REGISTRATION REPORT
Part A

Risk Management

Product name: BONTIMA

Product code: A15840C

Active Substance(s): Isopyrazam 62.5 g/L
Cyprodinil 187.5 g/L

COUNTRY: Germany

Central Zone
Zonal Rapporteur Member State: UK

NATIONAL ASSESSMENT

Applicant: Syngenta Agro GmbH

Date: 1 September 2017

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PART A – Risk Management

This document describes the acceptable use conditions required for the re-registration in Germany of Bontima (A15840C) containing:

□□62.5 g/L isopyrazam which is approved under Regulation (EC) 1107/2009, as specified in Commission Implementing Regulation (EU) No. 1037/2012 of 7 November 2012, amending the Annex to Commission Implementing Regulation No. 540/2011.

□□187.5 g/L cyprodinil which was included into Annex I of Council Directive 91/414/EEC (Commission Directive 2006/64/CE of 18 July 2006). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addenda for Germany. The information, data and assessments provided in Registration Report, Parts B include 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 A15840C where those data have not been considered in the EU review process. Otherwise assessments for the safe use of A15840C have been made using endpoints agreed in the EU review of isopyrazam or cyprodinil.

This document describes the specific conditions of use and labelling required for Germany for the re-registration of Bontima (A15840C).

Appendix 1: see Appendix 4

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

Appendix 3 of this document provides a List of Code Numbers.

Appendix 4 of this document provides a copy of the final product authorisation for Germany.

1 Details of the application

1.1 Application background

This application was submitted by Syngenta Agro on 05 November 2013.

The application was for approval of Bontima (A15840C), an emulsifiable concentrate containing 62.5 g/L isopyrazam and 187.5 g/L cyprodinil for use as a foliar fungicide on barley.

1.2 Annex I inclusion

Isopyrazam
Isopyrazam is an approved active substance under Regulation (EC) 1107/2009, as specified in Commission Implementing Regulation (EU) No. 1037/2012 of 7 November 2012, amending the Annex to Commission Implementing Regulation No. 540/2011.

For the implementation of the uniform principles according to Commission Regulation (EU) No. 546/2011 (which adopts Annex VI to Directive 91/414/EEC into Regulation (EC) 1107/2009), the conclusions of the review report on isopyrazam (on EFSA Journal (2012) 10(3), 2600), and in particular Appendices I and II thereof, as finalised in the Standing Committee the Food Chain and Animal Health on 28 September 2012, shall be taken into account.

The Commission Implementing Regulation (EU) No. 1037/2012 provides specific provisions for isopyrazam which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

In this overall assessment Member States shall pay particular attention to:

- the risk to aquatic organisms;
- the risk to earthworms if the substance is applied in the framework of no cultivation/minimum cultivation practices;
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.

These concerns were all addressed in the submission.

Cyprodinil
Cyprodinil was included on Annex I of Directive 91/414/EEC on 1 May 2007 under Inclusion Directive **2006/64/CE**. This active substance is currently approved under Regulation (EC) No. 1107/2009 (repealing Commission Directive 91/414/EEC); Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyprodinil (EFSA Scientific Report (2005) 51, 1-78), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 4 April 2006, shall be taken into account.

The Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011 provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

In this overall assessment Member States must pay particular attention to:

- the safety of operators and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, such as buffer zones.

These specific concerns are addressed within the current submission.

1.3 Regulatory approach

To obtain re-authorisation the product Bontima (A15840C) in Germany must (where appropriate) meet the conditions of EU inclusion and be supported by dossiers satisfying the requirements of Commission Regulation (EU) Nos. 544/2011, 545/2011 and 546/2011, which adopt the requirements of Annex II and Annex III, and the Uniform Principles (Annex VI) to Council Directive 91/414/EEC.

This application was submitted in order to allow the re-registration of an already approved product in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Bontima, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7, core assessment.

1.5 Letters of Access

Data access has been proven. The applicant provided own data for the product and the active ingredient. There is no need to use studies of third parties.

2 Details of the authorisation

2.1 Product identity

Product Name	A15840C Bontima
Authorization Number (for re-registration)	026883-00/00
Function	fungicide
Applicant	Syngenta Agro GmbH
Composition	62.5 g/L isopyrazam 187.5 g/L cyprodinil
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	5 L - 20 L canister, HDPE/PA and f-HDPE

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

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

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

Hazard classes and categories:	
Acute Tox. 4, Asp Tox. 1	
Hazard pictograms:	
GHS07	exclamation mark
GHS08	health hazard
GHS09	environment
Signal word:	
Danger	
Hazard statements:	
H304	May be fatal if swallowed and enters airways.
H332	Harmful if inhaled.
H351	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routs of exposure cause the hazard>.
H361d	Suspected of damaging the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statemtents:	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310+P331	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting.
P308+P310	IF exposed or concerned: Immediately call a POISON CENTER or a doctor/physician.
P391	Collect spillage
P405	Store locked up.
P501	Dispose of contents/container to ...
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208 - Contains cyprodinil. May produce allergic reactions.	
EUH 208 - Contains isopyrazam. May produce allergic reactions.	
EUH 066 - Repeated exposure may cause skin dryness or cracking.	

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.3 Other phrases notified under Regulation (EC) No 547/2011

2.3.1 Restrictions linked to the PPP

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

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SB199	When applying the product with tractor-mounted, trailed or self-propelled application equipment, only vehicles with closed pressurized cabins (e.g. cabin category 3, if no respiratory protective equipment or particle-filtering masks are necessary or category 4, if gas-tight respiratory protective equipment is needed acc. to EN 15695-1 and -2) are suited to replace personal protective equipment during application. During all other activities outside of the cabin the prescribed personal protective equipment must be worn. In order to avoid contamination of the cabin, it is not permitted to enter the cabin with contaminated personal protective equipment (it should be deposited e.g. in an appropriate storage facility). Contaminated gloves should be washed before removing the gloves and hands should be washed before entering the cabin with pure water, respectively.
SF264	Treated areas/crops may not be entered until the spray coating has dried. While entering the treated areas/crops long work clothing and sturdy shoes must be worn.
SS110	Wear standard protective gloves (plant protection) when handling the undiluted product.
SS120	Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
SS206	Working clothes (if no specific protective suit is required) and sturdy footwear (e.g. rubber boots) must be worn when applying/handling plant protection products.
SS2101	Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Integrated pest management (IPM)/sustainable use	
WMFD1	Mode of action (FRAC-group): D1 (for cyprodinil)

WMFC2	Mode of action (FRAC group): C2 (for isopyrazam)
NN3002	The product is classified as harmful for populations of relevant beneficial predatory mites and spiders.
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)
Ecosystem protection	
NW 262	The product is toxic for algae.
NW 264	The product is toxic for fish and aquatic invertebrates.
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

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

2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
WW7041 for uses 001, 004	Resistance to this active substance, or an active substance contained in this product, was proved to exist. Application only within the framework of a suitable resistance management.
Ecosystem protection	
NW 605-1 **(all uses)**	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 ('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".Drift reduction by 90% 5 75 % 5 50% 10 m
NW 606 **(all uses)**	The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro. Buffer zone of 15 m
NG342-1	No additional use of products containing the active substance isopyrazam within one

(all uses)	calendar year on the same area

2.4 Product uses

Reg.-No. **026883-00/00** **GAP rev.2, date: 2017-06-21**

PPP (product name/code): **BONTIMA**
Active substance 1: **Cyprodinil**
Active substance 2: **Isopyrazam**

Formulation Type: **EC**
Conc. of a.s. 1: **187.50 g/L**
Conc. of a.s. 2: **62.50 g/L**

Applicant: **Syngenta Agro GmbH**
Zone(s): **central/EU**

Professional use: **Yes**
Non-professional use: **No**

Verified by MS: **yes**

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**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	barley (HORVX)	F	net blotch (*Pyrenophora teres*) (PYRNTE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 59	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha b) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha	100 - 400	F*	WW7041
002	DE	barley (HORVX)	F	powdery mildew (*Erysiphe graminis*) (ERYSGR)	spraying	From spring at beginning of infestation	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha	100 - 400	F*	

						and/or when first symptoms become visible 30 to 59			b) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha			
003	DE	barley (HORVX)	F	leaf blotch of cereals (*Rhynchosporium secalis*) (RHYNSE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 59	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha b) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha	100 - 400	F*	
004	DE	barley (HORVX)	F	Ramularia leaf spot disease (*Ramularia collo-cygni*) (RAMUCC)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 59	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha b) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha	100 - 400	F*	WW7041
005	DE	barley (HORVX)	F	brown rust of barley (*Puccinia hordei*) (PUCCHD)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 59	a) 1 b) 1	a) 2 L/ha b) 2 L/ha	a) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha b) a.s. 1: 0.375 kg/ha a.s. 2: 0.125 kg/ha	100 - 400	F*	

(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, developmental 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 38263-3152-4), 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
Min. interval between applications (days) were relevant
(9) 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)
(10) 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)
(11) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(12) PHI - minimum pre-harvest interval
(13) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

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 plant protection product A15840C (Botima) is a brown/orange EC with sweet smelling. The safety properties are acceptable and it has a pH value around 6. All tests relevant to an EC formulation have been carried out before and after two years storage. The product retains its original appearance after storage. The active substance content is unaffected upon storage. The physical/chemical properties (pH, density, persistent foam and emulsifiability) of the product all remained essentially unchanged.
The product has been shown to be stable when stored for two years under ambient conditions in *f*-HDPE, HDPE/PA and PET containers.

Implications for labelling:
H304 May be fatal if swallowed and enters airways.

Compliance with FAO guidelines:
The product A15840C (Botima) complies with FAO specifications, as far as could be assessed.

Compatibility of mixtures:
No tank mixture foreseen.

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 A15840C (Botima) has been provided and is considered to be acceptable.

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

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

The analytical method SF-283/1 for the determination by capillary gas chromatography of isopyrazam and cyprodinil in A15840C (Botima) was submitted and deemed acceptable. Validation according to SANCO 3030/99 rev. 4 was performed.

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

The analytical methods are active substance data and were provided in the EU review of cyprodinil and isopyrazam. They were considered adequate for food of plant and animal origin, soil, water and air. Methods for body fluids and tissues are not required, because cyprodinil and isopyrazam are not considered to be toxic or very toxic (T / T+) nor are they classified according to GHS as follows: Acute toxicity (cat. 1 - 3), CMR (cat. 1) or STOT (cat. 1). New analytical methods for residues were not provided.

However, taking the data requirement in SANCO/825/00 rev 8.1 into account, the following minor data gaps have been noticed:

- A primary method and an independent laboratory validation (ILV) for the determination of cyprodinil and the metabolite CGA 304075 in eggs is required.
- A confirmatory method for the determination of cyprodinil and the metabolite CGA 304075 in milk, eggs, meat, fat, and liver or kidney is required.
- A confirmatory method for the determination of cyprodinil in surface water is required.

These data gaps can be addressed in the context of the next renewal of the approval of cyprodinil according to Reg. (EC) No 1107/2009 or in the context of the assessment of existing MRLs according to Reg. (EC) No 396/2005.

3.1.3 Mammalian Toxicology

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.
As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS UK.

3.1.3.1 Acute Toxicity

Please refer to the registration report of the zonal RMS UK.

3.1.3.2 Operator Exposure

Please refer to the registration report of the zonal RMS UK.

3.1.3.3 Bystander Exposure

Please refer to the registration report of the zonal RMS UK.

3.1.3.4 Worker Exposure

Please refer to the registration report of the zonal RMS UK.

Implications for labelling resulting from operator, worker, bystander assessments:
See 2.2

3.1.3.5 Groundwater Metabolites

The isopyrazam metabolites CSCD459488, CSCD459489 and CSCD465008 are predicted in groundwater with concentrations > 0.1 µg/l. No new studies for the toxicological evaluation of groundwater metabolites were submitted. As described in Part B.8 the metabolites CSCD459488 and CSCD465008 are of no toxicological relevance in the groundwater.
Remark: The EFSA proposal for classification and labelling of the active substance isopyrazam is carcinogenicity, Cat. 2, H351 and reprotoxicity, Cat. 2, H361d. Therefore, all metabolites predicted to occur in groundwater above the parametric limit of 0.1 µg/L are considered relevant by EFSA, as it cannot be excluded that they share the carcinogenic and/or reprotoxic potential of isopyrazam (EFSA Journal 2012;10(3):2600).
In the case of a legal classification and labelling of isopyrazam for carcinogenicity, Cat. 2, H351 and/or reprotoxicity, Cat. 2, H361d according to Regulation (EC) 1272/2008, it will be mandatory to update the

relevance assessment for the metabolites of isopyrazam in groundwater in order to demonstrate that the metabolites do not share the carcinogenic/reprotoxic potential of the parent substance.

