REGISTRATION REPORT
Part A

Risk Management

Product code: BAS 812 00 H

Product name: Biathlon 4D (Biathlon Super)

Active Substances: Tritosulfuron 714 g/kg
Florasulam 54 g/kg

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ASSESSMENT

Applicant: BASF

Date: 24/06/2013

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of BAS 812 00 H (Biathlon 4D) containing florasulam and tritosulfuron in Germany. This evaluation is required subsequent to the inclusion of florasulam and tritosulfuron on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in BAS 812 00 H Registration Report, Part B Sections 1-8 and Part C from Austria 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 812 00 H (Biathlon 4D) where that data has not been considered in the EU review. Otherwise assessments for the safe use of BAS 812 00 H (Biathlon 4D) have been made using endpoints agreed in the EU review of florasulam and tritosulfuron.

This document describes the specific conditions of use and labelling required for Germany registration of BAS 812 00 H (Biathlon 4D).

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

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions 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 of this document contains copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

1 Details of the application

1.1 Application background

This application was submitted by BASF on 15 December 2011.

The application was for approval of BAS 812 00 H (Biathlon 4D), water dispersible granules containing 54 g/kg Florasulam and 714 g/kg Tritosulfuron for the control of dicotyledonous weeds in winter cereals and summer cereals.

1.2 Annex I inclusion

Tritosulfuron was included on Annex I of Directive 91/414/EEC on 1 Dec. 2008 under Inclusion Directive 2008/70/EC.
Florasulam was included on Annex I of Directive 91/414/EEC 1 Oct. 2002 under Inclusion Directive 2002/64/EC. The expiry date was extended by Directive 2010/77/EU.

The Annex I Inclusion Directive for tritosulfuron (2008/70/EC) and for florasulam (2002/64/EC) provide 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 active substances tritosulfuron and florasulam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 May 2008 and on 18 September 2002, shall be taken into account in this overall assessment:

for tritosulfuron:
Member states must pay particular attention to:
- the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,
- the protection of aquatic organisms,
- the protection of small mammals.

Conditions of authorisation must include risk-mitigation measures, where appropriate.

and for florasulam
Member states:
- should pay particular attention to the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of authorisation must include risk-mitigation measures, where appropriate.

These concerns have been addressed within the current submission.

1.3 Regulatory approach

To obtain approval the product Biathlon 4D 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 order to allow the first approval of this product in Germany in accordance with the above.

1.4 Data protection claims

Data protection is claimed for studies submitted with this application. For details on data protection claims, please refer to the reference list in Appendix 1 in each section of the Registration Report.

1.5 Letters of Access

Where third party data have been used information is given in the dossier. Letters of Access for the active substance florasulam was submitted by Dow Agrosciences..

2 Details of the authorisation

2.1 Product identity

Product Name	Biathlon 4D (BAS 812 00 H)
Authorization Number (for re-registration)	007555-00
Function	herbicide
Applicant	BASF
Composition	714 g/kg Tritosulfuron 54 g/kg Florasulam
Formulation type	Water dispersible granules [WG]
Packaging	0.15-2.2 L HDPE bottle; 3 -10 L HDPE can

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/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 (i.e. in the 18th ATP published as Directive 93/21/EEC):

Symbol(s)/Indication(s) of danger:	
N	Dangerous for the environment
Xn	Harmful
Risk phrases:	
RA029	Contains tritosulfurone. May produce allergic reactions.
R22	Harmful if swallowed
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety phrases:	
S36/37	Wear suitable protective clothing and gloves.
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
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: (No Labelling-Requirement!)	
Hazard pictograms:	
GHS 09	
GHS 07	
Signal words:	
Warning	
Hazard statements:	
H302	Harmful if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
Special rule for labelling of PPP:	
EUH208-0041	Contains tritosulfuron. May produce allergic reaction
EUH401	To avoid risks to man and the environment, comply with the instructions for use

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

Risk Phrases: None.
Safety Phrases: None.

2.2.4 Other phrases

Restrictions linked to the PPP

Labelling phrases for 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.
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.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.

Labelling phrases for sustainable use/IPM

WMB	Mode of Action (HRAC-Group): B
WH9161	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.
WP710	Damage is possible to replanted dicotyledonous intermediate crops and winter rape.
WW742	The product has no sustainable effect in perennial weeds.
WH960	The risk of replanting has to be indicated on the package and in the instructions of use. Particularly, the endangered succeeding crops have to be declared and measures for a risk management have to be described.
WH951	The risk of resistance has to be indicated on the package and in the instructions for use. Particularly measures for an appropriate risk management have to be declared.
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)
NN1001	The product is classified as non-harmful for populations of relevant beneficial insects.
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

Labelling phrases for Ecosystem protection

NW262	The product is toxic for algae.
NW265	The product is toxic for higher aquatic plants.
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

Specific restrictions linked to the intended uses

NT103	In a strip at least 20 m wide which is adjacent to other areas, the product must be applied using loss reducing equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended, and be registered in at least drift reducing class 90 % (except agriculturally or horticulturally used areas, roads, paths and public places). Loss reducing equipment is not required if the product is applied with portable plant protection equipment or if adjacent areas (field boundaries, hedges, groups of woody plants) are less than 3 m wide or the product is applied in an area which has been declared by the Biologische Bundesanstalt in the "Index of regional proportions of ecotones" of 7 February 2002 (Federal Gazette no. 70 a of 13 April 2002), as amended, as agrarian landscape with a sufficient proportion of natural and semi-natural structures.
NW609-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product mustbe applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss

	Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, 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. Violations may be punished by fines of up to 50 000 EUR. 5 m

2.3 Product uses

GAP rev. (No), date: 2013-06-11

PPP (product name/code):	**Biathlon Super (007555-00)**	**Formulation type:**	**WG**
active substance 1:	**Tritosulfuron**	**Conc. of as 1:**	**714 g/kg**
active substance 2:	**Florasulam**	**Conc. of as 2:**	**54 g/kg**

Applicant:	**BASF SE**	**professional use**	☒
Zone(s):	**central EU**	**non professional use**	☐

Verified by MS: yes

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	Kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	winter soft wheat TRZAW, winter durum wheat TRZDW, spelt TRZSP, winter barley HORVW, winter rye SECCW, winter triticale TTLWI,	F	Annual dicotyledonous weeds TTTDS, Cornbine CONAR, creeping thistle CIRAR	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	Tritosulfuron a) 49.98 b) 49.98 Florasulam a) 3.78 b) 3.78	100 - 400	XF	NT103 NW609-1

		winter oats AVESW										
002	DE	winter soft wheat TRZAW, winter durum wheat TRZDW, winter barley HORVW, winter rye SECCW, winter triticale TTLWI	F	Annual dicotyledonous weeds TTTDS, Cornbine CONAR, creeping thistle CIRAR	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	Tritosulfuron a) 49.98 b) 49.98 Florasulam a) 3.78 b) 3.78	100 - 400	XF	As mixture with 005008-00 Dash EC a) 1.0 L/ha b) 1.0 L/ha NT103
003	DE	spring soft wheat TRZAS, spring barley HORVS, common oats AVESA	F	Annual dicotyledonous weeds TTTDS, Cornbine CONAR, creeping thistle CIRAR	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	Tritosulfuron a) 49.98 b) 49.98 Florasulam a) 3.78 b) 3.78	100 - 400	XF	NT103 NW609-1
004	DE	spring soft wheat TRZAS, spring barley HORVS, common oats AVESA	F	Annual dicotyledonous weeds TTTDS, Cornbine CONAR, creeping thistle CIRAR	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	Tritosulfuron a) 49.98 b) 49.98 Florasulam a) 3.78 b) 3.78	100 - 400	XF	As mixture with 005008-00 Dash EC a) 1.0 L/ha b) 1.0 L/ha NT103

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, develeopmental stages
(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(7) Growth stage of treatment(s) (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(9) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g.g or kg / ha)
(12) The range (min/max) of water volumn under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

3 Risk management

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

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

Overall Summary:
The product BAS 812 00 H is a water dispersible granule (WG). All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of a beige fine granule with a faint sweet odour. It is not explosive and has no oxidising properties. It has a self ignition temperature of 395 °C. In aqueous solution, it has a pH value around 4.2. The plant protection product was found to be stable after accelerated storage for two weeks at 54°C in both HDPE bottles and FFS bags.
The formulation will be marketed in HDPE bottles or cans. No leakage or rupture of the original container was observed during normal handling before and after storage. An interaction between the product and its original container was not observed.
No particular problems are to be expected if the preparation is used as recommended.
A minimum shelf life of 2 years would be expected for this product according to FAO specifications. A 2-year shelf life study is still ongoing and will be finished in 2013.

Implications for labelling: The product shall be stored at ambient temperature.

Compliance with FAO specifications:
There are no FAO specifications available for tritosulfuron or florasulam.

Compliance with FAO guidelines:
The product BAS 812 00 F complies with the general requirements according to the FAO/WHO manual (2010).

Compatibility of mixtures:
A complete report regarding physical and chemical compatibility of the tank mixes with Dash EC and several other plant protection products has been submitted which has demonstrated compatibility. These tank mixes can therefore be mentioned on the product label for BAS 812 00 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 812 00 H 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)

According to the Annex I inclusion Directive of tritosulfuron (2008/70/EC), only tritosulfuron TGAI batches containing **< 0.2 g/kg AMTT** (2-amino-4-methoxy-6-(trifluormethyl)-1, 3, 5-triazine; Reg No 231 700) are selected for the formulation process. Every non-compliant batch is rejected.

Upon different requests and discussions from some MSs during the EU evaluation process (ECCO meetings), it was agreed that the limit for AMTT to apply to the BAS 635H-containing formulations would be **< 0.2% (w/w, relative to the tritosulfuron content)**, ie 10 times higher. This was agreed in Addendum 3 to DAR (4 February 2005) and taken over in the EU Evaluation Table.

All provided analytical methods are acceptable.

Type	Analyte	Method	LOQ
Active substance	Tritosulfuron	HPLC-UV	-
	Florasulam		-
Relevant impurity	AMTT	HPLC-UV	0.05 %w/w

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

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of tritosulfuron and florasulam in food of plant and animal origin, soil, water and air.

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

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

Acute toxicity studies for Biathlon 4D were not evaluated as part of the EU review of the active substances tritosulfuron and florasulam. Therefore, all relevant data were provided and are considered adequate.
Biathlon 4D, containing 714 g/kg tritosulfuron and 54 g/kg florasulam, has a low toxicity in respect to acute oral and dermal toxicity and is slightly irritating to rabbit skin and is not a skin sensitiser to the mouse. Taking into account all submitted data and the labelling of tritosulfuron (Xn, R43) and florasulam (none) Biathlon 4D should be labelled as harmful (Xn) with the phrase R22.

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

Operator exposure to Biathlon 4D was not evaluated as part of the EU review of tritosulfuron and florasulam. Since the risk assessments performed indicate that the health-based limit values (AOELs) for florasulam, tritosulfuron and AMTT will not be exceeded under practical conditions of use, studies to provide field data on operator exposure to Biathlon 4D were not considered to be necessary and were, therefore, not carried out.
Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

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

Bystander and resident exposure to Biathlon 4D was not evaluated as part of the EU review of tritosulfuron and florasulam. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

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

Re-entry worker exposure to Biathlon 4D was not evaluated as part of the EU review of tritosulfuron, AMTT and florasulam. Therefore, all relevant data and risk assessments are provided here and are considered adequate. It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing, when re-entering crops treated with Biathlon 4D. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

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

Hazard Symbol: Xn
Indication of danger: Warning
Risk Phrases: RA029, R22
Safety Phrases: S2, S13, S20/21, S36/37
R and S phrases under Directive 2003/82/EC (Annex IV and V): -
SF245-01 - Treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.
Other phrases: -

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)

Subsequent to the EU review of tritosulfuron and florasulam an evaluation of all uses has been made to establish EU MRLs (tritosulfuron: Reg. (EC) No 839/2008, florasulam: Reg. (EC) No 149/2008). These evaluations reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA model. The MRLs for tritosulfuron and florasulam are published in Annex III of Regulation (EC) No 396/2005.
The proposed uses of Biathlon 4D are within those supported for the EU MRL assessment, therefore no further evaluation is required for national re-registration/registration. Application for additional crops or uses should be made by the appropriate process to establish an EU MRL and any additional risk assessment necessary to support additional uses should be submitted via relevant national label extension processes.

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

The estimated consumer intake levels do not exceed the EU agreed ADI of 0.06 mg/kg bw/day for tritosulfuron and the ADI of 0.05 mg/kg bw/day for florasulam. It can therefore be concluded that acceptable margins of safety exist for consumers.
Chronic risk:
In case of parent tritosulfuron the residue definition for MRL setting for monitoring and for risk assessment are different. No TMDI calculations are performed as the ADI used for risk assessment refers to tritosulfuron expressed in AMTT equivalents and the valid MRLs are referring to tritosulfuron alone.
Therefore, the TMDI calculation was conducted for the metabolite AMTT resulting in the maximum exposure of 42,9 % of the ADI of 0.0001 mg/kg bw/d.
For florasulam a TMDI calculation using the EFSA model was performed taking into account of all crops to which florasulam may be applied. According to the current EFSA model, the maximum chronic exposure (WHO Cluster Diet E) is 0.2 % of the ADI.
Acute risk:
No acute consumer risk for residues of parent tritosulfuron appears as no ARfD value is allocated for tritosulfuron. However, a residue definition for purposes of risk assessment applies, which is based on the sum of tritosulfuron and AMTT, calculated as AMTT equivalents.
Therefore, a conservative worst case estimation was conducted on AMTT. Corresponding IESTI calculations including crops of the intended uses show that no acute consumer risk is expected under normal agricultural conditions.
Due to the toxicological profile of florasulam no ARfD has been established. Therefore, no acute dietary risk assessment was conducted for the use of Biathlon 4D in cereals.

Based on the different calculations made to estimate the risk for consumers though diet and other means it can be concluded that the use of Biathlon 4D does not lead to unacceptable risks for consumers when applied according to the recommendations.

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

A full exposure assessment for the plant protection product BAS 812 00 H (Biathlon 4D) in its intended uses in cereals is documented in detail in the core assessment of the plant protection product BAS 812 00 H dated from November 2012 performed by Austria.

The following chapters summarise specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of BAS 812 00 H in Germany according to its intended use in cereals (Use No. 00-001 and 00-002).

Metabolites

No new study on the fate and behaviour of the active substances tritosulfuron and florasulam has been performed. Hence no potentially new metabolites need to be considered for environmental risk assessment.

Metabolites of Tritosulfuron

An assessment of the relevance of the metabolites of tritosulfuron (635M01, 635M02, 635M03 and 635M04) has been performed in the core assessment, section 6. They are all classified as not relevant. Hence an exposure assessment for national assessment in Germany is not required. However, for the soil metabolites of tritosulfuron, occurring in soil at relevant concentrations, national groundwater risk assessment was performed.

Metabolites of florasulam

An assessment of the relevance of the metabolites of florasulam (5-OH-XDE-570, DFP-ASTCA, ASTCA) has been performed in the core assessment, section 6. They are all classified as not relevant. Hence an national assessment of the metabolites is not required. However, for the soil metabolites of florasulam, occurring in soil at relevant concentrations, national groundwater risk assessment was performed.

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product BAS 812 00 H in cereals according to use No 00-001 and 00-002 PECsoil was calculated for the active substances tritosulfuron and florasulam considering a soil depth of 2.5 cm. Due to the fast degradation of the active substances in soil the accumulation potential was not considered. Therefore PECsoil used for risk assessment here is the maximum annual soil concentration PECact considering the relevant soil depth of 2.5 cm.

Details are given in Part B National Addendum-Germany, Section 5, chapter 5.5.

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

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

1. Direct leaching into groundwater

Results of modelling with FOCUS PELMO 5.5.3 show that the active substances tritosulfuron and florasulam are not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu g/L$ in the intended for uses in cereals (use No. 00-001 and 00-002).

For the metabolites of tritosulfuron 635M01, 635M02 and 635M03 concentrations of $\geq 0.1 \mu g/L$ in groundwater cannot be excluded. However the metabolites 635M01, 635M02 and 635M03 are classified as not ecotoxicological relevant for groundwater and do not show a herbicidal activity (see core assessment, Part B, Section 6).

The soil metabolite 635M04 of tritosulfuron is not expected to exceed the groundwater trigger value of 0.1 µg/L.

For the soil metabolites of florasulam 5-OH, DFP-ASTCA and ASTCA concentrations of $\geq 0.1 \mu g/L$ in groundwater can be excluded.

For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.1.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances tritosulfuron and florasulam and its soil metabolites due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded for the intended use in cereals (00-001 and 00-002).
For details see Part B, National Addendum-Germany, Section 5, chapter 5.7.2.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product BAS 812 00 H in cereals according to use No 00-001 and 00-002 PECsw was calculated for the active substances tritosulfuron and florasulam considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.
The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substances tritosulfuron and florasulam is $< 10^{-5}$ Pa. Hence the active substances are regarded as non-volatile. Therefore, exposure of surface water by the active substances tritosulfuron and florasulam due to deposition following volatilization was not considered.
The concentration of the active substance tritosulfuron and florasulam in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.0.
Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.
The results for PEC_{SW} for the active substance and its metabolites were used for the eco-toxicological risk assessment.

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

Both tritosulfuron and florasulam show a low vapour pressure of $< 10^{-5}$ Pa at 20 °C and are regarded as non-volatile. Photochemical oxidative degradation in air is fast for both actives, so that no detailed assessment of atmospheric concentrations is necessary.

Implications for labelling resulting from environmental fate assessment:

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 812 00 H (Biathlon Super) in its intended uses in cereals is documented in detail in the core assessment of the plant protection product BAS 812 00 H dated from November 2012 performed by Austria. The intended use of BAS 812 00 H in Germany is generally covered by the uses evaluated in the course of the core assessment by Austria.
The following chapters summarise specific risk assessment for non-target organisms and hence risk mitigation measures for the authorization of BAS 812 00 H in Germany according to its intended use in cereals.

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

The risk assessment for birds and other terrestrial vertebrates for the application of BAS 812 00H was performed by zRMS Austria based on the latest Guidance of EFSA on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

Acute and long-term risk for birds and mammals due to the application of BAS 812 00H was acceptable.

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 812 00 H in cereals based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
The PPP BAS 812 00H and the active substance Florasulam are toxic to the aquatic environment (Florasulam: *Selenastrum capricornutum* NOEC < 0.000788 mg/L, BAS 812 00 H: *Lemna gibba* NOErC < 0.0108 mg/L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practice are acceptable, and the conditions of use NW262, NW265 and NW468 are assigned.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.
1. Exposure by spraydrift and deposition following volatilization
The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressures at 20 °C of the active substances tritosulfuron and florasulam are $< 10^{-5}$ Pa. Therefore, exposure of surface water by the active substances tritosulfuron and florasulam due to deposition following volatilization was not considered.
The aquatic risk assessment of spray drift entries in surface water by the use of BAS 812 00 H in cereals according to use No. 00-001 and 00-002 is based on the effects of the formulation Bas 812 00 H on *Lemna gibba (*E_yC_{50} = 6 µg/L for BAS 812 00 H, E_yC_{50} = 8 µg/L for BAS 812 00 H + DASH E.C.).
Based on the relevant toxicity of the formulation, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to BAS 812 00 H according to the use No 00-001 only achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measures (5 m buffer stripe) are applied. For the intended use of BAS 812 00 H in mixture with DASH E.C. according to use No 00-002 no risk mitigation measures are required.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.3.
2. Exposure by surface run-off and drainage
The concentration of the active substances tritosulfuron and florasulam 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 organisms resulting from an exposure of surface water by the active substances tritosulfuron (relevant endpoint: *Lemna gibba* EC_{50} = 26 µg/L) due to run-off and drainage according to the use No 00-001 and 00-002 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.4.

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

Bees

For the active substances tritosulfuron and florasulam the EU agreed endpoints are used for the risk assessment on honeybees. Effects on bees of BAS 812 00 H were not evaluated as part of the EU review for tritosulfuron and florasulam. Therefore, additional relevant data for the toxicity of BAS 812 00 H on honeybees was presented.
Standard studies on the acute toxicity to honeybees have been performed using the formulation BAS 812 00 H, alone and also in combination with the adjuvant BAS 160 00 S, since in several countries an application with the adjuvant BAS 160 00 S is foreseen.
The calculated HQs for acute oral and acute contact exposure of honeybees to tritosulfuron, florasulam and BAS 812 00 H were considerably below the Commission regulation (EU) 546/2011 trigger value of 50.
The proposed uses of BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S, according to good agricultural practice present low risk to bees and will not adversely affect bees or bee colonies.

Other non-target arthropods

The calculated HQ values are below the respective trigger value of 2 for *T. pyri* and *A. rhopalosiphi* indicating low in-field and off-field risk to non-target arthropods following application of BAS 812 00 H to cereals.
Low risk for non-target arthropods is expected from the use of BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH EC) according to good agricultural practice. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

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

For the active substances tritosulfuron and florasulam and for the formulation BAS 812 00H (also in mixture with DASH E.C.) the acute TER values are above the trigger of 10 indicating an acceptable risk for earthworms. For the formulation also in mixture with DASH E.C. the chronic TER value is > 5 indicating an acceptable long-term risk for earthworms due to the application of BAS 821 00 H according to the use No. 00-001 and 00-002.

