13.5	no	Geometric mean (n=2, see Table 5.4-10)
$DT_{50,water}$ (d)	13.5	-	whole system - value
$DT_{50,sed}$ (d)	STEP 2: 13.5 STEP 3: 1000	- -	whole system – value FOCUS default
$K_{f,oc}$ (mL g^{-1})	9304	no	Arithmetic mean (n=6, see Table 5.4-6)
1/n (-)	0.945	no	Arithmetic mean (n=6, see Table 5.4-6)
Plant uptake factor	0		
Wash off coefficient	PRZM: 0.02 (cm^{-1}) MACRO: 0.002 (mm^{-1})		
Water solubility (at 20°C) (mg L^{-1})	1.9		

Results of FOCUS SW calculations for the worst-case application scenario of BAS 500 06 F are summarized in Table 5.6-2. Beside PEC_{act} value also PEC_{twa}, 21 d is given as it is necessary for risk assessment for birds and mammals.

Table 5.6-2: Summary of highest global maximum FOCUS surface water PEC_{SW} and PEC_{sed} values for active substance pyraclostrobin

Plant protection product:		BAS 500 06 F		
Use No evaluated		00-001 to 00-010		
Crop		cereals (winter/spring)		
Application method (-)		ground spray		
Growth stage at first application (BBCH)		25		
Crop interception		STEP 2: Average crop cover (50%) STEP 3: 2 x 50%		
Number of applications/intervall		2x, 21 d		
Application rate		2 x 250 g ai ha^{-1}		
Active Substance		pyraclostrobin		
FOCUS step	**Scenario/water body**	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**
		Actual, 0 h	**TWA, 21 d**	**Actual, 0 h**
STEP 1	-	17.03	7.92	1160.00
STEP 2	North / March -May	2.11	0.65	86.40
	South / March -May	2.11	1.09	158.07
STEP 3 FOCUS crop:	D1ditch	1.499	0.727	9.369
	D1 stream	1.201	0.0512	0.855
	D2 ditch	1.388	0.221	3.611
	D2 stream	1.223	0.141	2.107

cereals, winter	D3 ditch	1.370	0.063	1.364
	D4 pond	0.0601	0.0426	0.664
	D4 stream	1.076	0.00347	0.0675
	D5 pond	0.0621	0.0393	0.589
	D5 stream	1.213	0.00733	0.130
	D6 ditch	1.382	0.279	3.557
	R1 pond	0.0571	0.0377	0.803
	R1 stream	0.897	0.0131	3.903
	R3 stream	1.265	0.0256	0.996
	R4 stream	0.898	0.0382	8.753
STEP 3 FOCUS crop: cereals, spring	D1 ditch	1.497	0.645	9.446
	D1 stream	1.201	0.0509	0.988
	D3 ditch	1.375	0.0951	1.694
	D4 pond	0.0533	0.0308	0.493
	D4 stream	1.171	0.0153	0.273
	D5 pond	0.0583	0.0350	0.515
	D5 stream	1.266	0.0233	0.464
	R4 stream	0.898	0.0402	4.984

For information only, the $PEC_{sw/sed}$ calculations (Step 1 – 4 for single and multiple applications) by the applicant are provided below. The inputs values are the same as in the calculations by zRMS, with the exception of the DT_{50} values for water, sediment and whole system. The applicant used values from a study which was conducted under irradiated conditions (DT_{50} water = 10.3 d, DT_{50} sediment = 4 d and DT_{50} whole system = 10.3 d), whereas zRMS used data from a study which was carried out under dark conditions only. However, the DT_{50} values are in the same range. Note: The FOCUS SW simulations itself have not been checked by the zRMS.

5.6-3: Global maximum PEC_{sw} and PECsed of pyraclostrobin following single and twofold application of 250 g a.s. ha^{-1} to winter and spring cereals

FOCUS step	Scenario/water body	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Single application	**Twofold application**	**Single application**	**Twofold application**
STEP 1	-	8.516	17.031	578.377	1160.000
STEP 2	North / March -May	2.299	2.041	57.776	79.159
	South / March -May	2.299	2.041	107.357	150.826

5.6-4: Step 3 and 4 - Global maximum PEC_{sw} of pyraclostrobin in surface water following single application of 250 g a.s. ha^{-1} to winter cereals, considering nozzle reduction, runoff reduction and spray drift mitigation at Step 4

Winter cereals - single application													
$PEC_{sw,max}$ [µg L^{-1}] and dominant entry route													
Location Water body	Step 3	Step 4											
	Edge-of-field	Edge-of-field	Buffer zones, drift mitigation or drift and runoff mitigation						Buffer zones and nozzle reduction, drift mitigation				
			5 m	10 m	15 m	20 m	25 m	15 m	5 m	10 m	15 m	15 m	20 m
	-	90% N*	-	-	-	-	-	10 m**	50 % N*	30% N*	30% N*	50% N*	30% N*
D3 ditch	1.567	0.157	0.424	0.225	0.154	0.117	0.095	0.154	0.212	0.158	0.107	0.077	0.082
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D4 pond	0.054	0.005	0.047	0.034	0.027	0.022	0.019	0.027	0.023	0.024	0.019	0.013	0.016
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D4 stream	1.180	0.118	0.431	0.228	0.156	0.119	0.096	0.156	0.215	0.160	0.109	0.078	0.083
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D5 pond	0.054	0.005	0.047	0.034	0.027	0.022	0.019	0.027	0.023	0.024	0.019	0.013	0.016
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D5 stream	1.263	0.126	0.461	0.244	0.167	0.127	0.103	0.167	0.231	0.171	0.117	0.084	0.089
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
R1 pond	0.054	0.005	0.047	0.034	0.027	0.022	0.019	0.027	0.023	0.024	0.019	0.013	0.016
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
R1 stream	1.037	0.104	0.379	0.201	0.137	0.104	0.100	0.137	0.189	0.141	0.100	0.100	0.100
	Drift	Drift	Drift	Drift	Drift	Drift	Run-off	Drift	Drift	Drift	Run-off	Run-off	Run-off
R3 stream	1.463	0.146	0.534	0.283	0.193	0.147	0.121	0.193	0.267	0.198	0.135	0.121	0.121
	Drift	Drift	Drift	Drift	Drift	Drift	Run-off	Drift	Drift	Drift	Drift	Run-off	Run-off

* Drift reduction by nozzles
** Runoff reduction by vegetated filter strips

5.6-5: Step 3 and 4 - Global maximum PEC_{sw} of pyraclostrobin in surface water following twofold application of 250 g a.s. ha^{-1} to winter cereals, considering nozzle reduction, runoff reduction and spray drift mitigation at Step 4

Winter cereals - twofold application													
$PEC_{sw,max}$ [µg L^{-1}] and dominant entry route													
Location Water body	Step 3	Step 4											
	Edge-of-field	Edge-of-field	Buffer zones, drift mitigation or drift and runoff mitigation						Buffer zones and nozzle reduction, drift mitigation				
			5 m	10 m	15 m	20 m	25 m	15 m	5 m	10 m	15 m	15 m	20 m

	-	90% N*	-	-	-	-	-	10 m**	50 %N*	30% N*	30% N*	50% N*	30% N*
D3 ditch	1.370	0.137	0.355	0.184	0.125	0.094	0.075	0.184	0.178	0.129	0.087	0.062	0.066
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D4 pond	0.057	0.006	0.049	0.035	0.027	0.023	0.020	0.035	0.025	0.024	0.019	0.014	0.016
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D4 stream	1.076	0.107	0.380	0.197	0.133	0.100	0.081	0.197	0.190	0.138	0.093	0.067	0.070
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D5 pond	0.059	0.006	0.050	0.036	0.028	0.024	0.020	0.036	0.025	0.025	0.020	0.014	0.017
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
D5 stream	1.213	0.121	0.428	0.222	0.150	0.113	0.091	0.222	0.214	0.156	0.105	0.075	0.079
	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
R1 pond	0.052	0.011	0.045	0.032	0.026	0.021	0.018	0.032	0.023	0.023	0.018	0.013	0.015
	Drift	Run-off	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift	Drift
R1 stream	0.897	0.107	0.317	0.164	0.111	0.107	0.107	0.164	0.158	0.115	0.107	0.107	0.107
	Drift	Run-off	Drift	Drift	Drift	Run-off	Run-off	Drift	Drift	Drift	Run-off	Run-off	Run-off
R3 stream	1.265	0.126	0.447	0.232	0.156	0.121	0.121	0.232	0.223	0.162	0.121	0.121	0.121
	Drift	Drift	Drift	Drift	Drift	Run-off	Run-off	Drift	Drift	Drift	Run-off	Run-off	Run-off

* Drift reduction by nozzles
** Runoff reduction by vegetated filter strips

5.6-6: Step 3 - Global maximum PECsed of pyraclostrobin following single and twofold application of 250 g a.s. ha^{-1} to winter and spring cereals

Location	Water body	Step 3 (edge-of-field)			
		Winter cereals		Spring cereals	
		Single application	Twofold application	Single application	Twofold application
		$PEC_{sed,max}$ [µg kg^{-1}]	$PEC_{sed,max}$ [µg kg^{-1}]	$PEC_{sed,max}$ [µg kg^{-1}]	$PEC_{sed,max}$ [µg kg^{-1}]
D3	ditch	0.970	0.980	0.945	1.068
D4	pond	0.250	0.333	0.150	0.126
	stream	0.039	0.058	0.107	0.227
D5	pond	0.205	0.218	0.143	0.160
	stream	0.039	0.116	0.247	0.346
R1	pond	0.248	0.222	-*	-*
	stream	0.627	1.452	-*	-*
R3	stream	0.391	0.411	-*	-*

* Crop/scenario combination not defined

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance and its metabolites

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 pyraclostrobin and its metabolites in ground water have been assessed with standard FOCUS scenarios to obtain outputs from FOCUSPELMO 4.4.3. The FOCUS calculation was performed by zRMS.

The high sorption values of the two soil metabolites BF 500-6 and BF 500-7 show that they are non-mobile in soil (BF 500-6: K_{oc} of 3360-126800 mL g^{-1}; BF 500-7: K_{oc} of 4020-149900 mL g^{-1}, see section 5.4.2). Under field conditions the metabolites occured in soil only in negligible amounts (< 0.01 mg kg^{-1}) after application of BAS 500 06 F (taking into account the results for the metabolites in the pyraclostrobin field studies: BF 500-6 found only rarely at a single trial site, BF 500-7 not detected; see also section 5.4.1.2, section on metabolites of pyraclostrobin). Regarding the low occurrence of the metabolites and their immobility in soil it can be concluded that BF 500-6 and BF 500-7 do not pose a risk regarding groundwater contamination.

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

use evaluated	00-001 to 00-010 cereals (winter/spring)
application rate (kg as/ha)	2 x 0.250
crop (crop rotation)	winter cereals and spring cereals
date of application	**winter cereals spring cereals** **Northern Europe** *(Jokioinen)* 15th april 15th june **Central Europe** *(Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza)* 15th march 15th may **Southern Europe** *(Porto, Sevilla, Thiva)* 15th february 15th april
interception (%)	2 x 50 %
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	10

Table 5.7-2: Input parameters related to active substance for PEC_{GW} modelling

Parent	pyraclostrobin	Remarks/Reference
molecular mass	387.82	-
DT_{50} in soil (d)	18.0	Geometric mean (normalized field studies, n=4, see Table 5.4-5)

K_{foc}	9304	Arithmetic mean (n=6, see Table 5.4-6)
1/n	0.945	Arithmetic mean (n=6, see Table 5.4-6)

Table 5.7-3: PEC_{GW} at 1 m soil depth for pyraclostrobin (based on geom. mean for DT_{50} value and arithm. mean for K_{foc})

Use No /crop	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO 4.4.3
		pyraclostrobin
00-001 to 00-010 winter cereals	Châteaudun	< 0.001
	Hamburg	< 0.001
	Jokioinen	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001
00-001 to 00-010 spring cereals	Châteaudun	< 0.001
	Hamburg	< 0.001
	Jokioinen	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
	Porto	< 0.001

According to the PEC_{GW} modelling withFOCUSPELMO 4.4.3 a groundwater contamination of the active substance pyraclostrobin at a concentration of ≥ 0.1 µg/L is not expected for the FOCUS groundwater scenarios Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva.

For the soil metabolites BF 500-6 and BF 500-7 a groundwater concentration ≥ 0.1 µg/L can be excluded due to their high K_{foc}/K_{oc} values (arithmetic mean of 9315 and 48115, see section 5.4.2).

5.7.2 Summary of risk assessment for ground water

Results of modelling with FOCUSPELMO 4.4.3 show that the active substance pyraclostrobin is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in winter and spring cereals.

For the soil metabolites BF 500-6 and BF 500-7 concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance pyraclostrobin is < 10^{-5} Pa (2.6 x 10^{-8} Pa). Hence the active substance is regarded as non-volatile. Therefore exposure of surface water by pyraclostrobin due to deposition following volatilization does not need to be considered.

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*
OECD: KIIIA1 9.2.1	Horn, A.	2006	Normalisation of the degradation rate constant of BAS 500 F - Pyraclostrobin in the field to a reference temperature of 20°C and a reference soil moisture at pF2 Report No.: CALC-645	yes	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 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

KIIIA 9.2.1 Horn, 2006

Reference:	KIIIA1 9.2.1
Author:	Horn, A.
Report:	Normalisation of the degradation rate constant of BAS 500 F - Pyraclostrobin in the field to a reference temperature of 20°C and a reference soil moisture at pF2 Report No.: CALC-645
Date:	23.02.2006
Guideline(s):	no guidelines available
Deviations:	Not applicable
GLP:	No, not subject to GLP regulations
Acceptability:	Yes

Summary

Following the recommendations of FOCUS work group on degradation kinetics [FOCUS ,2006], field dissipation studies of BAS 500 F were evaluated against CTB criteria [CTB, 1999] and degradation rate constants were normalized to a reference temperature of 20°C and a reference soil moisture at pF2. DT50 values were calculated on the basis of the normalized degradation rate constants.

Materials and methods

Input data for the modeling study

Data from the two field dissipation studies with pyraclostrobin given in g/ha were used as input for the kinetic modeling approach. The modeled residue data represent a sum of the residue in the total horizon sampled. Regarding t = 0, the data from the soil-filled Petri dishes used in the application rate verification experiments were considered. For t > 0 the raw data were modified considering the generic guidance of FOCUS regarding values below the limit of detection (LOD) and the limit of quantification (LOQ). The resulting modified time series of concentrations used in the kinetic modeling approach are shown in Table 9.2.2.1.1-1.

Table A 2: Concentration of BAS 500 F in soil of the field trials after modification of LOQ data for kinetic modeling following FOCUS

D05/02/97 (Germany, Großharrie)							
DAT	0	14	26	53	96	173	350
Residue [g ha^{-1}]	206	140	107	40	18	7.5	-
D08/01/97 (Germany, Bad Sassendorf Lohne)							
DAT	0	12	26	64	98	182	362
Residue [g ha^{-1}]	193	152	123	54	30	xxx	7.5
DU2/02/97 (Germany, Meckenheim)							
DAT	0	12	29	57	96	174	347
Residue [g ha^{-1}]	208	92	105	59	7.5	-	-
ALO/01/98 (Manzanilla Spain)							
DAT	0	14	30	60	98	182	349
Residue [g ha^{-1}]	166	61	36	37	24	7.5	-
ALO/02/98 (Spain, Alcala del Rio)							
DAT	0	15	30	63	99	182	356
Residue [g ha^{-1}]	194	53	60	53	48	23	7.5
HUS/02/98 (Bjäred, Sweden)							
DAT	0	16	31	59	100	177	351
Residue [g ha^{-1}]	200	88	102	56	34	7.5	-

DAT = days after treatment

Suitability of field dissipation data for kinetic modelling

CTB criteria that provide guidance on whether the results of field dissipation studies can be used to derive transformation parameters of crop protection chemicals in soil, which in turn can be used in kinetic simulations of potential groundwater contamination by crop protection chemicals leaching [*CTB, 1999*] The field studies for pyraclostrobin were checked for compliance with the criteria.

Estimation and normalisation of the degradation rate constants

A single first-order kinetic approach was applied to the estimation and normalisation of the degradation rate constants of BAS 500 F. The principle equation is shown in Equation 9.2.2.1.1-1.

Equation 9.2.2.1.1-1 Principle equation of single first-order kinetics

$$C_t = C_{initial}\ e^{-k_{act}\ t} \qquad (a)$$

$$k_{act} = f_{temp} * f_{moist} * k_{ref} \qquad (b)$$

with C_t concentration at time t [g ha^{-1}]
$C_{initial}$ concentration at time 0 [g ha^{-1}]
k_{act} estimated actual degradation rate constant
(at current soil temperature and moisture conditions) [d^{-1}] t
time after application [d]
f_{temp} temperature correction factor [-]
f_{moist} moisture correction factor [-]
k_{ref} estimated degradation rate constant at reference conditions
(soil temperature 20°C, soil moisture at pF2) [d^{-1}]

The parameters $C_{initial}$ (initial concentration) and k_{ref} (degradation rate constant at reference conditions, i.e., the normalized degradation rate constant) were estimated with the program ModelMaker v.3 patch 3.0.4 whereby the Marquardt optimization procedure (option least squares) was used for calculation. The degradation rate constant at reference conditions (k_{ref}) resulting from the estimation procedure was used to derive the DT_{50}-value according to Equation 9.2.2.1.1-2.

Equation 9.2.2.1.1-2 Calculation of DT_{50}-value according to first-order kinetics

$$DT_{50} = \frac{\ln(2)}{k_{ref}}$$

The degradation rate constants k were corrected for differences between actual daily soil moisture and a reference soil moisture at pF2 using the modified Walker equation as recommended by FOCUS [*FOCUS , 2000*]. The correction factor f_{moist} for soil moisture is calculated using Equation 9.2.2.1.1-3.

Equation 9.2.2.1.1-3 Influence of the soil moisture on the degradation behavior

$$f_{moist} = \begin{cases} \left(\frac{\theta_{act}}{\theta_{ref}}\right)^{B} & \text{for } \theta_{ref} > \theta_{act} \\ 1 & \text{for } \theta_{ref} \le \theta_{act} \end{cases}$$

where	f_{moist}	moisture correction factor	[-]
	θ_{act}	actual soil moisture (volumetric water content)	[-]
	θ_{ref}	reference soil moisture at pF2	[-] B
	exponent of the moisture response function, B = 0.7		[-]

The daily actual soil moisture used for the moisture correction of the different field trials was estimated with the software tool FOCUS-PEARL version 2.2.2 using actual soil characteristics and weather data (temperature, global radiation, precipitation). For each study site a PEARL scenario was created. A soil depth of 0.5 m and a 0.025 m discretization scheme were selected for the PEARL simulations. The lower boundary condition of the simulation profile was set to "Free Drainage".

The weather data for the scenarios were derived from stations located in the vicinity of the trial sites. The actual evaporation amounts of the different field trials were estimated within PEARL using the Makkink approach. Weather data were available for the study period. To allow a model warm-up period the data were replicated such that three years of warm-up were established.

The soils were characterized according to the soil properties given in the field study reports (See monograph 12945 /ECCO/BBA/ 01). For derivation of hydraulic parameters, i.e., the van Genuchten parameters which describe the soil-water retention characteristics, soil hydraulic pedotransfer functions based on the HYPRES database [*Nemes et al, 2001*] were used. A bulk density of 1.5 g cm^{-3} was assumed. The results were also used for derivation of reference soil moisture at pF2 using the van Genuchten approach.

The PEARL simulations for actual soil moisture were evaluated for the 0-0.1 m soil layer, as BAS 500 F was found exclusively in this layer in the field trials. The simulated daily soil moisture data from the respective soil depths were averaged and compared to soil moisture measurements of samples from 0-0.1 m at the soil sampling dates. Regarding ALO/02/98 and HUS/02/98 the model underestimated the measured water content, which would result in a non-conservative soil moisture correction factor. Therefore a conservative correction factor f_{moist} = 1 was assumed for these soils. For the other trials correction factors were derived according to Equation 9.2.2.1.1-3.

The degradation rate constants k were also corrected for differences between actual daily temperatures and a reference temperature of 20°C using the Q_{10}-rule as described in the report of the FOCUS soil modeling working group [*FOCUS, 1997*]. The Q_{10} response function was applied for temperatures above 0°C. Below 0°C it was assumed that no degradation occurs. A temperature correction factor f_{temp} was thus derived according to Equation 9.2.2.1.1-4.

Equation 9.2.2.1.1-4 Influence of the daily temperature on the degradation behavior

$$f_{temp} = \begin{cases} Q_{10}^{\frac{Tact-Tref}{10}} & \text{for } T_{act} > 0°C \\ 0 & \text{for } T_{act} \le 0°C \end{cases}$$

where	f_{temp}	temperature correction factor	[-]
	T_{act}	actual soil temperature	[°C]
	T_{ref}	reference temperature (20°C)	[°C]
	Q_{10}	factor of increase of degradation rate with an increase in temperature of 10°C (Q_{10} = 2.2, FOCUS recommendation)	[-]

Average daily soil temperatures for the 0-0.1 m soil layer were also derived from the simulation runs with the software tool FOCUS-PEARL version 2.2.2.

Optimization statistics

The optimization was evaluated based on visual assessment and statistical goodness-of-fit measures.

The basic statistical indices for model evaluation were the coefficient of determination (r^2) and the minimum error to pass the Chi^2 test as recommended by the FOCUS work group on degradation kinetics [*FOCUS (2006)*]. The minimum error was calculated according to Equation 9.2.2.1.1-5.

Equation 9.2.2.1.1-5 Calculation of minimum error [%] value from χ2 test statistics

$$err = 100 \cdot \sqrt{\frac{1}{\chi^2_{tabulated}} \cdot \sum \frac{(C-O)^2}{\overline{O}^2}}$$

where	err	measurement error percentage
	C	calculated value
	O	observed value
	$\overline{O}$	mean of all observed values
	$\chi^2_{tabulated}$	tabulated Chi^2 value based on m degrees of freedom (number of measurements after averaging of replicates minus number of parameters according to FOCUS) and probability (5 % according to FOCUS)

The tabulated Chi^2, assuming a significance level of 5%, was obtained from Excel 2000 using the CHIINV(α,m) function.

In addition to the estimated parameters ($\hat{a}_i$) ModelMaker also provides the standard deviations ($_i$) of the estimates. These results were used to assess the confidence that can be assigned to the parameters returned from the optimization. Assuming normal distribution for the parameters, the parameter estimate and the respective standard deviation were combined to the ratio t = $\hat{a}_i$/$_i$, which is t-distributed. The probability (p-value) corresponding to the calculated t-value was calculated with the t-distribution function TDIST in Excel 2000. A one-sided distribution was chosen, the degrees of freedom equals the number of observations minus the total number of estimated parameters. The parameter is considered significantly different from zero if the p-value is smaller than 0.05, i.e., considering 5% significance level.

Results and discussions

Evaluation of field dissipation data for kinetic modeling according to CTB
The evaluation of the CTB criteria is summarized in Table 9.2.2.1.1-2. The trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 match the criteria completely, allowing normalisation of the degradation rate constants. The field trials ALO/01/98 and ALO/02/98 violate the requirement for a single first-order model (criterion 3) and were therefore excluded from the calculation of normalized degradation times.

Table A 3: Evaluation of suitability of field dissipation data of pyraclostrobin for kinetic modeling

Criterion 1: *Check that only a non-significant fraction of the dose can have leached out of the soil layers that were sampled (consider the amount of rainfall and concentration measured in the deepest sampled layer).*
The residues of BAS 500 F in the lowest sampled layer are always lower or equal to the detection limit. Therefore it can be concluded that all trials fulfill the criterion that only a non-significant fraction of the dose has leached out of the soil layers that were sampled.
Criterion 2: *Check that only a non-significant fraction of the dose disappeared via processes at the soil surface such as volatilisation or photochemical transformation (consider the period between spraying and the first significant rainfall event; check additionally that there is no initial fast decline followed by a slower decline; a recovery in the field that is much lower than the dose is also an indication of losses at the soil surface).*
<u>Volatilization:</u> Volatilization is not to be expected a significant loss route for BAS 500 F because of the very low the vapor pressure of 2.6×10^{-10} hPa at 20°C. <u>Phototransformation:</u> The soil photolysis study of BAS 500 F shows that the presence of light does not have a strong influence on the degradation of BAS 500 F on soil. When incubated at 40% MWC the soil photolytic half-life was 36.9 days (continuous radiation) and the half-life of the dark control samples (aerobic soil metabolism) was 31.7 days. Incubating the soil at 80% MWC decreased the half-life of BAS 500 F in the irradiated and the dark control samples (8.9 days and 10.4 days, respectively). The irradiated soil samples were subjected to 0 to 15 days of continuous illumination, which is equivalent to 30 days of 12 hr light and 12 h darkness per day. <u>Recovery:</u> Moderate recovery rates were observed for the initial samplings of the different field trials, but the first-order degradation kinetics are not influenced by the low initial value. Therefore, the low recoveries may be regarded as a problem of the application technique and the sampling of initial soil samples rather than an indication of significant surface losses that would influence the calculation of the half-life. <u>Phases of degradation:</u> The visual assessment of the fitted curve to the observed residues indicates a bi-phasic degradation behavior for the trials ALO/01/98 and ALO/02/98. There is no clear indication that these findings can be attributed to losses at the soil surface, i.e., other causes such as changes in the environmental settings during the experiment should also be considered for the interpretation. As no clear conclusion can be drawn regarding the cause of the bi-phasic behavior the field trials ALO/01/98 and ALO/02/98 were excluded from the calculation of degradation times. For the trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 it can be concluded that only a non-significant fraction of the dose disappeared via processes at the soil surface.
Criterion 3: *Check that the decrease of the total amount with time corresponds reasonably well with first-order kinetics (either via curve-fitting or via applying a simulation model); if there is much scatter in the relationship between total amount with time (probably due to an inadequate sampling strategy) the estimation of a transformation rate in soil may be not acceptable.*

The field trials ALO/01/98 and ALO/02/98 present a bi-phasic degradation behaviour and a single first-order model could not be fitted adequately to the data. The trials were therefore excluded from the calculation of degradation times. For the trials D05/02/97, D08/01/97, DU2/02/97 and HUS/02/98 a single first-order model could be fitted to the data. The coefficients of determination for the respective fits (Table 9.2.1-3) give much evidence for a successful estimation according to first-order kinetics.
Criterion 4: *Check whether the soil has been characterized (organic matter, clay etc.).*
The soil characteristics are described in detail in the reports of the field dissipation study.
Criterion 5: *Check whether the location can be considered representative with respect to soil type and climate for European conditions.*
The sites of the field dissipation studies are located in Europe and have been selected to cover the range of agroclimatic conditions across Europe (Sweden (north), Germany (middle), Spain (south)) and agricultural soil (sand - clay).
Criterion 6: *Check whether meteorological data are available, and whether a correction for the difference between the actual soil temperature (mean temperature measured during the day in top soil layer) and 20°C has been made (an acceptable alternative is temperature during the day in air measured on location, or nearby whether station).*
Meteorological data are available and have been used in the standardisation procedure.
Criterion 7: *Check whether the dose is reported and whether the formulated product is relevant (no granulate or slow release).*
The dose is reported. The trials were performed using the formulated product BAS 500 01 F (EC formulation) which is a typical type of formulation for end use products of BAS 500 F. Therefore, the degradation behaviour of BAS 500 F under field conditions could satisfactorily be investigated with the formulations used and therefore is relevant.
Criterion 8: *If inverse modelling was used, check whether the model used is acceptable.*
The model used is identical to the subroutines in FOCUS-PEARL, which is a simulation model recommended by FOCUS for EU-registration (*FOCUS 2000: "FOCUS groundwater scenarios in the EU review of active substances" Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202 pp.*).
Criterion 9: *Check whether analytical procedure was documented well and whether recovery was acceptable.*
The analytical procedure has been documented well and the recovery was acceptable.
Criterion 10: *Check history of pesticide use on plot. In preceding years no active ingredient or structure analog should be used.*
No active ingredient and no structural analog have been used in the preceding years.
Criterion 11: *Check method of application. Pesticide should not be applied below soil surface.*
The pesticide has been applied onto the bare soil surface.
Criterion 12: *Check method of sampling. Method of sampling should be adequate.*
The method of sampling is described in detail in the reports of the field studies and is seen to be adequate.
Criterion 13: Check influence of crop. Uptake of pesticide by crop should be negligible.
Application was onto bare soil and crops were not present during the field studies.

Estimated parameters of BAS 500 F and calculated half-lives in soil
The estimated parameters (initial concentrations and normalized degradation rate constants) and the goodness-of-fit measures for the different field trials are presented in Table 9.2.1.1-3.

Table A 4: Normalized rate constants k_{ref} and half-lives of pyraclostrobin according to single first-order kinetics

Field trial	$C_{initial}$ [g ha^{-1}]	k_{ref} [d^{-1}]	DT_{50} (20°C, pF2) [d]	r^2	err [%]
D05/02/97	204.9	0.0554*	12.5	0.994	5.1
D08/01/97	191.0	0.0262*	26.5	0.997	3.3
DU2/02/97	183.0	0.0452*	15.3	0.845	22.0
ALO/01/98	Bi-phasic degradation: single first-order model not applicable				
ALO/02/98	Bi-phasic degradation: single first-order model not applicable				
HUS/02/98	178.8	0.0337*	20.6	0.888	20.2
Geometric mean			18.0		

r^2 = coefficient of determination; err = minimum error to pass χ^2 test
* = significantly different from zero at P = 0.05

The field trials ALO/01/98 and ALO/02/98 were excluded from the calculation of degradation times as they showed a bi-phasic degradation behavior and a single first-order model could therefore not be fitted adequately to the data.

The high coefficients of determination and minimum error values of the other field trials give evidence of successful estimations. For D05/02/97 and D08/01/97 the goodness-of-fit indicators are close to the optimum values. For DU2/02/97 and HUS/02/98 a stronger deviation from the optimum can be observed which is mainly caused by differences to a single high residual value at the second sampling date. This finding must be attributed to the stronger natural variability of field data and is no indication for deficits in the model fits. The residual plots of the respective trials support this interpretation as no apparent systematic error can be observed.

Conclusion

Normalized single first-order half-lives (20°C, pF2) range from 12.5 - 26.5 days with a geometric mean of 18.0 days.

Comments of zRMS

Normalisation procedure was performed considering guidance documents and the study is considered acceptable by the ZRMS.

KIIA 7.3.1 Applicant BASF

Reference: KIIA 7.3.1

Author: Applicant BASF

Report: Kinetic evaluation of field dissipaten rates in two spanish soils

Guideline(s): FOCUS degradation kinetics [FOCUS, 2006]

Deviations: No

GLP: No, not subject to GLP regulations

Acceptability: Yes

Summary

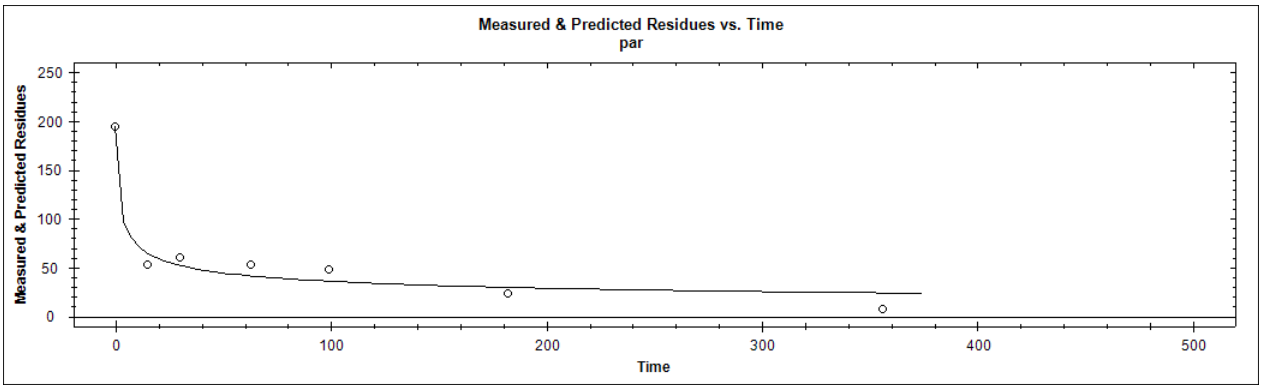
In order to derive reliable field dissipation rates, the applicant BASF performed new kinetic evaluations of the two Spanish sites (Manzanilla, Alcala del Rio). The residue data as provided in Appendix 2 from Horn *et al*. were considered for the two Spanish soils. Only the FOMC and DFOP Kingui files and graphs are presented.

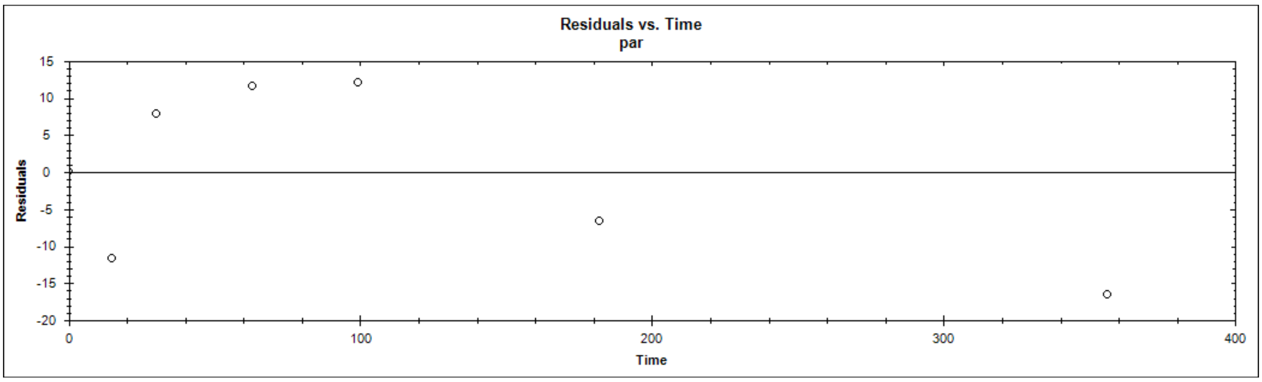
Materials and Methods

The kinetic evaluation of the data was performed using the software tool KinGUI.

Results

FOMC ALO 2: Alcala del Rio

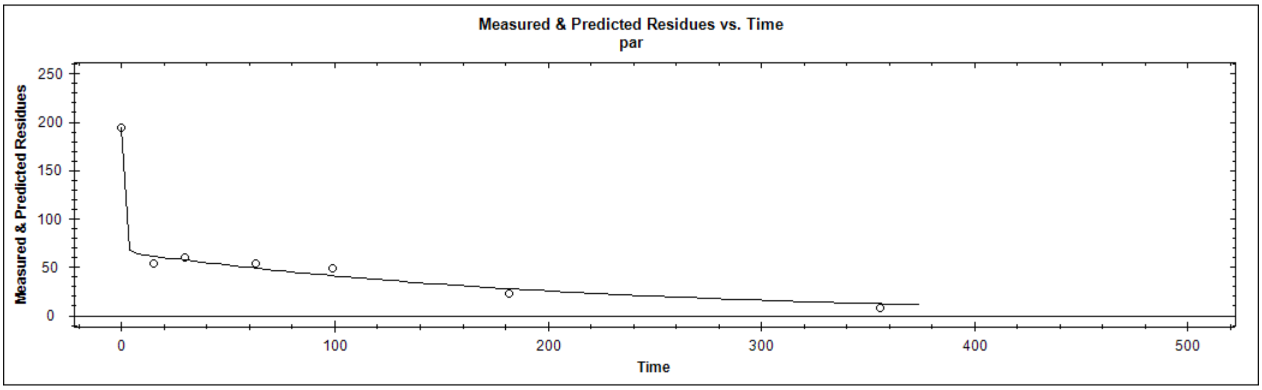


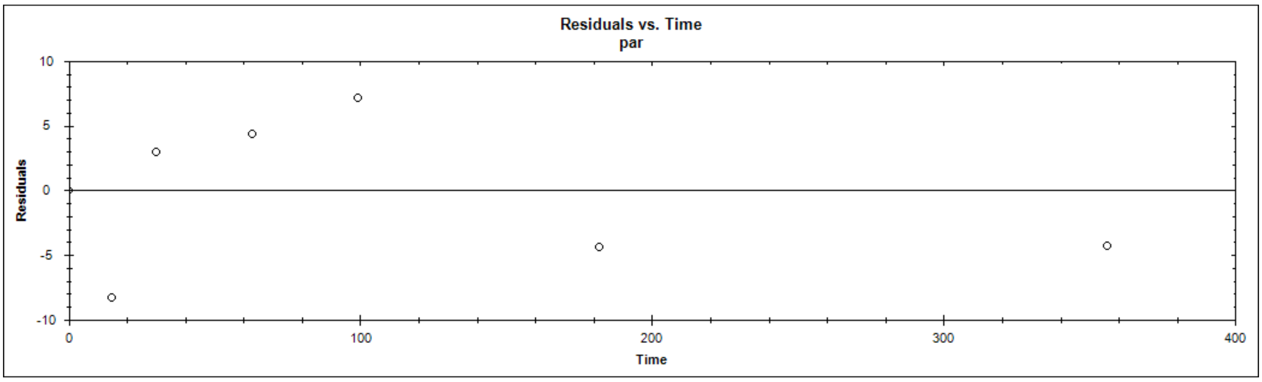



```
# Project:  BAS 500F
# Testsystem:     field degradation
# Comment:  ALO 2

# ================================
# Results of the kinetic evaluation
# ================================

# --------------------------------
# Initial values
```

```
# --------------------------------
                        Initial Value    Lower Bound      Upper Bound
Fixed
 M(0)  par            :           0.1              0              Inf
False
 alpha par            :           0.1              0              Inf
False
 beta  par            :           0.1              0              Inf
False

# --------------------------------
# Chi2 error estimation
# --------------------------------
                                    par         All
             Chi2Err% :         14.60       14.60
        Kinetic model :          FOMC

# --------------------------------
# Parameter estimation
# --------------------------------

  Degrees of Freedom : 4
  Parameter                  Estimate     Lower CI     Upper CI        St.Dev
Prob > t
 M(0)  par            :     193.93848    168.80575      219.071     12.82306
5.57e-05
 alpha par            :       0.31562      0.05193        0.579      0.13454
0.0394
 beta  par            :       0.47440     -1.35904        2.308      0.93545
0.3194

# --------------------------------
# DT50 and DT90 values
# --------------------------------
                                 par
                 DT50 :       3.7905
                 DT90 :       698.55
        Kinetic model :         FOMC

# --------------------------------
# Measured vs. predicted values
# --------------------------------
          Compartment par
     time observed err-std predicted residual
   0.0000 194.0000 10.6491  193.9385   0.0615
  15.0000  53.0000 10.6491   64.5624 -11.5624
  30.0000  60.0000 10.6491   52.1297   7.8703
  63.0000  53.0000 10.6491   41.3531  11.6469
  99.0000  48.0000 10.6491   35.8861  12.1139
 182.0000  23.0000 10.6491   29.6321  -6.6321
 356.0000   7.5000 10.6491   23.9868 -16.4868
```

DFOP ALO 2: Alcala del Rio

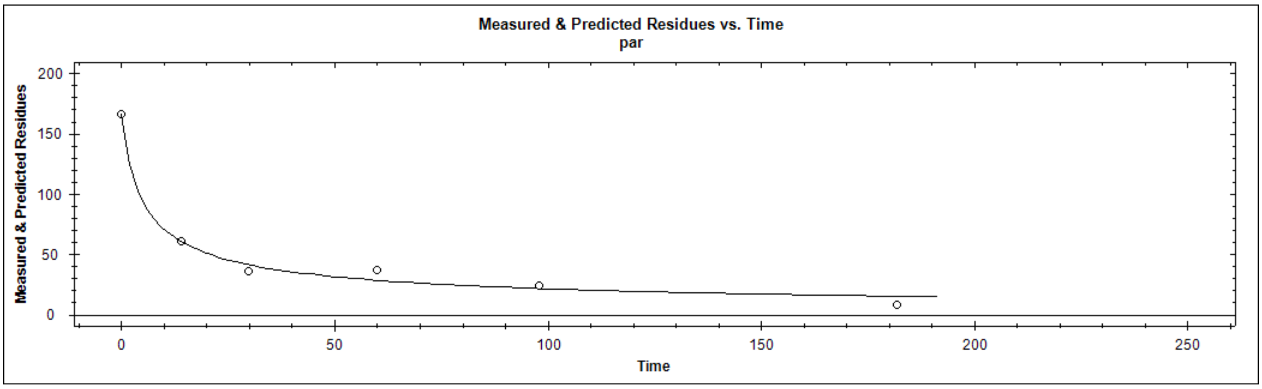


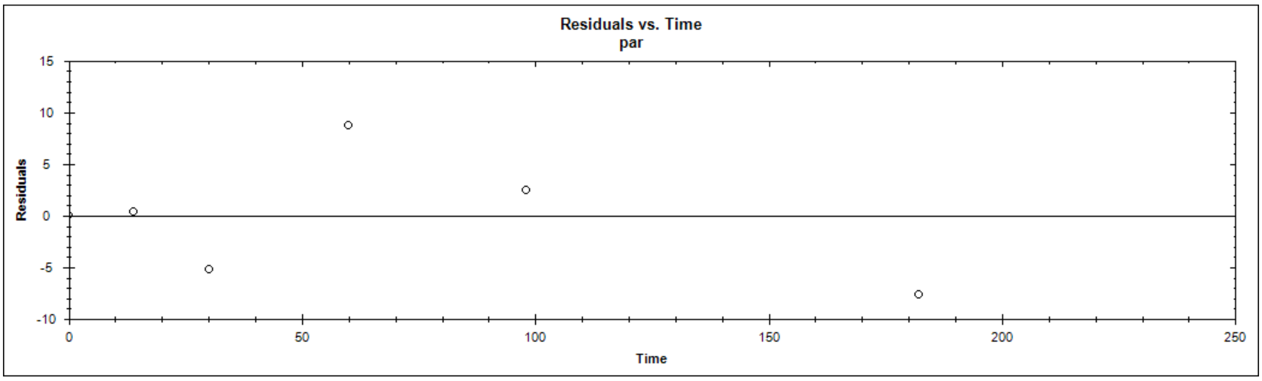



```
# Project:  BAS 500F
# Testsystem:     field degradation
# Comment:  ALO 2

# =================================
# Results of the kinetic evaluation
# =================================

# ---------------------------------
# Initial values
# ---------------------------------
                        Initial Value    Lower Bound      Upper Bound
Fixed
 M(0)  par            :          0.10              0              Inf
False
 k1    par            :          0.10              0              Inf
False
 k2    par            :          0.01              0              Inf
False
 g     par            :          0.50              0                1
False

# ---------------------------------
# Chi2 error estimation
# ---------------------------------
                                    par          All
             Chi2Err% :          7.78        7.78
        Kinetic model :          DFOP
```

```
# --------------------------------
# Parameter estimation
# --------------------------------

  Degrees of Freedom : 3
  Parameter                   Estimate     Lower CI     Upper CI       St.Dev
Prob > t
 M(0)  par            :    193.999769   178.186516      209.813     8.068134
7.88e-05
 k1    par            :      1.126041   -72.574827       74.827    37.603174
0.489
 k2    par            :      0.004825     0.002527        0.007     0.001173
0.013
 g     par            :      0.660475     0.603262        0.718     0.029191
9.45e-05

# --------------------------------
# DT50 and DT90 values
# --------------------------------
                                 par
                DT50 :        1.2453
                DT90 :        253.34
        Kinetic model :          DFOP

# --------------------------------
# Measured vs. predicted values
# --------------------------------
          Compartment par
     time observed err-std predicted residual
   0.0000 194.0000  5.1497  193.9998   0.0002
  15.0000  53.0000  5.1497   61.2690  -8.2690
  30.0000  60.0000  5.1497   56.9913   3.0087
  63.0000  53.0000  5.1497   48.6023   4.3977
  99.0000  48.0000  5.1497   40.8525   7.1475
 182.0000  23.0000  5.1497   27.3711  -4.3711
 356.0000   7.5000  5.1497   11.8216  -4.3216
```

FOMC ALO 1: Manzanilla

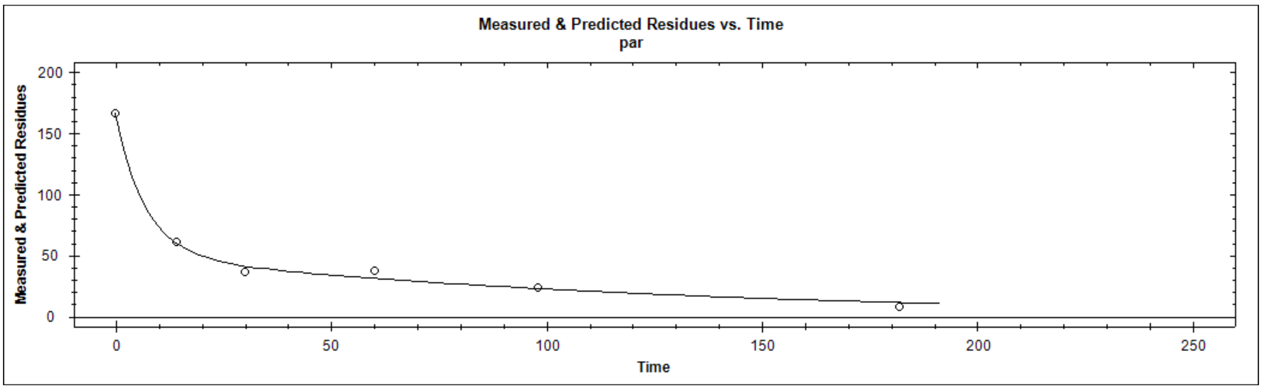


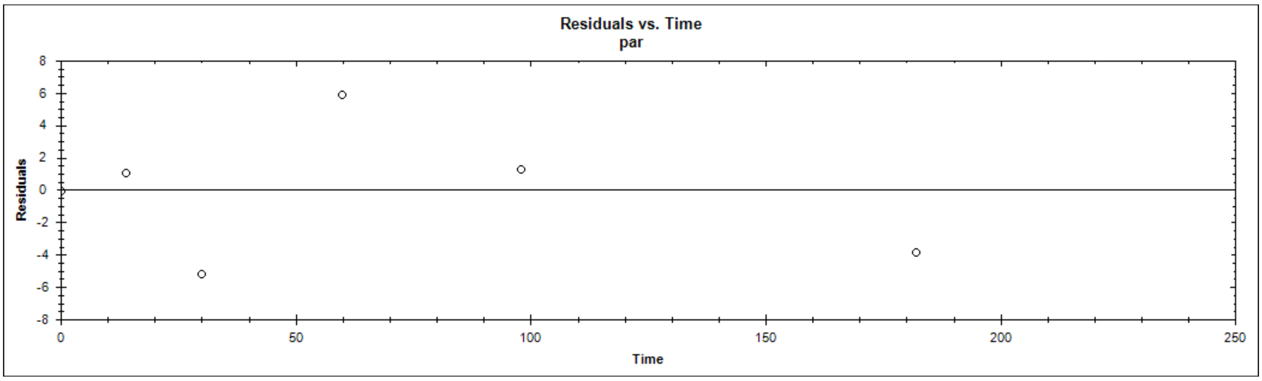



```
# Project:  BAS 500F
# Testsystem:     field degradation
# Comment:  ALO 1

# ================================
# Results of the kinetic evaluation
# ================================

# --------------------------------
# Initial values
# --------------------------------
                         Initial Value    Lower Bound      Upper Bound
Fixed
 M(0)  par             :           0.1              0              Inf
False
 alpha par             :           0.1              0              Inf
False
 beta  par             :           0.1              0              Inf
False

# --------------------------------
# Chi2 error estimation
# --------------------------------
                                     par          All
             Chi2Err% :         8.378        8.378
        Kinetic model :          FOMC

# --------------------------------
# Parameter estimation
```

```
# ---------------------------------

  Degrees of Freedom : 3
  Parameter                    Estimate     Lower CI     Upper CI        St.Dev
Prob > t
 M(0)  par           :       165.9757     151.9475      180.004        7.1574
8.78e-05
 alpha par           :         0.5837       0.2531        0.914        0.1686
0.0203
 beta  par           :         3.0343      -1.6126        7.681        2.3709
0.1453

# ---------------------------------
# DT50 and DT90 values
# ---------------------------------
                                  par
               DT50 :       6.9155
               DT90 :       153.77
      Kinetic model :         FOMC

# ---------------------------------
# Measured vs. predicted values
# ---------------------------------
          Compartment par
     time observed err-std predicted residual
   0.0000 166.0000  5.2824  165.9757   0.0243
  14.0000  61.0000  5.2824   60.6346   0.3654
  30.0000  36.0000  5.2824   41.1939  -5.1939
  60.0000  37.0000  5.2824   28.2519   8.7481
  98.0000  24.0000  5.2824   21.4515   2.5485
 182.0000   7.5000  5.2824   15.0688  -7.5688
```

DFOP ALO 1: Manzanilla






```
# Project:  BAS 500F
# Testsystem:     field degradation
# Comment:  ALO 1

# =================================
# Results of the kinetic evaluation
# =================================

# ---------------------------------
# Initial values
# ---------------------------------
                        Initial Value    Lower Bound      Upper Bound
Fixed
 M(0)  par            :          0.10              0              Inf
False
 k1    par            :          0.10              0              Inf
False
 k2    par            :          0.01              0              Inf
False
 g     par            :          0.50              0                1
False

# ---------------------------------
# Chi2 error estimation
# ---------------------------------
                                    par         All
             Chi2Err% :         6.582       6.582
        Kinetic model :          DFOP
```

```
# --------------------------------
# Parameter estimation
# --------------------------------

  Degrees of Freedom : 2
  Parameter                  Estimate     Lower CI     Upper CI        St.Dev
Prob > t
 M(0)  par            :     1.661e+02    1.527e+02      179.434    6.820e+00
0.000841
 k1    par            :     1.480e-01    5.466e-02        0.241    4.764e-02
0.044918
 k2    par            :     8.244e-03    2.228e-03        0.014    3.069e-03
0.057577
 g     par            :     6.925e-01    5.541e-01        0.831    7.059e-02
0.005116

# --------------------------------
# DT50 and DT90 values
# --------------------------------
                                   par
                 DT50 :       7.9931
                 DT90 :       136.26
        Kinetic model :         DFOP

# --------------------------------
# Measured vs. predicted values
# --------------------------------
          Compartment par
     time observed err-std predicted residual
   0.0000 166.0000  3.6342  166.0679  -0.0679
  14.0000  61.0000  3.6342   59.9776   1.0224
  30.0000  36.0000  3.6342   41.2352  -5.2352
  60.0000  37.0000  3.6342   31.1578   5.8422
  98.0000  24.0000  3.6342   22.7661   1.2339
 182.0000   7.5000  3.6342   11.3902  -3.8902
```

Comments of zRMS

The Chi-square error of the DFOP fits is lower than for the FOMC fits at both spanish sites, the visual fits are comparable. Thus, the dissipation rates derived from the DFOP fits are used for risk assessment.

KIIA 7.8.3 zRMS

Reference:	KIIA 7.8.3
Author:	zRMS
Report:	Kinetic evaluation of degradation rates in water/sediment studies
Guideline(s):	FOCUS degradation kinetics [FOCUS, 2006]
Deviations:	No

GLP: No, not subject to GLP regulations

Acceptability: Yes

Summary

In order to use the results of the water/sediment studies for this assessment, ZRMS performed a new kinetic modelling evaluation of data from the two water sediment systems under dark conditions "Pond" and "River" according to FOCUS kinetics guidance [*FOCUS, 2006*] to derive modelling endpoints for PEC_{sw} as presented below.
For comparability, some new kinetic modelling evaluation according to FOCUS kinetics guidance [*FOCUS, 2006*] was also performed for the water sediment study under irradiated conditions.

Materials and Methods

Applied Kinetic Models

The kinetic evaluation of the data from the two water/sediment systems "Pond" and "River" [Staudenmaier, 1999] and the irradiated water/sediment study "Kellmetschweiher" [Ebert, 1999] was performed using the software tool DegKinManager together with ModelMaker 4.0.

Input data for the modeling study

Data from water/sediment studies with pyraclostrobin in % TAR were used as input for the kinetic modeling approach. The raw data were modified considering the generic guidance of FOCUS [FOCUS, 2006] regarding values below the limit of detection (LOD) and the limit of quantification (LOQ) and regarding possible outliers. The resulting modified time series of concentrations of the water/sediment studies under dark conditions used in the kinetic modeling approach are shown in Table A 5. The resulting modified time series of concentrations of the water/sediment studies under irradiated conditions are shown in Table A 6.