3.1.4 Residues and Consumer Exposure

The indended uses in barley will not result in residues above the MRLs set in Regulation (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.
For further details please refer to the registration report of the zonal RMS UK.

3.1.4.1 Residues

Please refer to the registration report of the zonal RMS UK.

3.1.4.2 Consumer exposure

Please refer to the registration report of the zonal RMS UK.

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

No new studies are presented.

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

PEC_{soil} was calculated for the active substance Isopyrazam considering a soil depth of 1.0 cm. Due to the slow degradation of the active substance Isopyrazam in soil the accumulation potential of Isopyrazam was considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.
The PEC_{soil} values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Bontima in Germany.

PEC_{soil} was calculated for the active substance Cyprodinil considering a soil depth of 1.0 cm. Due to the slow degradation of the active substance Cyprodinil in soil the accumulation potential of Cyprodinil was considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.
The PEC_{soil} values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Bontima in Germany.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

Direct leaching into groundwater

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Isopyrazam is not expected to penetrate into groundwater at concentrations of $\geq 0.1 \mu g/L$ in the intended uses of Bontima in Germany according to use No. A.

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam concentrations of $\geq 0.1 \mu g/L$ in groundwater cannot be excluded. An assessment of metabolites of Isopyrazam regarding their relevance for groundwater is necessary.

Table: PEC_{gw} for Isopyrazam and its metabolites for the application of Bontima in cereals considered relevant for German exposure assessment

Group/use No.	Scenario	80^{th} percentile PEC_{gw} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Isopyrazam	Metabolite CSCD459488	Metabolite CSCD465008
A / spring cereals	Hamburg	<0.001	1.074	0.211
A / winter cereals	Hamburg	<0.001	1.149	0.223

Results of modelling with FOCUS PELMO show that the active substance Cyprodinil is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of Bontima in Germany according to use No. A.

For the metabolites of Cyprodinil concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Consequences for authorization:

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam an assessment regarding their relevance for groundwater is necessary. The relevance assessment show that both metabolites are considered not relevant for the time being.

According to the COMMISSION IMPLEMENTING REGULATION (EU) No 1037/2012 Member States are asked to initiate monitoring programs to verify potential groundwater contamination in vulnerable zones and pay attention to the protection of groundwater when applied in region with vulnerable soil and/or climatic conditions.

Therefore a monitoring requirement is set with the authorization. The application holder already initiated a monitoring program and the first annual reports were submitted.
Additional the direction of use- NG 342-1 is set.

NG 342-1	No additional use of products containing the active substance isopyrazam within one calendar year on the same area.

Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances Isopyrazam and Cyprodinil due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization:

none

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 uses of the plant protection product Bontima in Germany PEC_{sw} was calculated for the active substances Isopyrazam and Cyprodinil considering the two routes of entry (i) spray drift and

volatilization with subsequent deposition and (ii) runoff, drainage separately. Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.
Surface water exposure via surface runoff and drainage is estimated using the model EXPOSIT 3.0.
The results of the PEC surface water simulations for the active substances and its metabolites were used in the eco-toxicological risk assessment.

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

The vapour pressure at 20 °C of the active substance Isopyrazam is $< 10^{-5}$ Pa. Hence the active substance Isopyrazam is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Isopyrazam due to volatilization with subsequent deposition was not considered.

The vapour pressure at 20 °C of the active substance Cyprodinil is $> 10^{-4}$ Pa. Hence the active substance Cyprodinil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Cyprodinil due to volatilization with subsequent deposition was considered.

Implications for labelling resulting from environmental fate assessment: none

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

No new studies are presented.

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

The acute and long-term TER values for isopyrazam and cyprodinil exceed the acceptability criterion TER ≥ 10 for acute effects and TER ≥ 5 for long-term/reproductive effects according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1, indicating that the acute and long-term risk to birds and mammals from dietary and secondary poisoning exposure is acceptable following use of A15840C according to the proposed use pattern.
Also the combined risk is concluded to be acceptable as well as the risk from drinking water.

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

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for cyprodinil and BONTIMA and calculated exposure levels, according to the intended uses of the product BONTIMA in barley. The calculated TER values do achieve the acceptability criterion TER ≥ 100 for acute effects and the adjusted criterion TER ≥2 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BONTIMA in barley according to the label.

Consequences for authorisation

For the authorisation of the plant protection product BONTIMA, labelling and conditions of use are mandatory as follows:

Table Labelling requirements according to § 36 (3) PflSchG

NW 262	Cyprodinil:E_bC_{50} = 0.75 mg/L (*Desmodesmus subspicatus*) Isopyrazam: NOEC = 0.310 mg/L (*Pseudokirchneriella subcapitata*)
NW 264	Cyprodinil: LC_{50} = 0.98 mg/L (*O. mykiss*); LC_{50} = 0.008 mg/L (*M. bahia*) Isopyrazam: LC_{50} = 0.009 mg/L (*O. mykiss*); LC_{50} = 0.044 mg/L (*D. magna*) Product: LC50 = 0.36 mg/L (*O.mykiss*), EC_{50}= 0.22 mg/L (*D.magna*)

Table Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (use group A)

NW 605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 5 m; 50 % – 10 m; conv. – 15 m;
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

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

Bees

The effects on honey-bees for A15840C have not been evaluated as part of an EU review. Data on A15840C are evaluated, and these risk assessments for A15840C with the proposed use pattern are considered adequate.

Toxicity

The table below presents the results of bee toxicity studies for A15840K.

Table 3.1.6.3-1: Toxicity to bees

Substance	Endpoint	Value [b]	Reference
A15840C (tested as A15840K) [a]	48-h contact LD_{50}	362.44 nL A15840K/bee (366 µg A15840K/bee)	***Kling (2008)***
	48-h oral LD_{50}	245.16 nL A15840K/bee (250 µg A15840K/bee)	

[a] A15840K is considered to be identical to A15840C
[b] Based on a formulation density of 1.01 g/cm^3

Exposure

Applications of pesticides in the field may potentially result in exposure of bees either through direct over-spray (contact exposure) or *via* residues on plants while bees are foraging for food (contact or oral exposure). The highest proposed single application rate for A15840C on cereals is 2.0 L/ha. A15840C has a density of 1.015 g/cm^3 and therefore the highest single application rate is 2030 g A15840C/ha and this will be used in the risk assessment.

Hazard quotients

The acute risk to bees from use of A15840 was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (EPPO 2003)[1] as follows:

$$\text{Hazard Quotient} = \frac{\text{Maximum application rate (g formulation/ha)}}{\text{Acute } LD_{50} \text{ (µg/bee)}}$$

Table 3.1.6.3-2: Risk to bees from oral exposure to A15840C

Test substance	Application rate (g A15840C/ha)	Oral LD_{50} (µg formulation /bee)	Hazard quotient
A15840C (tested as A15840K) [a]	2030	250	8.1

[a] A15840K is considered to be identical to A15840C

The hazard quotient is less than 50, indicating that the risk to bees from oral exposure is acceptable following use of A15840C according to the proposed use pattern.

[1] EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145.

Table 3.1.6.3-3: Risk to bees from contact exposure to A15840C (tested as A15840K)

Test substance	Application rate (g A15840C/ha)	Contact LD_{50} (µg formulation /bee)	Hazard quotient
A15840C (tested as A15840K) [a]	2030	366	5.5

[a] A15840K is considered to be identical to A15840C

The hazard quotient is less than 50, indicating that the risk to bees from contact exposure is acceptable following use of A15840C according to the proposed use pattern.

Conclusions
Both oral and contact hazard quotients are less than 50, indicating that the risk to bees is acceptable following use of A15840C according to the proposed use pattern. Further data are not required as the acute risk assessment carried out above indicates an acceptable risk to honeybees from the proposed uses of A15840C, and A15840C is not an insect growth regulator.

Other non-target arthropods

The calculated TER values achieve the acceptability criterion TER ≥ 5 (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of BONTIMA in barley according to the label.

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

The calculated TER values achieve the acceptability criterion TER ≥ 10 for acute effects and the acceptability criterion TER ≥ 5 for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of BONTIMA in barley according to the label.

Concentrations of cyprodinil and isopyrazam and the product in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BONTIMA in barley. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended use of BONTIMA in barley according to the label.

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

No additional risk assessment on effects on organic matter breakdown was executed please refer to the core assessment.

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

No additional risk assessment on effects on soil non-target micro-organisms was executed please refer to the core assessment.

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

In agreement with the zRMS UK, the risk is considered acceptable as the initial screening data indicate less than 50 % phytotoxic effects at the maximum application rate.

Implications for labelling resulting from ecotoxicological assessment:

For the authorisation of the plant protection product BONTIMA, labelling and conditions of use are mandatory as follows:

Table Labelling requirements according to § 36 (3) PflSchG

NW 262	Cyprodinil:E_bC_{50} = 0.75 mg/L (*Desmodesmus subspicatus*) Isopyrazam: NOEC = 0.310 mg/L (*Pseudokirchneriella subcapitata*)
NW 264	Cyprodinil: LC_{50} = 0.98 mg/L (*O. mykiss*); LC_{50} = 0.008 mg/L (*M. bahia*) Isopyrazam: LC_{50} = 0.009 mg/L (*O. mykiss*); LC_{50} = 0.044 mg/L (*D. magna*) Product: LC50 = 0.36 mg/L (*O.mykiss*), EC_{50}= 0.22 mg/L (*D.magna*)

Table Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (use group A)

NW 605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 5 m; 50 % – 10 m; conv. – 15 m;
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.
NG 342-1	No additional use of products containing the active substance isopyrazam within one calendar year on the same area.

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

Information on the active substances

Isopyrazam is an orthosubstituted pyrazole-carboximide (OPA) belonging to the subclass benzonorbornenes and the mode of fungicidal action is classified as a newer generation II Succinate dehydrogenase inhibitor (SDHI). SDHI fungicides specifically block the ubiquinone-binding sites within succinate dehydrogenase, also known as mitochondrial complex II, thereby inhibiting fungal respiration. In addition, complex II plays an important role in the tricarboxylic acid cycle (Krebs' cycle) as part of the process of oxidation of succinate to fumarate and is assumed to belong to the FRAC mode of action group C2. Isopyrazam has good foliar surface tenacity coupled with low uptake into leaf tissues and limited xylem translocation. Key effects are inhibition of germ tube growth, reduction in the number of appressoria and consequently inhibition of penetration into and establishment in the host. Isopyrazam has persistent and broad-spectrum activity and is effective against a range of fungal diseases in cereals.

Cyprodinil is an established systemic, broad spectrum, foliar, anilinopyrimidine fungicide for use in cereals and other crops. Cyprodinil provides a high level of control against a wide range of diseases caused by Ascomycetes and Deuteromycetes. The mode of action of cyprodinil includes inhibition of

methionine biosynthesis and secondarily secretion of hydrolytic enzymes, which belongs to the FRAC mode of action group D1. The inhibition of methionine biosynthesis interferes with the fungal life cycle, inhibiting penetration and disrupting the mycelial growth in the plant. Cyprodinil is systemic and is translocated in the plant, cyprodinil has curative biological action.

Efficacy

Minimum effective dose tests

Evidence from two major diseases on barley (*Pyrenophora teres* (PYRNTE) and *Rhynchosporium secalis* (RHYNSE)) is considered sufficient justification for the proposed dose is the minimum effective dose to provide consistent effective performance in the field by the zRMS.

Efficacy tests

As a major disease of barley, data on powdery mildew showed in six trials carried out in the Maritime EPPO zone, 'Bontima' gave a mean 93.3% control whereas the product data on isopyrazam alone (as 'A15149W') were considered sufficient to support a claim of 'moderate control'. As a major disease of barley, data on *Rhynchosporium* carried out in 14 trials in the Maritime EPPO zone showed 'Bontima' gave a mean 89.8% control, whereas for the product data on isopyrazam alone (as 'A15149W') were considered sufficient to support a claim of 'moderate control'.