The risk assessment for the soil metabolites of tritosulfuron and florasulam was performed in the core assessment by AT and showed an acceptable risk for the soil metabolites of tritosulfuron and florasulam.

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

Risk assessment was performed based on a field study with the solo-formulation BAS 635 00 H (containing nominally 71.4% tritosulfuron) for the tritosulfuron metabolites 635M02, 635M03 and 635M01 (DT90 field > 365 d) although the toxicity studies conducted on earthworms, collembolans and soil microorganisms showed low toxicity.

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

Based on all available data, the use of BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH EC), poses no unacceptable risk to non-target soil micro-organisms at the proposed use rates.

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

Terrestrial non-target plants

For risk assessment for non-target plants relevant endpoints are ER_{50} = 2.93 g BAS 812 00 H/ha (sunflower) for use no. 001 and the ER50 = 1.3 g BAS 812 00 H + DASH E.C./ha (sunflower) for use no. 002. Based on the predicted rates of BAS 812 00 H in off-field areas, the TER values describing the risk for non-target plants following exposure to BAS 812 00 H according to use No. 00-001 and 00-002 achieve only 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, if appropriate risk mitigation measures are applied. Drift reduced spray equipment (90 % drift reduction) is necessary.
For details please refer to the national addendum Part B, section 6, chapter 6.9.

Implications for labelling resulting from ecotoxicological assessment:

According to Directive 67/548/EEC
Hazard Symbol: N
Indication of danger:
Risk Phrases: R50/53
According to Regulation (EC) No 1272/2008
H400, acute aquatic hazard, Cat. 1
H410, chronic aquatic hazard, Cat. 1
National labelling:
NB6641
NW 262 (Florasulam: *Selenastrum capricornutum* NOEC < 0.000788 mg/L)
NW 265 (BAS 812 00 H: *Lemna gibba* NOErC < 0.0108 mg/L)
NW 468
NW 609 (use No. 00-001 and 00-003)
NT103 (all uses)

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

Because of different selectivity and a different competition level, each use was splitted in one for winter cereals and one for spring cereals. Instead of crop groups the single crops are listed. This change is a formal one with no impact on the risk assessment and management.

According to the application form, the use of Biathlon Super is intended for the control of "dicotyledonous weeds". For some annual and perennial dicotyledonous weeds, which are described on the label as being controlled well, only a few or no efficacy results have been submitted, which entails that a reliable evaluation of these weed species is not possible. Therefore the scope of weeds was restricted to TTTDS, CONAR and CIRAR. Therefore and due to the fact that some cereals respond sensitively to sulfonylureas, the restriction WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is

applied. If long term control of perennial weeds is claimed, assessments in the following year are required (see EPPO PP1/93). Due to the missing results, a restriction (WW742: The product has no sustainable effect in perennial weeds.) is addressed on the label.
Labels applied: WH9161, WW742

Concerning the risk for succeeding crops, the comparison of EC_{10} values for the most sensitive crop (winter oilseed rape) with the PEC values revealed a theoretical risk of damage for time intervals < 90 days and only shallow soil cultivation. Due to the theoretical assessment and the biological properties of the active substances Tritosulfuron and Florasulam, the restrictions WP710 (Damage is possible to replanted dicotyledonous intermediate crops and winter rape.) and WH960 (The risk of replanting has to be indicated on the package and in the instructions of use. Particularly the endangered succeeding crops have to be declared and measures for a risk management have to be described.) are applied.
Labels applied: WP710, WH960

Due to a high risk of resistance, the restriction WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.
Label applied: WH951

Standard studies on the toxicity to non-target arthropods have been performed using the formulation BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S since in several countries an application with the adjuvant BAS 160 00 S is foreseen. Studies performed with BAS 812 00 H, alone and in combination with BAS 160 00 S, led to similar LR_{50} values, which are greater than the highest tested treatment rate. The calculated HQ values are below the respective trigger value of 2 for *Typhlodromus pyri* and *Aphidius rhopalosiphi* indicating low in-field and off-field risk to non-target arthropods following application of BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S to cereals.
Labels applied: NN1001, NN1002

3.2 Conclusions

Regarding compliance with MRLs of tritosulfuron and florasulam set according to Reg. (EC) No 396/2005 and based on the toxicological properties of Biathlon 4D no health risks of consumers, operators, workers, bystanders, and residents following the intended uses are identified. Therefore, an authorisation can be granted.

With respect to efficacy, sustainable use/IPM incl. protection of honey bees all criteria are fulfilled by BAS 812 00 H alone and in combination with the adjuvant BAS 160 00 S. Consequently an authorisation can be granted.

With respect to analytical methods for residues an authorisation can be granted.

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

An authorisation 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

The applicant needs to submit following confirmatory data :

AnnexIII point	Data
2.7.5	2 year shelf life study is to be submitted after finalisation in February 2013.

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

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007555-00/00.63082
(bitte bei Antwort angeben)

DATUM 5. Juli 2013

ZV3 007555-00/00

Biathlon 4D

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	714 g/kg	Tritosulfuron
	54 g/kg	Florasulam
Zulassungsnummer:	007555-00	
Versuchsbezeichnung:	BAS-81200-H-0-WG	
Antrag vom:	15. Dezember 2011	

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. Dezember 2016.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007555-00/00-003, 007555-00/00-004	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter	Sommerweichweizen, Sommergerste, Sommerhafer	
007555-00/00-001	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter	Winterweichweizen, Winterhartweizen, Dinkel, Wintergerste, Winterroggen, Wintertriticale, Winterhafer	
007555-00/00-002	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter	Winterweichweizen, Winterhartweizen, Wintergerste, Winterroggen, Wintertriticale	

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) festgesetzt:

(NW468)

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

Begründung:

Aufgrund der Auswirkungen der Wirkstoffe Tritosulfuron und Florasulam gegenüber aquatischen Organismen besitzt das Pflanzenschutzmittel Biathlon Super (Lemna gibba, EC50 = 6µg/L) einen den Naturhaushalt schädigenden Charakter, so dass jeder weitergehende, d. h. den als Folge der sachgerechten und bestimmungsgemäßen Anwendung des Pflanzenschutzmittels Nisshin übersteigende Eintrag von Rückständen in Gewässer zu einer erheblichen Gefährdung des Naturhaushaltes führen würde. Angesichts der Umstände, dass ein erheblicher Anteil an Pflanzenschutzmittelfrachten im einzelnen Gewässer auf Einträge aus kommunalen Kläranlagen zurückzuführen ist (vgl. Umweltpolitik - Wasserwirtschaft in

Deutschland, 10.5.2 Pestizide, S. 156 ff., BMU, Februar 1998 und Fischer, Bach, Frede: Abschlussbericht zum DBU-Projekt 09931, April 1998), ist es unverzichtbar, der Gefahr, die eine Verbringung von Pflanzenschutzmitteln in Gewässer mit sich bringt, durch die bußgeldbewehrte Auflage im Sinne der Zweckbestimmung des Pflanzenschutzgesetzes 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	HDPE	1		0,15	2,20	l
Kanister	HDPE	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:

(NW262)
Das Mittel ist giftig für Algen.

(NW265)
Das Mittel ist giftig für höhere Wasserpflanzen.

(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.

(SF245-01)

Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten.

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

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

(WMB)
Wirkungsmechanismus (HRAC-Gruppe): B

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

Sonstige Auflagen:

(WH951)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das Resistenzrisiko hinzuweisen. Insbesondere sind Maßnahmen für ein geeignetes Resistenzmanagement anzugeben.

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

R 22 : Gesundheitsschädlich beim Verschlucken

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

Enthält Tritosulfuron. Kann allergische Reaktionen hervorrufen.

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

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

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(EUH 208-0041)

Enthält Tritosulfuron. Kann allergische Reaktionen hervorrufen.

(EUH 401)

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

(H302)

Gesundheitsschädlich bei Verschlucken.

(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).

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

(NN1002)
Das Mittel wird als nicht schädigend für Populationen relevanter Raubmilben und Spinnen eingestuft.

Weitere Hinweise und Bemerkungen
Zu KIIIA1 6.2.8:
Hinweis und Begründung für die Kennzeichnungsauflage zum Wirkungsmechanismus (WMB: Florasulam und Tritosulfuron):
Die HRAC-Klassifizierung ist als neutrale Information direkt jedem einzelnen Wirkstoff (hier: Florasulam und Tritosulfuron) zuzuordnen. Die Kennzeichnung erleichtert der Praxis die Bestimmung des Wirkungsmechanismus von Herbiziden und ermöglicht so ein gezieltes Wirkstoffmanagement.

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. Hans-Gerd Nolting
Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 007555-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterweichweizen, Winterhartweizen, Dinkel, Wintergerste, Winterroggen, Wintertriticale, Winterhafer
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	13 bis 39
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	70 g/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WH960)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das hohe Nachbaurisiko hinzuweisen. Insbesondere sind gefährdete Folgekulturen zu benennen und Möglichkeiten für das Risikomanagement zu beschreiben.

(WP710)
Schäden an nachgebauten zweikeimblättrigen Zwischenfrüchten und Winterraps möglich.

(WW742)
Das Mittel besitzt keine nachhaltige Wirkung gegen ausdauernde Unkräuter.

2.3 Wartezeiten

(F)	Freiland: Winterweichweizen 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.
(F)	Freiland: Winterhartweizen 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.
(F)	Freiland: Dinkel 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.
(F)	Freiland: Wintergerste 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.

(F)	Freiland: Winterroggen 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.
(F)	Freiland: Wintertriticale 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.
(F)	Freiland: Winterhafer 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

(NT102)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 75 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 2,93 g/ha für Biathlon Super bzw. die ER50 von 1,3 g/ha für Biathlon Super mit DASH E.C. im Wachstumstest. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT 102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels Biathlon Super zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion

6, Kapitel 6.9).

(NW609-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.
5 m
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Pflanzen auf. Bewertungsbestimmend ist hier die EC50 für Lemna gibba von 6 µg/L aus den Test mit dem Mittel Biathlon Super. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 609 (5 m Abstand) erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels Biathlon Super in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.4.).

Anlage 1 zugelassene Anwendung: 007555-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Winterweichweizen, Winterhartweizen, Wintergerste, Winterroggen, Wintertriticale
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	13 bis 39
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	vorgeschriebene Mischung mit: 005008-00 Dash E. C. (1 l/ha)
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	70 g/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH9161)
In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WH960)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das hohe Nachbaurisiko hinzuweisen. Insbesondere sind gefährdete Folgekulturen zu benennen und Möglichkeiten für das Risikomanagement zu beschreiben.

(WP710)
Schäden an nachgebauten zweikeimblättrigen Zwischenfrüchten und Winterraps möglich.

(WW742)
Das Mittel besitzt keine nachhaltige Wirkung gegen ausdauernde Unkräuter.

2.3 Wartezeiten

(F)	Freiland: Winterweichweizen 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.
(F)	Freiland: Winterhartweizen 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.
(F)	Freiland: Wintergerste 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.

(F)	Freiland: Winterroggen 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.
(F)	Freiland: Wintertriticale 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

(NT103)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 2,93 g/ha für Biathlon Super bzw. die ER50 von 1,3 g/ha für Biathlon Super mit DASH E.C. im Wachstumstest. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT103 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels Biathlon Super zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.9).

Anlage 1 zugelassene Anwendung: 007555-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Sommerweichweizen, Sommergerste, Sommerhafer
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	13 bis 39
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	70 g/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

(WH9161)

In die Gebrauchsanleitung ist eine Zusammenstellung der Unkräuter aufzunehmen, die durch die Anwendung des Mittels gut, weniger gut und nicht ausreichend bekämpft werden, sowie eine Arten- und/oder Sortenliste der Kulturpflanzen, für die der vorgesehene Mittelaufwand verträglich oder unverträglich ist.

(WH960)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das hohe Nachbaurisiko hinzuweisen. Insbesondere sind gefährdete Folgekulturen zu benennen und Möglichkeiten für das Risikomanagement zu beschreiben.

(WP710)
Schäden an nachgebauten zweikeimblättrigen Zwischenfrüchten und Winterraps möglich.

(WW742)
Das Mittel besitzt keine nachhaltige Wirkung gegen ausdauernde Unkräuter.

2.3 Wartezeiten

(F)	Freiland: Sommerweichweizen 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.
(F)	Freiland: Sommergerste 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.
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Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 2,93 g/ha für Biathlon Super bzw. die ER50 von 1,3 g/ha für Biathlon Super mit DASH E.C. im Wachstumstest. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT 102 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels Biathlon Super zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.9).

(NW609-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.
5 m
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere aquatische Pflanzen auf. Bewertungsbestimmend ist hier die EC50 für Lemna gibba von 6 µg/L aus den Test mit dem Mittel Biathlon Super. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 10 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NW 609 (5 m Abstand) erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels Biathlon Super in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.4.).

Anlage 1 zugelassene Anwendung: 007555-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Acker-Winde, Acker-Kratzdistel, Einjährige zweikeimblättrige Unkräuter
Pflanzen/-erzeugnisse/Objekte:	Sommerweichweizen, Sommergerste, Sommerhafer
Verwendungszweck:	

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
- Erläuterungen:	
Anwendung im Haus- und Kleingartenbereich:	Nein
Erläuterung zum Schadorganismus:	
Stadium des Schadorganismus:	
- Erläuterungen:	
Erläuterung zur Kultur:	
Stadium der Kultur:	13 bis 39
- Erläuterungen:	
Anwendungszeitpunkt:	Nach dem Auflaufen, Frühjahr
- Erläuterungen:	
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
- Abstand:	
- Erläuterungen Anzahl Behandlungen:	
Mischungspartner:	vorgeschriebene Mischung mit: 005008-00 Dash E. C. (1 l/ha)
- Erläuterungen:	
Anwendungstechnik:	spritzen
- Erläuterungen:	
Aufwand:	
-	70 g/ha in 100 bis 400 l Wasser/ha
- Erläuterungen:	
Sonstige Ergänzungen und Hinweise:	- keine -

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

(WH9161)
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(WH960)
Auf der Verpackung und in der Gebrauchsanleitung ist auf das hohe Nachbaurisiko hinzuweisen. Insbesondere sind gefährdete Folgekulturen zu benennen und Möglichkeiten für das Risikomanagement zu beschreiben.

(WP710)
Schäden an nachgebauten zweikeimblättrigen Zwischenfrüchten und Winterraps möglich.

(WW742)
Das Mittel besitzt keine nachhaltige Wirkung gegen ausdauernde Unkräuter.

2.3 Wartezeiten

(F)	Freiland: Sommerweichweizen 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.
(F)	Freiland: Sommergerste 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.
(F)	Freiland: Sommerhafer 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

(NT103)
Die Anwendung des Mittels muss in einer Breite von mindestens 20 m zu angrenzenden Flächen (ausgenommen landwirtschaftlich oder gärtnerisch genutzte Flächen, Straßen, Wege und Plätze) mit einem verlustmindernden Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung, mindestens in die Abdriftminderungsklasse 90 % eingetragen ist. Bei der Anwendung des Mittels ist der Einsatz verlustmindernder Technik nicht erforderlich, wenn die Anwendung mit tragbaren Pflanzenschutzgeräten erfolgt oder angrenzende Flächen (z. B. Feldraine, Hecken, Gehölzinseln) weniger als 3 m breit sind oder die Anwendung des Mittels in einem Gebiet erfolgt, das von der Biologischen Bundesanstalt im "Verzeichnis der regionalisierten Kleinstrukturanteile" vom 7. Februar 2002 (Bundesanzeiger Nr. 70a vom 13. April 2002) in der jeweils geltenden Fassung, als Agrarlandschaft mit einem ausreichenden Anteil an Kleinstrukturen ausgewiesen worden ist.
Begründung:
Das Pflanzenschutzmittel Biathlon Super bzw. die darin enthaltenen Wirkstoffe Tritosulfuron und Florasulam weisen ein hohes Gefährdungspotenzial für terrestrische Nichtzielpflanzen auf. Bewertungsbestimmend ist hier die ER50 von 2,93 g/ha für Biathlon Super bzw. die ER50 von 1,3 g/ha für Biathlon Super mit DASH E.C. im Wachstumstest. Ausgehend von den geltenden Modellen zur Abdrift und einem Sicherheitsfaktor von 5 ist nach dem Stand der wissenschaftlichen Erkenntnisse die Anwendungsbestimmung NT103 erforderlich, um einen ausreichenden Schutz von terrestrischen Nichtzielpflanzen in Saumbiotopen vor Auswirkungen des Mittels Biathlon Super zu gewährleisten. Weitere Informationen hierzu sind dem nationalen Addendum zum Part B des Draft Registration Report zu entnehmen (Sektion 6, Kapitel 6.9).

REGISTRATION REPORT
Part B

Section 5 Environmental Fate

Detailed summary of the risk assessment

Product code: BAS 812 00 H

Active Substance(s): Tritosulfuron 714 g/kg

Florasulam 54 g/kg

Central Zone
Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM – Germany

Applicant: BASF

Date: April 2013

Table of Contents

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

The exposure assessment of the plant protection product BAS 812 00 H in its intended use as herbicide in cereals is documented in detail in the core assessment of the plant protection product BAS 812 00 H dated from November 2012 performed by Austria.

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 812 00 H 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 812 00 H

Code	ZV3 007555-00/00		
plant protection product	BAS 812 00 H		
applicant	BASF		
date of application	15.12.2011		
Formulation type (WP, EC, SC, …; density)	WG		
active substances (as)	Tritosulfuron	Florasulam	
Concentration of as	714 g/kg	54 g/kg	

Data pool/task force	---
letter of access/cross reference	Dow AgroScience for data of florasulam
existing authorisations in DE	none

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.
The intended uses in Germany (use No. 00-001 und 00-002) are covered by the core assessment performed by AT (Use No. 1 and 3)

Table 5.2-1: Classification of intended uses in Germany for BAS 812 00 H

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)

00-001/00-002*	cereals/ BBCH 13-39	Spraying, field crops	1 x, spring 1. 25 %	Tritosulfuron: 1 x 50 g/ha, Florasulam: 1 x 3.78 g/ha	Tritosulfuron: 1 x 37.5 g/ha, Florasulam: 1 x 2.835 g/ha

* In mixture with 005008-00 Dash E.C. (1 L/ha)

5.3 Information on the active substances

5.3.1 Tritosulfuron

See core assessment Table 9-5.

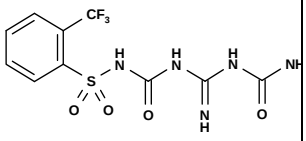
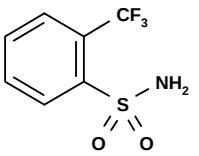
Metabolites of tritosulfuron:

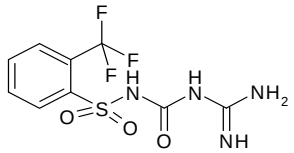
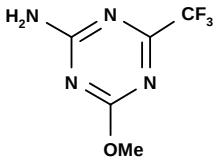
Environmental occurring metabolites of tritosulfuron requiring further assessment according to the results of the assessment of tritosulfuron for EU and in the core assessment are summarized in Table 9-7 of the core assessment, section 5.

An assessment of the relevance of the metabolites has been performed in the core assessment, section6. They are all classified as not relevant. Hence an exposure assessment for national assessment in Germany is not required. However, for the soil metabolites of tritosulfuron, occurring in soil at relevant concentrations, national groundwater risk assessment is performed (see chapter 5.7).

The metabolites are summarized in the table below.

Table 5.3-1: Metabolites of tritosulfuron potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/ Molecular formula**	**occurrence in compartments (Max. at day/ 2 x > 5 %)**	**Status of Relevance according to core assessment[3)]**
635M01	 M = 353.3 g/mol	Soil, aerob: max. 56 % after 60 d Water: max. 28.1 % after 100 d Sediment: max. 35 % after 100 d Lysimeter: 1.04 µg/L	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: relevant (Step 2)[1)], not relevant (Step 3 and 4)[1),2)]
635M02 (TBSA)	 M=225.2 g/mol	Soil, aerob: max. 23 % after 118 d Water: max. 15 % after 14 d Sediment: max. 0.9 % after 100d Lysimeter: 0.107 µg/L	Aquatic organism: Water: not relevant Sediment: not applicable Terrestrial organism: not relevant Groundwater: relevant (Step 2)[1)] not relevant (Step 3 and 4)[1),2)]

635M03	 M= 310.3 g/mol	Soil, aerob: max. 15 % after 120 d Water: max. 3.6 % after 100 d Sediment: max. 4.3 % after 100d Lysimeter: 0.84 µg/L	Aquatic organism: Water: not applicable Sediment: not applicable Terrestrial organism: not relevant Groundwater: relevant (Step 2)[1)] not relevant (Step 3 and 4)[1),2)]
635M04 (AMTT)	 M=194.1 g/mol	soil: max 6 % nach 90 d groundwater: Lysimeter < 0.1 µg/L water: max. 2.8 % nach 63 d	Aquatic organism: Water: not applicable Sediment: not applicable Terrestrial organism: not relevant Groundwater:not relevant (Step 2)[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)

[2)] Assessment of ecotoxicological relevance of metabolites 635M01, 635M02 (TBSA) and 635M03 was performed in core assessment, section6, chapter IIIA 10.2.8. The herbicidal activity of the metabolites were assessed in the core assessment, chapter IIA 10.8.