Table A 5: Concentration of pyraclostrobin in water/sediment systems "Pond" and "River" after modification of LOQ data for kinetic modeling following FOCUS

	Sysem "Pond"			System "River"		
DAT	**Water**	**Sediment**	**Total**	**Water**	**Sediment**	**Total**
0	87.1	8	95.1	87	7.5	94.5
0.25	74.2	19	93.2	63.1	30.2	93.3
1	60.2	32.8	93	38.5	55.3	93.8
2	50	35	85	24.7	62.1	86.8
7	24.6	32.1	56.7	8.8	47.7	56.5
14	15.5	52.5	68	1.7	14.8	16.5
30	6.9	32.5	39.4	0.8	8.9	9.7
61	3.5	17	20.5	1.1*	8.3*	9.4*
100	0.005	6.5	6.5	0.005*	9.6*	9.6*

* no further degradation of active substance possibly due to changes in microbial activity in system, excluded as outlier by the ZRMS

Table A 6: Concentration of pyraclostrobin in the irradiated water/sediment system "Kellmetschweiher" after modification of LOQ data for kinetic modeling following FOCUS

DAT	Water	Sysem "Kellmetschweiher"	
		Sediment	Total
0.04	82.7	n.s.	-
0.13	80.7	n.s.	-
0.25	79.3	n.s.	-
0.38	75	n.s.	-
1	69.1	9.5	78.6
2	58.2	n.s.	-
3	46.2	15.6	61.8
7	28.3	17.5	45.8
10	14.9	n.s.	-
14	12.5	9.7	22.2
21	3.8	n.s.	-
30	0.05	0.8	0.85
45	0.7	0.4	1.1
62	0.05	0.3	0.35

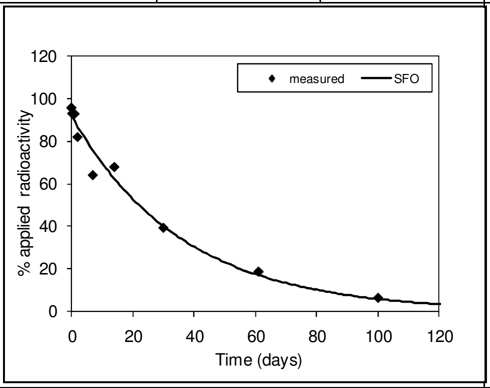
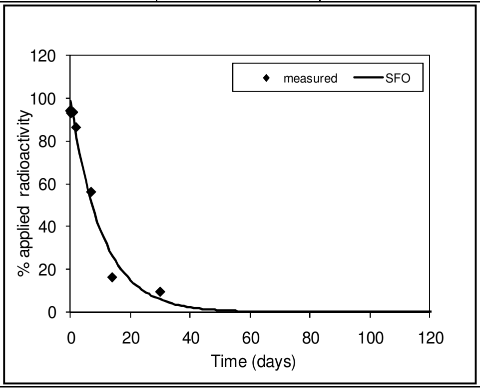
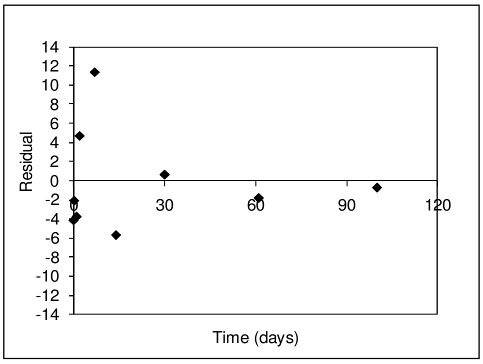
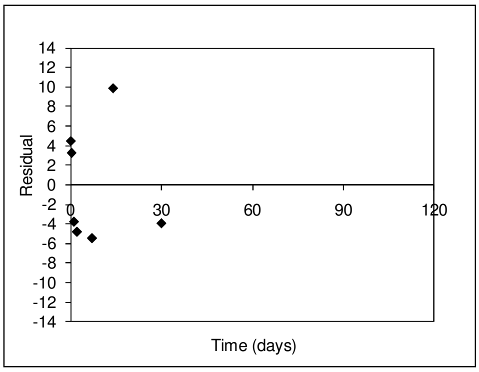
n.s.= not sampled

Results

$DegT_{50}$/$DegT_{90}$ values for the total system:

Degradation of pyraclostrobin in both water/sediment systems "Pond" and "River" under dark conditions followed SFO kinetics with acceptable fits. However, as no further degradation occurred in the water/sediment system "River" after 30 days in this system (possibly due to decline in the microbial activity), the last two data points were excluded in a second kinetic evaluation to further improve the fit. The two resulting fitted curves together with the residuals plots and the results of the statistic evaluation are shown in Table A 7.

Table A 7: SFO kinetics - visual fit and statistically parameter information for total systems Pond" and "River" for pyraclostrobin

Kinetic model	**SFO**					
System	**Pond**			**River**		
Parameter	k	M0	chi²	k	M0	chi²
Estimation	0.0276	91.7341	6.4	0.0943	98.99	7.0
Confidence	0.0014	1.2317		0.0943	1.458	
						
						

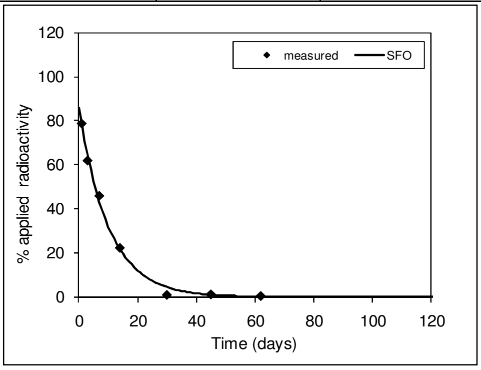
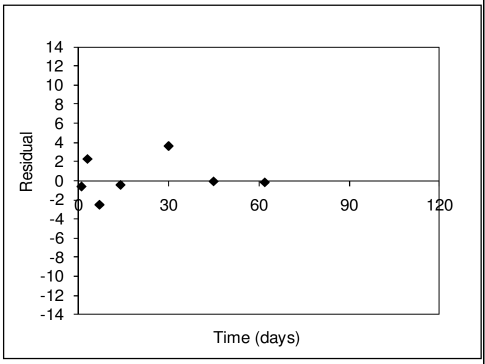
The resulting $DegT_{50}$ and $DegT_{90}$ values for both water/sediment systems are summarized in Table A 8.

Table A 8: New $DegT_{50}$ and $DegT_{90}$ values for pyraclostrobin in the water/sediment systems "Pond" and "River"

Wasser/sediment-system	**$DegT_{50}$ [d]**	**$DegT_{90}$ [d]**
	Total system	
Pond	25.1	83.3
River	7.3	24.4

Degradation of pyraclostrobin in the water/sediment system "Kellmetschweiher" under irradiated conditions also followed SFO kinetics with an acceptable fit. The resulting fitted curve together with the residuals plot and the results of the statistic evaluation are shown in Table A 9.

Table A 9: SFO kinetics - visual fit and statistically parameter information for total system“Kellmetschweiher” under irradiated conditions for pyraclostrobin

Kinetic model	**SFO**		
System	**Kellmetschweiher**		
Parameter	k	M0	chi²
Estimation	0.0979	86.028	5.06
Confidence	0.007	2.673	
			
			

The resulting $DegT_{50}$ and $DegT_{90}$ values for the water/sediment systems under irradiated conditions are summarized in Table A 10.

Table A 10: New $DegT_{50}$ and $DegT_{90}$ values for pyraclostrobin in the irradiated water/sediment systems “Kellmetschweiher”

	$DegT_{50}$ [d]	**$DegT_{90}$ [d]**
Wasser/sediment-system	**Total system**	
Kellmetschweiher	7.1	23.5

$DegT_{50}$/$DegT_{90}$ values for the water and for the sediment phase:

An attempt was made to derive $DegT_{50}$ values for pyraclostrobin in the water and in the sediment phase of the two systems under dark conditions. However, no robust values could be obtained both for the water and for the sediment phases of both systems with Chi^2 error values well above > 15% for all kinetic fits.

Appendix 3 Table of Intended Uses justification and GAP tables

Central zone (BE, CZ, DE, HU, NL, AT, PL, RO, SI, SK) - Summary of intended uses

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i) g/kg	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applica-tions (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (kg/ha) minmax		
w. wheat, s wheat durum, w barley s barley triticale, rye, *oat1*	Central EU (incl. CZ, SI)	RETENGO	F	Puccinia spp., R. secalis P. teres (MEHITE)	EC	0.2	SP	25-69	2	21 days	0.0625 – 0.25	100-400	0.25	0.8 - 1.25 *	35	
Wheat, barley, rye, triticale	DE, AT		F	P. recondita , *P. teres* P. hordei	EC	0.2	SP	25-69	2	21 days	0.0625-0.25	100-400	0.25	0.8 - 1.25	35	
Cereals	SK, HU, RO		F	Puccinia spp., R. secalis P. teres (MEHITE)	EC	0.2	SP	25-69	2	21 days	0.04-0.25	100-400	0.16-0.25	0.8-1.25	35	
Winter wheat, spring barley	PL		F	Puccinia spp., R. secalis P. teres + physiological effects	EC	0.2	SP	25-69	2	21 days	0.04-0.25	100-400	0.16-0.25	0.8-1.25	35	
Wheat, barley, spelt, rye, triticale	BE		F	Puccinia spp. *DTR* P. teres, R. secalis	EC	0.2	SP	31-59	2	21 days	0.0625-0.25	100-400	0.25	1.25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i) g/kg	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applica-tions (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (kg/ha) minmax		
Wheat, barley, *rye1*, *triticale1*	NL		F	*DTR* Puccinia spp., P. teres. R. secalis, (MEHITE) *(Michrodochium nivale)*	EC	0.2	SP	25-69	2	21 days	0.05-0.25	100-400	0.2-0.25	0.8 - 1.25	35	

* As discussed during pre-submission meeting with the German RMS, a range of 0.8-1.25 L product/ha will be applied for.
XXX => Critical GAP

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

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Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: **BAS 500 06 F**
Active Substance(s): **Pyraclostrobin 200 g/L**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **BASF**
Date: **2014-10-31**

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The exposure assessment of the plant protection product BAS 500 06 F in its intended uses in winter and spring cereals is documented in detail in the core assessment of the plant protection product BAS 500 06 F dated from 07/2013 performed by zRMS 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 500 06 F in Germany according to uses listed in Appendix 3.

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 Part B Section 6 National addendum and Part A).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation BAS 500 06 F

Code	BAS 500 06 F
plant protection product	-
applicant	BASF
date of application	09.05.2012
Formulation type (WP, EC, SC, …; density)	EC
active substances (as)	Pyraclostrobin
Concentration of as	200 g L^{-1}

Data pool/task force	-
letter of access/cross reference	-
existing authorisations in DE	-

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 3.

Table 5.2-1: Classification of intended uses in Germany for BAS 500 06 F

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)
00-001	Wheat 25-69	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500	1. 125 2. 125 = 250
00-002 00-003	wheat 25-61	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500

00-004 00-005 00-006	barley 25-61	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500
00-007	barley 31-61	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500
00-008	rye 25-61	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500
00-009	rye 25-69	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500
00-010	triticale 25-69	spraying, agriculture	spraying, agriculture	2x, 21 d, 2 x 50 %	2 x 250 = 500
A/ 00-001 to 00-010	**winter and spring cereals**	**spraying, agriculture**	**2 x, 21 d, Application dates: winter cereals 1st application: 15.03. 2nd application: 05.04. spring cereals 1st application: 15.05. 2nd application: 05.06., interception: 2 x 50 %**	**2x, 21 d, 2 x 50 %**	**2 x 250 = 500**

5.3 Information on the active substances

5.3.1 Pyraclostrobin

See core assessment

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Pyraclostrobin

See core assessment

5.4.2 Adsorption/desorption

Pyraclostrobin

See core assessment

5.4.3 Rate of degradation in water

Pyraclostrobin

See core assessment

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for BAS 500 06 F according to EU assessment considering 5 cm soil depth are given in Table 5.5-2 of Part B, Section 5.5 of the core assessment.

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 fast degradation of pyraclostrobin in soil (DT_{90} < 365 d, DFOP, field data) the accumulation potential of pyraclostrobin does not need to be considered.

The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters for pyraclostrobin as presented in Table 5.5-1.

Table 5.5-1: Input parameters for BAS 500 06 F for PEC_{soil} calculation

Active substance	DT_{50}
pyraclostrobin	37 d (SFO, maximum, field studies, see Table 5.4 4 core assesment)

Additional $PEC_{soil,act}$ was calculated for the formulation BAS 500 06 F 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 pyraclostrobin and for the formulation BAS 500 06 F 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 500 06 F				
use:		00-001 to 00-010 cereals (winter/spring)				
Number of applications/intervall		2 x, 21 d				
application rate:		active substance pyraclostrobin: 250 g ai ha^{-1} preparation BAS 500 06 F: (1.25 L ha^{-1} * density: 1044 g L^{-1}) = 1305 g ha^{-1}				
crop interception:		2 x 50				
active substance/ formulation	**soil relevant application rate (g/ha)**	**soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
active substance pyraclostrobin	2 x 125	1	1.3956	-	-	-
preparation BAS 500 06 F	2 x 625	1	7.2852	-	-	-

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

Results of PECsw calculation of pyraclostrobin for the intended for uses of BAS 500 06 F in winter and spring cereals using FOCUS Surface Water are given in Table 5.6.2 of Part B, Section 5.6 of the core assessment.

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

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 pyraclostrobin is < 10^{-5} Pa (2.6 x 10^{-8} Pa). Hence the active substance pyraclostrobin is regarded as non-volatile. Therefore exposure of surface water by the active substance pyraclostrobin due to deposition following volatilization does not need to be considered.

The calculation of PECsw after exposure via spray drift is performed using the model DRIFTOX 4.0. 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 with DRIFTOX 4.0 are summarized in Table 5.6-1.

Table 5.6-1 Endpoints of pyraclostrobin used for the PEC$_{SW}$ calculations with DRIFTOX 4.0

Parameter	Active substance pyraclostrobin	Reference
vapour pressure at 20 °C (Pa)	2.6 x 10^{-8}	See Table 5.3.2 core assessment
Solubility in water (mg/L)	1.9	See Table 5.3.2 core assessment
DissT$_{50}$ water (d)	25.1*	See Table 5.4.10 core assessment, DissT$_{50}$ has not been calculated, whole system DT$_{50}$ is used
hydrolysis/photolysis	1000	default

*SFO, worst case

The calculated PECsw values after exposure via spray drift for the active substance pyraclostrobin for the intended use in winter and spring cereals (2 x 250 g ai ha^{-1}) are summarized in Table 5.6-2.

Table 5.6-2 PEC$_{SW}$ for the active substance pyraclostrobin after exposure via spray drift modelled with DRIFTOX 4.0

active substance	pyraclostrobin
use pattern/gap:	A/00-001 to 00-010 winter and spring cereals

application rate/number of applications / interval	2 x 250 g ai ha^{-1}, 21 d						
$DissT_{50}$ (SFO) in water	25.1 d						
relevant PEC if applicable twa-interval	PEC_{act}						
scenario/percentile:	Agriculture/82. percentile						
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	130.00	-	-	130.00	-	-	-
1	2.38	3.0939	-	-	3.0939	0.3094	0.7735	1.5469
5	0.47	0.6110	-	-	0.6110	0.0611	0.1527	0.3055
10	0.24	0.3120	-	-	0.3120	0.0312	0.0780	0.1560
15	0.16	0.2080	-	-	0.2080	0.0208	0.0520	0.1040
20	0.12	0.1560	-	-	0.1560	0.0156	0.0390	0.0780

5.6.2 PEC_{SW} after exposure by surface run-off and drainage

The concentration of the active substance pyraclostrobin in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01.

The endpoints for pyraclostrobin used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in Table 5.6-3.

Table 5.6-3 Input parameters for pyraclostrobin used for PEC_{SW} calculations with EXPOSIT 3.01

Parameter	pyraclostrobin	Reference
$K_{foc, Runoff}$	9304	see Table 5.4.6 core assessment
$K_{foc, mobility\ class}$	9304	see Table 5.4.6 core assessment
DT_{50} soil (d)	37	see Table 5.4 4 core assesment (SFO, maximum, field studies,)
Solubility in water (mg/L)	1.9	see Table 5.3.2 core assessment

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substance pyraclostrobin for the intended for use in winter and spring cereals are summarized in Table 5.6-4.

Table 5.6-4 PEC_{SW} of pyraclostrobin in an adjacent ditch due to surface run-off and drainage modelled with EXPOSIT 3.01

Active substance:	pyraclostrobin
Use pattern/GAP:	A/00-001 to 00-010 winter and spring cereals
application rate/number of applications / interval:	2 x 250 g ai ha^{-1}, 21 d
Exposure by surface runoff	
vegetated buffer strip (m)	**PECsw in adjacent ditch (µg/L)**
0	0.28
5	0.24
10	0.21
20	0.15

Exposure by drainage	
time of application	**PECsw in adjacent ditch (µg/L)**
autuum/winter/early spring	0.10
Spring/summer	0.03

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of pyraclostrobin for the intended uses of BAS 500 06 F in winter and spring cereals according to EU assessment using FOCUSPELMO 4.4.3 are given in Table 5.7-3 of Part B, Section 5.7 of the core assessment.

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 in the core assessment (Table 5.7-1 of the core assesment) covers the intended uses of BAS 500 06 F in winter and spring cereals according to Table 5.2-1 (see also Appendix 1).

The endpoints according to INPUT DECISION 3.1 comply with the values used used for groundwater modelling in the core assessment (Table 5.7-2 of the core assessment).

The results of the groundwater simulation of the active substance pyraclostrobin for the Hamburg scenario are presented in Table 5.7-1.

For the soil metabolites BF 500-6 and BF 500-7 a groundwater concentration ≥ 0.1 µg/L can be excluded due to their high K_{foc}/K_{oc} values (arithmetic mean of 9315 and 48115, see section 5.4.2 of the core assessment).

Table 5.7-1 PEC_{GW} at 1 m soil depth of pyraclostrobin considered relevant for German exposure assessment

Use No.	Szenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) modeled by FOCUS PELMO 4.4.3
00-001 to 00-010 winter cereals	Hamburg	< 0.001
00-001 to 00-010 spring cereals	Hamburg	< 0.001

According to the results of the groundwater simulation with FOCUS-PELMO 4.4.3, a groundwater contamination of the active substance pyraclostrobin in concentrations of ≥ 0.1 µg/L is not expected for the intended use in winter and spring cereals.

5.7.1.2 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUSPELMO 4.4.3 show that the active substance pyraclostrobin is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses in spring and winter cereals.

For the soil metabolites BF 500-6 and BF 500-7 concentrations of ≥ 0.1 µg/L in groundwater can be excluded.

Consequences for authorization:

none

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

The input parameters for pyraclostrobin 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 5.7-2.

Table 5.7-2 Input parameters for pyraclostrobin used for PEC_{GW} calculations with EXPOSIT 3.01

Parameter	pyraclostrobin	Reference to Part B, Section 5, Core assessment
$K_{foc, Runoff}$	9304	see Table 5.4.6 core assessment
$K_{foc, mobility class}$	9304	see Table 5.4.6 core assessment
DT_{50} soil (d)	37	see Table 5.4 4 core assesment (SFO, maximum, field studies,)
Solubility in water (mg/L)	1.9	see Table 5.3.2 core assessment
Mobility class	1	-
Reduction by bank filtration	100 %	-

The calculated PECgw for pyraclostrobin after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-3.

Table 5.7-3 PEC_{gw} for pyraclostrobin after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		pyraclostrobin			
Use No.	**application rate, minimum application interval, interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001 to 00-010	2 x 250 g ai ha^{-1}, 21 d, 2 x 50 %	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 modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance pyraclostrobin due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites

The soil metabolites BF 500-6 and BF 500-7 of pyraclostrobin are formed > 10 % in soil (see Part B core assessment, Section 5, Table 5.3-3). Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be considered. However, the high sorption values of the two soil metabolites BF 500-6 and BF 500-7 show that they are non-mobile in soil (see section 5.4.2 of the core assessment). A groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites BF 500-6 and BF 500-7 due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can thus be excluded.

Consequences for authorization:

The authorization of the plant protection product BAS 500 06 F is linked with following labeling:
none

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

No additional data for national assessment submitted.

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).

KIIIA1 9 Fate and Behaviour in the Environment

KIIIA1 9.6. Stein and Maassen, 2012

Author	**Stein C. and Maassen K.**
Title:	Predicted environmental concentrations in soil, groundwater and surface water of BAS 500 F - Pyraclostrobin following application to cereals in Germany
Report No:	BASF DocID 2012/1022012
Date:	2012

PEC calculations were performed by Germany. The study by Stein and Maassen is used as information only.

Appendix 3 Table of Intended Uses in Germany (according to BVL 04.09.2012)

PPP (product name/code) **BAS 500 06 F** **Formulation type:** **EC**
active substance 1 **pyraclostrobin** **Conc. of as 1:** **200 g L^{-1}**

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		
00-001	DE	**Wheat (TRZSS)**	F	*Puccinia recondite* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-002	DE	**Wheat (TRZSS)**	F	*Puccinia striiformis* (PUCCST)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-003	DE	**Wheat (TRZSS)**	F	*Drechslera tritici-repentis* (PYRNTR)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-004	DE	**Barley (HORVX)**	F	*Pyrenophora teres* (PYRNTE)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

00-005	DE	**Barley (HORVX)**	F	*Rhynchosporium secalis* (RHYNSE_1)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-006	DE	**Barley (HORVX)**	F	*Puccinia hordei* (PUCCHD)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-007	DE	**Barley (HORVX)**	F	decrease of non-parasitic leaf spots (YBFMI)	spraying	32-61 (at starting of infestation , first symptoms visible)	a) 1 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-008	DE	**Rye (SECCE)**	F	*Rhynchosporium secalis* (RHYNSE_1	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-009	DE	**Rye (SECCE)**	F	*Puccinia recondita* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-010	DE	**Triticale (TTLSS)**	F	*Puccinia recondita* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

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Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **BAS 500 06 F**
Active Substance: **Pyraclostrobin 200 g/L**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT

Applicant: **BASF**
Date: **2014-10-31**

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Sec 6 ECOTOXICOLOGICAL STUDIES

This document reviews the ecotoxicological studies for the product BAS 500 06 F containing the active substance pyraclostrobin, which is 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. See also Commission Directive 2004/30/EC and 2009/25/EC.

BAS 500 06 F was not the representative formulation considered in the EU review process as part of the approval of the pyraclostrobin.

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.

Where appropriate, this document refers to the key document from the EU review of pyraclostrobin (SANCO/1420/2001 final; Monograph 12945/ECCO/BBA/01, August 2001), especially when data on the active substance is relied upon in the risk assessment of the formulation. Each section will begin with a table providing the EU endpoints used in this evaluation.

Appendix 2 of this document contains the list of references included in this document in support of the evaluation.

Appendix 3 of this document reports the detailed evaluation of studies relied upon.

Appendix 4 of this document is the table of intended uses for BAS 500 06 F.

Information on the detailed composition of BAS 500 06 F 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 BAS 500 06 F containing the active substance Pyraclostrobin 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 summarized below. Moreover, an overview of the metabolites of pyraclostrobin 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 (see also Section 5). It has been selected from the individual GAPs in the zone for cereals (winter and spring wheat, winter and spring barley, rye, oat). A list of all intended uses within the zone is given in Appendix 3.

Table 6.1-1: Critical use pattern of BAS 500 06 F

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 to 00-010	Cereals (winter and spring) / BBCH 25-69	Spray	2 x, 21 d, 01.07 2 x 50	2 x 250 = 500	2 x 125 = 250

6.1.2 Consideration of metabolites

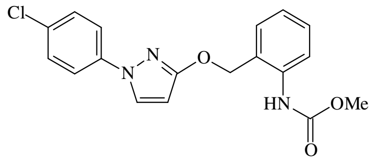
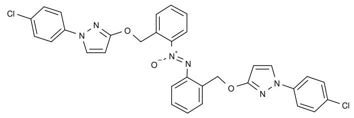
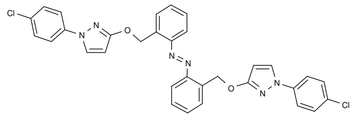
The occurrence and risk from potentially ecotoxicologically relevant metabolites have been considered in the EU review of pyraclostrobin.

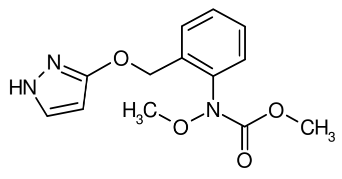
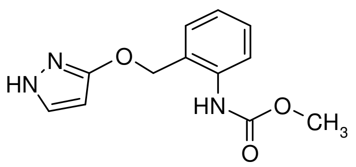
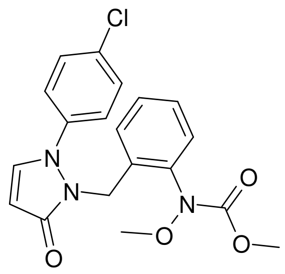
The metabolites summarized in Table 6.1-2 have been regarded as ecotoxicologically not relevant. Therefore the metabolites of pyraclostrobin will not be considered further in this core assessment.

Further information is provided and in Part B, Section 5. Environmental occurring metabolites of pyraclostrobin requiring further assessment according to the results of the assessment of pyraclostrobin for EU approval are summarized in Table 6.1-2.

Table 6.1-2: Metabolites of pyraclostrobin 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)

Metabolit	Structural formula/ Molecular formula	Molecular weight (g mol^{-1})	occurence in compartements (Max. at day)	Status of Relevance (SANCO/1420/2001–08/09/2004)

BF 500-3 (500M07)	 $C_{19}H_{18}ClN_3O_4$	357.80	Sediment: Max. 66 % at day 14	Aquatic organisms: Water: not relevant Sediment: not relevant Terrestrial organisms: : not applicable Groundwater: not relevant (Step 2)[1)]
BF 500-6 (500M01)	 $C_{32}H_{24}Cl_2N_6O_3$	611.5	Soil: Max. 30.9 % at day 120 Sediment: 2 x > 5%	Aquatic organisms: Water: not applicable Sediment: not relevant Terrestrial organisms: : not relevant Groundwater: not relevant (Step 1)[1)]
BF 500-7 (500M02)	 $C_{32}H_{24}Cl_2N_6O_2$	595.49	Soil: Max 12.5 % at day 62	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]

BF 500-11 (500M60)	 $C_{13}H_{15}N_3O_4$	277.28	Water: Max. 16.3%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]
BF 500-13 (500M62)	 $C_{12}H_{13}N_3O_3$	247.26	Water: Max. 15.7%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]
BF 500-14 (500M76)	 $C_{19}H_{18}ClN_3O_4$	387.82	Water: Max. 11.4%	Aquatic organisms: Water: not relevant Sediment: not applicable Terrestrial organisms: : not applicable Groundwater: not relevant (Step 1)[1)]

[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)

6.2 Effects on Birds

6.2.1 Overview and summary

Avian acute oral and long-term reproduction studies have been carried out with pyraclostrobin. Full details of avian toxicity studies are provided in the respective EU DAR as well as in Appendix 2 of this document (new studies). The studies with the relevant acute and long-term endpoints were agreed during EU review process and are used for the risk assessment.

Effects on birds of BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. However, the provision of further data on the formulation BAS 500 06 F is not considered essential as the available data on pyraclostrobin are deemed to be sufficient to assess the risk of birds exposed to BAS 500 06 F. However an acute study with the formulation is available.

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 Pyraclostrobin /BAS 500 06 F to birds with reference to agreed endpoints

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**	**ICS-No.**
Colinus virgianus	Pyraclostrobin	Acute	LD50 > 2000 mg a.s./kg bw/d [1]	[redacted] 1997 11W0494/96117	42114
Colinus virgianus	Pyraclostrobin	Long-term	NOEL = 105 mg a.s./kg bw/d [1]*	[redacted] 1999 147-175	42117
Colinus virgianus	BAS 500 06 F	Acute	LD50 > 2000 mg/kg bw/d [2]	[redacted] 2008 11W0023/065067	79478

* Daily Dose [mg/kg b.w./day] calculated based on study data for food consumption and body weight.

1) Review report for the active substance Pyraclostrobin, SANCO/1420/2001-final

2) New study submitted by the applicant

As indicated above, an acute oral study with the formulated product has been conducted. Results give no evidence for a higher toxicity of the product compared to the active substance. Therefore for risk assessment the endpoint provided by the study with pyraclostrobin is used. No long-term study is available. Consequently, the long-term toxicity of BAS 500 06 F has been assessed considering data generated on the individual active substance.

6.2.1.2 Exposure

BAS 500 06 F is an fungicide formulation containing pyraclostrobin as active substances. The product is an EC formulation. It will be used in cereals. The active substance inhibits the spore germination and controls mycelium growth and sporulation. Pyraclstrobin has a translaminar and a local-systemic action. The stage of spore germination is particulary sensitive to pyraclostrobin.

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.

6.2.1.3 Risk Assessment –overall conclusions

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
pyraclostrobin / BAS 500 06 F	Screening	Small omnivorous bird	Acute	>45.8	10
	Screening	Small omnivorous bird	Long-term	10.2	5

Based on the presumptions of the screening step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds to the active substance pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 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 pyraclostrobin 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 BAS 500 06 F 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):

$$DDD_{\text{single application}} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^{1}$$

[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):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The resulting TER_A values are summarised in the following table,a long 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
pyraclostrobin	Small omnivorous bird	0.25	158.8	1.1	43.67	>2000	>45.8
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 birds to the active substance pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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.

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 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):

$$TER_{LT} = \frac{\text{NOEL (mg/kg bw/day)}}{\text{Long-term DDD (mg/kg bw/day)}}$$

The relevant lowest NOEL for the reproduction exposure scenario for pyraclostrobin is 105 mg a.s./kg bw/d. Full details of the avian toxicity studies are provided in the respective EU DAR. The relevant long-term endpoint a long with the indicator species and the respective shortcut values are provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for birds exposed to pyraclostrobin following applications of BAS 500 06 F.

Table 6.2-4: Long-term screening risk assessment (TER_{LT}) for birds exposed to BAS 500 06 F 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}
pyraclostrobin	Small omnivorous bird	0.25	64.8	0.53	1.2	10.3	105	10.2
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 pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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.

6.2.3 Drinking water exposure

In case of uses as intend for BAS 500 06 F 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 pyraclostrobin formed on a field after rainfall. The ratios do not exceed the value of 3000 for pyraclostrobin (Koc = 6000 - 16000 L/kg), thus it is not necessary to conduct a drinking water risk assessment for birds.

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

BAS 500 06 F 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

BAS 500 06 F is not formulated as pellets, granules, prills or treated seeds. BAS 500 06 F 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 pyraclostrobin / BAS 500 06 F to birds and the outcome of the risk assessment for birds.

6.2.6 Metabolites

The desmethyl metabolite (500M07, 240266, BF 500-3) was found in grapes (BASF DocIDs 1998/10988 and 2000/1000201), potatoes (BASF DocIDs 1999/11419 and 2000/1000048) and wheat (BASF DocID 1999/11137). This metabolite was also detectable in rats (BASF DocID 1999/11781), goats (BASF DocIDs 2000/1000004) and hens (BASF DocID 1999/11480). It is assumed that the avian toxicity studies with pyraclostrobin cover this major metabolite and that the risk assessment for pyraclostrobin provided in the following chapters covers the potential risk from this metabolite.

6.2.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of BAS 500 06 F 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)

BAS 500 06 F 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 pyraclostrobin is 3.99, this active substance is 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 for bird through secondary poisoning is based on the evaluation of an earthworm eating birds (100 g bw, food intake rate, FIR = 104.6 g fresh weight /d). The calculation is performed for the worst case intended use in cereals with the maximal soil relevant amount of the formulation BAS 500 06 F.

Table 6.2-5: Assessement of the risk for earthworm eating birds from an exposure to pyraclostrobin through secondary poisoning

Parameter	pyraclostrobin	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.2311	See section 5, chapter 5.5 of the CA

K_{ow}	9772	log Pow = 3,99
K_{oc}	9304	arithmetic mean
F_{oc}	0.02	default
BCF_{worm}	0.635	BCF-worm = (PEC-worm / PEC-soil) = (0.84 + 0.012 × Kow) / (foc × Koc)
PEC_{worm}	0.147	PEC-worm = PEC-soil × BCF-worm
Daily dietara dose (mg/kg bw/d)	0.154	DDD = PEC-worm × 1.05
NOEL (mg/kg bw/d)	105	mg/kg KGW, *Colinus virginianus*
TER_{lt}	681.8	≥ 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 6.2-6: Assessement of the risk for fish eating birds from an exposure from an exposure to pyraclostrobinthrough secondary poisoning

Parameter	**pyraclostrobin**	**comments**
PEC_{sw} (twa = 21 d) [mg/L]	0.001090	See section 5, chapter 5.6 of the CA
BCF_{fish}	736	*Oncorhynchus mykiss*
PEC_{fish}	0.802	PECfish = PECwater x BCFfish
Daily dietara dose (mg/kg bw/d)	Appendix 1 0.128	DDD = PECfish x 0.159
NOEL (mg/kg bw/d)	105	mg/kg KGW, Colinus virginianus
TER_{lt}	823.2	≥ 5, acceptable risk

Based on the calculation of the risk arising from secondary poisoning , the calculated TER values for birds exposed to the active substance pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 Pyraclostrobin /BAS 500 06 F to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	Pyraclostrobin	Acute oral toxicity	LD50 >5000 mg a.i./kg bw/d [1]	[redacted] 1998 10A0183/961058	71557
Rat	Pyraclostrobin	Long-term toxicity and reproduction	NOAEC = 75 mg a.s./kg diet NOAEL = 8.2 mg a.s./kg bw/day [1] * (reproduction)	[redacted] 1999 70R0494/96172	71500
Rabbit	Pyraclostrobin	Long-term toxicity and reproduction	NOAEL = 3 mg a.s./kg bw/d [1] (maternal toxicity) NOAEL = 5 mg a.s./kg bw/d [1] (developmental toxicicty)	[redacted] 1999 1999/11512	75704
Rat	BAS 500 06 F	Acute oral toxicity	LD50 >= 500 mg/kg bw/d [2] **	[redacted] 2008 10A0023/061140	79313

* The Review Report for the active substance Pyraclostrobin (SANCO/1420/2001-final) does not provide a long-term endpoint for the terrestrial vertebrate risk assessment. Therefore, according to SANCO/4145/2000 the two-generation reproduction study in rats is chosen to derive the relevant toxicity values. This study covers the entire life-cycle and therefore is seen as the most appropriate study type for the wild mammal long-term risk assessment.

** Two animal groups were tested at 500 mg/kg bw with 3 animals each. All rats survived in the first group while 2 of 3 rats died in the second group. At the next concentration level of 2000 mg/kg bw all animals died.

1) Review report for the active substance Pyraclostrobin, SANCO/1420/2001-final

2) New study submitted by the applicant

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.

6.3.1.2 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 BAS 500 06 F in the intended uses

Substance	Risk assessment level	Indicator mammal	Time scale	TER	TER trigger
pyraclostrobin	Screening	Small herbivorous mammal	Acute	>153.6	10
	Screening	Small herbivorous mammal	Long-term	**0.39**	5
	Tier 2	Small omnivorous mammal “mouse”	Long-term	6.6	5
	Tier 2	Small insectivorous mammal "shrew"	Long-term	27.3	5
	Tier 2	Small omnivorous mammal “mouse”	Long-term	13.2	5
	Tier 2	Small herbivorous mammal "vole“	Long-term	2.4	2*
	Tier 2	Small omnivorous mammal “mouse”	Long-term	22.2	5
BAS 500 06 F	Tier 1	Small omnivorous mammal “mouse”	Acute	21.14	10
	Tier 1	Small insectivorous mammal "shrew"	Acute	67.29	10
	Tier 1	Small omnivorous mammal “mouse”	Acute	69.93	10
	Tier 2	Small herbivorous mammal "vole“Small granivorous mammal	Acute	8.89	5*
	Tier 1	Small omnivorous mammal “mouse” Small granivorous mammal	Acute	42.26	10
	Tier 1	Small omnivorous mammal “mouse”	Acute	42.26	10

*modified acceptability criterion (see below)

Based on the presumptions of the screening step and Tier 1 assessment for acute risk and higher Tier risk assessment for the long-term risk , the calculated TER values from an exposure of mammals to the active substance pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 pyraclostrobin 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.

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1.

Since a study with mammals conducted with the product BAS 500 06 F is also available, which delivers a lower endpoint than the study with the active substance, risk assessment is also performed with this endpoint.

The resulting TER_A values are summarised in the following table,a long with the indicator species and the respective shortcut values .

Table 6.3-3: Acute screening risk assessment (TER_A) 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
pyraclostrobin	Small herbivorous mammal	0.250	118.4	1.1	32.56	>5000	>153.6
BAS 500 06 F	Small herbivorous mammal	1.25	118.4	1.1	168.8	>500	>3

Based on the highly conservative presumptions of the screening step, the calculated TER values based on the endpoint from a study conducted with the active substance exceed the trigger value. However TER calculations using the endpoint from the study with formulated product are below the trigger and need further refinement.

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 6.3-4: Mammal generic focal species for the inteded uses of BAS 500 06 F in cereals (BBCH 25 – 69) and relevant shortcut values for acute risk assessment

Crop Growth Stage	Generic focal species	Shortcut value
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	17.2
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	5.4
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse”	5.2
Cereals BBCH ≥ 40	Small herbivorous mammal "vole“	40.9

Cereals BBCH ≥ 40	Small omnivorous mammal “mouse”	8.6

The outcome of the Tier 1 risk assessment step is presented in the following table:

Table 6.3-5: Acute mammal risk assessment of BAS 500 06 F uses in cereals (Tier 1)

Substance	Generic Focal Species	Application Rate (kg prep./ha)	MAF	Short cut Value	PT value	DDD (mg a.s./kg bw/d)	LD_{50} (mg prep./ kg bw/d)	TER
BAS 500 06 F	Small omnivorous mammal “mouse”	1.25	1.1	17.2	1	23.65	>500	21.14
	Small insectivorous mammal "shrew"			5.4	1	7.43		67.29
	Small omnivorous mammal “mouse”			5.2	1	7.15		69.93
	Small herbivorous mammal "vole“			40.9	1	56.24		**8.89**
	Small omnivorous mammal “mouse”			8.6	1	11.83		42.26

Based on refined Tier 1 assessment step, the calculated TER values for the acute risk resulting from an exposure of mammals to pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 for all the scenarios but the small herbivorous mammal “vole”. This scenario need refinement.

Please note: The notifier calculated the actue TER based on the LD_{50} of > 5000 mg a.s./kg bw/d instead the lower (worst case) value, which is used by the zRMS. Therfore the TER values calculated by the notifier are above the trigger of 10 for all scenarios. That is why the notifier provided no refinement options.

Refinement (Tier 2)

In cases where the relevant model species for assessment of the risk from the intended uses of pyraclostrobin is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europes' central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures). Therfore TER value (8.89) for the small herbivorous mammal scenario is above the modified trigger of 5 and thus acceptable. Please not that this is a German approach. Member States will need to satisfy themselves that this approach is relevant to their own conditions.

Therefore also the small herbivorous mammal “vole” is above the (modified) trigger value of 5. The results of the assessment indicate an acceptable risk for mammals due to the intended use of BAS 500 06 F 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 peformed.

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)) 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.

For the screening and Tier 1 assessment the relevant lowest NOEL for the reproduction exposure scenario for pyraclostrobin is the one from the developmental rabbit study, 3 mg a.s./kg bw/d based on the proposal of the notifier. Full details of the toxicity studies are provided in the respective EU DAR. The relevant long-term endpoint a long with the indicator species and the respective shortcut values are provided in the following table as well as calculated long-term toxicity exposure ratios (TER_{LT}) for mammals exposed to pyraclostrobin following applications of BAS 500 06 F.

Table 6.3-6: Long-term screening risk assessment (TER_{LT}) for mammals exposed to BAS 500 06 F according to the intended uses

Substance	Indicator bird	Applicationrate (kg a.s./ha)	Shortcut value (long-term)	f_{TWA}	MAF	DDD (mg/kg bw/day)	NOEL (mg a.s./kg bw/day)	TER_{LT}
pyraclostrobin	Small herbivorous mammal	0.250	48.3	0.53	1.2	7.68	3	**0.39**
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 mammals to the active substance pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 BAS 500 06 F 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 inteded uses of BAS 500 06 F in cereals (BBCH 25 – 69) and relevant shortcut values for long-term risk assessment

Crop Growth Stage	Generic focal species	Shortcut value
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9
Cereals BBCH 30 - 39	Small omnivorous mammal “mouse”	3.9
Cereals BBCH ≥ 40	Small herbivorous mammal "vole“	21.7
Cereals BBCH ≥ 40	Small omnivorous mammal “mouse”	2.3

The outcome of the Tier 1 risk assessment step is presented in the following table:

The outcome of the Tier 2 risk assessment after refinement of ecotoxicological endpoint is presented in the following table:

Table 6.3-8: Reproductive mammal risk assessment of BAS 500 06 F uses in cereals (Tier 2)

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
pyraclostobin	Small omnivorous mammal “mouse”	0.250	1.2 x 0.53	7.8	1	1.24	8.2	6.6
	Small insectivorous mammal "shrew"			1.9	1	0.30		27.3
	Small omnivorous mammal “mouse”			3.9	1	0.62		13.2
	Small herbivorous mammal "vole“			21.7	1	3.45		**2.4**
	Small omnivorous mammal “mouse”			2.3	1	0.37		22.2

Based on refined Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 for the scenarios Small omnivorous mammal “mouse”, Small insectivorous mammal "shrew", Small omnivorous mammal “mouse” and Small omnivorous mammal “mouse”. The TER values for the small herbivorous mammal scenario are below the trigger and need refinement.

In cases where the relevant model species for assessment of the risk from the intended uses of pyraclostrobin is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europes' central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, a TER ≥ 5 in the acute exposure scenario and a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures). Therfore TER value (2.4) for the small herbivorous mammal scenario is above the modified trigger of 2 and thus acceptable. Please not that this is a German approach. Member States will need to satisfy themselves that this approach is relevant to their own conditions.

Therefore also the small herbivorous mammal “vole” is above the (modified) trigger value of 2. The results of the assessment indicate an acceptable risk for mammals due to the intended use of BAS 500 06 F in cereals according to the label.

Pleas note: Further refinement options were submitted by the notifier. These are added here as additional information only. The refinements have not been checked by the zRMS. MS have to check if the refinement options are in line with their own conditions, if they do not agree with German refinement approach (see above).

Refinement options by the notifier (not checked by zRMS):

Residue decline in green plant material

The default DT_{50} of 10 days can be refined based on BASF own residue data, which confirm a mean DT_{50} in green plant material of 4.9 days (see Table 10.3.1.3-2).

Table 6.3-9: Foliar half life (DT_{50}) of pyraclostrobin based on residue trials in green cabbage, lettuce and leek

Crop	Pyraclostrobin DT_{50} [d]	Reference
green cabbage (curly cale)	5.6	2002/1004264
lettuce	1.9	2002/1004265
leek	7.2	2002/1004266
Mean	**4.9**	

Taking into account a DT_{50} of 4.9 days and the spray interval of 21 days, this results in a refined $\mathbf{f_{twa}}$ of **0.32** for pyraclostrobin. Accordingly, based on 2 applications with a spray interval of 21 days and a DT_{50} of 4.9 days the refined **MAF** is **1.05**.

Small omnivorous mammal "mouse"
The default indicator species of the small omnivorous mammal "mouse" scenario, represented by the wood mouse (*Apodemus sylvaticus*), is also considered in the higher tier assessment.

Small herbivorous mammal "vole"
Considering the ecological characteristics of vole populations in agricultural landscapes ([see 2011/1248329 Anonymous 2011 b], [see 2004/1025715 Pedall I.,Riffel M. 2004 a]), this generic focal species is not further assessed in a higher tier risk assessment. Arable crops do not constitute the common vole's primary habitat. Furthermore, common vole populations naturally display cyclical changes, and a strong ability to recover from decimation, contributing to its pest status in European countries. The notifier suggests that the small herbivorous mammal scenario is covered by another rodent, the omnivorous wood mouse (*Apodemus sylvaticus* L.). For the detailed argumentation on the relevance of common voles in arable crops please refer to document with BASF DocID 2011/1248329.

The refined risk assessment for pyraclostrobin applied as BAS 500 06 F in cereals will be carried out for two species representative of herbivorous (hare, *Lepus europaeus*) and omnivorous (wood mouse, *Apodemus sylvaticus*) mammals using cereals fields as foraging grounds.

Wood mouse

Fraction of food type in the diet (PD)
The wood mouse is known to be an opportunistic feeder adapted to utilise and exploit various food resources. The default diet (25% weeds 50% weed seeds 25% ground arthropods) according to EFSA/2009/1438 used in the tier 1 calculations above can be refined by data from scientific literature. Most suitable data to conclude on the diet composition of the wood mouse in arable land, especially cereal fields, are found in Green (1979) and Pelz (1989). The data also allow deducing proportions of the different feed items (PD) for the calendar months April to June corresponding to the growth stages BBCH 25 - 69 in cereals, the period when the product BAS 500 06 F is intended to be applied. For details of this evaluation please refer to Appendix 3.

The following PD values for the wood mouse in cereals are derived from the evaluation:
- Green plant matter PD = 0.107
- Weed seeds PD = 0.551
- Arthropods PD = 0.187
- Earthworms PD = 0.154

These PD values will be used for the calculation of the Food Intake Rate as summarized in Table 10.3.1.3-4.

Proportion of diet obtained from the treated area (PT)
PT values for the wood mouse (*Apodemus sylvaticus*) are proposed based on results of a generic radio-tracking study conducted in cereal fields with the specific purpose of deriving qualitative and quantitative information on foraging ecology of wood mice in arable crops to conduct refined risk assessments for wild mammals. The PT values proposed here are taken from the study of Barfknecht (2006, BASF DocID 2007/1042674, for study summary see Chapter 10.10).

The comprehensive field study by Barfknecht (2006) was conducted in and around 4 different winter cereal fields in the region of Thale, Sachsen-Anhalt, Germany. This region is a typical area of cereal cultivation (wheat and barley) in Europe. The field work started when most of the seedlings were in BBCH principal growth stage 2 (tillering) with a height of approximately 10 - 15 cm. Individual wood mice were radio-tracked continuously from dusk till dawn. From the telemetry data the portion of time/potential foraging time in cereal fields, the habitat preference (Jacob's index) and individual home ranges were calculated.
For evaluation and reporting the results were related to three BBCH groups: BBCH group 1 comprised early post-emergence and tillering stages (BBCH principal growth stages 1-2), BBCH group 2 included stem elongation and flowering (BBCH principal growth stages 3 - 6), and BBCH group 3 combined fruiting and ripening stages until just before harvest (BBCH principal growth stages 7 - 9).
The mean PT value for the wood mouse referring to BBCH stages defined in this report as group 2 (comprising radio-tracking results from BBCH 25 - 69 in cereals, and thus being relevant for the proposed use pattern for BAS 500 06 F) is PT = 0.88 (n = 12). Nevertheless, the default PT of 1 is sufficient to demonstrate an acceptable risk (see below) and hence PT = 1 will be used for the refined reproductive risk assessment presented in this document.

Calculation of Food Intake Rate (FIR/b.w.) for the focal species

The FIR/b.w. values for the focal species are calculated following EFSA/2009/1438 (Appendix G - Calculating exposure for the dietary intake approach).
First, based on $PD_{i,fresh}$ (the diet composition in fresh weight) and considering energy content, moisture content and assimilation efficiency the $FE_{total,\ fresh}$ can be calculated according to the following formula:

$$FE_{total,fresh} = \sum_i \left[PD_{i,fresh} \times FE_i \times \left(1 - \frac{MC_i}{100}\right) \times \frac{AE_i}{100} \right]$$

In which:

$FE_{total,\ fresh}$ =	Food energy of total mixed diet [kJ/g fresh weight]
$PD_{i,\ fresh}$ =	Fraction of food item [i] in mixed diet [related to fresh weight]
FE_i =	Food energy of of food item [i] in mixed diet [kJ/g dry weight]
MC_i =	Moisture content of food item [i] in mixed diet [%]
AE_i =	Assimilation efficiency of food item [i] in mixed diet [%]

Second, using the calculated specific energy content of the mixed fresh diet ($FE_{total,\ fresh}$) the required amount of the mixed diet ($FIR_{total,\ fresh}$) to reach the DEE of the indicator species can be determined.

$$FIR_{total,fresh} = \frac{DEE}{FE_{total,fresh}}$$

Third, the FIR/b.w. value is calculated as the quotient of $FIR_{total,\ fresh}$ and the species' body weight.

$$FIR/b.w. = FIR_{total,\ fresh} / b.w.$$

The FIR/b.w. value for the hare and the wood mouse are shown below in Table 10.3.1.3-4.

Table 6.3-10: FIR/b.w. for the hare and the wood mouse

Food	PD_i fresh	FE_i [kJ/g dry weight]	AE_i / 100	MC_i	$FE_{total, fresh}$ [kJ/ g fresh weight]	DEE [kJ]	FIR_{total} fresh [g]	Body weight [g]	FIR/b.w.
Hare									
Grasses / cereal shoots	1.0	17.60	0.47	76.4	1.95	23633.44	1210.66	3800 [1)]	0.319
Wood mouse									
Grasses / cereal shoots	0.107	17.60	0.47	76.4	0.21	58.83		21.7 [1)]	
Weed seeds	0.551	21.70	0.84	9.9	9.05				
Arthropods	0.187	22.70	0.87	68.8	1.15				
Earthworms	0.154	19.40	0.87	84.3	0.41				
Sum	0.999				10.82		5.44		0.251

1 Bodyweight data according to EFSA/2009/1438

Refined reproductive risk assessment and TER calculations

b) Wood mouse

The refined reproductive risk assessment for the wood mouse is shown in Table 10.3.1.3-6.

Table 10.3.1.3-6 Refined reproductive risk assessment for the wood mouse

Food type	FIR/b.w.	PD	PT	RUD [mg a.s./kg]	MAF	Ftwa	DF	Use rate [kg a.s./ha]	DDD [mg a.s./kg b.w./d]
Grasses/ cereal shoots	0.251	0.107	1	54.2	1.05	0.32	1	0.25	0.122
Weed seeds	0.251	0.551	1	40.2	1.23	0.53	1	0.25	0.906
Arthropods (ground)	0.251	0.187	1	7.5	1.23	0.53	1	0.25	0.057
Earthworms	0.251	0.154	1	0.112	1	1	1	1	0.004
Sum DDD [mg a.s./kg b.w./d]									1.089
Toxicity endpoint [mg a.s./kg b.w./d]									8.2
TER									7.53

6.3.3 Drinking water exposure

In case of uses as intend for BAS 500 06 F 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 pyraclostrobin formed on a field after rainfall. The ratios do not exceed the value of 3000 for pyraclostrobin (Koc = 6000 - 16000 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 BAS 500 06 F.

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

Please refer to section 6.3.1 for an overview of the submitted data on the toxicity of pyraclostrobin / BAS 500 06 F to mammals and the outcome of the risk assessment for mammals.

6.3.6 Metabolites

The desmethyl metabolite (500M07, 240266, BF 500-3) was found in grapes (BASF DocIDs 1998/10988 and 2000/1000201), potatoes (BASF DocIDs 1999/11419 and 2000/1000048) and wheat (BASF DocID 1999/11137). This metabolite was also detectable in rats (BASF DocID 1999/11781), goats (BASF DocIDs 2000/1000004) and hens (BASF DocID 1999/11480). It is assumed that the mammalian toxicity studies with pyraclostrobin cover this major metabolite and that the risk assessment for pyraclostrobin provided in the following chapters covers the potential risk from this metabolite.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of BAS 500 06 F pose no unacceptable acute or long-term risks to mamamls, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

BAS 500 06 F 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 pyraclostrobin is 3.99, this active substance 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 BAS 500 06 F 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 in cereals with the maximal soil relevant amount of the formulation.

Table 6.3-11: Assessment of the risk for earthworm eating mammal from an exposure to pyraclostrobin through secondary poisoning

Parameter	pyraclostrobin	comments
PEC_{soil} (twa = 21 d) [mg/kg soil]	0.231	See section 5, chapter 5.5 of the CA
K_{ow}	9772	log Pow = 3,99
K_{oc}	9304	arithmetic mean
F_{oc}	0.02	default
BCF_{worm}	0.635	BCF-worm = (PEC-worm / PEC-soil) = (0.84 + 0.012 × Kow) / (foc × Koc)
PEC_{worm}	0.147	PEC-worm = PEC-soil × BCF-worm
Daily dietary dose (mg/kg bw/d)	0.188	DDD = PEC-worm × 1.28
NOEL (mg/kg bw/d)	3	rabbit
TER_{lt}	16.0	≥ 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 6.3-12: Assessement of the risk for fish eating mammal from an exposure to pyraclostrobin through secondary poisoning

Parameter	pyraclostrobin	comments
PEC_{sw} (twa = 21 d) [mg/L]	0.001090	See section 5, chapter 5.6 of the CA

BCF_{fish}	736	Oncorhynchus mykiss
PEC_{fish}	0.802	PEC-fish = PEC-sw × BCF-fish
Daily dietary dose (mg/kg bw/d)	0.114	DDD = PEC-fish × 0.142
NOEL (mg/kg bw/d)	3	rabbit
TER_{lt}	26.3	≥ 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 pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 pyraclostrobin are reported in the lists of endpoints of pyraclostrobin (SANCO/1420/2001– 08/09/2004) (see table below).