In these trials against *Pyrenophora teres* and *Rhynchosporium secalis*, both the co-formulated mixture and the tank mixture showed higher mean relative disease control compared to the solo active substances. In addition, data on powdery mildew and *Rhynchosporium secalis*, two major diseases of barley, data showed improved levels of control compared to the solo active. The zRMS considers this is sufficient evidence justifying the benefit of the co-formulated product in terms of the range of diseases control and level of control.

Adverse effects on beneficial organisms (other than bees)

Based on laboratory tests (glass) the in-field risk for *A. rhopalosiphi* indicated a potential risk to non-target insects. At higher tier an acceptable risk was concluded for mortality and reproduction. However, the effects of the product on mortality and reproduction of *T. pyri* were comparable on glass and leaves *(Vicia faba)* and indicated overall effects > 50 % (mortality and reproduction) could not be excluded. Residue decline studies were used to demonstrate the potential for recovery within a year. An acceptable risk was concluded by the zRMS.

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

Possible development of resistance or cross-resistance

The overall resistance risk for SDHI's (succinate dehydrogenase inhibitors) including isopyrazam will be between low to medium and medium to high depending on the agronomic risk associated to each pathogen/crop system. The zRMS concludes, that in principle the resistance risk for the mixture of isopyrazam and cyprodinil is lower than the risk for each solo compound especially when both fungicides in the actual mixture are equally active on the current populations and the activity profiles of these components complement each other (different modes of action) in such a way that effective disease management is achieved. However, an application is allowed only within the framework of a suitable resistance management.

3.2 Conclusions

With respect to identity, physical, chemical and technical properties, further information and packaging as well as analytical methods (formulation and residues) an authorisation can be granted.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

With respect to efficacy/IPM and sustainable use incl. protection of honeybees and beneficial arthropods an authorisation can be granted.

With respect to fate and ecotoxicology assessment, 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 following information is required in order to obtain (a prolongation of) the authorisation:

AnnexIII point	Data
KIIA 7.12	Monitoring requirement for the isopyrazam metabolite CSCD459488 according to the implementation regulation (EU) No 1037/2012

Appendix 1 – Copy of the product authorisation

See Appendix 4

Appendix 2 – Copy of the product label

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

Appendix 3 – Letter of Access

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

Appendix 4 – Copy of the product authorisation

See below

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Syngenta Agro GmbH
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.026883-00/00.90385
(bitte bei Antwort angeben)

DATUM 1. September 2017

ZV3 026883-00/00

BONTIMA

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:	187,5 g/l	Cyprodinil
	62,5 g/l	Isopyrazam
Zulassungsnummer:	026883-00	
Versuchsbezeichnungen:	SYD-21700-F-0-EC	
Antrag vom:	1. November 2013	

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

Zulassungsende

Die Zulassung endet am 30. April 2019.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

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

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
026883-00/00-002	Echter Mehltau (Erysiphe graminis)	Gerste	
026883-00/00-001	Netzfleckenkrankheit (Pyrenophora teres)	Gerste	
026883-00/00-003	Rhynchosporium secalis	Gerste	
026883-00/00-004	Sprenkelkrankheit (Ramularia collo-cygni)	Gerste	
026883-00/00-005	Zwergrost (Puccinia hordei)	Gerste	

Festgesetzte Anwendungsbestimmungen

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

(NW468)
Anwendungsflüssigkeiten und deren Reste, Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Reinigungs- und Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Die im o.g. Pflanzenschutzmittel enthaltenen Wirkstoffe Cyprodinil und Isopyrazam weisen aufgrund ihrer Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

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

Verpackungen

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

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Kanister	HDPE, fluoriert	1		5,00	20,00	l
Kanister	HDPE/PA	1		5,00	20,00	l

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

Auflagen

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

Kennzeichnungsauflagen:

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

(NW262)
Das Mittel ist giftig für Algen.

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

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

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

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB110)

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

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

(SB199)
Wenn das Produkt mittels an den Traktor angebauten, gezogenen oder selbstfahrenden Anwendungsgeräten ausgebracht wird, dann sind nur Fahrzeuge, die mit geschlossenen Überdruckkabinen (z. B. Kabinenkategorie 3, wenn keine Atemschutzgeräte oder partikelfiltrierenden Masken benötigt werden oder Kabinenkategorie 4, wenn gasdichter Atemschutz erforderlich ist (gemäß EN 15695-1 und -2)) ausgestattet sind, geeignet, um die persönliche Schutzausrüstung bei der Ausbringung zu ersetzen. Während aller anderen Tätigkeiten außerhalb der Kabine ist die vorgeschriebene persönliche Schutzausrüstung zu tragen. Um die Kontamination des Kabineninnenraumes zu vermeiden, ist es nicht erlaubt, die Kabine mit kontaminierter persönlicher Schutzausrüstung zu betreten (diese sollte in einer entsprechenden Vorrichtung aufbewahrt werden). Kontaminierte Handschuhe sollten vor dem Ausziehen abgewaschen werden, beziehungsweise sollten die Hände vor Wiederbetreten der Kabine mit klarem Wasser gereinigt werden.

(SF264)
Behandelte Flächen/Kulturen erst nach dem Abtrocknen des Spritzbelages wieder betreten. Dabei sind lange Arbeitskleidung und festes Schuhwerk zu tragen.

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

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

(SS206)
Arbeitskleidung (wenn keine spezifische Schutzkleidung erforderlich ist) und festes Schuhwerk (z.B. Gummistiefel) tragen bei der Ausbringung/Handhabung von Pflanzenschutzmitteln.

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

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

(WMFC2)
Wirkungsmechanismus (FRAC-Gruppe): C2

(WMFD1)
Wirkungsmechanismus (FRAC-Gruppe): D1

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

Sonstige Auflagen:

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

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

Dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit sind Unterlagen zu den nachfolgend aufgeführten Punkten und den dabei jeweils genannten Terminen vorzulegen:
Antragspunkt:
KIIA 7.12 (Isopyrazam-Metaboliten CSCD 459 488)
Termin:
31. Dezember 2018
Forderung:
Vorlage der Ergebnisse eines mehrjährigen Grundwassermonitorings für den Metaboliten CSCD 459 488. Die Ergebnisse sind jährlich zu berichten.

Begründung:
Im Ergebnis der Bewertung einer möglichen Versickerung in das Grundwasser können für den Metaboliten des Wirkstoffs Isopyrazam folgende Einträge (maximale jährliche Durchschnittskonzentrationen) in Konzentrationen = 0.1 µg/L nicht ausgeschlossen werden.

Metabolit CSCD 459488: 1.149 µg/L

Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im Besonderen auf den Schutz des Grundwassers zu achten, sowie in empfindlichen Gebieten Monitoringprogramme zur Ermittlung potenzieller Verunreinigungen des Grundwassers zu veranlassen.

Zum Schutz der Ressource Grundwasser ist daher die Sicherheit der zugelassenen Anwendungen von Pflanzenschutzmitteln mit dem Wirkstoff Isopyrazam, welches den Metaboliten CSCD 459 488 bildet, mit einem zulassungsbegleitenden Grundwassermonitoring zu belegen.

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

Vorbehalt

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

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

Signalwort:

(S2) Gefahr

Gefahrenpiktogramme:

(GHS07) Ausrufezeichen

(GHS08) Gesundheitsgefahr

(GHS09) Umwelt

Gefahrenhinweise (H-Sätze):

(H304)

Kann bei Verschlucken und Eindringen in die Atemwege tödlich sein.

(H332)
Gesundheitsschädlich bei Einatmen.

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

(H361d)
Kann vermutlich das Kind im Mutterleib schädigen.

(H400)
Sehr giftig für Wasserorganismen.

(H410)
Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 066)
Wiederholter Kontakt kann zu spröder oder rissiger Haut führen.

(EUH 208-0025)
Enthält Cyprodinil. Kann allergische Reaktionen hervorrufen.

(EUH 208-0139)
Enthält Isopyrazam. Kann allergische Reaktionen hrvorrufen.

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

Sicherheitshinweise (P-Sätze):
(P101)
Ist ärztlicher Rat erforderlich, Verpackung oder Kennzeichnungsetikett bereithalten.

(P102)
Darf nicht in die Hände von Kindern gelangen.

(P201)
Vor Gebrauch besondere Anweisungen einholen.

(P261)
Einatmen von Staub/Rauch/Gas/Nebel/Dampf/Aerosol vermeiden.

(P270)
Bei Gebrauch nicht essen, trinken oder rauchen.

(P280)
Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P281)
Vorgeschriebene persönliche Schutzausrüstung verwenden.

(P301+P310+P331)
BEI VERSCHLUCKEN: Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen. Kein Erbrechen hervorrufen.

(P304+P340)
BEI EINATMEN: Die Person an die frische Luft bringen und für ungehinderte Atmung sorgen.

(P308+P310)
BEI Exposition oder falls betroffen: Sofort GIFTINFORMATIONSZENTRUM oder Arzt anrufen.

(P331)
KEIN Erbrechen herbeiführen.

(P391)
Verschüttete Mengen aufnehmen.

(P405)
Unter Verschluss aufbewahren.

(P501)
Inhalt/Behälter ... zuführen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Hinweise

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

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

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

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

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

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

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 026883-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Netzfleckenkrankheit (Pyrenophora teres)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 59
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

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

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NG342-1)
Auf derselben Fläche innerhalb eines Kalenderjahres keine zusätzliche Anwendung von Mitteln, die den Wirkstoff Isopyrazam enthalten.
Begründung:

Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im Besonderen auf den Schutz des Grundwassers zu achten.
In Auswertung der vorliegenden Daten ist zum Schutz des Grundwassers und der Vermeidung von schädlichen Effekten ist der Eintrag des Wirkstoffes Isopyrazam und der damit verbundenen sich bildenden Metaboliten auf derselben Fläche in einem Kalenderjahr zu begrenzen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% 5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist unter Verwendung der Bewertung durch den erstzulassenden Mitgliedsstaat die EC50 für Daphnia magna von 220 µg Produkt/L (entspricht 55 µg sum. a.s./L) mit einem Sicherheitsfaktor von 100 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) Unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften der enthaltenen Wirkstoffe ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte Anwendungsbestimmung NW 605-1 bzw. 606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BONTIMA in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

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

Siehe Begründung NW605-1.

Anlage 1 zugelassene Anwendung: 026883-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (Erysiphe graminis)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 59
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NG342-1)
Auf derselben Fläche innerhalb eines Kalenderjahres keine zusätzliche Anwendung von Mitteln, die den Wirkstoff Isopyrazam enthalten.
Begründung:
Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im

Besonderen auf den Schutz des Grundwassers zu achten.
In Auswertung der vorliegenden Daten ist zum Schutz des Grundwassers und der Vermeidung von schädlichen Effekten ist der Eintrag des Wirkstoffes Isopyrazam und der damit verbundenen sich bildenden Metaboliten auf derselben Fläche in einem Kalenderjahr zu begrenzen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% 5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist unter Verwendung der Bewertung durch den erstzulassenden Mitgliedsstaat die EC50 für Daphnia magna von 220 µg Produkt/L (entspricht 55 µg sum. a.s./L) mit einem Sicherheitsfaktor von 100 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) Unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften der enthaltenen Wirkstoffe ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte Anwendungsbestimmung NW 605-1 bzw. 606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BONTIMA in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

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

Anlage 1 zugelassene Anwendung: 026883-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Rhynchosporium secalis

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 59
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NG342-1)
Auf derselben Fläche innerhalb eines Kalenderjahres keine zusätzliche Anwendung von Mitteln, die den Wirkstoff Isopyrazam enthalten.
Begründung:
Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im

Besonderen auf den Schutz des Grundwassers zu achten.
In Auswertung der vorliegenden Daten ist zum Schutz des Grundwassers und der Vermeidung von schädlichen Effekten ist der Eintrag des Wirkstoffes Isopyrazam und der damit verbundenen sich bildenden Metaboliten auf derselben Fläche in einem Kalenderjahr zu begrenzen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% 5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist unter Verwendung der Bewertung durch den erstzulassenden Mitgliedsstaat die EC50 für Daphnia magna von 220 µg Produkt/L (entspricht 55 µg sum. a.s./L) mit einem Sicherheitsfaktor von 100 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) Unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften der enthaltenen Wirkstoffe ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte Anwendungsbestimmung NW 605-1 bzw. 606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BONTIMA in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

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

Anlage 1 zugelassene Anwendung: 026883-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Sprenkelkrankheit (Ramularia collo-cygni)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 59
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

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

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NG342-1)
Auf derselben Fläche innerhalb eines Kalenderjahres keine zusätzliche Anwendung von Mitteln, die den Wirkstoff Isopyrazam enthalten.
Begründung:

Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im Besonderen auf den Schutz des Grundwassers zu achten.
In Auswertung der vorliegenden Daten ist zum Schutz des Grundwassers und der Vermeidung von schädlichen Effekten ist der Eintrag des Wirkstoffes Isopyrazam und der damit verbundenen sich bildenden Metaboliten auf derselben Fläche in einem Kalenderjahr zu begrenzen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% 5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist unter Verwendung der Bewertung durch den erstzulassenden Mitgliedsstaat die EC50 für Daphnia magna von 220 µg Produkt/L (entspricht 55 µg sum. a.s./L) mit einem Sicherheitsfaktor von 100 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) Unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften der enthaltenen Wirkstoffe ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte Anwendungsbestimmung NW 605-1 bzw. 606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BONTIMA in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

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

Siehe Begründung NW605-1.