[3)] For assessment of metabolites to aquatic organism see core assessment, section 6, chapter IIIA 10.2. For assessment of metabolites to terrestrial organism see core assessment, section6, chapter IIIA 10.6

5.3.2 Florasulam

See core assessment Table 9-6.

Metabolites of florasulam:

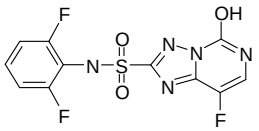
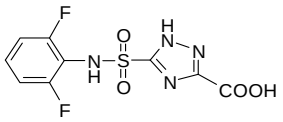
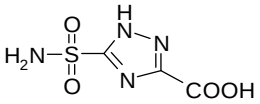
Environmental occurring metabolites of florasulam requiring further assessment according to the results of the assessment of florasulam for EU approval are summarized in the core assessment Table 9-7. Please note that the metabolite TSA that is also listed in the LoEP is regarded as an artifact already in the EU assessment (see also core assessment IIIA 9.1.1).

An assessment of the relevance of the metabolites has been performed in the core assessment, section 6. They are all classified as not relevant. Hence an national assessment of the metabolites is not required. However, for the soil metabolites of florasulam, occurring in soil at relevant concentrations, national groundwater risk assessment was performed (see chapter 5.7).

The metabolites are summarized in the table below.

Table 5.3-2: Metabolites of florasulam potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	**Structural formula/ Molecular formula**	**occurrence in compartments (Max. at day/ 2 x > 5 %)**	**Status of Relevance according to core assessment[3)]**

5-OH-XDE-570 (XDE-570 5-hydroxy) N-(2,6-difluorophenyl)-8-fluoro-5-hydroxyl (1,2,4) triazolo(1,5c) pyrimidine-2-sulphonamide	 M = 345.26 g/mol	Soil, aerob: max. 71.6 % after 3 d Water: max. 64 % after 60 d Sediment: max. 35 % after 60 d (Soil photolysis: 60%)	Aquatic organism: Water: not relevant Sediment: not relevant Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]
DFP-ASTCA (M3) N-(2,6-difluorophenyl)-5-aminosulphonyl-1H-1,2,4)triazole-3-carboxylic acid	 M = 304.23 g/mol	Soil, aerob: max. 17.8 % after 28 d Water: max. 15 % after 100 d Sediment: max. 9.15 % after 182 d	Aquatic organism: Water: not relevant Sediment: not applicable Terrestrial organism: not relevant Groundwater: not relevant (Step 2)[1)]
ASTCA (M4) 5-(aminosulphonyl)-1H-1,2,4-triazole-3-carboxylic acid	 M = 192.15g/mol	Soil, aerob: max. 40.0 % after 59 d	Aquatic organism: Water: not relevant Sediment: not applicable Terrestrial organism: not relevant Groundwater: relevant (Step 2)[1)] not relevant (Step 3 and 4)[1),2)]

[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)

[2)] Assessment of ecotoxicological relevance of metabolite ASTCA was performed in core assessment, section6, chapter IIIA 10.2.8.

[3)] For terrestrial organism according to EU assessment for florasulam. For assessment of metabolites to aquatic organism see core assessment, section6, chapter IIIA 10.2.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Tritosulfuron

Laboratory studies

No new study on the soil degradation of tritosulfuron has been submitted. zRMS AT has normalised DT50 values of DAR (Timme and Frehse or Topfit) to 20 °C and moisture at field capacity (see core assessment Part B, section 5, Table 9.1.1-1).

The DT50 values were recalculated to SFO-Kinetics by Germany. The values are summarized in the table below.

Table 5.4-1 Summary of aerobic degradation rates for tritosulfuron - laboratory studies (values in brackets originate from the study in the DAR)

Soil type	**pH ($CaCl_2$)**	**T (^oC)***	**Moisture (MWHC)***	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/ 10kPa**	**Fit (Chi^2 error level)**	**Method of calculation**	**Reference** **
Lufa 2.2, sandy loam	5.8	20	41	16.1 (16)	53.6 (53)	14.5 (--)	2.8 (--)	SFO (TF = Timme+ Frehse)	Kellner (1998, RepNo 1998/10687)
US, sandy loam	4.9	20	29	14.0 (13)	46.4 (45)	9.9 (--)	7.7 (--)	SFO (TF)	
Bruch West, sandy loam	7.6	20	31	39.6 (38)	131.5 (126)	26.4 (--)	3.0 (--)	SFO (TF)	
Canadian soil, sandy loam	8.1	20	49	126.8 (141)	421.2 (--)	n.c. (--)	6.5 (--)	SFO (TF)	
Li35B (phenyl) , sandy loam	6.3	20	31	24.8 (31)	82.43 (--)	18.4 (--)	6.8 (--)	SFO (--)	Kellner (1998, RepNo 1998/10662)
Li35B (triazin) , sandy loam	6.5	20	33	34.2 (32)	113.5 (--)	26.5 (--)	4.9 (--)	SFO (--)	
Speyerer Wald, sandy loam	5.4	20	24	20.0 (20.0)	66.46 (66.3)	15.4 (--)	5.5 (--)	SFO (--)	Staudenmaier (1999)
Aggregated DT_{50} (n=6)		**Coefficient of variation (%)**				36			
		Geomean (d)				17.5			
		90^{th} percentile (d)				26.5			

* All studies were conducted at 20 °C and 40% MWHC

** Reference in DAR

The laboratory DT_{50} values of tritosulfuron do not show a pH dependency.

For the soil metabolites the DT50 values are taken from the core assessment as presented in table 9.1.1-2.

The formation fractions of the metabolites are presented in the core assessment, Part B, section 5, table 9.1.1-3.

Field studies:

Evaluation of ten field trials showed that degradation of tritosulfuron in the field followed SFO kinetics. The half-lives were normalized to reference temperature of 20 °C and reference soil moisture at pF2.

A geometric mean value of 8.43 d of the normalized field DT50 values (20 °C, pF2) is used for modelling (see core assessment, Part B, section 5, table 9.2.1-14.)

Florasulam

No new study on the soil degradation of florasulam has been submitted. However, a new study containing re-evaluations of the degradation kinetics of florasulam for the study Jackson and Gosh, 1997 already evaluated in the EU assessment together with temperature and moisture normalizations for the recalculated DT_{50} values has been submitted (Jackson, 2010). These re-calculated DT50 values were not considered in the exposure assessment by zRMS AT based on the „Guidance Document on the Evaluation of New Annex II Data Post Annex I Inclusion/Approval of an Active Substance". However, as the regulation 1107/2009 requires an assessment in the light of current scientific and technical knowledge (Article 29.1 e) and Article 36.1) the re-caluclated DT50 values are considered in the national assessment. A detailed evaluation of this study is presented in Appendix 2.

Additionally, DT_{50} values of the studies Pillar, 1997 (GHE-P-6749) and Pillar, 1997 (GHE-P-6750), that are already evaluated in the EU assessment, were temperature and moisture normalized for this assessment according to guidance of the FOCUS groundwater scenarios workgroup [FOCUS, 2000, FOCUS, 2002]. The recalculated and/or normalized DT_{50} values for florasulam are summarized in Table 5.4-2.

Table 5.4-2: Summary of aerobic degradation rates for florasulam - laboratory studies

Soil type	**pH (H_2O)**	**T (^oC)**	**moisture**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**		**Method of calculation**	**Reference**
Speyer 2.2 loamy sand	7.7	20	40 % MWHC	0.17	5.6	-		FOMC	Jackson and Gosh, 1997***/ Jackson, 2010
				-	1.7	1.7		SFO*	
Marcham sandy clay loam	8.0	20	40 % MWHC	1.94	16.1	-		FOMC	
					5.0	4.2		SFO*	
Kenslow, humus silt loam	6.3	20	40 % MWHC	0.6	1.7	0.6		SFO	
Andover, silt loam	7.9	20	40 % MWHC	1.0	3.37	0.9		SFO	
Marcham, Sandy clay loam	8.8	15	40 % MWHC	15	50	9.9	8.2 **	1st order	Pillar 1997(GHE-P-6749) ***
		25		5,2	17	7.6		1st order	
		20	pF2	7.4	25	7.4		1st order	Pillar 1997 (GHE-P-6750)***

Cuckney, sand	8.0	15	40 % MWHC	3.5	11	2.4	3.4 **	1st order	Pillar 1997(GHE-P-6749)
		25		1.1	3.6	1.6		1st order	
		20	pF2	10	34	10		1st order	Pillar 1997 (GHE-P-6750)
Aggregated DT_{50} (n=6)		**Coefficient of variation (%)**				90			
		Geomean (d)				2.2			
		Geomean neutral and alkaline soils (pH>7.0)				2.49			
		Median (d)				2.6			
		90th percentile (d)				6.3			

* DT_{90} FOMC/3.32

** Geomean

*** Reference in DAR

The DT_{50} values of florasulam show a pH dependency. The active substance degrades slower in alkaline/neutral soils (tau: 0.828, p-value: 0.018).

No new studies on the soil degradation of the florasulam soil metabolites 5-OH-XDE-570, DFP-ASTCA, and ASTCA have been submitted. However, the newly submitted study from Jackson, 2010 on the degradation of florasulam contains also re-evalulations of the degradation kinetics of 5-OH-XDE-570, DFP-ASTCA, and ASTCA from the study Jackson and Gosh, 1997 together with temperature and moisture normalizations for the recalculated DT_{50} values. Additionally, degradation kinetics of DFP-ASTCA, and ASTCA were re-evaluated for the also in the EU assessment evaluated soil degradation study for these metabolites from the Jackson and Massart, 1998 again with subsequent DT_{50} temperature and moisture normalization. In addition DT_{50} values for 5-OH-XDE-570 from the studies Pillar, 1997 (GHE-P-6749) and Pillar, 1997 (GHE-P-6750) were temperature and moisture normalized for this assessment according to guidance of the FOCUS groundwater scenarios workgroup [*FOCUS, 2000, FOCUS, 2002*].

The DT50 values for the metabolites are summarized in the tables below.

Table 5.4-3: Summary of aerobic degradation rates for metabolite 5-OH-XDE-570 - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Method of calculation**	**Reference**
Speyer 2.2, loamy sand	7.7	20	40 % MWHC	14.1/ 46.7	0.9162	14.1	SFO	Jackson and Gosh, 1997***/ Jackson, 2010
Marcham, sandy clay loam	8.0	20	40 % MWHC	15.2/ 50.5	0.7823	12.8	SFO	
Kenslow, humus silt loam	6.3	20	40 % MWHC	17.6/ 58.4	0.8779	17.6	SFO	
Andover, silt loam	7.9	20	40 % MWHC	6.9/ 22.8	0.7801	6.2	SFO	

Marcham, Sandy clay loam	8.8	15	40 % MWHC	42/ 139.5[x]	n.c.	27.8	30.1 **	1st order	Pillar 1997(GHE-P-6749)***
		25		18/ 59.8[x]	n.c.	26.3		1st order	
		20	pF2	36/ 120[x]	n.c.	36		1st order	Pillar 1997(GHE-P-6750)***
Cuckney , sand	8.0	15	40 % MWHC	33/ 109.6[x]	n.c.	22.2	30.8 **	1st order	Pillar 1997(GHE-P-6749)
		25		21/ 69.8[x]	n.c.	31.1		1st order	
		20	pF2	42/ 139[x]	n.c.	42		1st order	Pillar 1997(GHE-P-6750)
Aggregated DT_{50} (n=6)		**Coefficient of variation (%)**				41			
		Geomean (d)				19.7			
		Median (d)				17.6			
		90th percentile (d)				30.5			
Formation Fraction from florasulam → 5-OH (n=4)		**Arithmetic mean**			0.8391				
		Maximum			0.9162				

** Geomean
n.c.: not calculated
[x] DT_{90} value estimated by ZRMS using the DT_{50} value
*** Reference in DAR

Table 5.4-4: Summary of aerobic degradation rates for the metabolite DFP-ASTCA - laboratory studies

Soil type	**pH (H_2O)**	**T (°C)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**	**Method of calculation**	**Reference**
Speyer 2.2, loamy sand	7.7	20	40 % MWHC	44.6/ 149	0.4261	44.6	SFO	Jackson and Gosh, 1997*/ Jackson, 2010
Marcham, sandy clay loam	8.0	20	40 % MWHC	12/ 39.9	0.4597	10.1	SFO	
Andover, silt loam	7.9	20	40 % MWHC	11.3/ 37.4	0.2803	10.1	SFO	
Cuckney, sand	7.2	20	40% MWHC	16.1/ 53.3	n.c.	15.5	SFO	Jackson and Massart, 1998*/ Jackson, 2010
Marcham, sandy clay loam	7.9	20	40% MWHC	4.2/ 14.07	n.c.	4.2	SFO	
Aggregated DT_{50} (n=5)		**Coefficient of variation (%)**				95		
		Geomean (d)				12.4		

	Median (d)		10.1	
	90th percentile (d)		33.0	
Formation Fraction from 5-OH → DFP-ASTCA (n=3)	**Arithmetic mean**	0.3887		
	Maximum	0.4597		

* Reference in DAR

Table 5.4-5: Summary of aerobic degradation rates for the metabolite ASTCA - laboratory studies

Soil type	**pH (H2O)**	**T (oC)**	**Moisture**	**DT_{50}/ DT_{90} (d)**	**f.f.**	**DT_{50} (d) 20 °C pF2/10kPa**		**Method of calculation**	**Reference**
Cuckney, Sand, treated with DFP-ASTCA	7.2	20	40% MWHC	122/ 404	0.7281	118	234	SFO	Jackson and Massart, 1998**/ Jackson, 2010
Cuckney, Sand, treated with ASTCA				482/ 1601	n.c.	465		SFO	
Marcham, sandy clay loam, treated with DFP-ASTCA	7.9	20	40% MWHC	214/ 711[x]	0.7822	214	173.7	SFO	
Marcham, sandy clay loam, treated with ASTCA				141/ 468[x]	n.c.	141		SFO	
Aggregated DT_{50} (n=2)		**Coefficient of variation (%)**				21			
		Geomean (d)				201.6			
		Median (d)				228.0			
		Maximum (d)				234.0			
Formation Fraction from DFP-ASTCA→ ASTCA (n=2)		**Arithmetic mean**		0.7552					
		Maximum		0.7822					

[x] DT_{90} value estimated by ZRMS using the DT_{50} value

** Reference in DAR

5.4.2 Adsorption/desorption

Tritosulfuron and ist metabolites

Please refer to core assessment, Part B, section5, table 9.3-2 till table 9.3.-6.

Florasulam

The K_{foc} values of florasulam as presented in the core assessment were analysed according to Holdt et al. 2011 (Holdt et al: Recommendations for simulations to predict environmental concentrations of active substances of plant protection products and their metabolites in groundwater (PEC_{GW}) in the National assessment for authorization in Germany, Texte Umweltbundesamt 56, 2011).

For zonal authorization of a different formulation containing florasulam an additional study on adsorption/desorption in soil of florasulam (Simmonds, 2011 Rep. No YR/11/005) was submitted. This study is also summarized in Appendix 2. As studies on adsorption/desorption in soil belong to the basic data set of an active substance Kfoc values from all available studies are considered for exposure assessment.

For the dissociating active substance florasulam a significant correlation could be found between the K_{foc} values and pH of the soils (n=14). In this case, the selection of two K_{foc} values at different pH values and two simulation runs (Hamburg scenario and Kremsmünster scenario) are required by using the pH-Tool in FOCUS PELMO 5.5.3. The results are summarized in Table 5.4-6 and Table 5.4-7.

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

Soil Type	**OC [%]**	**pH (H_2O)**	**K_f [mL g^{-1}]**	**K_{foc} [mL g^{-1}]**	**1/n [-]**	**Reference**
Catlin, Silty clay loam	2.2	7.4*	0.89	40	0.88	Ostrander, 1996 (see DAR)
Hanford, Sandy loam	1.0	7.6*	0.22	22	0.86	
Pewamo, clay	2.4	6.4*	1.88	78	0.92	
Fuquay, sand	0.64	5.5*	0.35	55	1.00	
Kenslow, Silt loam	6.8	6.7*	1.47	22	0.94	
Speyer, Sandy loam	3.9	7.7*	0.13	3	0.95	
Calke, Sandy Loam	3.6	5.9	0.30	8.3	0.949	Simmonds, 2011 (YR/11/005)
S-Witham, Clay Loam	3.8	7.6	0.10	2.7	0.983	
Longwoods, Sandy Loam	1.5	7.7	0.03	1.7	0.885	
Kenslow, Loam	3.8	5.3	0.47	12.3	0.914	
Lufa 6S, Clay	1.8	7.3	0.04	2.5	1.041	
Lufa 5M, Sandy Loam	1.0	7.7	0.03	2.6	0.947	
RefeSol 06-A, Clay Loam	1.9	7.6	0.08	4.2	0.938	
RefeSol 01-A, Sandy Loam	1.0	6.0	0.30	29.9	1.018	
Arithmetic mean (n=14)			**0.45**	**20.0**	**0.945**	

*calculated from measured pH values in KCl

Table 5.4-7: Statistic values according to INPUT DECISION 3.3 for florasulam for PEC_{GW} modelling

Does the active substance dissociate ?	yes, pKs = 4.54	
correlation K_{foc} and pH	Kendall-τ: -0.421 p-value: 0.046	positiv significant → use pH-Tool
correlation K_f and pH	Kendall-τ: -0.529 p-value: 0.012	negativ significant (expected for acid)

correlation K_f and oc	Kendall-τ: 0.261 p-value: 0.112	not positive significant (p-Wert > significance level)
coefficient of variation K_{foc}	117 %	not relevant
coefficient of variation Kf	127 %	not relevant
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_{foc} for PEC_{GW}	pH ≥7: 2.0 pH <7: 55	pH-Tool of FOCUS PELMO, selection of 2 Kfoc values at different pH values. n= 14
1/n PECgw	0.945	arithmetic mean all soils n= 14

Metabolites of Florasulam

For zonal authorization of a different formulation containing florasulam additional studies on adsorption/desorption in soil of the soil metabolites 5-OH-XDE-570 (Simmonds, 2011, Rep.No YR/11/006), DFP-ASTCA (Burgess and Simmonds, 2011, Rep. No YR/11/009) and ASTCA (Burgess and Simmonds, 2011, Rep.No YR/11/008) were submitted. These studies are also summarized in Appendix 2. As studies on adsorption/desorption in soil belong to the basic data set of an active substance Kfoc values from all available studies are considered for exposure assessment.

For the metabolite 5-OH-XDE-570 the coefficient of variation of the measured K_{foc} values is > 60% and a correlation could be found between the K_{foc} / K_f values and pH of the soils. In this case, the arithmetic mean of the K_f values from neutral and alkaline soils are used for the five soil horizons of the model scenario Kremsmünster in FOCUS PELMO 5.5.3. Furthermore, the arithmetic mean of the K_f values from all soils are used for the first three soil horizons of the model scenario Hamburg together with a default value of zero for the soil horizons 4-6. The results are summarized in Table 5.4-8 and Table 5.4-9.

Table 5.4-8: K_f, K_{foc} and 1/n (Freundlich exponent) values for metabolite 5-OH-XDE-570

Soil Type	**OC [%]**	**pH (H_2O)**	**K_f [mL g^{-1}]**	**K_{foc} [mL g^{-1}]**	**1/n [-]**	**Reference**
Catlin ,Silty clay loam	2.2	7.4*	0.69	31	0.88	Ostrander, 1996 (see DAR)
Hanford, Sandy loam	1.0	7.6*	0.21	21	0.95	
Pewamo, clay	2.4	6.4*	0.73	72	0.90	
Fuquay, sand	0.64	5.5*	0.24	4	0.98	
Kenslow, Silt loam	6.8	6.7*	1.55	23	0.90	
Speyer, Sandy loam	3.9	7.7*	0.07	2	1.10	
Calke, Sandy Loam	3.6	5.9	0.29	8.0	0.832	Simmonds, 2011 (YR/11/006)
S-Witham, Clay Loam	3.8	7.6	0.16	4.1	0.792	
Lufa 5M, Sandy Loam	1.0	7.7	0.06	6.1	0.864	
RefeSol 06-A, Clay Loam	1.9	7.6	0.12	6.1	0.866	

Arithmetic mean			**0.51**	**21.0**	**0.906**	

*calculated from measured pH values in KCl

Table 5.4-9: Statistic values according to INPUT DECISION 3.3 for metabolite 5-OH-XDE-570 for PEC_{GW} modelling

Does the active substance dissociate ?	no	No data available.
correlation K_f and oc	Kendall-τ: 0.135 p-value: 0.327	not positiv significant (p-Wert > significance level)
coefficient of variation K_{foc}	98 %	too high (> 60%)
correlation K_f and pH	Kendall-τ: -0.629 p-value: 0.018	negative significant (p-Wert < significance level)
correlation K_f and other soil parameters (clay, CEC)	-	not relevant
K_f for PEC_{GW}	Kremsmünster: 1.-5. horizon: Kf = 0.22 Hamburg: 1.-3. horizon: kf = 0.51 4.-6. horizon: kf = 0	1. Kremsmünster scenario: 1.-5. horizon, arithmetic mean of kf values (neutral/alkaline soils), n=6 2. Hamburg scenario: 1.-3. horizon: arithmetic mean of kf values (all soils), 4.-6. horizon: kf=0, n=10
1/n PEC_{GW}	Kremsmünster: 0.909 Hamburg: 0.906	1. Kremsmünster scenario: arithmetic mean of neutral/alkaline soils 2. Hamburg scenario: arithmetic mean of all soils

For the soil metabolites DFP-ASTCA and ASTCA Kfoc values from the new studies could be derived whereas from EU-assessment only Kd values are available (see core assessment Section 5 Table 9.3-9). The exposure assessment is therefore based on the Kfoc values (see tables below). The Kfoc values of both metabolites show a low coefficient of variation (< 60%) and no significant correlation between Kf and oc and Kf and pH. Therefore, arithmetic mean of the Kfoc values is taken for exposure assessment.