The applicant provides further studies on the risk for aquatic organisms with the formulation BAS 500 06 F. Detailed study summaries for the studies performed with the formulated product BAS 500 06 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 Pyraclostrobin and BAS 500 06 F with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity to fish					
O.mykiss	Pyraclostrobin	Acute	LC50 (96 h) = 0.00616 mg a.s./L [1]	[redacted] 1999 12F0494/965180	42119
Lepomis macrochirus	Pyraclostrobin	Acute	96 h LC_{50} = 0.0242 mg a.s./L [2]	[redacted] 1998 14F0494/965179	42120
Cyprinus carpio	Pyraclostrobin	Acute	96 h LC_{50} = 0.0177 mg a.s./L [2]	[redacted] 1998 11F0494/965178	42121
Pimephales promelas	Pyraclostrobin in BAS 500 00 F (Cabrio; Pyraclostrobin 250 EC)	Acute	96 h LC_{50} = 0.015 mg a.s./L [2]	[redacted] 1999 15F0185/975117	441846
Oryzias latipes		Acute	96 h LC_{50} = 0.0452 mg a.s./L [2]	[redacted] 1999 13F0185/975122	41847
Brachydanio rerio		Acute	96 h LC_{50} = 0.0569 mg a.s./L [2]	[redacted] 1999 17F0185/975120	41845
Leuciscus idus		Acute	96 h LC_{50} = 0.0192 mg a.s./L [2]	[redacted] 1999 10F0185/975121	41844
SSD, 7 fish species	Pyraclostrobin	Acute	**96 h HC_5 = 0.0059** a.s. mg/L		

O.mykiss	BF 500-11	Acute	LC50 (96 h) > 100 mg a.s./L [1]	[redacted] 1999 12F0251/995037	42122
O.mykiss	BF 500-13	Acute	LC50 (96 h) > 50 < 100 mg a.s./L [1]	[redacted] 1999 12F0252/995034	42123
O.mykiss	BF 500-14	Acute	LC50 (96 h) > 39.4 < 82.6 mg a.s./L [1]	[redacted] 1999 12F0249/995035	42107
O.mykiss	BAS 500 06 F	Acute	LC50 (96 h) = 0.046 mg/L[3]	[redacted] 2008 12F0023/065054	79310
Chronic toxicity to fish					
O.mykiss	Pyraclostrobin	Chronic, ELS	NOEC (98 d) = 0.00235 mg a.s./L [1]	[redacted] 1999 52F0494/965141	42109
L. macrochirus	Pyraclostrobin	Chronic, bioaccumulation	BCF = 736 (whole fish) [1]	[redacted] 1999 17015	71560
Acute toxicity to aquatic invertebrates					
D. magna	Pyraclostrobin	Acute	EC50 (48 h) = 0.0157 mg a.s./L[1]	Dohmen, G.P. 1999 35806	42111
D. magna	BF 500-11	Acute	EC50 (48 h) > 100 mg a.s./L[1]	Jatzek, J. 1999 99/0517/50/1	42112
D. magna	BF 500-13	Acute	EC50 (48 h) > 100 mg a.s./L[1]	Jatzek, J. 1999 99/0518/50/1	42113
D. magna	BF 500-14	Acute	EC50 (48 h) > 60.9 mg a.s./L[1]	Jatzek, J. 1999 99/0519/50/1	42095
D. magna	BAS 500 06 F	Acute	EC50 (48 h) = 0.065 mg/L[3]	Funk, M. 2004 181354	79305
Chronic toxicity to aquatic invertebrates					
D. magna	Pyraclostrobin	Chronic	NOEC (21 d) = 0.004 mg a.s./L[1]	Dohmen, G.P. 1999 35811	42096
Sediment dwellers					
C. riparius	Pyraclostrobin	Chronic	NOEC (28 d) = 0.04 mg a.s./L[1] (NOEC (28 d) = 0.12 mg/kg dry sediment) *	Dohmen, G.P. 2000 35966	42101
Toxicity to algae					

P. subcapitata	Pyraclostrobin	Acute	EyC50 (72 h) = 0.152 mg a.s./L[1] ErC50 (72 h) > 0.843 mg a.s./L[1]	Dohmen, G.P. 1999 35803	42097
S. subspicatus	BF 500-11	Acute	EyC50 (72 h) > 100 mg a.s./L[1] ErC50 (72 h) > 100 mg a.s./L[1]	Reuschenbach, P. 1999 99/0517/60/1	42098
S. subspicatus	BF 500-13	Acute	EyC50 (72 h) = 66 mg a.s./L[1] ErC50 (72 h) > 100 mg a.s./L[1]	Reuschenbach, P. 1999 99/0518/60/1	42099
S. subspicatus	BF 500-14	Acute	EyC50 (72 h) = 46.6 mg a.s./L[1] ErC50 (72 h) > 100 mg a.s./L[1]	Reuschenbach, P. 1999 99/0519/60/1	42100
S. subspicatus	BAS 500 06 F	Acute	EyC50 (72 h) = 2.4 mg a.s./L[3] ErC50 (72 h) = 14.2 mg a.s./L[3] NOEyC = 0.39 mg a.s./L	Hoffmann, F. 2008 300286	79304
Mesocosm					
Mesocosm, multiple endpoints (algae and invertebrates)	Pyraclostrobin	6 months	NOEC = 0.008 mg/L RAC = 0.008 mg/L **	Dohmen, G.P. 2000 35980	34573

* based on sediment concentration in spiked water study
** Study was performed with the solo-formulation BAS 500 00 F (containing 250 g Pyraclostrobin/L, nominally) using multiple applications.
1) Review report for the active substance Pyraclostrobin, SANCO/1420/2001-final
2) DAR Pyraclostrobin, 2001
3) New study submitted by the applicant

Pyraclostrobin is high toxic against fish. The mode of action of Pyraclostrobin is based on the inhibition of the mitochondrial respiration. Relevant for the effects observed is the excess of a threshold concentration. This threshold concentration is in the range of 5 µg a.s./L for the most sensitive species, *O. mykiss.* Both the acute fish test and the ELS study (98 d) conducted with *O. mykiss* lead to no mortality or any other relevant effects at concentrations of 4.5 µg as/L and 2.3 µg as/L, respectively. The dose-response curve is pretty steep. At a concentration of 10.1 µg a.s./L (factor 2.2 compared to NOEC/LC_0) in the acute study and at a concentration of 6.4 µg a.s./L (factor 2.8 compared to NOEC/LC_0) in the ELS study, a 100 % mortality was observed. Regarding the mode of action as well as the mentioned toxicity data, it is justifiable to waive a separate consideration of the risk due to long-term exposure.

As results from several fish studies are available, seven studies were used to calculate the HC5 of 5.9 µg a.s./L for fish. The value was calculated with the programme ETX 2.0. Due to a steep dose-response curve as well as test results from different fish families, which are similar regarding their sensitivity against the test substance, a reduction of the assessment factor to 20 is justifiable. Hence the HC5 for fish is relevant for the risk assessment of pyraclostrobin.

Studies performed with the formulated product BAS 500 06 F indicate no higher (or unexpected) toxicity than predicted based on the results of the active substance. Therefore, the risk assessment presented for the active substance also covers the risk to aquatic organisms following application of BAS 500 06 F according to the proposed uses.

6.4.1.2 Exposure

BAS 500 06 F is an EC formulation containing pyraclostrobin as active substances. The product is formulated as spray application. The applications are considered to take place at BBCH growth stage 25 - 69 with a minimum 21 days between applications. It will be used as fungiciede in cereals.

Aquatic organisms may be exposed to plant protection products as a result of emission from treated fields. When BAS 500 06 F is applied according to good agricultural practice, the active ingredients can reach surface waters unintentionally by spraydrift 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 2 x 250 g/ha. For details on the FOCUS modeling, see dRR CA Part B, Section 5.7.

The relevant global maximum FOCUS Step 1 and 2 PEC_{SW} for risk assessments covering all proposed use patterns are summarized in the following table. For refined risk assessments, the FOCUS Step 3 PECsw values for the different scenarios are presented in the table below, too.

Table 6.4-2: Summary of highest global maximum FOCUS surface water PEC_{SW} and PEC_{sed} values for active substance pyraclostrobin

Plant protection product:		BAS 500 06 F		
Use No evaluated		00-001 to 00-010		
Crop		cereals (winter/spring)		
Application method (-)		ground spray		
Growth stage at first application (BBCH)		25		
Crop interception		STEP 2: Average crop cover (50%) STEP 3: 2 x 50%		
Number of applications/intervall		2x, 21 d		
Application rate		2 x 250 g ai ha^{-1}		
Active Substance		pyraclostrobin		
FOCUS step	**Scenario/water body**	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**
		Actual, 0 h	**TWA, 21 d**	**Actual, 0 h**
STEP 1	-	17.03	7.92	1160.00
STEP 2	North / March -May	2.11	0.65	86.40
	South / March -May	2.11	1.09	158.07
STEP 3	D1ditch	1.499	0.727	9.369

FOCUS crop: cereals, winter	D1 stream	1.201	0.0512	0.855
	D2 ditch	1.388	0.221	3.611
	D2 stream	1.223	0.141	2.107
	D3 ditch	1.370	0.063	1.364
	D4 pond	0.0601	0.0426	0.664
	D4 stream	1.076	0.00347	0.0675
	D5 pond	0.0621	0.0393	0.589
	D5 stream	1.213	0.00733	0.130
	D6 ditch	1.382	0.279	3.557
	R1 pond	0.0571	0.0377	0.803
	R1 stream	0.897	0.0131	3.903
	R3 stream	1.265	0.0256	0.996
	R4 stream	0.898	0.0382	8.753
STEP 3 FOCUS crop: cereals, spring	D1 ditch	1.497	0.645	9.446
	D1 stream	1.201	0.0509	0.988
	D3 ditch	1.375	0.0951	1.694
	D4 pond	0.0533	0.0308	0.493
	D4 stream	1.171	0.0153	0.273
	D5 pond	0.0583	0.0350	0.515
	D5 stream	1.266	0.0233	0.464
	R4 stream	0.898	0.0402	4.984

6.4.1.3 Risk assessment –overall conclusions

Based on the HC_5 derived from seven fish studies (acute) with pyraclostrobin and on the FOCUS Step 3 PECsw, the TER_A values for pyraclostrobin are below the trigger value for several scenarios. This indicates that the active substance poses a risk to aquatic organisms following application of BAS 500 06 F at the proposed application rates. Further refinement is necessary.

TER values for the most sensitive aquatic organisms based on PEC_{SW} FOCUS calculations are summarized in the following table.

Table 6.4-3: Aquatic TER values for pyraclostrobin after applications of BAS 500 06 F.

Test organism	EC_{50}	FOCUS	Scenario	Max. PEC_{SW}	TER_A	Trigger

	NOE(AE)C (µg/L)	Step		worst case (µg/L)		value
pyraclostrobin						
Fish acute (HC_5)	HC_5 = 5.9	1	-	17.03	**0.3**	20
		2	N/S-EU, Mar.-May	2.11	**2.8**	
pyraclostrobin						
Fish acute (HC_5)	HC_5 = 5.9	3	D2 ditch*	1.388	**4.3**	20
		3	D2 stream*	1.223	**4.8**	
		3	D3 ditch*	1.37	**4.3**	
		3	R1 pond*	0.0571	103.3	
		3	R1 stream*	0.897	**6.6**	
TER-values in bold are below the relevant trigger						

* FOCUS scenarios relevant for the Central Zone are highlighted are listed only

6.4.2 Toxicity to Exposure ratio

The risk for aquatic organisms exposed to pyraclostrobin was assessed according to the intended uses.

In the table below, the TER values of the active substance relative to the most sensitive endpoint of each organisms' group are given.

Table 6.4-4: Aquatic organisms: PECsw for pyraclostrobin and relevant ecotoxicological endpoints for each organism' group.

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged	Mesocosm
		Oncorhynchus mykiss	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Chironomus riparius***	***Algae Invertebrates***
		HC_5 (µg/L) 5.9	**NOEC (µg/L) 2.35**	**EC_{50} (µg/L) 15.7**	**NOEC (µg/L) 4**	**E_bC_{50} (µg/L) 152**	**NOEC (µg/L) 40**	**NOEC (µg/L) 8**
FOCUS Step 1								
	17.03	0.3	0.1	0.9	0.2	8.9	2.3	0.5
FOCUS Step 2								
North Europe	2.11	2.8	1.1	7.4	1.9	72	19	3.8
South Europe	2.11	2.8	1.1	7.4	1.9	72	19	3.8
FOCUS Step 3								
D1ditch	1.499	3.9	1.6	10.5	2.7	101.4	26.7	5.3
D1 stream	1.201	4.9	2	13.1	3.3	126.6	33.3	6.7
D2 ditch*	1.388	4.3	1.7	11.3	2.9	109.5	28.8	5.8
D2 stream*	1.223	4.8	1.9	12.8	3.3	124.3	32.7	6.5
D3 ditch*	1.37	4.3	1.7	11.5	2.9	110.9	29.2	5.8
D4 pond	0.0601	98.2	39.1	261.2	66.6	2529.1	665.6	133.1
D4 stream	1.076	5.5	2.2	14.6	3.7	141.3	37.2	7.4
D5 pond	0.0621	95	37.8	252.8	64.4	2447.7	644.1	128.8
D5 stream	1.213	4.9	1.9	12.9	3.3	125.3	33	6.6
D6 ditch	1.382	4.3	1.7	11.4	2.9	110	28.9	5.8
R1 pond*	0.0571	103.3	41.2	275	70.1	2662	700.5	140.1

R1 stream*	0.897	6.6	2.6	17.5	4.5	169.5	44.6	8.9
R3 stream	1.265	4.7	1.9	12.4	3.2	120.2	31.6	6.3
R4 stream	0.898	6.6	2.6	17.5	4.5	169.3	44.5	8.9
D1 ditch	1.497	3.9	1.6	10.5	2.7	101.5	26.7	5.3
D1 stream	1.201	4.9	2	13.1	3.3	126.6	33.3	6.7
D3 ditch	1.375	4.3	1.7	11.4	2.9	110.5	29.1	5.8
D4 pond	0.0533	110.7	44.1	294.6	75	2851.8	750.5	150.1
D4 stream	1.171	5	2	13.4	3.4	129.8	34.2	6.8
D5 pond	0.0583	101.2	40.3	269.3	68.6	2607.2	686.1	137.2
D5 stream	1.266	4.7	1.9	12.4	3.2	120.1	31.6	6.3
R4 stream	0.898	6.6	2.6	17.5	4.5	169.3	44.5	8.9
TER criterion		20	10	100	10	10	10	1

* FOCUS scenarios relevant for the Central Zone are highlighted in bold

Based on the HC_5 derived from seven fish studies (acute) with pyraclostrobin (crucial for risk assessment) and on the FOCUS Step 3 PECsw, the calculated TER values for the acute from an exposure of aquatic organisms to pyraclostrobin according to the GAP of the formulation BAS 500 06 F does not achieve the acceptability criteria TER ≥ 20, 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 aquatic organisms due to the intended use of BAS 500 06 F in cereals according to the label. Therefore further refinement is necessary.

According to the results of the TER-values calculations based on $FOCUS_{SW}$ Step 3 PEC values for the intended use BAS 500 06 F, the implementation of management practices will be necessary to reduce the exposure of aquatic organisms to BAS 500 06 F. Management practices relevant for Germany are given in the respective Addendum.

General note: In public literature pyraclostrobin was demonstrated to be highly toxic to amphibians (http://www.nature.com/srep/2013/130124/srep01135/full/srep01135.html). Since test guideline for amphibians is not available at the moment respectively no specific risk assessment procedure for amphibians, it is not possible to perform a specific risk assessment, yet. Hence it might be possible that the current risk assessment (higher tier risk assessment for fish) is not enough conservative to protect amphibians. For the active substance pyraclostrobin the Renewal of Approval (AIR 3) procedure has already started on EU level (RMS: Germany). In this context also the risk to amphibians will be investigated as this is part of the future data requirements.

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 BAS 500 06 F on aquatic organisms. Section 6.4.2, page 35, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

6.4.4 Metabolites of pyraclostrobin

Please refer to section 6.1.2, page 6 for the assessment of the metabolites of pyraclostrobin 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 pyraclostrobin metabolites on aquatic organisms. Section 6.4.2, page 35, gives the details of the risk assessment for aquatic organisms on the basis of all available data.

Aquatic organisms may be exposed to residues of the metabolites BF 500-11, BF 500-13, BF 500-14 (see part B, section 5). According to risk assessment on EU level it can be concluded that the metabolites are not of ecological relevance with respect to aquatic organisms. Hence no additional risk assessment for the metabolites is conducted by the zRMS.

6.4.5 Accumulation in aquatic non-target organisms

A bioaccumulation study in fish has been performed with **pyraclostrobin**; for details see Monograph 12945/ECCO/BBA/01 (Vol. 3, B.9). An apparent steady state was reached after 2 - 4 days of exposure. The bioconcentration factors for whole fish were 379 - 507 (two labels). The half-life for elimination was 0.9 days. The time for elimination of 90% of the activity varied between 2.8 and 3.0 days. The nature of radioactivity in fish tissues after 28 days of exposure consisted of the parent substance (39% - 74%) and 4 metabolites (2% - 9%). Due to the limited bioaccumulation and the rapid metabolization and excretion of the active substance (and its metabolites), there is no risk of bioaccumulation. In addition pyraclostrobin dissipates rapidly in water prohibiting continuous exposure.

6.5 Effects on Bees

Effects on bees

Effects on bees of BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. Therefore, all relevant data and assessments are provided here and are considered adequate. EU agreed endpoints for the active substance pyraclostrobin (SANCO/1420/2001-final, Monograph 12945/ECCO/BBA/01) are used as further information.

Toxicity

Table 10.4-1 presents the results of laboratory bee toxicity studies with the formulation. Further details regarding the tests with the formulation are provided in section 10.4.2.

Table 10.4-1: Results of laboratory bee toxicity studies

Test substance	Exposure route	LD_{50}	Reference
BAS 500 06 F	oral 48 h	381.8 µg product/bee	Bocksch, 2004; 20041288/01-BLEU
	contact 48 h	368.2 µg product/bee	
pyraclostrobin tech.	oral 48 h	> 73.1 µg/bee *	Sack,1999 35842
	contact 48 h	> 100 µg/bee *	

* EU agreed endpoint

Exposure

The recommended use pattern for BAS 500 06 F includes application in cereals at a maximum application rate of up to 1.25 L/ha. This maximum single application rate is equivalent to 1305 g product/ha.

Bees may be exposed to 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.

6.5.1 Hazard quotients for bees

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 10.4-2 Hazard quotients for honeybees

Test substance	Max. single application rate [µg product/ha]	Exposure route	LD_{50} [µg product/bee]	Hazard quotient (HQ)	HQ trigger
BAS 500 06 F	1305	oral	381.8	3.4	50
		contact	368.2	3.5	

Risk assessment

Due to the results of laboratory tests BAS 500 06 F 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. Bee brood testing is not required since the test item is not an IGR.

Overall conclusion:

It is concluded that BAS 500 06 F will not adversely affect bees or bee colonies when used as recommended.

6.5.2 Acute toxicity of the formulation to bees

6.5.2.1 Oral

Refer to 6.5.1

6.5.2.2 Contact

Refer to 6.5.1

6.5.3 Effects on bees of residues on crops

Not required.

6.5.4 Cage tests

Not required.

6.5.5 Field tests

Not required.

6.5.6 Investigation into special effects

Not required.

6.5.6.1 Larval toxicity

Not required since the test item is not an IGR.

6.5.6.2 Long residual effects

Not required.

6.5.6.3 Disorienting effects on bees

Not required.

6.5.7 Tunnel tests

Not required.

6.6 Effects on Arthropods Other Than Bees

6.6.1 Overview and summary

Effects on arthropods other than bees for BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. Data on BAS 500 06 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 BAS 500 06 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. Since the data on the product BAS 500 06 F are most relevant for risk assessment, only these studies are summarized in the following tbale. For EU agreed endpoints please refer to EU review report for pyraclostrobin.

Table 6.6-1: Toxicity of pyraclostrobin / BAS 500 06 F to non-target arthropods with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Aphidius rhopalosiphi	BAS 500 06 F	laboratory glass plate , 2 D	LR50 = 40 mLprod./ha * [1]	Sipos, K. 2007 07/495-335FD	79354
Typhlodromus pyri	BAS 500 06 F	2 D glass plate	LR50 = 870 mL prod./ha * [1]	Sipos, K. 2007 07/495-335RA	79355
Aphidius rhopalosiphi	BAS 500 06 F	extended lab, 3D: barley plants, mortality and reproduction	LR50 > 2500 mL prod./ha [1] ER50 > 2500 mL prod./ha [1]	Stevens, J. 2008 300300	79454
Typhlodromus pyri	BAS 500 06 F	extended lab, 2D: bean leaves, mortality and reproduction	LR50 = 2452 mL prod./ha [1] ER50 > 2500 mL prod./ha [1]	Vaughan, R. 2008 300298	79457
Chrysoperla carnea	BAS 500 06 F	extended lab, 2D: bean leaves, mortality and reproduction	LR50 = 720 mL prod./ha [1] ER50 > 630 mL rod./ha [1]	Roehlig, U. 2008 08 10 48 030 A	79350
Chrysoperla carnea	BAS 500 06 F	Aged residue study; 3D: bean leaves, mortality and reproduction	0 DAT: LR50 > 1250 mL prod./ha [1] ** ER50 > 1250 mL prod./ha [1] ** No unacceptable effects on survival and reproduction on DAT 7 up to 2.5 L/ha	Roehlig, U. 2008 08 10 48 046 A	79351

Aleochara bilineata	BAS 500 06 F	extended lab, *2D: natural soil, Reproduction*	ER50 > 3750 mL prod./ha [1]	Schmitzer, S. 2008 41651071	79459

* not relevant for RA as tier II tests are available, therefore not validated

** results from bioassay with fresh residues are presented

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 BAS 500 06 F by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items.

BAS 500 06 F is applied at a maximum rate of 2 x 1.25 L/ha, considering a spay interval of 21 days.

The in-field exposure, given as predicted environmental rates, PER, for non-target arthropods resulting from the intended uses of BAS 500 06 F is calculated according to published agreement after ESCORT 2 workshop (Candolfi et al. 2001[1] -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 MAF values for given numbers of applications are listed in the Guidance Document. For leaf substrates a half-life : spray interval ratio of 2.3 : 1 is recommended to be used for the calculation of a MAF. For 2 applications, the default MAF of 1.7 (foliar) is used. As a pre-emergence or early post-emergence application is not foreseen according to the proposed use pattern, the PER (soil) will not be considered.

The maximum predicted environmental rate (PER) occurring in the field after application of BAS 500 06 F at the maximum application rate is presented in the following table.

Table 6.6-2: In-field predicted environmental rates (PER) for BAS 500 06 F in cereals

Substance	**Application rate (L Product/ha)**	**in-field PER (foliar) (L Product/ha)**

[1] 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.

BAS 500 06 F	e.g. 2 × 1.25	2.125

Off-field

Exposure of non-target arthropods living in non-target off-field areas to BAS 500 06 F 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[2]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\ in-field\ PER\ x\left({drift\ rate}\big/_{100} \right)}{vegetation\ distribution\ factor\ (vdf)}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here considers a dilution factor of 5 more appropriated. For endpoint resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used.

The drift rates are 2.38% and 0.47 % at 1m and 5 m, respectively, of the application rate (82nd percentile drift).

For the results of study with *T. pyri, A. bilineata* and *C. carnea* exposed to BAS 500 06 F, a vegetation distribution factor has to be considered (study conducted in 2D environment). Regarding the results of the study with *A. rhopalosiphi* exposed to BAS 500 06 F, 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 BAS 500 06 F

Study type	Max. rate (l Prod./ha)	MAF	Maximum in-field PER (l Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (l Prod./ha)

[2] 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.

3-dimensional	2 x 1.25	1.7	2.125	2.38%	1	0.05
2-dimensional	2 x 1.25	1.7	2.125	2.38%	5	0.01

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing a in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[3]) are given in the table below.

Table 6.6-4: Maximum off-field PER (predicted environmental rates) of BAS 500 06 F at increasing distances from the sprayed areas following intended uses

Study type	Maximum intended in-field rate	Maximum PERoff-field at 1m (2.38% drift)	Maximum PERoff-field at 5m (0.47% drift)
	(L BAS 500 06 F/ha)		
3 D	2.125	0.05	0.01
2 D	2.125	0.01	0.002

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to BAS 500 06 F is given in the table below.

Higher tier

Table 6.6-5: Acceptability criteria for higher tier data and minimal TER values for arthropod species other than bees after use of BAS 500 06 F

Test substance	Species	Test type	Endpoint L(E)R50 (L Prod./ha)	PER in-field (L Prod./ha)	effects <50% at calc. rate?	PER off-field (1 m) (L Prod./ha)	PER off-field x correction factor 5	effects <50% at calc. rate?	TER Off-field
BAS 500 06 F	*T. pyri*	ext Lab. 2D	LR50 = 2.45 ER50 > 2.5	2.125	yes	0.01	0.05	yes	245
	A. rhopalosiphi	ext Lab. 3D	LR50 > 2.5 ER50 > 2.5	2.125	yes	0.05	0.25	yes	>50

[3] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

	A. bilineata	ext Lab. 2D	ER50 > 3.75	2.125	yes	0.01	0.05	yes	>375
	C. carnea	ext Lab. 2D	LR50 = 0.72 ER50 > 0.63	2.125	no	0.01	0.05	yes	72
	C. carnea	Semi-field, 3D	LR/ER50 > 1.25	2.12	no	-	-	-	-

Based on the calculated rates of pyraclostrobin/BAS 500 06 F in in-field areas, the calculated HQ values describing the potential risk resulting from an exposure of non-target arthropods to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F does not achieve the acceptability criteria of less than 50% effects at calculated drift rates regarding the species *C. carnea* according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. For refinement the notifier submitted an aged residue study with *C. carnea* (Roehlig, U.; 2008;08 10 48 046). In this study, two application rates (1.25 and 2.5 L/ha) were tested. No unacceptable effects on survival and reproduction were observed at DAT 0 following application at 1.25 L/ha BAS 500 06 F and on DAT 7 following application at 2.5 L/ha BAS 500 06 F. This is higher than the maximum PERin-field of 2.125 L/ha. Therefore the aged residue study is suitable to release the effects on reproduction observed in the extended laboratory study with *C. carnea*.

Based on the calculated rates of pyraclostrobin/BAS 500 06 F in off-field areas, the calculated HQ and TER values describing the potential risk resulting from an exposure of non-target arthropods to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria regarding all species tested.

Regarding the in-field and off-field scenario the results indicate an acceptable risk.

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 BAS 500 06 F 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:

$$\text{In field HQ} = \frac{\text{In - field PER}}{\text{LR}_{50}}$$

The resulting HQ in-field values for the standard species are presented in the following table.

Table 6.6-6: Tier 1 in-field HQ values for non-target arthropods other than bees and acceptability criteria for Tier 1 data

Species	LR50 (L Product/ha)	PER (L Product/ha)	In-field HQ	Trigger value
Aphidius rhopalosiphi	0.04	2.125	53	2
Typhlodromus pyri	0.87		**2.4**	2
HQ values in bold are above the trigger				

Based on the calculated HQin-field of *T. pyri* and *A. rhopalosiphi*, a potential in-field risk to non-target arthropods cannot be excluded (HQ > 2) at this level of testing. According to ESCORT 2, higher tier studies with *T. pyri and A. rhopalosiphi* on natural substrate are required, as well as testing of one additional species. Besides the higher tier tests with *T. pyri and A. rhopalosiphi*, extended laboratory studies were carried out with the foliage-dweller *C. carnea* and the soil-dweller *A. bilineata*.

Higher Tier

The potential risk for non-target arthropods exposed in-field to BAS 500 06 F was assessed by comparing the environmental rate (PER in-field) to the lowest lethal rate (LR50) estimated in toxicity tests with non-target arthropods. With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % are considered acceptable, provided that the tests covered the appropriate field rate.

Table 6.6-7: Risk assessment for non-target arthropods other than bees and acceptability criteria for higher tier data

Species	L/ER50 (L Product/ha)	PER in-field (L Product/ha)	effects < 50% at calc. rate?
T. pyri, 2D exposure scenario, extended laboratory test	LR50 = 2.45 ER50 > 2.5	2.125	yes
A. rhopalosiphi, 3D exposure scenario, extended laboratory test	LR_{50} > 2.5 ER_{50} > 2.5	2.125	yes
A. bilineata, 2D exposure scenario, extended laboratory test	ER_{50} > 3.75	2.125	yes
C. carnea, 2D exposure scenario, extended laboratory test	LR_{50} = 0.72 ER_{50} > 0.63	2.125	no
C. carnea, 3D exposure scenario, Aged residue study; under semi field conditions	LR/ER_{50} > 1.25 L/ha	2.125	no

For *T. pyri*, *A. rhopalosiphi* and *A. bilineata* no effect of 50% under the foliar $PER_{in-field}$ was observed. However based on the extended laboratory study with *C. carnea* a potential in-field risk to non-target arthropods cannot be excluded. For refinement the notifier submitted an aged residue study with *C. carnea* (Roehlig, U.; 2008;08 10 48 046).

The aged residue study presents a more realistic exposure scenario, since the application was done on whole bean plants, representing a 3-dimensional structure, whereas the application in the extended laboratory study was done on detached leaves, representing a 2-dimensional structure. Further, application in this study was carried out under more realistic conditions, *i.e.* using field application techniques instead of laboratory sprayer and aging under rain protected outdoor conditions instead of laboratory conditions. In this study, two application rates (1.25 and 2.5 L/ha) were tested. No unacceptable effects on survival and reproduction were observed at DAT 0 following application at 1.25 L/ha BAS 500 06 F and on DAT 7 following application at 2.5 L/ha BAS 500 06 F. This is higher than the maximum $PER_{in-field}$ of 2.125 L/ha.

Therefore the aged residue study is suitable to release the effects on reproduction observed in the extended laboratory study with *C. carnea.*

The results indicate that BAS 500 06 F poses a 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 BAS 500 06 F 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.

<u>Tier 1</u>

Since higher Tier data are available, Tier 1 risk assessment is waived.

<u>Higher Tier</u>

With regard to extended laboratory tests and semi-field tests, lethal and sublethal effects of less than 50 % at the calculated deposition rates are considered acceptable provided that the tests covered the appropriate field rate.

Table 6.6-8: Acceptability criteria for higher tier non-target arthropods data

Species	Test type	L/ER50 (L product/ha)	PER in-field (L product/ha)	Distance (m)	PER off-field	PER off-field x correction factor (L product/ha)	effects <50% at calc. rate?
T. pyri	2 D extended lab	LR50 = 2.45 ER50 > 2.5	2.125	1	0.01	0.05	yes
				5	0.002	0.01	yes
A. rhopalosiphi	3 D extended lab	LR50 > 2.5 ER50 > 2.5		1	0.05	0.25	yes
				5	0.01	0.05	yes
A. bilineata	2 D extended lab	ER50 > 3.75		1	0.01	0.05	yes
				5	0.002	0.01	yes
C. carnea	2 D extended lab	LR50 = 0.72 ER50 > 0.63		1	0.01	0.05	yes
				5	0.002	0.01	yes

At the calculated deposition rates, the effects in the extended laboratory tests are lower than 50%, indicating that BAS 500 06 F does not pose an unacceptable risk to non-target arthropods in off-field areas. Refinement is not necessary.

TER approach

Additionally to the HQ-approach, the assessment of the risk to non-target arthropods due to an exposure to BAS 500 06 F 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.

Table 6.6-9: Calculated TER values for non-target arthropods exposed to BAS 500 06 F in off-field areas according to intended uses

Species	Test type	Correction factor	L/ER50 (L product/ha)	PER in-field (L product/ha)	Distance (m)	PERoff-field (L product/ha)	TER
Typhlodromus pyri	2 D	5	LR50 = 2.45 ER50 > 2.5	2.125	1	0.01	245
Aphidius rhopalosiphi	3 D	-	LR50 > 2.5 ER50 > 2.5		1	0.05	>50
A. bilineata	2 D	5	ER50 > 3.75	2.125	1	0.01	>375
C. carnea	2 D	5	LR50 = 0.72 ER50 > 0.63		1	0.01	72
TER values in bold are below the trigger							

Based on the calculated rates of pyraclostrobin/BAS 500 06 F in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria of TER ≥ 5, resp., 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 BAS 500 06 F 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 pyraclostrobin whenever contamination of soil may occur as a result of the intended uses of BAS 500 06 F.

Effects on earthworms and other soil non-target organisms resulting from an exposure to BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. All relevant study data for the assessment of the risk to earthworm and other soil non-target macro-and mesofauna from the inteded uses of BAS 500 06 F are provided here. New data are listed in Appendix 2 and summarized in Appendix 3 (new studies).

6.7.1.1 Toxicity

Table 6.7-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to pyraclostrobin and BAS 500 06 F with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.

Eisenia fetida	Pyraclostrobin	Acute 14 d, 10 % peat	LC50 = 566 mg a.s./kg soil dw[1] LC50, corr = 283 mg a.s./kg soil dw[1] Mortality	Krieg, W. 1999 35801	42103
Eisenia fetida	BF 500-6	Acute 14 d, 10 % peat	LC50 > 1000 mg/kg soil dw[1] Mortality	Krieg, W. 1999 35987	42104
Eisenia fetida	BF 500-7	Acute 14 d, 10 % peat	LC50 > 1000 mg/kg soil dw1 Mortality	Krieg, W. 1999 54484	42105
Eisenia fetida	BAS 500 06 F	Acute 14 d, 10 % peat	LC50 = 385.63 mg/kg soil dw [2] LC50, corr = 192.82 LC50 = 36.94 mg a.s./kg soil dw [2]	Fleischer, G. 2004 181351	79466
Eisenia fetida	BAS 500 06 F	Chronic 56 d, 5 % peat	NOEC = 30 mg/kg soil dw (21.55 L/ha) * NOEC = 5.75 mg a.s./kg soil dw [2] Reproduction	Lührs, U. 2008 41652022	79467
Eisenia fetida	BAS 500 06 F	Field study 12 months	NOEC = 8.33 mg/kg soil dw * [2]	Lührs, U. 2010 41654023	79477
Folsomia candida	BAS 500 06 F	Chronic 28 d, 5 % peat	NOEC = 125 mg/kg soil dw [2] NOEC = 24 mg a.s./kg soil dw [2] Reproduction	Friedrich, S. 2008 08 10 48 054S	79460
Organic matter breakdown (all organisms)	BAS 500 06 F	6 months, 1.25 L/ha, 0.333 mg a.s./kg dry soil *	- 0.1 % effect on mass loss [2]	Luehrs U. and Schabio S. 2010 41655081	79502

* Considering a soil depth of 5 cm and a bulk density of 1.5 g/cm³

1) Review report for the active substance Pyraclostrobin, SANCO/1420/2001-final

2) New study submitted by the applicant

Acute and chronic data on the product BAS 500 06 F are available and these endpoints are most relevant for risk assessment.

The log KOW value for Pyraclostrobin is above the agreed trigger value of 2. Therefore, 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, BAS 500 06 F is intended to be applied 2 times per season with a maximum application rate of 1.25 L BAS 500 06 F/ha (equivalent to 250 g pyraclostrobin/ha) assuming a 21 day application interval. It will be used in cereals.

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 pyraclostrobin. Calculations considered the maximum application rate of 1.25 L formulation/ha and a minimum of 50 % foliar interception for applications to cereals at BBCH growth stage 25 - 69. 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 pyraclostrobin was considered when necessary.

Table 6.7-2: Maximum predicted environmental concentrations in soil PEC_S[1)] for pyraclostrobin / BAS 500 06 F and following application in the intended use.

plant protection product:		BAS 500 06 F				
use:		00-001 to 00-010 cereals (winter/spring)				
Number of applications/intervall		2 x, 21 d				
application rate:		active substance pyraclostrobin: 250 g ai ha^{-1} preparation BAS 500 06 F: 1250 g ha^{-1}				
crop interception:		2 x 50				
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)**
active substance pyraclostrobin	2 x 125	0.2791	-	-	-	-
product BAS 500 06 F	2 x 625	1.4570	-	-	-	-

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

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 BAS 500 06 F according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
pyraclostrobin	2x 250 g pyraclostrobin/ha 2 x 1.25 L prod/ha	Acute	283	0.2791	1014	10
		Long-term	-		-	5
BAS 500 06 F		Acute	192.82	1.4570	132.3	10
		Long-term	30		20.6	5
Other soil meso-and macrofauna						
Collembola (*Folsomia candida*)						
BAS 500 06 F	2 x 1.25 L prod/ha	Long-term	125	1.4570	85.8	5
Organic matter breakdown (all organisms)						
BAS 500 06 F	2 x 1.25 L prod/ha	Long-term, 6 month	6 months, 1.25 L/ha, 0.333 mg a.s./kg dry soil ** - 0.1 % effect on mass loss	0.2791	n.a.	n.a.
TER values in bold are below the trigger						

** Considering a soil depth of 5 cm and a bulk density of 1.5 g/cm³

The application rate of 1.25 L BAS 500 06 F (250 g pyraclostrobin/ha) results in a soil concentration of pyraclostrobin of 0.333 mg/kg dry soil considering a soil depth of 5 cm and a default density of 1.5 g/cm³. The maximum PEC value of 0.2792 mg pyraclostrobin/kg dry soil is therefore covered. Therefore, the risk of BAS 500 06 F to soil-dwelling organism communities is considered to be low.

Based on the predicted concentrations of pyraclostrobin/BAS 500 06 F in soils, the TER values describing the acute and longterm risk for earthworms and other non-target soil organisms following exposure to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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 BAS 500 06 F in cereals according to the label.

Additionally, information on potential effects on earthworm populations is available from a field study conducted with BAS 500 06 F (for details see Appendix 2). The test site in this study was a grassland site. At an application scenario of up to 6.25 L BAS 500 06 F/ha (equivalent to 1250 g pyraclostrobin/ha) no unacceptable effects to earthworm populations are expected. The intended maximum use of BAS 500 06 F, *i.e.* 2 x 1.25 L/ha (equivalent to 2 x 250 g pyraclostrobin/ha) for cereals is therefore covered by the tested field rate. Thus, it can be concluded that the use of BAS 500 06 F will be of low risk to natural earthworm communities.

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 BAS 500 06 F / pyraclostrobin 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

According to SANCO/10329/2002 rev2-final, the test on 'sub-lethal effects on collembola or soil mites' is required if the $DT_{90,\ field}$ is between 100 and 365 days and the standard HQ for arthropods (*T. pyri* and *A. rhopalosiphi*) is above 2.

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 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

These criteria are met for pyraclostrobin ($DT_{90field}$ > 365 d) and the standard HQ values for arthropods exceed the trigger of 2. Data are available and reported in Table 6.7-1.

The potential chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to BAS 500 06 F / pyraclostrobin as well as the major soil degradation products of pyraclostrobin 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 Metabolites of pyraclostrobin

According to risk assessment on EU level it can be concluded that the metabolites BF 500-6 and BF 500-7 are not of ecological relevance with respect to soil organism. Hence no additional risk assessment (e.g. no PEC_{Soil} calculation) is deemed necessary.

6.7.4 Residue content of earthworms

No study is available.

6.8 Effects on Soil Microbial Activity

6.8.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing pyraclostrobin whenever contamination of soil may occur as a result of the intended uses of BAS 500 06 F.

Effects on soil microorganisms resulting from an exposure to pyraclostrobin / BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. All relevant study data for the assessment of the risk to soil microorganisms from the intended uses of BAS 500 06 F are provided here. New studies are listed in Appendix 2 and summarized in Appendix 3.

6.8.1.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for soil microbial activity following exposure to pyraclostrobin and BAS 500 06 F with indication to agreed endpoints

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-tranformation	BF 500-6 & BF 500-7 (mixture)	28 d, silty sand + loamy sand; 0.075 kg BF 500-6/ha + 0.0375 kg BF 500-7/ha; 0.75 kg BF 500-6/ha + 0.375 kg BF 500-7/ha	No effect > = 25% 1)	Krieg,W. 1999 54482	71651
C-transformation	BF 500-6 & BF 500-7 (mixture)	28 d, silty sand + loamy sand; 0.075 kg BF 500-6/ha + 0.0375 kg BF 500-7/ha; 0.75 kg BF 500-6/ha + 0.375 kg BF 500-7/ha	No effect > = 25% 1)	Krieg,W. 1999 54483	71641
N-tranformation	BAS 500 06 F	42 d, loamy sand + sandy loam; 17.30 mg BAS 500 06 F/kg	No effect > = 25% 2	Schulz, L. 2012 12 10 48 052 N 2012/1129443	82100
N-tranformation	BAS 500 01 F *	28 d, loamy sand + sandy loam 3.333 mg a.s./kg dry soil,equivalent to 10.0 L/ha (2.5 kg a.s./ha)	No effect > = 25% 2	Krieg W. 1998 41053	79499
C-transformation	BAS 500 01 F *	28 d, loamy sand + sandy loam 3.333 mg a.s./kg dry soil,equivalent to 10.0 L/ha (2.5 kg a.s./ha)	No effect > = 25% 2	Krieg W. 1998 41047	79498

* test carried out with formulation BAS 500 01 F (250 g/L Pyraclostrobin)

1) Review report for the active substance Pyraclostrobin, SANCO/1420/2001-final

2) 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 pyraclostrobin and BAS 500 06 F.

6.8.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation BAS 500 06 F, the active substance pyraclostrobin 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 BAS 500 06 F/ pyraclostrobin

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Pyraclostrobin in BAS 500 01 F	N transformation	0.2792	3.333	12
	C transformation		3.333	12
BAS 500 06 F	N transformation	1.457	17.3	11.9

Pyraclostrobin in BAS 500 01 F, which is a minor changed formulation cause no effects deviations greater than ±25% in the activity of the soil microorganisms. To proof, if the activity of BAS 500 01 F is comparable with the applies formulation BAS 500 06 F, thenotifier submitted a N-transformation study with BAS 500 06 F. The results are comparable with those from BAS 500 01 F. Hence the C transformation test with BAS 500 01 F can be used as surrogate for BAS 500 06 F.

For the active ingredients in BAS 500 06 F, pyraclostrobin as well as for the formulated product BAS 500 06 F, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 12-times higher than the corresponding maximum PEC in soil. According to EU risk assessment also the two metabolites (BF 500-6 and BF 500-7) have no lasting effects on carbon- and nitrogen conversion.

Based on the predicted concentrations of pyraclostrobin/BAS 500 06 F in soils, the risk to soil microbial processes following exposure to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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 BAS 500 06 F were not evaluated as part of the EU review of pyraclostrobin. Therefore, all relevant study data for the assessment of the risk to non-target plants from the inteded uses of BAS 500 06 F are provided here, listed in Appendix 2 and summarized Appendix 3 (new studies).

6.9.1.1 Toxicity

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure to BAS 500 06 F with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Seedling emergence					
carrot (*Daucus carota L.)*; lettuce (*Lactuca sativa L.*); oilseed rape (*Brassica napus L.*); cabbage (*Brassica oleracea L. var. capitata L. f. alba*); soybean (*Glycine max L.*); tomato (*Lycopersicon esculentum Mill.*); onion (*Allium cepa L.*); ryegrass (*Lolium perenne L.*); oat (*Avena sativa L.*); corn (*Zea mays L.*) (10 species)	BAS 500 06 F	Seedling emergence	ER50 > 1.25 L/ha [1]	Strömel, C., 2012 2012/1115895	82012
Vegetative vigour					
carrot (*Daucus carota L.)*; lettuce (*Lactuca sativa L.*); oilseed rape (*Brassica napus L.*); cabbage (*Brassica oleracea L. var. capitata L. f. alba*); soybean (*Glycine max L.*); tomato (*Lycopersicon esculentum Mill.*); onion (*Allium cepa L.*); ryegrass (*Lolium perenne L.*); oat (*Avena sativa L.*); corn (*Zea mays L.*) (10 species)	BAS 500 06 F	Vegetative vigour	ER50 > 1.25 L/ha [1]	Strömel, C., 2013 2012/1115894	82015

1) New study submitted by the applicant

The studies conducted with formulated product are most relevant for risk assessment. Regarding the studies for the active substances please refer to SANCO/1420/2001-final.

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 45.

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 BAS 500 06 F following intended uses

Maximum intended in-field rate	Maximum PERoff-field at 1m (2.38% drift)
(L BAS 500 06 F/ha)	
2.125	0.05

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 to BAS 500 06 F

Endpoint	ER50 (L product/ha)	PERin-field (mL product/ha)	Distance (m)	Exposure PERoff-field (mL product/ha)	TER
Seedling emergence	> 1.25	2.125	1	0.05	25
Vegetative vigour	> 1.25		1	0.05	25

Based on the predicted rates of BAS 500 06 F in off-field areas, the TER values describing the risk for non-target plants following exposure to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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 acceptable risk for non-target terrestrial plants due to the intended use of BAS 500 06 F 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

6.12 Overall Summary

6.12.1.1 Predicted distribution and fate in the environment and time courses involved

The predicted distribution and fate of pyraclostrobin BAS 500 06 F in the environment is described in Part B, Section 5.

6.12.1.2 Short and long term risks for non-target species, populations, communities and processes

Birds

Under the assumptions of a screening assessment acute TER_A value as well as long-term TER_{LT} for pyrcalostrobin for small omnivorous birds exceed the trigger of 10 set by Regulation (EC) 1107/2009, Annex IV, uniform principles, point 2.5.2.1. This indicates a low and acceptable acute risk to birds from the application of BAS 500 06 F in cereals.

Based on a Tier 1 assessment according to EFSA Journal 2009, the TER_{lt} values for earthworm-eating and fish-eating birds exceed the trigger value set by Regulation (EC) 1107/2009, Annex IV, uniform principles, point 2.5.2.1, indicating that the application of BAS 500 06 F in cereals does not provide reason for concern regarding a potential accumulation of the active substance pyraclostrobin in the food chain or for concern of secondary poisoning.

Overall, it can be concluded that the application of BAS 500 06 F according to good agricultural practice will not adversely affect birds under natural conditions.

Terrestrial vertebrates other than birds

Under the assumptions of a screening assessment acute TER_A value for pyraclostrobin for small herbivorous mammals exceed the trigger of 10 set by Regulation (EC) 1107/2009, Annex IV, uniform principles, point 2.5.2.1. However TER calculations using the endpoint from the study with formulated product are below the trigger and need further refinement. Based on refined assessment step (including reduction of acceptability criteria for mice and voles), the calculated TER values for the acute risk resulting from an exposure of mammals to pyraclostrobin according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria TER ≥ 10 resp. TER ≥ 5.

Based on Tier 1 assessment step, the calculated TER values for the long-term risk resulting from an exposure of mammals to pyraclostrobin according to the GAP of the formulation BAS 500 06 F 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 for the scenarios Small insectivorous mammal "shrew" and Small omnivorous mammal “mouse”. The TER values for small omnivorous mammal “mouse” and the small herbivorous mammal scenario are below the trigger and need to be refined.

For the refined risk assessment the following parameters are considered:

- Reduce of the acceptability criteria for mice and voles
- Refinement of the ecotoxicological endpoint,

Taking these factors into account, the long-term risk to mammals resulting from an exposure to BAS 500 06 F, can be regarded as acceptable.

Based on a Tier 1 assessment according to EFSA Journal 2009, the TER_{lt} values for earthworm-eating and fish-eating mammals exceed the trigger value set by Regulation (EC) 1107/2009, Annex IV, uniform principles, point 2.5.2.1, indicating that the application of BAS 500 06 F in cereals does not provide reason for concern regarding a potential accumulation of the active substance pyraclostrobin in the food chain or for concern of secondary poisoning.

Overall, it can be concluded that the application of BAS 500 06 F according to good agricultural practice will not adversely affect mammals under natural conditions.

Aquatic Organisms

Based on the HC_5 derived from seven fish studies (acute) with pyraclostrobin (crucial for risk assessment) and on the FOCUS Step 3 PECsw, the calculated TER values for the acute from an exposure of aquatic organisms to pyraclostrobin according to the GAP of the formulation BAS 500 06 F does not achieve the acceptability criteria TER ≥ 20, 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 aquatic organisms due to the intended use of BAS 500 06 F in cereals according to the label. Therefore further refinement is necessary.

Consequences: Risk mitigations measures necessary.

Bees

Please refer to the risk assessment procedure as provided by JKI.

Arthropods other than bees

For *T. pyri*, *A. rhopalosiphi* and *A. bilineata* no effect of 50% under the $PER_{in\text{-}field}$ was observed. However based on the on the extended laboratory study with *C. carnea* a potential in-field risk to non-target arthropods cannot be excluded. For refinement the notifier submitted an aged residue study with *C. carnea*. In this study, two application rates (1.25 and 2.5 L/ha) were tested. No unacceptable effects on survival and reproduction were observed at DAT 0 following application at 1.25 L/ha BAS 500 06 F and on DAT 7 following application at 2.5 L/ha BAS 500 06 F. This is higher than the maximum $PER_{in\text{-}field}$ of 2.125 L/ha.

Therefore the aged residue study is suitable to release the effects on reproduction observed in the extended laboratory study with *C. carnea.*

In off-field areas, the effects in the extended laboratory tests are lower than 50% respectively the calculated TER values for the risk resulting from an exposure of non-target arthropods to BAS 500 06 F 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 BAS 500 06 F in cereals according to the label.

Earthworms and other soil non-target marco-organisms

Based on the predicted concentrations of pyraclostrobin and BAS 500 06 F in soils, the TER values describing the acute and long-term risk for earthworms following exposure to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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. Additionaly a field study with BAS 500 06 F and earthworms is available, which showed no significant effects.

For BAS 500 06 F a litter bag as well as a laboratory study with collembola is available. According to the results, as there were no significant effects observable, it can be concluded, that risk to organic matter and other soil macroorganism after exposure to BAS 500 06 F according to the GAP is acceptable.

Consequences: No

Soil microbial activity

Based on the predicted concentrations of pyraclostrobin in soils, the risk to soil microbial processes following exposure to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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, when applied up to 17.3 mg/kg soil dry weight.

Consequences: No

Non-target plants

Based on the predicted rates of BAS 500 06 F in off-field areas, the TER values describing the risk for non-target plants following exposure to pyraclostrobin according to the GAP of the formulation BAS 500 06 F does 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 acceptable risk for non-target terrestrial plants due to the intended use of BAS 500 06 F in all indication groups according to the label. Risk mitigation measures will not have to be implemented.