Anlage 1 zugelassene Anwendung: 026883-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Zwergrost (Puccinia hordei)

Pflanzen/-erzeugnisse/Objekte: Gerste

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	30 bis 59
Anwendungszeitpunkt:	Ab Frühjahr bei Befallsbeginn bzw. bei Sichtbarwerden der ersten Symptome
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen
Aufwand:	
-	2 l/ha in 100 bis 400 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

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

3 Anwendungsbezogene Anwendungsbestimmungen

(NG342-1)
Auf derselben Fläche innerhalb eines Kalenderjahres keine zusätzliche Anwendung von Mitteln, die den Wirkstoff Isopyrazam enthalten.
Begründung:
Aufgrund der Sonderbestimmung im Anhang I der Durchführungsverordnung (EU) Nr. 1037/2012 der Kommission vom 7. November 2012 zur Genehmigung des Wirkstoffes Isopyrazam gemäß der Verordnung (EG) Nr. 1107/2009 sind die Mitgliedstaaten verpflichtet im

Besonderen auf den Schutz des Grundwassers zu achten.
In Auswertung der vorliegenden Daten ist zum Schutz des Grundwassers und der Vermeidung von schädlichen Effekten ist der Eintrag des Wirkstoffes Isopyrazam und der damit verbundenen sich bildenden Metaboliten auf derselben Fläche in einem Kalenderjahr zu begrenzen.

(NW605-1)
Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.
reduzierte Abstände: 50% 10 m, 75% 5 m, 90% 5 m
Begründung:
Wie vom erstbewertenden Mitgliedsstaat im core assessment ausgeführt, ist der Schutz von Gewässerorganismen bei Anwendung des o.g. Pflanzenschutzmittels zu beachten. Für die Festsetzung geeigneter Maßnahmen in Deutschland ist unter Verwendung der Bewertung durch den erstzulassenden Mitgliedsstaat die EC50 für Daphnia magna von 220 µg Produkt/L (entspricht 55 µg sum. a.s./L) mit einem Sicherheitsfaktor von 100 heranzuziehen. Ausgehend von den in Deutschland geltenden Modellen zur Abdrift sowie zur Verflüchtigung von Zielflächen und anschließender Deposition (hier: EVA 3) Unter Berücksichtigung der vom erstbewertendem Mitgliedsstaat angegebenen charakteristischen Eigenschaften der enthaltenen Wirkstoffe ist nach dem Stand der wissenschaftlichen Erkenntnis die für das Risikomanagement in Deutschland etablierte Anwendungsbestimmung NW 605-1 bzw. 606 erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Mittels BONTIMA in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Draft Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

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

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: A15840C

Product name(s): Bontima

Chemical active substances:

Isopyrazam	62.5 g/L
Cyprodinil	187.5 g/L

Central Zone

Zonal Rapporteur Member State: UK

NATIONAL ADDENDUM – GERMANY

(authorization)

Applicant: Syngenta

Submission date: 01/11/2013

MS Finalisation date: 31/05/2017

Version history

When	What

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8 Fate and behaviour in the environment (KCP 9)

The exposure assessment of the plant protection product Bontima in its intended uses in cereals is documented in detail in the core assessment of the plant protection product Bontima performed by UK.
This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Bontima for the intended for uses in Germany considering specific environmental or agricultural circumstances.
Regarding PEC_{gw} relevant risk mitigation measures, if necessary, are documented in this document.
PEC_{soil}, PEC_{sw} are used for risk assessment to derive specific risk mitigation measures if necessary (see National Addendum Germany, Part B, section 9).
The plant protection product Bontima (026883-00/00) has already been authorized in Germany in cereals (use No. 00-001 to 00-005, 01-001 to 01-005). Therefore the exposure assessment of the intended use of Bontima in cereals according to use No. A refers also to the German registration report 006883-00/00.

8.1 Critical GAP and overall conclusions

8.1.1 Table of critical GAPs

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ syner-gist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L 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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Germany	Barley	F	*Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Erysiphe graminis* *Rhynchosporium secalis*	Foliar Spray	BBCH 30-59	a) 1 b) 1	-	a) 2 b) 2	Isopyrazam a) 125 b) 125 Cyprodinil a) 375 b) 375	100-400	n/a*	* No PHI stated; last application determined by growth stage	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
--														
Minor uses according to Article 51 (zonal uses)														
--														
Minor uses according to Article 51 (interzonal uses)														
--														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

8.1.2 Overall conclusion

8.1.2.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} was calculated for the active substance Isopyrazam considering a soil depth of 1.0 cm. Due to the slow degradation of the active substance Isopyrazam in soil the accumulation potential of Isopyrazam was considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.
The PEC_{soil} values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Bontima in Germany.

PEC_{soil} was calculated for the active substance Cyprodinil considering a soil depth of 1.0 cm. Due to the slow degradation of the active substance Cyprodinil in soil the accumulation potential of Cyprodinil was considered. Therefore PEC_{soil} used for risk assessment comprises background concentration in soil (PEC_{accu}) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC_{act} considering the relevant soil depth of 2.5 cm or 1.0 cm, respectively.
The PEC_{soil} values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Bontima in Germany.

8.1.2.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Direct leaching into groundwater

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Isopyrazam is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of Bontima in Germany according to use No. A.

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. An assessment of metabolites of Isopyrazam regarding their relevance for groundwater is necessary.

Results of modelling with FOCUS PELMO show that the active substance Cyprodinil is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of Bontima in Germany according to use No. A.

For the metabolites of Cyprodinil concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Consequences for authorization:

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam an assessment regarding their relevance for groundwater is necessary.

Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

According modelling with EXPOSIT 3, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substances Isopyrazam and Cyprodinil due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization: none

8.1.2.3 Predicted environmental concentrations in surface water (PEC_{sw})

For the intended uses of the plant protection product Bontima in Germany PEC_{sw} was calculated for the active substances Isopyrazam and Cyprodinil considering the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately. Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.
Surface water exposure via surface runoff and drainage is estimated using the model EXPOSIT 3.0.
The results of the PEC surface water simulations for the active substances and its metabolites were used in the eco-toxicological risk assessment.

8.1.2.4 Fate and behaviour in air

The vapour pressure at 20 °C of the active substance Isopyrazam is $< 10^{-5}$ Pa. Hence the active substance Isopyrazam is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Isopyrazam due to volatilization with subsequent deposition was not considered.

The vapour pressure at 20 °C of the active substance Cyprodinil is $> 10^{-4}$ Pa. Hence the active substance Cyprodinil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Cyprodinil due to volatilization with subsequent deposition was considered.

8.1.3 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 8.1-2: Critical use pattern of Bontima grouped according to soil

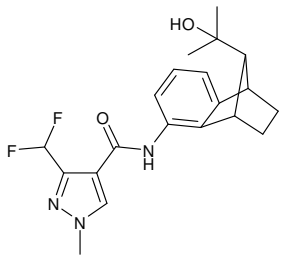
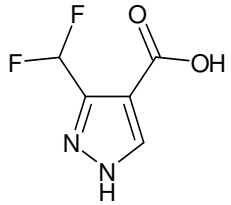
Grouping according to soil			
Group	**Intended uses**	**Application rate (g/ha) (interception, %)**	**Soil-relevant effective applic. rate, cumulative (g/ha)**
A / 00-001 – 00-005	Barley (winter and spring cereals), BBCH 30-59	Isopyrazam: 1 x 125 g a.s./ha Cyprodinil: 1 x 375 g a.s./ha Interception: 1 x 70 %	Isopyrazam: 37.5 g a.s./ha Cyprodinil: 112.5 g a.s./ha

8.2 Metabolites considered in the assessment

Metabolites of Isopyrazam

Environmental occurring metabolites of Isopyrazam requiring further assessment according to the results of the assessment of Isopyrazam for EU approval are summarized in Table 8.2-1.
In April 2017 an addendum to the DAR part Environmental Fate and Behaviour was distributed for peer review by Member States and EFSA. In the addendum the assessment of Confirmatory Data was prepared by RMS UK.
Content of the Confirmatory Data are the specific provisions listed in Part B of the Inclusion Directive No 1037/2012:
'The applicant shall submit confirmatory information as regards the relevance of the metabolites CSCD 459488 and CSCD 459489 for groundwater. The applicant shall submit to the Commission, the Member States and the Authority this information by 31 March 2015.'
In the addendum from April 2017 is stated: 'The applicant submitted data to address this requirement by the deadline of 31 March 2015. However please note that this addendum only includes assessment of environmental fate data related to metabolite CSCD 459489 given that further toxicology work is currently underway to support metabolite CSCD 459488 with an extended submission deadline of 31 July 2017. Therefore an assessment of metabolite CSCD 459488 cannot be completed at this stage.'
In summary the RMS UK concludes in this addendum from April 2017 that:
'CSCD459488 is the *syn* form of a major soil metabolite of isopyrazam, formed following hydroxylation of the isopropyl group on the parent *syn* isomer. CSCD459489 is the corresponding *anti* isomer and it is this isomer which forms the focus of this assessment.
Using a weight of evidence approach CSCD459489 is determined by the RMS not to trigger a groundwater assessment as it is formed at less than 5 % of the active substance across all time points and studies and subsequently does not require the generation of PECgw values. In the EFSA conclusion the *syn:anti* ratio of the metabolites; CSCD459488 and CSCD459489 was assumed to be the same as the parent, however the RMS considers that the ratio of the metabolite isomers deviates from the parent isomeric ratio, in favour of the *syn*- isomer with only very small amounts of the *anti*- isomer being formed.'
Regarding the assessment of the plant protection product A18996C the applicant submitted the same fate data which are presented in addendum from April 2017. At this point in time (May 2017) no final outcome of the peer review by Member States and EFSA is available.
In consideration of the outstanding final conclusion regarding the relevance of the metabolite CSCD459489 for groundwater UBA decided after review of the data to follow the approach by RMS UK. According to that metabolite CSCD459489 is formed at less than 5 % of the active substance Isopyrazam and therefore the calculation of PECgw values is not triggered.
The risk assessment for the metabolites CSCD459488 and CSCD465008 has already been performed for EU approval (see SANCO/12138/2012 rev 3 – 26/09/2012).
Potential ground water contamination by the soil metabolites CSCD459488 and CSCD465008 was evaluated for EU approval of isopyrazam. PECgw modelled with FOCUS Pearl (v3.3.3) and FOCUS Pelmo (v3.3.2) was up to 3.45 µg/L for the metabolite CSCD459488 and up to 0.21 µg/L for the metabolite CSCD465008 in the 9 scenarios based on an application of 2 x 125 g isopyrazam/ha in winter and spring cereals.
However, the leaching potential into groundwater of the soil metabolites CSCD459488 and CSCD465008 will be assessed for the application of the plant protection product and its intended uses (see chapter 8.8).