Table 5.4-10: Kf, Kfoc and 1/n (Freundlich exponent) values for the metabolite DFP-ASTCA

Soil Type	**OC [%]**	**pH (H_2O)**	**K_f [mL g^{-1}]**	**K_{foc} [mL g^{-1}]**	**1/n [-]**	**Reference**
Calke, Sandy Loam	3.6	5.9	0.88	24.4	0.84	Burgess and Simmonds, 2011 (YR/11/009)
S-Witham, Clay Loam	3.8	7.6	0.63	16.6	0.80	
RefeSol 06-A, Clay Loam	1.9	7.6	0.45	23.6	0.88	
Arithmetic mean			**0.65**	**22.0**	**0.84**	

Table 5.4-11: Kf, Kfoc and 1/n (Freundlich exponent) values for the metabolite ASTCA

Soil Type	**OC [%]**	**pH (H_2O)**	**K_f [mL g^{-1}]**	**K_{foc} [mL g^{-1}]**	**1/n [-]**	**Reference**

Calke, Sandy Loam	3.6	5.9	1.34	37.2	0.91	Burgess and Simmonds, 2011 (YR/11/008)
S-Witham, Clay Loam	3.8	7.6	1.27	33.4	0.94	
RefeSol 06-A, Clay Loam	1.9	7.6	0.98	51.8	0.94	
Arithmetic mean			**1.20**	**41.0**	**0.93**	

Table 5.4-12: Statistic values according to INPUT DECISION 3.2 for DFP-ASTCA for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation K_f and oc	Kendall-τ: 0.333 p-value: 0.5	not positive significant (p-Wert < significance level)
coefficient of variation K_{foc}	20 %	sufficiently low (≤ 60%)
Correlation K_f and pH	--	not relevant
Correlation K_f and other soil parameters (clay, CEC)	--	not relevant
K_{foc}/K_f for PEC_{GW}	22	arithmetic mean all soils
1/n PEC_{GW}	0.84	arithmetic mean all soils

Table 5.4-13: Statistic values according to INPUT DECISION 3.2 for ASTCA for PEC_{GW} modelling

Does the active substance dissociate ?	no	
correlation K_f and oc	Kendall-τ: 0.333 p-value: 0.5	not positive significant (p-Wert < significance level)
coefficient of variation K_{foc}	23 %	sufficiently low (≤ 60%)
Correlation K_f and pH	--	not relevant
Correlation K_f and other soil parameters (clay, CEC)	--	not relevant
K_{foc}/K_f for PEC_{GW}	41	arithmetic mean all soils
1/n PEC_{GW}	0.93	arithmetic mean all soils

5.4.3 Rate of degradation in water

Tritosulfuron

See core assessment chapter IIIA 9.2.4.1

Florasulam

See core assessment chapter IIIA 9.2.4.1

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

Results of PECsoil calculation for BAS 812 00 H and its active susbstances tritosulfuron and florasulam according to EU assessment considering 5 cm soil depth are given in chapter IIIA 9.4 of Part B, Section 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 the active substances tritosulfuron and florasulam in soil (DT_{90} < 365 d, laboratory data) the accumulation potential of the active substances does not need to be considered.

Additional $PEC_{soil,act}$ was calculated for the formulation BAS 812 00 H for a soil depth of 2.5 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 tritosulfuron and florasulam and for the formulation BAS 812 00 H are summarized in Table 5.5-1.

For the soil metabolites of florasulam and tritosulfuron no PECsoil values were calculated as the risk assessment for the soil metabolites has already been performed in the EU assessment as well in the core assessment by AT (see also section 6 of the national addendum for Germany)

Table 5.5-1: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

plant protection product:		BAS 812 00 H				
use:		00-001 and 00-002				
Number of applications/intervall		1 x				
application rate:		70 g/ha = 50 g tritosulfuron/ha, 3.78 g florasulam/ha				
crop interception:		25 %				
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)**
Tritosulfuron	37.5	2.5	0.100	--	--	--
Florasulam	2.835	2.5	0.008	--	--	--
BAS 812 00 H	52.5	2.5	0.140	--	--	--

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

Results of PECsw calculation of tritosulfuron and florasulam for the intended for uses of BAS 812 00 H in cereals using FOCUS Surface Water are given in chapter IIIA 9.7 of Part B, Section 5 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 and deposition following volatilisation

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 substances tritosulfuron and florasulam is $< 10^{-5}$ Pa. Hence the active substances tritosulfuron and florasulam are regarded as non-volatile. Therefore exposure of surface water by the active substances due to deposition following volatilization needs to be considered.

The calculation of PECsw after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 2.1. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities.

The calculated PECsw values after exposure via spray drift for the active substances tritosulfuron and florasulam for the intended for use in cereals according to use No 00-001 and 00-002 are presented in the National addendum Germany, Part B, section 6, chapter 6.4.

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

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

The endpoints for tritosulfuron and florasulam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with EXPOSIT 3.0 are summarized in the tables below.

Table 5.6-1 Input parameters for tritosulfuron used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	Tritosulfuron	Reference
$K_{foc, Runoff}$	7.4	Arithm. Mean (see core assessment table 9.3-2)
$K_{foc, mobility\ class}$	7.4	Arithm. Mean (see core assessment table 9.3-2)
DT_{50} soil (d)	26.5	90th percentile (see Table 5.4-1)
Solubility in water (mg/L)	38.6	See core assessment table 9-5

Table 5.6-2 Input parameters for tritosulfuron used for PEC_{SW} calculations with EXPOSIT 3.0

Parameter	florasulam	Reference
$K_{foc, Runoff}$	20	arithm. mean (see Table 5.4-6)
$K_{foc, mobility\ class}$	2	10th percentile ((see Table 5.4-6)

DT_{50} soil (d)	6.3	90th percentile (see Table 5.4-2)
Solubility in water (mg/L)	6360	see core assessment table 9-6

The calculated PEC_{SW} in an adjacent ditch due to surface run-off and drainage for the active substances tritosulfuron and florasulam for the intended for use in cereals according to use No. 00-001 and 00-002 are summarized in the National addendum Germany, Part B, section 6, chapter 6.4.

5.7 Risk assessment for groundwater (KIIIA1 9.6)

Results of PECgw calculation of tritosulfuron and florasulam for the intended uses of BAS 812 00 H in cereals according to EU assessment using FOCUS PELMO are presented in 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 is summarized in Table 5.7-1. It covers the intended uses of BAS 812 00 H in cereals according to Table 5.2-1 (see also Appendix 3).

Table 5.7-1 Input parameters related to application for PEC_{GW} modelling with FOCUS PELMO 5.5.3

use evaluated	00-001 and 00-002
application rate	Tritosulfuron: 0.050 kg/ha Florasulam: 0.00378 kg/ha
crop (crop rotation)	Spring cereals (spring application)
date of application	06.04.
interception	25 %
soil moisture	100 % FC

Q10-factor	2.58
moisture exponent	0.7
plant uptake	0
simulation period (years)	26

Tritosulfuron

The endpoints used for groundwater modelling for tritosulfuron and its soil metabolites ccording to INPUT DECISION 3.1 are summarized in Table 5.7-2 and Table 5.7-3.

Table 5.7-2 Input parameters related to tritosulfuron for PEC_{GW} modelling

Parent	**tritosulfuron**	**Remarks/Reference to Part B, Section 5, Core assessment**
molecular mass	445.3	
DT_{50} in soil (d)	8.43 17.5	Geom mean of Field studies 20°C, pF2, see core assessment Geom mean of laboratory studies n= 7(20 °C, pF2) see Table 5.4-1
DT50→ Met (d)	→ M01: 23.1 →M04: 318.2 →CO2: 92.1	
K_{foc}	7.4	Arithm mean see core assessment
1/n	0.913	Arithm. Mean see core assessment

Table 5.7-3 Input parameters of soil metabolites of tritosulfuron for PEC_{GW} modelling

Metabolite	**635M01**	**635M02**	**635M03**	**635M04**
Label in FOCUS PELMO	A1	B2	B1	C1
molecular mass	353.3	225.2	310.3	194.1
Formation fraction* **	0.759 from parent	0.719 from 635M01 0.580 from 635M03	0.240 from 635M01	0.055 from parent
DT_{50} in soil (d) (geom mean of laboratory values. 20 °C, pF2, Q10 = 2.58)*	56.7 (n= 7)	35.2 (n= 4)	102.2 (n= 3)	36.1 (n=4)
DT50 → Met,CO2 (d)	→ M02: 78.9 → M03: 236.3		→ M02: 176.2 → CO2: 243.3	
K_{foc} (arithm mean)**	89	40.6	30.1	20.8
1/n (arithm mean)**	0.923	0.957	0.912	0.935
Plant uptake factor	0	0	0	0

* geom. mean values calculated from DT50 values as presented in core assessment Table 9.1.1-2

** see core assessment Table 9.3-3 till Table 9.3-6

*** see core assessment Table 9.1.1-3

The results of the groundwater simulation are presented in Table 5.7-4.

Table 5.7-4 PEC_{GW} at 1 m soil depth of tritosulfuron and its soil metabolites 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 5.5.3				
		Tritosulfuron	Metabolite 635M01	Metabolite 635M02	Metabolite 635M03	Metabolite 635M04
00-001, -002	Hamburg (lab DT50)	0.329	0.502	0.710	0.814	0.044
00-001, -002	Hamburg (Field DT50)	0.013	--	--	--	--

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3 simulated with field DT50 values for tritosulfuron, a groundwater contamination of the active substance tritosulfuron in concentrations of ≥ 0.1 µg/L is not expected for the intended use in cereals.

For the soil metabolites 635M01, 635M02 and 635M03 a groundwater concentration of ≥ 0.1 µg/L cannot be excluded for the application in cereals according to use No. 00-001 and 00-002, whereby metabolite 635M03 results in concentration above 0.75 µg/L.

Groundwater simulations for metabolite 635M04 resulted in concentrations below 0.1 µg/L in groundwater.

The Results of the groundwater simulation go in line with those presented by zRMS AT. However on national assessment results in a groundwater concentration of above 0.75 µg/l for metabolite 635M03.

Florasulam

The endpoints used for groundwater modelling for florasulam and its metabolites according to INPUT DECISION 3.1 are summarized in the tables below.

Table 5.7-5 Input parameters related to florasulam for PEC_{GW} modelling

Parent	florasulam	Remarks/Reference
molecular mass	359.3	
DT_{50} in soil (d)	2.2 2.49	Geomean, all soils for scenario Hamburg, see Table 5.4-2 Geomean, neutral and alkaline soils (pH>7)) for scenario Kremsmünster, see Table 5.4-2
K_{foc}	pH ≥7 (7.7): 2.0 pH <7 (5.5): 55	pH-Tool of FOCUS PELMO, Selection of 2 Kfoc values at different pH values. (See Table 5.4-7)
pKa	4.54	
1/n	0.945	Arithmetic mean of all soils (see Table 5.4-7)

Table 5.7-6 Input parameters related to soil metabolite 5-OH-XDE-570 for PEC_{GW} modelling

Metabolite 1	**5-OH-XDE-570**	**Remarks/Reference**
molecular mass	345.26	-
Formation fraction from florasulam → 5-OH-XDE-570	0.8391	Arithmetic mean (see Table 5.4-3)
DT_{50} in soil (d)	19.7	Geometric mean (see Table 5.4-3)
K_{foc}	Kremsmünster: 1.-5. horizon: Kf = 0.22 Hamburg: 1.-3. horizon: kf = 0.51 4.-6. horizon: kf = 0	1. Kremsmünster scenario: 1.-5. horizon, arithmetic mean of kf values (neutral/alkaline soils) 2. Hamburg scenario: 1.-3. horizon: arithmetic mean of kf values (all soils), 4.-6. horizon: kf=0 (See Table 5.4-9)
1/n	Kremsmünster: 0.909 Hamburg: 0.906	Kremsmünster scenario: arithmetic mean of neutral/alkaline soils Hamburg scenario: arithmetic mean of all soils (see Table Table 5.4-9)
plant uptake factor	0	default

Table 5.7-7: Input parameters related to metabolites DFP-ASTCA for PEC_{GW} modelling

Metabolite 2	**DFP-ASTCA**	**Remarks/Reference**
molecular mass	304.23	-
Formation fraction (5-OH → DFP-ASTCA)	0.3887	Arithmetic mean (see Table 5.4-4)
DT_{50} in soil (d)	12.4	Geometric mean (see Table 5.4-4)
K_{foc}	22.0	Arithmetic mean (see Table 5.4-12)
1/n	0.84	Arithmetic mean (see Table 5.4-12)
plant uptake factor	0	default

Table 5.7-8: Input parameters related to metabolites ASTCA for PEC_{GW} modelling

Metabolite 3	**ASTCA**	**Remarks/Reference**
molecular mass	192.15	-
Formation fraction (DFP-ASTCA → ASTCA)	0.7822	Maximum (see Table 5.4-5), n=2
DT_{50} in soil (d)	234	Maximum (see Table 5.4-5), n=2
K_{foc}	41.0	Arithmetic mean (see Table 5.4-13)
1/n	0.93	Arithmetic mean (see Table 5.4-13)
plant uptake factor	0	default

The results of the groundwater simulation are presented in Table 5.7-4.

Table 5.7-9 PEC_{GW} at 1 m soil depth of florasulam and its metabolites 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 5.5.3			
		florasulam	metabolite 5-OH	metabolite DFP-ASTCA	metabolite ASTCA
00-001 and 00-002	Hamburg	0.000	0.000	0.000	0.076
	Kremsmünster	0.000	0.005	0.003	0.072

According to the results of the groundwater simulation with FOCUS-PELMO 5.5.3, a groundwater contamination of the active substance florasulam in concentrations of ≥ 0.1 µg/L is not expected for the intended use in cereals according to use No. 00-001 and 00-002.

For the metabolites of florasulam a groundwater concentration of ≥ 0.1 µg/L can be excluded for the application in cereals according to the results of the groundwater simulation with FOCUS-PELMO 5.5.3.

5.7.1.2 Experimental data to the leaching behaviour of the active aubstance

Not required.

5.7.1.3 Summary on risk assessment for groundwater after direct leaching

Results of modelling with FOCUS PELMO 5.5.3 show that the active substances tritosulfuron and florasulam are not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended for uses in cereals (use No. 00-001 and 00-002).

For the metabolites of tritosulfuron 635M01, 635M02 and 635M03 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. However the metabolites 635M01, 635M02 and 635M03 are classified as not ecotoxicological relevant for groundwater and do not show a herbicidal activity (see core assessment, Part B, Section 6 and national addendum Table 5.3-1).

The soil metabolite 635M04 of tritosulfuron is not expected to exceed the groundwater trigger value of 0.1 µg/L.

For the soil metabolites of florasulam 5-OH, DFP-ASTCA and ASTCA concentrations of ≥ 0.1µg/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 tritosulfuron and florasulam used for modelling surface water exposure via run-off and drainage in an adjacent ditch with subsequent bank filtration into the groundwater with EXPOSIT 3.0 are summarized inTable 5.7-10 and Table 5.7-11

Table 5.7-10 Input parameters for tritosulfuron used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Tritosulfuron	Reference/comment
$K_{foc, Runoff}$	7.4	Arithm. Mean (see core assessment table 9.3-2)
$K_{foc, mobility\ class}$	7.4	Arithm. Mean (see core assessment table 9.3-2)
DT_{50} soil (d)	26.5	90th percentile (see Table 5.4-1)
Solubility in water (mg/L)	38.6	See core assessment table 9-5
Mobility class	3	
Reduction by bank filtration	90 %	default

Table 5.7-11 Input parameters for florasulam used for PEC_{GW} calculations with EXPOSIT 3.0

Parameter	Florasulam	Reference/comment
$K_{foc, Runoff}$	20	arithm. mean (see Table 5.4-6)
$K_{foc, mobility\ class}$	2	10th percentile
DT_{50} soil (d)	6.3	90th percentile (see Table 5.4-2)
Solubility in water (mg/L)	6360	see core assessment
Mobility class	4	
Reduction by bank filtration	100 %	default

The calculated PECgw for tritosulfuron and florasulam after surface run-off and drainage with subsequent bank filtration are summarized in Table 5.7-12 and Table 5.7-13.

Table 5.7-12 PEC_{gw} for tritosulfuron after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Tritosulfuron**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001/00-002	50 g/ha 25 %	0	0.001	autumn/winter/ early spring	0.003
		5			
		10		spring/summer	0.001
		20			
required labelling		none			

Table 5.7-13 PEC_{gw} for florasulam after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Active substance		**Florasulam**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001/00-002	3.78 g/ha 25 %	0	< 0.001	autumn/winter/ early spring	< 0.001
		5			
		10		spring/summer	< 0.001
		20			
required labelling		none			

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances tritosulfuron and florasulam due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded for the intended use in cereals (00-001 and 00-002).

Metabolites of tritosulfuron

The soil metabolites of tritosulfuron 635M01, 635M02, 635M03 and 635M04 need to be considered for potential groundwater contamination due to bank filtration via surface water exposure by run-off and drainage.

The input parameters for the model EXPOSIT 3.01 are summarized in the results are given in

Parameter	**Metabolite 635M01**	**Metabolite 635M02**	**Metabolite 635M03**	**Metabolite 635M04**
Molecular weight (g/mol)	353.3	225.2	310.3	194.1
Correction factor molecular weight	0.793	0.506	0.70	0.429
Maximum occurance in soil (%)	71.6	17.8	40	6
$K_{foc, Runoff}$ (see chapter 5.4.2)	89	40.6	30.1	20.8
$K_{foc, mobility\ class}$	89	40.6	30.1	20.8
DT_{50} soil (d)[1)]	110	60	243	64
Solubility in water (mg/L) (default)	1000	1000	1000	1000
Mobility class	3	3	2	3
Reduction by bank filtration (%)	90	90	100	90

[1)] 90. Percentile from DT50 values as presented in core assessment Table 9.1.1-2. The DT50 value is only relevant for classification to a mobility class.

For the soil metabolite 635M03 there is no calculation necessary because this metabolite is assigned to mobility class 2 that means that the metabolites is reduced bank filtration.

The other soil metabolites are belonging to the mobility class 3. Due to the Kfoc values the same runoff discharge factor is applied for the metabolites 635M01 and 635M02, for metabolite 635M04 the factor is lower. Therefore only the risk assessment for metabolite 635M01 is presented below as its maximum occurrence was higher than for the other metabolites.

Metabolit		**635M01**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001/00-002	28.6 g/ha*	0	0.002	autumn/winter/ early spring	0.002
		5			
		10		spring/summer	0.001
		20			
required labelling		none			

* calculation based on application rate of parent, maximum occurance in soil and correction factor for molecular weight

According to modeling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of tritosulfuron due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Metabolites of florasulam

The soil metabolites of Florasulam (Table 5.3-2) are formed > 10 % in soil. Therefore potential ground water contamination due to bank filtration via surface water exposure by run-off and drainage needs to be assessed using EXPOSIT 3.01.

The input parameters for the model EXPOSIT 3.01 are summarized in Table 5.7-14, the results are given in Table 5.7-15.

Table 5.7-14: Input parameter for soil metabolites of florasulam for EXPOSIT 3.01

Parameter	**Metabolite 5-OH-XDE-570**	**Metabolite DFP-ASTCA**	**Metabolite ASTCA**
Molecular weight (g/mol)	345.26	304.23	192.15
Correction factor molecular weight	0.961	0.847	0.535
Maximum occurance in soil	71.6	17.8	40.0
$K_{foc, Runoff}$ (see chapter 5.4.2)	21	22	41
$K_{foc, mobility\ class}$	4[2)]	22	41
DT_{50} soil (d)[1)]	30.5	33.0	234

Solubility in water (mg/L)	1000	1000	1000
Mobility class	3	3	2
Reduction by bank filtration (%)	90	75	75

[1)] only relevant for mobility class
[2)] 10th percentil

According to the Kfoc values the three soil metabolites belong to the same group (Kfoc > 20 -50). That means the same runoff discharge factor is applied for all three metabolites. Hence, the risk to ground water by surface runoff and drainage with subsequent bank filtration is characterized by the mobility class because it defines the reduction values by bank filtration. Therefore the risk assessment will be performed for soil metabolite DFP-ASTCA considering the application rate for the active substance florasulam as a worst case. The assessment covers the risk assessment for the other soil metabolites of florasulam 5-OH-XDE-570 and ASTCA.