Appendix 2 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/ Use*
KIIIA 10.1.6/1	[redacted]	2008 a	BAS 500 06 F - Acute toxicity in the bobwhite quail (Colinus virginianus) after single oral administration (LD50) BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2008/1078602 Yes Unpublished	Yes	BASF	1
KIIIA 10.2.2.1/1	[redacted]	2008 a	BAS 500 06 F - Acute toxicity study with the rainbow trout (Oncorhynchus mykiss) BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2008/1018046 Yes Unpublished	Yes	BASF	1
KIIIA 10.2.2.2/1	Funk M.	2004 a	Effect of BAS 500 06 F on the immobility of Daphnia magna STRAUS in a 48 hours static, acute toxicity test BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2004/1004393 Yes Unpublished	Yes	BASF	1
KIIIA 10.2.2.3/1	Hoffmann F.	2008 a	Effect of BAS 500 06 F on the growth of the green alga Pseudokirchneriella subcapitata BASF SE, Limburgerhof, Germany Fed.Rep. 2008/1009325 Yes Unpublished	Yes	BASF	1
KIIIA 10.3/1	[redacted]	2011 a	BAS 500 F - Pyraclostrobin - Ecologically relevant chronic toxicity endpoint for the wild	Yes	BASF	3

			mammal reproductive risk assessment (Ecotoxicology) BASF SE, Limburgerhof, Germany Fed.Rep. 2011/1249375 No, not subject to GLP regulations Unpublished			
KIIIA 10.3/2	[redacted]	2011 b	Generic statement - Relevance of the common vole scenario in arable crops BASF SE, Limburgerhof, Germany Fed.Rep. 2011/1248329 No, not subject to GLP regulations Unpublished	Yes	BASF	3
KIIIA 10.3/3	[redacted]	2004 a	Population dynamics of common voles in winter cereal fields - Field monitoring in South Western Germany Riffel BioConsult, Hirschberg, Germany Fed.Rep. 2004/1025715 No Unpublished	Yes	BASF	3
KIIIA 10.3/4	[redacted]	2012 a	BAS 500 06 F: Acute risk to mammals of the formulated product BASF SE, Limburgerhof, Germany Fed.Rep. 2012/1067590 No, not subject to GLP regulations Unpublished	Yes	BASF	3
KIIIA 10.3/5	[redacted]	2012 a	Activity patterns and foraging time in wood mouse (Apodemus sylvaticus), common vole (Microtus arvalis), European brown hare (Lepus europaeus) and European rabbit (Oryctolagus cuniculus) - A short literature survey RIFCon GmbH, Heidelberg, Germany Fed.Rep. 2012/1021009 No, not subject to GLP regulations Unpublished	Yes	BASF	3
KIIA 8.7.1	Sack, D.	1999	Effect of Reg.No. 304 428 on the honeybee (Apis mellifera L.) in laboratory trials. Study code:	Yes	BASF	1

			35842. BASF Aktiengesellschaft, D-Limburgerhof. 1999/11457 Yes Unpublished			
KIIIA 10.4.2.2/1	Bocksch S.	2004 a	Assessment of side effects of BAS 500 06 F to the honey bee, Apis mellifera L. in the laboratory GAB Biotechnologie GmbH & GAB Analytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. 2004/1015008 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.1/1	Sipos K.	2007 a	Effect of BAS 500 06 F on the predatory mite (Typhlodromus pyri) in a laboratory trial LAB International Research Centre Hungary Ltd., Veszprem, Hungary 2007/1035599 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.1/2	Sipos K.	2007 b	Effect of BAS 500 06 F on the parasitic wasp (Aphidius rhopalosiphi) in a laboratory trial LAB International Research Centre Hungary Ltd., Veszprem, Hungary 2007/1035600 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.1/3	Sipos K.	2007 c	Amendment to the final report: Effect of BAS 500 06 F on the parasitic wasp (Aphidius rhopalosiphi) in a laboratory trial LAB International Research Centre Hungary Ltd., Veszprem, Hungary 2007/1050841 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.2/1	Vaughan R.	2008 a	A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom 2008/1010712 Yes Unpublished	Yes	BASF	1

KIIIA 10.5.2/2	Stevens J.	2008 a	A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae) Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom 2008/1010713 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.2/3	Roehlig U.	2008 a	Effects of BAS 500 06 F on the green lacewing Chrysoperla carnea STEPH. under extended laboratory conditions - Rate-response test BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2008/1032666 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.2/4	Schmitzer S.	2008 a	Effects of BAS 500 06 F on the reproduction of rove beetles (Aleochara bilineata) - Extended laboratory study Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2008/1010700 Yes Unpublished	Yes	BASF	1
KIIIA 10.5.2/5	Roehlig U.	2008 b	Effects of BAS 500 06 F on the green lacewing Chrysoperla carnea STEPH. in an extended laboratory test (under semi-field conditions aged residues on bean plants) BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2008/1042190 Yes Unpublished	Yes	BASF	1
KIIIA 10.6.2/1	Fleischer G.	2004 a	Effect of BAS 500 06 F on the mortality of the earthworm Eisena fetida BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2004/1004367	Yes	BASF	1

			Yes Unpublished			
KIIIA 10.6.3/1	Luehrs U.	2008 a	Effects of BAS 500 06 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. 2008/1036409 Yes Unpublished	Yes	BASF	1
KIIIA 10.6.4/1	Luehrs U.	2010 a	Field study to evaluate the effects of BAS 500 06 F on earthworms Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2010/1000056 Yes Unpublished	Yes	BASF	1
KIIIA 10.6.6/1	Friedrich S.	2008 a	Effects of BAS 500 06 F on the reproduction of the collembolans Folsomia candida in artificial soil with 5% peat BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2008/1037495 Yes Unpublished	Yes	BASF	1
KIIIA 10.6.7/1	Luehrs U., Schabio S.	2010 a	Effects of BAS 500 06 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. 2010/1000081 Yes Unpublished	Yes	BASF	1
KIIIA 10.7.1/1	Krieg W.	1998 a	Effects of BAS 500 01 F on soil respiration BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1998/11253 Yes Unpublished	Yes	BASF	1
KIIIA 10.7.1/2	Krieg W.	1998 b	Effects of BAS 500 01 F on the nitrogen turnover in soil	Yes	BASF	1

			BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1998/11259 Yes Unpublished			
KIIIA 10.7.1/3	Schulz, L.	2012	Effects of BAS 500 06 F on the activity of soil microflora (Nitrogen transformation test) BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2012/1129443, Yes Unpublished	Yes	BASF	1
KIIIA 10.8.1.2/1	Oberwalder C., Schmidt O.	2000 a	BAS 500 01 F: Effects on non-target plants in the greenhouse - A limit test BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2000/1011456 No Unpublished	Yes	BASF	2
KIIIA 10.8.1.2/2	Strömel, C. et al.,	2013	Effect of BAS 500 06 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions BASF SE, Ludwigshafen Germany 2012/1115894 Yes Unpublished	Yes	BASF	1
KIIIA 10.8.1.3	Strömel, C. et al.,	2013	Strömel, C. et al., 2013 Effect of BAS 500 06 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions 2012/1115895 Yes Unpublished	Yes	BASF	1
KIIIA 10.10.2/1	[redacted]	2011 a	Field monitoring of hares and rabbits in cereal fields RIFCon GmbH, Heidelberg, Germany Fed.Rep. 2011/1112612 Yes Unpublished	Yes	BASF	3
KIIIA 10.10.2/2	[redacted]	2012 a	First amendment to final report - Field monitoring of hares and rabbits in cereals fields	Yes	BASF	3

			RIFCon GmbH, Heidelberg, Germany Fed.Rep. 2012/1105899 Yes Unpublished			
KIIIA 10.10.2/3	[redacted]	2006 a	Generic field monitoring of mammals in cereal fields in spring and summer in Germany Bayer CropScience AG, Monheim, Germany Fed.Rep. 2007/1042674 Yes Unpublished	Yes	BCS	3

*

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 3 Detailed evaluation of studies relied upon

A2-1 Active substance (generally only relevant in the case that new annex II data is provided after pyraclostrobin approval)

A2-2 Formulation

IIIA 10.1 Effects on birds

IIIA 10.1.6 Acute oral toxicity of the preparation to the more sensitive of the species identified in tests with the active substance

Reference:	IIIA 10.1.6
Report	Zok S., 2008a BAS 500 06 F - Acute toxicity in the bobwhite quail (Colinus virginianus) after single oral administration (LD50) BASF DocID 2008/1078602 2291115
Guideline(s):	Yes EPA 540/9-82-024, EPA 71-1, EPA 540/9-85-007, EPA 850.2100, EPA 712-C-96-139
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

An acute oral avian toxicity test with BAS 500 06 F was conducted. The objective of the study was to test the item on its acute toxicity in the bobwhite quail and to determine the LD_{50} and the no observed effect level (NOEL). The test item was administered via a single-dose of 500, 1000 or 2000 mg BAS 500 06 F/kg body weight to 6-month old northern bobwhite quails. Ten birds (5 males and 5 females) were used in each group. The doses were emulsified in drinking water. Feed was removed for 21-22 hours prior to dosing. All groups were observed for mortality, signs of clinical toxicity, impact on food consumption and body weight for 14 consecutive days post dosing. All groups received food and water *ad libitum* throughout the test. The test was terminated after 14 days.

In males, no mortality and no toxic signs were observed in the control and any of the test item treatments up to the highest tested concentration of 2000 mg BAS 500 06 F/kg bw. One female of the 2000 mg/kg bw group died on the day after dosing, but it was concluded that the mortality cannot be clearly attributed to the test item. Diarrhea, which was observed in the first time after dosing, is a consequence of the fasting period and is usually observed in all dose groups as well as in the control group and is not considered to be a toxic effect. In the 2000 mg/kg bw group the feed uptake during the 1st week after dosing was reduced to 70% in males and to 65% of the control group in females. In the 2nd week after

dosing the feed uptake returned to normal. The body weights were not statistically significantly different from the control after 7 and 14 days in any of the dose groups. However, in the 2000 mg/kg bw group a slight tendency towards a decreased body weight was observed 7 days after dosing. No treatment-related macroscopic abnormalities were detected in the gross post-mortem examination.

In an acute toxicity test with the bobwhite quail, the LD_{50} of BAS 500 06 F was > 2000 mg/kg body weight. The NOEL was 1000 mg/kg body weight.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304 428): 202.7 g/L (nominal 200 g/L).
Test species:	Bobwhite quail (*Colinus virginianus*); indistinguishable from wild birds; age: approx. 6 month; source: H. & E. Küberich, Geesdorf/Wiesenheid, Germany.
Test design:	Birds were administered different doses of the test item BAS 500 06 F in drinking water in a total amount of 10 g per kg body weight by gavage into the crop; 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 three times on day of dosing, daily thereafter; assessment of body weight was carried out on day 7 and 14. Gross-mortem examinations of all birds at termination of the test.
Endpoints:	LD_{50}, mortality, clinical signs, feed consumption, body weight (bw), gross pathological examinations were conducted on all birds sacrificed at the termination of the test.
Test concentrations:	Control, 500, 1000 and 2000 mg BAS 500 06 F/kg body weight.
Test conditions:	Birds fasted for about 21 - 22 h before administration of the test item; temperature 20.0 °C to 24.4 °C, deviation for 2 days, 21 h and 45 min from the temperature range of 19 °C - 23 °C; relative humidity: 38% - 75%, deviation of 10 h and 15 minutes above the limit of 45% - 70%; deviation of 2 h and 30 minutes below the limit of 45% - 70%; photoperiod: 8 hours light : 16 hours dark.
Statistics:	Descriptive statistics, Dunnett-test for body weight data ($\alpha = 0.05$).

Results and discussions

Analytical measurements:

The results of the analytical verification of the test item concentration in the diet were within a range of 101% to 102% of the nominal concentrations during the test. The biological results are therefore based on the nominal values.

Biological results:

In males, no mortality and no toxic signs were observed in the control and any of the test item treatments up to the highest tested concentration of 2000 mg BAS 500 06 F/kg bw. One female of the 2000 mg/kg bw group died on the day after dosing. According to the test guideline 10% mortality is acceptable for the control group. Thus it was concluded that the mortality cannot be clearly attributed to the test item.

Diarrhea in the first time after dosing is a consequence of the fasting period and is usually observed in all dose groups as well as in the control group and is not considered to be toxic effect. In the 2000 mg/kg bw group the feed uptake during the 1st week after dosing was reduced to 70% in males and to 65% of the control group in females. In the 2nd week after dosing the feed uptake returned to normal. The body weights were not statistically significantly different from the control after 7 and 14 days in any of the dose groups. However, in the 2000 mg/kg bw group a slight tendency towards a decreased body weight was observed 7 days after dosing. No treatment-related macroscopic abnormalities were detected in the gross post-mortem examination.

The relevant endpoints are summarized in the following table:

Acute toxicity of BAS 500 06 F to the bobwhite quail (*Colinus virginianus*)

Mortality	Dose [mg BAS 500 06 F/kg bw]
Highest dose causing no treatment-related mortality	males: 2000 females: 1000
LD_{50} (14 d)	> 2000
NOEL	1000

bw = body weight

Conclusion

In an acute toxicity test with the bobwhite quail, the LD50 of BAS 500 06 F was > 2000 mg/kg body weight. The NOEL was 1000 mg/kg body weight.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In an acute toxicity test with the bobwhite quail, the LD50 of BAS 500 06 F was > 2000 mg/kg body weight. The NOEL was 1000 mg/kg body weight.

IIIA 10.2 Effects on Aquatic organisms

10.2.2.1 Fish acute toxicity

Reference:	IIIA 10.1.6
Report	[redacted] 2008a BAS 500 06 F - Acute toxicity study with the rainbow trout (Oncorhynchus mykiss) 12F0023/065054, BASF DocID 2008/1018046 2291117
Guideline(s):	Yes OECD 203
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a static acute toxicity laboratory study, juvenile rainbow trout were exposed to nominal concentrations of 0.005, 0.010, 0.022, 0.050 and 0.100 mg BAS 500 06 F/L and a water control 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 nominal concentrations. After 96 hours of exposure no mortality was observed in the control and at concentrations of up to and including 0.022 mg/L (nominal), whereas 80% mortality was observed at 0.050 mg/L. 100% mortality was observed at the highest tested concentration of 0.100 mg/L.

In a static acute toxicity study with rainbow trout, the LC50 (96 h) of BAS 500 06 F was 0.046 mg/L based on nominal concentrations. The NOEC (96 h) was determined to be 0.022 mg/L (nominal).

Materials and methods

Test item: BAS 500 06 F, batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304 428): 202.7 g/L (nominal: 200 g/L); density: 1.044 g/cm3.

Test species:	Rainbow trout (Oncorhynchus mykiss); age: approx. 4 months; mean body length: 5.8 cm (5.2 – 6.3 cm); mean body weight: 1.81 g (1.14 – 2.29 g); supplied by “Forellenzucht Trostadt GbR”, Trostadt, Germany.
Test design:	Static system (96 hours); 10 fish per aquarium (loading: 0.36 g fish/L) and per concentration, assessments of mortality and symptoms of toxicity within 1 h after start of exposure and 6, 24, 48, 72 and 96 h after start of exposure.

Endpoints: LC50, NOEC, mortality and sub-lethal effects.

Test concentrations: Control, 0.005, 0.010, 0.022, 0.050 and 0.100 mg BAS 500 06 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 mixed with deionized water; temperature: 13 °C; pH 8.0 - 8.2; oxygen content: 8.1 mg/L - 10.3 mg/L; total hardness about 1 mmol/L; conductivity approx. 250 µS/cm; acid capacity about 2.5 mmol/L; photoperiod: 16 h light : 8 h dark; light intensity: approx. 100 lux - 490 lux; no aeration, no feeding.

Analytics: Analytical verification of test item concentrations was conducted using an HPLC-method with MS-detection.

Statistics: Descriptive statistics; probit analysis for calculation of LC50.

Results and discussions

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and at the end of the test. The initially measured concentrations of pyraclostrobin in the three highest test concentrations were within 10% of the nominal concentrations (93% - 97%). In the two lowest concentrations the initially measured values ranged from 124% to 135% of nominal. At test termination, the analytically determined values for pyraclostrobin decreased to 54% - 93 % of the nominal concentrations. As the nominal concentrations in the relevant three highest test groups are confirmed by initially measured values, 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 0.022 mg/L, whereas 80% mortality was observed at 0.050 mg/L. 100% mortality was observed at the highest tested concentration of 0.100 mg/L.

The results are summarized in the following table:

Acute toxicity (96 h) of BAS 500 06 F on rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] nominal	Control	0.005	0.010	0.022	0.050	0.100
Mortality [%]	0.0	0.0	0.0	0.0	80	100
Symptoms	none	none	none	none	none	--
Endpoints [mg BAS 500 06 F/L] (nominal)						
LC_{50} (nominal)	0.046					
NOEC (nominal)	0.022					

-- not observed/ all animals dead

Conclusion

In a static acute toxicity study with rainbow trout, the LC50 (96 h) of BAS 500 06 F was 0.046 mg/L based on nominal concentrations. The NOEC (96 h) was determined to be 0.022 mg/L (nominal).

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a static acute toxicity study with rainbow trout, the LC50 (96 h) of BAS 500 06 F was 0.046 mg/L based on nominal concentrations.

10.2.2.2 Daphnia acute toxicity

Reference:	IIIA 10.2.2.2
Report	Funk, M., 2004a Effect of BAS 500 06 F on the immobility of Daphnia magna STRAUS in a 48 hours static, acute toxicity test 181354, BASF DocID 2004/1004393 2291119
Guideline(s):	Yes OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a static acute toxicity laboratory study, water flea neonates were exposed to BAS 500 06 F at nominal concentrations of 0.0056, 0.010, 0.018, 0.032, 0.056 and 0.100 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 no immobility of daphnids were observed in the control and at test item concentrations of up to and including 0.032 mg BAS 500 06 F/L. After 48 hours of exposure 25% and 100% of the daphnids were immobile at 0.056 and 0.100 mg/L, respectively. In a 48-hour static acute toxicity study with Daphnia magna the EC50 of BAS 500 06 F was 0.065 mg/L based on nominal concentrations. The NOEC was determined to be 0.032 mg/L (nominal).

Materials and methods

Test item:	BAS 500 06 F, batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304 428): 202.7 g/L (nominal: 200 g/L).
Test species:	Water flea (Daphnia magna STRAUS), neonates collected from in-house culture (originally obtained from Institute National de Recherche Chimique Appliquée, France), less than 24 hours old at test initiation.
Test design:	Static system (48 hours), 6 test concentrations plus control, 4 replicates with 5 daphnids each; assessment of immobility after 24 and 48 hours.
Endpoints:	NOEC, EC50 based on immobility of daphnids.
Test concentrations:	
	Control, 0.0056, 0.010, 0.018, 0.032, 0.056 and 0.100 mg/L (nominal).
Test conditions:	Glass vessels; test volume 50 mL; dilution water "M4" (Elendt medium); pH 7.87 - 8.03; oxygen content: 9.11 mg/L - 9.95 mg/L; total hardness: 2.52 mmol/L at test initiation; conductivity: 615 µS/cm at test initiation; temperature 20.0 °C – 21.5 °C; light intensity: < 1500 lux; photoperiod: 16 h light :8 h dark; no feeding, no aeration.
Analytics:	Analytical verification of test item concentrations was conducted using an HPLC-method with UV-detection.
Statistics:	Descriptive statistics; log-log and probit analysis for calculation of EC50.

Results and discussions

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and at the end of the test. The analytically detected concentrations for pyraclostrobin ranged from 83.1% to 100.6% of the nominal concentration at test initiation. At test termination recoveries ranged from 89.8% to 94.5%. 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 no immobility of daphnids were observed in the control and at test item concentrations of up to and including 0.032 mg BAS 500 06 F/L. After 48 hours of exposure 25% and 100% of the daphnids were immobile at 0.056 and 0.100 mg/L, respectively.

The results are summarized in the following table:

Effect of BAS 500 06 F on *Daphnia magna* immobility

Concentration [mg/L] nominal	Control	0.0056	0.010	0.018	0.032	0.056	0.100
Immobility (24 h) [%]	0	0	0	0	0	15	70
Immobility (48 h) [%]	0	0	0	0	0	25	100
	Endpoints [mg BAS 500 06 F/L] (nominal)						
EC_{50} (48 h)	0.065 (95% confidence limits: 0.057 – 0.075)						
NOEC (48 h)	0.032						

Conclusion

In a 48-hour static acute toxicity study with Daphnia magna the EC50 of BAS 500 06 F was 0.065 mg/L based on nominal concentrations. The NOEC was determined to be 0.032 mg/L (nominal).

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 48-hour static acute toxicity study with Daphnia magna the EC50 of BAS 500 06 F was 0.065 mg/L based on nominal concentrations.

10.2.2.3 Effects on algal growth and growth rate

Reference:	IIIA 10.2.2.3
Report	Hoffmann F., 2008a Effect of BAS 500 06 F on the growth of the green alga Pseudokirchneriella subcapitata 300286, BASF DocID 2008/1009325 2291120
Guideline(s):	Yes OECD 201
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a 72-hour static toxicity laboratory study, the effect of BAS 500 06 F on the growth of the green alga Pseudokirchneriella subcapitata was investigated. The following nominal concentrations of BAS 500 06 F were applied: 0 (control), 0.31, 0.77, 1.92, 4.80, 12.0 and 30.0 mg/L (corresponding to mean measured concentrations of 0.39, 0.84, 2.11, 4.80, 13.0 and 34.0 mg/L). Assessment of growth was conducted 0 h, 24 h, 48 h and 72 h after test initiation. The percentage growth inhibition, relative to the control, was calculated for each test concentration from mean growth rates and yield based on number of cells.

The biological results are based on mean measured concentrations. No morphological effects on algae were observed up to and including a concentration of 1.92 mg/L. At 4.8 mg/L about 10%, at 12.0 mg/L about 50% and at 30.0 mg/L nearly all cells got round.

In a 72-hour algae test with Pseudokirchneriella subcapitata the ErC50 of BAS 500 06 F was determined to be 14.2 mg/L, the EyC50 was 2.4 mg/L based on mean measured concentrations.

Materials and methods

Test item:	BAS 500 06 F, batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304428): 202.7 g/L (nominal: 200 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; 6 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, 0.31, 0.77, 1.92, 4.80, 12.0 and 30.0 mg/L(nominal); corresponding to mean measured concentrations of 0.39, 0.84, 2.11, 4.80, 13.0 and 34.0 mg/L.
Test conditions:	Erlenmeyer dimple flasks; test volume 60 mL; test medium according to OECD 201; initial cell densities: 1 x 10^4 cells/mL; pH 8.1 at test initiation and pH 7.82 – 8.04 at test end; temperature: 22 ° ± 1 °C; continuous light at about 8000 lux; continuous shaking.
Analytics:	Analytical verification of test item concentrations was conducted using an HPLC-method with MS-detection.
Statistics:	Descriptive statistics, probit analysis for determination of EC_x values for growth rate and yield.

Results and discussions

Analytical measurements: Analytical verification of test item concentration was conducted in each concentration at the beginning and at the end of the test. The analytically detected concentrations for pyraclostrobin ranged from 115.9% to 142.0% of the nominal concentration at test initiation. At test termination the detected concentrations ranged from 82.9% to 108.8% of nominal. The biological results are based on mean measured concentrations.

Biological results: No morphological effects on the algae were observed up to the concentration of 1.92 mg/L. At 4.8 mg/L about 10%, at 12.0 mg/L about 50% and at 30.0 mg/L nearly all cells got round. The effects on algal growth are summarized in the following table:

Effect of BAS 500 06 F on the growth of the green alga *Pseudokirchneriella subcapitata*

Concentration (nominal) [mg/L]	**Control**	**0.31**	**0.77**	**1.92**	**4.80**	**12.0**	**30.0**
Concentration (mean measured) [mg/L]	**Control**	**0.39**	**0.84**	**2.11**	**4.80**	**13.0**	**34.0**
Inhibition in 72 h (growth rate) [%]	-	0.8	7.3	14.7	23.7	44.1	72.7
Inhibition in 72 h (yield) [%]	-	3.6	28.8	49.7	67.2	87.8	97.4
Endpoints [mg BAS 500 06 F/L] (mean measured)							
E_rC_{50} (0-72 h)	14.2 (95% confidential limits: 13.1 - 15.4)						
E_rC_{10} (0-72 h)	1.6 (95% confidential limits: 1.4 - 1.7)						
E_yC_{50} (0-72 h)	2.4 (95% confidential limits: 2.3 - 2.5)						
E_yC_{10} (0-72 h)	0.42 (95% confidential limits: 0.38 - 0.46)						

Conclusion

In a 72 hour algae test with *Pseudokirchneriella subcapitata* the E_rC_{50} of BAS 500 06 F was determined to be 14.2 mg/L, the E_yC_{50} was 2.4 mg/L based on mean measured concentrations.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 72 hour algae test with *Pseudokirchneriella subcapitata* the E_rC_{50} of BAS 500 06 F was determined to be 14.2 mg/L, the E_yC_{50} was 2.4 mg/L based on mean measured concentrations.

IIIA 10.4 Effects on Bees

IIIA 10.4.2 Acute toxicity of the formulation to bees

The following bee acute oral toxicity study performed on BAS 500 06 F is provided in support of the assessment and has not been previously evaluated. 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:	**KIIIA1 10.4.2.1/01**
	Boksch, S. (2004): Assessment of side effects of BAS 500 06 F to the honey bee, Apis mellifera L. in the laboratory. Study code: 20041288/01-BLEU. GAB Biotechnologie GmbH, Niefern-Öschelbronn, Germany.
Document No:	20041288/01-BLEU
Guidelines:	OECD 213 and 214
GLP	Yes

Materials and Methods

Test item:	BAS 500 06 F, batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304428): 200 g/L (202.7 g/L analyzed); density: 1.044 g/cm^3.
Test species:	Honeybees *Apis mellifera carnica*; young worker bees
Test design:	Dose response test for oral and contact toxicity; duration 48 h; 5 replicates per treatment group, each replicate consisting of 10 bees per cage; assessment of mortality after 4, 24 and 48 hours.
Endpoints:	Mortality, LD_{50}; behavioural abnormalities.
Reference item:	Perfekthion (dimethoate, nominal 400 g/L).
Test concentrations:	Oral test: Control, 12.5, 25.0, 50.0, 100.0 and 150.0 µg a.s./bee (nominally equivalent to 65.3, 130.5, 261.0, 522.0 and 783.0 µg product/bee); resulting in an actual uptake of 10.61, 22.99, 33.52, 58.98 and 75.25 µg a.s./bee (nominally equivalent to 55.4, 120.0, 175.0, 307.9 and 392.8 µg product/bee). Contact test: Control, 12.5, 25.0, 50.0, 100.0 and 150.0 µg a.s./bee (nominally equivalent to 65.3, 130.5, 261.0, 522.0 and 783.0 µg product/bee).

Findings

No mortality was observed after 48 hours in the control variants. In the oral test with the test item mortality between 0.0% and 50% after 48 hours was observed. The LD_{50} was determined to be 73.15 µg as/bee, equivalent to 381.84 µg product/bee. No behavioural abnormalities of the surviving bees could be observed. In the contact test with the test item treatment mortality between 0.0% and 100.0% was observed after 72 hours. The LD_{50} was determined to be 70.53 µg as/bee, equivalent to 368.2 µg product/bee. No behavioural abnormalities of the surviving bees could be observed.

The LD_{50} value (24 h) for the toxic reference item in the oral toxicity test was determined to be 0.15 µg as/bee and 0.17 µg as/bee in the contact toxicity test to be.

Conclusion

The oral LD_{50} value (48 h) for BAS 500 06 F was 73.15 µg as/bee, equivalent to 381.84 µg BAS 500 06 F/bee and the contact LD_{50} value (72 h) was 70.53 µg as/bee, equivalent to 368.2 µg BAS 500 06 F/bee.

IIIA 10.5 Effects on Arthropods Other Than Bees

IIIA 10.5.1 Effects on sensitive species already tested, using artificial substrates

Reference:	IIIA 10.5.1/1
Report	Sipos K., 2007a Effect of BAS 500 06 F on the predatory mite (*Typhlodromus pyri*) in a laboratory trial 07/495-335RA, 2007/1035599, 2291134
Guideline(s):	Yes Bluemel et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a laboratory study, *Typhlodromus pyri* (Acarina: Phytoseiidae) was exposed to dried residues of BAS 500 06 F. The test item was applied to glass plates at application rates of 0.046, 0.139, 0.417, 1.25 and 3.75 L BAS 500 06 F/ha. Additional test units were treated with deionised water as control and with Perfekthion as a toxic reference item. Endpoint of the study was the mortality after 7 days of exposure, including determination of the LR50. After 7 days of exposure, the mortality in the test item treatments was between 18.33% and 95.00% in comparison to 8.00% in the control. Based on this, the corrected mortality for the different test item rates ranged between 11.23% and 94.57%. Statistically significant difference compared to the control was observed at the test rates of 0.417, 1.25 and 3.75 L BAS 500 06 F/ha. In a worst-case laboratory study with BAS 500 06 F the LR50 for the predatory mite Typhlodromus pyri was determined to be 0.87 L/ha BAS 500 06 F in 200 L water/ha.

Materials and methods

Test item: BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).

Test species: The predatory mite *Typhlodromus pyri*; protonymphs (not older than 24 h); source: in-house originating from PK- Nützlingszuchten, Germany.

Test design: The mites were exposed to dried residues on glass plates. Seven treatments (5 test item rates, water treated control and reference item) were tested. For the control 5 replicates

	were set up, for the test item and the reference item 3 replicates were used. Each replicate contained 20 mites. Assessment of mortality was done 1, 3 and 7 days after application. Investigation of effects on reproduction was not conducted,
Test rates:	Control, 0.046, 0.139, 0.417, 1.25 and 3.75 L BAS 500 06 F/ha. All treatment groups were applied in 200 L water/ha. The substances were sprayed onto glass plates with a laboratory spraying equipment and air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 0.015 L/ha.
Test conditions:	Temperature: 23.7 °C - 26.4 °C; relative humidity: 63% - 89%; photoperiod: 16 h light : 8 h dark; light intensity: 911.0 lux; food: pollen of Pinus sp..
Endpoints:	Mortality after exposure over 7 days, including determination of a LR50.
Statistics:	Descriptive statistics. Probit analysis for calculation of LR50 and Bonferroni t-test (α = 0.05).

Results and discussions

After 7 days of exposure, the mortality in the test item treatments was between 18.33% and 95.00% in comparison to 8.00% in the control. Based on this, the corrected mortality for the different test item rates ranged between 11.23% and 94.57%. Statistically significant difference compared to the control was observed at the test rates of 0.417, 1.25 and 3.75 L BAS 500 06 F/ha. 100% mortality was observed in the toxic reference item treatment after 7 days of exposure.

The LR_{50} was calculated to be 0.87 L/ha BAS 500 06 F in 200 L water/ha (Bonferroni t-test, α = 0.05). The results are summarized in the following table:

Effects of BAS 500 06 F on predatory mites (*Typhlodromus pyri*) mortality under worst-case laboratory conditions

Treatment	Rate 1) [L/ha]	Mortality 2) [%]	Corrected mortality 3) [%]
Control	--	8.00	--
BAS 500 06 F	0.046	18.33	11.23
BAS 500 06 F	0.139	25.00	18.48
BAS 500 06 F	0.417	40.00*	34.78
BAS 500 06 F	1.25	76.67*	74.64
BAS 500 06 F	3.75	95.00*	94.57
	Endpoint [L/ha BAS 500 06 F]		
LR_{50} (95% CL 4))	0.87 (0.65 - 1.10)		

1) Application rate in 200 L water/ha.
2) Mortality after 7 day exposure to BAS 500 06 F on treated glass plates.
3) Corrected overall mortality according to Abbott (19259:
4) 95% CL means lower and upper 95% confidence limits.
* = statistically significant differences compared to the control (Bonferroni t-test, $\alpha = 0.05$)

Conclusion

In a laboratory study with BAS 500 06 F the LR50 for the predatory mite *Typhlodromus pyri* was determined to be 0.87 L/ha BAS 500 06 F in 200 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a laboratory study the LR50 for the predatory mite *Typhlodromus pyri* was determined to be 0.87 L/ha BAS 500 06 F.

Reference:	IIIA 10.5.1/2
Report	Sipos K., 2007b Effect of BAS 500 06 F on the parasitic wasp (*Aphidius rhopalosiphi*) in a laboratory trial 07/495-335FD, 2007/1035600, 2291135
Guideline(s):	Yes Mead-Briggs M. et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a laboratory study, adults of *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) were exposed to dried residues of BAS 500 06 F. The test item was applied to glass plates at application rates of 0.006, 0.019, 0.056, 0.167, 0.25 and 0.5 L BAS 500 06 F/ha. Additional test units were treated with deionized water as control and with Perfekthion as a toxic reference item. Endpoint of the study was the mortality after 48 hours of exposure, including determination of the LR50. After 48 hours, the mortality in the test item treatments was between 22.50% and 100.00% in comparison to 7.50% in the control. Based on these results the corrected mortality for the different rates ranged between 16.22% and 100.00%. Statistically significant difference compared to the control was observed at the test item rates of 0.056, 0.167, 0.25 and 0.5 L/ha BAS 500 06 F.

In laboratory study with BAS 500 06 F, the LR50 for the parasitic wasp *Aphidius rhopalosiphi* was determined to be 0.04 L/ha BAS 500 06 F in 200 L water/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).
Test species:	The parasitic wasp *Aphidius rhopalosiphi*; adults less than 48 hours old; source: Katz Biotech AG, Welzheim, Germany.
Test design:	Exposure of the wasps was reached via air-dried residues on treated glass plates. Eight treatments (6 test item rates, water treated control and a toxic reference item) were set up with 4 replicates each. Each replicate contained 10 wasps. Assessment of mortality was carried out 2, 24 and 48 h after test initiation.
Test rates:	Control, 0.006, 0.019, 0.056, 0.167, 0.25 and 0.5 L BAS 500 06 F/ha. All treatment groups were applied in 200 L water/ha. The test item was sprayed onto glass plates via laboratory spraying equipment and air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 0.3 mL/ha.
Test conditions:	Temperature: 18.9 °C - 21.3 °C; relative humidity: 63% - 81%; photoperiod: 16 h light: 8 h dark; light intensity: 925.0 lux; food: 1:3 v/v solution of honey and water.
Endpoints:	Mortality after exposure over 48 h, including determination of a LR50.
Statistics:	Descriptive statistics. Probit analysis for calculation of LR50 and Dunnett`s Test (α = 0.05).

Results and discussions

After 48 hours, the mortality in the test item treatments was between 22.50% and 100.00% in comparison to 7.50% in the control. Based on these results the corrected mortality for the different rates ranged between 16.22% and 100.00%. Statistically significant difference compared to the control was observed at the test item rates of 0.056, 0.167, 0.25 and 0.5 L/ha BAS 500 06 F (Dunnett`s Test, $\alpha = 0.05$). The LR_{50} was calculated to be 0.04 L/ha BAS 500 06 F in 200 L water/ha. The results are summarized in the following table:

Effects of BAS 500 06 F on parasitic wasps (*Aphidius rhopalosiphi)* mortality under laboratory conditions

Treatment	Rate 1) [L/ha]	Mortality 2) [%]	Corrected mortality 3) [%]
Control	--	7.50	--
BAS 500 06 F	0.006	22.50	16.22
BAS 500 06 F	0.019	27.50	21.62
BAS 500 06 F	0.056	62.50*	59.46
BAS 500 06 F	0.167	100.00*	100.00
BAS 500 06 F	0.250	100.00*	100.00
BAS 500 06 F	0.500	100.00*	100.00
	Endpoint [L/ha BAS 500 06 F]		
LR_{50} (95% CL 4))	0.04 (0.03 - 0.05)		

1) Application rate in 200 L water/ha.
2) Mortality: after 48 hours of exposure to BAS 500 06 F on treated glass plates.
3) Corrected mortality according to Abbott (1925).
4) 95% CL means lower and upper 95% confidence limits.
* = statistically significant differences compared to the control (Dunnett`s Test, $\alpha = 0.05$)

Conclusion

In a laboratory study with BAS 500 06 F, the LR_{50} for the parasitic wasp *Aphidius rhopalosiphi* was determined to be 0.04 L/ha BAS 500 06 F in 200 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a laboratory study with BAS 500 06 F, the LR_{50} for the parasitic wasp *Aphidius rhopalosiphi* was determined to be 0.04 L/ha BAS 500 06 F.

IIIA 10.5.2 Effects on non-target terrestrial arthropods in extended laboratory studies

Reference:	IIIA 10.5.2/1
Report	Vaughan R., 2008a A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae) 300298, 2008/1010712, 2291137
Guideline(s):	Yes Bluemel et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

A rate response extended laboratory study was carried out to determine the toxicity of BAS 500 06 F on protonymphs of the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae). For determination of mortality the mites were exposed to fresh residues of BAS 500 06 F on leaf disks from bean plants (*Phaseolus vulgaris*). Application rates were 0.3125, 0.625, 1.25, 2.50 and 3.75 L/ha BAS 500 06 F. A water treated control and a toxic reference were applied to additional leaves. Endpoints were mortality in order to determine a LR_{50} and effects on reproduction for those treatments in which ≤ 60% corrected mortality was observed. After 7 days of exposure the mortality was 14.0% in the control, compared to 25.0% to 71.7% in the test item treatments. This resulted in corrected mortality rates between 12.8% and 67.1%. The results for mortality differed significantly from the control in the four highest test item treatments. The mean number of eggs per female was 9.9 in the control. The mean number of eggs produced in the test item treatments was 5.8 to 8.7 eggs/female, resulting in an effect on reproduction of 11.7% to 41.3%. There were no statistically significant reductions in egg production compared to the control at treatment rates up to and including 0.625 L/ha.

The LR50 of BAS 500 06 F on *Typhlodromus pyri* under extended laboratory conditions was 2.4524 L/ha. No unacceptable effects on reproduction were observed at treatment rates up to and including 2.50 L/ha BAS 500 06 F in 200 L water/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).
Test species:	Predatory mite (*Typhlodromus pyri*), protonymphs (less than 24 h old); source: in-house culture.
Test design:	Exposure of the mites was reached via air-dried residues on the treated upper (adaxial) side of leaves of dwarf French bean plants (*Phaseolus vulgaris).* Seven treatment groups (5 test item rates, control and toxic reference item) with 5 replicates for the control and 3 replicates for the test item and reference item were set up, each with 20 mites. Assessment of mortality was carried out 1 and 7 days after application. For the reproduction assessment mites from the control and the test item treatments displaying a corrected mortality rate ≤ 60% were sexed, left *in situ* and the number of eggs/female was recorded during the second week. Reproduction capacity of the mites was assessed 7 and 14 days after application.
Test rates:	Control, 0.3125, 0.625, 1.25, 2.50 and 3.75 L/ha BAS 500 06 F. All substances were applied in 200 L water/ha. The substances were sprayed onto the upper (adaxial) surfaces of bean leaf disks via a calibrated laboratory track-sprayer and left air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 30 mL/ha.
Test conditions:	Exposure period: temperature: 25 °C - 27 °C, relative humidity: 65% - 80%. Reproduction period: temperature: 25 °C - 26 °C, relative humidity: 67% - 74%. Photoperiod: 16 h light : 8 h dark; light intensity: 900 lux - 1600 lux. Food: 1:1 mixture of almond (Prunus sp.) and apple (Malus sp.) pollen.
Endpoints:	Mortality after 7 days of exposure; reproduction capacity between day 7 and 14 after application.
Statistics:	Descriptive statistics. Probit analysis for calculation of LR50, Fishers exact test for mortality data and Dunnett-test for reproduction data ($\alpha = 0.05$).

Results and discussions

After 7 days of exposure the mortality was 14.0% in the control, compared to 25.0% to 71.7% in the test item treatments. This resulted in corrected mortality rates between 12.8% and 67.1%. The results for mortality differed significantly from the control in the four highest test item treatments (Fishers exact test, $\alpha = 0.05$). The mean number of eggs per female was 9.9 in the control. The mean number of eggs produced in the test item treatments was 5.8 to 8.7 eggs/female, resulting in an effect on reproduction of 11.7% to 41.3%. There were no statistically significant reductions in egg production compared to the control at treatment rates up to and including 0.625 L/ha (Dunnett-test, $\alpha = 0.05$). The toxic reference item produced a corrected mortality of 84.5% of exposed mites after 7 days. The LR_{50} value was determined to 2.4524 L/ha BAS 500 06 F. The results are summarized in the following table:

Effects on predatory mites (*Typhlodromus pyri*), exposed to fresh dried residues of BAS 500 06 F in an extended laboratory trial.

Treatment	Rate 1) [L/ha]	Mortality 2) [%]	Corrected mortality 3) [%]	Reproduction 4) [eggs/female]	Effect on reproduction [%]
Control	--	14.0	--	9.9	--
BAS 500 06 F	0.3125	25.0 n.s.	12.8	8.7 n.s.	11.7
BAS 500 06 F	0.625	31.7*	20.5	7.5 n.s.	24.6
BAS 500 06 F	1.25	28.3*	16.7	5.8*	41.3
BAS 500 06 F	2.50	60.0*	53.5	6.2*	36.8
BAS 500 06 F	3.75	71.7*	67.1	--	--
Endpoint [L/ha BAS 500 06 F]					
LR_{50} (95% CL 5))	2.4524 (1.6105 - 5.3037)				
Effects on reproduction	$ER_{50} > 2.5$				

1) Application rate in 200 L water/ha
2) Mortality after 7 day exposure to BAS 500 06 F on the treated bean leaves
3) Corrected overall mortality according to Abbott (1925)
4) Reproduction: mean number of eggs per female from day 7 to 14
5) 95% CL means lower and upper 95% confidence limits.
* = statistically significant effects compared to the control (Fishers exact-test for mortality, Dunnett-test for reproduction, $\alpha = 0.05$)

Conclusion

The LR50 of BAS 500 06 F on *Typhlodromus pyri* under extended laboratory conditions was 2.4524 L/ha. No unacceptable effects on reproduction were observed at treatment rates up to and including 2.50 L/ha BAS 500 06 F in 200 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	The LR50 of BAS 500 06 F on *Typhlodromus pyri* under extended laboratory conditions was 2.4524 L/ha. No unacceptable effects on reproduction were observed at treatment rates up to and including 2.50 L/ha BAS 500 06 F in 200 L water/ha.

Reference:	IIIA 10.5.2/2
Report	Stevens J., 2008a

	A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) 300300, 2008/1010713, 2291138
Guideline(s):	Yes Mead-Briggs M. et al. (in preparation) An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp *Aphidius rhopalosiphi* (De Stefani-Perez) (Hymenoptera Braconidae)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In an extended laboratory study adults of the parasitic wasp, *Aphidius rhopalosiphi* (Hymenoptera Braconidae) were exposed to dried residues of 0.07, 0.15, 0.30, 0.60, 1.25 and 2.50 L/ha BAS 500 06 F on treated barley seedlings. The mortality of the wasps was assessed 2, 24 and 48 h after treatment. Additionally, for the reproduction assessment 15 females from the control and the 3 highest treatment groups displaying ≤ 60% corrected mortality were transferred individually to pots with untreated, aphid-infested barley plants for 24 h and then removed. The number of parasitized aphid mummies was recorded after 10 days. Additional test units were treated with water as a control and with Perfekthion as toxic reference item. During the first 3 h of the test 38.7% of the wasps in the control treatment settled on the treated plants compared to 28.7% to 34.0% in the test item treatments. After 24 h and 48 h 43.3% of the wasps in the control treatment settled on the treated plants compared to 35.8% to 41.4% in the test item treatments. A statistically significant difference compared to the control was not observed. After 48 h of exposure no mortality could be detected in the control. Corrected mortalities of 0.0% to 20.0% were observed in the test item treatments. Only the mortality in the 2.50 L/ha treatment rate differed significant from the control. The mean number of mummies per female was 26.1 in the control and ranged from 23.9 to 25.9 in evaluated test item groups. This resulted in effects on reproduction between 0.8% and 8.7%. There were no significant effects on reproduction, relative to the control, at rates up to and including the highest rate of 2.50 L/ha BAS 500 06 F.

The LR_{50} of BAS 500 06 F on *Aphidius rhopalosiphi* under extended laboratory conditions was > 2.50 L/ha. The test item caused no unacceptable effects on reproduction if applied up to and including a rate of 2.50 L/ha BAS 500 06 F in 400 L water/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).

Test species:	Parasitic wasp *(Aphidius rhopalosiphi)*, adults, age: less than 48 h; source: in-house culture.
Test design:	Exposure of the parasitoids was reached via air-dried residues on treated barley seedlings (*Hordeum vulgare)*. The study included 8 treatment groups (6 test item rates, water treated control, toxic reference item) with 6 replicates per treatment, each containing 5 female wasps. Repellence was assessed after 3, 24 and 48 h. Wasp mortality was assessed 2, 24 and 48 hours after test initiation. At 48 h 15 female wasps from the 3 highest treatment groups displaying ≤ 60% corrected mortality were transferred individually to pots with untreated, aphid-infested barley plants for 24 h and then removed for the reproduction assessment. The number of parasitized aphid mummies was recorded after 10 days. Host: cereal aphids (*Rhopalosiphum padi, Metopolophium dirhodum*).
Test rates:	Control, 0.07, 0.15, 0.30, 0.60, 1.25 and 2.50 L/ha BAS 500 06 F. All treatments were applied in 400 L/ha water. The treatments were sprayed on potted barley seedlings using a calibrated laboratory track sprayer and left air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 0.01 L/ha.
Test conditions:	Exposure period: temperature: 20 °C; relative humidity: 68% - 88%; photoperiod: 16 h light : 8 h dark; light intensity: 2810 lux. Reproduction period: temperature: 18 °C - 22° C; photoperiod: 16 h light : 8 h dark, light intensity: 4590 lux. Food: fructose-water solution (10%), sprayed onto test plants before application.
Endpoints:	Mortality after 48 h of exposure; effects on reproduction capacity after additional 24 h.
Statistics:	Descriptive statistics. Fishers exact test for mortality, one-way analysis of variance (ANOVA) for repellence and for reproduction data ($\alpha = 0.05$).

<u>Results and discussions</u>

During the first 3 h of the test 38.7% of the wasps in the control treatment settled on the treated plants compared to 28.7% to 34.0% in the test item treatments. After 24 h and 48 h 43.3% of the wasps in the control treatment settled on the treated plants compared to 35.8% to 41.4% in the test item treatments. A statistically significant difference compared to the control was not observed (ANOVA, $\alpha = 0.05$). After 48 h of exposure no mortality could be detected in the control. Corrected mortalities of 0.0% to 20.0% were observed in the test item treatments. Only the mortality in the 2.50 L/ha treatment rate differed significantly from the control (Fishers exact test, $\alpha = 0.05$). The mean number of mummies per female was 26.1 in the control and ranged from 23.9 to 25.9 in evaluated test item groups. This resulted in effects on reproduction between 0.8% and 8.7%. There were no significant effects on reproduction, relative to the control, at rates up to and including the highest rate of 2.50 L/ha BAS 500 06 F (ANOVA, α = 0.05). The toxic reference item caused 73.3% corrected mortality after 48 h of exposure. The LR_{50} value was determined to be > 2.50 L/ha BAS 500 06 F. The results are summarized in the following table:

Effects of BAS 500 06 F on parasitoids (*Aphidius rhopalosiphi*) mortality and reproduction under extended laboratory conditions

Treatment	Rate [1)] [L/ha]	Mortality [2)] [%]	Corrected mortality [3)] [%]	Reproduction [4)] [mummies/ female]	Effects on reproduction [%]
Control	--	0.0	0.0	26.1	--
BAS 500 06 F	0.07	0.0	0.0	--	--
BAS 500 06 F	0.15	0.0	0.0	--	--
BAS 500 06 F	0.30	0.0	0.0	--	--
BAS 500 06 F	0.60	0.0	0.0	25.9	0.8
BAS 500 06 F	1.25	10.0	10.0	23.9	8.7
BAS 500 06 F	2.50	20.0*	20.0	25.9	0.8
Endpoint [L/ha BAS 500 06 F]					
LR_{50}	> 2.5				
Effects on reproduction	ER_{50} > 2.5				

1) Application rate in 400 L water/ha
2) Mortality: after 48 hours of exposure to BAS 500 06 F on barley seedlings
3) Corrected mortality according to Abbott (1925)
4) Reproduction: mean number of parasitized aphids/surviving female
* = statistically significant differences compared to the control (Fisher's exact test, α = 0.05)

Conclusion

The LR_{50} of BAS 500 06 F on *Aphidius rhopalosiphi* under extended laboratory conditions was > 2.50 L/ha. The test item caused no unacceptable effects on reproduction if applied up to and including a rate of 2.50 L/ha BAS 500 06 F in 400 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	The LR_{50} of BAS 500 06 F on *Aphidius rhopalosiphi* under extended laboratory conditions was > 2.50 L/ha. The test item caused no unacceptable effects on reproduction if applied up to and including a rate of 2.50 L/ha BAS 500 06 F in 400 L water/ha.

Reference:	IIIA 10.5.2/3

Report	Roehlig U., 2008a Effects of BAS 500 06 F on the green lacewing *Chrysoperla carnea* STEPH. under extended laboratory conditions - Rate-response test 08 10 48 030 A, 2008/1032666, 2291139
Guideline(s):	Yes Vogt, H. et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

An extended laboratory study was carried out to determine the effects of the fungicide BAS 500 06 F on the green lacewing *Chrysoperla carnea* (Neuroptera: Chrysopidae). For determination of the mortality larvae were exposed to fresh, dry residues of BAS 500 06 F on bean leaves at rates of 0.31, 0.63, 1.25, 2.5 and 3.75 L/ha with a water volume of 200 L/ha. Additional test units were treated with deionized water as control and with Perfekthion as toxic reference item. Endpoints of the study were the pre-imaginal mortality and additionally effects on reproduction. Assessment of mortality was carried out regularly until hatching of adult lacewings. Effects on reproduction were assessed by number of eggs produced per female and the hatching rate. In the water treated control 2.0% mortality was observed. Corrected mortalities between 8.2% and 100.0% were observed in the test item treatments. No statistically significant effect on mortality was determined in the 0.31 L/ha treatment group. In all other test item treatment groups a statistically significant effect on mortality was observed. In the control as well as in the 0.31 and 0.63 L/ha BAS 500 06 F test item treatments the number of eggs per female per day was ≥ 15 and the hatching rate was ≥ 70%.

In an extended laboratory study with BAS 500 06 F the LR_{50} for *Chrysoperla carnea* was determined to be 0.72 L/ha BAS 500 06 F in 200 L water/ha. No unacceptable effects on reproduction of *Chrysoperla carnea* occurred when BAS 500 06 F was applied at rates up to and including 0.63 L/ha BAS 500 06 F.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).
Test species:	Green lacewing (*Chrysoperla carnea*); larvae (2-3 days old); source: in-house.
Test design:	Exposure of the lacewings was reached via air-dried residues on excised bean leaves. The study encompassed seven treatment groups (5 test item rates, control, toxic reference item), each with 50 replicates (1 larvae/replicate) per treatment. Condition of exposed individuals was assessed until emergence of adult lacewings. Mortality assessment was carried out regularly until hatching of the adult lacewings. In addition, for the control and the test item

	groups, in which corrected mortality was < 50% the reproduction performance, i.e. egg deposition and hatching rate, was determined (2 assessments/week, 24 h period each).
Test rates:	Control, 0.31, 0.63, 1.25, 2.5 and 3.75 L/ha BAS 500 06 F. All substances were applied in 200 L/ha water. The substances were sprayed on bean leaves (Phaseolus vulgaris) via calibrated laboratory spraying equipment and air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 40 mL/ha.
Test conditions:	Temperature: 23 °C - 27 °C; relative humidity: 68% - 73%; photoperiod: 16 hours light : 8 hours dark; light intensity: 2180 lux. Food: larvae: *Sitotroga cerealella* eggs (UV-sterilized); adults: artificial diet
Endpoints:	Pre-imaginal mortality (mortality of exposed larvae and pupae until hatching of adults) including the determination of a LR_{50}. Reproductive capacity: assessment of number of eggs per female per day and hatching rate.
Statistics:	Descriptive statistics. Fishers Exact Binominal Test for pre-imaginal mortality data ($\alpha = 0.05$), Probit analysis for LR_{50}.

Results and discussions

In the water treated control 2.0% mortality was observed. Corrected mortalities between 8.2% and 100.0% were observed in the test item treatments. No statistically significant effect on mortality was determined in the 0.31 L/ha treatment group. In all other test item treatment groups a statistically significant effect on mortality was observed (Fisher's Exact Binominal Test, $\alpha = 0.05$). In the control as well as in the 0.31 and 0.63 L/ha BAS 500 06 F test item treatments the number of eggs per female per day was ≥ 15 and the hatching rate was ≥ 70%. In the toxic reference treatment 75.5% corrected mortality was observed. The LR_{50} value was determined to be 0.72 L/ha BAS 500 06 F. The results are summarized in the following table:

Effects on lacewings (*Chrysoperla carnea*) exposed to BAS 500 06 F in an extended laboratory trial

Treatment	Rate 1) [L/ha]	Mortality2) [%]	Corrected mortality3) [%]	Mean number [eggs/female/ day]	Hatching rate [%]
Control	--	2.0	--	22.8	79.4
BAS 500 06 F	0.31	10.0	8.2	26.7	78.7
BAS 500 06 F	0.63	46.0*	44.9	23.0	78.1
BAS 500 06 F	1.25	82.0*	81.6	n.d.	n.d.
BAS 500 06 F	2.5	94.0*	93.9	n.d.	n.d.
BAS 500 06 F	3.75	100.0*	100.0	n.d.	n.d.
	Endpoint [L/ha BAS 500 06 F]				
LR_{50} (95% CL4))	0.72 (0.62 - 0.84)				
Effects on reproduction	ER_{50} > 0.63				

1) Application rate in 200 L water/ha
2) Percentage of individuals, which did not reach maturity
3) Corrected mortality according to Abbott (1925)
4) 95% CL means lower and upper 95% confidence limits
* = statistically significant differences compared to the control (Fishers exact binominal test, α = 0.05)
n.d. = not determined, corrected mortality > 50% compared to the control

Conclusion

In an extended laboratory study with BAS 500 06 F the LR50 for *Chrysoperla carnea* was determined to be 0.72 L/ha BAS 500 06 F in 200 L water/ha. No unacceptable effects on reproduction of *Chrysoperla carnea* occurred when BAS 500 06 F was applied at rates up to and including 0.63 L/ha BAS 500 06 F

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In an extended laboratory study with BAS 500 06 F the LR50 for *Chrysoperla carnea* was determined to be 0.72 L/ha BAS 500 06 F in 200 L water/ha. No unacceptable effects on reproduction of *Chrysoperla carnea* occurred when BAS 500 06 F was applied at rates up to and including 0.63 L/ha BAS 500 06 F.