Table 8.2-1: Metabolites of Isopyrazam potentially relevant for exposure assessment (> 10 % of as or > 5 % of as in 2 sequential measurements or > 5 % of as and maximum of formation not yet reached at the end of the study)

Metabolite	Structural formula/ Molecular formula	occurrence in compartments (Max. at day)	Status of Relevance (SANCO/12138/2012 rev 3 – 26/09/2012)
CSCD 459488 (syn isomer of CSCD 460260) SYN 545364 R 959964		Soil: 23.6 % (day 195) Surface water: max. 9.6 % (day 21, 2 x > 5%) Sediment: max. 6.7 % (day 58, 2 x > 5%)	Aquatic organism: not relevant Terrestrial organism: not relevant Groundwater: open* (Step 2/Step 3-4)[1)]
CSCD 465008 R 958945		Soil (lab): 11.5 % (day 150), [pyrazole labelled] Soil (field): 17.3 %	Aquatic organism: not relevant Terrestrial organism: not relevant Groundwater: open* (Step 2/Step 3-4)[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)

* refers to EFSA conclusion (EFSA Journal 2012;10(3):2600). In the national assessment the metabolite CSCD 460260 and its isomers CSCD 459488 and CSCD 459489 are not relevant but pending on the proposed classification and labeling of the active substance isopyrazam (R40). Therefore, further assessment for the metabolites CSCD 459488 and CSCD 459489 will be required.

Metabolites of Cyprodinil

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Isopyrazam

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK..

8.3.1.2 Cyprodinil

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant for assessment.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Isopyrazam and its metabolites

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.4.1.2 Cyprodinil and its metabolites

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.5 Mobility in soil (KCP 9.1.2)

8.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)

8.5.1.1 Isopyrazam and its metabolites

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.5.1.2 Cyprodinil and its metabolites

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

8.5.2 Column leaching (KCP 9.1.2.1)

Not required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Not required.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Not required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

8.6.1 Water/sediment study (KCP 9.2.2)

8.6.1.1 Isopyrazam

Please refer to the German registration report 006883-00/00.

Table 8.6-1: Accumulation of active substance Isopyrazam and relevant metabolites in the sediment

Active substance	Isopyrazam
Accumulation potential in sediment	yes ($DT_{90,whole\ system}$ > 1 year)
Accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	2.724 based on $DT_{50,\ whole\ system}$ = 809 (maximum), t = 365 d

8.6.1.2 Cyprodinil

Please refer to the German registration report 006883-00/00.

Table 8.6-2: Accumulation of active substance Cyprodinil and relevant metabolites in the sediment

Active substance	Cyprodinil
Accumulation potential in sediment	yes ($DT_{90,whole\ system}$ > 1 year)
Accumulation factor (SFO) $\mathbf{f_{accu} = e^{-kt}/(1 - e^{-kt})}$	0.318 based on $DT_{50,\ whole\ system}$ = 178 (maximum), t = 365 d

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

8.7.1 Jusitification of new endpoints

Not applicable, german scenario.

8.7.2 Active substances and relevant metabolite(s)

Results of PEC_{soil} calculation for Bontima according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 5.
For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{Foc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{Foc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.
The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in the tables below.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No	A
Crop	cereals
Application rate (g as/ha)	Isopyrazam: 125 Cyprodinil: 375
Number of applications/interval	1 x
Crop interception (%)	70 %
Depth of soil layer (relevant for plateau concentration) (cm)	20

Table 8.7-2: Input parameter for active substances and relevant metabolite(s) for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Molar correction factor [-]**	**Max. occurrence (%)**	**DT_{50} (days) EU endpoint**	**DT_{50} (days) updated endpoint**
Isopyrazam	359	-	-	629 (SFO, Maximum, Field studies)	236 (SFO, Maximum, Field studies/ German locations)
Metabolite CSCD459488	375	1.045	23.6	1000 (SFO, Maximum, Field studies)	-
Metabolite CSCD465008	162	0.451	17.3	190 (SFO, Maximum, Lab studies)	-

Due to the slow degradation of Isopyrazam in soil (DT_{90} > 365 d, SFO, field data) the accumulation potential of Isopyrazam needs to be considered. Therefore an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) and the maximum annual soil concentration PEC_{act}.

Due to the slow degradation of Cyprodinil in soil (DT_{90} > 365 d, SFO, field data) the accumulation potential of Cyprodinil needs to be considered. Therefore an accumulated soil concentration (PEC_{accu}) is used for risk assessment that comprises background concentration in soil (PEC_{bkgd}) and the maximum annual soil concentration PEC_{act}.

8.7.2.1 PEC_{soil}

Please refer to the German registration report 006883-00/00.

Table 8.7-3: Results of PEC_{soil} calculation for the intended use in cereals used for German risk assessment

Active substance/ formulation	**Soil relevant application rate (g/ha)**	**Soil $depth_{act}$ (cm)**	**PEC_{act} (mg/kg)**	**Tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Isopyrazam Metabolite CSCD465008	2.9	2.5	0.0077	20	0.0003	0.0081

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Results of the PECgw calculation of Isopyrazam and Cyprodinil for the intended uses of Bontima in cereals according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment, part B, section 5.
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 runoff 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 (PECgw) 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 with FOCUS PELMO for the groundwater scenarios “Hamburg” or with the scenarios “Hamburg” and “Kremsmünster”.
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 runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01.

8.8.1 Jusitification of new endpoints

New endpoints for metabolite CSCD465008 of Isopyrazam regarding DT_{50} and K_{foc} values were used. These data were not considered in the core assessment by zRMS UK but were submitted by the applicant.

In May 2015 an addendum was distributed. In this addendum common endpoints for the metabolite CSCD465008 were summarized by RMS UK. The metabolite is a common metabolite of four active substances (abbreviated as DMPac). From these data one additional study on the degradation of metabolite CSCD465008 in soil under field conditions is available. This study (Unold, Bayer, and Zangmeister, 2009) was original submitted in the course of the evaluation of fluxapyroxad. The study summary is presented in the DAR Vol. 3, B.8 of fluxapyroxad dated from January 2011. The soil metabolite of fluxapyroxad is named M700F002 and is chemically identical to the isopyrazam metabolite CSCD465008. The kinetic modeling analysis and normalization of the field data with the metabolite M700F002 was performed by Hardy (2009).

From these addendum (May 2015) one additional study on the adsorption of metabolite CSCD465008 (DMPac metabolite) is available. This study (Hassink and Stephan, 2009) was original submitted in the course of the evaluation of fluxapyroxad. The study summary is presented in the DAR Vol. 3, B.8 of fluxapyroxad dated from January 2011.

In the PECgw calculation for metabolite CSCD465008 a formation fraction of 1 is used. The plant uptake factor is set to 0.

Regarding the metabolite CSCD459488 of Isopyrazam DT_{50} values from field studies were re-evaluated by the applicant (Hayes, 2011) in order to calculate $DegT_{50}$ and formation fractions for use in PECgw modelling.

Detail information is presented in the German registration report 006883-00/00.

8.8.2 Active substances and relevant metabolite(s) (KCP 9.2.4.1) Direct Leaching into groundwater

The FOCUS calculation considering input parameters according to Holdt et al (2011) was performed by the UBA.

Table 8.8-1: Input parameters related to application of Bontima for PEC_{gw} calculations

Use No.	A
Crop	spring and winter cereals
Application rate (kg as/ha)	Isopyrazam: 0.125
Number of applications (d)	1x
Relative application date	21.04. (winter cereals), 29.04. (spring cereals)
Crop interception (%)	70 %
Soil effective application rate (g as/ha)	Isopyrazam: 37.5
Frequency of application	annual
Models used for calculation	FOCUS PELMO 5.5.3
Soil moisture	100 % FC
Q10-factor	2.58
Moisture exponent	0.7
Simulation period (years)	26

8.8.2.1 Isopyrazam and its metabolites

The endpoints used for groundwater modelling for Isopyrazam and its metabolites CSCD459488 and CSCD465008 according to INPUT DECISION 3.3 are summarised in the table below.

Table 8.8-2: Input parameters related to active substance Isopyrazam and its metabolites for PEC_{gw} calculations

Parent	**Isopyrazam**	**Remarks**
Molecular weight (g/mol)	359	
DT_{50} in soil (d)	171 23.1	90^{th} percentile, field, 10^{th} percentile, field
K_{Foc}	2416	Arithmetic mean
1/n	0.94	Arithmetic mean
Plant uptake factor	0	default
Metabolite	**CSCD459488**	
Molecular weight (g/mol)	375	
Formation fraction	0.17	Mean, field data
DT_{50} in soil (d)	346	Geometric mean, field
K_{Foc}	124	Arithmetic mean

1/n	0.96	Arithmetic mean
Plant uptake factor	0	default
Metabolite	**CSCD465008**	
Molecular weight (g/mol)	162	
Formation fraction	1.0	default
DT_{50} in soil (d)	25.9	Geometric mean, field
K_{Foc}	1.-3. horizon: 0.065 4.-6. horizon: 0	K_F-values (arithmetic mean) specific for soil horizons, Hamburg scenario
1/n	0.93	Arithmetic mean
Plant uptake factor	0	default

PEC_{gw} of Isopyrazam and its metabolites due to direct leaching

Table 8.8-3: PEC_{gw} for Isopyrazam and its metabolites for the application of Bontima in cereals considered relevant for German exposure assessment

Group/use No.	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 5.5.3		
		Isopyrazam	Metabolite CSCD459488	Metabolite CSCD465008
A / spring cereals	Hamburg	<0.001	1.074	0.211
A / winter cereals	Hamburg	<0.001	1.149	0.223

According to the results of the groundwater simulation with FOCUS-PELMO, a groundwater contamination of the active substance Isopyrazam in concentrations ≥ 0.1 µg/L is not expected for the intended use in spring and winter cereals.

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam a groundwater concentrations ≥ 0.1 µg/L cannot be excluded for the application in cereals according to the results of the groundwater simulation with FOCUS-PELMO.

8.8.2.2 Cyprodinil and its metabolites

The endpoints used for groundwater modelling for Cyprodinil and its metabolites CGA249287, CGA321915 and CGA275535 according to INPUT DECISION 3.1 are summarised in the German registration report 006883-00/00.

PEC_{gw} of Cyprodinil and its metabolites due to direct leaching

Table 8.8-4: PEC_{gw} for Cyprodinil and its metabolite(s) for the application of Bontima in cereals considered relevant for German exposure assessment

Group/use No.	Scenario	80th percentile PEC_{gw} at 1 m soil depth (µg L^{-1}) groundwater model: FOCUS PELMO 4			
		Cyprodinil	metabolite CGA249287	metabolite CGA321915	metabolite CGA275535
A/ spring and winter cereals	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001

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

For the metabolites CGA249287, CGA321915 and CGA275535 of Cyprodinil a groundwater concentrations ≥ 0.1 µg/L can be excluded for the application in cereals according to the results of the groundwater simulation with FOCUS-PELMO.

8.8.3 Additional field test (KCP 9.2.4.2)

Isopyrazam

A ground water monitoring study in Germany was carried out by the applicant. The 2nd Interim Report of the monitoring covering the study period May 2012 to October 2015 is available:

Liss and Naeb (2016): Isopyrazam (SYN520453) - Groundwater Monitoring for Isopyrazam (SYN520453) and its Metabolites CSCD459488 and CSCD459489 in Germany (Interim Report Number 2). Report Number: IF-12/02265870-INT02

The monitoring study is presented in the Addendum (April 2017) to the DAR by RMS UK.

In this registration report the monitoring is not evaluated by UBA. The study is not finalised at this time point and the decision by UBA is still open.

Cyprodinil

Not required.

8.8.4 Summary on estimation of PECgw after direct leaching

Results of modelling with FOCUS PELMO 5.5.3 show that the active substance Isopyrazam is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of Bontima in cereals according to use No. A.

For the metabolites CSCD459488 and CSCD465008 concentrations of ≥ 0.1µg/L in groundwater cannot be excluded. An assessment of metabolites of Isopyrazam regarding their relevance for groundwater is necessary.

Results of modelling with FOCUS PELMO show that the active substance Cyprodinil is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended uses of Bontima in cereals according to use No. A.

For the metabolites CGA249287, CGA321915 and CGA275535 concentrations of ≥ 0.1µg/L in groundwater can be excluded.

Consequences for authorization:

For the metabolites CSCD459488 and CSCD465008 of Isopyrazam an assessment regarding their relevance for groundwater is necessary in prinipal. However, the metabolites CSCD459488 und CSCD465008 are of no toxicological relevance in the groundwater because isopyrazam is not yet classified legally.

8.8.5 Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage

Surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3.01.