Table 5.7-15: PEC_{gw} for soil metabolites of … after surface run-off and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01 beta)

Metabolit		**DFP-ASTCA**			
Use No.	**application rate interception**	**PECgw due to**			
		run-off		**drainage**	
		vegetated buffer strip (m)	**bank filtrate (µg/L)**	**Time of application**	**bank filtrate (µg/L)**
00-001/00-002	3.78 g/ha 25 %	0	< 0.001	autumn/winter/ early spring	< 0.001
		5			
		10		spring/summer	< 0.001
		20			
required labelling		none			

According to modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites of florasulam (5-OH-XDE-570, DFP-ASTCA and ASTCA) due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

none

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data used for 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: KIIA 7.2.1/01	Jackson, R.	2010	Re-evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to FOCUS Guidance report no. GHE-P-12511	Y	DAS	4*
OECD: KIIA 7.4.1/01	Simmonds, R.	2011	Florasulam: Adsorption and Desorption properties of [^{14}C]-Florasulam in Eight Soils report no. YR/11/005 2351198 //YR/11/005	Y	DAS	4*
OECD: KIIA 7.4.2/01	Simmonds, R.	2011	Florasulam: Adsorption Properties of [^{14}C]-5-Hydroxyflorasulam in Four Soils report no. YR/11/006 2351206//YR/11/006	Y	DAS	4*
OECD: KIIA 7.4.2/02	Burgess, M and Simmonds, M.	2011	Florasulam: Adsorption Properties of [^{14}C]-DFP-ASTCA in Four Soils report no. YR/11/009 2351208//YR/11/009	Y	DAS	4*
OECD: KIIA 7.4.2/03	Burgess, M and Simmonds, M.	2011	Florasulam: Adsorption Properties of [^{14}C]-ASTCA in Four Soils report no. YR/11/008 2351219//YR/11/008	Y	DAS	4*

* Endpoints from this study were used together with others for groundwater risk assessment and/or exposure modelling. However, studies submitted by the applicant were alone sufficient to fulfill data requirements.

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 (approval of active substance).

K IIA 7.2. Jackson, 2010

Reference:	KIIA 7.2
Report	Re-Evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to FOCUS Guidance, Jackson, R., 2010, report no. GHE-P-12511, BVL Doc. No. 2200235
Guideline(s):	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Report of the FOCUS Work Group on Degradation Kinetics, EC Document Ref. Sanco/10058/2005 ver.1, 2005
Deviations:	Yes see comment of DE
GLP:	Not applicable "no laboratory study"
Acceptability:	Yes
	letter of access provided by applicant

Materials and methods

The degradation kinetics of florasulam and its three major aerobic soil metabolites (5-OH, DFP-ASTCA, ASTCA) have been re-evaluated according to the FOCUS kinetics guidance (2006). As input, the data from two laboratory aerobic soil studies with florasulam „Jackson and Gosh, 1997 (Jackson, R. and Gosh, D., 1997. *The aerobic degradation of XDE-570 in soil*. *report no. GHE-P-4710*), and its metabolites DFP-ASTCA and ASTCA, Jackson and Massart, 1998 (Jackson, R. and Massart, J., 1998. *The degradation of DFP-ASTCA and ASTCA (tow metabolites of DR-570) in soil*. Report no. GHE-P-7522), already evaluated during the EU assessment were used.

The re-calculation of the kinetic parameters was performed with the kinetics modelling tool KinGUI (ver. 1.1) using single first-order (SFO) for florasulam and its metabolites and for florasulam also using first-order multiple compartment (FOMC) and bi-exponential (DFOP) models to determine the best fit.

The data of the four soils (Andover, Kenslow, Marcham and Speyer soil) used in the study Jackson and Gosh, 1997, were fitted to the different kinetics model sequentially, starting with florasulam alone then adding the metabolites one at a time and optimising the model at each step. The following degradation scheme of florasulam was used in the model.

Florasulam → 5-OH → DFP-ASTCA →ASTCA

The data of the 2 soils (Marcham and Cockney soil) used in the study Jackson and Massart, 1998 to investigate the degradation of the metabolites DFP-ASTCA and ASTCA were modeled for both metabolites together where DFP-ASTCA was applied to the soil and for the metabolite ASTCA alone where ASTCA was applied to the soil.

Results and discussions

The degradation of florasulam was best described with biphasic models in all for soils (good visual fits, chi^2 error <15%). However, for the degradation of florasulam in the Kenslow soil, the SFO model describes the degradation of florasulam also adequately (good visual fit, chi^2 error <15%). For the degradation in the Andover soil, the SFO model gave an acceptable fit (good visual fit, chi^2 error <15%)

after the data point at day 3 was removed as an outlier. Additionally, the kinetic fit after removal of the data point at day 1 was tested. For the degradation of florasulam in the Marcham soil, the SFO model gave an acceptable statistical fit (chi^2 error <15%), however the visual fit of the data points was poor. The applicant choose the SFO model nevertheless with the arguments of that the statistical fit was acceptable and that the SFO model describes the degradation in the first 7 days adequately, where 80% of florasulam is degraded. The kinetic parameters derived for the metabolites 5-OH and DFP-ASTCA, however, are based on the FOMC model for florasulam. For the Speyer soil, the FOMC model was chosen to describe the degradation of florasulam.

Acceptable kinetic parameters could also be obtained for the formation and degradation of 5-OH in all four soils (good visual fits, chi^2 error <15%). Acceptable kinetic parameters could be obtained for DFP-ASTCA in the soils Andover and Speyer. For the soil Marchham, an acceptable fit could only be obtained when the concentrations of DFP-ASTCA were combined with the concentrations of the metabolite DFP-TSA, although the chi^2 error was with 17.2% slightly above the recommended 15%. It was not possible to obtain acceptable fits to describe the formation and degradation of the metabolite ASTCA in the four soils.

The kinetic parameters, finally used to describe the degradation of florasulam and its metabolites 5-OH and DFP-ASTCA in the soils Andover, Kenslow, Marcham and Speyer, are presented in the tables below. For the Andover and the Kenslow soil, the kinetic parameters of the SFO fit of the parent alone are also presented. For the Marcham soil, the kinetic parameters of the FOMC fit for florasulam are presented too.

Table A 2 Optimised kinetic parameters for the degradation of florasulam and its metabolites 5-OH and DFP-ASTCA in the Andover soil (without data point at day 3)

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
Florasulam	SFO (parent only)	M_0 (%) k (d^{-1})	95.03 0.6565	91.65 0.5800	98.40 0.7329	 1.8e-6	good	1.1	4.2
Florasulam	SFO (parent & metaboliltes)	M_0 (%) k (d^{-1})	95.55 0.6833	93.01 0.6292	98.10 0.7373	- 2.0e-14	good	1.0	4.5
5-OH		ff k (d^{-1})	0.7802 01010	0.7118 0.0891	0.8487 0.1130	- 7.4e-12	good	6.9	6.7
DFP-ASTCA		ff k (d^{-1})	0.2339 0.0668	0.1270 0.0201	0.3407 0.1135	- 0.0041	good	10.4	15

Table A 3 Optimised kinetic parameters for the degradation of florasulam and its metabolite 5-OH in the Kenslow soil

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
Florasulam	SFO (parent only)	M_0 (%) k (d^{-1})	88.23 1.1510	86.43 1.0861	90.04 1.2159	 5.0e-9	good	0.6	3.3
Florasulam	SFO (parent & metaboliltes)	M_0 (%) k (d^{-1})	88.66 1.2195	81.83 0.9983	95.48 1.4408	- 2.4e-8	good	0.57	4.7
5-OH		ff k (d^{-1})	0.8779 0.0394	0.7737 0.0311	0.9821 0.0477	- 1.2e-7	good	17.6	9.2

Table A 4 Optimised kinetic parameters for the degradation of florasulam and its metabolites 5-OH and DFP-ASTCA in the Marcham soil

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
Florasulam	SFO (parent only)	M_0 (%) k (d^{-1})	89.98 0.2487	78.06 0.1618	101.89 0.3357	 2.1e-4	poor	2.8	13.1
Florasulam	FOMC (parent) & SFO (metabolites)	M_0 (%) alpha beta	96.03 1.0468 2.0713	91.61 0.7716 1.1594	100.45 1.3220 2.9832	 1.7e-7 8.5e-5	good	5.0*	3.9
5-OH		ff k (d^{-1})	0.7823 0.0456	0.6886 0.0367	0.8762 0.0544	0.0445 0.0242	good	15.2	9.8
DFP-ASTCA**		ff k (d^{-1})	0.4597 0.0577	0.1564 0.0065	0.7630 0.1088	0.1438 0.0242	good	12.0	17.2

*DT50 SFP= DT_{90} FOMC/3.32

**combined concentrations of DFP-ASTCA and DFP-TSA

Table A 5 Optimised kinetic parameters for the degradation of florasulam and its metabolites 5-OH and DFP-ASTCA in the Speyer soil

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
Florasulam	FOMC (parent) & SFO (metabolites)	M_0 (%) alpha beta	94.55 1.1754 0.9346	90.55 0.8178 0.4750	98.55 1.5330 1.3942	 2.7e-8 9.3e-5	good	1.7*	7.8
5-OH		ff k (d^{-1})	0.9174 0.0494	0.8421 0.0431	0.9926 0.0557	 2.5e-19	good	14.0	8.0
DFP-ASTCA		ff k (d^{-1})	0.2790 0.0088	0.4738 0.0231	0.0482 0.0035	 2.8e-5	good	43.5	10.4

*DT50 SFP= DT_{90} FOMC/3.32

Acceptable kinetic parameters could be obtained for the SFO model for the two metabolites DFP-ASTCA and ASTCA (good visual fits, chi^2 error <15%), in the experiments where DFP-ASTCA was applied as test substance to the Marcham and the Cockney soil and for ASTCA also in the case, where ASTCA was applied as test substance. For deriving kinetic parameters, the measured DFP-ASTCA concentration were again combined with the measured concentrations for DFP-ASTCA.

The kinetic parameters, finally used to describe the degradation DFP-ASTCA and ASTCA in the soils Cuckney and Marcham, are presented in the tables below.

Table A 6 Optimised kinetic parameters for the degradation of the metabolites DFP-ASTCA and ASTCA in the Cuckney soil

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
DFP-ASTCA	SFO	M_0 (%) k (d^{-1})	94.0 0.0432	87.64 0.0337	100.45 0.0526	5.8e-8	good	16.1	8.1
ASTCA*		ff k (d^{-1})	0.7281 0.0057	0.5269 0.0015	0.9292 0.0099	 0.006	good	121.6	10.9
ASTCA**	SFO	M_0 (%)	91.81	89.53	94.10	1.3e-4	good	485	1.7

		k (d^{-1})	0.0014	0.0009	0.0019				

*soil treated with DFP-ASTCA, **soil treated with DFP-ASTCA

Table A 7 Optimised kinetic parameters for the degradation of the metabolites DFP-ASTCA and ASTCA in the Marcham soil

Substance	Kinetic	Parameter	Value	Lower CI	Upper CI	Prop>t	Visual fit	DT_{50} (d)	Chi^2 error (%)
DFP-ASTCA	SFO	M_0 (%) k (d^{-1})	88.21 0.1636	83.21 0.1409	93.21 0.1863	1.7e-41	accep-table	4.2	8.6
ASTCA		ff k (d^{-1})	0.7822 0.0032	0.6947 0.0018	0.8697 0.047	1.1e-4	good	214	4.4
ASTCA	SFO	M_0 (%) k (d^{-1})	76.95 0.0049	66.62 0.002	87.29 0.0078	0.0038	accep-table	141	7.1

The $DT_{50(}$was adjusted to standard moisture (pF2) according to FOCUS guidance. No temperature adjustment was necessary since all studies were performed at 20°C. The moisture correction factors for the soils together with the corrected and uncorrected DT_{50} values and the formation fractions for the metabolites are summarized in the following table.

Table A 8 Kinetic parameters for florasulam and its soil metabolites corrected for standard moisture

Substance	Soil	Moisture correction factor	Uncorrected DT_{50} (d)	Moisture Corrected $DT_{5}0$ (d)	Formation Fraction
Florasulam	Andover	0.897	1.0	0.9	-
	Kenslow	1	0.6	0.6	-
	Marcham	0.839	2.8	2.3	-
	Speyer 2.2	1	1.7	1.7	-
5-OH	Andover	0.897	6.9	6.2	0.7801
	Kenslow	1	17.6	17.6	0.8779
	Marcham	0.839	15.2	12.8	0.7823
	Speyer 2.2	1	14.1	14.1	0.9162
DFP-ASTCA	Andover	0.897	11.3	10.1	0.2803
	Marcham [1)]	0.839	12.0	10.1	0.4597
	Speyer 2.2	1	44.6	44.6	0.4261
	Cuckney[2)]	0.965	16.1	15.5	-
	Marcham [2)]	1	4.2	4.2	-
ASTCA	Cuckney [2)]	0.965	122	118	0.7822
	Cuckney [3)]	0.965	482	465	-
	Marcham[2)]	1	214	214	0.7822
	Marcham[3)]	1	141	141	-

1) florasulam applied to soil, 2) DFP-ASTCA applied to soil, 3) ASTCA applied to soil

Conclusion

The degradation kinetics of florasulam and its major soil metabolites 5-Oh, DFP-ASTCA and ASTCA have been re-evaluated according to FOCUS degradation kinetics, 2006. The resulting DT50 values were normalized to standard moisture conditions (pF2). The normalized DT50 values for florasulam ranged from 0.9 to 2.3 d. The metabolite 5-OH degraded with normalized DT50 values between 6.2 and 17.6 d, the metabolite DFP-ASTCA with normalized DT50 values between 4.2 and 44.6 d and ASTCA with normalized DT50 values between 118 and 465 d.

Comments of evaluator (UBA-Germany)

For degradation of florasulam in the Andover soil, the data point at day 3 was removed as an outlier. The applicant gave no scientific judgment for removing this data point and it is not obvious from the data if the data point at day 1 or day 3 is the outlier. However, the applicant tested the kinetics without both data points and derived the better fit when removing the data point at day 3. As no acceptable fit could be obtained when using all data points, the approach is considered acceptable by the ZRMS.

For degradation of florasulam in the Marcham soil, the SFO model was used although the visual fit was poor. This is not according to FOCUS degradation kinetics, 2006, and is not considered acceptable by the ZRMS since the FOMC model gave a good visual fit and was also used by the applicant when deriving kinetic parameters for the metabolites. Thus, the DT_{50} value of 5 days (DT90 FOMC/3.32) derived from the FOMC model was moisture normalized from the ZRMS and used instead.

Besides, it is not considered valid to use the two DT_{50} values for ASTCA derived with different experimental conditions in the same soils as separate degradation parameters. Thus, the geomean of both DT_{50} values were used by the ZRMS instead.

The resulting final normalized DT_{50} values for florasulam and its metabolites used for exposure assessment is summarized in table below.

Table A 9 Normalized DT_{50} values for florasulam and its soil metabolites used for exposure assessment

Soil	DT_{50} (d) (SFO, at 20°C and pF2)			
	Florasulam	**5-OH**	**DFP-ASTCA**	**ASTCA**
Andover	0.9	6.2	10.1	n.c.
Kenslow	0.6	17.6	n.c.	n.c.
Marcham [1)]	4.2*	12.8	10.1	n.c.
Speyer 2.2	1.7*	14.1	44.6	n.c.
Cuckney	n.a.	n.a.	15.5	234
Marcham [2)]	n.a.	n.a.	4.2	174
1) florasulam applied to soil, 2) DFP-ASTCA applied to soil *DT_{90} FOMC/3.32				

K IIA 7.4.1 Simmonds, 2011

Reference:	KIIA 7.4.1/01
Author:	Simmonds, R.

Report:	Florasulam: Adsorption and Desorption properties of [^{14}C]-Florasulam in Eight Soils.
Report No:	YR/11/005
Date:	2011
Guideline(s):	OECD Guideline for the Testing of Chemicals – Test No. 106: Adsorption – Desorption Using a Batch Equilibrium Method
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The adsorption and desorption of ^{14}C-florasulam was studied in eight soils using the batch equilibrium method. The soils used are shown in Table A 10.

Table A 10: Soil Properties

Soil Reference	**11-013 Calke**	**11-014 South Witham**	**11-015 Longwoods**	**11-016 Kenslow**
Source	UK	UK		UK
Textural classification (USDA)	Sandy Loam	Clay Loam	Sandy Loam	Loam
% Sand (50-2000 µm)	75	39	79	39
% Silt (2-50 µm)	15	26	6	40
% Clay (< 2 µm)	10	25	15	21
pH:				
H_2O (1:1)	5.9	7.6	7.7	5.3
1N KCl (1:1)	5.4	7.1	7.2	4.6
0.01M $CaCl_2$ (1:2)	5.6	7.4	7.4	5.0
Organic Carbon % [a]	3.6	3.8	1.5	3.8
Organic Matter %	6.1	6.6	2.6	6.5
CEC (meq/100g)	12.8	27.8	12.1	11.6
Water holding capacity				
pF 2.0 – WHC 0.1 bar	23.0	28.7	13.8	32.9
pF 2.5 – WHC 0.3 bar	17.0	24.7	9.4	26.7
Moisture content (% w/w)	17.52	15.42	6.73	30.38
Bulk Density (g/mL)	1.13	1.18	1.34	1.02
Soil Reference	**11-017 Lufa 6S**	**11-018 Lufa 5M**	**11-019 RefeSol 06-A**	**11-020 RefeSol 01-A**
Source	Germany	Germany	Germany	Germany
Textural classification (USDA)	Clay	Sandy Loam	Clay Loam	Sandy Loam
%Sand (50-2000 µm)	23	57	31	77
%Silt (2-50 µm)	26	26	33	15
%Clay (< 2 µm)	51	17	36	8
pH:				
H_2O (1:1)	7.3	7.7	7.6	6.0

1N KCl (1:1) 0.01M $CaCl_2$ (1:2)	6.6 7.0	7.3 7.4	6.7 7.2	5.1 5.5
Organic Carbon % [a]	1.8	1.0	1.9	1.0
Organic Matter %	3.0	1.6	3.4	1.7
CEC (meq/100g)	23.7	10.6	15.6	5.5
Water holding capacity pF 2.0 – WHC 0.1 bar pF 2.5 – WHC 0.3 bar	 36.4 28.5	 21.3 12.7	 32.7 27.8	 12.8 14.9
Moisture content (% w/w)	7.85	7.29	11.04	6.13
Bulk Density (Disturbed) (g/mL)	1.27	1.23	1.08	1.28

[a] *Organic matter/1.724*

The tests were performed using eight European agricultural soils that had been sterilised by gamma irradiation to minimize degradation of florasulam during the test. The experiments were conducted in accordance with the OECD Guideline for the Testing of Chemicals No. 106 and to fulfil the requirements of the EU Council directive 91/414/EEC, as amended by Commission directive 95/36/EC Section 7.1.2.

The adsorption phase of the study was carried out at concentrations of 0.25, 0.1, 0.025, 0.01 and 0.0025 mg/L in the dark at 20°C for 24 hours. The equilibration solution used was 0.01M aqueous $CaCl_2$, with a soil solution ratio of 1:1. The desorption phase of the study was carried out for 2 hours. After desorption, soils were extracted with organic solvent then combusted to determine mass balance. Stability of florasulam during the test was determined by HPLC analysis. The adsorption parameters (Kf and 1/n) were calculated using the Freundlich isotherm.

Results and discussions

Florasulam was shown to be stable under the test conditions. Material balance was in the range 99-101% (mean for each soil) for all soils. The amount of florasulam adsorbed ranged from 1.9% to 47%. The calculated adsorption constants (K_F) ranged from 0.03 to 0.47 mL/g (mean 0.17 mL/g). The Freundlich exponents (1/n) ranged from 0.885 to 1.041 (mean 0.960). The adsorption K_{FOC} values ranged from 1.7 to 29.9 mL/g (mean 8.0 mL/g). There was a clear pH dependence with lower sorption in soils with higher pH. The mean K_{FOC} in the five soils with pH ≥7 was 2.7 mL/g whereas the mean K_{FOC} in the three soils with pH <7 was 16.8 mL/g.

Conclusion

There is a clear relationship between sorption of florasulam and soil pH. Therefore, to derive sorption inputs for environmental fate modelling, different mean Freundlich adsorption parameters have been calculated based on soil pH. The results showed weaker sorption in the five soils with pH ≥ 7. The mean sorption parameters based on soil pH are shown in Table A 11.