Reference:	IIIA 10.5.2/4
Report	Schmitzer S., 2008a Effects of BAS 500 06 F on the reproduction of rove beetles (*Aleochara bilineata*) - Extended laboratory study 41651071, 2008/1010700, 2291140

Guideline(s):	Yes Grimm et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

An extended laboratory study was performed to determine the effects of the fungicide BAS 500 06 F on the staphylinid beetle *Aleochara bilineata*. The test item was applied to the soil (LUFA 2.1) surface at rates of 2.5 and 3.75 L BAS 500 06 /ha. The study covers the complete life cycle of the beetle: parental generation, mating and oviposition of parental generation, hatching of F1 larvae and parasitization period until emergence of the F1 adults. The endpoint of the study was the effect on reproduction represented by the living offspring hatched from the onion fly pupae, which were added to the natural test soil during the first 3 weeks of the study. The number of hatched beetles was 550 in the control. In the two test item treatments 471 and 492 beetles hatched. This is corresponding to an effect of 14.4% and 10.6%, respectively, relative to the control. No statistically significant difference compared to control was observed. In an extended laboratory study with BAS 500 06 F, no unacceptable effects on reproduction of Aleochara bilineata occurred after exposure to natural soil treated with 2.5 and 3.75 L BAS 500 06 F/ha in 400 L water/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).
Test species:	Staphylinid beetle (*Aleochara bilineata*), adults 2 - 4 days old, source: De Groene Vlieg, Nieuwe Tonge, Netherlands.
Test design:	The test item rates, a control and a toxic reference item were sprayed via laboratory spray applicator on the soil surface. Exposure of the beetles was reached via treated natural soil LUFA 2.1. The beetles were introduced to the test units immediately after treatment. Four replicates per treatment group were set up with 10 female and 10 male beetles each. This study included the complete life cycle of the beetles: parental generation, mating and oviposition of parental generation, hatching of F1 larvae and parasitization period until emergence of the F1 adults. On day 7, 14 and 21 approximately 500 pupae of *Delia antiqua* were dug into the soil to be parasitized by larvae of the beetles. On day 28 adults were separated from the soil and the soil with the pupae was allowed to dry for seven days. On day 35 the pupae

	were sieved out of the natural soil and transferred into an emergence container. The emergence of the F1-generation of beetles was observed from day 38 - 75.
Test rates:	Control, 2.5 and 3.75 L/ha BAS 500 06 F. All substances were applied in 400 L water/ha directly on soil surface via laboratory spraying equipment.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 4.4 L/ha.
Test conditions:	Temperature: 18 °C - 22 °C; relative humidity: 68% - 90%; photoperiod: 16 h light : 8 h dark; light intensity: 520 lux - 1250 lux. Food: frozen midge larvae (*Chironomus sp.).*
Endpoints:	Effect on reproduction (reproduction capacity).
Statistics:	Descriptive statistics. Student t-test, one-sided smaller, for reproduction data (α = 0.05).

Results and discussions

The number of hatched beetles was 550 in the control. In the two test item treatments 471 and 492 beetles hatched. This is corresponding to an effect of 14.4% and 10.6%, respectively, relative to the control. No statistically significant difference compared to control was observed (Student t-test, one-sided smaller, α = 0.05). The results are summarized in the table below:

Effects on staphylinid beetles (*Aleochara bilineata*) exposed to BAS 500 06 F in an extended laboratory trial

Treatment	Rate 1) [L/ha]	Reproduction [mean number of emerged beetles ± Standard deviation]	Effects on reproduction 2) [%]
Control	--	550 ± 71	--
BAS 500 06 F	2.5	471 ± 56	14.4
BAS 500 06 F	3.75	492 ± 91	10.6
	Endpoint [L/ha BAS 500 06 F]		
ER_{50}	> 3.75		

1) Application rate in 400 L water/ha

2) Effects on reproduction calculated based on the exact raw data (calculation: (1-Rt/Rc)*100%)

The toxic reference item resulted in a reduction of reproduction of 99.8% compared to the control.

Conclusion

In an extended laboratory study with BAS 500 06 F, no unacceptable effects on reproduction of *Aleochara bilineata* occurred after exposure to natural soil treated with 2.5 and 3.75 L BAS 500 06 F/ha in 400 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In an extended laboratory study with BAS 500 06 F the ER50 for *Aleochara bilineata* was determined to be > 3.75 L/ha. No unacceptable effects on reproduction of *Aleochara bilineata* occurred after exposure to natural soil treated with 2.5 and 3.75 L BAS 500 06 F/ha.

Reference:	10.5.2/5
Report	Roehlig U., 2008b Effects of BAS 500 06 F on the green lacewing Chrysoperla carnea STEPH. in an extended laboratory test (under semi-field conditions aged residues on bean plants) 08 10 48 046 A, 2008/1042190, 2291140
Guideline(s):	Yes Vogt et al. (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

An aged residue extended laboratory study was carried out to determine the effects of the fungicide BAS 500 06 F on the green lacewing, *Chrysoperla carnea* (Neuroptera: Chrysopidae). For determination of the mortality, larvae were exposed to both freshly-dried and field aged residues of BAS 500 06 F on bean leaves at rates of 1.25 and 2.50 L/ha with a water volume of 400 L/ha. Additional test units were treated with deionized water as control and with Perfekthion as toxic reference item. Extended laboratory bioassays were initiated within 1 hour after application (DAT 0) and also at 7 and 14 days after treatment (DAT 7, DAT 14). Endpoints of the study were the pre-imaginal mortality and additionally effects on reproduction. Assessment of mortality was carried out regularly until hatching of adult lacewings. Effects on reproduction were assessed by number of eggs produced per female and the hatching rate.

In the bioassay started at DAT 0 corrected mortality rates of 36.2% and 66.0% were observed. Statistically significant effects on mortality were determined in both test item treatments. In the control as well as in the 1.25 L/ha treatment the number of eggs per female per day was > 15 and the hatching rate was > 70%. In the 2.50 L/ha test item treatment group no reproduction test was carried out, because corrected mortality was > 50%.

In the bioassay started on DAT 7 corrected mortality rates of 6.3% and 41.7% were observed. Statistically significant effects on mortality were determined only in the 2.5 L/ha treatment. In the control as well as in both BAS 500 06 F treatments the number of eggs per female per day was > 15 and the hatching rate was > 70%.

In the bioassay started on DAT 14 corrected mortality rates of 2.0% and 10.0% were observed. No statistically significant effects on mortality were determined in both test item groups. In the control as well as in both BAS 500 06 F treatments the number of eggs per female per day was > 15 and the hatching rate was > 70%.

In an aged residue extended laboratory study with BAS 500 06 F no unacceptable effects on survival were observed after exposure to freshly dried residues (DAT 0) obtained from a rate of 1.25 L/ha in 400 L water/ha. However, at an application rate of 2.5 L BAS 500 06 F/ha 68 % effect on mortality was observed. After exposure to aged residues (DAT 7) no unacceptable effects on survival were observed at an application rate of 2.5 L BAS 500 06 F/ha.

No unacceptable effects on reproduction were observed after exposure to freshly dried residues (DAT 0) obtained from a rate of 1.25 L/ha or aged residues (DAT 7) obtained from a rate of 2.5 L/ha BAS 500 06 F/ha in 400 L water/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed).
Test species:	Green lacewing (*Chrysoperla carnea*); larvae (2-3 days old); source: in-house.
Test design:	Exposure of the lacewings was reached via both, freshly-dried and field aged residues on bean leaves, which were taken from treated potted bean plants. The study encompassed four treatment groups (2 test item rates, control and toxic reference item), each with 50 replicates (1 larvae/replicate) per treatment. Following treatment, the plants were maintained outdoors but under UV light-permeable rain protection for air-drying of the spray deposits. Bioassays under laboratory conditions were initiated within 1 hour after application (DAT 0) and also at 7, 14 and 21 days after treatment (DAT 7, DAT 14, DAT 21). The results of the DAT 14 bioassay indicated that the test item had no adverse effects and the bioassay started on DAT 21 was terminated and not reported. For each bioassay exposure lasted until pupae were transferred to oviposition boxes for development of adults. Mortality assessment was carried out regularly until hatching of the adult lacewings. In addition, for the control and the test item groups, in which < 50% corrected pre-imaginal mortality was observed, the reproduction performance, i.e.

	egg deposition and hatching rate, was determined (2 assessments/week, 24 h period each).
Test rates:	Control, 1.25 and 2.50 L/ha BAS 500 06 F. All substances were applied in 400 L/ha water. The substances were sprayed on potted bean plants via plot-sprayer and air dried afterwards.
Reference item:	Perfekthion (dimethoate: nominal 400 g/L). The toxic reference item was applied at an application rate of 0.10 L/ha.
Test conditions:	Temperature: 23 °C - 26 °C (DAT 0, DAT 7 and DAT 14); relative humidity: 64% - 88% (DAT 0 and DAT 7), 64% - 84% (DAT 14); light intensity: 2070 lux (DAT 0), 2180 lux (DAT 7) and 2190 lux (DAT 14). Photoperiod: 16 hours light : 8 hours dark; food: larvae: *Sitotroga cerealella* eggs (UV-sterilized), adults: artificial diet.
Endpoints:	Pre-imaginal mortality (mortality of exposed larvae and pupae until hatching of adults). Reproductive capacity: assessment of number of eggs per female per day and hatching rate.
Statistics:	Descriptive statistics. Fishers Exact Binominal Test for pre-imaginal mortality data ($\alpha = 0.05$).

Results and discussions

In the bioassay started at DAT 0 corrected mortality rates of 36.2% and 66.0% were observed. Statistically significant effects on mortality were determined in both test item treatments (Fishers Exact Binominal Test, $\alpha = 0.05$). In the control as well as in the 1.25 L/ha treatment the number of eggs per female per day was > 15 and the hatching rate was > 70%. In the 2.50 L/ha test item treatment group no reproduction test was carried out, because corrected mortality was > 50%.

In the bioassay started on DAT 7 corrected mortality rates of 6.3% and 41.7% were observed. Statistically significant effects on mortality were determined only in the 2.5 L/ha treatment. In the control as well as in both BAS 500 06 F treatments the number of eggs per female per day was > 15 and the hatching rate was > 70%.

In the bioassay started on DAT 14 corrected mortality rates of 2.0% and 10.0% were observed. No statistically significant effects on mortality were determined in both test item groups (Fishers Exact Binominal Test, $\alpha = 0.05$). In the control as well as in both BAS 500 06 F treatments the number of eggs per female per day was > 15 and the hatching rate was > 70%. The results are summarized in the table below:

Effects on lacewings (*Chrysoperla carnea*) exposed to BAS 500 06 F in an aged residue extended laboratory study

Treatment	Rate 1) [L/ha]	Mortality2) [%]	Corrected mortality3) [%]	Mean number [eggs/female/ day]	Hatching rate [%]
DAT 04)					
Control	--	6.0	--	25.4	81.0
BAS 500 06 F	1.25	40.0*	36.2	20.8	80.8
BAS 500 06 F	2.50	68.0*	66.0	n.d.	n.d.
DAT 74)					
Control	--	4.0	--	21.8	78.4
BAS 500 06 F	1.25	10.0	6.3	22.1	79.2
BAS 500 06 F	2.50	44.0*	41.7	20.3	79.5
DAT 144)					
Control	--	0	--	19.4	79.1
BAS 500 06 F	1.25	2.0	2.0	20.3	79.3
BAS 500 06 F	2.50	10.0	10.0	20.8	78.4

1) Application rate in 400 L water/ha
2) Percentage of individuals, which did not reach maturity
3) Corrected mortality according to Abbott (1925)
4) DAT = Days After Treatment (equivalent to days over which residues were aged before bioassay initiated
* = statistically significant differences compared to the control (Fishers exact binominal test, $\alpha = 0.05$)
n.d. = no determined, corrected mortality > 50% compared to control

In the bioassay DAT 0, the toxic reference item caused 85.1% corrected mortality of exposed lacewings.

Conclusion

In an aged residue extended laboratory study with BAS 500 06 F no unacceptable effects on *Chrysoperla carnea* on survival were observed after exposure to freshly dried residues (DAT 0) obtained from a rate of 1.25 L/ha in 400 L water/ha. However, at an application rate of 2.5 L BAS 500 06 F/ha 68 % effect on mortality was observed. After exposure to aged residues (DAT 7) no unacceptable effects on survival were observed at an application rate of 2.5 L BAS 500 06 F/ha.

No unacceptable effects on reproduction were observed after exposure to freshly dried residues (DAT 0) obtained from a rate of 1.25 L/ha or aged residues (DAT 7) obtained from a rate of 2.5 L/ha BAS 500 06 F/ha in 400 L water/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In an aged residue extended laboratory study with BAS 500 06 F no unacceptable effects on survival were observed after exposure to freshly

	dried residues (DAT 0) obtained from a rate of 1.25 L/ha in 400 L water/ha. The LR50 was determined to be > 1.25 L/ha (0 DAT). On DAT 7 following application at 2.5 L/ha BAS 500 06 F no unacceptable effects on survival and reproduction were observed.

IIIA 10.6 Effects on Earthworms and Other Soil Non-target Macro-organisms

IIIA 10.6.2 Acute toxicity

Reference:	IIIA 10.6.2
Report	Fleischer G., 2004a Effect of BAS 500 06 F on the mortality of the earthworm *Eisena fetida* 181351, 2004/1004367, 2291142
Guideline(s):	Yes ISO 11268-1 (1993)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

Adult earthworms, of the species *Eisenia fetida*, were exposed to BAS 500 06 F. The test item was mixed into artificial soil at a rate of 197.5, 296.3, 444.4, 666.7 and 1000.0 mg BAS 500 06 F/kg dry soil. For the control treatment, the soil was left untreated. The test soil had an organic content of approximately 10% (as sphagnum peat). The worms were placed on the surface of the soil. Four replicates were prepared for each treatment group and the control, each containing 10 worms. Assessment of mortality was made 7 and 14 days after treatment. Assessment of worm weight was made after 14 days.

After 14 days of exposure no mortality was observed in treatment groups up to 296.3 mg/kg soil. High mortality was observed at test concentrations of 444.4 mg/kg soil and higher. All treatment groups including the control showed reduction in biomass. Statistically significant differences were determined in the treatment group with the test concentration of 444.4 mg/kg dry soil, surviving worms in this test concentration were shorter and thinner. No other particular behavioral or morphological changes were observed.

In a 14-d toxicity study with BAS 500 06 F on earthworms (Eisenia fetida) the LC50 was 385.63 mg BAS 500 06 F/kg dry soil. The NOEC related to mortality and biomass was 296.3 mg BAS 500 06 F/kg dry soil.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed), density: 1.044 g/cm³.
Test species:	Earthworm (*Eisenia fetida)*, adult worms (with clitellum and weight 300 - 600 mg), less than 1 year old; source: in-house culture.
Test design:	14-d exposure in treated artificial soil; different concentrations of the test item were mixed homogeneously into the soil which was filled in glass vessels before the earthworms were introduced on top of the soil; 6 treatment groups (5 test item rates, control); 4 replicates/group with 10 worms each. Earthworm mortality effects were assessed after 7 and 14 d, measurement of weight change as sublethal parameter after 14 d.
Test rates:	Control, 197.5, 296.3, 444.4, 666.7 and 1000.0 mg BAS 500 06 F/kg dry soil.
Reference item:	2-chloroacetamide. The effects of the toxic reference item were evaluated in a separate study.
Test conditions:	Artificial soil according to ISO 11268-1:1993(E) with 10% sphagnum peat; pH 6.1; water content: 28.8 g/100 g dry soil at test initiation, 26.4 g/100 g dry soil at test termination; temperature: 20 °C ± 2 °C; photoperiod: 16 h light : 8 h dark, light intensity: 400 lux - 800 lux.
Endpoints:	Mortality of earthworms after exposure over 14 days, weight change.
Analytics:	Analytical verification of pyraclostrobin in 5 soil cores taken from each treated plot using an LC-MC/MS method.
Statistics:	Descriptive statistics. Spearman-Karber Estimate for determination of LC_{50} and Bonferroni t-Test for biomass development ($\alpha = 0.05$).

Results and discussions

After 14 days of exposure no mortality was observed in treatment groups up to 296.3 mg/kg soil. High mortality was observed at test concentrations of 444.4 mg/kg soil and higher. All treatment groups including the control showed reduction in biomass. Statistically significant differences (Bonferroni t-Test, $\alpha = 0.05$) were determined in the treatment group with the test concentration of 444.4 mg/kg soil, surviving worms in this test concentration were shorter and thinner. No other particular behavioral or morphological changes were observed. The results are summarized in the table below:

Effect of BAS 500 06 F on earthworm (*Eisenia fetida)* mortality and biomass (14 d)

BAS 500 06 F [mg/kg dry soil]	Control	197.5	296.3	444.4	666.7	1000
Mortality [%]	0.00	0.00	0.00	85.00	100.00	100.00
Weight change [%]	-12.87	-8.90	-14.82	-34.02 *	--	--
Endpoints [mg/kg dry soil]						
NOEC	296.3					
LC_{50} (95% CL)[1)]	385.63 (368.71 - 403.32)					

1) Median effect concentration calculated using Spearman-Karber Estimate (with 95% Confidence Limits)
* = statistically significant differences compared to the control (Bonferroni t-Test; α = 0.05)

The LC_{50} was derived to be 385.63 mg BAS 500 06 F/kg dry soil.

Conclusion

In a 14-d toxicity study with BAS 500 06 F on earthworms (Eisenia fetida) the LC50 was 385.63 mg BAS 500 06 F/kg dry soil. The NOEC related to mortality and biomass was 296.3 mg BAS 500 06 F/kg dry soil.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 14-d toxicity study with BAS 500 06 F on earthworms (Eisenia fetida) the LC50 was determined to 385.63 mg BAS 500 06 F/kg dry soil.

IIIA 10.6.3 Sublethal effects

Reference:	IIIA 10.6.3
Report	Luehrs U., 2008a Effects of BAS 500 06 F on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat 41652022, 2008/1036409, 2291143
Guideline(s):	Yes OECD 222, ISO 11268-2 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

The effects of BAS 500 06 F on mortality, biomass development and reproduction of the earthworm *Eisenia fetida* were investigated in a 56-day extended laboratory study. Five application rates (3.8, 7.5, 15.0, 30.0 and 60.0 mg BAS 500 06 F/kg dry soil were incorporated into the soil (5% peat) with four replicates per treatment (each containing 10 worms). An untreated control with 8 replicates was included. The toxic reference item was tested in a separate study. Assessment of adult worm mortality and biomass development was carried out after 28 days, assessment of reproduction rate (number of juveniles) was carried out after 56 days. No mortality of parent earthworms was observed in any treatment group. No statistically significant effects on body weight were observed up to the highest test concentration of 60 mg BAS 500 06 F/kg dry soil. The number of juveniles was statistically significantly reduced in the highest test item concentration of 60 mg BAS 500 06 F/kg dry soil. No behavioral abnormalities were observed in any of the treatment groups.

In a 56-day reproduction study with BAS 500 06 F, no statistically significant effects on mortality and growth of earthworms (Eisenia fetida) were observed up to a rate of 60 mg BAS 500 06 F/kg dry soil. The NOEC for reproduction was 30 mg BAS 500 06 F/kg dry soil.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed), density: 1.044 g/cm³.
Test species:	Earthworm (Eisenia fetida), adult worms (with clitellum and weight of 300 - 600 mg), approximately 10 months old; source: in-house culture.
Test design:	56-day test in treated artificial soil according to OECD 222 (5% peat). Different concentrations of the test item are mixed homogeneously into the soil. 6 treatment groups (5 test item rates, control) were set up with 8 replicates for the control and 4 replicates for the test item group, each with 10 worms. Assessment of worm mortality, behavioral effects and weight change was done after 28 days of exposure, after an additional 28 days (56 days after application) the number of offspring was counted.
Test rates:	Control, 3.8, 7.5, 15.0, 30.0 and 60.0 mg BAS 500 06 F/kg dry soil.
Reference item:	Brabant Carbendazim Flowable (carbendazim, 500 g/L nominal). The effects of the toxic reference item were investigated in a separate study.
Test conditions:	Artificial soil according to ISO 11268-1:1993(E) with 10% sphagnum peat; pH 6.1; water content: 28.8 g/100 g dry soil at test initiation, 26.4 g/100 g dry soil at test termination; temperature: 20 °C ± 2 °C; photoperiod: 16 h light : 8 h dark, light intensity: 400 lux - 800 lux.
Endpoints:	Mortality, weight change, behavioral effects, reproduction rate.

Statistics: Descriptive statistics. Dunnett-test for weight changes and reproduction data ($\alpha = 0.05$).

Results and discussions

No mortality of parent earthworms was observed in any treatment group. No statistically significant effects on body weight were observed up to the highest test concentration of 60 mg BAS 500 06 F/kg dry soil (Dunnett-test, $\alpha = 0.05$). The number of juveniles was statistically significantly reduced in the highest test item concentration of 60 mg BAS 500 06 F/kg dry soil (Dunnett-test, $\alpha = 0.05$). No behavioral abnormalities were observed in any of the treatment groups. The feeding activity in the test item groups was comparable to the control. The results are summarized in the table below:

Effect of BAS 500 06 F on earthworm (*Eisenia fetida*) in a 56-day reproduction study

BAS 500 06 F [mg/ kg dry soil]	**Control**	**3.8**	**7.5**	**15.0**	**30.0**	**60.0**
Mortality (28 d) [%]	0	0	0	0	0	0
Weight change (28 d) [%]	29.9	35.6	34.0	29.8	27.8	26.7
Number of juveniles (56 d)	234	193	207	224	208	151*
Reproduction (56 d) [% of control]	--	82.6	88.5	95.9	88.7	64.4
	Endpoints [mg BAS 500 06 F/kg dry soil]					
$NOEC_{mortality, weight change}$ (28 d)	60					
$NOEC_{reproduction}$ (56 d)	30					

* = statistically significant compared to the control (Dunnett-test, $\alpha = 0.05$)

Conclusion

In a 56-day reproduction study with BAS 500 06 F, no statistically significant effects on mortality and growth of earthworms (*Eisenia fetida*) were observed up to a rate of 60 mg BAS 500 06 F/kg dry soil. The NOEC for reproduction was 30 mg BAS 500 06 F/kg dry soil.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 56-day reproduction study with BAS 500 06 F the NOEC for reproduction was determined to 30 mg BAS 500 06 F/kg dry soil.

IIIA 10.6.4 Field tests

Reference:	IIIA 10.6.4
Report	Luehrs U., 2010a Field study to evaluate the effects of BAS 500 06 F on earthworms 41654023, , 2010/1000056, 2291144
Guideline(s):	Yes ISO 11268-3 (1999), Kula et al. (2006) - Technical Recommendations for the Update of the ISO Earthworm Field Test Guideline (ISO 11268-3)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

A grassland site was chosen as a natural habitat of earthworms. The treatments with 1.25 L/ha, 2.5 L/ha and 6.25 L BAS 500 06 F/ha were assigned randomly to the plots within each replicate. Over the experimental period from May 2009 until May 2010 four earthworm samplings were evaluated. Earthworm extraction was achieved using the electrical octet method in combination with hand sorting.

Prior to the treatment, the test site yielded sufficiently high numbers of earthworms of 202.8 individuals per m^2 representing various common earthworm species such as *Aporrectodea caliginosa*, *Octolasion tyrtaeum* and *Lumbricus terrestris*.

No statistically significant differences between BAS 500 06 F treatments and the untreated control could be detected in terms of total earthworm abundance 1.5, 5 and 12 months after application. The total biomass was reduced after 6 weeks with statistically significant differences compared to the control at 1.25 L and 6.25 L BAS 500 06 F/ha. However, total biomass had fully recovered after 5 months of exposure. After one year exposure biomass was reduced at a rate of 1.25 L BAS 500 06 F/ha, which was not considered to be treatment related as no dose relation statistical significance could be observed. For the most abundant earthworm species *Lumbricus terrestris* and *Aporrectodea caliginosa* the abundance was slightly but not statistically significantly reduced at 6.25 L BAS 500 06 F/ha after 6 weeks and had recovered after 5 months. The slight but not significant reduction of juvenile earthworms after 6 weeks had recovered after 12 months. Moreover, no statistically significant effects were found at the end of the study. Based on the results of this field study, it is concluded that exposure of earthworm populations to rates up to 6.25 L BAS 500 06 F/ha does not cause unacceptable long-term effects.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed), density: 1.044 g/cm³.
Test species:	Naturally occurring population of earthworms comprising all mobile stages (juveniles and adult worms) including epilobous species such as *Aporrectodea caliginosa*, *Aporrectodea limicola*, *Aporrectodea rosea*, *Octolasion tyrtaeum* and *Octolasion cyaneum* as well as tanylobous species such as *Lumbricus castaneuss* and *Lumbricus terrestris*
Test site:	Grassland site near Klein-Zimmern in municipality Groß-Umstad, Germany. The site had not received chemical applications for the past 5 years and none were applied during the study apart from the test and toxic reference item.
Test design:	Randomized block design with 5 treatment groups (control, 3 test item rates and reference item) each with of 4 replicates. A number of 20 plots each 10 m x 10 m, were arranged. The substances in all treatments were applied in a water volume equivalent to 400 L/ha. Application was performed using a plot sprayer with 2.5 m boom width. Natural rainfall within 2 days after application was 23 mm, therefore no additional irrigation.
Test rates:	Untreated control; BAS 500 06 F: 1.25 L/ha, 2.5 L/ha, 6.25 L/ha; reference item: 6 kg carbendazim/ha..
Reference item:	Luxan Carbendazim-500 FC (carbendazim, 500 g/L).
Test conditions:	Natural field conditions; strong clayey silt to strong silty clay (according to DIN 4220), pH 5.9 - 6.2, 2.2 - 2.3% total organic carbon, max. water holding capacity 61.0%. Air temperature at application day: 13.4 °C - 16.6 °C, Soil temperature at application day: 14.9 °C - 15.6 °C.
Method of extraction:	Earthworm extraction was achieved by using the electrical octet method in combination with hand sorting. 4 samples per plot were taken from the inner area of the plots.
Endpoints:	Total abundance and biomass of earthworms
Sampling dates:	Pre-sampling: 2 to 3 days before application (12. + 13.05.2009); 1st sampling: approx. 6 weeks after application (24. + 25.06.2009); 2nd sampling: approx. 5 months after application (20. + 21.10.2009); 3rd sampling: approx. 12 months after application (10. + 11.05.2010).
Observations:	Total abundance and biomass of earthworms
Analytics:	Analytical verification of pyraclostrobin in 5 soil cores taken from each treated plot using an LC-MC/MS method.
Statistics:	Descriptive statistics; Dunnett's t-test and Bonferroni-Welch t-test for the test item treatment groups, Student t-test for the reference item group ($\alpha = 0.05$).

Results and discussions

No measurable residues of BAS 500 06 F were determined in any of the soil samples of the control plots. In the plots treated with the test item BAS 500 06 F, mean residue values of 58% to 68% (ranging from 44% to 92% of the expected soil concentration) of the application rate were found. All mean recoveries were in the recommended range of 50-150%.

Prior to the treatment, the test site yielded sufficiently high numbers of earthworms of 202.8 individuals per m^2 representing various common earthworm species such as *Aporrectodea caliginosa*, *Octolasion tyrtaeum* and *Lumbricus terrestris*.

Surface monitoring on days 1-3 after application showed that there was no acute primary effect on earthworms by the test item. No alive, moribund and dead earthworms were found on the soil surface in any of the plots treated with BAS 500 06 F and in the control plots. No statistically significant differences between BAS 500 06 F treatments and the untreated control could be detected in terms of total earthworm abundance 1.5, 5 and 12 months after application. The total biomass was reduced after 6 weeks (maximum 27.7%) with statistically significant differences compared to the control at 1.25 L and 6.25 L BAS 500 06 F/ha (Bonferroni-Welch t-test, $\alpha = 0.05$). However, total biomass had fully recovered after 5 months of exposure. After one year exposure biomass was reduced at a rate of 1.25 L BAS 500 06 F/ha, which was not considered to be treatment related as no dose relation could be observed. For the most abundant earthworm species *Lumbricus terrestris* and *Aporrectodea caliginosa* the abundance was slightly but not statistically significantly reduced at 6.25 L BAS 500 06 F/ha after 6 weeks and had recovered after 5 months (Dunnett's t-test, $\alpha = 0.05$). The slight but not significant reduction of juvenile earthworms after 6 weeks had recovered after 12 months. Moreover, no statistically significant effects were found at the end of the study. The results are summarized in the table below:

Summary of total earthworm abundance and biomass in a field study with BAS 500 06 F

Treatment	Pre sampling 12. + 13.05.2009	First sampling 24. + 25.06.2009	Second sampling 20. + 21.10.2009	Third sampling 10. + 11.05.2010
Total earthworm abundance [Ind./m²]				
Control	202.8	216.0	235.0	211.0
1.25 L/ha BAS 500 06 F	195.5	235.5	214.0	185.5
% of control	**96.4**	**90.2**	**91.1**	**87.9**
2.5 L/ha BAS 500 06 F	202.5	218.5	209.0	205.5
% of control	**99.9**	**83.7**	**88.9**	**97.4**
6.25 L/ha BAS 500 06 F	206.8	185.0	188.5	197.0
% of control	**102.0**	**70.9**	**80.2**	**93.4**
Reference item: carbendazim	102.2% of control	38.5% of control *	38.9% of control *	55.0% of control *
Total earthworm biomass [g/m²]				
Control	75.3	80.9	60.9	66.7
1.25 L/ha BAS 500 06 F	65.3	58.9	61.9	46.6
% of control	**86.7**	**72.8 ***	**101.7**	**69.8**
2.5 L/ha BAS 500 06 F	66.4	65.9	60.4	59.3
% of control	**88.2**	**81.5**	**99.2**	**88.9**
6.25 L/ha BAS 500 06 F	78.7	59.0	61.1	56.2
% of control	**104.5**	**73.0 ***	**100.4**	**84.2**
Reference item: carbendazim	101.2% of control	31.6% of control *	47.7% of control *	57.9% of control *

* Statistically significantly different compared to the control (Dunnett's t-test, Bonferroni-Welch t-test or Student t-test, $\alpha = 0.05$).

Validity of the reference item Luxan Carbendazim-500 FC was proved by clear statistically significant differences in earthworm abundance and biomass at the first, second and third sampling (Student t-test, $\alpha = 0.05$).

Conclusion

Based on the results of this field study, it is concluded that exposure of earthworm populations to rates up to 6.25 L BAS 500 06 F/ha does not cause unacceptable long-term effects.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	Based on the results of this field study, it is concluded that exposure of earthworm populations to rates up to 6.25 L BAS 500 06 F/ha does not cause unacceptable long-term effects.

IIIA 10.6.6 Effects on other non-target soil macro-organisms

Reference:	IIIA 10.6.6
Report	Friedrich S., 2008a Effects of BAS 500 06 F on the reproduction of the collembolans Folsomia candida in artificial soil with 5% peat 08 10 48 054S, 2008/1037495, 2291145
Guideline(s):	Yes ISO 11267 (1999)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

The effects of BAS 500 06 F on mortality and reproduction of Collembola *(Folsomia candida)* were investigated in a laboratory study over 28 days. Six application rates (15.7, 31.3, 62.5, 125.0, 250.0 and 500.0 mg BAS 500 06 F) were incorporated into the soil (5% peat only) with 5 replicates per treatment (each containing 10 juvenile collembolans). An untreated control with 5 replicates was included. Assessment of adult springtail mortality and reproduction rate (number of juveniles) was carried out after 28 days. A mortality of 4% was observed in the control group compared to 0% - 8% mortality at 15.7, 31.3, 62.5 and 125 mg BAS 500 06 F/kg dry soil. At the concentrations of 250 and 500 mg/kg dry soil statistically significant mortality of 52% and 80% was determined. In the control a mean of 575.4 juveniles was counted. In the treatment groups a mean number of juveniles of 535.8 to 19.0 was counted with statistically significant differences compared to the control for the two highest treatment groups.

In a 28-day collembolan reproduction study with BAS 500 06 F the NOEC based on mortality and reproduction was 125 mg BAS 500 06 F/kg dry soil. The EC50 was 189.6 mg BAS 500 06 F/kg dry soil, the LC50 was determined to be 283.8 mg BAS 500 06 F/kg dry soil.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed), density: 1.044 g/cm³.
Test species:	Collembola (Folsomia candida), juveniles (10-12 days old); source: in-house culture.
Test design:	28-day test in treated artificial soil according to ISO 11267 (5% peat only); artificial soil was filled in glass vessels after treatment with different concentrations of the test item before collembolans were introduced. 7 treatment groups (6 test item concentrations, control) were set up with 5 replicates for each and each containing 10 juvenile

	collembolans. Assessment of adult collembolans mortality and reproduction rate (number of juveniles) was carried out after 28 days.
Test rates:	Control, 15.7, 31.3, 62.5, 125.0, 250.0 and 500.0 mg BAS 500 06 F/kg dry soil (nominal).
Reference item:	Betosip (phenmedipham, 114 g/L). The effects of the toxic reference item were investigated in a separate study.
Test conditions:	Artificial soil according to ISO 11267 (with reduced content of peat: 5%); pH 6.1 at test initiation, pH 5.9 - 6.0 at test termination; water content at study initiation 59.6% - 59.8% of maximum water holding capacity (WHC) and 58.9% - 59.3% of maximum WHC at test termination; temperature: 20 °C - 22 °C; photoperiod: 16 h light : 8 h dark; light intensity: 570 lux; food: 2 mg granulated dry yeast at the start of the test and after 14 days.
Endpoints:	Mortality, reproduction rate.
Statistics:	Descriptive statistics. Fisher-exact test for mortality, Welch-t-test for reproduction, Probit analysis for determination of the LC50, Logit analysis for determination of the EC50.

Results and discussions

A mortality of 4% was observed in the control group compared to 0% - 8% mortality at 15.7, 31.3, 62.5 and 125 mg BAS 500 06 F/kg dry soil. At the concentrations of 250 and 500 mg/kg dry soil a statistically significant mortality of 52% and 80% was determined (Fisher-exact test, $\alpha = 0.05$). In the control a mean of 575.4 juveniles was counted. In the treatment groups a mean number of juveniles of 535.8 to 19.0 was counted with statistically significant differences compared to the control for the two highest treatment groups (Welch-t-test, $\alpha = 0.05$). The results are summarized in the table below:

Effect of BAS 500 06 F on Collembola (*Folsomia candida)* in a 28-day reproduction study

BAS 500 06 F [mg/kg dry soil]	**Control**	**15.7**	**31.3**	**62.5**	**125.0**	**250.0**	**500.0**
Mortality (day 28) [%]	4	4 $^{n.s.}$	0 $^{n.s.}$	2 $^{n.s.}$	8 $^{n.s.}$	52*	80*
No. of juveniles (day 28)	575.4	535.8 $^{n.s.}$	601.8 $^{n.s.}$	576.8 $^{n.s.}$	579.4 $^{n.s.}$	76.6*	19.0*
Reproduction in [%] of control (day 28)	--	93	105	100	101	13	3
Endpoints [mg/kg dry soil]							
$NOEC_{mortality,\ reproduction}$	125						
EC_{50}	189.6						
LC_{50}	283.8						

* = statistically significant differences compared to the control (Fisher-exact test for mortality; Welch-t-test for reproduction, $\alpha = 0.05$)

Conclusion

In a 28-day collembolan reproduction study with BAS 500 06 F the NOEC based on mortality and reproduction was 125 mg BAS 500 06 F/kg dry soil. The EC_{50} was 189.6 mg BAS 500 06 F/kg dry soil, the LC_{50}.was determined to be 283.8 mg BAS 500 06 F/kg dry soil.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 56-day reproduction study with BAS 500 06 F the NOEC based on mortality and reproduction was 125 mg BAS 500 06 F/kg dry soil.

IIIA 10.6.7 Effects on organic matter breakdown

Reference:	IIIA 10.6.7
Report	Luehrs U., Schabio S., 2010a Effects of BAS 500 06 F on the breakdown of organic matter in litter bags in the field 41655081, 2010/1000081, 2291146
Guideline(s):	Yes Roembke et al. (2003), OECD 56 (2006)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

The test item BAS 500 06 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 an application on soil surface at 1.25 L BAS 500 06 F/ha. An incorporation of a plateau concentration was omitted for this test because the active substance pyraclostrobin is not persistent (max. DT50,field of 37 days), and therefore does not build up a plateau concentration in soil even after long-term use.

The mass loss of the straw material in the untreated control was 80.5% at the end of the experiment after 179 days. In the treatment group exposing the soil to 1.25 L BAS 500 06 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 -5.5%, +0.2% and -0.1%, respectively. There were no statistically significant differences between this treatment group and the water treated control. The results of this 6-month field study on an arable field site emphasize that BAS 500 06 F has no treatment-related ecologically relevant effects on the organic matter breakdown following application of 1.25 L BAS 500 06 F/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 8265; content of a.s.: pyraclostrobin (BAS 500 F): 200 g/L (202.7 g/L analyzed), density: 1.044 g/cm³.
Test species:	Naturally occurring non-target soil organisms.
Test site:	Arable crop site in Rossdorf (Darmstadt-Dieburg), Germany; total size about 1460 m2, 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 two treatments (1 test item groups, water treated control) and six replicates each treatment. Exposure via application of the annual rate on the soil surface. An incorporation of a plateau concentration was omitted for this test because pyraclostrobin is not persistant (max. DT50 of 37 days). 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 plot sprayer with a distance between nozzles and soil of 0.5 m. Immediately after the application the test site was irrigated with 10.4 mm.
Test rates:	Treatment group 1: Untreated control Treatment group 2: 1.25 L BAS 500 06 F/ha (equivalent to 250 g a.s./ha)
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, 1 day before application of the annual rate of BAS 500 06 F.
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: 17.1 - 110.2 L/m².
Endpoints:	Mean weight loss of organic matter based on ash-free dry weight per plot per treatment.
Sampling dates:	1st sampling: 29.05.2009 (after 25 days of exposure) 2nd sampling: 31.07.2009 (after 88 days of exposure) 3rd sampling: 30.10.2009 (after 179 days of exposure)
Sample processing:	Sampling was done at three different time intervals (25, 88 and 179 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 pyraclostrobin according to the analytical method M432.

Statistics: Descriptive statistics, Student t test ($\alpha = 0.05$).

Results and discussions

Recovery rates for the active substance pyraclostrobin ranged from 51% - 92% of the expected soil concentration (mean 75%).

The mass loss of the straw material in the untreated control was 80.5% at the end of the experiment after 179 days. In the treatment group exposing the soil to 1.25 L BAS 500 06 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 -5.5%, +0.2% and -0.1%, respectively. There were no statistically significant differences between this treatment group and the water treated control (Student t-test, $\alpha = 0.05$). Effects on the degradation of buried wheat straw are summarized in the table below:

Mass loss [%] of wheat straw following exposure to BAS 500 06 F

Treatment	Mean mass loss [%]		
	Sampling 1	Sampling 2	Sampling 3
Control	16.9	54.1	80.5
1.25 L BAS 500 06 F/ha, % effect (mass loss)	17.8 (-5.5 n.s.)	54.0 (+0.2 n.s.)	80.6 (-0.1 n.s.)

n.s. = not statistically significant differences compared to the control (Student t-test, $\alpha = 0.05$)

Conclusion

The results of this 6-month field study on an arable field site emphasize that BAS 500 06 F has no treatment-related ecologically relevant effects on the organic matter breakdown following application of 1.25 L BAS 500 06 F/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	In a 6-month field study on an arable field site no treatment-related ecologically relevant effects on organic matter breakdown following application of 1.25 L BAS 500 06 F/ha were observed.

IIIA 10.7 Effects on Soil Microbial Activity

IIIA 10.7.1 Laboratory testing

Reference:	IIIA 10.7.1/1
Report	Krieg W., 1998a Effects of BAS 500 01 F on soil respiration 41047, 1998/11253 2291147
Guideline(s):	Yes BBA VI 1-1
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a soil microbial activity study, the effects of BAS 500 01 F on the carbon transformation were investigated in two loamy sand soils. BAS 500 01 F was applied to samples of the soils at nominal application rates of 1.33 and 13.33 µL/kg dry soil, equivalent to 1 and 10 L BAS 500 01 F/ha. Four replicates of each treatment were removed for analysis of carbon content 0, 14 and 28 days after application. No adverse influences of BAS 500 01 F on soil respiration could be observed in both soils at the single application rate after 28 days, only slight deviations from the control of -1.2% and -4.0% were measured. At the ten-fold application rate the deviations from the control were -1.2 and -1.6%, respectively.

BAS 500 01 F caused no adverse effects (according to BBA-classification) on the soil C-transformation (measured as oxygen consumption) through the 28-day incubation period. The study was performed in two field soils (loamy sand soil) at concentrations equivalent to field application rates of 1.0 L and 10.0 L/ha.

Materials and methods

Test item: BAS 500 01 F, batch no. 97-2, content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304 428): 247.47 g/L (nominal: 250 g/L).

Test soil: Biologically active agricultural soils: 1) loamy sand soil I; pH 6.6, 1.0% Corg and 33% WHC; 2) loamy sand soil II; pH: pH 7.5, 1.5% Corg and 42% WHC.

Test design: Determination of carbon-transformation (O2-consumption) in soil after addition of glucose (concentration in the soil 0.4%). Comparison of test item treated soil with a non-treated soil, 4 replicates per concentration. The O2-consumption was measured using a BSB digi apparatus over a period of maximum 20 hours at different sampling intervals. Sampling

	scheme: 0, 14 and 28 days after treatment, sub-samples were withdrawn from the bulk batches and subjected to measurement.
Test rates:	Control, 1.33 µL BAS 500 01 F per kg soil (corresponding to an application rate of 1.0 L BAS 500 01 F/ha) and 13.33 µL BAS 500 01 F per kg soil (corresponding to an application rate of 10.0 L BAS 500 01 F/ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm3).
Reference item:	Dinoterb; effects on C-transformation were investigated in a separate study.
Test conditions:	Soil moisture: 45% of its water holding capacity in case of the loamy sand soil I and 40% in case of the loamy sand soil II. Soil samples were incubated at 20 °C ± 2 °C while stored in glass bottles.
Endpoints:	Effects on O2 consumption after 28 days of exposure.
Statistics:	Descriptive statistics.

Results and discussions

No adverse influences of BAS 500 01 F on soil respiration could be observed in both soils at the single application rate after 28 days, only slight deviations from the control of -1.2% and -4.0% were measured. At the ten-fold application rate the deviations from the control were -1.2 and -1.6%, respectively. The results are summarized in the following table:

Effects of BAS 500 01 F on soil micro-organisms (carbon transformation) on days 14 and 28 of incubation

Soil (days)	Control	1.33 µL BAS 500 01 F per kg dry soil equivalent to 1.0 L/ha		13.33 µL BAS 500 01F per kg dry soil equivalent to 10.0 L/ha	
	O_2 consumption [mg/kg dry soil]	O_2 consumption [mg/kg dry soil]	% Deviation from the control 1)	O_2 consumption [mg/kg dry soil]	% Deviation from the control 1)
Loamy sand soil I (14 d)	8.1	8.6	+6.2	8.0	-1.2
Loamy sand soil I (28 d)	8.0	7.9	-1.2	7.9	-1.2
Loamy sand soil II (14 d)	13.1	13.1	0.0	12.7	-3.1
Loamy sand soil II (28 d)	12.6	12.1	-4.0	12.4	-1.6

1) - = inhibition; + = stimulation

Conclusion

BAS 500 01 F caused no adverse effects (according to BBA-classification) on the soil C-transformation (measured as oxygen consumption) through the 28-day incubation period. The study was performed in two field soils (loamy sand soil) at concentrations equivalent to field application rates of 1.0 L and 10.0 L/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	BAS 500 01 F caused no adverse effects (according to BBA-classification) on the soil C-transformation (measured as oxygen consumption) through the 28-day incubation period up to concentrations of 10 L/ha.

Reference:	IIIA 10.7.1/2
Report	Krieg W., 1998a Effects of BAS 500 01 F on the nitrogen turnover in soil 41053, 1998/11259 2291148
Guideline(s):	Yes BBA VI 1-1
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a soil microbial activity study, the effects of BAS 500 01 F on the nitrogen transformation was investigated in two loamy sand soils. BAS 500 01 F was applied to samples of the soil at nominal application rates of 1.33 and 13.33 µL/kg dry soil, equivalent to 1 and 10 L BAS 500 01 F/ha. Triplicate samples of each treatment were removed for analysis of carbon content 0, 14 and 28 days after application. No significant influence of BAS 500 01 F on the nitrogen turnover could be observed in both soils at the single application rate after 28 days, only slight deviations from the control of +6.6% and -2.1% were measured. At the ten-fold application rate the deviation rates in both soils were +10:0% and +6.5%, respectively.

BAS 500 01 F caused no adverse effects (according to BBA-classification) on the soil N-transformation (measured as NO3-N production) through the 28-day incubation period. The study was performed in two field soils (loamy sand soil) at concentrations of 1.33 and 13.33 µL product per kg dry soil (equivalent to a field application rate of 1 and 10 L product/ha, respectively).

Materials and methods

Test item:	BAS 500 01 F, batch no. 97-2, content of a.s.: pyraclostrobin (BAS 500 F, Reg. No. 304 428): 247.47 g/L (nominal: 250 g/L).
Test soil:	Biologically active agricultural soils: 1) loamy sand soil I; pH 6.6, 1.0% Corg and 33% WHC; 2) loamy sand soil II; pH: pH 7.5, 1.5% Corg and 42% WHC.
Test design:	Determination of the N-transformation (NO3-nitrogen production) in soil enriched with Lucerne meal (concentration in soil 0.5%). Comparison of test item treated soil with a non-treated soil. 3 replicates per treatment were used. NH4-nitrogen formed from organically bound nitrogen in the soil and NO3-nitrogen from the nitrification process was determined using calibrated ion-sensitive electrodes and the Orion expandable ionanalyzer EA 940, respectively, Sampling scheme: 0, 7 and 14 days after treatment. Sub-samples were withdrawn from the bulk batches and subjected to measurement.
Test rates:	Control, 1.33 µL BAS 500 01 F per kg soil (corresponding to an application rate of 1.0 L BAS 500 01 F/ha) and 13.33 µL BAS 500 01 F per kg soil (corresponding to an application rate of 10.0 L BAS 500 01 F/ha; related to a soil depth of 5 cm and a soil density of 1.5 g/cm3).
Reference item:	N-SERVE; effects on N-transformation were investigated in a separate study.
Test conditions:	Soil moisture: 45% of its water holding capacity in case of the loamy sand soil I and 40% in case of the loamy sand soil II. Soil samples were incubated at 20 °C ± 2 °C while stored in glass bottles.
Endpoints:	Effects on NO3-nitrogen production after 28 days of exposure.
Statistics:	Descriptive statistics.

Results and discussions

No significant influences of BAS 500 01 F on the nitrogen turnover could be observed in both soils at the single application rate after 28 days, only slight deviations from the control of +6.6% and -2.1% were measured. At the ten-fold application rate the deviations from the control were +10.0% and +6.5%, respectively. The results are summarized in the following table:

Effects of BAS 500 01 F on soil micro-organisms (nitrogen transformation) on days 14 and 28 of incubation

Soil (days)	Control	1.33 µL BAS 500 01 F per kg dry soil equivalent to 1.0 L/ha		13.33 µL BAS 500 01 F per kg dry soil equivalent to 10.0 L/ha	
	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 I (14 d)	3.83	4.44	+ 15.9	4.61	+ 20.4
Loamy sand soil I (28 d)	4.99	5.32	+ 6.6	5.49	+ 10.0
Loamy sand soil II (14 d)	4.75	4.82	+.1.5	4.93	+ 3.8
Loamy sand soil II (28 d)	5.22	5.11	- 2.1	5.56	+.6.5

1) - = inhibition; + = stimulation

Conclusion

BAS 500 01 F caused no adverse effects (according to BBA-classification) on the soil N-transformation (measured as NO_3-N production) through the 28-day incubation period. The study was performed in two field soils (loamy sand soil) at concentrations of 1.33 and 13.33 µL product per kg dry soil (equivalent to a field application rate of 1 and 10 L product/ha, respectively).

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	BAS 500 01 F caused no adverse effects (according to BBA-classification) on the N-transformation (measured as NO_3-N production) through the 28-day incubation period up to concentrations of 10 L/ha.

Reference:	IIIA 10.7.1/3
Report	Schulz, L., 2012 Effects of BAS 500 06 F on the activity of soil microflora (Nitrogen transformation test) 12 10 48 052 N, 2012/1129443, 2441905
Guideline(s):	Yes OECD guideline 216 (2000)
Deviations:	No
GLP:	Yes

Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

In a soil microbial activity study, the effects of BAS 500 06 F on the nitrogen transformation were investigated in a loamy sand soil. BAS 500 06 F was applied to samples of the soil at nominal test concentrations of 1.73 mg/kg BAS 500 06 F and 17.30 mg/kg BAS 500 06 F of soil (dry weight) corresponding to 0.33 and 3.33 mg Pyraclostrobin kg soil d.w. The amount of BAS 500 F was calculated based on the nominal content of a.s. The density of 1.038 g/cm³ was taken into account. BAS 500 06 F treated soils and controls were incubated at approx. 20 °C in the dark. Triplicate samples of each treatment were removed for analysis of mineral nitrogen 0, 7, 14, 28 and 42 days after application. There were no significant effects on the rate of conversion of NH4-N to NO3-N at any application rate at the end of the 42-day incubation period. Exposure of BAS 500 06 F in a field soil up to a test concentration of 17.30 mg BAS 500 06 F/kg soil dry weight caused no adverse effects (deviation from control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO3-N production) at the end of the 42-day incubation period (time interval 0-42).

Materials and methods

Test item:	BAS 500 06 F, batch No. 0003223026, Pyraclostrobin (BAS 500 F) 200.0 g/L (nominal); 200.7 g/L (analysed)
Test soil:	Biologically active agricultural soil: loamy sand (DIN 4220) / sandy loam (USDA), pH 6.5, 1.45 % Corg, WHC: 33.45 g/100 g dry soil.
Test design:	Determination of the N-transformation (NO3-nitrogen production) in soil enriched with lucerne meal (concentration in the soil 0.5 %). Comparison of test item treated soil with a non-treated soil. NH4-nitrogen formed from organically bound nitrogen and NO3-nitrogen formed from the nitrification process was determined using an Autoanalyzer (Bran and Luebbe). Sampling scheme: 0, 7, 14, 28 and 42 days after treatment. Sub-samples (3 replicates) were withdrawn from the bulk batches and subjected to the measurement.
Test rates:	Control, 1.73 mg and 17.30 mg BAS 500 06 F/kg soil dry weight
Reference item:	Dinoterb (purity: 98.0% ±0.5 analysed). The reference item was tested in a separate study at rates of 6.80, 16.00 and 27.00 mg/kg.
Test conditions:	Water content: approx. 45 % of maximum water holding capacity; measured water content: 14.02 - 14.67 g/100 g dry soil; pH 5.8 - 6.2. Soil samples were incubated at 19.2 - 21.0 °C while stored in glass flasks in the dark.

Endpoints: Effects on NO3-nitrogen production after 28 days of exposure.

Statistics: Descriptive statistics.

Results and discussions

No adverse effects of BAS 500 06 F on nitrogen transformation in soil could be observed at a test item concentration of 1.73 mg/kg dry soil after 28 days. Only a negligible deviation from control of +20.1 % (test concentration 1.73 mg/kg dry soil) was measured at the end of the 28-day incubation period (time interval 0-28). Due to a measured deviations of > 25 % observed in the treatment group treated with 17.30 mg BAS 500 06 F/kg dry soil, 28 days after application, the test had to be prolonged up to day 42 after application. Only a negligible deviation from control of +22.1 % (test concentration 17.30 mg/kg dry soil) was measured at the end of the 42-day incubation period (time interval 0-42). In a separate study the reference item Dinoterb produced a stimulation of nitrogen transformation of +40.4 %, +68.1 % and +83.5 % % at 6.80 mg, 16.00 mg and 27.00 mg/kg soil dry weight, respectively, 28 days after application. The results are summarized in the following table:

Effects of BAS 500 01 F on soil micro-organisms (nitrogen transformation) on days 14 and 28 of incubation

(days)	Control	1.73 mg BAS 500 06 F per kg dry soil		17.30 mg BAS 500 06 F per kg dry soil	
	NO3-N in mg/kg soil dry weight 1)	NO3-N in mg/kg soil dry weight 1)	% Deviation from the control	NO3-N in mg/kg soil dry weight 1)	% Deviation from the control
0 – 7 d	11.33	12.20	+7.6	17.43	+53.8
0 – 14 d	14.77	18.40	+ 24.6	23.70	+ 60.5
0 - 28 d	24.43	29.33	+20.1	32.87	+34.5
0 - 42 d	32,67	- *	-	39.90	+22.1

The calculations were performed with unrounded values

1) measured values sampling day “x” - measured values sampling day 0, mean of 3 replicates

* no analysis was performed

Conclusion

Exposure of BAS 500 06 F in a field soil up to a test concentration of 17.30 mg BAS 500 06 F/kg soil dry weight caused no adverse effects (deviation from control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO3-N production) at the end of the 42-day incubation period (time interval 0-42).

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	Exposure of BAS 500 06 F in a field soil up to a test concentration of 17.30 mg BAS 500 06 F/kg soil dry weight caused no adverse effects (deviation from control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO3-N production) at the end of the 42-day incubation period (time interval 0-42).

IIIA 10.8 Effects on non-target plants

IIIA 10.8.1.2 Vegetative vigour

Reference:	IIIA 10.8.1.2
Report	Strömel, C. et al., 2013 Effect of BAS 500 06 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 397735, 2012/1115894 2441903
Guideline(s):	Yes OECD 227
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

The effect of BAS 500 06 F on vegetative vigour of ten species of terrestrial plants was assessed in a greenhouse study. BAS 500 06 F was applied post-emergence at growth stage BBCH 12 – 14 at test rates ranging from 0.078 L BAS 500 06 F/ha to 1.250 L BAS 500 06 F/ha plus one control (tap water only). Following the application, the plants were cultivated for 21 days under greenhouse conditions. Assessments for plant damage (phytotoxicity), plant survival and plant length were done 7, 14 and 21 days after treatment (DAT). Shoot dry weight was determined at study termination 21 DAT.