Table 8.8-5: Input parameters related to application of Bontima for PEC_{gw} calculations

Use No.	A
Crop	cereals
Application rate (g as/ha)	Isopyrazam: 0.125 Cyprodinil: 0.375
Number of applications/interval (d)	1 x
Crop interception (%)	70 %

8.8.5.1 Isopyrazam and its metabolites

For Isopyrazam and its metabolite CSCD459488 please refer to the German registration report 006883-00/00.

The soil metabolites of Isopyrazam are formed >10 % in soil. Therefore potential groundwater contamination due to bank filtration via surface water exposure by runoff and drainage needs to be assessed.

Table 8.8-6: Input parameter for soil metabolites of Isopyrazam for EXPOSIT 3.01

Parameter	**Metabolite CSCD465008**
Molecular weight (g/mol)	162
Correction factor molecular weight	0.451
Maximum occurrence in soil (%)	17.3
$K_{Foc, Runoff}$	6.0
$K_{Foc, mobility\ class}$	1.0 (10^{th} percentile)
DT_{50} soil (d)	190
Solubility in water (mg/L)	8200

Mobility class	2
Reduction by bank filtration	75 %

PEC_{gw} of Isopyrazam and its metabolites due to bank filtration

Table 8.8-7: PEC_{gw} for soil metabolites of Isopyrazam after surface runoff and drainage with subsequent bank filtration (modelled with EXPOSIT 3.01)

Metabolite		**CSCD465008**			
Use No.	**Application rate**	**PEC_{gw} due to**			
		Runoff		**Drainage**	
		Vegetated buffer strip (m)	**Bank filtrate (µg/L)**	**Time of application**	**Bank filtrate (µg/L)**
A	9.8 g a.s./ha 70%	0	<0.001	spring/summer	<0.001
		5	-		
		10	-	autumn/winter/ early spring	0.001
		20	-		
Required labelling		none			

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

Groundwater contamination at concentrations ≥ 0.1 µg/L by the soil metabolites CSCD459488 and CSCD465008 of Isopyrazam due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization: none

8.8.5.2 Cyprodinil and its metabolites

For Cyprodinil and its metabolite CGA249287 please refer to the German registration report 006883-00/00.

According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance Cyprodinil and its metabolite CGA249287 due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

Consequences for authorization: none

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Results of PEC_{sw} calculation of Isopyrazam and Cyprodinil for the intended uses of Bontima in cereals using FOCUS Surface Water are given in the core assessment, part B, section 5.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spray drift and volatilisation with subsequent deposition and (ii) runoff, drainage separately in order to allow risk mitigation measures separately for each entry route.
Surface water exposure via spray drift and volatilization with subsequent deposition is estimated with the model EVA. Surface water exposure via surface runoff and drainage is estimated using the model EXPOSIT.

Please refer to the German registration report 006883-00/00.

8.9.1 Jusitification of new endpoints

Not applicable as no new endpoints used.

8.9.2 PECsw after exposure by spray drift and volatilization with subsequent deposition

The calculation of PEC_{sw} after exposure via spray drift and volatilization with subsequent deposition is performed using the model EVA 3. For a single application, the exposure assessment via spray drift is based on the application rate in conjunction with the 90th percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90th percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

Table 8.9-1: Input parameters for Bontima related to the application used for PEC_{sw} calculations with EVA 3

Use No.:	A
Number of applications/ interval:	1 x
Application rate (g a.s./ha)	Isopyrazam: 125 Cyprodinil: 375

8.9.2.1 Isopyrazam and its metabolites

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Isopyrazam is $< 10^{-5}$ Pa. Hence the active substance Isopyrazam is regarded as non-volatile. Therefore exposure of surface water by the active substance Isopyrazam due to volatilization with subsequent deposition does not need to be considered.

The input parameters used for modelling of surface water exposure via spray drift and volatilization with subsequent deposition with EVA 3 are summarized below.

Table 8.9-2: Input parameters for Isopyrazam used for the PEC_{sw} calculations with EVA 3

Parameter	Isopyrazam	Reference
Vapour pressure at 20 °C (Pa)	not required since no v/d	
Solubility in water at 20°C (mg/L)	not required since no v/d	
$DissT_{50}$ water (d)	not required for single applications	
$DegT_{50}$ water/sediment study, total system (d)	809	SFO (worst case)

For $PEC_{sw/sed}$ due to spray drift and volatilization with subsequent deposition for Isopyrazam please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

8.9.2.2 Cyprodinil and its metabolites

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. The vapour pressure at 20 °C of the active substance Cyprodinil is > 10^{-4} Pa. Hence the active substance Cyprodinil is regarded as volatile (volatilization from soil and plant surfaces). Therefore exposure of surface water by the active substance Cyprodinil due to volatilization with subsequent deposition needs to be considered.

Table 8.9-3: Input parameters for Cyprodinil used for the PEC_{sw} calculations with EVA 3

Parameter	Cyprodinil	Reference
Vapour pressure at 20 °C (Pa)	2.7×10^{-4}	
Solubility in water at 20 °C (mg/L)	13	
$DissT_{50}$ water (d)	not required for single applications	
$DegT_{50}$ water/sediment study, total system (d)	178	SFO (worst case)

For $PEC_{sw/sed}$ due to spray drift and volatilization with subsequent deposition for Cyprodinil please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

8.9.3 PEC_{sw} after exposure by surface runoff and drainage

The concentration of the active substance Isopyrazam and Cyprodinil in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.

Table 8.9-4: Input parameters for Bontima related to the application used for PEC_{sw} calculations with Exposit 3

Use No.:	A
Number of applications/ interval:	1 x
Application rate (g a.s./ha)	Isopyrazam: 125 Cyprodinil: 375
Crop interception:	70 %

The substance specific input parameters used for modelling surface water exposure via runoff and drainage in an adjacent ditch with EXPOSIT 3.01 are summarized in chapter 8.8.5 of this document.

For $PEC_{sw/sed}$ due to surface runoff and drainage please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Please refer to chapter 8.9.2.

8.11 Classification and labelling

8.11.1 GHS Classification and labelling

Please refer to the core assessment Part B Section 9.

8.11.2 National labelling

No specific labelling required.

8.11.3 Standard phrases under Regulation (EU) No 547/2011

Use No.	Safety precautions related to the environment

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Detailed evaluation of the new Annex II studies

Appendix 3 Additional information provided by the applicant

REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: A15840C

Product name: BONTIMA

Chemical active substances:

Isopyrazam, 62.5 g/L
Cyprodinil, 187.5 g/L

Central Zone

Zonal Rapporteur Member State: UK

NATIONAL ADDENDUM DE

(authorisation)

Applicant: Syngenta

Submission date: dd/mm/yyyy

MS Finalisation date: dd/05/2017

Version history

When	What

Table of Contents

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	Germany	barley	F	*Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Erysiphe graminis* *Rhynchosporium secalis*	Foliar Spray	BBCH 30-59	a) 1 b) 1	-	a) 2 b) 2	Isopyrazam a) 125 b) 125 Cyprodinil a) 375 b) 375	100-400	n/a*	* No PHI stated; last application determined by growth stage							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(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) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
(5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
(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 at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(8) The maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The acute and long-term TER values for isopyrazam and cyprodinil exceed the acceptability criterion TER ≥ 10 for acute effects and TER ≥ 5 for long-term/reproductive effects according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1, indicating that the acute and long-term risk to birds and mammals from dietary and secondary poisoning exposure is acceptable following use of A15840C according to the proposed use pattern.
Also the combined risk is concluded to be acceptable as well as the risk from drinking water.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for cyprodinil and BONTIMA and calculated exposure levels, according to the intended uses of the product BONTIMA in barley. The calculated TER values do achieve the acceptability criterion TER ≥ 100 for acute effects and the adjusted criterion TER ≥2 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BONTIMA in barley according to the label.

Consequences for authorisation

For the authorisation of the plant protection product BONTIMA, labelling and conditions of use are mandatory as follows:

Table 9.1-2 Labelling requirements according to § 36 (3) PflSchG

NW 262	Cyprodinil:E_bC_{50} = 0.75 mg/L (*Desmodesmus subspicatus*) Isopyrazam: NOEC = 0.310 mg/L (*Pseudokirchneriella subcapitata*)
NW 264	Cyprodinil: LC_{50} = 0.98 mg/L (*O. mykiss*); LC_{50} = 0.008 mg/L (*M. bahia*) Isopyrazam: LC_{50} = 0.009 mg/L (*O. mykiss*); LC_{50} = 0.044 mg/L (*D. magna*) Product: LC50 = 0.36 mg/L (*O.mykiss*), EC_{50}= 0.22 mg/L (*D.magna*)

Table 9.1-3 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (use group A)

NW 605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 5 m; 50 % – 10 m; conv. – 15 m;
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

9.1.1.3 TER values for aquatic organisms were calculated, taking into account the

relevant toxicity data for cyprodinil and BONTIMA and calculated exposure levels, according to the intended uses of the product BONTIMA in barley. The calculated TER values do achieve the acceptability criterion TER ≥ 100 for acute effects and the adjusted criterion TER ≥2 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BONTIMA in barley according to the label.

9.1.1.4 Consequences for authorisation

9.1.1.5 For the authorisation of the plant protection product BONTIMA, labelling and conditions of use are mandatory as follows:

Table 9.5-6 Labelling requirements according to § 36 (3) PflSchG

NW 262	Cyprodinil:EbC50 = 0.75 mg/L (*Desmodesmus subspicatus*) Isopyrazam: NOEC = 0.310 mg/L (*Pseudokirchneriella subcapitata*)
NW 264	Cyprodinil: LC50 = 0.98 mg/L (*O. mykiss*); LC50 = 0.008 mg/L (*M. bahia*) Isopyrazam: LC50 = 0.009 mg/L (*O. mykiss*); LC50 = 0.044 mg/L (*D. magna*) Product: LC50 = 0.36 mg/L (*O.mykiss*), EC50= 0.22 mg/L (*D.magna*)

Table 9.5-7 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (use group A)

NW 605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 5 m; 50 % – 10 m; conv. – 15 m;
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

9.1.1.6 Effects on bees (KCP 10.3.1)

Please refer to the core assessment provided by zRMS UK.

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

The calculated TER values achieve the acceptability criterion TER ≥ 5 (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of BONTIMA in barley according to the label.

9.1.1.8 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

The calculated TER values achieve the acceptability criterion TER ≥ 10 for acute effects and the acceptability criterion TER ≥ 5 for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of BONTIMA in barley according to the label.

Concentrations of cyprodinil and isopyrazam and the product in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BONTIMA in barley. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended use of BONTIMA in barley according to the label.

9.1.1.9 Effects on non-target terrestrial plants (KCP 10.6)

In agreement with the zRMS UK, the risk is considered acceptable as the initial screening data indicate less than 50 % phytotoxic effects at the maximum application rate.

9.1.1.10 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

-

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-4: Critical use pattern of BONTIMA grouped according to soil

Grouping according to soil			
Group	**Intended uses**	**Application rate (g/ha) (interception, %)**	**Soil-relevant effective applic. rate, cumulative (g/ha)**
A / 00-001 – 00-005	Barley (winter and spring cereals), BBCH 30-59	Isopyrazam: 1 x 125 g a.s./ha Cyprodinil: 1 x 375 g a.s./ha Interception: 1 x 70 %	Isopyrazam: 37.5 g a.s./ha Cyprodinil: 112.5 g a.s./ha

9.1.3 Consideration of metabolites

For consideration of metabolites of isopyrazam, please refer to the core asssement provided by zRMS UK and also to section 8 of the national addendum for Germany.
For metabolites of cyprodinil, please refer to the core assessment provided by zRMS UK.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Please refer to the core assessment provided by zRMS UK.

9.2.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.2.2 Risk assessment for spray applications

Please refer to the core assessment as the risk assessment presented by zRMS UK covers the intended uses in Germany.

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the core assessment provided by zRMS UK. The acute and long-term TER values for isopyrazam and cyprodinil exceed the acceptability criterion TER ≥ 10 for acute effects and TER ≥ 5 for long-term/reproductive effects according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1, indicating that the acute and long-term risk to birds is acceptable following use of A15840C according to the proposed use pattern. Also the combined risk is concluded to be acceptable.

9.2.2.2 Higher-tier risk assessment

Not triggered.

9.2.2.3 Drinking water exposure

An acceptable risk was concluded, since the calculated AReff to endpoint ratios are below the trigger. For details please refer to the core assessment provided by zRMS UK.

9.2.2.4 Effects of secondary poisoning

An acceptable risk was concluded, for details please refer to the core assessment provided by zRMS UK.

9.2.2.5 Biomagnification in terrestrial food chains

The biomagnification potential was concluded to be low, for details please refer to the core assessment provided by zRMS UK.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

The acute and long-term TER values for isopyrazam and cyprodinil exceed the acceptability criterion TER ≥ 10 for acute effects and TER ≥ 5 for long-term/reproductive effects according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1, indicating that the acute and long-term risk to birds from dietary and secondary poisoning exposure is acceptable following use of A15840C according to the proposed use pattern.
Also the combined risk is concluded to be acceptable as well as the risk from drinking water.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Please refer to the core assessment provided by zRMS UK.
Please note, that Germany previously (i.e. for the previous approval of BONTIMA according to the old legislation) used differing endpoints in tier 1 than the ones listed in the list of endpoints (and used by zRMS UK). The endpoints Germany used to apply were derived from the same studies, yet they were the respective NOEC values instead of the NOAEL values. Since it may be relevant for future evaluation, both endpoints (NOEC and NOAEL) are reported here for transparency reasons:
isopyrazam: NOEC = 8 mg/kg bw/d; NOAEL = 41 mg/kg bw/d
cyprodinil: NOEC = 5.2 mg/kg bw/d; NOAEL = 72.7 mg/kg bw/d.

9.3.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.3.2 Risk assessment for spray applications

For the acute risk assessment, please refer to the core assessment provided by zRMS UK.
For the long-term risk, the risk assessment presented in the core assessment is based on the agreed NOAEL values listed in the EFSA conclusion. Based on these values an acceptable risk was concluded already in the screening step for both cyprodinil and isopyrazam.
If the NOEC values as reported above would be used (as in the previous approval report for BONTIMA in Germany, i.e. registration report 006883-00/00) an unacceptable risk would be indicated in the screening step, yet based on tier 1 assumptions an acceptable risk can be shown for isopyrazam and for cyprodinil tier 1 under consideration of the EU agreed endpoint also results in an acceptable risk. Hence overall, the conclusion in the core assessment is supported.

9.3.2.1 First-tier assessment (screening/generic focal species)

Please refer to the explanations above in 9.3.2.

9.3.2.2 Higher-tier risk assessment

Not needed.

9.3.2.3 Drinking water exposure

An acceptable risk was concluded, for details please refer to the core assessment provided by zRMS UK.

9.3.2.4 Effects of secondary poisoning

An acceptable risk was concluded, for details please refer to the core assessment provided by zRMS UK

9.3.2.5 Biomagnification in terrestrial food chains

The biomagnification potential was concluded to be low, for details please refer to the core assessment provided by zRMS UK.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

The acute and long-term TER values for isopyrazam and cyprodinil exceed the acceptability criterion TER ≥ 10 for acute effects and TER ≥ 5 for long-term/reproductive effects according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.1, indicating that the acute and long-term risk to mammals from dietary and secondary poisoning exposure is acceptable following use of A15840C according to the proposed use pattern.
Also the combined risk is concluded to be acceptable as well as the risk from drinking water.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available yet.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Please refer to the German registration report 006883-00/00 and the core assessment performed by zRMS UK.

9.5.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.5.2 Risk assessment

For authorisation in Germany, three entry routes are considered separately in the exposure assessment for surface water: (i) spray drift together with volatilisation and subsequent deposition (where relevant), (ii) run-off, and (iii) drainage. Consequently, specific risk mitigation measures are defined and can be imposed separately for each entry route. Thus, the risk assessment from the core assessment is replaced by a specific national assessment for Germany, which is described below.

Exposure of surface water bodies via spray drift and volatilisation with subsequent deposition

Exposure assessment

Concentrations of the a.s. and BONTIMA in surface water due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3, which refers to spray drift data by Rautmann and Ganzelmeier and an empirical model for volatilisation/deposition, based on vapour-pressure classes. The vapour pressure at 20 °C of the active substance Isopyrazam is $< 10^{-5}$ Pa. Hence the active substance Isopyrazam is regarded as non-volatile and deposition following volatilisation can be disregarded in the exposure assessment. The vapour pressure at 20 °C of the active substance Cyprodinil is $> 10^{-4}$ Pa. Hence the active substance Cyprodinil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Cyprodinil due to volatilization with subsequent deposition was considered. The model input parameters for cyprodinil are provided in the Environmental Fate section.

Selection of relevant toxicity endpoint

Since for several endpoints no acceptable risk was concluded at tier 1, several refinements were proposed by the applicant and evaluated by the zRMS UK. For several areas of concern zRMS UK also highlights in the core assessment that they "[the respective area of concern] should be considered further by Member States, taking into account relevant risk mitigation measures."
For the active substance isopyrazam, we agree with the HC5 of 12.6 µg a.s./L and AF 9 as calculated and applied by the zRMS UK for fish acute, and we fully agree with the zRMS UK with respect to the reasoning for rejecting the PECsw,twa in this case for fish chronic.
With respect to acute risk for aquatic invertebrates from exposure to isopyrazam, we agree with the zRMS UK with respect to the reasoning for not following the SSD approach as suggested by the applicant (based on data from Ashwell and Langridge, 2007). We support using the 48 h EC50 44 µg a.s./L (Daphnia magna) for the risk assessment as suggested by the zRMS UK.
Invertebrates (chronic) as well as primary producers are not decisive for the derivation of risk mitigation measures due to the exposure from isopyrazam resulting from the use of BONTIMA.
For cyprodinil, we support the consideration of the microcosm study by Ashwell et al. (2007) and we agree with the derived NOEC of 1.5 µg a.s./L. In line with EFSA Journal 2013;11(7):3290 we consider an AF of 2 in the given case as relevant to derive an ETO-RAC of 0.75 µg/L to derive risk mitigation measures for Germany. This covers the acute risk that needed refinement as well.
For the product, the risk for invertebrates is most critical. The zRMS UK has shown that the calculated versus the measured toxicity of the product ("mixture toxicity") indicated no synergistic effect (and no antagonistic effect), consequently allowing for assuming concentration additivity. Not shown by the zRMS UK is a comparison of the toxic units to establish whether a driver of the toxicity can be identified. If done, however, this would result in about 80 % of TU deriving from cyprodinil and about 20 % of TU deriving from isopyrazam. Thus both a.s. contribute to the overall toxicity and thus the measured toxicity endpoint

of the product is considered for the risk assessment.

Thus, in order to select the relevant endpoint for the derivation of risk mitigation measures for Germany, the following endpoints and respective AF values are considered:

Table 9.5-1: Critical endpoints and effect values relevant for the risk assessment for aquatic organisms

Species	Substance	Exposure System	Results	Reference	AF	RAC [µg/L]	Fraction of compd. in product	RAC/ fraction-compd.
SSD fish acute	isopyrazam	96 h, s	HC_5 = 12.6 µg a.s./L $_{mm}$	Please refer to the core assessment by zRMS UK	9	1.4	0.0625	22.4
Pimephales promelas	isopyrazam	32 d, f	NOEC = 2.87 µg a.s./L $_{mm}$	XXX. 05.07.2007 XXX XXX Lit no. 73215	10	0.287	0.0625	4.592
Daphnia magna	isopyrazam	48 h, s	EC_{50} = 44 µg a.s./L $_{mm}$	Benyon, K., Richardson, M. 11.01.2007 T002590-05-REG, 2033945 ICS Lit. no. 73269	100	0.44	0.0625	7.04
Daphnia magna	A15840C (tested as A15840K)[a]	48 h, s	EC_{50} = 220 µg product/L $_{nom}$ (initially measured)	Höger, S 22.08.2008 B89223 ICS Lit no. 73163	100	2.2	1	2.2
Higher-tier studies (microcosm studies)								
Cyprodinil (CGA 219417) 300 g/L EC formulation A14325E, 3 x 1.5 ; 5; 10; 20 und 50 µg/L, 7 d interval, 114 d test duration after 1st application	**NOEC = 1.5 µg a.s /L**		Ashwell, J. et al. 11.09.2007 T008777-05-REG ICS Lit no. 68479		2	0.75	0.1875	4

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations. RAC: regulatory acceptable concentration; AF: Assessment factor

The selection of the relevant assessment scenario is based on a comparison of the ratios between the regulatory acceptable concentrations (RAC; effect value for toxicity divided by relevant assessment factor) for

each substance and their respective numerical shares in the product.

Overall, for the entrance pathway spraydrift, the endpoint for the product is decisive for the derivation of relevant risk mitigation measures in Germany. Since cyprodinil is classified as semivolatile, its contribution to the composition of total deposits (spray drift and deposition following volatilisation) becomes more important with increasing buffer zones or more effective technical drift reduction. No simplified approach is available in such cases for estimating relative risk levels of individual components in a product. To identify the decision-relevant realistic worst case, the quantitative risk assessment is therefore performed for all relevant components of BONTIMA (here cyprodinil is covering isopyrazam) as well as for the product itself. For the product, endpoint and PEC are expressed as sum of a.s. to account for the differing properties of the two a.s. (i.e. for isopyrazam only drift is considered and added to the PEC for cyprodinil, for which drfit and v/d are considered).

Table 9.5-2: Assessment of the risk for aquatic organisms due to the use of BONTIMA in barley (use group A) – exposure to entries of cyprodinil via spray drift and volatilisation/deposition, considering risk mitigation measures

Active substance/product:			cyprodinil					
Intended use:			A: Barley (winter and spring cereals), BBCH 30-59					
Application parameters:			1 x 375 g a.s./ha					
DisT$_{50}$ water phase (SFO):			Not required for single application					
Scenario, drift percentile:			90th					
PEC type:			ini					
Buffer zone (m)	**Spray drift**		**Deposition following volatilisation**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**(µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
1	2.77%	3.463	0.221%	0.276	3.738	2.007	1.141	0.622
5	0.57%	0.713	0.178%	0.222	0.934	0.578	0.400	0.293
10	0.29%	0.363	0.135%	0.169	0.531	0.350	0.259	0.205
15	0.20%	0.250	0.103%	0.129	0.379	0.254	0.191	0.154
20	0.15%	0.188	0.079%	0.098	0.285	0.192	0.145	0.117
Endpoint (µg/L) and AF:			NOEC = 1.5 µg a.s./L, AF 2					
TER acceptability criterion / RAC (µg/L):			2 / 0.75					
Buffer zone (m)					**TER**			
1					0.400	0.700	1.300	2.400
5					1.600	2.600	3.800	5.100
10					2.800	4.300	5.800	7.300
15					4.000	5.900	7.900	9.800
20					5.300	7.800	10.400	12.900
Risk mitigation measures:			NW 605/606 (no drift reduction 10 m, 50% 5 m, 75% 5 m, 90 % 1 m)					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger;

AF: Assessment factor; RAC: Regulatory acceptable concentration

Table 9.5-3: Assessment of the risk for aquatic organisms due to the use of BONTIMA in barley (use group A) – exposure to entries of BONTIMA via spray drift, considering risk mitigation measures

Active substance/product:	BONTIMA							
Intended use:	A: Barley (winter and spring cereals), BBCH 30-59							
Application parameters:	1 x 2 L./ha, corresponding to 125 g isoyprazam + 375 g cyprodinil = 500 g sum of a.s./ha							
DisT$_{50}$ water phase (SFO):	Not required for single application							
Scenario, drift percentile:	90th							
PEC type:	ini							
Buffer zone (m)	**Spray drift**		**Deposition following volatilization (relevant for cyprodinil and thus considered in sum of a.s. calculation for cyprodinil only)**		**PEC$_{sw}$; conventional and drift-reducing technique**			
					0 % red.	**50 % red.**	**75 % red.**	**90 % red.**
	(%)	**Product as sum of a.s. (µg/L)**	**(%)**	**(µg/L)**	**(µg/L)**			
1	2.77%	4.617	0.221%	0.276	4.892	2.584	1.430	0.737
5	0.57%	0.95	0.178%	0.222	1.172	0.697	0.459	0.317
10	0.29%	0.483	0.135%	0.169	0.652	0.410	0.290	0.217
15	0.20%	0.333	0.103%	0.129	0.462	0.295	0.212	0.162
20	0.15%	0.25	0.079%	0.098	0.348	0.223	0.160	0.123
Endpoint (µg/L) and AF:	EC50 = 220 µg product/L, corresponding to **55 µg sum of a.s./ha**, AF 100							
TER acceptability criterion / RAC (µg/L):	100 / 2.2 µg product/L= 0.55 µg sum of a.s./L							
Buffer zone (m)					**TER (for product expressed as sum of a.s.)**			
1					**11.2**	**21.3**	**38.5**	**74.6**
5					**46.9**	**79.0**	119.8	173.7
10					**84.3**	134.0	189.9	253.3
15					119.1	186.3	259.6	339.7
20					158.1	246.7	342.8	447.5
Risk mitigation measures:	NW 605/606 (no drift reduction 15 m, 50% 10 m, 75% 5 m, 90 % 5 m)							

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger;
AF: Assessment factor; RAC: Regulatory acceptable concentration

An acceptable risk is concluded considering the measured toxicity of the product (expressed as sum of a.s.) under consideration of drift reduction; refinement is not needed.

Exposure of surface water bodies via run-off or drainage

Exposure assessment

The concentrations of the active substances cyprodinil and isopyrazam in an adjacent ditch due to surface run-off or drainage are calculated using the model EXPOSIT 3.01. The relevant input parameters for exposure modelling are provided in the Environmental Fate section.

Selection of relevant toxicity endpoint

See above (assessment for exposure via spray drift and volatilisation with subsequent deposition).

Table 9.5-4: Assessment of the risk for aquatic organisms due to the use of BONTIMA in barley (use group A) – exposure to entries of cyprodinil via run-off or drainage, considering risk mitigation measures

Active substance:	cyprodinil	
Intended use	A: Barley (winter and spring cereals), BBCH 30-59	
Application parameters:	1 x 375 g a.s./ha, 70 % interception	
Endpoint (µg/L) and AF:	NOEC = 1.5 µg a.s./L, AF 2	
TER acceptability criterion / RAC (µg/L):	2 / 0.75	
Run-off		
Buffer zone (m)	**PEC (µg/L)**	**TER**
0	0.75	**2.0**
5	0.65	**2.3**
10	0.56	**2.7**
20	0.39	**3.8**
Drainage		
Time of application	**PEC (µg/L)**	**TER**
Spring/summer	0.05	27.9
Autumn/winter	0.02	86.0
Risk mitigation measures:	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; RAC: Regulatory acceptable concentration

Table 9.5-5: Assessment of the risk for aquatic organisms due to the use of BONTIMA in barley (use group A) – exposure to entries of isopyrazam via run-off or drainage, considering risk mitigation measures

Active substance:	isopyrazam	
Intended use	A: Barley (winter and spring cereals), BBCH 30-59	
Application parameters:	1 x 125 g a.s./ha, 70 % interception	
Endpoint (µg/L) and AF:	NOEC = 2.87 µg a.s./L, AF 10	
TER acceptability criterion / RAC (µg/L):	10 / 0.287	
Run-off		
Buffer zone (m)	**PEC (µg/L)**	**TER**
0	0.12	23.9
5	0.10	27.58
10	0.09	32.17
20	0.06	45.96
Drainage		
Time of application	**PEC (µg/L)**	**TER**
Spring/summer	0.01	494.15
Autumn/winter	0.02	160.6
Risk mitigation measures:	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger; AF: Assessment factor; RAC: Regulatory acceptable concentration

For considerations on metabolites, please refer to the core assessment by zRMS UK.

9.5.3 Overall conclusions

TER values for aquatic organisms were calculated, taking into account the relevant toxicity data for cyprodinil and BONTIMA and calculated exposure levels, according to the intended uses of the product BONTIMA in barley. The calculated TER values do achieve the acceptability criterion TER ≥ 100 for acute effects and the adjusted criterion TER ≥2 for effects on aquatic organisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.2, provided that risk mitigation measures (spray drift reduction) are applied. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of BONTIMA in barley according to the label.

Consequences for authorisation

For the authorisation of the plant protection product BONTIMA, labelling and conditions of use are mandatory as follows:

Table 9.5-6 Labelling requirements according to § 36 (3) PflSchG

NW 262	Cyprodinil:E_bC_{50} = 0.75 mg/L (*Desmodesmus subspicatus*) Isopyrazam: NOEC = 0.310 mg/L (*Pseudokirchneriella subcapitata*)
NW 264	Cyprodinil: LC_{50} = 0.98 mg/L (*O. mykiss*); LC_{50} = 0.008 mg/L (*M. bahia*) Isopyrazam: LC_{50} = 0.009 mg/L (*O. mykiss*); LC_{50} = 0.044 mg/L (*D. magna*) Product: LC50 = 0.36 mg/L (*O.mykiss*), EC_{50}= 0.22 mg/L (*D.magna*)

Table 9.5-7 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (use group A)

NW 605-1/606	Drift-reduction technique– corresponding buffer zone: 90 % – 5 m; 75 % – 5 m; 50 % – 10 m; conv. – 15 m;
NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

9.6 Effects on bees (KCP 10.3.1)

Please refer to the core assessment provided by zRMS UK.

9.6.1 Toxicity data

Please refer to the core assessment provided by zRMS UK.

9.6.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.6.2 Risk assessment

Please refer to the core assessment provided by zRMS UK and the report provided by JKI.

9.6.2.1 Hazard quotients for bees

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

No information available yet (see core assessment provided by zRMS UK).

9.6.4 Effects on solitary bees

No information available yet (see core assessment provided by zRMS UK).

9.6.5 Overall conclusions

Please refer to the core assessment provided by zRMS UK and the report provided by JKI.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Please refer to the core assessment provided by zRMS UK.

9.7.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.7.2 Risk assessment

9.7.2.1 Risk assessment for in-field exposure

Not considered by UBA.

9.7.2.2 Risk assessment for off-field exposure

An acceptable risk was concluded for off-field exposure based on tier 1 data (i.e. glass plate tests) for A15840C (tested as A15840K, which contains isopyrazam with *syn*:*anti* ratio of 70:30 but despite is identical to A15840C which contains varying *syn*:*anti* ratio from 70:30 to 100:0).
The zRMS UK deviates from the original study evaluation for *Aphidius rhopalosiphi* (study by Stevens (2008), report no. SYN-08-1, internal ICS lit no. 73417) due to some concern over the derivation of the LR_{50} value for *Aphidius.* As a worst-case approach, the HQ has also been calculated using an LR_{50} of 75 ml product/ha, although this application rate resulted in only 2.5 % mortality in the study, instead of 177.4 mLA15840K/ha. This very conservative LR_{50} results in a HQ of 1.1, thus still below the Annex VI trigger. The corresponding and acceptable TER value is 6.7 based on PECact of 11.08 mL/ha (1 x 2 L product/ha, 90. Percentile, correction factor of 5), which is acceptable since additional species have been tested.
For further details please refer to the core assessment. (Reference can also be made to the previous approval report of BONTIMA – registration report no. 006883-00/01 – in Germany under old legislation)

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The calculated TER values achieve the acceptability criterion TER ≥ 5 (extended toxicity database) for effects on non-target arthropods, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that overrides the prescriptions of Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.4. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of BONTIMA in barley according to the label.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

The critical endpoints for earthworms are the NOEC of 13.5 L/ha for A15840C (tested as A15840K) (study of Friedrich, 2008, report no. 081048032 S, internal ICS lit no. 73500), the NOEC(corrected) of 20 mg/kg soil dw for cyprodinil (study of Ehlers, 2001, report no. 10291022, internal ICS lit no. 33718) and the NOEC of 1.13 mg/kg soil dw for the metabolite CGA249287 (study by Pfeilfle, 2001, report no. L01-000120, internal ICS lit no. 53406).
For other soil macroorganisms the NOEC of 240mg/kg soil dw for A15840C (tested as A15840K) (study of Friedrich, 2008, report no. 081048033 S, internal ICS lit no. 73499) has been considered by the zRMS UK as well as endpoints for the active substances and the metabolites CSCD459488 and CSCD465008, i.e. NOEC of 15 mg/kg soil dw for isopyrazam (study of Friedrich, 2008, report no. 081048019 S, internal ICS lit no. 73512), NOEC of 50 mg/kg soil dw for CSCD 459488 (study of Friedrich, 2008, report no. 0810024 S, internal ICS lit. no 73511), NOEC of 50 mg/kg soil dw for CSCD465008 (study by Friedrich, 2008, report no. 081048026 S, internal ICS lit no. 73510) and NOEC of 21.6 mg/kg soil dw for cyprodinil (tested as A9219B, product "Switch", containing cyprodinil and fludioxonil) (study by Friedrich, 2014, report no. 14 10 48 185 S, internal ICS lit no. 86843). We agree with these endpoints except for the use of the endpoint for cyprodinil since the particular test conducted with the product formulation A9219B shows significant mortality. Thus we suggested to use the LC50 with an assessment factor of 10 instead of the NOEC with an assessment factor of 5 in the product assessment of A9219B. For the active substance cyprodinil this would correspond to LC50 = 90 mg/kg soil dw (uncorrected since the test was conducted with 5 % peat).
Further Germany previously requested a test with CGA 249287 on Folsomia candida, which was submitted as confirmatory data for the previous approval report of BONTIMA – registration no. 006883-00/01 – in Germany under old legislation. The NOEC for CGA 249287 is 31 mg/kg soil dw (study of Vinall, 2012, report no. SYN-12-40, internal ICS lit no. 81264.
For further details please refer to the core assessment provided by zRMS UK. (Reference can also be made to the previous approval report of BONTIMA – registration no. 006883-00/01 – in Germany under old legislation).

9.8.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

9.8.2.1 First-tier risk assessment

For the product formulation the relevant application rate can be compared to application rate (NOEC = 13.5 L/ha, PECsoil = 2 L/ha) resulting in an acceptable TER value of 6.75.
For the risk assessment concerning the other critical endpoints exposure values for Germany have to be considered which are identical to those given in the former German registration report 006883-00/00 for BONTIMA. Since all TER values where above the critical TER threshold, no further quantitative risk assessment is given within this national addendum.
The newly calculated PECsoil for the isopyrazam metabolite CSCD465008 is 0.0081 mg/kg and the corresponding TER value based on the 56-day NOEC = 10 mg CSCD465008/kg as reported by zRMS UK is also well above the TER threshold.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

The calculated TER values achieve the acceptability criterion TER ≥ 10 for acute effects and the acceptability criterion TER ≥ 5 for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5. The results of the assessment indicate an acceptable risk for earthworms due to the intended use of BONTIMA in barley according to the label.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with the active substances and their relevant metabolites as well as with the product (tested as A15840K). Full details of these studies are provided in the respective EU DAR and related documents as well as in the core assessment of zRMS UK.

9.9.1.1 Justification for new endpoints

Please refer to the core assessment provided by zRMS UK.

9.9.2 Risk assessment

Since up to 20 kg cyprodinil/ha, 1.5 kg isopyrazam/ha and 6 L A15840K/ha effects were < 25 % (i.e. at

amounts well above the max. soil relevant amount according to the GAP), no further quantitative risk assessment is carried out for Germany.

9.9.3 Overall conclusions

Concentrations of cyprodinil and isopyrazam and the product in soil were determined where effects on nitrogen and carbon mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product BONTIMA in barley. The comparison indicates no exceedance of the acceptability criterion ≤ 25 % effects on soil microorganisms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.6. The results of the assessment indicate an acceptable risk for soil microorganisms due to the intended use of BONTIMA in barley according to the label.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Please refer to the core assessment provided by zRMS UK.

9.10.1.1 Justification for new endpoints

Please refer to the core assessment by zRMS UK.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Please refer to the core assessment provided by zRMS UK.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

Not triggered.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

In agreement with the zRMS UK, the risk is considered acceptable as the initial screening data indicate less than 50 % phytotoxic effects at the maximum application rate.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not applicable.

9.12 Monitoring data (KCP 10.8)

Not applicable.

9.13 Classification and Labelling

Provide a justification for the proposed classification and labelling of the product.

Appendix 1 Lists of data considered in support of the evaluation

Please refer to the core assessment provided by zRMS UK.

Appendix 2 Detailed evaluation of the new studies

Please refer to the core assessment provided by zRMS UK.