Table A 11: Freundlich Sorption Data - Florasulam

Soil	% OC	% Clay	pH	Kf (mL/g)	Kfoc (mL/g)	1/n
Calke	3.6	10	5.6	0.30	8.3	0.949
S Witham	3.8	35	7.4*	0.10	2.7	0.983
Longwoods	1.5	15	7.4*	0.03	1.7	0.885
Kenslow	3.8	21	5.0	0.47	12.3	0.914

Lufa 6S	1.8	51	7.0*	0.04	2.5	1.041
Lufa 5M	1.0	17	7.4*	0.03	2.6	0.947
RefSol 06-A	1.9	36	7.2*	0.08	4.2	0.938
RefSol 01-A	1.0	8	5.5	0.30	29.9	1.018
Mean of all soils (Std Dev):				0.17 (0.17)	8.0 (9.6)	0.96 (0.05)
Mean of soils with pH ≥ 7 (Std Dev):				0.06 (0.03)	2.7 (0.9)	0.96 (0.06)
Mean of soils with pH < 7 (Std Dev):				0.36 (0.10)	16.8 (11.5)	0.96 (0.05)

* Soils with pH ≥ 7

Comments of evaluator (UBA-Germany)

Study and endpoints are acceptable and used in evaluation for active substance florasulam.

K IIA 7.4.2/01 Simmonds, 2011

Reference:	KIIA 7.4.2/01
Author:	Simmonds, R.
Report:	Florasulam: Adsorption Properties of [14C]-5-Hydroxyflorasulam in Four Soils.
Report No:	YR/11/006
Date:	2011
Guideline(s):	OECD Guideline for the Testing of Chemicals – Test No. 106: Adsorption – Desorption Using a Batch Equilibrium Method
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The adsorption/desorption of ^{14}C-5-OH-florasulam was studied in four EU soils with a range of properties using the Freundlich batch equilibrium method. The soils used are shown in Table A 12.

Table A 12: Soil Properties

Soil Reference	**11-013 Calke**	**11-014 South Witham**	**11-018 Lufa 5M**	**11-019 RefeSol 06-A**
Source	UK	UK	Germany	Germany
Textural classification (USDA)	Sandy Loam	Clay Loam	Sandy Loam	Clay Loam
% Sand (50-2000 µm)	75	39	57	31
% Silt (2-50 µm)	15	26	26	33
% Clay (< 2 µm)	10	25	17	36
pH:				
H_2O (1:1)	5.9	7.6	7.7	7.6
1N KCl (1:1)	5.4	7.1	7.3	6.7
0.01M $CaCl_2$ (1:2)	5.6	7.4	7.4	7.2
Organic Carbon % [a]	3.6	3.8	1.0	1.9
Organic Matter %	6.1	6.6	1.6	3.4
Cation Exchange Capacity	12.8	27.8	10.6	15.6

(meq/100g)				
Water holding capacity pF 2.0 – WHC 0.1 bar pF 2.5 – WHC 0.3 bar	 23.0 17.0	 28.7 24.7	 21.3 12.7	 32.7 27.8
Moisture content (% w/w)	17.52	15.42	7.29	11.04
Bulk Density (g/mL)	1.13	1.18	1.23	1.08

[a] Organic matter/1.724

The experiments were conducted in accordance with the OECD Guideline for the Testing of Chemicals No. 106 and to fulfil the requirements of the EU Council directive 91/414/EEC, as amended by Commission directive 95/36/EC Section 7.1.2.

Duplicate tubes were prepared for each soil at each of five concentrations. Portions of soil (20 g) were weighed into tubes, calcium chloride solution (*ca* 19 mL) was added and the mixture was shaken for *ca* 16 hours to pre-equilibrate. Aliquots (1 mL) of the appropriate treatment solutions were added to the tubes to give nominal concentrations of 0.25, 0.1, 0.025, 0.01 and 0.0025 mg/L. The soil solutions were shaken for 48 hours on an end-over-end shaker. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC.

Following adsorption, the soils were extracted with acetonitrile:water (80:20 v/v) by shaking for *ca* 30 minutes. After centrifugation, the supernatants were analysed by LSC. The soils were then to air dried prior to homogenisation and combustion.

The adsorption parameters (Kf and 1/n) were calculated using the Freundlich isotherm.

Results and discussions

^{14}C-5-OH-florasulam was determined to be soluble at 0.55 mg/L which is more than twice the highest concentration used in the definitive study. No significant sorption to test vessels was measured with mean recoveries of 101.1% for the glass tubes and 101.7% for the PTFE tubes. PTFE tubes were chosen for use in the remaining phases of the study. The level of background radioactivity detected was negligible in all soils.

^{14}C-5-OH-florasulam exhibited low adsorption to the soil (less than the preferred 20-80% in all three ratios tested for six of the eight soils and <30% for the other two soils). A soil:solution ratio of 1:1 was chosen for all four soils to maximise adsorption.

Adsorption of ^{14}C-5-OH-florasulam reached equilibrium at 48 hours for all soils with little significant increase in adsorption between the 72 hour and the 96 hour samples. A 48 hour adsorption time was selected for the definitive study for all soils.

Following a 96 hour adsorption period, HPLC analysis of the adsorption supernatant and soil extracts showed that >90% AR was 5-OH-florasulam. Stability of the test item was therefore demonstrated for longer than the duration of the definitive phase.

The recoveries were quantitative, with mean recoveries of 97.3-99.5% AR.

The K_F values for 5-OH-florasulam in four soils ranged from 0.06 to 0.29 mL/g. The Freundlich exponents (1/n) ranged from 0.792 to 0.866 (mean 0.839). The K_{FOC} values ranged from 4.1 to 8.0 mL/g (mean 6.1 mL/g). There was no clear relationship between sorption and pH.

Conclusion

Table A 13 summarises the key data for the study.

Table A 13: Freundlich Sorption Data – 5-OH

Soil	K_F (mL/g)	1/n	R^2	K_{FOC} (mL/g)
Calke	0.29	0.832	0.997	8.0
South Witham	0.16	0.792	0.997	4.1
Lufa 5M	0.06	0.864	0.994	6.1
RefeSol 06-A	0.12	0.866	0.999	6.1
Mean	**0.16**	**0.839**	**0.997**	**6.1**

Comments of evaluator (UBA-Germany)

Study and endpoints are acceptable and used in evaluation for the metabolite 5-OH of the active substance florasulam.

KIIA 7.4.2/02 Burgess and Simmonds, 2011

Reference:	KIIA 7.4.2/02
Author:	Burgess, M. and Simmonds, M.
Report:	Florasulam: Adsorption Properties of [^{14}C]-DFP-ASTCA in Four Soils.
Report No:	YR/11/009
Date:	2011
Guideline(s):	OECD Guideline for the Testing of Chemicals – Test No. 106: Adsorption – Desorption Using a Batch Equilibrium Method
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The adsorption of ^{14}C-DFP-ASTCA was studied in four soils with a range of properties using the Freundlich batch equilibrium method. The soils used are shown in Table A 14.

Table A 14: Soil Properties

Soil Reference	11-013 Calke	11-014 South Witham	11-018 Lufa 5M	11-019 RefeSol 06-A
Source	UK	UK	Germany	Germany
Textural classification (USDA)	Sandy Loam	Clay Loam	Sandy Loam	Clay Loam
% Sand (50-2000 µm)	75	39	57	31
% Silt (2-50 µm)	15	26	26	33
% Clay (< 2 µm)	10	25	17	36
pH: H_2O (1:1)	5.9	7.6	7.7	7.6

1N KCl (1:1) 0.01M $CaCl_2$ (1:2)	5.4 5.6	7.1 7.4	7.3 7.4	6.7 7.2
Organic Carbon % [a]	3.6	3.8	1.0	1.9
Organic Matter %	6.1	6.6	1.6	3.4
Cation Exchange Capacity (meq/100g)	12.8	27.8	10.6	15.6
Water holding capacity pF 2.0 – WHC 0.1 bar pF 2.5 – WHC 0.3 bar	 23.0 17.0	 28.7 24.7	 21.3 12.7	 32.7 27.8
Moisture content (% w/w)	17.52	15.42	7.29	11.04
Bulk density (g/mL)	1.13	1.18	1.23	1.08

[a] Organic matter/1.724

The experiments were conducted in accordance with the OECD Guideline for the Testing of Chemicals No. 106 and to fulfil the requirements of the EU Council directive 91/414/EEC, as amended by Commission directive 95/36/EC Section 7.1.2.

Solubility: A solution of ^{14}C-DFP-ASTCA in de-ionised water was prepared at a target concentration of 20 mg/L. The solution was sonicated for 20 minutes and maintained at 20ºC for 24 hours, after which triplicate aliquots were taken for LSC analysis.

Adsorption to test apparatus: A treatment solution at a concentration of 0.01 mg/L was added to glass tubes and to PTFE tubes, which were shaken for 24 hours. Aliquots of the solutions were analysed by LSC.

Background radioactivity in soil: Samples of each soil (*ca* 4g) and calcium chloride solution (*ca* 20 mL) were added to tubes and shaken for 24 hours. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC.

Soil:solution ratio: Samples of each soil (10, 13.3 and 20 g) were mixed with an appropriate volume of calcium chloride solution to give soil:solution ratios of approximately 1:4, 1:3 and 1:2. The tubes were shaken for *ca* 16 hours to pre-equilibrate. A treatment solution of ^{14}C-DFP-ASTCA was added to each tube to give a concentration of 0.25 mg/L. The tubes were shaken for 24 hours, centrifuged and aliquots of the supernatant were analysed by LSC and HPLC.

Stability in 0.01M calcium chloride: A single tube containing 0.01M calcium chloride (*ca* 40 mL) without soil was treated with 1 mL of the treatment solution prepared for the soil: solution ratios determination. The solution was analysed periodically by HPLC.

Determination of adsorption equilibration time: Samples of soil (20 g) were mixed with 0.01 M calcium chloride solution (19 mL) and the tubes were shaken for *ca* 16 hours to pre-equilibrate. A treatment solution of ^{14}C-DFP-ASTCA (1 mL) was added to each tube to give a concentration of 0.5 mg/L. The tubes were shaken using an end-over-end shaker and one tube from each soil type was removed after *ca* 2, 4, 24, 48 and 72 hours. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC. The soils were extracted with acetone: water (1:1 v/v) + 1% formic acid and the extracts were analysed by LSC. Selected adsorption supernatants and solvent extracts were analysed by HPLC.

Definitive Test

All solutions were shaken in the dark at a temperature of 20 ± 1°C.

Duplicate tubes were prepared for each soil at each of five concentrations. Portions of soil (10 g) were weighed into tubes, calcium chloride solution (*ca* 19 mL) was added and the mixture was shaken for *ca* 16 hours to pre-equilibrate. Aliquots (1 mL) of the appropriate treatment solution were added to the tubes to give nominal concentrations of 0.25, 0.1, 0.025, 0.01 and 0.0025 mg/L. The soil solutions were

shaken for 48 hours on an end-over-end shaker. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC.

Following the adsorption phase, the soils were extracted with acetone by shaking for *ca* 20 minutes. After centrifugation, the supernatants were analysed by LSC. The soils were then air dried prior to homogenisation and combustion.

Results and discussions

^{14}C-DFP-ASTCA was determined to be soluble at 19.39 mg/L which is well above the highest concentration used in the definitive study. No significant sorption to test vessels was measured with mean recoveries of 98.7% for the glass tubes and 99.1% for the PTFE tubes. PTFE tubes were chosen for use in the remaining phases of the study. The level of background radioactivity detected was negligible in all soils.

^{14}C-DFP-ASTCA exhibited good adsorption to the soil, with values ranging from 13.7 to 59.2% depending on soil and ratio. A 1:2 soil: solution ratio was adopted for all soils as all had over the 20% minimum adsorption at this ratio.

Adsorption of ^{14}C-DFP-ASTCA reached equilibrium at 24 hours for all soils with little significant change in adsorption between the 24 hour and the 72 hour samples. A 24 hour adsorption time was selected for the definitive study for all soils.

The ^{14}C-DFP-ASTCA was found to be stable in 0.01M calcium chloride for up to 7 days indicating stability for greater than the duration of the definitive phase of the study.

The recoveries of radioactivity from solutions, extracts and soil from the definitive study were quantitative, with mean recoveries of 95-98% AR.

The K_F values for DFP-ASTCA in four soils ranged from 0.45 to 2.36 mL/g. The Freundlich exponents (1/n) ranged from 0.80 to 0.91 (mean 0.86). The K_{FOC} values ranged from 16.6 to 236 mL/g (mean 22 mL/g, excluding Lufa 5M which showed unusually high sorption compared with the other three soils).

Conclusion

Table A 15 summarises the key data for the study.

Table A 15: Freundlich Sorption Data – DFP-ASTCA

Soil	Kf (mL/g)	1/n	R^2	K_{FOC} (mL/g)
Calke	0.88	0.84	0.999	24.4
South Witham	0.63	0.80	0.999	16.6
Lufa 5M	2.36	0.91	0.999	236.2
RefeSol 06-A	0.45	0.88	1.000	23.6
Mean	**1.08**	**0.86**	**0.999**	**75.2**
Mean (excluding Lufa 5M)	**0.65**	**0.84**	**0.999**	**21.5**

Comments of evaluator (UBA-Germany)

Study and endpoints are acceptable and used in evaluation for the metabolite DFP-ASTCA of the active substance florasulam.

KIIA 7.4.2/03 Burgess and Simmonds, 2011

Reference:	KIIA 7.4.2/03
Author:	Burgess, M. and Simmonds, M.
Report:	Florasulam: Adsorption Properties of [^{14}C]-ASTCA in Four Soils.
Report No:	YR/11/008
Date:	2011
Guideline(s):	OECD Guideline for the Testing of Chemicals – Test No. 106: Adsorption – Desorption Using a Batch Equilibrium Method
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The adsorption of ^{14}C-ASTCA, a soil metabolite of florasulam was studied in four EU soils with a range of properties using the Freundlich batch equilibrium method. The soils used are shown in Table A 16.

Table A 16: Soil Properties

Soil Reference	**11-013 Calke**	**11-014 South Witham**	**11-018 Lufa 5M**	**11-019 RefeSol 06-A**
Source	UK	UK	Germany	Germany
Textural classification (USDA)	Sandy Loam	Clay Loam	Sandy Loam	Clay Loam
% Sand (50-2000 µm)	75	39	57	31
% Silt (2-50 µm)	15	26	26	33
% Clay (< 2 µm)	10	25	17	36
pH:				
H_2O (1:1)	5.9	7.6	7.7	7.6
1N KCl (1:1)	5.4	7.1	7.3	6.7
0.01M $CaCl_2$ (1:2)	5.6	7.4	7.4	7.2
Organic Carbon % [a]	3.6	3.8	1.0	1.9
Organic Matter %	6.1	6.6	1.6	3.4
Cation Exchange Capacity (meq/100g)	12.8	27.8	10.6	15.6
Water holding capacity				
pF 2.0 – WHC 0.1 bar	23.0	28.7	21.3	32.7
pF 2.5 – WHC 0.3 bar	17.0	24.7	12.7	27.8
Moisture content (% w/w)	17.52	15.42	7.29	11.04
Bulk Density (g/mL)	1.13	1.18	1.23	1.08

[a] Organic matter/1.724

The experiments were conducted in accordance with the OECD Guideline for the Testing of Chemicals No. 106 and to fulfil the requirements of the EU Council directive 91/414/EEC, as amended by Commission directive 95/36/EC Section 7.1.2.

Solubility: A solution of ^{14}C-ASTCA in de-ionised water was prepared at a target concentration of 20 mg/L. The solution was sonicated for 20 minutes and maintained at 20ºC for 24 hours, after which triplicate aliquots were taken for LSC analysis.

Adsorption to test apparatus: A treatment solution at a concentration of 0.01 mg/L was added to glass tubes and to PTFE tubes, which were shaken for 24 hours. Aliquots of the solutions were analysed by LSC.

Background radioactivity in soil: Samples of each soil (*ca* 4g) and calcium chloride solution (*ca* 20 mL) were added to tubes and shaken for 24 hours. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC.

Soil:solution ratio: Samples of each soil (10, 13.3 and 20 g) were mixed with an appropriate volume of calcium chloride solution to give soil:solution ratios of approximately 1:4, 1:3 and 1:2. The tubes were shaken for *ca* 16 hours to pre-equilibrate. A treatment solution of ^{14}C-ASTCA was added to each tube to give a concentration of 0.25 mg/L. The tubes were shaken for 24 hours, centrifuged and aliquots of the supernatant were analysed by LSC and HPLC.

Stability in 0.01M calcium chloride: A single tube containing 0.01M calcium chloride (*ca* 40 mL) without soil was treated with 1 mL of the treatment solution prepared for the soil: solution ratios determination. The solution was analysed periodically by HPLC.

Determination of adsorption equilibration time: Samples of soil (20 g) were mixed with calcium chloride solution (19 mL) and the tubes were shaken for *ca* 16 hours to pre-equilibrate. A treatment solution of ^{14}C-ASTCA (1 mL) was added to each tube to give a concentration of 0.5 mg/L. The tubes were shaken using an end-over-end shaker and one tube from each soil type was removed after *ca* 2, 4, 24, 48 and 72 hours. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC. The soils were extracted with a series of organic solvents and the extracts were analysed by LSC. Selected adsorption supernatants and solvent extracts were analysed by HPLC.

Definitive Test

All solutions were shaken in the dark at a temperature of 20 ± 1°C.

Duplicate tubes were prepared for each soil at each of five concentrations. Portions of soil (10 g) were weighed into tubes, calcium chloride solution (*ca* 19 mL) was added and the mixture was shaken for *ca* 16 hours to pre-equilibrate. Aliquots (1 mL) of the appropriate treatment solution were added to the tubes to give nominal concentrations of 0.25, 0.1, 0.025, 0.01 and 0.0025 mg/L. The soil solutions were shaken for 48 hours on an end-over-end shaker. The tubes were centrifuged and aliquots of the supernatant were analysed by LSC.

Following the adsorption phase, the soils were extracted with acetone by shaking for *ca* 30 minutes. After centrifugation, the supernatants were analysed by LSC. The soils were then air dried prior to homogenisation and combustion.

Results and discussions

^{14}C-ASTCA was determined to be soluble at 21.66 mg/L which is many times higher than the highest concentration used in the definitive study. No significant sorption to test vessels was measured with mean recoveries of 99.8% for the glass tubes and 99.6% for the PTFE tubes. PTFE tubes were chosen for use in the remaining phases of the study. The level of background radioactivity detected was negligible in all soils.

^{14}C-ASTCA exhibited good adsorption to the soil, with values ranging from 20.5 to 56.6% depending on soil and ratio. A 1:2 soil:solution ratio was adopted for all soils to get as close to the ideal 50% adsorption value as possible.

Adsorption of ^{14}C-ASTCA reached equilibrium at 48 hours in all soils with little significant increase in adsorption between the 48 hour and the 72 hour samples. A 48 hour adsorption time was selected for the definitive study for all soils.

The ^{14}C-ASTCA was found to be stable in 0.01M calcium chloride for up to 5 days indicating stability for greater than the duration of the definitive phase of the study.

The recoveries of radioactivity from solutions, extracts and soil from the definitive study were quantitative, with mean recoveries of 95-99% AR.

The K_F values for ASTCA in four soils ranged from 0.98 to 2.97 mL/g. The Freundlich exponents (1/n) ranged from 0.91 to 0.95 (mean 0.93). The K_{FOC} values ranged from 33.4 to 297 mL/g (mean 41 mL/g, excluding Lufa 5M which showed unusually high sorption compared with the other three soils).

Conclusion

Table A 17 summarises the key data for the study.

Table A 17: Freundlich Sorption Data – ASTCA

Soil	**Kf (mL/g)**	**1/n**	**R^2**	**K_{FOC} (mL/g)**
Calke	1.34	0.91	1.000	37.2
South Witham	1.27	0.94	0.999	33.4
Lufa 5M	2.97	0.95	1.000	297.1
RefeSol 06-A	0.98	0.94	1.000	51.8
Mean	**1.64**	**0.93**	**1.000**	**104.9**
Mean (excluding Lufa 5M)	**1.20**	**0.93**	**1.000**	**40.8**

Comments of evaluator (UBA-Germany)

Study and endpoints are acceptable and used in evaluation for the metabolite ASTCA of the active substance florasulam.

Appendix 3 Table of Intended Uses in Germany (according to BVL 08.03.2012)

PPP (product name/code) BAS 812 00 H
active substance 1 Tritosulfuron
active substance 2 Florasulam

Formulation type: WG
Conc. of as 1: 714 g/kg
Conc. of as 2: 54 g/kg

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	Cereals (barley, oat, rye, triticale, wheat)	F	Annual dicots	Spraying	Spring BBCH 13-39	a) 1 b) 1	a) 0.07 kg/ha	a) as1:50 g/ha as 2: 3.78 g/ha b) see a)	100/400	n.a.	
00-002	DE	Cereals (barley, oat, rye, triticale, wheat)	F	Annual dicots	Spraying	Spring BBCH 13-39	a) 1 b) 1	a) 0.07 kg/ha	a) as1:50 g/ha as 2: 3.78 g/ha b) see a)	100/400	n.a.	used with adjuvant 005008-00 DASH E.C. (1 L/ha)

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product code: **BAS 812 00H**
Active Substance: **Tritosulfuron 714 g/kg**
Florasulam 54 g/kg

Central Zone
Zonal Rapporteur Member State: Austria (AT)

NATIONAL ADDENDUM-Germany

Applicant: **BASF**
Date: **April 2013**

Table of content

Sec 6 ECOTOXICOLOGICAL STUDIES

A full risk assessment according to Uniform Principles for the plant protection product BAS 812 00H in its intended uses in cereals is documented in detail in the core assessment of the plant protection product BAS 812 00H dated from November 2012 performed by Austria.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product BAS 812 00H in Germany according to the uses listed in Appendix 2.

General information on BAS 812 00H can be found in Table 5.1-1of Section 5 of the National addendum Germany (April 2013).

6.1 Proposed use pattern and considered metabolites

Introduction

Full details or the proposed use pattern that will be assessed are shown in Appendix 2 of this document and summarized in the table below. The GAP is covered by the GAPs evaluated in the course of the core assessment by Austria.

Table 6.1-1: Critical use pattern of BAS 812 00H

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)
00-001/00-002*	cereals/ BBCH 13-39	Spraying, field crops	1 x, spring 1. 25 %	Tritosulfuron: 1 x 50 g/ha, Florasulam: 1 x 3.78 g/ha	Tritosulfuron: 1 x 37.5 g/ha, Florasulam: 1 x 2.835 g/ha

* In mixture with adjuvant Dash E.C. (1 L/ha) (= BAS 160 00 S). The adjuvant DASH e.C. is authorized in Germany (ZA 005008-00) It has a a density of 0.93 kg/L.

Consideration of metabolites

Both active substances tritosulfuron and florasulam have several metabolites.

The metabolites of tritosulfuron and florasulam were assessed in the core assessment section 6 and classified as not relevant. Hence not further assessment is required in the national assessment .

For details please refer to national assessment germany, Part B, section5, chapter 5.3.1 and 5.3.2.

6.2 Effects on Birds

The risk assessment for birds for the application of BAS 812 00H was performed by zRMS Austria (see Section 6, chapter III10.1.core assessment , November 2012) based on the latest Guidance of EFSA on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

Acute and long-term risk for birds due to the application of BAS 812 00H was acceptable.

Consequences for authorization:

none

6.3 Effects on Terrestrial Vertebrates Other Than Birds

The risk assessment for mammals for the application of BAS 812 00H was performed by zRMS Austria (see Section 6, chapter III10.3.core assessment , November 2012) based on the latest Guidance of EFSA on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12):1438).

Acute and long-term risk for mammals due to the application of BAS 812 00H was acceptable.

Consequences for authorization:

none

6.4 Effects on Aquatic Organisms

6.4.1 Overview

Results of aquatic risk assessment for the intended for uses of BAS 812 00 H in cereals based on FOCUS Surface Water PEC values is presented in the Core assessment, Part B, Section 6, chapter IIIA 10.2.

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. Hence aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of BAS 812 00 H is outlined in the following chapters.

6.4.2 Toxicity

For the endpoints considered for the risk assessment for aquatic organisms are summarised in the core assessment Part B, section 6, table IIIA 10.2-1.

For the herbicidal active substances tritosulfuron and florasulam effects on alge and aquatic plants are relevant for risk assessment

Table 6.4-1 Most sensitive ecotoxicological endpoints for aquatic species exposed to tritosulfuron, florasulam and BAS 812 00 H (see core assessment chapter IIIA 10.2)

Species	Substance	Exposition Duration System	Results Toxicity (mg/L)	Reference Date author Report No.	ICS-No.
Toxicity to algae					
Pseudokirchneriella subcapitata	tritosulfuron	72 h, s	E_rC_{50} = 1.09 $_n$ E_bC_{50} = 0.23 $_n$	Dohmen, G. P. 1999 19538	44436
Selenastrum capricornutum	florasulam	72 h, s	E_rC_{50} = 0.00894 $_m$ E_bC_{50} = 0.00942 $_m$ NOErC : < 0.000788	Milazzo, D.P.; Humbert, L.M.; Hugo, J.M. and Martin, M.D. 1995 DECO-ES-2946	25425
Pseudokirchneriella subcapitata	BAS 812 00 H	72 h, s	E_rC_{50} > 0.1 $_n$ E_yC_{50} = 0.056 $_n$	Nierzedska, E., 2010[a] BASF DocID 2010/1057062	See core assessment
Pseudokirchneriella subcapitata	BAS 812 00 H +DASH E.C.	72 h, s	E_rC_{50} = 4.82 $_n$ ≙ 0.337 [a] E_yC_{50} = 0.60 $_n$ ≙ 0.043 [a]	Nierzedska, E., 2011b BASF DocID 2011/1000263	See core assessment

Toxicity to aquatic plants					
Lemna gibba	tritosulfuron	7 d, ss	E_rC_{50} = 0.048 $_n$ E_bC_{50} = 0.026 $_n$	Dohmen, G. P. 1999 36422	44459
Lemna gibba	florasulam	14 d, s	EC_{50} = 0.00118 $_n$	Milazzo, D.P.; Kirk, H.D.; Hugo, J.M and Martin, M.D. 1995 ES-2988	39414
Lemna gibba	BAS 812 00 H	7 d, ss	E_rC_{50} = 0.0108 E_yC_{50} = 0.006	Rzodeczko, H., 2010	See core assessment
Lemna gibba	BAS 812 00 H +DASH E.C.	7 d, ss	E_rC_{50} = 0.196 ≙ 0.014 [a] E_yC_{50} = 0.114 ≙ 0.008 [a]	Rzodeczko, H., 2011	See core assessment

f…flow-through, s…static, ss…semi-static, m…mean measured, n…nominal
[a] Endpoint is recalculated to BAS 812 00 H (7% BAS 812 00 H and 93% BAS 160 00 S)

The risk assessment is based on the effects on aquatic plants.

The toxicity of BAS 812 00 H is higher as expected by the content of the active substances tritosulfuron and florasulam. That applies also to the mixuture BAS 812 00 H and DASH E.C.

The risk mitigation measures are therefore based on the risk assessment for the formulation.

6.4.3 Exposure by spraydrift and deposition following volatilisation

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 tritosulfuron and florasulam are < 10^{-5} Pa. Hence the active substances tritosulfuron andflorasulam are regarded as non-volatile. Therefore exposure of surface water by the active substances tritosulfuron and florasulam due to deposition following volatilization do not need to be considered.

Considering the relevant toxicity of tebuconazole following TER-values are calculated for the use of BAS 812 00 H according to use No. 00-001 and 00-002.

Table 6.4-2 TER calculation for use of BAS 812 00 H in cereals according to use No. 00-001

formulation	BAS 812 00 H
use pattern/gap:	00-001 (cereals)
application rate **number of applications / interval**	1 x 70 g/ha 1/-
DissT50 (SFO) in water	not applicable
relevant PEC **if applicable twa-interval**	Actual

scenario/percentile:			Field crops / 90th percentile					
buffer (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	23.33	-	-	23.33	-	-	-
1	2.77	0.6463	-	-	0.6463	0.0646	0.162	0.323
5	0.57	0.1330	-	-	0.1330	0.0133	0.033	0.067
Toxicity: *Lemna gibba* EyC50 = 6 µg/L **TER: 10**								
buffer (m)					TER calculated			
0					0.3	--	--	--
1					9.3	**93**	**37**	**19**
5					**45**			
required labelling: NW 609 (common: 5 m)								

Table 6.4-3 TER calculation for use of BAS 812 00 H in cereals according to use No. 00-002

formulation			BAS 812 00 H + DASH E.C.					
use pattern/gap:			00-001 (cereals)					
application rate			1 x 70 g/ha + 1 L/ha DASH E.C.					
number of applications / interval			1/-					
DissT50 (SFO) in water			not applicable					
relevant PEC if applicable twa-interval			Actual					
scenario/percentile:			Field crops / 90th percentile					
buffer (m)	**PECsw via drift[1)]**		**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	23.33	-	-	23.33	-	-	-
1	2.77	0.6463	-	-	0.6463	0.0646	0.162	0.323
5	0.57	0.1330	-	-	0.1330	0.0133	0.033	0.067
Toxicity: *Lemna gibba* EyC50 = 8 µg/L **TER: 10**								
buffer (m)					TER calculated			
0					0.3	--	--	--
1					**12**	**124**	**50**	**25**
required labelling: none								

[1)] PEC values refer to BAS 812 00 H

Based on the relevant toxicity of the formulation BAS 812 00 H the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to BAS 812 00 H according to

the use No 00-001 achieve only the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2 if appropriate risk mitigation measure (5 m buffer stripe) are applied. For use No. 00-002 no risk mitigation measure are required.

6.4.4 Exposure by surface run-off and drainage

The concentration of the active substances tritosulfuron and florasulam in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.0.

The input parameter are summrised in the following tables (see also National addendum-Germany, Part B, section 5, chapter 5.6.2.

Table 6.4-4 Input parameter for azoxystrobin and tebuconazole for exposure calculation by Exposit 3.0

Parameter	**Tritosulfuron**	**Florasulam**
$K_{foc, Runoff}$	7.4	20
$K_{foc, mobility\ class}$	7.4	2
DT_{50} soil (d)	26.5	6.3
Solubility in water (mg/L)	38.6	6360

For the relevant toxicity data for tritosulfuron and florasulam please refer to chapter 6.4.2.

Table 6.4-5 TER calculation for exposure of surface water by tritosulfuron due to runoff and drainage during application of BAS 812 00 H

Active substance: Tritosulfuron **Use No.:** 00-001 and 00-002 **Application rate:** 50 g a.i./ha / 80 % interception		
Toxicity: *Lemna gibba* EC_{50} = 26 µg/L **TER: 10**		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch (µg/L) (runoff)**	**calculated TER**
0	0.15	177
Exposure by drainage Drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	**calculated TER**
autuum/winter/early spring	0.33	240
Spring/summer	0.11	78
required labelling: none		

Table 6.4-6 TER calculation for exposure of surface water by florasulam due to runoff and drainage during application of BAS 812 00 H

Active substance:	florasulam	
Use No.	00-001 and 00-002	
Application rate:	3.78 g a.i./ha / 25 % interception	
Toxicity: *Lemna gibba* EC50 = 1.18 µg/L **TER: 10**		
Exposure by surface runoff		
vegetated buffer strip (m)	**PECsw in adjacent ditch (µg/L)**	**calculated TER**
0	0.01	118
Exposure by drainage Drainage		
time of application	**PECsw in adjacent ditch (µg/L)**	**calculated TER**
autuum/winter/early spring	0.02	60
Spring/summer	0.01	118
required labelling: none		

The calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by the active substances tritosulfuron an florasulam due to runoff an drainage according to the use No 00-001 and 00-002 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. Risk mitigation measure do not need to be applied.

Consequences for authorization:

For the authorization of the plant protection product BAS 812 00 H following labeling and conditions of use are mandatory:

Required Labelling

NW 262 Florasulam: *Selenastrum capricornutum* NOEC < 0.000788 mg/L

NW 265 BAS 812 00 H: *Lemna gibba* NOErC < 0.0108 mg/L

Conditions for use

BAS 812 00 H NW 468
use No. 00-001 NW 609 (common: 5 m)

6.5 Effects on Bees

All resulting Hazard Quotients for oral and contact exposure are significantly below the trigger of 50 indicating a low risk to honey-bees after the use of BAS 812 00 H according to GAP (see core assessment Part B, section 6, chapter IIIA 10.4).

Consequences for authorization:

none

6.6 Effects on Arthropods Other Than Bees

Standard studies on the toxicity to non-target arthropods have been performed using the formulation BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S. Studies performed with BAS 812 00 H, alone and in combination with BAS 160 00 S, led to similar LR50 values, which are greater than the highest tested treatment rate.

Please erefer to the core assessment Part B, section6, chapter IIIA 10.5 for further details.

Due to the herbicidal activity of the active substances tritosulfuron and florasulam the effects of the formulation BAS 812 00H (also in combination with DASH E:C.) to terrestrial arthropods are significantly lower than to terrestrial plants.

A quantitative risk assessment for terrestrial arthropods is therefore not performed.

TER values are therefore not calculated for the risk assessment

Consequences for authorization:

none

6.7 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.7.1 Exposure assessment

The calculated PEC_{soil} used for German risk assessment for the active substances tritosulfuron and florasulam and for the formulation BAS 812 00 H are summarized in Section 5, Table 5.5-1 of the national addendum for Germany

6.7.2 TER Calculation for Earthworms

The acute and chronic toxicity to earthworms of the active substances tritosulfuron, florasulam and of the formulation BAS 812 00 H as well as the mixture BAS 812 00H and DASH E.C. (BAS 160 00 H) is summarized in the core assessment Table IIIA 10.6-1.

It should be noted that additional chronic reproduction earthworm studies with the metabolites of tritosulfuron 635M02 (Witte, B., 2009a), 635M03 (Friedrich, S., 2009a), 635M04 (Friedrich, S., 2009b) and 635M01 (Witte, B., 2009b) were submitted to refine the long-term risk for earthworms. These studies were conducted with a soil containing only 5% peat. However, these studies are not required for the risk assessment as peer-reviewed chronic endpoints are available. Hence, the studies were not considered for the core risk assessment. Nevertheless, these data were submitted for the other tritosulfuron containing formulations (e.g. ZA 6242) in Germany.

Table 6.7-1 TER calculation for acute and sublethal effects of BAS 812 00 H to earthworms

Plant protection product	BAS 812 00 H / BAS 812 00 H + DASH E.C.		
Use pattern/GAP	00-001 and 00-002 (cereals)		
Acute Effects to Earthworms			
relevant TER:	10		
Active substance/plant protection product	**LC_{50} (mg/kg)**	**PEC (mg/kg)**	**TER**
Tritosulfuron	> 1000	0.100	> 10000
Florasulam	> 1320	0.008	> 16500
BAS 812 00 H	> 1000	0.140	> 7143
BAS 812 00 H (in mixture with DASH E.C. (=BAS 160 00H)	25[1)]	0.140	179
Sublethal effects to Earthworms			
Relevant TER:	**5**		
Active substance/plant protection product	**NOEC (mg/kg)**	**PEC (mg/kg)**	**TER**
BAS 812 00 H	≥ 2.99	0.140	21
BAS 812 00 H (in mixture with DASH E.C. (=BAS 160 00H)	≥ 7 [2)]	0.140	50

[1)] The acute and chronic toxicity to earthworms of the formulation BAS 812 00 H in mixture with DASH E.C. was investigated (Witte 2010, BASF DocID 2010/1075820, see core assessment chapter IIIA 10.6.2). The test item was mixed at a ratio of 7w% BAS 812 00 H : 93 w% BAS 160 00 S (DASH E.C.). For the mixture a LC50 of 357.4 mg/kg soil dw was determined. Considering a content of 7 w% for BAS 812 00H in the mixture the LC50 for BAS 812 00 H is 25 mg/kg soil dw.

[2)] For chronic effects of the mixture BAS 812 00 H and DASH E.C. a NOC of ≥ 100 mg/ kg soil dw was determined (Witte 2010, BASF DocID 2010/1075817, see core assessment chapter IIIA 10.6.3). The test item was mixed at a ratio of 7w% BAS 812 00 H : 93 w% BAS 160 00 S (DASH E.C.) so that for BAS 812 00 H a NOEC of ≥ 7 was calculated.

For the active substances tritosulfuron and florasulam an for the formulation BAS 812 00H (also in mixture with DASH E.C.) the acute TER values are above the trigger of 10 indicating an acceptable risk for earthworms. For the formulation also in mixture with DASH E.C. the chronic TER value is > 5 indicating an acceptable long-term risk for earthworms due to the application of BAS 821 00 H according to the use No. 00-001 and 00-002.

The risk assessment for the soil metabolites was performed in the core assessment and showed an acceptable risk for the soil metabolites of tritosulfuron and florasulam.

Consequences for authorization:

none

6.7.3 TER calculation for other non-target macro-organisms

The risk assessment was performed by zRMS for the soil metabolites of tritosulfuron because the the $DT_{90\ lab}$ values of the tritosulfuron metabolites 635M02, 635M03, 635M01 and 635M04 are above 365 days.
Studies on the toxicity of the metabolites to *Folsomia candida* were submitted as no toxicity values are avaible from EU assessment. The studies have been submitted also inGermany for other tritosulfuron containing formulations (e.g. ZA 6242).

The long-term TER values calculated for the relevant metabolites of tritosulfuron 635M02, 635M03, 635M01 and 635M04 were above the relevant trigger of 5, indicating low chronic risk for collembolans following the use of BAS 812 00 H according to the proposed uses. (see core assessment chapter IIIA 10.6.6)

Consequences for authorization:

none

6.7.4 Effects on organic matter breakdown

Please refer to the core assessment chapter IIIA 10.6.7.

Risk assessment was performed based on a field study with the solo-formulation BAS 635 00 H (containing nominally 71.4% tritosulfuron) for the tritosulfuron metabolites 635M02, 635M03 and 635M01 (DT90 field > 365 d) although the toxicity studies conducted on earthworms, collembolans and soil microorganisms showed low toxicity.

Consequences for authorization:

none

6.8 Effects on Soil Microbial Activity

Please refer to the core assessment chapter IIIA 10.7.

Based on all available data, the use of BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH EC), poses no unacceptable risk to non-target soil micro-organisms at the proposed use rates.

Consequences for authorization:

none

6.9 Effects on Non-Target Plants

Toxicity

Please refer to the core assessment chapter IIIA 10.8.1.

The results of the toxicity of the formulation BAS 812 00 H are summarized in the table below and are derived from studies with 10 plant species.

Table 6.9-1: Ecotoxicological endpoints for non-target plants following exposure to BAS 812 00 H

Species	**Substance**	**Exposition Duration System**	**Results Toxicity**	**Reference Author Date Report No.**
Green cabbage	BAS 812 00 H	Seedling emergence	ER_{50}= 4.39 g/ha	Minarski,A. Marqaurdt J.
sunflower	BAS 812 00 H	Vegetative vigour	ER_{50}= 2.93 g/ha	
Oilseed rape	BAS 812 00 H + DASH E.C.	Seedling emergence	ER_{50} = 2.65 g/ha*	
sunflower	BAS 812 00 H + DASH E.C.	Vegetative vigour	ER_{50} = 1.3 g/ha*	

* endpoint is based on BAS 812 00 H alone.

The risk assessment is based on the results oft he vegetative vigour tests.

A HC5 value was calculated from the results of the seedling emergence test with BAS 812 00 H as well as from the seedling emergence and vegetative vigour test with BAS 812 00 H + DASH E.C., respectively.

The use of a HC5 value in combination with a safety factor of 1 is not applicable. However, for the deterministic approach the safety factor can reduced from 10 to 5 beacause 10 plant specie were tested.

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.

Risk assessment

The risk assessment results are summarized in the tables below.

Table 6.9-2 Risk assessment for terrestrial non-target plants exposed to BAS 812 00 H (use No. 00-001)

active substance/formulation			BAS 812 00 H					
use pattern/gap:			00-001					
application rate/number of applications / interval			1 x 70 g/ha					
MAF			1					
scenario/percentile:			Agriculture /90.					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (g/ha) depending on application technique (drift reduction)			
	(%)	(g/ha)	(%)	(g/ha)	common	90% red.	75% red.	50% red.
1	2.77	1.94	--	--	1.94	0.194	0.485	0.97
5	0.57	0.40	--	--	0.40	0.04	0.1	0.2
relevant toxiciy:	**ER50 = 2.93 g/ha (sunflower)**							
relevant TER:	**5**							
Distance (m)					TER-values (calculated)			
1					1.5	15.1	**6.0**	3.0
5					7.3			
required labelling:	**NT 102**							

active substance/formulation			BAS 812 00 H + DASH E.C.					
use pattern/gap:			00-002					
application rate/number of applications / interval			1 x 70 g/ha for BAS 812 00 H + 1 L/ha DASH E.C.					
MAF			1					
scenario/percentile:			Agriculture /90.					
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (g/ha) depending on application technique (drift reduction)			
	(%)	(g/ha)	(%)	(g/ha)	common	90% red.	75% red.	50% red.
1	2.77	1.94	--	--	1.94	0.194	0.485	0.97
5	0.57	0.40	--	--	0.40	0.04	0.1	0.2
relevant toxiciy:	**ER50 = 1.3 g/ha (sunflower)**							
relevant TER:	**5**							
Distance (m)					TER-values (calculated)			
1					0.7	**6.7**	2.7	1.3
5					3.3	32.6	13.0	6.5
required labelling:	**NT 103**							

Based on the predicted rates of BAS 812 00 H in off-field areas, the TER values describing the risk for non-target plants following exposure to BAS 812 00 H according to use No. 00-001 and 00-002 achieve

only 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 if appropriate risk mitigation measures are applied. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of BAS 812 00 H in cereals according to use No. 00-001 and 00-002 if appropriate risk mitigation is applied.

Consequences for authorization:

For authorization of BAS 812 00 H following labeling and conditions of use are mandatory:

Use No. 00-001: NT 102

Use No. 00-002: NT 103

Appendix 1 List of data submitted in support of the evaluation

No additional data for the assessment submitted or used.

Appendix 2 Table of Intended Uses justification and GAP tables

PPP (product name/code) BAS 812 00 H
active substance 1 Tritosulfuron
active substance 2 Florasulam

Formulation type: WG
Conc. of as 1: 714 g/kg
Conc. of as 2: 54 g/kg

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	Cereals (barley, oat, rye, triticale, wheat)	F	Annual dicots	Spraying	Spring BBCH 13-39	a) 1 b) 1	a) 0.07 kg/ha	a) as1:50 g/ha as 2: 3.78 g/ha b) see a)	100/400	n.a.	
00-002	DE	Cereals (barley, oat, rye, triticale, wheat)	F	Annual dicots	Spraying	Spring BBCH 13-39	a) 1 b) 1	a) 0.07 kg/ha	a) as1:50 g/ha as 2: 3.78 g/ha b) see a)	100/400	n.a.	used with adjuvant 005008-00 DASH E.C. (1 L/ha)

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Biathlon Super (BAS 812 00 H)

Reg. No.: 007555-00/00.

Active Substance: Tritosulfuron 714 g/kg

Florasulam 54 g/kg

Central Zone

Zonal Rapporteur Member State: Austria

National Addendum Germany

Applicant: BASF

Date: November2012

Evaluator: Julius Kühn-Institut

Date: 2013-04-09

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IIIA1 6 Efficacy Data and Information on the Plant Protection Product

General information

Refer to Registration Report from November 2012 for further information.

Information on the intended uses

There is only one use for winter and spring cereals. Because of different selectivity and a different competition level, each use should be splitted in one for winter and one for spring cereals. Instead of crop groups the single crops should be listed (see below).

Use No.	**007555-00/00-001**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	cereals (barley, oats, rye, triticale, wheat) (NNNGG)
Crop stage(s) (BBCH)	13 to 39
Pest(s)/target(s)/aim(s)	dicotyledonous weeds (TTTDD)
Area of use	Outdoors
Time of treatment	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	70 g/ha in 100 to 400 l water/ha
---	---
Use No.	**007555-00/00-002**
Area of application	Agriculture (field crops)
Crop(s)/object(s)	cereals (barley, oats, rye, triticale, wheat) (NNNGG)
Crop stage(s) (BBCH)	13 to 39
Pest(s)/target(s)/aim(s)	dicotyledonous weeds (TTTDD)
Area of use	Outdoors
Time of treatment	After emergence, spring
Max. number of treatments for the use	1
Max. number of treatments per crop or season	1
Application technique/type of treatment	spraying
Dose rate(s) in amount of water to be used	70 g/ha in 100 to 400 l water/ha
App. partner	as mixture with: 005008-00 Dash E. C. (1 l/ha)

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Refer to Registration Report from November 2012 for further information.

IIIA1 6.1.2 Minimum effective dose tests

Refer to Registration Report from November 2012 for further information.

IIIA1 6.1.3 Efficacy tests

According to the application form, the use of Biathlon Super is intended for the control of “dicotyledonous weeds”. For some annual and perennial dicotyledonous weeds, which are described on the label as being controlled well, only a few or no efficacy results have been submitted, which entails that a reliable evaluation of these weed species is not possible. Therefore the scope of weeds should be restricted to TTTDS, CONAR and CIRAR.
Therefore and due to the fact that some cereals respond sensitively to sulfonylureas, the restriction WH9161 (The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.) is proposed.
If long term control of perennial weeds is claimed, assessments in the following year are required (see EPPO PP1/93). Due to the missing results, a restriction (WW742: The product has no sustainable effect in perennial weeds.) should be addressed on the label.

For further information refer to Registration Report from November 2012.

IIIA1 6.1.4 Effects on yield and quality

Refer to Registration Report from November 2012 for further information.

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Refer to Registration Report from November 2012 for further information.

IIIA1 6.1.4.2 Effects on the processing procedure

Refer to Registration Report from November 2012 for further information.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2 Adverse effects

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.1 Phytotoxicity to host crop

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.2 Adverse effects on health of host animals

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.3 Adverse effects on site of application

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

Effects on relevant beneficial arthropods

The herbicide Biathlon Super (50 g/kg tritosulfuron + 3.8 g/kg florasulam, WG) has been proposed for one post emergence treatment per crop and season in cereals at an application rate of 0.07 kg/ha.

Laboratory tests with the two indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* have been performed using the formulation BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH E.C.). The test product had no lethal effects up to the proposed field rate (Table 6.2.4-1). Sublethal effects were not examined.

Tab. 6.2.4-1: The effects of BAS 812 00 H (724 g/kg tritosulfuron + 56.6 g/kg florasulam, EC) + BAS 160 00 S (DASH E.C.) (Oleic acid) on beneficial arthropods

Species (Exposed Stage)	Substrate	Rate Product [kg/ha]	Rate Adjuvant [L/ha]	Corrected Mortality [%]	Reference
T. pyri (PN)	Glass	0.00875		1	10 10 48 021 A
		0.0175		1	
		0.035		2.1	
		0.07		0	
		0.14		0	
		0.00875	0.125	1	10 10 48 046 A
		0.0175	0.25	2	
		0.035	0.5	2	
		0.07	1	5.1	
		0.14	2	31.6	
A. rhopalosiphi (A)	Glass	0.00875		0	10 10 48 020 A
		0.0175		2.5	
		0.035		0	
		0.07		0	
		0.14		0	
		0.00875	0.125	0	10 10 48 045 A
		0.0175	0.25	-2.6	
		0.035	0.5	-2.6	
		0.07	1	0	
		0.14	2	0	

PN = protonymph, A = adult

Conclusion

On the basis of the results of laboratory tests with the two indicator species, the test product proved to have no lethal effects on the predatory mite *Typhlodromus pyri* and the parasitic wasp *Aphidius rhopalosiphi*. However, Biathlon Super cannot be classified as not harmful, because results on sublethal effects are missing.

Effects on soil quality
Effects on soil macro-organisms being used as indicators of soil quality

Summary

For the active substances tritosulfuron and florasulam and their relevant metabolites EU agreed endpoints and endpoints from new, supplementary studies are used for the risk assessment on earthworms and other non-target macro-organisms.

Standard studies on the acute toxicity to earthworms have been performed using the formulation BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH EC), since in several countries an application with the adjuvant BAS 160 00 S (DASH EC) is foreseen.

TER values were derived from EU agreed endpoints and exposure data regarding a thickness of the soil layer of 2.5 cm in accordance with national guidance.

Table 6.2.4-2: Toxicity/exposure ratios for earthworms and other soil non-target macro-organisms

Test substance	Use pattern	Species	Test type	Endpoint [mg/kg dry soil]	PEC [mg/kg dry soil]	TER	TER risk assessment trigger
tritosulfuron	1 x 0.05 kg tritosulfuron/ha	*Eisenia fetida*	14-d acute toxicity	LC50 > 1000	0.100 1)	> 10000	10
BH635-2 (635M02)	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 1000	0.012 1)	> 83333	10
BH635-2 (635M02)	n.a.	*Eisenia fetida*	56-d reproduction test	NOEC ≥ 0.3	0.012 1) 0.012 2)	≥ 25 ≥ 25 3)	5
BH635-2 (635M02)	n.a.	*Folsomia candida*	28-d reproduction test	NOEC ≥ 100	0.012 1) 0.012 2)	≥ 8333 ≥ 8333 3)	5
BH635-3 (635M03)	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 1000	0.011 1)	> 90909	10
BH635-3 (635M03)	n.a.	*Eisenia fetida*	56-d reproduction test	NOEC ≥ 0.3	0.011 1) 0.012 2)	≥ 27 ≥ 25 3)	5
BH635-3 (635M03)	n.a.	*Folsomia candida*	28-d reproduction test	NOEC ≥ 100	0.011 1) 0.012 2)	≥ 9091 ≥ 8333 3)	5
BH635-4 (635M01)	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 1000	0.044 1)	> 22727	10
BH635-4 (635M01)	n.a.	*Eisenia fetida*	56-d reproduction test	NOEC ≥ 0.6	0.044 1) 0.045 2)	≥ 14 ≥ 13 3)	5
BH635-4 (635M01)	n.a.	*Folsomia candida*	28-d reproduction test	NOEC ≥ 107.5	0.044 1) 0.045 2)	≥ 2443 ≥ 2389 3)	5
BH635-5 (635M04)	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 = 671	0.003 1)	223667	10
BH635-5 (635M04)	n.a.	*Eisenia fetida*	56-d reproduction test	NOEC ≥ 0.3	0.003 1) 0.003 2)	≥ 100 ≥ 100 3)	5

Test sub-stance	Use pattern	Species	Test type	Endpoint [mg/kg dry soil]	PEC [mg/kg dry soil]	TER	TER risk assessment trigger
BH635-5 (635M04)	n.a.	*Folsomia candida*	28-d repro-duction test	NOEC ≥ 100	0.003 1) 0.003 2)	≥ 33333 ≥ 33333 3)	5
florasulam	1 x 0.00375 kg florasulam/ha	*Eisenia fetida*	14-d acute toxicity	LC50 > 1320	0.008 1)	> 165000	10
5-OH-florasulam	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 1120	0.005 1)	> 224000	10
DFP-ASTCA	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 0.1 mg/kg dry soil	0.001 1)	> 100	10
ASTCA	n.a.	*Eisenia fetida*	14-d acute toxicity	LC50 > 100 mg/kg dry soil	0.002 1)	> 50000	10
ASTCA	n.a.	*Eisenia fetida*	56-d repro-duction test	NOEC ≥ 1.0	0.002 1) 0.002 2)	≥ 500 ≥ 500 3)	5
BAS 812 0 0 H	1 x 0.05 kg tritosulfuron/ha	*Eisenia fetida*	14-d acute toxicity	LC50 > 714 4)	0.100 1)	> 7140	10
	1 x 0.003755 kg florasulam/ha			LC50 > 54 4)	0.008 1)	> 6750	
BAS 812 0 0 H*	1 x 0.05 kg tritosulfuron/ha	*Eisenia fetida*	14-d acute toxicity	LC50 = 17.86 4)	0.100 1)	179	10
	1 x 0.00375 kg florasulam/ha			LC50 = 1.35 4)	0.008 1)	169	
BAS 812 0 0 H	1 x 0.05 kg tritosulfuron/ha	*Eisenia fetida*	56-d chronic toxicity	NOEC ≥ 2.13 4)	0.100 1)	≥ 21	5
	1 x 0.003755 kg florasulam/ha			NOEC ≥ 0.16 4)	0.008 1)	≥ 20	
BAS 812 0 0 H*	1 x 0.05 kg tritosulfuron/ha	*Eisenia fetida*	56-d chronic toxicity	NOEC ≥ 5.0 4)	0.100 1)	≥ 150	5
	1 x 0.00375 kg florasulam/ha			NOEC ≥ 0.38 4)	0.008 1)	≥ 48	

* Study was conducted with BAS 812 00 H + BAS 160 00 S (DASH EC).
1) PECmax for a soil layer of 2.5 cm.
2) PECaccu for a soil layer of 2.5 cm.
3) Long-term TER value following multi-year use of BAS 812 00 H.
4) Calculated from the results of the study with the formulated product taking into account the nominal content of the active substances (71.4% tritosulfuron and 5.4% florasulam).

Tritosulfuron, florasulam and the florasulam metabolites 5-OH-florasulam and DFP-ASTCA were tested in acute toxicity studies on earthworms. The tritosulfuron metabolites BH635-2 (635M02), BH635-3 (635M03), BH635-4 (635M01) and BH635-5 (635M04) and the florasulam metabolite ASTCA were tested in acute and chronic studies on earthworms. In the risk assessment, all TER values for a soil layer of 2.5 cm (specific national requirement for Germany) exceed the Commission Regulation (EU) 546/2011 trigger of 10 for acute exposure and the trigger of 5 for chronic exposure.

Acute and chronic studies on earthworms were performed with BAS 812 00 H, alone and in combination with the adjuvant BAS 160 00 S (DASH EC). In the risk assessment the TER values for a soil layer of 2.5 cm exceed the Commission Regulation (EU) 546/2011 trigger of 10 for acute exposure and 5 for chronic exposure indicating low risk to natural earthworm populations following the use of BAS 812 00 H.

Chronic studies on collembolans were performed with the metabolites BH635-2 (635M02), BH635-3 (635M03), BH635-4 (635M01) and BH635-5 (635M04). The calculated TER values for a soil layer of 2.5 cm exceed the Commission Regulation (EU) 546/2011 trigger of 5 indicating low risk to collembolans.

In a litterbag study with a solo-formulation of tritosulfuron it was demonstrated that the organic matter breakdown process will be at low risk following exposure scenarios covering the intended uses of BAS 812 00 H.

Overall conclusion:

It is concluded that the proposed use of BAS 812 00 H will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, if applied according to the recommended use pattern.

Instructions and information: None

Effects on soil quality
Effects on soil micro-organisms being used as indicators of soil quality

Effects on soil non-target micro-organisms exposed to Biathlon Super

Table 6.2.4-3: Ecotoxicological endpoints for soil micro-organisms

Active substance	**Test design[1]**	**EU-agreed endpoints**	**Reference**
BAS 812 00 H[2]	C	No significant effect > 25% at day 28 at 0.09 mg and at 0.93 mg product/kg soil dw. (corresponding 0.7 kg/ha)	Schulz, L.. (2011); Final report 10 10 48 031 C
	N		
Tritosulfuron	C	No significant effect > 25% at day 28 at 0.333 mg a.s./kg soil dw.	Schulz, L. (2010) 1144222
	N		Schulz, L. (2010) 1144218
BH635-2 (635M02)	C	No significant effect > 25% at day 28 at 0.336 mg a.s./kg soil dw.	Koelzer, 2004/1004410 + 2004/1020884
	N	No significant effect > 25% at day 28 at 0.330 mg a.s./kg soil dw.	Krieg, 1998/11161
BH635-3 (635M03)	C	No significant effect > 25% at day 28	Koelzer,

		at 0.333 mg a.s./kg soil dw.	2004/1004411
	N	No significant effect > 25% at day 28 at 0.330 mg a.s./kg soil dw.	Krieg, 1999/10041
BH635-4 (635M01)	C	No significant effect > 25% at day 28 at 0.342 mg a.s./kg soil dw.	Koelzer, 2004/1004412
	N	No significant effect > 25% at day 28 at 0.330 mg a.s./kg soil dw.	Krieg, 1999/10042
BH635-5 (635M04)	C	No significant effect > 25% at day 28 at 0.330 mg a.s./kg soil dw.	Koelzer, 2004/1004413
	N		
Florasulam	C	No significant effect > 25% at day 28 at 0.050 mg a.s./kg soil dw.	Krieg, 1999/10043
	N		
ASTCA	C	No significant effect > 25% at day 28 at 1.00 mg a.s./kg soil dw.	Feil, U. (2008) Letter of Access (see Part A, chapter 1.5)
	N		

[1] C = Carbon mineralization, N = Nitrogen transformation.
2 Studies were performed with BAS 812 01 H + BAS 160 00 S (DASH EC).

Risk assessment for soil microflora functions

Table 6.2.4-4: Risk assessment for soil microflora functions

Test substance	**NOEC [mg a.s./kg d.w.soil] (< 25% effect at 28 d)**	**Maximum PEC_{soil} [mg/kg]**	**MoS[**]**
Tritosulfuron	0.66	0.050	13.2
Florasulam	0,05	0.004	12.5
BH635-2 (635M02)	0.336 (Carbon mineralization) 0.330 (Nitrogen-transformation)	0.006	56 55
BH635-3 (635M03)	0.333 (Carbon mineralization) 0.330 (Nitrogen- transformation)	0.005	66.6 66
BH635-4 (635M01)	0.342 (Carbon mineralization) 0.330 (Nitrogen- transformation)	0.022	15.5 15
BH635-5 (635M04)	0.330	0.001	330
ASTCA	1.00	0.001	1000

[**] Margin of Safety.

Biathlon Super and its main metabolites in soil has no significant effect of $\geq \pm$ 25% compared to the control on soil microbial respiration and on nitrification at 0.93 mg product/kg dry soil, corresponding to 0.66 mg tritosulfuron/kg dry soil and 0.05 mg florasulam/kg dry soil. This is much higher than the maximum PEC_{soil} of 0.050 mg a.s./kg for tritosulfuron and of 0.004 mg a.s./kg for florasulam following the worst-case application in maize.

An acceptable risk to soil microbial activity can be concluded for the proposed use of Biathlon Super.

Biathlon Super and its main metabolites in soil has no significant effect of $\geq$ ± 25% compared to the control on soil microbial respiration and on nitrification at 0.93 mg product/kg dry soil, corresponding to 0.66 mg tritosulfuron/kg dry soil and 0.05 mg florasulam/kg dry soil. This is much higher than the maximum PEC_{soil} of 0.050 mg a.s./kg for tritosulfuron and of 0.004 mg a.s./kg for florasulam following the worst-case application in maize.

An acceptable risk to soil microbial activity can be concluded for the proposed use of Biathlon Super.

Summary and Assessment of data according to points 6.1 to 6.5

On the basis of the results of laboratory tests with the two indicator species, the test product proved to have no lethal effects on the predatory mite *Typhlodromus pyri* and the parasitic wasp *Aphidius rhopalosiphi.* However, Biathlon Super cannot be classified as not harmful, because results on sublethal effects are missing.

Overall conclusion with respect to effects on soil quality

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

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.6 Impact on succeeding crops

Concerning the risk for succeeding crops, the comparison of EC_{10} values for the most sensitive crop (winter oilseed rape) with the PEC values revealed a theoretical risk of damage for time intervals < 90 days and only shallow soil cultivation.
Due to the theoretical assessment and the biological properties of the active substances Tritosulfuron and Florasulam, the restrictions WP710 (Damage is possible to replanted dicotyledonous intermediate crops and winter rape.) and WH960 (The risk of replanting has to be indicated on the package and in the instructions of use. Particularly the endangered succeeding crops have to be declared and measures for a risk management have to be described.) are proposed.

For further information refer to Registration Report from November 2012.

IIIA1 6.2.7 Impact on other plants including adjacent crops

Refer to Registration Report from November 2012 for further information.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

Due to a high risk of resistance, the restriction WH951 (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.

For further information refer to Registration Report from November 2012.

IIIA1 6.3 Economics

For further information refer to Registration Report from November 2012.

IIIA1 6.4 Benefits

For further information refer to Registration Report from November 2012.

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

For further information refer to Registration Report from November 2012.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

For further information refer to Registration Report from November 2012.

IIIA1 6.7 List of test facilities including the corresponding certificates

For further information refer to Registration Report from November 2012.

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

No additional studies submitted

Appendix 2: GAP table

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES
(Application on agricultural and horticultural crops)

Federal Office of Consumer Protection and Food Safety
Department 2 - Plant Protection Product - Unit 207
D-38104 Braunschweig, Messeweg 11 - 12

Date : 2013-MÄR-15

Country : Federal Republic of Germany

Pesticide(s) (common name(s)) : **Florasulam** Tritosulfuron
EEC, CIPAC and CCPR No(s). : , 0616 , , 0725 ,
Trade name(s) : **Biathlon Super (007555-00)**
Main uses e.g. insecticide, fungicide : Herbicide
Applicant : BASF SE

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 a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Cereals (barley HORSS, oats AVESS, rye SECCE , triticale TTTLI, wheat TRZSS)	F	Dicotyledonous weeds TTTDD	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	a) 0.004 b) 0.004	100 - 400	XF	
002	DE	Cereals (barley HORSS, oats AVESS, rye SECCE , triticale TTTLI, wheat TRZSS)	F	Dicotyledonous weeds TTTDD	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	a) 0.004 b) 0.004	100 - 400	XF	As mixture with 005008-00 Dash EC a) 1.0 L/ha b) 1.0 L/ha

Pesticide(s) (common name(s)) : **Tritosulfuron** Florasulam
EEC, CIPAC and CCPR No(s). : , 0725 , , 0616 ,
Trade name(s) : **Biathlon Super (007555-00)**
Main uses e.g. insecticide, fungicide : Herbicide
Applicant : BASF SE

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 a.s./ha a) max. rate per appl. [b) max. total rate per crop/season]	Water L/ha min / max		
001	DE	Cereals (barley HORSS, oats AVESS, rye SECCE , triticale TTTLI, wheat TRZSS)	F	Dicotyledonous weeds TTTDD	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	a) 0.05 b) 0.05	100 - 400	XF	
002	DE	Cereals (barley HORSS, oats AVESS, rye SECCE , triticale TTTLI, wheat TRZSS)	F	Dicotyledonous weeds TTTDD	spraying	13 - 39; After emergence, spring	a) 1 b) 1	a) 0.070 b) 0.070	a) 0.05 b) 0.05	100 - 400	XF	As mixture with 005008-00 Dash EC a) 1.0 L/ha b) 1.0 L/ha