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that BAS 500 06 F applied post emergence with rates up to 1.250 L/ha did not cause adverse effects to plant mortality, plant length and plant dry weight of all tested species, although cabbage showed slight biomass reduction with significant response at the highest tested rate of 1.250 L BAS 500 06 F/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 0004863761 content of a.i Pyraclostrobin (BAS 500 F): 200.0 g/L
Test species:	10 plant species: carrot (*Daucus carota L.)*; lettuce (*Lactuca sativa L.*); oilseed rape (*Brassica napus L.*); cabbage (*Brassica oleracea L. var. capitata L. f. alba*); soybean (*Glycine max L.*); tomato (*Lycopersicon esculentum Mill.*); onion (*Allium cepa L.*); ryegrass (*Lolium perenne L.*); oat (*Avena sativa L.*); corn (*Zea mays L.*)
Test design:	Greenhouse trial, dose response design; applied post emergence at BBCH 12 – 14; plants were cultivated for 21 days under greenhouse conditions.
Test rates:	The following rates were tested for all 10 plant species: 0.078, 0.156, 0.313, 0.625 and 1.250 L BAS 500 06 F/ha and one control (tap water only). The factor between two consecutive rates was 2.
Test conditions:	Greenhouse conditions: daily average temperature: between 20.5 °C and 26.3 °C; daily mean relative humidity: 47.8 % to 73.3 %; photoperiod: day length ≥ 16 hours. Additional light supply automatically when outdoor illumination was less than 10 klux.
Observations:	Assessments for plant damage (using a scale of 0 – 100 % with 0 % = no effects and 100 % = complete effects), plant survival and plant length were done 7, 14 and 21 days after treatment (DAT). Shoot dry weight was determined at study termination 21 DAT.
Statistics:	Calculation of mean values and standard deviations, outlier test and analysis of variance followed by Dunnett´s t-test / Welch-t test; Normal Sigmoid Response-Model for ERx calculation using Linear Maximum Likelihood Regression as curve fitting method.

Results and discussions

Phytotoxicity:

Carrot, lettuce, onion, ryegrass and oat showed no phytotoxic symptoms. A very slight damage (1 – 6 %) was assessed in oilseed rape, cabbage, soybean and tomato. Corn was more sensitive than all other tested species with necrosis up to 12 % at a rate of 1.250 L BAS 500 06 F/ha.

Survival /mortality:

No plant mortality was observed for all tested plant species after application of BAS 500 06 F up to a rate of 1.250 L/ha at BBCH 12-14.

Plant length:

No dose response related to plant length reduction could be found for all tested plant species. However, plant length (21 DAT) was not influenced by BAS 500 06 F after application at BBCH 12 – 14 (effects < 15 %).

Biomass (dry weight):

The plant biomass (shoot dry weight) was determined 21 DAT. No influence of BAS 500 06 F on plant weight was observed (effects < 15 %) for all tested plant species except for cabbage. In cabbage a slight but significant biomass reduction of 8.4 % occurred at a rate of 1.250 L BAS 500 06 F/ha. In onion significantly reduced plant dry weight was found at a rate of 0.313 L product/ha, but not at the higher tested rates indicating that the difference at 0.313 L/ha was not test item related.

All control plants remained healthy throughout the entire trial period. No control mortality was observed. Thus any adverse influences on the study results can be excluded and the study can be considered as valid. No influence of BAS 500 06 F up to 1.250 L/ha on plant survival and plant length was observed. After application of BAS 500 06 F at BBCH 12-14 slight phytotoxic damage occurred in oilseed rape, cabbage, soybean, tomato and corn. Dry biomass of all tested species was not affected after application of 1.250 L BAS 500 06 F/ha, except cabbage with a slight reduction of 8 %.

Conclusion

It can be concluded that BAS 500 06 F applied post emergence with rates up to 1.250 L/ha did not cause adverse effects to plant mortality, plant length and plant dry weight of all tested species, although cabbage showed slight biomass reduction with significant response at the highest tested rate of 1.250 L BAS 500 06 F/ha. The ER50 was > 1.250 L BAS 500 06 F/ha for all tested plant species, the NOER was 0.625 BAS 500 06 F/ha due to a slight but significant biomass reduction for cabbage at the highest test rate of 1.250 L BAS 500 06 F/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	The ER50 is > 1.250 L BAS 500 06 F/ha for all tested plant species with respect to plant mortality, plant length and plant dry weight.

IIIA 10.8.1.3 Seedling emergence

Reference:	IIIA 10.8.1.3
Report	Strömel, C. et al., 2013

	Effect of BAS 500 06 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions 423107, 2012/1115895 2456974
Guideline(s):	Yes OECD 208
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

Executive Summary

The effect of BAS 500 06 F on seedling emergence and seedling growth of ten species of terrestrial plants was assessed in a greenhouse study. BAS 500 06 F was applied pre-emergence shortly after seeding at test rates ranging from 0.078 L BAS 500 06 F/ha to 1.250 L BAS 500 06 F/ha plus one control (tap water only). After application the plants were cultivated for 21 days (28 days for carrot and onion) under greenhouse conditions. Assessments for plant damage (phytotoxicity), plant survival and plant length were done 7, 14 and 21 days after application (DAT) (carrot and onion 14, 21 and 28 days). Shoot dry weight was determined at study termination 21 DAT (28 days for carrot and onion).

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that the fungicide BAS 500 06 F did not cause adverse effects to the seedling emergence, plant survival, phytoxicity, plant length and dry biomass production of the tested plant species when applied up to rates of 1.250 L BAS 500 06 F/ha.

Materials and methods

Test item:	BAS 500 06 F; batch no. 0004863761, content of a.i Pyraclostrobin (BAS 500 F): 200.0 g/L
Test species:	10 plant species: carrot (*Daucus carota L.)*; lettuce (*Lactuca sativa L.*); oilseed rape (*Brassica napus L.*); cabbage (*Brassica oleracea L. var. capitata L. f. alba*); soybean (*Glycine max L.*); tomato (*Lycopersicon esculentum Mill.*); onion (*Allium cepa L.*); ryegrass (*Lolium perenne L.*); oat (*Avena sativa L.*); corn (*Zea mays L.*)
Test design:	Greenhouse trial, dose response design; applied pre emergence shortly after seeding; plants were cultivated for 21 days (28 days for carrot and onion) under greenhouse conditions.
Test rates:	The following rates were tested for all 10 plant species: 0.078, 0.156, 0.313, 0.625 and 1.250 L BAS 500 06 F/ha and one control (tap water only). The factor between two consecutive rates was 2.

Test conditions:	Greenhouse conditions: daily average temperature ranged between 17.4 °C and 28.8 °C; daily mean relative humidity ranged between 42.4 % and 73.3 %; photoperiod: day length ≥ 16 hours. Additional light supply automatically when outdoor illumination was less than 10 klux.
Observations:	Assessments for plant damage (phytotoxicity), plant survival and plant length were done 7, 14 and 21 days after application (DAT) (carrot and onion 14, 21 and 28 days). Shoot dry weight was determined at study termination 21 DAT (28 days for carrot and onion).
Statistics:	Calculation of mean values and standard deviations, outlier test, analysis of variance followed by Dunnett's t-Test/ Welch-t-test, Normal Sigmoid Response-Model for ERx calculation using Linear Maximum Likelihood Regression as curve fitting method.

Results and discussions

Plant emergence and survival:

All plant species had reached the 50 % emergence rate after 7 days after application except carrot and onion (14 days). None of the tested plant species were adversely affected concerning seedling emergence and plant survival after pre emergence application of BAS 500 06 F.

Phytotoxicity:

None of the tested species showed phytotoxic symptoms after use of BAS 500 06 F pre emergence.

Plant length:

The plant length was determined 7, 14 and 21 DAT (14, 21, 28 DAT for carrot and onion. For none tested plant species reduction in plant length was observed exept for onion. Slight impact was found for onion, where the highest tested rate of 1.250 L BAS 500 06 F/ha reduced plant length by about 9 % and even 0.625 L BAS 500 06 F/ha reduced plant length significantly by about 8 %.

Biomass (dry weight):

The plant biomass (shoot dry weight) was determined 21 DAT (28 DAT for carrot and onion). No influence of BAS 500 06 F on plant dry weight was observed in all tested plant species. A statistically significant difference was found only in onion in the treatments 0.156 L BAS 500 06 F/ha (18 % reduction) and 0.625 L BAS 500 06 F/ha (19 % reduction) but not in the highest rate. Thus it can be assumed that this was not related to the treatment but to any other circumstances.

All emerged control plants remained healthy throughout the entire trial period. No control mortality was

observed. The rate of emergence in the controls was >70 % for all tested plant species. Thus any adverse influences on the study results can be excluded and the study can be considered as valid. The seedling emergence and plant survival as well as dry biomass were not influenced by the pre-emergence application of BAS 500 06 F up to the highest tested rate of 1.250 L/ha. Slight reduction of plant length at rates 0.625

and 1.250 L BAS 500 06 F/ha in onion was not reflected by dry biomass production and phytotoxicty assessments.

Conclusion

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that the fungicide BAS 500 06 F did not cause adverse effects to the seedling emergence, plant survival, phytoxicity, plant length and dry biomass production of the tested plant species at test rates up to1.250 L BAS 500 06 F/ha. The ER50 was > 1.250 L BAS 500 06 F/ha for all tested plant species, the NOER was 1.250 L BAS 500 06 F/ha.

Comments of zRMS [Commenting box]

Study Comments:	
Agreed Endpoints:	The ER50 is > 1.250 L BAS 500 06 F/ha for all tested plant species with respect to seedling emergence, plant survival, phytoxicity, plant length and dry biomass production.

Appendix 4 Table of Intended Uses justification and GAP tables

Central zone (BE, CZ, DE, HU, NL, AT, PL, RO, SI, SK) - Summary of intended uses

Crop and/ or situation	**Member State or Country**	**Product name**	**F G or I**	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days)	**Remarks:**
(a)			(b)	(c)	Type (d-f)	Conc. of as (i) g/kg	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applica-tions (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (kg/ha) minmax	(l)	(m)
w. wheat, s wheat durum, w barley s barley triticale, rye, *oat1*	Central EU (incl. CZ, SI)	RETENGO	F	Puccinia spp., R. secalis P. teres (MEHITE)	EC	0.2	SP	25-69	2	21 days	0.0625 – 0.25	100-400	0.25	0.8 - <u>1.25</u> *	35	
Wheat, barley, rye, triticale	DE, AT		F	P. recondita , *P. teres* P. hordei	EC	0.2	SP	25-69	2	21 days	0.0625-0.25	100-400	0.25	0.8 - 1.25	35	
Cereals	SK, HU, RO		F	Puccinia spp., R. secalis P. teres (MEHITE)	EC	0.2	SP	25-69	2	21 days	0.04-0.25	100-400	0.16-0.25	0.8-1.25	35	
Winter wheat, spring barley	PL		F	Puccinia spp., R. secalis P. teres + physiological effects	EC	0.2	SP	25-69	2	21 days	0.04-0.25	100-400	0.16-0.25	0.8-1.25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i) g/kg	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applica-tions (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (kg/ha) minmax		
Wheat, barley, spelt, rye, triticale	BE		F	Puccinia spp. *DTR* P. teres, R. secalis	EC	0.2	SP	31-59	2	21 days	0.0625-0.25	100-400	0.25	1.25	35	
Wheat, barley, *rye1*, *triticale1*	NL		F	*DTR* Puccinia spp., P. teres. R. secalis, (MEHITE) *(Michrodochium nivale)*	EC	0.2	SP	25-69	2	21 days	0.05-0.25	100-400	0.2-0.25	0.8 - 1.25	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 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **BAS 500 06 F**
Active Substance: **Pyraclostrobin 200 g/L**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

NATIONAL ADDENDUM

Applicant: **BASF**
Date: **2014-10-31**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

Please refer to the core assessment part B section 6 for the central zone.

6.1 Proposed use pattern and considered metabolites

Please refer to the core assessment part B section 6 for the central zone.

6.2 Effects on Birds

Please refer to the core assessment part B section 6 for the central zone.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

Please refer to the core assessment part B section 6 for the central zone.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.4.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.4.1.2 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 models DRIFTOX 4.0. 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.

6.4.1.3 Risk assessment –overall conclusions

Based on the HC_5 = 5.9 µg/L (fish, pyraclostrobin) risk mitigation measurements in form of NW 605/606 (90 % - 5m; 75 % - 5 m; 50 % - 10m; 0 % - 15m) are necessary.

6.4.2 Toxicity to Exposure ratio

Given that for the assessment of effects on aquatic organism for BAS 512 16 F several toxicity endpoints are available, the selection of the crucial toxicity endpoint respectively effect value is based on the lowest ratio of effect value and related PEC_{sw} taking into account the appropriate assessment factor. As this approach demonstrates the worst case scenario a risk assessment for other toxicity endpoints respectively species which are less sensitive is not required.

The lowest toxicity endpoint is derived from an acute fish study with pyraclostrobin (96 h LC_{50} = 0.00616 mg/L). Since Pyraclostrobin is high toxic against fish, this is crucial for risk assessment. As results from several (acute) fish studies are available, refinement of the endpoint is possible. Seven studies were used to calculate the HC_5 of 5.9 µg/L for fish (based on acute studies). The value was calculated with the programme ETX 2.0. Due to a steep dose-response curve as well as test results from different fish families, which are similar regarding their sensitivity against the test substance, a reduction of the assessment factor to 20 is justifiable. The risk assessment by the MS is solely based on the HC_5 of 0.0059 mg/L considering an assessment factor of 20 as it is the worst case scenario.

6.4.2.1 TER: Entry pathway spray drift and volatilization/deposition (IIIA1 10.2.1)

Deposition in surface water of the active substance pyraclostrobin is generally not expected as the substance has a vapour pressure below 10^{-5} Pa (20°C) and hence is not volatile. Therefore a calculation of inputs resulting from volatilization and deposition with the model EVA 2.0 is not necessary.

The calculated PECsw and TER values after exposure via spray drift for the active substance pyraclostrobin for the intended uses of BAS 500 06 F are summarized in the following table (TER values in bold are above the trigger).

Table 6.4-1: TER-values for the active substance pyraclostrobin regarding the entry pathway spray drift (Model: DRIFTOX 4.0 a) for the intended use in cereals

active substance			pyraclostrobin					
use pattern/gap:			A/00-001 to 00-010 winter and spring cereals					
application rate/number of applications / interval			2 x 250 g ai ha^{-1}, 21 d					
$DissT_{50}$ (SFO) in water			25.1 d					
relevant PEC if applicable twa-interval			PEC_{act}					
scenario/percentile:			Agriculture/82. percentile					
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	130.00	-	-	130.00	-	-	-
1	2.38	3.0939	-	-	3.0939	0.3094	0.7735	1.5469
5	0.47	0.6110	-	-	0.6110	0.0611	0.1527	0.3055
10	0.24	0.3120	-	-	0.3120	0.0312	0.0780	0.1560
15	0.16	0.2080	-	-	0.2080	0.0208	0.0520	0.1040
20	0.12	0.1560	-	-	0.1560	0.0156	0.0390	0.0780
Endpoint:			HC_5 = 0.0059 mg a.s/L					
TER risk assessment trigger:			20					
Buffer zone [m]					TER			

0	0.0454	-	-	-
1	1.9070	19.0699	7.6280	3.8140
5	9.6567	**96.5667**	**38.6267**	19.3133
10	18.9110	**189.1097**	**75.6439**	**37.8219**
15	**28.3665**	**283.6646**	**113.4658**	**56.7329**
20	**37.8219**	**378.2194**	**151.2878**	**75.6439**
Risk mitigation measures :	**NW 605/606 (90% - 5m, 75% - 5m, 50% - 10m, 0% - 15m)**			

The TER_{LT} values are greater than the modified Annex VI trigger value of 20 for all intended uses under consideration of risk mitigation measures (drift reduction and/or buffer zone). This indicates that the active substance pyraclostrobin contained in BAS 500 06 F poses an acceptable long-term risk to aquatic organism following application of BAS 500 06 F at the proposed application rates.

6.4.2.2 TER: Entry pathway run-off and drainage

The calculated PECsw and TER values after exposure via run-off and drainage for the active substance pyraclostrobin for the intended uses of BAS 500 06 F are summarized in the following tables (TER values in bold are below the trigger).

Table 6.4-2: TER of pyraclostrobin in an adjacent ditch due to surface run-off and drainage for cereals

Active substance:	Pyraclostrobin	
Use pattern/GAP:	A/00-001 to 00-010 winter and spring cereals	
Application rate/Intervall/Interception:	2 x 250 g ai ha^{-1};21 d; 2 x 50%	
Endpoint:	HC_5 = 0.0059 mg a.s/L	
TER risk assessment trigger:	20	
Entry pathway run-off		
Buffer zone [m]	PEC_{sw} [µg/L]	TER
0	0.28	**20.95**
5	0.24	**24.17**
10	0.21	**28.20**
20	0.15	**40.29**
Entry pathway drainage		
Time of application	PEC_{sw} [µg/L]	TER
autuum/winter/early spring	0.10	**62.01**
Spring/summer	0.03	**190.80**
Risk mitigation measures :	-	

For pyraclostrobin as active substances the calculated TER values are above the trigger of 20 without considering risk mitigation measures. Regarding the entry pathways run-off and drainage, it is concluded by the MS that the proposed use of BAS 500 06 F will not pose an unacceptable risk to aquatic organism, if applied according to the recommended use pattern.

6.4.3 Acute toxicity and chronic toxicity of the formulation

Please refer to the core assessment part B section 6 for the central zone.

6.4.4 Metabolites of pyraclostrobin

Please refer to the core assessment part B section 6 for the central zone.

6.4.5 Accumulation in aquatic non-target organisms

Please refer to the core assessment part B section 6 for the central zone.

6.5 Effects on Bees

Please refer to the core assessment part B section 6 for the central zone.

6.6 Effects on Arthropods Other Than Bees

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.

6.6.1.2 Exposure

In field

No in field assessment was performed on national level.

Off-field

Exposure of non-target arthropods living in non-target off-field areas to BAS 500 06 F 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[1]) as shown in the following equation:

$$Off-field\ PER = \frac{Maximum\, in-field\ PER\ x \left({}^{drift\ rate}\!/_{100} \right)}{vegetation\ distribution\ factor\ (vdf)}$$

[1] 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.

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

Vegetation distribution factor: The model used to estimate spray drift was developed for drift onto a two-dimensional (2-D) water surface and, i.e. interception and dilution by three-dimensional (3-D) vegetation in off-crop areas is not taken into account. Therefore, a vegetation distribution or dilution factor is included into the equation when calculating PERs to be used in conjunction with toxicity endpoints derived from two-dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2. In line with German national requirements, a vegetation distribution factor of 5 has to be applied, based on experimental data. However, for 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used, as any dilution over the 3-dimensional vegetation surface is accounted for in the study design.

The drift rates are 2.38% and 0.47 % at 1m and 5 m, respectively, of the application rate (82nd percentile drift).

For the results of study with *T. pyri, A. bilineata* and *C. carnea* exposed to BAS 500 06 F, a vegetation distribution factor has to be considered (study conducted in 2D environment). Regarding the results of the study with *A. rhopalosiphi* exposed to BAS 500 06 F, 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 6.6-1: Off-field predicted environmental rates (PER) resulting from the intended uses of BAS 500 06 F

Study type	Max. rate (l Prod./ha)	MAF	Maximum in-field PER (l Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (l Prod./ha)
3-dimensional	2 x 1.25	1.7	2.125	2.38%	1	0.05
2-dimensional	2 x 1.25	1.7	2.125	2.38%	5	0.01

Reduction of the amount of drift reaching the off-field areas can be achieved by implementing a in-field buffer strip of a given width. The resulting drift values (according also to spray-drift predictions of Ganzelmeier & Rautmann (2000)[2]) are given in the table below.

[2] Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Pesticide Application, Aspects of Applied Biology 57

Table 6.6-2: Maximum off-field PER (predicted environmental rates) of BAS 500 06 F at increasing distances from the sprayed areas following intended uses

Study type	Maximum intended in-field rate	Maximum PERoff-field at 1m (2.38% drift)	Maximum PERoff-field at 5m (0.47% drift)
	(L BAS 500 06 F/ha)		
3 D	2.125	0.05	0.01
2 D	2.125	0.01	0.002

Risk assessment –overall conclusions

The outcome of the risk assessment for non-target arthropods exposed to BAS 500 06 F is given in the table below.

Higher tier

Table 6.6-3: Acceptability criteria for higher tier data and minimal TER values for arthropod species other than bees after use of BAS 500 06 F

Species	Test type	Correction factor	L/ER50 (L product/ha)	PER in-field (L product/ha)	Distance (m)	PERoff-field (L product/ha)	TER
Typhlodromus pyri	2 D	5	**LR_{50} = 2.45** ER_{50} > 2.5	2.125	1	0.01	245
Aphidius rhopalosiphi	3 D	-	LR_{50} > 2.5 **ER_{50} > 2.5**		1	0.05	>50
A. bilineata	2 D	5	**ER_{50} > 3.75**	2.125	1	0.01	>375
C. carnea	2 D	5	**LR_{50} = 0.72** ER_{50} > 0.63		1	0.01	72
TER values in bold are below the trigger							

Based on the calculated rates of pyraclostrobin/BAS 500 06 F in off-field areas, the calculated TER values describing the potential risk resulting from an exposure of non-target arthropods to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria. 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 BAS 500 06 F in cereals according to the label.

6.6.2 Risk assessment for Arthropods other than Bees

6.6.2.1 Off field

TER approach

The risk assessment for non-target arthropods is done on basis of the calculation of toxicity-exposure ratio (TER) values as in line with German national requirements 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.

Table 6.6-4: Calculated TER values for non-target arthropods exposed to BAS 500 06 F 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
Typhlodromus pyri	2 D	5	**LR_{50} = 2.45** ER_{50} > 2.5	2.125	1	0.01	245
Aphidius rhopalosiphi	3 D	-	LR_{50} > 2.5 **ER_{50} > 2.5**		1	0.05	>50
A. bilineata	2 D	5	**ER_{50} > 3.75**	2.125	1	0.01	>375
C. carnea	2 D	5	**LR_{50} = 0.72** ER_{50} > 0.63		1	0.01	72
TER values in bold are below the trigger							

Based on the calculated rates of pyraclostrobin/BAS 500 06 F in off-field areas, the calculated TER values for the risk resulting from an exposure of non-target arthropods to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F achieve the acceptability criteria of TER ≥ 5, resp., 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 BAS 500 06 F 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

Please refer to the core assessment part B section 6 for the central zone.

6.7.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.7.1.2 Exposure

In accordance with national guidance (Füll, 2003)[3] a reduced thickness of the soil layer of 2.5 cm may be considered for substances with K_{oc}-values below 500 mL/g. A soil depth of 1 cm is considered additionally for substances with K_{oc}-values above 500 mL/g.

The average K_{oc}-value is 9304 for pyraclostrobin. Thus, PEC_{soil} of pyraclostrobin is calculated for a soil layer of 1 cm (see Part B, Section 5 of the Part B, National Addendum Germany).

For full details of the calculation see Part B, Section 5 of the National Addendum. The resulting initial PEC_{soil} value is given in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Table 6.7-1: Maximum predicted environmental concentrations in soil PEC_S[1)] for pyraclostrobin / BAS 500 06 F and following application in the intended use.

plant protection product:		BAS 500 06 F				
use:		00-001 to 00-010 cereals (winter/spring)				
Number of applications/intervall		2 x, 21 d				
application rate:		active substance pyraclostrobin: 250 g ai ha^{-1} preparation BAS 500 06 F: (1.25 L ha^{-1} * density: 1044 g L^{-1}) = 1305 g ha^{-1}				
crop interception:		2 x 50				
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)**
active substance pyraclostrobin	2 x 125	1	1.3956	-	-	-
product BAS 500 06 F	2 x 625	1	7.2852	-	-	-

6.7.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in Table 6.7-2. PECs were calculated in line with German national requirements.

Table 6.7-2: Ecotoxicological endpoints, PECsoil values and Toxicity to Exposure ratios to assess the risk for earthworms and other soil macro- and mesofauna following application of BAS 500 06 F according to the intended uses

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger

[3] Füll, C.; Schulte, C.; Kula C. (2003): *Assessment of effects of plant protection products on earthworms.* Umweltwissenschaften und Schadstoff-Forschung 15.2: 78-84

Earthworms (*Eisenia fetida*)						
pyraclostrobin	2x 250 g pyraclostrobin/ha 2 x 1.25 L prod/ha	Acute	283	1.3956	202.8	10
		Long-term	-		-	5
BAS 500 06 F		Acute	192.82	7.2852	52.9	10
		Long-term	30		**4.11**	5
Other soil meso-and macrofauna						
Collembola (*Folsomia candida*)						
BAS 500 06 F	2 x 1.25 L prod/ha	Long-term	125	7.2852	17.2	5
Organic matter breakdown (all organisms)						
BAS 500 06 F	2 x 1.25 L prod/ha	Long-term, 6 month	6 months, 1.25 L/ha, 0.333 mg a.s./kg dry soil - 0.1 % effect on mass loss	1.3956	6.8	n.a.
TER values in bold are below the trigger						

Effects on organic matter breakdown were investigated. The application rate of 1.25 L BAS 500 06 F (250 g pyraclostrobin/ha) results in a soil concentration of pyraclostrobin of 0.333 mg/kg dry soil considering a soil depth of 5 cm and a default density of 1.5 g/cm³. The maximum PEC value of 1.3957 mg pyraclostrobin/kg dry soil is therefore not covered. Hence in this case, the litter bag test is not sufficient to unburden the risk of BAS 500 06 F to soil-dwelling organism communities because its low application rate. As TER_{LT} earthworm is below th trigger value of 5 (Tier 1) and $DT_{90,f}$ of pyraclostrobin is above 365 d, formally according to the terrestrial guidance document testing on organic matter breakdown would be required, which means in this case a new test with an adequate application rate.

However in the view of the UBA and other involved European agencies as well as according to scientific opinions (e.g. “Scientific Panel on Plant protection products and their Residues”, EFSA panel) the litter bag study endpoint and the subsequent use in the assessment are of concern. Since the litter bag test is a functional test, it has not the ability to unburden potential adverse effects on structural level. Hence litter bag studies are not suitable to unburden an identified risk. Thus to address risk to other non-target soil organisms, testing on other non-target macro-organism (IIIA 10.6.6) is required. Since a study with *Folsomia candida* is available, which shows an acceptable risk (TER = 17.2), regarding this specific application no further data to assess risk to other non-target macro-organism are required in the opinion of the MS.

Based on the predicted concentrations of pyraclostrobin/BAS 500 06 F in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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. . Longterm risk TER-value for earthworm is below the trigger of 5. The results of the assessment indicate an unacceptable risk for soil organisms due to the intended use of BAS 500 06 F in cereals according to the label.

Additionally, information on potential effects on earthworm populations is available from a field study conducted with BAS 500 06 F (for details see core assessment). The test site in this study was a grassland site. At an application scenario of up to 6.25 L BAS 500 06 F/ha (equivalent to 1250 g pyraclostrobin/ha) no unacceptable effects to earthworm populations are expected. The intended maximum use of BAS 500 06 F, *i.e.* 2 x 1.25 L/ha (equivalent to 2 x 250 g pyraclostrobin/ha) for cereals is therefore covered by the tested field rate. Thus, it can be concluded that the use of BAS 500 06 F will be of low risk to natural earthworm communities.

6.8.1 Toxicity to Exposure Ratio

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 substance pyraclostrobin in soil (DT_{90} > 365 d, FOMC, field data) the accumulation potential needs to be considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}).

6.8.1.1 Acute risk

The potential acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to BAS 500 06 F / pyraclostrobin 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 The risk assessment results are summarized in Table 6.7-2. PECs were calculated in line with German national requirements.

Table 6.7-2 above.

6.8.1.2 Chronic risk

According to SANCO/10329/2002 rev2-final, the test on 'sub-lethal effects on collembola or soil mites' is required if the $DT_{90,\ field}$ is between 100 and 365 days and the standard HQ for arthropods (*T. pyri* and *A. rhopalosiphi*) is above 2.

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 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

These criteria are met for pyraclostrobin ($DT_{90field}$ > 365 d) and the standard HQ values for arthropods exceed the trigger of 2. Data are available and reported in **Fehler! Verweisquelle konnte nicht gefunden erden.**.

The potential chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to BAS 500 06 F / pyraclostrobin as well as the major soil degradation products of pyraclostrobin was assessed by comparing the maximum PECsoil with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{\text{NOEC (mg/kg)}}{PEC_{soil}\ \text{(mg/kg)}}$$

The resulting TER_{LT} values are shown in The risk assessment results are summarized in Table 6.7-2. PECs were calculated in line with German national requirements.

Table 6.7-2 above.

6.8.2 Residue content of earthworms

Please refer to the core assessment part B section 6 for the central zone.

6.9 Effects on Soil Microbial Activity

6.9.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.9.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.9.1.2 Exposure

Please refer to Table 6.7-1 above for the predicted environmental concentrations in soil (PECsoil) of pyraclostrobin and BAS 500 06 F.

6.9.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the formulation BAS 500 06 F, the active substance pyraclostrobin 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 6.9-1: Summary of risk assessment for soil micro-organisms exposed to BAS 500 06 F/ pyraclostrobin

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
	N transformation	1.3957	3.333	2.4

Pyraclostrobin in BAS 500 01 F	C transformation		3.333	2.4
BAS 500 06 F	N transformation	7.2856	17.3	2.4

Pyraclostrobin in BAS 500 01 F, which is a minor changed formulation cause no effects deviations greater than ±25% in the activity of the soil microorganisms. To proof, if the activity of BAS 500 01 F is comparable with the applies formulation BAS 500 06 F, thenotifier submitted a N-transformation study with BAS 500 06 F. The results are comparable with those from BAS 500 01 F. Hence the C transformation test with BAS 500 01 F can be used as surrogate for BAS 500 06 F.

For the active ingredients in BAS 500 06 F, pyraclostrobin as well as for the formulated product BAS 500 06 F, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 2.4-times higher than the corresponding maximum PEC in soil. According to EU risk assessment also the two metabolites (BF 500-6 and BF 500-7) have no lasting effects on carbon- and nitrogen conversion.

Based on the predicted concentrations of pyraclostrobin/BAS 500 06 F in soils, the risk to soil microbial processes following exposure to pyraclostrobin /BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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.

6.10 Effects on Non-Target Plants

6.10.1 Overview and summary

Please refer to the core assessment part B section 6 for the central zone.

6.10.1.1 Toxicity

Please refer to the core assessment part B section 6 for the central zone.

6.10.1.2 Exposure

Please refer to the core assessment part B section 6 for the central zone.

6.10.1.3 Risk assessment –TER values and overall conclusions

The risk assessment results are summarized in the following table:

Table 6.10-1: Summary of risk assessment for non-target terrestrial plants exposed to BAS 500 06 F/ pyraclostrobin

Substance:	**BAS 500 06 F**
Indication:	A/00-001 to 00-010 winter and spring cereals
GAP:	2 x 250 g ai ha^{-1}, 21 d
MAF:	1.7
Scenario/Percentile:	82.
Interception:	None

Distance (m)	Drift		Volatilisation/ Deposition		PECact (g/ha) (incl. Volatilisation, Interception)			
	(%)	(g/ha)	(%)	(g/ha)	konv. T.	90% Red.	75% Red.	50% Red.
1	2.38	0.05	-	-	0.05	-	-	-
relevant toxiciy: relevant TER:	ER$_{50}$ = 1.25 L/ha 5							
Distance (m)					TER-values (calculated)			
1					25	-	-	-
Risk mitigation:	**-**							

Based on the predicted rates of BAS 500 06 F in off-field areas, the TER values describing the risk for non-target plants following exposure to bAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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 acceptable risk for non-target terrestrial plants due to the intended use of BAS 500 06 F in cereals according to the label.

6.11 Other Non-Target Species (Flora and Fauna)

Please refer to the core assessment part B section 6 for the central zone.

6.12 Other/Special Studies

Please refer to the core assessment part B section 6 for the central zone.

6.12.1 Laboratory studies

Please refer to the core assessment part B section 6 for the central zone.

6.12.2 Field studies

Please refer to the core assessment part B section 6 for the central zone.

6.13 Summary and Evaluation of Points 9 and 10.1-10.10

6.13.1 Predicted distribution and fate in the environment and time courses involved (IIIA 10.11.1)

The predicted distribution and fate of CHA 1270 in the environment is described in Part B, Section 5.

6.13.1 Non-target species at risk and extent of potential exposure (IIIA1 10.11.2)

Please refer to chapter 6.11.3

6.13.2 Short and long term risks for non-target species, populations, communities and processes (IIIA 10.11.3)

Birds

Please refer to the core dossier for the central zone.

Terrestrial vertebrates other than birds

Please refer to the core dossier for the central zone.

Aquatic Organisms

Risk assessments for aquatic organisms were conducted based on the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 final).

The risk assessment for pyraclostrobin 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 (crucial) endpoint for the risk assessment is **HC_5 of 5.9 µg/L (AF = 20)** derived from seven acute fish studies. Risk assessment was done only based on this value because the endpoints/by the corresponding safety factor for the other organisms are higher.

Predicted environmental concentrations in surface water have been calculated in accordance with German national requirements for drift-, run-off and drainage entry into surface water.
Based on the HC_5 = 5.9 µg/L (fish, pyraclostrobin) risk mitigation measurements in form of NW 605/606 (90 % - 5m; 75 % - 5 m; 50 % - 10m; 0 % - 15m) are necessary.

An assessment of major pyraclostrobin metabolite on EU risk assessment level indicated that they will pose no significant risk to aquatic organisms.

Bees

Please refer to the core dossier for the central zone.

Arthropods other than bees

Extended laboratory studies with BAS 500 06 F, and the indicator species *T. pyri, A.* rhopalosiphi, A. bilineata and C. carnea were conducted. The off-field TER values are above the trigger value of 5, indicating low risk to terrestrial non-target arthropods off-field, from applications of BAS 500 06 F at the proposed use pattern.

In-field: Please refer to the core dossier for the central zone.

Earthworms and other soil non-target marco-organisms

Based on the predicted concentrations of pyraclostrobin and BAS 500 06 F in soils, the TER values describing the acute and long-term risk for earthworms following exposure to BAS 500 06 F according to the GAP of the formulation BAS 500 06 F 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. Additionaly a field study with BAS 500 06 F and earthworms is available, which showed no significant effects.

For BAS 500 06 F a litter bag as well as a laboratory study with collembola is available. According to the results, as there were no significant effects observable, it can be concluded, that risk to organic matter and other soil macroorganism after exposure to BAS 500 06 F according to the GAP is acceptable.

Consequences: No

Soil microbial activity

Studies performed for the formulation BAS 500 06 Fand the relevant soil metabolites resulted in no effects greater than ±25% even at treatment levels equivalent to at least 2-times the maximum concentrations expected in soil following applications of BAS 500 06 F. Use of BAS 500 06 F in cereals is not expected to pose a risk to soil micro-organisms.

Non-target plants

Vegetative vigour and seedling emergence studies were conducted for BAS 500 06 F, testing 10 terrestrial plant species in each study. No effects up to the highest concentration tested were observed in the seedling emergence study and in the vegetative vigour study. Therefore the EC_{50} is above 1.25 L/ha.

Based on these endpoints for seedling emergence and vegetative vigour, treatment of BAS 500 06 F according to the proposed uses, poses low and acceptable risk to terrestrial non-target plants.

6.13.3 Risk of fish kills and fatalities in large vertebrates or terrestrial predators (IIIA 10.11.4)

Please refer to the core dossier for the central zone.

6.13.4 Precautions necessary to avoid/minimise environmental contamination and to protect non-target species (IIIA 10.11.5)

Use of drift reducing nozzles in combination with buffer zones (90 % - 5m; 75 % - 5 m; 50 % - 10m; 0 % - 15m) are required to achieve acceptable risk assessments for aquatic organism. As with any application of pesticides not intended for direct application to water, direct overspray of water bodies with BAS 500 06 F should be strictly avoided.

Appendix 1 List of data submitted in support of the evaluation

Please refer to the core dossier for the central zone.

Appendix 2 Detailed evaluation of studies relied upon

Please refer to the core dossier for the central zone.

Appendix 3 Table of Intended Uses in Germany (according to BVL 04.09.2012)

PPP (product name/code) **BAS 500 06 F** **Formulation type:** **EC**
active substance 1 **pyraclostrobin** **Conc. of as 1:** **200 g L^{-1}**

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		
00-001	DE	**Wheat (TRZSS)**	F	*Puccinia recondite* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-002	DE	**Wheat (TRZSS)**	F	*Puccinia striiformis* (PUCCST)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-003	DE	**Wheat (TRZSS)**	F	*Drechslera tritici-repentis* (PYRNTR)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-004	DE	**Barley (HORVX)**	F	*Pyrenophora teres* (PYRNTE)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest

												(PHI of 35 days is used for the risk assessments)
00-005	DE	**Barley (HORVX)**	F	*Rhynchosporium secalis* (RHYNSE_1)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-006	DE	**Barley (HORVX)**	F	*Puccinia hordei* (PUCCHD)	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-007	DE	**Barley (HORVX)**	F	decrease of non-parasitic leaf spots (YBFMI)	spraying	32-61 (at starting of infestation , first symptoms visible)	a) 1 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-008	DE	**Rye (SECCE)**	F	*Rhynchosporium secalis* (RHYNSE_1	spraying	25-61 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-009	DE	**Rye (SECCE)**	F	*Puccinia recondita* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
00-010	DE	**Triticale (TTLSS)**	F	*Puccinia recondita* (PUCCRE)	spraying	25-69 (at starting of infestation , first symptoms visible)	a) 2 b) 2 (21 days)	a) 1,25 b) 2,5	a) 0,25 b) 0,5	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: BAS 500 06 F

Reg. No.: ZV1 007643-00/00

Active Substance: Pyraclostrobin 200 g/L

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: BASF SE

Finalized: 2014-10-31

Table of Contents

IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Current document indicates the information related to the efficacy data of the plant protection product BAS 500 06 F containing the active substance pyraclostrobin. DE acts as the zonal rapporteur member state; AT, BE, CZ, HU, IE, LU, NL, PL, RO, SK, SI and UK are concerned member states (Table 6-1).

Table 6-1: Zonal rapporteur member state (zRMS) and concerned member states (cMS)

zRMS	Germany	DE
cMS	Austria	AT
	Belgium	BE
	Czech Republic	CZ
	Hungary	HU
	Ireland	IE
	Luxemburg	LU
	Netherland	NL
	Poland	PL
	Romania	RO
	Slovak Republic	SK
	Slovenia	SI
	United Kingdom	UK

Recent registration situation/history of the PPP

BAS 500 06 F is a strobilurin fungicide. It is formulated as an emulsifiable concentrate (EC) and contains 200 g/L pyraclostrobin. The envisaged maximum individual application rate is 1.25 L/ha which would deliver 250 g/ha pyraclostrobin. BAS 500 06 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). In Spain, Greece and Portugal, a mutual recognition application is currently under evaluation for the use in cereals which is based on the French authorization and GAP.

Table 6-2: Existing registrations for BAS 500 06 F in cereal crops in Europe

Country	Trade name	Formulation		Authorisation	Registered	crops
		Type	Conc.	No.	rate	
France	COMET® 200 SOLARAM 200	EC	200	2100151	1.10 L/ha	wheat, barley, oats, rye, triticale
Denmark	COMET® PRO	EC	200	19-184	1.25 L/ha	cereals
Estonia	COMET® Pro	EC	200	383	1.25 L/ha	cereals
Latvia	COMET® Pro	EC	200	354	1.25 L/ha	cereals
Lithuania	COMET® Pro	EC	200	0396F/10	1.25 L/ha	cereals
Norway	COMET® PRO	EC	200	TBA	1.25 L/ha	cereals
Finland	COMET® 200	EC	200	3053	1.25 L/ha	cereals

Ireland	COMET® 200 MODEM® 200 PLATOON® 200	EC	200	03696 03695 02615	1.25 L/ha	wheat, barley, oats, rye, triticale
United Kingdom	BAS 500 06 COMET® 200 PLATOON®	EC	200	12338 12639 12325	1.25 L/ha	wheat, barley, oats

Information on the active ingredients (Uptake and mode of action)

Pyraclostrobin is a fungicide belonging to the group of Quinone outside-Inhibitors (=strobilurins), specially to the chemical group of methoxy-carbamates. The active substance is classified according to the target site and code by FRAC to respiration inhibition C3: complex III, cytochrome bc1.
Pyraclostrobin is intended to be used in grape vines, on cereals, turf and banana. Especially the substance is active against *Plasmopara viticola* and *Unicinula necator* in grape vines, against *Erysiphe graminis, Puccinia spp., Pyrenophora* sp*., Leptosphaeria nodorum* and *Rhynchosporium secalis* in cereals, *Microdochium nivale* in turf and *Mycosphaerella* sp. in banana.
The biochemical mode of action of the strobilurin is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubihydroquinone to cytochrome c by means of a binding to the ubihydroquinone oxidation centre (Qo) to the cytochrome bc1 complex (Complex III). The interruption of the electron transport chain in this way prevents oxidative phosphorulation, thus causing a severe reduction in the availability of ATP. This reduction of energy-rich ATP inhibits a range of essential processes in the fungal cell.
Based on the current evidence the resistance risk assessment for strobilurin fungicides can, at least with some fungi, be moderate to high. The rapid appearance of field resistance in some of the above cases indicates that a single-step (also termed disruptive, qualitative or monogenic) resistance is involved.
The published use pattern for strobilurins covered by the FRAC STAR Working Group guidelines for management strategy reflects the resistance risk assessment.
Pyraclostrobin is active against fungal development stages both on the plant surface and within the tissues. Pyraclostrobin inhibits spore germination, mycelial growth, and the development of infection structures is thus prevented. Post infection applications leads to the rapid collapse of fungal structures already established on the leaf surface.
Pyraclostrobin has a protective as well as an eradicative/curative action. Pyraclostrobin is selective on a wide range of dicotyledonous and monocotyledonous crop species.
After foliar application (spraying), pyraclostrobin is absorbed by the plant tissue and – to a limited extent - translocated acropetally in the transpiration stream. A small systemic activity can be observed in some indications based on the very high intrinsic activity of pyraclostrobin. Pyraclostrobin will be used for foliar application and as seed treatment.

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 500 06 F containing the active substance pyraclostrobin for use as a fungicide for the control of *Puccinia recondita* f.sp. *tritici* (PUCCRT), *Puccinia striiformis* (PUCCST) and *Pyrenophora tritici-repentis* (PYRNTR) on wheat, *Puccinia hordei* (PUCCHD), *Pyrenophora teres (*PYRNTE) and *Rhynchosporium secalis* (RHYNSE) on barley, *Puccinia recondita* f.sp. *recondita* (PUCCRR) and *Rhynchosporium secalis (*RHYNSE) on rye and *Puccinia recondita* (PUCCRE) on triticale.

<u>Wheat</u>

Brown rust (*Puccinia recondita* f.sp. *tritici* - PUCCRT)

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* - 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* - 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

Barley brown rust (*Puccinia hordei* - 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* - 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* - 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.

Non-parasitic leaf spots

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

Brown rust (*Puccinia recondita* f.sp. *recondita* - PUCCRR)

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* - 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 practise.

Triticale

Brown rust (*Puccinia recondita* - 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.

A summary of information about classification of these crops and diseases in the rapporteur member state (zRMS) and in the concerned member states (cMS) was applied by the applicant, as demanded by EPPO standard "Principles of zonal data production and evaluation" in Table 6-2.

Table 6-2: Classification of crop and disease (including abiotic damage) in the zRMS and cMS

crop / pathogen	EPPO-code	classification of crop major	classification of crop minor	classification of disease major	classification of disease minor
1	2	3		4	
Wheat / *Puccinia recondita*	TRZSS / PUCCRE	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE	
Wheat / *Puccinia striiformis*	TRZSS / PUCCST	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE	
Wheat / *Drechslera tritici-repentis*	TRZSS / PYRNTR	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO	UK, IE
Barley / *Puccinia hordei*	HORVX / PUCCHD	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE	
Barley / *Pyrenophora teres*	HORVX / PYRNTE	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE	
Barley / *Rhynchosporium secalis*	HORVX / RHYNSE	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE	
Barley / non-parasitic leaf spots	HORVX / YBFMI*	DE, BE, NL, PL, CZ, SK, SI, HU, RO, UK, IE		DE, BE, NL, CZ, SK, SI, HU, RO	UK, IE
Rye / *Puccinia recondita* f.sp. *recondite*	SECCE / PUCCRR	DE, PL, CZ, SK, SI, HU[1]), RO	BE, NL, UK, IE	DE, BE[1]), NL, PL, CZ, SK, SI, HU[1]), RO	UK, IE
Rye / *Rhynchosporium secalis*	SECCE / RHYNSE	DE, PL, CZ, SK, SI, HU[1]), RO	BE, NL, UK, IE	DE, BE[1]), NL, PL, CZ, SK, SI, HU[1]), RO	UK, IE
Triticale / *Puccinia recondita*	TRZSS / PUCCRE	DE, PL, CZ, SK, SI, HU[1]), RO	BE, NL, UK, IE	DE, BE[1]), NL, PL, CZ, SK, SI, HU[1]), RO	UK, IE

* no EPPO code
1 common name (see field of use)
2 EPPO-Code
3 classification of crop/situation (major/minor) in zRMS and cMS, if is renamed
4 classification of pest/disease (major/minor) in zRMS and cMS, if is renamed

Information on the intended uses applied for Germany (zRMS):

(2012-06-28)

No.	**007643-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Wheat (TRZSS)
Crop stage(s) (BBCH)	25 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals (*Puccinia recondita* f.sp. *tritici*) (PUCCRT)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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No.	**007643-00/00-002**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Wheat (TRZSS)
Crop stage(s) (BBCH)	25 to 61
Pest(s)/target(s)/aim(s)	stripe rust of grasses (*Puccinia striiformis*) (PUCCST)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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No.	**007643-00/00-003**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Wheat (TRZSS)
Crop stage(s) (BBCH)	25 to 61
Pest(s)/target(s)/aim(s)	tan spot of cereals (*Drechslera tritici-repentis*) (PYRNTR)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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No.	**007643-00/00-004**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Barley (HORVX)
Crop stage(s) (BBCH)	25 to 61
Pest(s)/target(s)/aim(s)	net blotch (*Pyrenophora teres*) (PYRNTE)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha

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No.	**007643-00/00-005**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Barley (HORVX)
Crop stage(s) (BBCH)	25 to 61
Pest(s)/target(s)/aim(s)	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha

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No.	**007643-00/00-006**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Barley (HORVX)
Crop stage(s) (BBCH)	25 to 61
Pest(s)/target(s)/aim(s)	brown rust of barley (*Puccinia hordei*) (PUCCHD)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha

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No.	**007643-00/00-007**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Barley (HORVX)
Crop stage(s) (BBCH)	32 to 61
Pest(s)/target(s)/aim(s)	decrease of non-parasitic leaf spots (YBFMI*)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha

*no EPPO code

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No.	**007643-00/00-008**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Rye (SECCE)
Crop stage(s) (BBCH)	25 to 61

Pest(s)/target(s)/aim(s)	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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No.	**007643-00/00-009**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Rye (SECCE)
Crop stage(s) (BBCH)	25 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals (*Puccinia recondita* f.sp. *recondita*) (PUCCRE)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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No.	**007643-00/00-010**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	Triticale (TTLSS)
Crop stage(s) (BBCH)	25 to 69
Pest(s)/target(s)/aim(s)	brown leaf rust of cereals (*Puccinia recondita*) (PUCCRE)
Area of use	Outdoors
Time of treatment	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 technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	1.25 L/ha in 100 to 400 L water/ha
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IIIA1 6.1 Efficacy data

The applicant applied for a registration in all member states of the central regulatory zone covering countries in the EPPO climatic zones “maritime”, “north-east” and “south-east” as described in EPPO standard PP 1/241. The applicant supposed that the submission includes data from all these EPPO zones which are representative of the proposed GAP. EPPO climatic zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. The applicant mentions that similarities have been detected in the efficacy results for BAS 500 06 F from trials carried out in the northeast and southeast EPPO climatic zones, where the continental climate dominates. Therefore, these results have been summarized and presented as one group for “central east” Europe. This group includes trials from Poland (north-east EPPO climatic zone), Slovakia and Hungary (south-east EPPO climatic zone) and results from Czech Republic (maritime EPPO climatic zone) as the trial sites in Czech Republic were

very close to the zonal border of the eastern zones. The applicant claims that in all of these countries, the presence of the diseases and the intensity of fungicide treatments are comparable. This grouping is supported by specific Site Similarity Certificates, where trial locations from Poland and Czech Republic were proven to be comparable. Another such document is available to demonstrate similarity of trial sites from Czech Republic and Hungary (2011/1285016).
In the other group, trial results from the countries from “central west” Europe out of the maritime EPPO climatic zone were summarized including Germany, Austria, United Kingdom, Ireland, France and Denmark (Table 6.1-1).

Table 6.1-1: Spatial distribution of trials submitted to support the efficacy section in the central zone

Country	EPPO zone	Regulatory zone
FR, UK, IE, DE, CZ, DK, AT	maritime	central
PL	north east	central
HU, SK	south east	central
Country	**Data zone**	**Regulatory zone**
FR, UK, IE, DE, DK, AT	central west	central
PL, CZ, HU, SK	central east	central

IIIA1 6.1.1 Preliminary range-finding tests

Since it was first launched pyraclostrobin has been a major component of the European cereal fungicide, extensive trials and development work has been carried out by the applicant with products containing this active substance.
With the novel product BAS 500 06 F, identical amounts of pyraclostrobin are delivered per hectare as from the earlier formulation BAS 500 01 F, which is registered under the trade name Comet® in many countries in Europe. The applicant believes that additional range-finding tests were therefore not deemed to be necessary.

Application timing

The application date depends on the pathogen and the start of infection or re-infection. BAS 500 06 F can be used in wheat, barley, rye and triticale for the control of *Puccinia recondita, Puccinia striiformis, Pyrenophora tritici-repentis, Puccinia hordei, Pyrenophora teres, Rhynchosporium secalis* from growth stages 25 to 61/69. Application for reduction of non-parasitic leaf spots in barley is performed from growth stages 32 to 61.
For control of brown rust it is recommended to apply from growth stages 25 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 2005 to 2011, the minimum effective dose for BAS 500 06 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 and 6.1.2-2 according to the above mentioned grouping.

Table 6.1.2-1: Efficacy (%) in minimum effective dose trials of BAS 500 06 F for the central east group

Crop	Disease	Grouping	# trials	disease level in % (UTC)	Efficacy of BAS 500 06 F in %					
					full rate 1.25 l/ha			reduced rate 0.8-0.83 l/ha		
					mean	min	max	mean	min	max
Wheat	*Puccinia recondita*	central east	6	23.8	81.5	56.2	97.7	73.4	48.5	92.0
	Pyrenophora tritici-repentis	central east	2	11.0	87.0	78.5	93.0	65.0	63.7	65.9
Barley	*Puccinia hordei*	central east	1	16.3	98.0	98.0	98.0	86.0	86.0	86.0
	Pyrenophora teres	central east	6	27.6	85.0	68.6	97.5	75.8	54.2	96.3
	Rhynchosporium secalis	central east	4	13.7	75.4	62.5	84.4	65.9	48.9	73.4
Rye	*Rhynchosporium secalis*	central east	1	22.5	94.2	94.2	94.2	80.0	80.0	80.0
Triticale	*Puccinia recondita*	central east	1	15.3	93.5	93.5	93.5	85.0	85.0	85.0

Table 6.1.2-2: Efficacy (%) in minimum effective dose trials of BAS 500 06 F for the central west group

Crop	Disease	Grouping	# trials	disease level in % (UTC)	Efficacy of BAS 500 06 F in %					
					full rate 1.25 l/ha			reduced rate 0.8-0.83 l/ha		
					mean	min	max	mean	min	max
Wheat	*Puccinia recon-dita*	central west	4	16.6	91.9	86.9	97.7	81.0	71.9	88.6
	Pyrenophora tritici-repentis	central west	4	14.0	62.4	50.0	65.9	82.3	78.5	93.0
Barley	*Pyrenophora teres*	central west	10	35.9	78.7	58.1	97.5	66.7	47.4	96.3
	Rhynchospori-um secalis	central west	8	27.2	66.7	49.8	90.0	50.1	13.5	84.4
Rye	*Puccinia recon-dita*	central west	2	75.7	76.2	70.9	83.5	69.1	65.1	74.5
	Rhynchospori-um secalis	central west	2	26.3	93.1	92.3	94.2	84.8	80.0	88.3
Tritica-le	*Puccinia recon-dita*	central west	1	35.0	83.4	83.4	83.4	74.3	74.3	74.3

The results can be summarized as following:

Wheat: Against brown rust (*Puccinia recondita* f.sp. *tritici*) and tan spot (*Pyrenophora tritici-repentis*), a reduction of the dose rate resulted in clearly reduced efficacy in average of 8-22%. In consequence, the obtained yield results were inferior.
Mean results of the western Europe and the eastern Europe are comparable for both efficacy and yield. The observed efficacy differences in the single trials were in most cases significant. However, some situations were identified where the reduced dose rate of 0.80 - 0.83 L/ha provided satisfactory control. In the case of lower disease pressure, usage of reduced dose rates such as 0.8 – 1.0 L/ha might provide sufficient activity.

Barley: Against net blotch (*Pyrenophora teres*), Rhynchosporium and brown rust (*Puccinia hordei*), a reduced dose rate resulted in clearly reduced efficacy in average of 9-17%. In consequence, the obtained yield results were inferior. With both, full and reduced dose rates, BAS 500 06 F achieved in eastern Europe slightly higher control levels compared to western Europe.
The observed efficacy differences in the single trials were in most cases significant. However, situations were identified where the reduced dose rate of 0.80 - 0.83 L/ha provided satisfactory control. In the case of lower disease pressure, usage of reduced dose rates such as 0.8 – 1.0 L/ha might provide sufficient activity.

Rye: Against Rhynchosporium and brown rust (*Puccinia recondita* f.sp. *recondita*), a reduction of the dose rate resulted in clearly reduced efficacy in average of 7-8%.

Triticale: The reduced dose rate showed in average 9% inferior efficacy against brown rust (*Puccinia recondita*) compared to the target dose rate of 1.25 L/ha.

In conclusion the applicant is convinced that the dose of 1.25 L/ha of BAS 500 06 F provided the optimum overall level of activity and was effective against all the major cereal diseases for which activity of BAS 500 06 F is claimed. As a result, the proposed rate of 1.25 L/ha should be considered as the minimum effective dose to deliver broad spectrum control under a wide range of environmental conditions. In accordance with the EPPO standard PP 1/225 for minimum effective dose tests, situations were identified where the reduced dose rate did provide satisfactory control. It is therefore concluded, that in regions with lower disease pressure and/or shorter vegetation period, a reduced dose rate of 0.8 – 1.0 L/ha of BAS 500 06 F may provide sufficient control under practical conditions, especially if the product is used in mixture with other compounds.

IIIA1 6.1.3 Efficacy tests

At the present study, efficacy data of BAS 500 06 F against *Puccinia recondita* f.sp. *tritici* (PUCCRT), *Puccinia striiformis* (PUCCST) and *Pyrenophora tritici-repentis* (PYRNTR) on wheat, *Puccinia hordei* (PUCCHD), *Pyrenophora teres (*PYRNTE) and *Rhynchosporium secalis* (RHYNSE) on barley, *Puccinia recondita* f.sp. *recondita* (PUCCRR) and *Rhynchosporium secalis (*RHYNSE) on rye and *Puccinia recondita* (PUCCRE) on triticale are presented from totally 206 efficacy trials assessed between1999 to 2011.

Table 6.1.3-1: Location and number of BAS 500 06 F efficacy trials*

Country		Year													Total
		1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	
Central West	AT						1	1							2
	DE	1	3		2		7	36	30	2	7	9	7	11	115
	DK		2							1		3			6
	FR		2	1	2	2	1	6	3	19	2				38
	IE											1			1
	UK					2	1	1				3		5	12
Central East	CZ												9	6	15
	HU													2	2
	SK													2	2
	PL												5	8	13
Total		1	7	1	4	4	10	44	33	22	9	16	21	34	206

*Countries were grouped according to the above mentioned concept

The applicant claims that all trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organizations. Efficacy of BAS 500 06 F in these trials was compared to the commercial standards Comet (pyraclostrobin 200 g/L), Opus (epoxiconazole 125 g/L), Opus top (fenpropimorph 250 g/L and epoxiconazole 84 g/L), Caramba (metconazole 60 g/L), Champion (epoxiconazole 67 g/L and boscalid 233 g/L), Input (spiroxamine 300 g/L and prothioconazole 160 g/L), Alert (flusilazole 125 g/L and carbendazim 250 g/L), Opera (epoxiconazole 50 g/L and pyraclostrobin 133 g/L), Folicur (tebuconazole 250 g/L), Amistar (azoxystrobin 250 g/L), Capalo (fenpropimorph 200 g/L, epoxiconazole 62.5 g/L and metrafenone 75 g/L), Opera New (epoxiconazole 62.5 g/L and pyraclostrobin 85 g/L), Fandango (fluoxastrobin 100 g/L and prothioconazole 100 g/L), Juwel Top (fenpropimorph 150 g/L, epoxiconazole 125 g/L and kresoxim-methyl 125 g/L) and Artea Plus (cyproconazole 160 g/L and propiconazole 250 g/L). He also adds additional 15 exact trials without the GEP flag as supportive data (this efficacy data belongs to the former registration of the desired fungicide in Germany). The supportive data will be summarized separately and give additional information of the efficacy of the plant protection product.

Table 6.1.3-2: Guidelines and trial design

GEP	Yes (191 Trials), No (15 Trials)		
standards	PP 1/26(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: 67; barley: 97; rye: 32; triticale: 10		
trial per intended use	Wheat	Brown rust (Puccinia triticina)	34 trial results
		Yellow rust (Puccinia striiformis)	11 trial results
		Yellow rust - supportive data	9 trial results
		DTR tan spot (Pyrenophora tritici-repentis)	21 trial results
	Barley	Brown rust (Puccinia hordei)	25 trial results
		Net blotch (Pyrenophora teres)	47 trial results
		Rhynchosporium leaf blotch (Rhynchosporium secalis)	35 trial results
		Non-parasitic leaf spots (sun burn injury)	12 trial results
		Non-parasitic leaf spots - supportive data	6 trial results
	Rye	Brown rust (Puccinia recondita)	26 trial results
		Rhynchosporium leaf blotch (Rhynchosporium secalis)	17 trial results
	Triticale	Brown rust (Puccinia recondita)	10 trial results
crop stage (BBCH) at application	BBCH 29-65		
reference product(s) (dorsage), act. subst	Comet,1.0 L/ha; Opus Top 1.5 L/ha, 1.0 L/ha; Caramba 1.5 L/ha; Champion 1.5 L/ha; Input 1.25 L/ha; Alert (Harvesan) 0.8 L/ha (Slovakia); Opera 1.5 L/ha (France, Denmark); Folicur 1.0 L/ha; Amistar 1.0 L/ha; Capalo 1.4 L/ha (Poland); Opera New 2.0 L/ha; Fandango 1.25 L/ha; Juwel Top 1.0 L/ha; Artea Plus 0.5 L/ha (Czech Republik)		

Efficacy data as a summary table for each tested intended uses for all countries is presented at Table 6.1.3-3. Efficacy results in details for each group are presented at Table 6.1.3-4 and 6.1.3-5.

Table 6.1.3-3: Mean efficacy (%) against various diseases taken from trials during 1999 to 2011 (All countries)

Crop	Disease	Grouping	# trials	Disease level in % (UTC)	BAS 500 06 F			Standard		
					mean	min	max	mean	min	max
Wheat	Brown rust (*Puccinia recondita*)	All	26 (8)*	17.8 (157.2)*	92.2	56.2	100.0	88.6	56.9	100.0
	Yellow rust *(Puccinia striiformis)*	All	11	34.6	93.9	83.7	100.0	88.1	50.0	100.0
		Supportive data (Non-GEP)	9	30.9	99.2	96.3	100.0	98.9	92.1	100.0
	DTR tan spot *(Pyrenophora tritici-repentis)*	All	21	23.4	81.6	55.5	100.0	63.0	34.3	100.0
Barley	Brown rust *(Puccinia hordei)*	All	18 (7)*	11.0 (195.7)*	91.1	65.3	100.0	87.1	55.0	100.0
	Net blotch *(Pyrenophora*	All	47	29.4	85.3	62.9	100.0	66.4	10.5	100.0

	teres)									
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	All	35	16.9	73.0	53.8	92.0	65.7	14.7	95.1
	Non-parasitic leaf spots (sun burn injury)	All	12	29.3	60.7	44.4	96.0	59.4	29.4	72.3
		Supportive data (Non-GEP)	6	17.6	61.8	33.3	81.0	62.7	25.0	92.6
Rye	Brown rust *(Puccinia recondita)*	All	22 (4)*	23.1 (183.2)*	87.1	42.5	100.0	77.0	23.0	95.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	All	17	14.8	72.2	38.6	100.0	67.8	38.6	100.0
Triticale	Brown rust *(Puccinia recondita)*	All	9 (1)*	15.3 (100.4)*	96.7	92.0	100.0	91.8	64.0	100.0

*first number based on infect (P%INF), second number in brackets based on numbers of pustules (ZCOUNT)

Table 6.1.3-4: Mean efficacy (%) against various diseases taken from trials during 1999 to 2011 (central east group)

Crop	Disease	Grouping	# trials	Disease level in % (UTC)	BAS 500 06 F			Standard		
					mean	min	max	mean	min	max
Wheat	Brown rust (*Puccinia recondita*)	central east	9	20.4	92.8	56.2	100.0	91.0	56.9	100.0
	DTR tan spot *(Pyrenophora tritici-repentis)*	central east	3	17.4	90.4	88.3	93.0	70.9	58.3	94.6
Barley	Brown rust *(Puccinia hordei)*	central east	3	8.9	90.8	81.0	97.7	90.3	81.0	100.0
	Net blotch *(Pyrenophora teres)*	central east	16	17.7	84.7	77.0	97.5	78.7	65.2	97.1
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central east	6	6	78.1	60.5	92.0	54.4	24.3	88.0
	Non-parasitic leaf spots (sun burn injury)	supportive data (Non-GEP)	6	17.6	61.8	33.3	81.0	62.7	25.0	92.6
Rye	Brown rust *(Puccinia recondita)*	central east	2	14.3	84.6	75.8	93.4	76.0	58.6	93.4
	Rhynchosporium leaf blotch *(Rhynchosporium secal-*	central east	1	22.5	94.4	94.4	94.4	92.2	92.2	92.2

	is)									
Triticale	Brown rust *(Puccinia recondi-ta)*	central east	1	15.3	93.4	93.4	93.4	83.6	83.6	83.6

Table 6.1.3-5: Mean efficacy (%) against various diseases taken from trials during 1999 to 2011 (central west group)

Crop	Disease	Grouping	# trials	disease level in % (UTC)	BAS 500 06 F			Standard		
					mean	min	max	mean	min	max
Wheat	Brown rust (*Puccinia recon-dita*)	central west	17 (8)*	16.5 (157.2)*	91.9	76.0	100.0	87.4	57.0	100.0
	Yellow rust *(Puccinia strii-formis)*	central west	11	34.6	93.9	83.7	100.0	88.1	50.0	100.0
		Supportive data (Non-GEP)	9	30.9	99.2	96.3	100.0	98.9	92.1	100.0
	DTR tan spot *(Pyrenophora tritici-repentis)*	central west	18	24.4	80.1	55.5	100.0	61.7	34.3	100.0
Barley	Brown rust *(Puccinia hordei)*	central west	15 (7)*	11.4 (195.7)*	91.2	65.3	100.0	86.7	55.0	100.0
	Net blotch *(Pyrenophora teres)*	central west	31	35.4	85.7	62.9	100.0	60.1	10.5	100.0
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central west	29	10.5	71.9	53.8	90.3	68.0	14.7	95.1
	Non-parasitic leaf spots (sun burn injury)	Supportive data (Non-GEP)	6	17.6	61.6	33.3	81.0	62.7	25.0	92.6
Rye	Brown rust *(Puccinia recon-dita)*	central west	20 (4)*	24.0 (183.2)*	87.4	42.5	100.0	77.1	23.0	95.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central west	16	14.3	70.9	38.6	93.5	66.3	38.6	100.0
Triticale	Brown rust *(Puccinia recon-dita)*	central west	8 (1)*	15.4 (23.8)*	96.8	92.0	100.0	92.1	64.0	100.0

*first number based on infect (P%INF), second number in brackets based on numbers of pustules (ZCOUNT)

Brown rust in wheat
The efficacy of BAS 500 06 F against brown rust in wheat was tested in 34 trials central west 25 and central east 19 trials.

The reference products selected were Opus with an application rate of 1.0 L/ha in 14 trials, Opus Top with an application rate of 1.5 L/ha in 14 trials, 1.0 L/ha Comet, 2.0 L/ha Capalo and 1.0 L/ha Folicur. The infestation assessments were carried out 22 to 58 days after treatment. In 27 trials the percentage infestation of the leaf surface was determined, and in 8 trials the number of pustules was assessed.
In 12 trials it was confirmed that BAS 500 06 F generally reduced infestation better than the reference products, in the other trials the reduction of infestation was at the same level as that with the standard products.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 17.8% in the control was reduced by BAS 500 06 F to 1.8% and by the reference products to 2.2%. The degree of efficacy of BAS 500 06 F was 92.2% compared with the standard fungicides 88.6%.

Yellow rust in wheat
The efficacy of BAS 500 06 F against yellow rust in wheat was tested in 11 trials with GEP classification. In addition, 9 exact trials without GEP classification were separately analysed.

All trials were located in the central west group. For the central east group, no exact trials with an important infection were reported. The first observations of the elongation of this disease in the eastern countries were done in the last years. With increasing intensity of production and with the usage of high yield varieties in south and east Europe, the yellow rust in wheat can become an important disease in this region in a couple of years. The importance of protection from yellow rust will be comparable with the estimations done in Western Europe.

The reference products selected for all trials were Opus with an application rate of 1.0 L/ha, Opus Top with 1.5 L/ha and Champion with 1.5 L/ha. The infestation assessments were carried out 15 to 44 days after treatment. In 1 trial the percentage infestation of all leaf levels was determined as a mean value, whereas in 10 trials the percentage infestation of single leaf levels was assessed.
In all trials it was confirmed that BAS 500 06 F generally reduced infestation equally well as the reference product, in 3 cases slightly better and in 1 slightly weaker.
The degrees of efficacy of both variants were in each case markedly more than 80%, which means that both variants shows very good efficacy against yellow rust.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 34.6% in the control was reduced by BAS 500 06 F to 2.8% and by the reference products to 2.7% on average. The mean degree of efficacy of BAS 500 06 F was 93.9% compared with 88.1% for the reference products.

The reference products selected for the additionally trials without GEP-signet were Opus with an application rate of 1.0 L/ha and Opera with 1.5 L/ha. The infestation assessments were carried out 28 to 48 days after treatment. In all trials the percentage infestation of single leaf levels were assessed.
In all trials it was confirmed that BAS 500 06 F generally reduced infestation equally well as the reference product, in 1 case slightly better.
The degrees of efficacy of both variants were in each case markedly more than 90%, which means that both variants showed very good efficacy against yellow rust.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 30.9% in the control was reduced by BAS 500 06 F to 0.3% and by the reference products to 0.4%. The mean degree of efficacy of BAS 500 06 F was 99.2% compared with 98.9% for the reference products.

DTR tan spot in wheat
The efficacy of BAS 500 06 F against DTR tan spot in wheat was tested in 21 trials. Eighteen trials were located in the central west group. 2 trials were located in the central east group and one trial in Austria, nearby the Czech Republic border. For that reason, this result was included in the central east group summary.

The reference products selected were Opus with an application rate of 1.0 L/ha; Opus Top with 1.5 L/ha and Amistar with 1.0 L/ha. Infestation assessments were carried out 13 to 55 days after treatment. In 14 trials the percentage infestation of single leaf levels was determined, and in 7 trials the infection of all leaf levels was assessed as mean value.

In 12 trials it was confirmed that BAS 500 06 F reduced infestation in some cases markedly better than the reference products, in the other trials the reduction of infestation was at the same level as with the reference products.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 23.4% in the control was reduced by BAS 500 06 F to 4.2%, and by the reference products to 9.5%. The degree of efficacy of BAS 500 06 F was 81.6% compared with 63.0% for the reference products.

Brown rust in barley
The efficacy of BAS 500 06 F against brown rust in barley was tested in 25 trials. Twenty two trials were located in the central west group, 3 trials were located in the central east group.

The reference products selected were Opus with an application rate of 1.0 L/ha, Opus Top with 1.5 L/ha and 1.0 L/ha (registered dose rate in Poland), Capalo with 2.0 L/ha and Fandango with 1.25 L/ha. The infestation assessments were carried out 20 to 54 days after treatment. In all trials, the severity of leaf surface attack was determined by single leaf level assessments, using the parameters percentage infestation (P%INF) or number of pustules (ZCOUNT).
In all trials it was confirmed that BAS 500 06 F reduced infestation equally well as or markedly better than the reference products. The degree of efficacy was - in some cases markedly - over 80% in almost all trials, only in 1 trial the degree of efficacy with BAS 500 06 F was only 70.0%, but the reference product achieved only 55.0%.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 11.0% in the control was reduced by BAS 500 06 F to 0.7%. The mean infestation with the reference products was 1.0%. The degree of efficacy of BAS 500 06 F was 91.1%, that of the reference products 87.1%.

Net blotch in barley
The efficacy of BAS 500 06 F against net blotch in barley was tested in 47 trials. Thirty one trials were located in the central west group, 16 trials were located in the central east.

The reference products selected were Opera New with 2.0 L/ha; Opus with 1.0 L/ha, Opus Top with 1.5 L/ha and Champion with 1.5 L/ha. The infestation assessments were carried out 7 to 63 days after treatment. In all trials, the infestation was assessed as % severity of leaf surface infection, determined on single leaf levels or as a whole plant assessment (mean over leaf levels). In all trials without exception it was confirmed that BAS 500 06 F reduced infestation better than the reference products. The degree of efficacy was very high in almost all of the trials, in some cases markedly over 90%.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 29.4% in the control was reduced by BAS 500 06 F to 4.0%. Mean infestation for the reference products was 11.9%. The degree of efficacy of BAS 500 06 F was 85.3%, that of the reference products 66.4%.

Rhynchosporium leaf blotch in barley

The efficacy of BAS 500 06 F against Rhynchosporium leaf blotch in barley was tested in 35 trials. Twenty nine trials were located in the central west group, 6 trials were located in the central east group.

The reference products selected were Opus with an application rate of 1.0 L/ha, Opus Top with 1.5 L/ha and 1.0 L/ha (registered dose rate in Poland), Champion with 1.5 L/ha, Opera New with 2.0 L/ha and Fandango with 1.25 L/ha. The infestation assessments were carried out 12 to 54 days after treatment. In all trials, the percentage infestation of the leaf surface was determined as single leaf level assessment or as a whole plant assessment (mean over leaf levels).
In all trials it was confirmed that BAS 500 06 F reduced infestation equal or better than the reference products. The degree of efficacy was in some cases mainly over 80%, regardless of whether single or double treatments were carried out due to medium or heavy infestation.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 16.9% in the control was reduced by BAS 500 06 F to 4.7%. Mean infestation for the reference products was 5.6%. The degree of efficacy of BAS 500 06 F was 73.0%, that of the reference products 65.7%.

Reduction of non-parasitic leaf spots in barley

The efficacy of BAS 500 06 F against non-parasitic leaf spots in barley was tested in 12 trials with GEP classification and additional in 6 trials without GEP classification - but also in exact trials. Results of these supportive trials were shown separately at the end of this chapter. These trials give additional information of the activity of BAS 500 06 F against non parasitic leaf spots in barley.

The reference products selected were Opus Top with an application rate of 1.5 L/ha, Opus with 1.0 L/ha, Fandango with 1.25 L/ha and Juwel Top with 1.0 L/ha.
The infestation assessments were carried out 20 to 59 days after treatment. In all trials the percentage infestation of the leaf surface was determined as a single leaf level assessment or as a whole plant assessment.
In all trials it was confirmed that BAS 500 06 F reduced infestation equal or better than the reference products. The degree of efficacy was in many cases markedly over references.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 29.3% in the control was reduced by BAS 500 06 F to 10.5%. Mean infestation for the reference products was 12.1%. The degree of efficacy of BAS 500 06 F was 60.7%, that of the reference products 59.4%.

The reference product selected for the additionally trials without GEP signet were Opus with an application rate of 1.0 L/ha and Opus Top with 1.5 L/ha, Champion with 1.5 L/ha and Fandango with 1.25 L/ha. The infestation assessments were carried out 11 to 41 days after treatment. In all trials the percentage infestation of the leaf surface was determined as a single leaf level assessment or as a whole plant assessment.
In all trials it was confirmed that BAS 500 06 F generally reduced infestation equally well as the reference product.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 17.6% in the control was reduced by BAS 500 06 F to 5.2% and by the reference products to 4.7%. The mean degree of efficacy of BAS 500 06 F was 61.8% compared with 62.7% for the reference products.

In summary, it can be stated that non-parasitic leaf spot was equally well controlled by BAS 500 06 F than by the reference products. The additional trials prove the thesis, that BAS 500 06 F shows a good activity against non-parasitic leaf spots in barley.

Brown rust in rye

The efficacy of BAS 500 06 F against brown rust in rye was tested in 26 trials. Twenty four trials were located in the central west group, 2 trials were located in the central east group.

The reference products selected were Opus with an application rate of 1.0 L/ha, Opus Top with 1.5 L/ha, Champion with 1.5 L/ha and Artea Plus with 0.5 L/ha. The infestation assessments were carried out 18 to 71 days after treatment. In all trials, the percentage infestation of the leaf surface was determined as a single leaf level assessment or as a whole plant assessment.
In 6 trials it was confirmed that BAS 500 06 F generally reduced infestation better than the reference products, in the other trials the reduction of infestation was at the same level as that with the standards.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 23.1% in the control was reduced by BAS 500 06 F to 2.3% and by the reference products to 4.4%. The degree of efficacy of BAS 500 06 F was 87.1% compared to 77.0% with the reference fungicides.

Rhynchosporium leaf blotch in rye

The efficacy of BAS 500 06 F against Rhynchosporium leaf blotch in rye was tested in 17 trials. Sixteen trials were located in the central west group, 1 trial was located in the central east group.

The reference products selected were Opus Top with an application rate of 1.5 L/ha, Champion with 1.5 L/ha and Artea Plus with an application rate of 0.5 L/ha. The infestation assessments were carried out 9 to 71 days after treatment. In all trials the percentage infestation of the leaf surface was determined as a single leaf level assessment or as a whole plant assessment.
In the trials it was confirmed that BAS 500 06 F reduced infestation better than many reference products.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 14.8% in the control was reduced by BAS 500 06 F to 3.5%. Mean infestation for the reference product was 4.3%. The degree of efficacy of BAS 500 06 F was 72.2%, that of the reference products 67.8%.

Brown rust in triticale

The efficacy of BAS 500 06 F against brown rust in triticale was tested in 10 trials. Nine trials were located in the central west group, 1 trial was located in the central east group.

The reference products selected were Champion with 1.5 L/ha, Caramba with 1.5 L/ha, Alert with 0.8 L/ha, Input with 1.25 l/ha and Opus Top with 1.5 L/ha. The infestation assessments were carried out 21 to 74 days after treatment.

In two trials it was confirmed that BAS 500 06 F reduced infestation markedly better than the reference products, in the other trials the infestation was regulated equally in both test variants.

The mean of all trials, where percentage infestation was determined, showed that the disease infestation of 15.3% in the control was reduced by BAS 500 06 F to 0.6% and to 1.4% by the reference products. The degree of efficacy of BAS 500 06 F was 96.7%, that of the reference products 91.8%.

In conclusion, the applicant describes that the results show that BAS 500 06 F provided very good to excellent fungicidal activity against the target pathogens. The fungicidal performance of BAS 500 06 F against all diseases was at least equivalent to that of the standard; although as a rule the efficacy of BAS 500 06 F often significantly exceeded that of the standards. Thus documentary evidence is provided to support the spectrum of activity of BAS 500 06 F against important and relevant leaf and ear diseases of cereal crops. The data also demonstrated that there was no difference in the performance of BAS 500 06 F when trial data was grouped in “central east” and “central west” Europe.

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. Any detailed data is existed neither in BAD nor dRR.

The applicant mentions that a total of 206 efficacy trials were carried out between 1999 and 2011 in Germany, Austria, United Kingdom, Ireland, France, Denmark, Czech Republic, Poland, Slovakia and Hungary. Measurements of the thousand grain mass (TGM) and hectolitre weight (HLW) were made in 172 and 161 trials, respectively. The objective was to confirm the response in terms of grain quality to applications of BAS 500 06 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	n		Untreated control		BAS 500 06 F		Standard	
		TGM	HLW	TGM	HLW	TGM	HLW	TGM	HLW
Wheat	Brown rust (*Puccinia recondita*)	21	23	38.4	72.8	40.9	75	40.8	74.1
	Yellow rust *(Puccinia striiformis)*	9	9	38.4	73.3	41.4	78.9	41.8	75.2
	Yellow rust *- supportive data*	5	5	41	72.2	44.6	75.7	45.5	75.9
	DTR tan spot *(Pyrenophora tritici-repentis)*	12	12	38.5	68.7	41.3	70.2	41.4	69.4
Barley	Brown rust *(Puccinia hordei)*	15	17	40.8	62.5	44	64	42.9	63.5
	Net blotch *(Pyrenophora teres)*	39	33	43.4	63.9	46.5	65.4	45.1	64.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	27	22	47.7	66.9	49	67.9	49	67.8
	Non-parasitic leaf spots (sun burn injury)	11	12	41.7	66.2	45.5	67.9	45.4	67.8
	Non-parasitic leaf spots - supportive data	3	4	42.7	60.7	44.8	64.8	44.4	64.3

Rye	Brown rust *(Puccinia recondita)*	16	11	33.3	69.9	34.7	70.8	34.4	70.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	14	8	31.6	70.3	32.9	71	32.6	71
Triticale	Brown rust *(Puccinia recondita)*	6	6	45.6	68.7	48.5	71.3	47.3	71.1

Altogether, BAS 500 06 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.

IIIA1 6.1.4.2 Effects on the processing procedure

The applicant submitted no data and no concrete information to support this point. He just mentions that Comet, the previous 250 g/L EC formulation of pyraclostrobin (BAS 500 01 F), has been tested intensively for potential effects on the malting and brewing processes of just winter and spring barley by IFBM in France. The results demonstrated that Comet had no effect on the malting and brewing processes and so consequently, Comet was included in the list of recommended products for brewing barley. No other information exists for wheat, rye and triticale. Furthermore, the active substances pyraclostrobin is accepted by the British Beer and Pubs Association (BBPA) for use in cereals at its full recommended application rate of 250 g/ha.

The applicant believes that BAS 500 06 F has been formulated in a similar way to Comet, and so it is therefore considered reasonable to conclude that BAS 500 06 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). Results in details for each group are presented at Table 6.1.4.3-2 and 6.1.4.3-3.
In general, the applicant mentions that a total of 253 efficacy results were obtained between 1999 and 2011 in Germany, Austria, United Kingdom, Ireland, France, Denmark, Czech Republic, Poland, Slovakia and Hungary. Although the applicant presented any statistical analysis for the results but he is convinced that BAS 500 06 F, applied at the proposed label rate of 1.25 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 500 06 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-all countries)

Crop	Disease	Grouping	# trials	yield (dt/ha) Untreated	% yield relative to the untreated at target dose rate BAS 500 06 F			Standard		
					mean	min	max	mean	min	max
Wheat	Brown rust (*Puccinia recondita*)	All	34	67.7	119.4	102.8	198.6	117.1	100.6	202.6
	Yellow rust	All	11	73.4	128.5	106.8	172.3	128.7	105.9	173.4

	(Puccinia striiformis)	Supportive data (Non-GEP)	9	79.0	123.4	101.8	153.3	124.3	106.9	149.9
	DTR tan spot *(Pyrenophora tritici-repentis)*	All	21	64.9	117.7	104.9	140.1	114.0	102.1	136.7
Barley	Brown rust *(Puccinia hordei)*	All	25	64.8	116.8	102.8	142.2	113.5	100.2	135.9
	Net blotch *(Pyrenophora teres)*	All	47	63.7	119.8	99.1	181.6	113.8	98.5	168.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	All	35	68.8	112.1	100.7	138.6	111.0	95.2	137.5
	Non-parasitic leaf spots (sun burn injury)	All	12	69.1	123.4	96.1	190.8	119.1	98.4	157.8
		Supportive data (Non-GEP)	6	69.6	122.8	108.4	147.7	121.7	110.0	148.3
Rye	Brown rust *(Puccinia recondita)*	All	25	65.0	118.3	89.4	200.3	108.5	79.9	156.9
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	All	17	73.8	114.9	101.0	136.9	111.9	99.7	125.9
Triticale	Brown rust *(Puccinia recondita)*	All	10	73.3	124.2	105.2	183.8	112.2	100.8	187.7

Table 6.1.4-3-2 Summary of yield data in the presence of disease (mean yield relative to the untreated - Data for central east)

Crop	Disease	Grouping	# trials	yield (dt/ha)	% yield relative to the untreated at target dose rate					
				Untreated	BAS 500 06 F			Standard		
					mean	min	max	mean	min	max
Wheat	Brown rust (*Puccinia recondita*)	central east	9	56.9	122.7	102.8	169.5	122.4	100.7	202.6
	DTR tan spot *(Pyrenophora tritici-repentis)*	central east	3	75.8	120.4	112.2	129.5	114.3	105.2	119.8
Barley	Brown rust *(Puccinia hordei)*	central east	3	48.8	111.7	102.8	117.3	113.4	108.1	116.0
	Net blotch *(Pyrenophora teres)*	central east	16	48.0	120.6	102.8	181.6	118.1	100.5	168.6
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central east	6	54.2	117.2	106.6	138.6	117.6	103.7	137.5
Rye	Brown rust	central east	2	51.9	116.8	109.4	124.3	107.0	104.8	109.3

	(Puccinia recon-dita)									
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central east	1	62.7	124.3	124.3	124.3	109.3	109.3	109.3
Triticale	Brown rust *(Puccinia recon-dita)*	central east	1	49.0	147.2	147.2	147.2	147.0	147.0	147.0

Table 6.1.4-3-3 Summary of yield data in the presence of disease (mean yield relative to the untreated - Data for central west)

Crop	**Disease**	**Grouping**	**# trials**	**yield (dt/ha)**	**% yield relative to the untreated at target dose rate**					
				Untreated	**BAS 500 06 F**			**Standard**		
					mean	**min**	**max**	**mean**	**min**	**max**
Wheat	Brown rust (*Puccinia recon-dita*)	central west	25	71.6	118.3	104.5	198.6	115.2	100.6	160.4
	Yellow rust *(Puccinia strii-formis)*	Supportive data (Non-GEP)	9	79.0	123.4	101.8	153.3	124.3	106.9	149.9
	DTR tan spot *(Pyrenophora tritici-repentis)*	central west	18	63.1	116.5	104.9	140.1	114.0	102.1	136.7
Barley	Brown rust *(Puccinia hordei)*	central west	21	67.1	116.8	103.3	142.2	113.5	100.2	135.9
	Net blotch *(Pyrenophora teres)*	central west	31	71.8	119.4	99.1	154.1	111.6	98.5	135.9
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central west	29	71.9	111.0	100.7	127.5	109.6	95.2	120.2
	Non-parasitic leaf spots (sun burn injury)	Supportive data (Non-GEP)	6	69.6	122.8	108.4	147.7	121.7	110.0	148.3
Rye	Brown rust *(Puccinia recon-dita)*	central west	23	66.1	118.4	89.4	200.3	111.2	79.9	156.9
	Rhynchosporium leaf blotch *(Rhynchosporium secalis)*	central west	16	74.5	114.3	101.0	136.9	112.0	99.7	125.9
Triticale	Brown rust *(Puccinia recon-dita)*	central west	9	76.0	121.7	105.2	183.8	120.8	100.8	187.7

In conclusion the applicant demonstrated that BAS 500 06 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.

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 500 06 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 500 06 F at the proposed use rate of 1.25 L/ha. Trials were carried out on cereal crops from 1999 to 2011 in Germany, Austria, United Kingdom, Ireland, France, Denmark, Czech Republic, Poland, Slovakia and Hungary on a wide range of commercially grown varieties. According to him all of the available data clearly demonstrates the excellent crop safety of BAS 500 06 F in all cereal species.
The applicant also mentions that in the vast majority of the trials, treatment with BAS 500 06 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 500 06 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.

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)

Effects on relevant beneficial organisms

The toxicity of BAS 500 06 F on beneficial organisms has been investigated by carrying out different laboratory tests on *Aphidius rhopalosiphi*, *Chrysoperla carnea*, *Aleochara bilineata* and *Typhlodromus pyri.*
2.5 L/ha BAS 500 06 F (corresponding to 2 times the recommended field rate/ha and application) are not harmful (effects < 25% in the higher tier test) to *Aphidius rhopalosiphi* (Table 6.2.4-1).
The results of the laboratory test on *Aleochara bilineata* are presented in Table 6.2.4-3. Application rates of 2.2 L/ha and 3.75 L/ha (corresponding to 1.8 times and 3 times the recommended field rate/ha and application) led to reduction of reproductive capacity of the beetle < 15%.
Chrysoperla carnea reacted more sensitive on BAS 500 06 F than the insect species *Aphidius rhopalosiphi* and *Aleochara bilineata* (Table 6.2.4-2). In the aged residue test fresh residues of 1.25 L/ha and 2.5 L/ha BAS 500 06 (corresponding to 1.0 times and 2.0 times the recommended field rate/ha and application) caused lethal effects > 25% and > 50%, respectively. Hence, two application of 1.25 L/ha BAS 500 06 are harmful (effects > 50%) for populations of *Chrysoperla carnea* in fields with wheat, barley and rye. The aged residue test demonstrates that the effects on *Chrysoperla carnea* dissipate largely within two weeks at most.

Table 6.2.4-1: Effects of BAS 500 06 F on *Aphidius rhopalosiphi* (exposed stage: male and female)

Application rate [L/ha]	Corrected mortality [%]	Effect on parasitisation rate [%]	Reference
1 Laboratory test using glass			
0.006	22.5	-	Sipos, K., 2007

0.019	27.5	-	BASF DocID: 2007/1035600
0.056	62.5	-	
0.167	100	-	
0.250	100	-	
0.500	100	-	
LR_{50} : 0.04 L/ha (95% Confidence limits: 0.03 L/ha – 0.05 L/ha)			
2 Laboratory test using barley plants			
0.070	0	-	Stevens, J., 2008 BASF DocID: 2008/1010713
0.150	0	-	
0.300	0	-	
0.600	0	0.8	
1.2500	10.0	8.7	
2.500	20.0	0.8	

Table 6.2.4-2: Effects of BAS 500 06 F on *Chrysoperla carnea* (exposed stage: larva)

Application rate [L/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
1 Laboratory test using bean leaves			
0.310	8.2	-16.1	RÖHLIG, U., 2008 BASF DocID: 2008/1032666
0.630	44.9	0.8	
1.250	81.6	-	
2.500	93.9	-	
3.750	100	-	
LR_{50} : 0.72 L/ha (95% Confidence limits: 0.62 L/ha – 0.84 L/ha)			
2 Laboratory test using leaves from treated bean plants (aged residue test) Test item was applied on potted bean plants at two different rates. 0, 7 and 14 days after treatment (T) leaves were collected from apple trees and returned to the laboratory. Aging of the spray residues of the test item on the potted bean plants took place under semi-field conditions during the whole study.			
	0 days after T		RÖHLIG, U., 2008 BASF DocID: 2008/1042190
1.250	36.2	18.3	
2.500	66.0	-	
	7 days after T		
1.250	6.3	2.4	
2.500	41.7	5.6	
	14 days after T		
1.250	2.0	-4.9	
2.500	10.0	-6.3	

Table 6.2.4-3: Effects of BAS 500 06 F on *Aleochara bilineata* (exposed stage: male and female) in an extended laboratory test (substrate: Lufa 2.1)

Application rate [L/ha]	Reduction of reproductive capacity (relative to control)	Reference
2.200	14.4	Schmitzer, S., 2008 BASF DocID: 2008/1010700
3.750	10.6	

Table 6.2.4-4 shows the results of the two laboratory tests on *Typhlodromus pyri*. An application rate of 2.5 L/ha (corresponding to 2 times the recommended field rate/ha and application) led to lethal effect of 53.5% in the higher tier test. Therefore, the recommended two applications of 1.25 L/ha BAS 500 06 are harmful for populations of *Typhlodromus pyri* (effects > 50%). But,

the indicator test species *Typhlodromus pyri* is not relevant antagonist in fields with wheat, barley and rye.
With today's level of knowledge, the results for *Typhlodromus pyri* indicate that two applications of the recommended rate of BAS 500 06 to wheat, barley, triticale and rye might reduce the population of relevant predatory mites and spiders > 50%.

Table 6.2.4-4: Effects of BAS 500 06 F on *Typhlodromus pyri* (exposed stage: protonymph)

Application rate [L/ha]	Corrected mortality [%]	Effect on reproduction [%]	Reference
1 Laboratory test using glass			
0.046	11.2	-	Sipos, K., 2007 BASF DocID: 2007/1035599
0.139	18.5	-	
0.417	34.8	-	
1.250	74.6	-	
3.750	94.6	-	
LR_{50} : 0.87 L/ha (95% Confidence limits: 0.65 L/ha – 1.10 L/ha)			
2. Laboratory test using bean leaves			
0.313	12.8	11.7	Vaughan, R., 2008 BASF DocID: 2008/1010712
0.625	20.5	24.6	
1.250	16.7	41.3	
2.500	53.5	36.8	
3.750	67.1	-	
LR_{50} : 2.452 L/ha (95% Confidence limits: 1.611 L/ha – 5.304 L/ha)			

Conclusions
BAS 5000 06 F is classified as not harmful for populations of *Aphidius rhopalosiphi* and *Aleochara bilineata*.
BAS 5000 06 F is classified as harmful for populations of *Chrysoperla carnea*.
BAS 5000 06 F is classified as harmful for populations of relevant predatory mites and spiders.

Effects on soil quality

Effects on soil macro-organisms being used as indicators of soil quality

Effects on earthworms

Active substances
The active substance pyraclostrobin was included into Annex I of Directive 91/414 EEC (see Commission Directive 2004/30/EC and 2009/25/EC), respectively is approved according to Commission Implementing Regulation (EU) No 540/2011 (Expiry date: 2014-05-31) under the current regime Regulation (EC) No 1107/2009.

Table 6.2.4-5: Toxicology of the active ingredient

Test product/parent compound	Duration, organism	EU agreed endpoints (pyraclostrobin: SANCO/1420/2001-final, Monograph 12945/ECCO/BBA/01)	Value mg a.s./kg dry soil	Reference

pyraclostrobin	Acute, 14 d *Eisenia fetida*	Mortality LC_{50}	283 1)	Krieg, 1999/10708
	chronic, 56 d *Eisenia fetida*	Reproduction, NOEC	0.443 (corre-sponding to 1 L product/ha)	SANCO/1420/2001-final, Appendix II

1) 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.

Metabolites

Table 6.2.4-6: Ecotoxicological endpoints for relevant metabolites

Test prod-uct/parent compound	Duration, organism	EU agreed endpoints	Value	Dimension	Reference
BF 500-6	Acute, 14 d *Eisenia fetida*	Mortality LC_{50}	>1000	mg a.s./kg dry soil	pyraclostrobin: SAN-CO/1420/2001-final, Appendix II; Mono-graph 12945/ECCO/BBA/01)
	chronic, 56 d *Eisenia fetida*	Reproduction, NOEC	1000		ARW2000-84 ((PPP ‘Maccani ‘, DE-registration No. 006459)
BF 500-7	Acute, 14 d Eisenia fetida	Mortality LC50	>1000	mg a.s./kg dry soil	
	chronic, 56 d Eisenia fetida	Reproduction, NOEC	1000		ARW2000-85 (PPP ‘Maccani ‘, DE-registration No. 006459)

Product

The Commission Implementing Regulation (EU) No 540/2011 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.

Member States should pay particular attention to the:

- protection of aquatic organisms, especially fish;
- protection of terrestrial arthropods and earthworms
  Reproduction NOEC =0.443 (corresponding to1 L product/ha)

The formulated product BAS 500 06 F was tested in an acute study on earthworms and in chronic studies on earthworms. All TER values for or a soil layer of 2.5 cm and 1 cm exceeded the Commission Regulation (EU) 546/2011 trigger value of 10 for acute and 5 for chronic expo-sure.

Table 6.2.4-7: Toxicology of the product

Test product	Duration, organism	Endpoint	Value	Dimension	Reference
BAS 500 06 F	14 d, mortality *Eisenia fetida*	LC_{50}	37[1)](corresponding to LC_{50} = 193mg product./kg dry soil[1)])	mg a.s./kg dry soil	-
	56 d, reproduction	NOEC	5.75 30.0		-

1) Toxicity endpoint is re-adjusted by a soil factor of 2 to address the organic content of the soil since the log Pow for the active substance is > 2.

Proposed use pattern
See GAP table for DE and intended uses for all cMS, Part B, Appendix 2.

Table 6.2.4-8: Proposed use pattern of BAS 500 06 F

Crop	Spray volume	Maximum individual application rate	Number of applications	Max. total application rate	Application timing e.g. BBCH
Cereals DE: wheat, rye, barley, triticale	100 – 400 water l/ha	250 g a.s./ha	2	500 g a.s./ha	25 - 69

Exposure

In accordance with national guidance [*Füll, C., Schulte, C., Kula C. (2003): Assessment of effects of plant protection products on earthworms. Umweltwissenschaften und Schadstoff-Forschung 15.2: 78-84*] a reduced thickness of the soil layer of 2.5 cm was considered for substances with K_{oc}-values below 500 mL/g. A thickness of the soil layer of 1 cm is considered additionally for substances with K_{oc}-values above 500 mL/g.

The K_{oc}-values of pyraclostrobin ranged from 6000 to 16000 mL/g (refer to Chapter 9.4 and 9.5).

The predicted environmental concentrations of pyraclostrobin in soil (PEC_{soil}) were calculated as described in chapters 9.4 and 9.5.

Table 6.2.4-9: Maximum soil PEC values for BAS 500 06 F and pyraclostrobin.

Test substance	Maximum PEC_{soil} [mg/kg]
pyraclostrobin	0.212[1)] 1.062[2)] 0.425[3)]
BAS 500 06 F	0.212[1)] 1.062 [2)] 0.425[3)]

1) PEC_{max} for a soil layer of 5 cm
2) PEC_{max} for a soil layer of 1 cm.

3) PEC_{max} for a soil layer of 2.5 cm.

For the two soil metabolites BF 500-6 and BF 500-7, their levels in soil will be negligible (expected to be < 0.01 mg/kg), based on the rare detection of the metabolites in the pyraclostrobin field studies where the active substance was applied to bare soil with a distinctly higher rate than the expected soil load after application of BAS 500 06 F. Therefore, no special PEC_{soil} values were calculated for BF 500-6 and BF 500-7.

Risk assessment (Toxicity exposure ratios, TER_A and TER_{LT})

Acute risk TER_A

The potential acute risk of BAS 500 06 F was assessed by comparing the maximum acute PEC_{soil} with the 14-day LC_{50} value to generate acute TER values. The log K_{OW} value for pyraclostrobin is above 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. The TER_A was calculated as follows:

The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_S\ (mg/kg)}$$

Acute TER values for earthworms were derived from EU agreed endpoints and exposure data regarding a thickness of the soil layer of 2.5 cm and 1 cm were calculated in accordance with national guidance

Table 6.2.4-10: Toxicity/exposure ratios for earthworms

Test substance	Use pattern [L/ha]	Species	Test type	Endpoint [mg/kg dry soil]	PEC [mg/kg dry soil]	TER_a	Annex VI trigger
pyraclostrobin	2 x 1.25	*Eisenia fetida*	14-d acute toxicity test	LC_{50} = 283 1)	1.062 2) 0.425 3) 0.212 4)	266 666 1335)	10
BAS 500 06 F	2 x 1.25	*Eisenia fetida*	14-d acute toxicity test	LC_{50} = 37 1)	1.062 2) 0.425 3) 0.212 4)	35 87 175	10

1) 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.
2) PEC_{max} for a soil layer of 1 cm.
3) PEC_{max} for a soil layer of 2.5 cm.
4) PEC_{max} for a soil layer of 5 cm

Thus, all TER_a are above the relevant trigger value of 10 indicating a low and acceptable acute risk to earthworms of the active substances and the relevant soil degradation products following treatment with BAS 500 06 F in accordance with the intended worst-case use pattern.

Long-term risk TER_{LT}

The potential long-term risk of the product to earthworms was assessed by calculating long-term TER (TER_{LT}) value by comparing the NOEC value and the maximum acute PEC_S using the following equation:

$$TER_{LT} = \frac{\mathrm{NOEC(mg/kg)}}{\mathrm{PEC_S\ (mg/kg)}}$$

Table 6.2.4-11: Risk assessment for earthworms

Test substance	Use pattern [L/ha]	Species	Test type	Endpoint [mg/kg dry soil]	PEC [mg/kg dry soil]	TER_{LT}	Annex IV trigger
BAS 500 06 F	2 x 1.25	*Eisenia fetida*	56-d reproduction test	NOEC = 5.75	1.062 [1)] 0.425 [2)] 0.212 [3)]	5.4 13.5 27	5

1) PEC_{max} for a soil layer of 1 cm.
2) PEC_{max} for a soil layer of 2.5 cm.
3) PEC_{max} for a soil layer of 5 cm

All long-term TER values exceed the Commission Regulation (EU) 546/2011 trigger value of 5 considering a soil layer of 1 and 2.5 cm, indicating low chronic risk for earthworms following application of BAS 500 06 F according to the proposed use rates.

Conclusion

Thus, all TER are above the relevant trigger value of 5 indicating a low and acceptable chronic risk for earthworms to BAS 500 06 F following treatment with the product in accordance with the intended worst-case use pattern.

Field tests

In addition, the potential risk to earthworms was also addressed in an earthworm field study carried out with BAS 500 06 F. No unacceptable effects on earthworm communities were observed at application rates higher than the maximum intended use pattern. Therefore, it can be concluded that the use of BAS 500 06 F will be of low risk to natural earthworm populations.

Table 6.2.4-12: Endpoint of the field test

Test substance	Test species	EU agreed endpoints (pyraclostrobin: SANCO/1420/2001-final, Monograph 12945/ECCO/BBA/01)	Endpoints used in risk assessment
Field studies			
BAS 500 06 F	earthworm field population	--	no unacceptable effects up to 6.25 L/ha

Since the maximum application rate is 2x1.25 L product/ha no unacceptable risk to earthworms has been identified.

Effects on other non-target macro-organisms

According to SANCO/10329/2002 rev2-final, the test on 'sub-lethal effects on collembola or soil mites' is required if the $DT_{90,\ field}$ is between 100 and 365 days and the standard HQ for arthropods (*T. pyri* and *A. rhopalosiphi*) is above 2.

Since the worst-case $DT_{90,\ field}$ value of pyraclostrobin exceeds 100 days (*i.e.* 230 days, see SANCO/1420/2001-final) and the standard HQ values for arthropods exceed the trigger of 2 (please refer to chapter 10.5), a test with other soil macro-organisms than earthworms was triggered. According to SANCO/10329/2002 rev2-final, the test for sub-lethal effects on collembola or soil mites could be omitted, if a litter bag test is triggered (see chapter 10.6.7). Litter bag tests were conducted with the pyraclostrobin solo-formulation (see chapter 10.6.7). Additionally, a reproduction study with collembola was carried out with BAS 500 06 F, in order to gain additional information for the risk assessment. The study is considered appropriate to be used in the risk assessment.
In this 28-day collembolan reproduction study with BAS 500 06 F the NOEC based on mortality and reproduction was 125 mg BAS 500 06 F/kg dry soil. The EC_{50} was 189.6 mg BAS 500 06 F/kg dry soil, the LC_{50}.was determined to be 283.8 mg BAS 500 06 F/kg dry soil.
All TER values for or a soil layer of 2.5 cm and 1 cm exceeded the Commission Regulation (EU) 546/2011trigger value of 5 for chronic exposure (SANCO/1420/2001-final, Monograph 12945/ECCO/BBA/01).

Table 6.2.4-13: Chronic toxicity/exposure ratios for other soil non-target macro-organisms

Test substance	Use pattern [L/ha]	Species	Test type	Endpoint [mg/kg dry soil]	PEC [mg/kg dry soil]	TER_{LT}	TER risk assessment trigger
BAS 500 06 F	2 x 1.25	*Folsomia candida*	28-d reproduction test	NOEC = 23.9[3)] (Friedrich, 2008/1037495)	1.062 [1)] 0.425[2)]	23 56	5

1) PEC_{max} for a soil layer of 1 cm.
2) PEC_{max} for a soil layer of 2.5 cm.
3) Test was conducted with only 5% peat in the test substrate

The long-term TER values for BAS 500 06 F for the soil dwelling collembolan species *Folsomia candida* are above the trigger of 5. Thus, no risk to soil non-target macro-organisms is expected.

Effects on organic matter breakdown

According to SANCO/10329/2002 rev2-final, a litter bag test is required if *(a)* the $DT_{90,\ field}$ of the active substance is above 365 days, *(b)* effects on soil micro-organisms are above 25% after 100 days or *(c)* long-term TER values for earthworm or other soil macro-organisms are below 5.

The $DT_{90,\ field}$ for pyraclostrobin was calculated to be < 365 days. The earthworm reproduction studies exceeded the Commission Regulation (EU) 546/2011 trigger of 5. Furthermore, effects on soil microorganisms are < 25% (refer to chapter 10.7). A study on organic matter breakdown was therefore not triggered.

However, reference is made to a new litter bag study with the formulation BAS 500 06 F (Luehrs U., Schabio S., 2010a). The mass loss of the straw material in the untreated control was 80.5% at the end of the experiment after 179 days. In the treatment group exposing the soil to 1.25 L BAS 500 06 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 -5.5%, +0.2% and -0.1%, respectively. There were no statistically significant differences between this treatment group and the water treated control (Student t-test, α = 0.05).

The results of the field study with BAS 500 06 F demonstrated that the organic matter break-down process will be at low risk following exposure scenarios covering the intended uses of BAS 500 06 F. Therefore, the risk of BAS 500 06 F to soil-dwelling organism communities is considered to be low, following application of 1.25 L BAS 500 06 F/ha.

Overall conclusion with respect to effects on soil macro-organisms

It is concluded that the proposed use of BAS 500 06 F will not pose any unacceptable risks to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Instructions and information: None

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

Effects on soil quality

Effects on soil non-target micro-organisms exposed to BAS 500 06 F

Table 6.2.4.-14: Ecotoxicological endpoints for soil micro-organisms

Test item	Test design1	EU agreed endpoints	Reference
Pyraclostrobin in BAS 500 01 F 2	C	No significant effect > 25% at day 28 at 1.0 L or 10 L product/ha (1.33 µl or 13.33 µl /kg soil dw)	Krieg,W. (1998) Reg.Doc. BASF 98/11253
	N	No significant effect > 25% at day 28 at 1.0 L or 10 L product/ha (1.33 µl or 13.33 µl /kg soil dw)	Krieg,W. (1998) Reg.Doc. BASF 98/11259
BF 500-6	C	No significant effect > 25% at day 28 at 0.1 mg metabolite or 1.0 mg/kg soil dw (parent substance: 250.0 g BAS 500 F/ha)	Krieg,W. (1999)BASF Doc. ID 1999/11120
	N		Krieg,W. (1999) BASF Doc. ID 1999/11311
BF 500-7	C	No significant effect > 25% at day 28 at 0.05 mg metabolite or 0.5 mg/kg soil dw (parent substance: 250.0 g BAS 500 F/ha)	Krieg,W. (1999) BASF Doc. ID 1999/11120
	N		Krieg,W. (1999) BASF Doc. ID 1999/11311

1) C = Carbon Mineralization, N = Nitrogen transformation.
2) Tests were carried out with formulation BAS 500 01 F (250 g pyraclostrobin/L), which is comparable to BAS 500 06 F

Risk assessment for soil microflora functions

Table 6.2.4.-15: Risk assessment for soil microflora functions

Test substance	NOEC (< 25% effect at 28 d)	Maximum PEC_{soil}	MoS*
BAS 500 01 F (contains 250 g pyraclostrobin/L)	3.333 mg a.s./kg d.w.soil	0.212 mg pyraclostrobin/kg soil dw.	15.7

* Margin of Safety

The results of these studies showed no effects of ≥ ± 25% compared to the control on soil microbial activity up to a maximum tested concentration of 3.333 mg a.s./kg soil (equivalent to 10.0 L/ha), after 28 days. As this maximum tested concentration was much higher than the maximum initial PEC_{soil} (0.212 mg a.s./kg) calculated based on the specific requirements for Germany. The metabolites of pyraclostrobin, BF 500-6 and BF 500-7, were considered to be environmentally non-relevant based on the soil field dissipation studies.
As the proposed use of BAS 500 06 F an acceptable risk to soil microbial activity can be concluded.

Overall conclusion with respect to effects on soil quality

There is no indication of any unacceptable adverse effects on soil macro- or soil micro-organisms relevant for the maintenance of soil quality.

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 and barley. 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 500 06 F.
The applicant also mentions that trials which done with the earlier formulation BAS 500 01 F (Comet) has no detrimental effect on the germination of cereal grain harvested from treated crops.

IIIA1 6.2.6 Impact on succeeding crops

The applicant claims that the evaluation given below of the influence of BAS 500 06 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 2.5 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, corn, winter wheat, sugar beet, oilseed rape, pea and radish.
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 500 06 F presents a low risk of damage to the most of the following crops.
It may therefore be concluded that the application of BAS 500 06 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 500 06 F.

Table 6.2.6-1: NOEC values* (mg/kg soil)

test plant		EPPO-Code	NOEC (mg/kg soil)	
1	2	3	4	
			BAS 500 06 F	Pyraclostrobin
Bean	*Phaseolus vulgaris*	PHSVN	> 1.728	> 0.333
Corn	*Zea mays*	ZEAMX	> 1.728	> 0.333
Winter wheat	*Triticum aestivum*	TRZAW	> 1.728	> 0.333
Sugar Beet	*Beta vulgaris*	BEAVA	> 1.728	> 0.333
Oilseed rape	*Brassica napus*	BRSNW	> 1.728	> 0.333
Peas	*Pisum sativum*	PIBSA	> 1.728	> 0.333
Radish	*Raphanus sativus*	RAPSR	> 1.728	> 0.333

* No Observed Effect Concentration

1 common name
2 scientific name (lat.)

3 EPPO-Code

4 NOEC (mg/kg soil) for test product and active substance was calculated with following parameters: Bulk density (soil) = 1.5 g/cm³; Depth = 10 cm; Product dose rate = 2 N (2.5 l/ha); product density = 1.037 g/cm³

Table 6.2.6-2 Effect of BAS 500 06 F on seedling emergence - Biomass of plant species (% to untreated control) after pre emergence application of BAS 500 06 F (mean of all replicates, 21 DAT)

Plant species	Rate - BAS 500 06 F [L/ha]					
	0.000	0.078	0.156	0.313	0.625	1.250
Carrot**	100.0	110.4	102.6	100.8	101.4	105.2
Lettuce	100.0	89.8	99.1	97.8	96.2	92.1
Oilseed rape	100.0	95.4	95.2	98.2	98.6	98.2
Cabbage	100.0	94.7	109.7	103.5	99.7	102.3
Soybean	100.0	97.8	90.2	93.8	93.3	92.7
Tomato	100.0	100.9	99.1	100.7	96.5	103.2
Onion**	100.0	92.8	82.0*	102.9	80.5*	85.0
Ryegrass	100.0	116.2	134.4	108.1	112.9	132.5
Oat	100.0	108.9	106.9	98.9	101.8	102.4
Corn	100.0	101.9	101.7	105.3	101.7	102.9

* significantly different to the untreated control (Dunnett's t-test. α=0.05) - based on dry weight data
** carrot and onion 28 DAT

Table 6.2.6-3 Effect of BAS 500 06 F on seedling emergence - Plant length of plant species (% to untreated control) after pre emergence application of BAS 500 06 F (mean of all replicates) (21 DAT)

Plant species	Rate - BAS 500 06 F [L/ha]					
	0.000	0.078	0.156	0.313	0.625	1.250
Carrot**	100.0	100.6	93.8	96.5	97.1	96.4
Lettuce	100.0	93.9	95.0	98.2	97.8	95.6
Oilseed rape	100.0	108.6	106.7	102.7	99.7	102.6
Cabbage	100.0	106.6	101.0	101.4	97.8	96.3
Soybean	100.0	104.5	101.6	102.9	96.9	104.4
Tomato	100.0	98.5	101.8	98.2	97.0	99.7
Onion**	100.0	93.8	94.2	101.4	92.0*	91.1*
Ryegrass	100.0	103.5	102.4	96.9	102.4	98.8
Oat	100.0	99.0	100.2	98.9	100.6	100.0
Corn	100.0	102.5	99.7	99.5	98.4	100.5

* significantly different to the untreated control (Dunnett´s t-test, α=0.05) - based on the plant length data
** carrot and onion 28 DAT

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 500 01 F. Vegetative vigour evaluations were made for a range of monocotyledon (Onion, Ryegrass, Oat and Corn) and dicotyledon (Carrot, Lettuce, Oilseed Rape, Cabbage, Soybean and Tomato) indicator crops for BAS 500 06 F (DocID 2012/1115894). ER 50 values were > 1.25 L/ha for BAS 500 06 F for all tested crops. (Table 6.2.7-1 and 6.2.7-2). The equivalent dose rate for BAS 500 06 F would be 3.75 L/ha, which is three times the target dose rate for the intended use.

Table 6.2.7-1: Effect of BAS 500 06 F on vegetative vigour - biomass production dry weight (% to untreated control) – 21 DAT for all plant species

Plant species	Rate - BAS 500 06 F [L/ha]					
	0.000	0.078	0.156	0.313	0.625	1.250
Carrot	100.0	104.1	99.4	101.0	100.7	93.1
Lettuce	100.0	105.0	110.7	109.6	106.9	105.2
Oilseed rape	100.0	96.0	103.4	104.2	104.8	104.9
Cabbage	100.0	94.5	99.1	98.7	95.5	91.6*
Soybean	100.0	99.9	101.9	91.3	96.2	94.6
Tomato	100.0	96.4	97.7	96.8	98.7	97.5
Onion	100.0	98.1	101.9	88.5*	91.6	94.4
Ryegrass	100.0	95.5	95.7	101.9	96.3	96.0
Oat	100.0	101.4	102.7	100.3	100.2	99.0
Corn	100.0	106.8	106.8	95.2	105.3	105.4

* significantly different to the untreated control (Dunnett´s t-test, α=0.05) - based on dry weight data

Table 6.2.7-2: Effect of BAS 500 06 F on vegetative vigour - plant length (% to untreated control) 21 DAT for all plant species

Plant species	Rate - BAS 500 06 F [L/ha]					
	0.000	0.078	0.156	0.313	0.625	1.250
Carrot	100.0	100.9	101.4	101.5	98.7	102.5
Lettuce	100.0	102.1	101.8	102.5	102.1	101.6
Oilseed rape	100.0	103.0	100.2	101.9	105.0	103.2
Cabbage	100.0	96.5	96.1	99.4	95.7	99.1
Soybean	100.0	102.3	106.8	101.9	102.8	94.4
Tomato	100.0	101.7	101.2	102.7	102.6	100.2
Onion	100.0	102.6	99.1	102.8	102.4	103.7
Ryegrass	100.0	97.9	98.8	99.6	98.2	101.3
Oat	100.0	97.7	96.8	102.1	100.6	99.6
Corn	100.0	102.0	102.8	96.8	102.5	103.6

No treatment significantly different to the control - based on the plant length data

The applicant is convinced that since a safe use of pyraclostrobin 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 500 06 F.

Table 6.2.7-3: PEC-values* (g/ha) (drift)

distance (m)	%	drift test product (g/ha)
1	2	3
1	2.77	35.91
3	0.95	12.31
5	0.57	7.39
10	0.29	3.76
15	0.2	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 500 06 F of 1.037 g/cm³)		

* Predicted Environmental Concentration

IIIA1 6.2.8 Possible development of resistance or cross-resistance

BAS 500 06 F is a fungicide product containing 200 g/L of the active ingredient pyraclostrobin. It is intended for the control of various plant pathogenic fungi in cereals: rusts (*Puccinia* spp.), leaf scald (*Rhynchosporium secalis*), net blotch (*Pyrenophora teres*), tan spot *(Pyrenophora tritici-repentis),* Septoria leaf blotch and glume blotch (*Mycosphaerella graminicola / Septoria tritici* and *Phaeosphaeria nodorum / Septoria nodorum,* respectively).

Mode of action

Pyraclostrobin belongs to the QoI group of fungicides and the mode of action is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubihydroquinone to cytochrome *c* by means of a binding to the ubihydroquinone oxidation centre (Qo) of the cytochrome bc_1 complex (Complex III). This leads to a reduction of energy-rich ATP that is available to support a range of essential processes in the fungal cell.

Mechanism of resistance

There is evidence from studies with other inhibitors of the bc_1 complex on the mechanism of resistance with baker's yeast and several non-pathogenic fungi that various target site mutations can lead to amino acid substitutions within the cytochrome *b* protein and that these changes can prevent the binding of a range of mitochondrial electron transport inhibitors to the cytochrome *b* protein. For plant pathogenic fungi, there is evidence for different pathogens (FRAC 2011) that a mutation which leads to the substitution of glycine by an alanine residue at codon 143 is the main mechanism of resistance to QoIs.

It is interesting to note that some fungal species do not show this mutation even after several years of intensive control by QoI fungicides, e.g. different rust species (*Puccinia* spp., *Phakopsora pachyrhizi*), *Pyrenophora teres, Monilinia laxa, Monilinia fructicola, Guignardia bidwellii* and *Alternaria solani.* For these examples this is connected with the presence of an intron starting within or directly after the codon 143. It is assumed that a mutation from a glycine- to an alanine-codon would lead to an incorrect splicing and consequently to a non-functional cytochrome *b*.

A mutation at codon 129 which leads to the substitution of phenylalanine by leucine (F129L) is described for some species (e.g. *Pyrenophora teres*, and *Alternaria solani*). The mutation F129L results generally in low resistance factors and the field efficacy of pyraclostrobin is not significantly affected by this mutation (FRAC 2011).

Another mutation, the G137R is rarely found in *Pyrenophora teres* and *Pyrenophora tritici-repentis* and plays obviously only a minor role in the sensitivity response to QoI fungicides (FRAC 2011).

For the target pathogens in this resistance risk analysis an intron after the G143A is present in *Puccinia* spp. and *Pyrenophora teres* (= "intron pathogens").

Evidence of resistance

The evidence of resistance to QoIs comes from cases of field resistance shown by different plant pathogens. The pathogens have been isolated and found to be resistant to high concentrations of QoIs indicating a disruptive (single step) resistance (FRAC 2011).

The G143A mutation in the cytochrome *b* gene has been detected in several plant pathogenic fungi, including some of the target pathogens of this resistance risk analysis, but not in *Puccinia* species or *Pyrenophora teres. O*nly one single case is known for *Rhynchosporium secalis* from the applicant sensitivity monitoring in 2008. However, no resistant isolates were found in intensive monitorings in 2009, 2010 and 2011 in the area where the resistance was first detected or in any other European region.

The mutation F129L has been found in *Pyrenophora teres* and also – but rarely - the mutation G137R mutation.

An actual list of plant pathogenic fungi where QoI resistance has been detected can be found on the FRAC webpage. This list is updated yearly by the FRAC QoI Working Group (FRAC 2011).

Cross-resistance

Studies to date have shown that there is cross resistance between QoI fungicides (FRAC 2011), in particular when the mutation G143A in the cytochrome *b* gene is the cause of resistance. In case of F129L and G137R, differences between the QoI fungicides exist, while pyraclostrobin showed good performance in microtiter tests, greenhouse trials and field tests. There is so far no indication of cross resistance with pyraclostrobin and fungicides from outside the QoI group.

Baseline sensitivity / Sensitivity monitoring data

Extensive monitoring studies are running for some of the target pathogens of this resistance risk analysis. The monitoring results are summarised below and a short summary of the FRAC meeting 2011 is also given for each pathogen.

***Puccinia* spp.:** No reduced sensitivity has been detected for *Puccinia recondita* towards pyraclostrobin in any sample in the applicant monitoring studies since market introduction up to now (2011).

FRAC: FRAC reported in 2011 again no cases of QoI resistance for *Puccinia recondita.*
For *Puccinia hordei* some isolates with slightly higher EC_{50} values were detected in UK and northern France (mean factor 15). The practical relevance of these findings is not currently known. The mechanism is not known, no relevant mutations have been found (FRAC 2011).

Rhynchosporium secalis: Sensitivity monitoring (detection of G143A, F129L and G137R by pyrosequencing) on *Rhynchosporium secalis* did not show up any QoI-resistance in 2011 at any site analysed.
Some isolates were found in 2009 and 2010 with slightly higher ED_{50} values. As mechanism an increased expression of the enzyme alternative oxidase (AOX) was identified (unpublished internal data from the applicant). All tested isolates were not able to infect wheat plants under the tested greenhouse conditions which might indicate a fitness penalty. No isolates with higher ED_{50} values (outside baseline) were detected in 2011.

FRAC: No detection of the G143A mutation in any monitoring in 2011 is reported (FRAC 2011).

Pyrenophora teres: No G143A mutation in the cytochrome *b* was detected up to now in samples of *Pyrenophora teres*. The mutations F129L and/or G137R (G137R very seldom) could be found mainly in France, UK and Denmark, and not or less frequent in other European countries. The applicant method used was pyrosequencing of the cytochrome *b* gene.

FRAC: No G143A mutation was found in 2011. A list of countries with frequencies of the F129L mutation is given on the webpage (FRAC 2011).
Field and glasshouse studies showed that the F129L and G137R in *Pyrenophora teres* do not significantly affect the performance of pyraclostrobin.

Pyrenophora tritici repentis: The G143A, F129L and (seldom) the G137R mutation were detected in Europe in the last years. The most important mutation is the G143A. The mutation was detected in different countries and fields with different levels.

FRAC: FRAC states that resistance of *Pyrenophora tritici-repentis* to QoI fungicides has spread further during 2011 with variable levels in different European countries (FRAC 2011).
Field trials from the Danish Institute of Agricultural Science and from the applicant showed that pyraclostrobin may contribute to the control of *Pyrenophora tritici-repentis* even in fields where the G143A mutation is present at high frequency. Bas 500 06F (Platoon contains 250 g as/L pyraclostrobin) increases efficacy of the fungicide Osiris by ~20% in a Danish trial. A single treatment (field trail in Germany) was made at growth stage 37, evaluation 35 days later. Detection of mutations in the untreated control plot at July 4th provided 82% G143A and 12% F129L mutation in the population. Pyraclostrobin (BAS 500 F) increases efficacy of the fungicide Osiris by reducing diseased leaf area by 5% even under conditions with high frequency of G143A.

Mycosphaerella graminicola: High frequencies of G143A mutation have been detected in intensive wheat growing areas in north-western Europe since 2003. Resistance to QoIs spread in the last years to southern parts of Germany and France. The situation in Southern and Eastern European countries is much more favourable, QoI resistance is still absent or present at low levels.

FRAC: FRAC summarizes the status of QoI resistance based on all available data from the different members of the FRAC QoI Working Group in this way:

"The status at the end of the season 2011 is as follows:
France, Germany, The Netherlands, Poland, Lithuania: widespread resistance all over these countries at high levels.
Czech Republic: 2011 data show a generally stable situation with the majority of samples ranging from low to medium resistance levels. A few samples with high resistance levels were detected in parts of the country.
Italy, Belarus: heterogeneous populations from no to moderate levels of resistance.
Ukraine, Spain, Romania, Bulgaria, Russia and Slovakia: sampling in 2011 showed no to low levels of resistance." (FRAC 2011).

Phaeosphaeria nodorum: No data from 2011 is available. The last monitoring for this fungal species was carried out in 2010. Most samples were full sensitive; only 6 out of 30 samples contained the G143A mutation at low to high frequency.

FRAC: *Phaeosphaeria nodorum* is listed as a pathogen where the G143A mutation has been detected. A current overview of the distribution and frequency of resistance is not available on the FRAC webpage.

Use pattern

BAS 500 06 F is to be applied against cereal diseases between growth stages 25-69 with up to 1.25 l/ha and a maximum of two applications per season with a minimum spray interval of 21 days.

Resistance risk assessment of unrestricted use pattern

Product risk:
FRAC describes the QoI fungicides in general as high risk compounds (FRAC 2011).

Pathogen risk:
The pathogen risk is assessed as follows:

Medium risk pathogens: *Puccinia* spp., *Rhynchosporium secalis, Pyrenophora teres, Pyrenophora tritici-repentis, Mycosphaerella graminicola, Phaeosphaeria nodorum.*

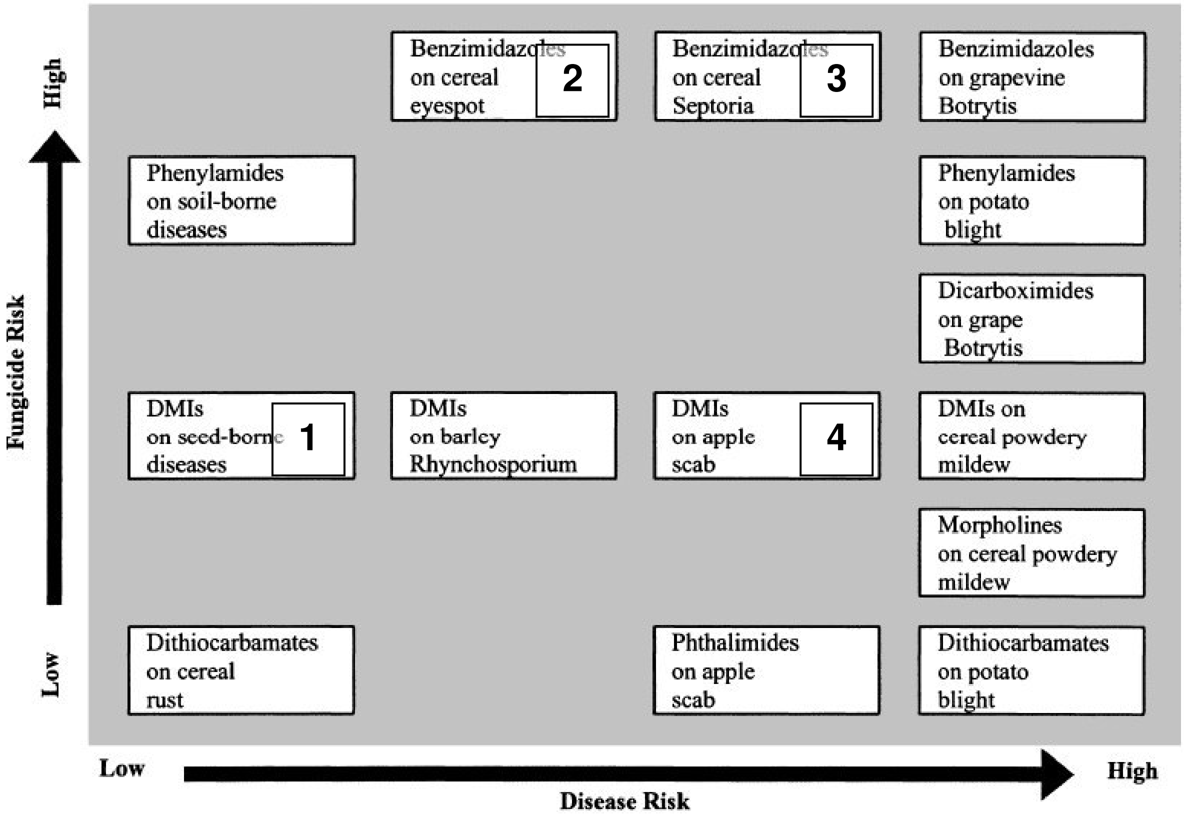
The combined pathogen and fungicide risk is assessed as follows:

Puccinia spp., *Rhynchosporium secalis, Pyrenophora teres, Pyrenophora tritici-repentis, Mycosphaerella graminicola, Phaeosphaeria nodorum* X pyraclostrobin: medium (score 6).

The combined resistance risk of pyraclostrobin and the different pathogens in the following scheme can be positioned as follows:

1: Pyraclostrobin on *Puccinia* spp. (= "intron pathogens" → reduction of fungicide risk in this case!)

2: Pyraclostrobin on *Rhynchosporium secalis*
3: Pyraclostrobin on *Pyrenophora tritici-repentis, Mycosphaerella graminicola, Phaeosphaeria nodorum*
4: Pyraclostrobin on *Pyrenophora teres* (= "intron pathogen" → reduction of fungicide risk in this case!)



Scheme for visualizing the inherent combined resistance risk. Resistance risk of QoIs is generally high, but lower for "intron pathogens".

Taken the classifications of both schemes together, it can be concluded that the combined resistance risk of pyraclostrobin and *Puccinia* spp. and *Pyrenophora teres* is rather low, for pyraclostrobin and *Rhynchosporium secalis* it is low to moderate and for pyraclostrobin and *Pyrenophora tritici-repentis*, *Mycosphaerella graminicola, Phaeosphaeria nodorum* is medium. This reflects also the findings of the sensitivity monitoring studies of the last years.

Management strategy

The objective of anti-resistance management strategies is the reduction of selection pressure to avoid or delay the occurrence of resistance or - once emerged - to keep resistance frequency at low and acceptable levels.

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 such as delayed sowing, ploughing, optimised seed rate, optimal fertilization, crop rotation).

Limiting the number of sprays is an important factor in delaying the build-up of resistant pathogen populations. The number of BAS 500 06 F applications will be restricted to two per crop cycle in cereals.

A further tool is the use of fungicide mixtures and is therefore considered in the recommendations for disease control.
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 500 06 F should be applied at early stages of disease development following the recommendations on the label and highly curative applications should be avoided.

The applicant is a member of the FRAC QoI Working Group and has participated in forming the guidelines for management strategies. The general recommendations for resistance management of QoIs are shown on the FRAC web page (FRAC 2011) and can be summarised as follows:

Guidelines for using QoI fungicides on cereal crops

- Apply QoI fungicides always in mixtures with non-cross resistant fungicides to control cereal pathogens. At the rate chosen the respective partner(s) on its/ their own has/ have to provide effective disease control. Refer to manufacturers recommendations for rates.
- Apply a maximum of 2 QoI fungicide containing sprays per cereal crop. Limiting the number of sprays is an important factor in delaying the build-up of resistant pathogen populations.
- Apply QoI fungicides according to manufacturer's recommendations for the target disease (or complex) at the specific crop growth stage indicated.
- Apply the QoI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of QoI fungicides.
- Split / reduced rate programmes, using repeated applications, which provide continuous selection pressure, accelerate the development of resistant populations and therefore must not be used.

Besides, according to the previous studies at resistance risk assessment and baseline of sensitivity, there are resistant isolates of *Pyrenophora teres* (PYRNTE) in barley and also in *Pyrenophora tritici-repentis* (PYRNTR) in wheat. Therefore in these cases, resistance management strategies should be strongly concerned.

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. 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 *Puccinia recondita, Rhynchosporium secalis, Pyrenophora teres, Pyrenophora tritici-repentis* and *Mycosphaerella graminicola* towards pyraclostrobin is monitored 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 pyraclostrobin 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.

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 500 06 F containing the active substance pyraclostrobin which is a strobilurin fungicide. It is formulated as an emulsifiable concentrate (EC) and contains 200 g/L pyraclostrobin. The proposed application rate is 1.25 L/ha which delivers 250 g/ha pyraclostrobin. BAS 500 06 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 1.25 L/ha of BAS 500 06 F provided the optimum overall level of activity and was effective against all the major cereal diseases for which activity of BAS 500 06 F is claimed. As a result, the proposed rate of 1.25 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 500 06 F, when applied at the proposed rate of 1.25 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 500 06 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 500 06 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.

IIIA1 6.7 List of test facilities including the corresponding certificates

Test Centre	**Officially recognized**
BASF spol. s.r.o., **Czech Republic**	**Yes**
Ing. Vaclav Marecek (Ing. Jitka Marečková since 7.2011) Krasne	**Yes**

Udoli, **Czech Republic**	
Vyzkumny ustav rostlinne vyroby (VURV), **Czech Republic**	**Yes**
Zemedelska zkusebni stanice KUJAVY, s.r.o., **Czech Republic**	**Yes**
Zemedelsky vyzkumny ustav Kromeriz, s.r.o., **Czech Republic**	**Yes**
ZEMSERVIS zkusebni stanice Domaninek, s.r.o., **Czech Republic**	**Yes**
Zkusebni stanice Kluky, spol. s r.o., **Czech Republic**	**Yes**
Zkusebni stanice Trutnov s.r.o, **Czech Republic**	**Yes**
BASF A/S, **Denmark**	**Yes**
Pesticide Testing: Diseases and Pests Department of Crop Protection Research Centre Flakkebjerg, **Denmark**	**Yes**
BASF AGRO, **France**	**Yes**
BASF, **Germany**	**Yes**
Regierungspräsidium Stuttgart - Pflanzenschutzdienst - Stuttgart, **Germany**	**Yes**
Ingenieurbüro für landwirtschaftliche Feldversuche, Schwarzach OT Düllstadt, **Germany**	**Yes**
Direktor der Landwirtschaftskammer Nordrhein- Westfalen als Landesbeauftragter - Pflanzenschutzdienst - Münster, **Germany**	**Yes**
Landwirtschaftskammer Niedersachsen - Pflanzenschutzamt - Oldenburg, **Germany**	**Yes**
Landwirtschaftskammer Niedersachsen - Pflanzenschutzamt - Hannover, **Germany**	**Yes**
Bayerische Landesanstalt für Landwirtschaft Institut für Pflanzenschutz, Freising, **Germany**	**Yes**
Agrartest Aarbergen-Panrod, **Germany**	**Yes**
Landesamt für Ernährung und Landwirtschaft Amtlicher Pflanzenschutzdienst, Frankfurt (Oder), **Germany**	**Yes**
Landwirtschaftskammer Schleswig-Holstein, -Abteilung Pflanzenbau und Pflanzenschutz - Fachbereich Pflanzenschutz, Rends-	**Yes**

burg, **Germany**	
Hochschule für Angewandte Wissenschaften - FH Kiel - Fachbereich Agrarwirtschaft – Osterrönfeld, **Germany**	**Yes**
U. A. S. Umwelt- und Agrarstudien GmbH Jena, **Germany**	**Yes**
Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei Mecklenburg-Vorpommern Rostock, **Germany**	**Yes**
Sächsisches Landesamt für Umwelt, Landwirtschaft und Geologie, Abteilung Pflanzliche Erzeugung, Referat Pflanzenschutz, Dresden, **Germany**	**Yes**
Eurofins-GAB GmbH Eutinger Str. 24, Niefern-Öschelbronn, **Germany**	**Yes**
Regierungspräsidium Gießen - Pflanzenschutzdienst -, Wetzlar, **Germany**	**Yes**
Thüringer Landesanstalt für Landwirtschaft – Referat Pflanzenschutz –, Erfurt-Kühnhausen, **Germany**	**Yes**
Field Research Support - Königs und Zöllner GbR, Wunstorf, **Germany**	**Yes**
BASF, Hungary	**Yes**
Agricultural Office of County Csongrad, **Hungary**	**Yes**
Agricultural Office of County Komarom, **Hungary**	**Yes**
Crop Plot Trials, **Ireland**	**Yes**
Agrostat Sp. z o.o., **Poland**	**Yes**
BASF**, Poland**	**Yes**
Institute of Plant Protection –National Research Institute Poznań, **Poland**	**Yes**
Plant Protection Institute Sosnicowice Branch, **Poland**	**Yes**
Gemerprodukt Valice, **Slovakia**	**Yes**
Agrisearch UK limited **United Kingdom**	**Yes**

BASF plc, **United Kingdom**	**Yes**
Eurofins Agroscience Serv, **United Kingdom**	**Yes**

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

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
Document J	Nieslony C.	Registration report - Part C Confidential information BAS 500 06 F 200g/L Pyraclostrobin - All Zones - Core assessment-	2012	269427
Document J	Nieslony C.	Registration report - Part C Confidential information BAS 500 06 F 200g/L Pyraclostrobin - All Zones - Core assessment-	2012	269428
KIIIA1 4.1.2	Schreiner, B.	EU performance tests of BAS 500 06 F (Standard-Coex-Bottle, 1 L, Spec.-No. 7755108)	2005	2005/1025057 269429
KIIIA1 4.1.3	Kroehl, T.	Shelf life at 23°C in original container of the formulation BAS 500 06 F, 24 month storage, analytical results and physical properties	2006	2006/1019717 269430
KIIIA1 4.2.1	Nolte M.	BAS 500 06 F: Effectiveness of procedures for cleaning application equipment and protective clothing	2010	2010/1048392 269431
KIIIA1 4.2.2	Nolte, M.	BAS 500 06 F: Effectiveness of procedures for cleaning application equipment and protective clothing	2010	2010/1048392 269432
KIIIA1 9.4.1	Eickler B.	Predicted environmental concentrations of BAS 500 F - Pyraclostrobin and its metabolites in soil, groundwater, surface water and sediment following twofold application of 350 g a.s. ha-1 to cereals	2012	2012/1022008 269433
KIIIA1 9.4.1	Eickler B.	Predicted environmental concentrations of BAS 500 F - Pyraclostrobin and its metabolites in soil, groundwater, surface water and sediment following twofold application of 350 g a.s. ha-1 to cereals	2012	2012/1022008 269434
KIIIA1 9.4.1	Stein C.	Predicted environmental concentrations in soil, groundwater and surface water of BAS 500 F - Pyraclostrobin following application to cereals in Germany	2012	2012/1022012 269435
KIIIA1 9.4.1	Stein C.	Predicted environmental concentrations in soil, groundwater and surface water of BAS 500 F - Pyraclostrobin following application to cereals in Germany	2012	2012/1022012 269436
KIIIA1 10.5.1	Sipos K.	Effect of BAS 500 06 F on the predatory mite (Typhlodromus pyri) in a laboratory trial	2007	2007/1035599 269439
KIIIA1 10.5.1	Sipos K.	Effect of BAS 500 06 F on the parasitic wasp (Aphidius rhopalosiphi) in a laboratory trial	2007	2007/1035600 269440

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.5.1	Sipos K.	Amendment to the final report: Effect of BAS 500 06 F on the parasitic wasp (Aphidius rhopalosiphi) in a laboratory trial	2007	2007/1050 841 ! 2007/1035 600 269441
KIIIA1 10.5.2	Vaughan R.	A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae)	2008	2008/1010 712 269442
KIIIA1 10.5.2	Stevens J.	A rate-response extended laboratory test to determine the effects of BAS 500 06 F on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae)	2008	2008/1010 713 269443
KIIIA1 10.5.2	Roehlig U.	Effects of BAS 500 06 F on the green lacewing Chrysoperla carnea STEPH. under extended laboratory conditions - Rate-response test	2008	2008/1032 666 269445
KIIIA1 10.5.2	Schmitzer S.	Effects of BAS 500 06 F on the reproduction of rove beetles (Aleochara bilineata) - Extended laboratory study	2008	2008/1010 700 269446
KIIIA1 10.5.2	Roehlig U.	Effects of BAS 500 06 F on the green lacewing Chrysoperla carnea STEPH. in an extended laboratory test (under semi-field conditions aged residues on bean plants)	2008	2008/1042 190 269447
KIIIA1 10.6.2	Fleischer G.	Effect of BAS 500 06 F on the mortality of the earthworm Eisena fetida	2004	2004/1004 367 269448
KIIIA1 10.6.3	Luehrs U.	Effects of BAS 500 06 F on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat	2008	2008/1036 409 269449
KIIIA1 10.6.4	Luehrs U.	Field study to evaluate the effects of BAS 500 06 F on earthworms	2010	2010/1000 056 269450
KIIIA1 10.6.6	Friedrich S.	Effects of BAS 500 06 F on the reproduction of the collembolans Folsomia candida in artificial soil with 5% peat	2008	2008/1037 495 269451
KIIIA1 10.6.7	Luehrs U.	Effects of BAS 500 06 F on the breakdown of organic matter in litter bags in the field	2010	2010/1000 081 269452
KIIIA1 10.7.1	Krieg W.	Effects of BAS 500 01 F on soil respiration	1998	1998/1125 3 269453
KIIIA1 10.7.1	Krieg W.	Effects of BAS 500 01 F on the nitrogen turnover in soil	1998	1998/1125 9 269454

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.8.1.2	Oberwalder C.	BAS 500 01 F: Effects on non-target plants in the greenhouse - A limit test	2000	2000/1011 456 269455
KIIIA1 6	Prochnow, J.	Registration report - Biological Assessment Dossier - BAS 500 06 F Core C - ZRMS: Germany	2012	2012/1071 950 269456
KIIIA1 6	Prochnow, J.	Attachment: Registration report - Biological Assessment Dossier - BAS 500 06 F Core C - ZRMS: Germany	2012	2012/1071 950 269457
KIIIA1 6	Nieslony, C.	BAS 500 06 F - Comparison in composition with preceding formulation	2012	2012/1015 459 269458
KIIIA1 6	Schulze, L.	BAS 500 06 F - Synopsis of bridging data in wheat - OECD Annex Point 6	2011	2011/1284 031 269459
KIIIA1 6	Schulze, L.	BAS 500 06 F - Synopsis of bridging data in barley - OECD Annex Point III 6	2011	2011/1284 032 269460
KIIIA1 6	Schulze, L.	BAS 500 06 F - Bridging data in the auhtorized use: Yellow rust in wheat - OECD Annex Point III 6	2011	2011/1284 033 269461
KIIIA1 6	Schulze, L.	BAS 500 06 F - Bridging data in the authorized use: Non-parasitic leaf spot in barley - OECD Annex Point III 6	2011	2011/1284 034 269462
KIIIA1 6.1.2	Strobel, D.	Influence of dose rate reduction of BAS 500 06 F against cereal diseases (Minimum effective dose)	2012	2011/1178 332 269463
KIIIA1 6.1.2	Poppe, A.	BAS 500 06 F - Efficacy data for the minimum effective dose test (individual trial reports) - OECD Annex Point III 6.1.2 (minimum effective dose tests)	2012	2011/1285 011 269464
KIIIA1 6.1.3	Born, K.	SSC - Site similarity certificate comparing cereal growing regions Zachodniopomorskie in Poland (POL) and Kralovehradecky in Czech Republic (CZE)	2012	2011/1285 015 269465
KIIIA1 6.1.3	Born, K.	SSC - Site similarity certificate comparing cereal growing regions Jihomoravsky in the Czech Republic (CZE) and Csongrad in Hungary (HUN)	2012	2011/1285 016 269466
KIIIA1 6.1.3	Prochnow, J.	BAS 500 06 F - Reference products - OECD Annex Point III 6.1.3, 6.1.4, 6.2.1	2011	2011/1285 008 269467
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for authorized use: Brown rust in wheat - OECD Annex Point III 6.1.3, III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 039 269468

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 040 269469
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 041 269470
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Tan spot in wheat - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 042 269471
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 043 269472
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Net blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 044 269473
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 045 269474
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 046 269475
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicty)	2011	2011/1284 047 269476
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 048 269477
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 049 269478
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in triticale - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 050 269479

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Synopsis of efficacy data in wheat - OECD Annex Point III 6.1.3	2011	2011/1284 035 269480
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Synopsis of efficacy data in barley - OECD Annex Point III 6.1.3	2011	2011/1284 036 269481
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Synopsis of efficacy data in rye - OECD Annex Point III 6.1.3	2011	2011/1284 037 269482
KIIIA1 6.1.3	Schulze, L.	BAS 500 06 F - Synopsis of efficacy data in triticale - OECD Annex Point III 6.1.3	2011	2011/1284 038 269483
KIIIA1 6.1.4.1	Prochnow, J.	BAS 500 06 F - Reference products - OECD Annex Point III 6.1.3, 6.1.4, 6.2.1	2011	2011/1285 008 269484
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for authorized use: Brown rust in wheat - OECD Annex Point III 6.1.3, III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 039 269485
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 040 269487
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 041 269488
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Tan spot in wheat - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 042 269489
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 043 269490
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Net blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 044 269491
KIIIA1 6.1.4.1	Schulze L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 045 269492

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 046 269493
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicty)	2011	2011/1284 047 269494
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 048 269495
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 049 269496
KIIIA1 6.1.4.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in triticale - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 050 269497
KIIIA1 6.1.4.2	Anonymous	Etudes effets non intentionnels des produits phytopharmaceutiques sur l elaboration et la qualite du malt et de la biere - Demande d equivalence des etudes Comet pour inscription F 500 06 fongicide bles et orges	2007	2011/1285 012 269499
KIIIA1 6.1.4.3	Prochnow, J.	BAS 500 06 F - Reference products - OECD Annex Point III 6.1.3, 6.1.4, 6.2.1	2011	2011/1285 008 269500
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for authorized use: Brown rust in wheat - OECD Annex Point III 6.1.3, III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 039 269501
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 040 269502
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 041 269503
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Tan spot in wheat - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 042 269504

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 043 269506
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Net blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 044 269507
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 045 269508
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 046 269509
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicty)	2011	2011/1284 047 269510
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 048 269511
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 049 269512
KIIIA1 6.1.4.3	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in triticale - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 050 269513
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for authorized use: Brown rust in wheat - OECD Annex Point III 6.1.3, III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 039 269514
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 040 269515
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Yellow rust in wheat - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 041 269516

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Tan spot in wheat - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 042 269517
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 043 269518
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Net blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 044 269519
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in barley - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 045 269520
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - With GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 046 269521
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Non-parasitic leaf spot in barley - Without GEP - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicty)	2011	2011/1284 047 269522
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 048 269523
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Leaf blotch in rye - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 049 269525
KIIIA1 6.2.1	Schulze, L.	BAS 500 06 F - Efficacy data for the authorized use: Brown rust in triticale - OECD Annex Point III 6.1.3 (efficacy), III 6.1.4 (quality, yield), III 6.2.1 (phytotoxicity)	2011	2011/1284 050 269526
KIIIA1 6.2.1	Strobel, D.	Yield effect of BAS 500 06 F in the absence of disease	2012	2011/1285 013 269527
KIIIA1 6.2.5	Merk, M.	Germination trials with harvested grains from winter wheat and winter barley treated with BAS 500 06 F	2006	2006/1049 133 269529
KIIIA1 6.2.5	Saur, R.	Germination trials with harvested grains from wheat, barley and rye treated with BAS 500 01 F	2000	2000/1023 871 269532

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6.2.6	Wuts, M., Dunker, S., Hoepke, C.	Cultivation of different crops in BAS 500 06 F treated soil	2009	2009/1090821 269535
KIIIA1 6.2.7	Oberwalder, C.	BAS 500 01 F: Effects on non-target plants in the greenhouse - A limit test	2000	2000/1011456 269536
KIIIA1 6.2.8	Stammler, G.	BAS 500 06 F - Resistance risk analysis	2012	2012/1000561 269537
KIIIA1 6.7	Prochnow, J.	BAS 500 06 F - Information on the test facilities and the corresponding certificates - OECD Annex Points III 6.7	2011	2011/1285009 269538
Document LIIIA1	Anonymous	BAS 500 06 F - Document L-III Core C - Reference list by Annex point	2012	2012/1047753 269539
Document LIIIA1	Anonymous	Attachment: BAS 500 06 F Core C Ref List by Annexpoint	2012	2012/1047753 269540
MIIIA1 Sec 1	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 1 ¿ Identity, physical and chemical properties, other information - Core assessment	2012	2012/1022061 269541
MIIIA1 Sec 1	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 1 ¿ Identity, physical and chemical properties, other information - Core assessment	2012	2012/1022061 269542
MIIIA1 Sec 5	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE- Section 5 - Environmental fate - Core assessment	2012	2012/1022065 269543
MIIIA1 Sec 5	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE- Section 5 - Environmental fate - Core assessment	2012	2012/1022065 269544
MIIIA1 Sec 5	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 5 - Environmental fate - National addendum	2012	2012/1047749 269545
MIIIA1 Sec 5	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 5 - Environmental fate - National addendum	2012	2012/1047749 269546
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 6 ¿ Ecotoxicology - Core assessment	2012	2012/1022066 269547
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 6 ¿ Ecotoxicology - Core assessment	2012	2012/1022066 269548

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 6 - Ecotoxicology - National addendum	2012	2012/1047 750 269550
MIIIA1 Sec 6	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 6 - Ecotoxicology - National addendum	2012	2012/1047 750 269552
MIIIA1 Sec 7	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 7 ¿ Efficacy Data and Information - Core assessment	2012	2012/1022 067 269553
MIIIA1 Sec 7	BASF	Draft Registration Report - Part B - BAS 500 06 F - DE - Section 7 ¿ Efficacy Data and Information - Core assessment	2012	2012/1022 067 269554
Document N	BASF	Draft Registration Report - Part A - BAS 500 06 F ¿ DE ¿ Risk Management ¿ National Addendum	2012	2012/1047 752 269555
Document N	BASF	Draft Registration Report - Part A - BAS 500 06 F ¿ DE ¿ Risk Management ¿ National Addendum	2012	2012/1047 752 269556
Anlagenverzeichnis	Gall A.	Attachment: BAS 500 06 F_Gesamtanlagenverzeichnis	2012	BAS 500 06 F Gesamta 269557
Anlagenverzeichnis	Gall A.	Attachment: BAS 500 06 F_Gesamtanlagenverzeichnis	2012	BAS 500 06 F Gesamta 269558
Document LIIA	Gall A.	Pyraclostrobin Referenzliste J-II OECD nach Annexpunkten	2008	Pyraclostrobin Refer 269559
Document LIIA	Gall A.	Attachment: Pyraclostrobin_Referenzliste_J II_OECD_Caddy_vertr	2008	Pyraclostrobin Refer 269560
Document LIIA	Gall A.	Pyraclostrobin Referenzliste L-II OECD nach Annexpunkten	2012	Pyraclostrobin Refer 269561
Document LIIA	Gall A.	Attachment: Pyraclostrobin_Referenzliste_LII_OECD_Caddy	2012	Pyraclostrobin Refer 269562
KIIIA1 3.9	Prochnow J.	BAS 500 06 F - Gebrauchsanleitung -	2011	2011/1285 014 269563

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 3.9	Prochnow J.	BAS 500 06 F - Gebrauchsanleitung -	2011	2011/1285014 269564
Document O	Gall A.	BAS 500 06 F - Form for use in checking zonal applications for completeness	2012	2012/1137262 269565
Document O	Gall A.	Attachment: BAS 500 06 F_DE_Form_Checking Completeness_final	2012	2012/1137262 269566
Document N	Anonymous	66892 GAP-Tabelle	2012	269567
Document N	Anonymous	BAS 500 06 F_dRR Part B Section 7_GAP tables	2012	269568
KIIA 6.3	Heck, W., Benz, A., Mackenroth, C.	Determination of the residue variability of BAS 500 F and KIF-230 in grapes after treatment with BAS 525 00 F under field conditions in Germany and Spain, 2000	2002	2002/1008790 269569
KIIA 6.3	Benz, A., Bross, M.	Preliminary summary of the variability data in grapes	2002	2002/1007092 269570
KIIA 6.3	Wofford, J.T., Abdel-Baky, S., Riley, M. E.	Magnitude of BAS 500 F residues in bananas for import tolerance	1999	1999/5095 269571
KIIA 6.3	Regenstein, H.	Statement - BAS 500 F: Residues in bananas below LOD	2000	2000/1004148 269572
KIIA 6.3	Beck, J.	Study on the residue behavior of BAS 500 F, epoxiconazole and kresoxim-methyl in cereals after treatment with BAS 500 01 F, BAS 512 00 F and BAS 513 00 F under field conditions in BE, FR, DE, UK, ES, SE and NL, 1998	1999	1999/11509 269573
KIIA 6.3	Beck, J., Benz, A., Mackenroth, C.	Study on the residue behavior of BAS 500 F in cereals after treatment with BAS 500 01 F under field conditions in Denmark, France, Germany, Great Britain, Spain and Sweden, 1999	1999	1999/11824 269574
KIIA 6.3	Meumann, H., Benz, A., Mackenroth, C.	Evaluation of the residue behavior of BAS 500 F after application of BAS 500 01 F in cereals under field conditions in Germany, France and Sweden, 1998	1999	1999/11825 269575
KIIA 6.3	Perny, A.	Residue study in barley following treatments with the preparation BAS 500 01 F under field conditions in southern France in 2001	2002	2002/1004077 269576

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 6	Anonymous	BAS 500 06 F_dRR Part B Section 7_GAP tables	2012	269577
KIIIA1 6	Anonymous	66892 GAP-Tabelle	2012	269578
KIIA 6.3	Weber, S., Blumenstiel , S.	Investigation of residue behaviour of Signum (BAS 516 00 F, BAS 516 07 F) in raspberries, parsley, cabbage, kohlrabi, radish and curly kale	2007	2207/1045 125 ! 276298 269579
KIIA 6.3	Anonymous	Residue behaviour af Boscalid and Pyraclorstrobin in/on celery and celeriac after outdoor application of Signum, BAS 516 F (WG 33,4, 267 g/kg Boscalid, 67 g/kg Pyraclostrobin) in Germany, 2007	2009	2008/1090 964 269581
KIIA 6.3	Weber, S., Blumenstiel , S.	Report Amendment no.1: Investigation of the residue behaviour of Signum (BAS 516 00 F, BAS 516 07 F) in raspberries, parsley, cabbage, kohlrabi, radish and curly kale	2008	2008/1002 718 ! 276298 269582
KIIA 6.3	Anonymous	Residue behaviour of Boscalid and Pyraclostrobin in/on black currants after indoor application and in/on raspberries after outdoor application of Signum, BAS 516 00 F (WG 33.4. 267 g/kg Boscalid, 67 g/kg Pyraclostrobin) in Germany, 2007	2008	2008/1090 416 269583
KIIA 8.9.1	Krieg, W.	Effect of BAS 500 F on the mortality of the earthworm Eisenia foetida	1999	1999/1070 8 ! 35801 269585
KIIA 8.9.1	Krieg, W.	Effect of BF 500-6 on the mortality of the earthworm Eisenia foetida	1999	1999/1130 8 ! 35987 269586
KIIA 8.9.1	Krieg, W.	Effect of BF 500-7 on the mortality of the earthworm Eisenia foetida	1999	1999/1130 9 ! 54484 269587
KIIA 8.9.1	Ebert, D.	Investigations on the release of soil-bound residues of 14C-BAS 500 F by earthworms	1999	1999/1128 9 ! 53058 269588
KIIA 8.10.1	Krieg, W.	Effect of BF 500-6 and BF 500-7 on soil respiration	1999	1999/1112 0 ! 54483 269589
KIIA 8.10.1	Krieg, W.	Effects of BF 500-6 and BF 500-7 on the nitrogen turnover in soil	1999	1999/1131 1 ! 54482 269590
KIIA 6.3	Anonymous	Residue behaviour of Boscalid and Pyraclostrobin in/on black currants after indoor application and in/on raspberries after outdoor application of Signum, BAS 516 00 F (WG 33,4, 267 g/kg Boscalid, 67 g/kg Pyraclostrobin) in Germany, 2008	2009	2009/1086 168 269591

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIA 6.3	Schulz, H.	Study on the residue behaviour of BAS 500 F and BAS 510 F in strawberries after application of BAS 516 00 F under Glasshouse conditions in Italy, France (S) and Spain, 2003	2004	2004/1015 928 269592
KIIA 6.3	Johnston, R.L.	Study on the residue behaviour of BAS 510 F and BAS 500 F in strawberries (glasshouse) after application of BAS 516 00 F under glasshouse conditions in France (S), Spain and Italy, 2004	2005	2004/7007 479 269593
KIIA 6.3	Anonymous	Residue behaviour of Boscalid and Pyraclostrobin in/on head cabbage after post harvest application of Signum, BAS 516 00 F (WG 33,4, 267 g/kg Boscalid, 67 g/kg Pyraclostrobin) in Germany, 2007	2008	2008/1090 584 269594
KIIA 6.3	Anonymous	Residue behaviour of Pyraclostrobin and Boscalid in/on parsley indoor after application of Signum (WG 33.4) in Germany, 2008	2009	2009/1070 977 269595
Document J	Braun, J.	Pyraclostrobin- Document J M II- Summary and evaluation- Confidential information- 2008-	2008	2008/1014 239 269596
KIIA 2.8.1	Tuerk W.	Determination of the octanol/water-partition coefficient of Reg.No. 304 428 by HPLC	1996	1996/1038 3 269597
KIIA 2.8.2	Tuerk W.	Determination of the octanol/water-partition coefficient of Reg.No. 304 428 by HPLC	1996	1996/1038 3 269598
KIIIA1 3.9	Prochnow, J.	vorläufige Gebrauchsanleitung	2012	269599
MIIIA1 Sec 7	Anonymous	NL_2013_1125358_BAS 500 06 F_ RR_Part B_Section_7.	2013	309120
KIIIA1 10.8.1	Strömel, C., Friedemann, A., Teresiak, H.	Effect of BAS 500 06 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions	2013	2012/1115 894 ! AC/BASF/12/11 309121
KIIIA1 6.2.6	Strömel, C., Friede-mann, A., Teresiak, H.	Effect of BAS 500 06 F on seeding emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions	2012	AC/BASF/12/13 ! 2012/1115 895 309122
KIIIA1 10.7.1	Schulz, L.	Effects of BAS 500 06 F on the activity of soil micro-flora (Nitrogen transformation test)	2012	2012/1129 443 ! 12 10 48 052 N 309123

Annex Point	Author	Title	Year	Ref. App. Ref. JKI
KIIIA1 10.8.1	Strömel, C., Friede-mann, A., Teresiak, H.	Effect of BAS 500 06 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions	2012	AC/BASF/12/13 ! 2012/1115895 309124

Appendix 2a: GAP table for Germany

GAP rev. , date: 2012-06-25

PPP (product name/code)	**BAS 500 06 F**	**Formulation type:**	**EC**
active substance	**Pyraclostrobin**	**Conc. of as :**	**0.2 kg/L**
Applicant:	**BASF SE**	**professional use**	☒
Zone(s):	**central**	**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		
1	DE	Wheat TRZSS	F	brown leaf rust of cereals *Puccinia recondita* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
2	DE	Wheat TRZSS	F	stripe rust of grasses *Puccinia striiformis* PUCCST	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

3	DE	Wheat TRZSS	F	tan spot of cereals *Drechslera tritici-repentis* PYRNTR	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
4	DE	Barley HORVX	F	net blotch *Pyrenophora teres* PYRNTE	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
5	DE	Barley HORVX	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
6	DE	Barley HORVX	F	brown rust of barley *Puccinia hordei* PUCCHD	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
7	DE	Barley HORVX	F	decrease of non-parasitic leaf spots YBFMI* no EPPO code	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 32 - 61	a) 1 b) 2	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
8	DE	Rye SECCE	F	leaf blotch of cereals *Rhynchosporium secalis* RHYNSE	spraying	from spring at beginning of infestation and/or when first symp-toms become visible BBCH 25 - 61	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

9	DE	Rye SECCE	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)
10	DE	Triticale TTLSS	F	brown leaf rust of cereals *Puccinia recondite* PUCCRE	spraying	from spring at beginning of infestation and/or when first symptoms become visible BBCH 25 - 69	a) 2 b) 2 (21 days)	a) 1.25 L/ha b) 2.5 L/ha	a) 0.25 kg /ha b) 0.5 kg /ha	100-400	F*	* F – the PHI is covered by the time remaining between application and harvest (PHI of 35 days is used for the risk assessments)

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

Appendix 2b: GAP table for cMS

GAP rev. 1, date: 2013-07-09

PPP (product name/code) **BAS 500 06 F**
active substance **Pyraclostrobin**

Formulation type: **EC**
Conc. of as : **0.2 kg/L**

Applicant: **BASF SE**
Zone(s): **central**

professional use ☒
non professional use ☐

Verified by MS: yes

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Cereals	**Central zone**		F	*As detailed below*	EC	0.2	SP	25-69	2	21 days	0.0625 – 0.25	100-400	0.25	0.8-1.25*	35	*As discussed during the pre-submission meeting with the German zRMS, a range of 0.8-1.25 L product/ha will be applied for in Eastern European countries

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Wheat (spring, winter, durum, spelt)	**AT**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-61 (*P. recondita*: 25-69)	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Barley (spring, winter)	**AT**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Rye	**AT**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**AT**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**BE, LU**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**BE, LU**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Rye	**BE, LU**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**BE, LU**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Oat	**BE, LU**		F	*Puccinia coronata*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**NL**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**NL**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* *Sunburn injury*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Rye	**NL**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**NL**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**CZ**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Barley (spring, winter)	**CZ**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Rye	**CZ**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Triticale	**CZ**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	
Wheat (spring, winter, durum, spelt)	**SK**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Barley (spring, winter)	**SK**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**SK**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**SK**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Wheat (spring, winter, durum, spelt)	**SI**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Barley (spring, winter)	**SI**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**SI**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**SI**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**RO**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Formulation**		**Application**				**Application rate per treatment**				**PHI** (days) (l)	**Remarks:** (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Barley (spring, winter)	**RO**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**RO**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**RO**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**HU**		F	*Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Barley (spring, winter)	**HU**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Rye	**HU**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**HU**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Wheat (spring, winter, durum, spelt)	**PL**		F	*Septoria tritici* *Puccinia striiformis* *Puccinia recondita* *Pyrenophora tritici-repentis*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Barley (spring, winter)	**PL**		F	*Puccinia hordei* *Pyrenophora teres* *Rhyncho-sporium secalis* Sunburn injury	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Rye	**PL**		F	*Rhyncho-sporium secalis* *Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	
Triticale	**PL**		F	*Puccinia recondita*	EC	0,2	SP	25-69	2	21 days	0,04-0,25	100-400	0,16-0,25	0,8-1,25	35	

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as kg/L (i)	Method Kind (f-h)	Growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	Product (L/ha) min max		
Wheat (spring, winter)	**UK, IE**		F	*P. recondita* *P. striiformis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Barley (spring, winter)	**UK, IE**		F	*P. recondita* *P. striiformis* *P. teres,* *R. secalis*	EC	0,2	SP	25-59	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Oat (winter, spring)	**UK, IE**		F	*P. coronata*	EC	0,2	SP	25-59	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Triticale	**IE**		F	*P. recondita* *P. striiformis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered
Rye	**IE**		F	*P. recondita* *P. striiformis* *R. secalis*	EC	0,2	SP	25-69	2	21 days	0,0625 – 0,25	100-400	0,25	1,25	35	already registered

(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 plant - 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) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions