

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: BAS 717 00 F**

**Product name(s): Brivela**

**Chemical active substance(s):**

**Difenoconazole, 50 g/L**

**Fluxapyroxad, 75 g/L**

### **Central Zone**

**Zonal Rapporteur Member State: Poland**

**NATIONAL ASSESSMENT Germany  
(authorization)**

**Applicant: BASF**

**Submission date: 2018-12-12**

**MS Finalisation date: 15.07.2021**

## Version history

<b>When</b>	<b>What</b>
20.12.2019	dRR of zRMS PL for commeting
10.11.2020	Final RR of zRMS (PL)
15.07.2021	Final decision Germany

## Table of Contents

<b>1</b>	<b>Details of the application .....</b>	<b>5</b>
1.1	Application background .....	5
1.2	Letters of Access .....	5
1.3	Justification for submission of tests and studies .....	6
1.4	Data protection claims .....	6
<b>2</b>	<b>Details of the authorization decision .....</b>	<b>6</b>
2.1	Product identity .....	6
2.2	Conclusion .....	7
2.3	Substances of concern for national monitoring .....	7
2.4	Classification and labelling .....	8
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008 .....	8
2.4.2	Standard phrases under Regulation (EU) No 547/2011 .....	9
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) .....	9
2.5	Risk management .....	9
2.5.1	Restrictions linked to the PPP .....	9
2.5.2	Specific restrictions linked to the intended uses .....	10
2.6	Intended uses (only NATIONAL GAP) .....	11
<b>3</b>	<b>Background of authorization decision and risk management .....</b>	<b>13</b>
3.1	Physical and chemical properties (Part B, Section 2) .....	13
3.2	Efficacy (Part B, Section 3) .....	13
3.3	Efficacy data .....	13
3.3.1	Information on the occurrence or possible occurrence of the development of resistance .....	14
3.3.2	Adverse effects on treated crops .....	14
3.3.3	Observations on other undesirable or unintended side-effects .....	14
3.4	Methods of analysis (Part B, Section 5) .....	14
3.4.1	Analytical method for the formulation .....	14
3.4.2	Analytical methods for residues .....	14
3.5	Mammalian toxicology .....	15
3.5.1	Acute toxicity .....	15
3.5.2	Operator exposure .....	15
3.5.3	Worker exposure .....	15
3.5.4	Bystander and resident exposure .....	15
3.6	Residues and consumer exposure .....	15
3.6.1	Residues .....	15
3.6.2	Consumer exposure .....	15
3.7	Environmental fate and behaviour (Part B, Section 8) .....	16
3.7.1	Predicted environmental concentrations in soil (PEC <sub>soil</sub> ) .....	16
3.7.2	Predicted environmental concentrations in groundwater (PEC <sub>gw</sub> ) .....	16
3.7.3	Predicted environmental concentrations in surface water (PEC <sub>sw</sub> ) .....	17
3.7.4	Predicted environmental concentrations in air (PEC <sub>air</sub> ) .....	17
3.8	Ecotoxicology (Part B, Section 9) .....	17
3.8.1	Effects on terrestrial vertebrates .....	17

3.8.2	Effects on aquatic species .....	18
3.8.3	Effects on bees .....	18
3.8.4	Effects on other arthropod species other than bees.....	19
3.8.5	Effects on soil organisms .....	19
3.8.6	Effects on non-target terrestrial plants.....	20
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	21
3.9	Relevance of metabolites (Part B, Section 10) .....	21
<b>4</b>	<b>Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) .....</b>	<b>21</b>
<b>5</b>	<b>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization .....</b>	<b>22</b>
<b>Appendix 1</b>	<b>Copy of the product authorization (see Appendix 6).....</b>	<b>23</b>
<b>Appendix 2</b>	<b>Copy of the product label.....</b>	<b>23</b>
<b>Appendix 3</b>	<b>Letter of Access .....</b>	<b>24</b>
<b>Appendix 4</b>	<b>Lists of data considered for national authorization.....</b>	<b>25</b>
<b>Appendix 5</b>	<b>Comparative Assessment – original reports.....</b>	<b>26</b>
	<b>Stellungnahme des JKI zur vergleichenden Bewertung hinsichtlich zur Verfügung stehender alternativen Bekämpfungsmöglichkeiten.....</b>	<b>26</b>
	<b>Stellungnahme des BfR zur vergleichenden Bewertung gesundheitlicher Risiken.....</b>	<b>34</b>
<b>1</b>	<b>Gegenstand der Bewertung.....</b>	<b>34</b>
<b>2</b>	<b>Ergebnis .....</b>	<b>34</b>
<b>3</b>	<b>Begründung .....</b>	<b>35</b>
	<b>Stellungnahme des UBA zur vergleichenden Bewertung gesundheitlicher Risiken.....</b>	<b>37</b>
<b>Appendix 6</b>	<b>Copy of the product authorization .....</b>	<b>59</b>

# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application was submitted by BASF SE on 12.12.2018 in order to allow the registration (Art. 29) of this product in Germany according to Regulation (EC) No 1107/2009.

Poland is the zRMS for the evaluation of the core assessment and Germany is cMS.

The application is for registration of Brivela containing 50 g/L Difenconazole and 75 g/L Fluxapyroxad. The product is intended to be used as fungicide to control different pests in wheat and winter soft wheat. It is a SC formulation.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 0-10 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Brivela where that data have not been considered in the EU review. Otherwise assessments for the safe use of Brivela have been made using endpoints agreed in the EU review of Difenconazole and Fluxapyroxad.

This document describes the specific conditions of use and labelling required for the German registration of Brivela.

As difenconazole was approved as a candidate for substitution a comparative assessment has been prepared (see chapter 4 of this document).

Appendix 1 should include the authorisation of the final product in Germany. Due to technical reasons, the authorisation of the final product in Germany is inserted under Appendix 5.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the German label has to fulfil the requirements according to Article 31 of Regulation (EC) No 1107/2009 and PflSchG § 31.

Appendix 3: Letters of access are classified as confidential and, thus, are not attached to this document.

Appendix 4 of this document contains the lists of data considered for national authorisation.

Appendix 5 of this document provides a copy of the final product authorisation in Germany.

Appendix 6 of this document provides the original reports of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009).

#### 1.2 Letters of Access

No letter of access is required. The data requirements are addressed by own and publicly available data.

### 1.3 Justification for submission of tests and studies

To obtain approval the product *Brivela* must meet for difenoconazole the conditions of Commission Implementing Regulation (EU) No 540/2011 (included into Annex I of Directive 91/414 by Directive 2008/69/EC, and approved as an active substance in accordance with Regulation (EC) No. 1107/2009 by the Commission Implementing Regulation (EU) No. 540/2011 amended by Regulation (EU) No. 1100/2011) and for Fluxapyroxad the Commission Implementing Regulation (EU) No 589/2012 of 04 July 2012 and be supported by dossiers satisfying the requirements according to Commission Regulation (EU) No 284/ 2013, with an assessment to Uniform Principles, using agreed end-points.

This application was submitted in order to allow the registration of this product in Germany in accordance with the above.

The reference list included in Part A Appendix 4 defines the list of studies and reports, submitted by the applicant and relied on as well as a list of studies submitted by the applicant but not relied on for the authorisation. Furthermore, Appendix 4 includes studies already evaluated at EU peer review and studies necessary but not submitted.

### 1.4 Data protection claims

The list of studies for which the applicant requests data protection in accordance with Article 59 of Regulation (EC) No 1107/2009 is reported in Appendix 4 of the Registration Report. The applicant confirms that no period of data protection has previously been granted in respect of these studies or has been granted and expired. Studies marked “N” in the data protection list are not protected.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	BAS 717 00 F
Product name in MS	Brivela
Authorization number	New product; authorisation number not available
Function	fungicide
Applicant	BASF
Active substance(s) (incl. content)	Difenoconazole, 50 g/L Fluxapyroxad, 75 g/L
Formulation type	Suspension Concentrate [Code: SC]
Packaging	0.15 – 1.0 L HDPE bottles; 0.15 – 1.0 L F-HDPE bottles; 1 – 20 L HDPE jerry cans; 1 – 20 L F-HDPE jerry cans; 50 L HDPE jerry cans 50 L F-HDPE jerry cans, professional user
Coformulants of concern for	not applicable

national authorizations	
Restrictions related to identity	Related to the specified limit of 0.6 g/kg toluene in fluxapyroxad (TGAI) the maximum content of toluene in the formulation should be $\leq 43$ mg/kg
Mandatory tank mixtures	not applicable
Recommended tank mixtures	not applicable

## 2.2 Conclusion

With respect to identity, physical, chemical and technical properties, further information and analytical methods for the formulation an authorisation can be granted.

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

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

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

The product is classified as non-hazardous to bees.

From the efficacy point of view, an authorisation can be granted to all uses applied for, however, the crops have to be restricted to winter soft wheat only.

The comparative assessment demonstrated that for the uses 003+004 alternatives which are significantly safer for the environment and human health exist.

The evaluation of the application for Brivela resulted in the decision to grant the authorization.

All uses applied for were authorised except for use(s) on <insert crop(s)> due to <insert reason(s) for refusal> or

The evaluation of the application for <product name> resulted in the decision to refuse the authorization. The reason(s) for the refusal is/are <insert reason for refusal>.

**An authorisation can be granted for uses 001 and 002 but not for uses 003 and 004 due to existing alternatives which are significantly safer for the environment and human health.**

## 2.3 Substances of concern for national monitoring

-

## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	Skin Sens. 1, Lact. 2, Aquatic Chronic 1
-------------------------------	--

The following labelling information is derived from the classification and to be mentioned in the safety data sheet.

Hazard pictograms:	
GHS07	exclamation mark
GHS09	environment
Signal word:	
	Warning
Hazard statement(s):	
H317	May cause an allergic skin reaction.
H362	May cause harm to breast-fed children.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P263	Avoid contact during pregnancy and while nursing.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water/...
P308+P313	IF exposed or concerned: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash before reuse.
P391	Collect spillage
P501	Dispose of contents/container to ...
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	'Contains 1,2-benzisothiazole-3(2H)-one. May produce an allergic reaction.' [EUH208]
	'Contains 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.' [EUH208]

Special rule for labelling of plant protection product (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 1,2-benzisothiazole-3(2H)-one. May produce allergic reactions.
EUH 208	Contains 2-methyl-2H-isothiazol-3-one. May produce allergic reactions.

## 2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
------	---

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator 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.
SB111	Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
SB166	Do not eat, drink or smoke when using this product.
SS110-1	Protective gloves (plant protection) must be worn when handling the undiluted product.
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.
SS530	Wear face protection when handling the undiluted product.
SS610	Wear a rubber apron when handling the undiluted product.
Worker protection:	
SF245-02	It must be ensured that treated areas/crops may not be entered until the film of the plant protection product has dried.
Integrated pest management (IPM)/sustainable use:	
WMFC2	Mode of action (FRAC-group): C2 (for fluxapyroxad)
WMFG1	Mode of action (FRAC-group): G1 (for difenoconazole)

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)
WH952	The indication identifying the mode of action must be assigned directly to each corresponding name of the active substance as supplementary information on the packaging and in the instructions for use.
Environmental protection	
NW262	The product is toxic for algae.
NW264	The product is toxic for fish and aquatic invertebrates.
NW265	The product is toxic for higher aquatic plants.
NW470	Where applicable, fluids left over from application, granules and their remains as well as 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.
Other specific restrictions	
None	

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.
NN1002	The product is classified as non-harmful for populations of relevant beneficial predatory mites and spiders.

## 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
WW709	Repeated applications of the product, or products of the same active substance group, may result or have resulted in a reduction of effectivity. To prevent resistance, the product should be applied alternately with products from other active substance groups.	use number 001 from GAP table in 2.6
Environmental protection:		Relevant for use no.
NW609-1	When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water-bearing surface waters - the product must be applied observing the minimum buffer zone stated below. It is not necessary to observe this buffer zone if the product is applied using equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993 (Federal Gazette No 205, p. 9780) as amended. Irrespective of this, in addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times. Violations may be punished by fines of up to 50 000 EUR.  5 m	001, 002
Other specific restrictions:		Relevant for use no.
None		

## 2.6 Intended uses (only NATIONAL GAP)

**Reg.-No.** 00A343-00/00  
**PPP (product name/code):** Brivela  
 Active substance 1: Difenoconazol  
 Active substance 2: Fluxapyroxad  
 Applicant: BASF SE  
 Zone(s): central (d)  
 Verified by MS: Yes

**GAP rev.1, date:** 2020-11-19  
**Formulation type:** SC (a, b)  
 Conc. of as 1: 50.00 g/L (e)  
 Conc. of as 2: 75.00 g/L (e)  
 Professional use: Yes  
 Non professional use: No  
 Field of use: fungicid

1 Use- No. (e)	2 Member state(s)	3 Crop and/ or situation  (crop destination / purpose of crop)	4 F, Fn, Fpn G, Gn, Gpn or I	5 Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	6 Application				10 Application rate			13 PHI (days)	14 Remarks:  e.g. g safener/synergist per ha (f)
					6 Method / Kind	7 Timing / Growth stage of crop & season	8 Max. number a) per use b) per crop/ season	9 Min. interval between ap- plications (days)	10 kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	11 g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	12 Water L/ha min / max		
001	DE	wheat (TRZSS) winter soft wheat (TRZAW)	F	leaf spot of wheat (SEPTTR)	spraying	From spring at beginning of infesta- tion and/or when first symptoms become visible 30 to 49	a) 1 b) 1		a) 1.50 L/ha b) 1.50 L/ha	a) a.s. 1: 0.075 kg/ha a.s. 2: 0.1125 kg/ha b) 0.075 kg/ha 0.1125 kg/ha	200 - 300 L/ha	56	An authorization only for TRZAW is possible be- cause of the evaluation of the RMS.
002	DE	wheat (TRZSS) winter soft wheat (TRZAW)	F	brown leaf rust of cereals ( <i>Puccinia recondita</i> ) (PUCCRE)	spraying	From spring at beginning of infesta- tion and/or when first symptoms become visible 30 to 49	a) 1 b) 1		a) 1.50 L/ha b) 1.50 L/ha	a) a.s. 1: 0.075 kg/ha a.s. 2: 0.1125 kg/ha b) 0.075 kg/ha 0.1125 kg/ha	200 - 300 L/ha	56	An authorization only for TRZAW is possible be- cause of the evaluation of the RMS.
003	DE	wheat (TRZSS) winter soft wheat (TRZAW)	F	powdery mildew ( <i>Erysiphe graminis</i> ) (ER- YSGR)	spraying	From spring at beginning of infesta- tion and/or when first	a) 1 b) 1		a) 1.50 L/ha b) 1.50 L/ha	a) a.s. 1: 0.075 kg/ha a.s. 2: 0.1125 kg/ha b) 0.075 kg/ha 0.1125 kg/ha	200 - 300 L/ha	56	An authorization only for TRZAW is possible be- cause of the evaluation of the RMS. The comparative assessment demonstrated that for the use

						symptoms become visible 30 to 49							alternatives which are significantly safer for the environment and human health exist.
004	DE	wheat (TRZSS) winter soft wheat (TRZAW)	F	stem break of cereals ( <i>Pseudocercospora herpotrichoides</i> ) (PSDCHE)	spraying	From spring at beginning of infestation and/or when first symptoms become visible 30 to 32	a) 1 b) 1		a) 1.50 L/ha b) 1.50 L/ha	a) a.s. 1: 0.075 kg/ha a.s. 2: 0.1125 kg/ha b) 0.075 kg/ha 0.1125 kg/ha	200 - 300 L/ha	56	An authorization only for TRZAW is possible because of the evaluation of the RMS. The comparative assessment demonstrated that for the use alternatives which are significantly safer for the environment and human health exist.

**Remarks table heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (b) Catalogue of pesticide formulation types and international coding system Crop Life International Technical Monograph n°2, 6th Edition Revised May 2008
- (c) g/kg or g/l

- (d) Select relevant
- (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when 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 38263-3152-4), 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/m<sup>3</sup> 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 equipment (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

## 3 Background of authorization decision and risk management

### 3.1 Physical and chemical properties (Part B, Section 2)

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

The appearance of the product is that of off-white free flowing medium viscosity liquid suspension, with an aromatic odour. It is not explosive, has no oxidising properties. The product has no flash point up to 67°C (ignition flame expires at approx. 67 °C). It has an auto-ignition temperature of 460°C. In aqueous solution, it has a pH value between 5 and 7 at room temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE container. Its technical characteristics are acceptable for a SC formulation. After shelf life an off-white free flowing medium viscosity liquid suspension, with 25% light brown supernatant was observed and no sediment. The contents of the package should be mixed before use.

**Implications for labelling:** None.

**Compliance with FAO specifications:**

The product BAS 717 00 F complies with FAO specifications.

**Compatibility of mixtures:** A report regarding physical and chemical compatibility of the tank mixes with Masai<sup>®</sup> (WP), Polyram WG<sup>®</sup> (WG), Cabrio Duo<sup>®</sup> (EC), Forum<sup>®</sup> (DC), Scala<sup>®</sup> (SC), Revus<sup>®</sup> (SC), Fastac ME<sup>®</sup> (ME), Steward<sup>®</sup> (WG), Karate Zeon<sup>®</sup> (CS), Calypso<sup>®</sup> (SC) and Regalis Plus<sup>®</sup> (WG) has been submitted which has demonstrated compatibility.

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

**Nature and characteristics of the protective clothing and equipment:** Information regarding the required protective clothing and equipment for the safe handling of BAS 717 00 F has been provided and is considered to be acceptable.

### 3.2 Efficacy (Part B, Section 3)

Presented data confirm efficacy of BAS 717 00 F against target pathogens as well as lack of any adverse effects on treated crop, adjacent and succeeding crops.

### 3.3 Efficacy data

The submission includes 76 efficacy trials from 2016-2018 carried out in winter soft wheat (75 trials) and in spring soft wheat (1 trial), and two low-pest-incidence selectivity trials from 2016-2017, carried out in winter soft wheat. All the trials were conducted in different locations in three EPPO zones: Maritime, North-East and South-East.

Based on the submitted efficacy trial results it can be concluded that the fungicide BAS 717 00 F/ Brivela at dose rate of 1,5 l/ha is effective in the control of target pathogens: *Zymoseptoria tritici* (SEPTTR – 41 trials), *Puccinia triticina* (PUCCRT – 35 trials), *Blumeria graminis* (ERYSGR – 22 trials) and *Oculimac-ula* spp. (PSDCHE – 18 trials) in winter soft wheat.

No efficacy trials were carried out in durum wheat or in spelt wheat in any of the concerned EPPO zones, and only one trial was conducted in spring soft wheat.

### **3.3.1 Information on the occurrence or possible occurrence of the development of resistance**

Fluxapyroxad is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI), and the mode of action of fluxapyroxad at the molecular level is the inhibition of the enzyme succinate dehydrogenase. Isolates with reduced SDHI sensitivity have been found.

Difenoconazole is a fungicide belonging to the group of the sterol biosynthesis inhibitors (SBI group Class I (DMI)). Within the SBIs, it belongs to the subgroup of demethylation inhibitor (DMI, G1) and the chemical group of triazoles. Some pathogens have shown a shift towards lower DMI sensitivity in the period since DMI introduction.

BAS 717 00 F is a combination of two fungicides which are active against the target pathogens and therefore, BAS 717 00 F can be considered a valuable tool in resistance management strategy.

### **3.3.2 Adverse effects on treated crops**

No phytotoxicity was observed in the efficacy trials after treatments with the maximum target dose rate 1.5 l/ha. For yield and quality, in five efficacy trials overall a positive impact is measured (*i.e.* higher yield is observed), whereas in majority of trials the yield and quality are higher than in the untreated plots and the level of the relevant standards used. The foliar treatments with BAS 717 00 F do not have any impact on germination of harvested cereal seeds.

### **3.3.3 Observations on other undesirable or unintended side-effects**

Result of the studies indicate that there is no necessity for restrictions in the choice of succeeding crops after the application of BAS 717 00 F, and no damage to adjacent crops should be expected as the result of the application.

## **3.4 Methods of analysis (Part B, Section 5)**

### **3.4.1 Analytical method for the formulation**

An analytical HPLC-DAD method for the determination of difenoconazole and fluxapyroxad was provided and was considered acceptable according to SANCO/3030/99 rev.4.

The GC-MSD method for the determination of the relevant impurity toluene in plant protection product BAS 717 00 F was provided and was considered acceptable according to SANCO/3030/99 rev.4.

### **3.4.2 Analytical methods for residues**

#### Difenoconazole

The analytical methods are active substance data and were provided in the EU review of difenoconazole. They were considered adequate for the monitoring of residues in food of plant and animal origin, soil, water and air. The applicant has got access to the EU dossier of the active substance. A new method for the determination of difenoconazole residues in water was provided and was found acceptably validated.

#### Fluxapyroxad

The analytical methods are active substance data and were evaluated in the EU review of fluxapyroxad. They were considered adequate for the monitoring of food of plant and animal origin, soil, water and air. The applicant has access to the EU dossier of the active substance. New methods for the determination of fluxapyroxad residues were provided by the applicant (ILV for drinking water and a method for body fluids) and were found acceptably validated.

### **3.5 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 PL.

#### **3.5.1 Acute toxicity**

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

#### **3.5.2 Operator exposure**

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

#### **3.5.3 Worker exposure**

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

#### **3.5.4 Bystander and resident exposure**

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

### **3.6 Residues and consumer exposure**

The intended uses in wheat 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 PL.

#### **3.6.1 Residues**

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

#### **3.6.2 Consumer exposure**

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

### **3.7 Environmental fate and behaviour (Part B, Section 8)**

#### **3.7.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

The PEC in soil have been assessed by the ZRMS following the latest guidance of the FOCUS working groups on degradation kinetics, soil persistence models and groundwater scenarios. A soil bulk density of 1.5 g cm<sup>-3</sup> and a soil layer depth of 5 cm were assumed for the calculations. Additionally, PEC<sub>soil</sub> were calculated for the formulated product. For compounds that may potentially accumulate in soil, PEC<sub>soil,plateau</sub> and PEC<sub>soil,accu</sub> were calculated.

The results of the calculations are presented in Part B, Section 8 of the core dossier. The obtained PEC<sub>soil</sub> values are suitable for subsequent ecotoxicological risk assessment. In the national addendum additional PEC<sub>soil</sub> values considering a soil depth of 1 cm are presented.

#### **3.7.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

##### **Direct leaching into groundwater**

As indicated in the core assessment results of modelling with FOCUS PELMO / PEARL show that the active substances Fluxapyroxad and Difenconazole and their soil metabolites M700F001, CGA 205375 and CGA 71019 (1,2,4-triazole) are not expected to penetrate into groundwater at concentrations of  $\geq 0.1 \mu\text{g/L}$  in the intended uses of Brivela in Germany according to use No. 001-004 in the scenario Hamburg.

For the metabolite M700F002 of Fluxapyroxad concentrations of  $\geq 0.1 \mu\text{g/L}$  in groundwater cannot be excluded. For the assessment of the relevance of metabolite M700F002 of active substance Fluxapyroxad please refer to the results of the core assessment, Part B, section 10.

Triazol is considered as relevant metabolite according to the definition of the guidance document on the assessment of the relevance of metabolites in groundwater (2003) .

1,2,4-Triazol is formed as metabolite of several active substances of plant protection products, which are used in different crops against a wide range of crop deceases. It is therefore possible that several 1,2,4-triazol forming active substances will be applied onto the same agricultural field in the same year and season, which may result in a summation of groundwater entries of 1,2,4-triazol from different active substances.

The higher tier assessment of the groundwater risk for 1,2,4-triazole is based on monitoring studies (listed in Appendix 1) conducted by member companies on behalf of the TDMG (Triazole Derivatives Metabolite Group). The available studies do not indicate entries of 1,2,4-triazole into the groundwater  $>0.1 \mu\text{g/L}$  if the azole fungicides are applied in terms of good agricultural practice for cereals .

##### **Consequences for authorization:**

none

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

According modelling with EXPOSIT 3, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substances Fluxapyroxad and Difenconazole due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.



### **Consequences for authorization:**

none

### **3.7.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.

The results of the specific national exposure assessment for the active substances were used in the ecotoxicological risk assessment.

### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

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

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

## **3.8 Ecotoxicology (Part B, Section 9)**

### **3.8.1 Effects on terrestrial vertebrates**

#### **Birds**

In his assessment, zRMS has concluded on an acceptable risk for birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### **Terrestrial vertebrates other than birds**

In his assessment, zRMS has concluded on an acceptable risk for terrestrial vertebrates other than birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### **Terrestrial vertebrate wildlife**

Not yet considered.

## Consequences for authorisation

None

### 3.8.2 Effects on aquatic species

Risk ratios of predicted environmental versus regulatory acceptable concentrations (PEC/RAC) for aquatic organisms were calculated. Calculated exposure concentrations in surface water bodies, according to the intended uses of the product Brivela in spring and winter wheat were considered in the exposure term. The regulatory acceptable concentration (RAC) is obtained by division of the relevant toxicity data for fluxapyroxad and difenoconazole by an assessment factor of 10 for chronic effects on aquatic organisms. The calculated risk ratios do achieve the acceptability criterion  $PEC/RAC \leq 1$  for aquatic organisms, as derived from the prescriptions in 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 Brivela in spring and winter wheat according to the label.

Consequences for authorisation

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

#### Labelling requirements according to § 36 (3) PflSchG

NW 262	Difenoconazole: <i>S. subspicatus</i> E <sub>b</sub> C <sub>50</sub> = 0.032 mg a.s./L [ $\leq 1$ mg/L] Fluxapyroxad: <i>P. subcapitata</i> E <sub>r</sub> C <sub>50</sub> = 0.7 mg a.s./L [ $\leq 1$ mg/L]
NW 264	Difenoconazole: <i>O. mykiss</i> LC <sub>50</sub> = 0.65 mg a.s./L [ $\leq 10$ mg/L], <i>P. promelas</i> NOEC = 0.0036 mg a.s./L [ $\leq 1$ mg/L] <i>M. bahia</i> EC <sub>50</sub> = 0.15 mg a.s./L [ $\leq 10$ mg/L], <i>D. magna</i> NOEC = 0.0056 mg a.s./L [ $\leq 1$ mg/L] Fluxapyroxad: <i>C. carpio</i> LC <sub>50</sub> = 0.29 mg a.s./L [ $\leq 10$ mg/L], <i>P. promelas</i> NOEC = 0.0359 mg a.s./L [ $\leq 1$ mg/L] <i>C. virginica</i> EC <sub>50</sub> = 1.1 mg a.s./L [ $\leq 10$ mg/L], <i>D. magna</i> NOEC = 0.5 mg a.s./L [ $\leq 1$ mg/L]
NW 265	Fluxapyroxad: <i>Lemna gibba</i> 7 d E <sub>r</sub> C <sub>10</sub> = 0.69 mg/L [ $\leq 1$ mg/L]

#### Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (uses 001 - 004)

NW 470	
NW 609-1	Drift-reduction technique– corresponding buffer zone: conv. – 5 m;

### 3.8.3 Effects on bees

The risk to honeybees from the use of fluxapyroxad, difenoconazole and BAS 717 00 F was assessed using the maximum single application rate and the LD<sub>50</sub> values to calculate hazard quotients (HQ) for oral

The hazard quotients for BAS 717 00 F and the active substances fluxapyroxad and difenoconazole for acute oral and acute contact exposure of honeybees were considerably below the Commission Regulation (EU) 546/2011 trigger of 50 (see table below).

#### First-tier assessment of the risk for bees due to the use of BAS 717 00 F in wheat

Intended use	wheat		
Product	BAS 717 00 F		
Application rate (L/ha)	1 x 1.5		
Test design	LD <sub>50</sub> (lab.) (µg/bee)	Single application rate (g/ha)	Q <sub>HO</sub> , Q <sub>HC</sub> criterion: Q <sub>H</sub> ≤ 50
Oral toxicity	> 1035.8	1611 <sup>1)</sup>	< 1.6
Contact toxicity	> 863.2		< 1.9

Q<sub>HO</sub>, Q<sub>HC</sub>: Hazard quotients for oral and contact exposure.

<sup>1)</sup> Taking into account a single application of 1.5 L product/ha and the density of BAS 717 00 F of 1.074 g/cm<sup>3</sup>.

Furthermore, a honeybee tunnel test indicates no unacceptable effects of BAS 717 00 F on honeybee mortality, foraging conditions, behavior, colony development, colony strength, and bee brood development at the worst case single application rate of BAS 717 00 F according to the proposed use pattern.

Based on these results it can be concluded that low risk to honeybees is expected from applications of BAS 717 00 F according to the proposed uses.

### 3.8.4 Effects on other arthropod species other than bees

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  (standard 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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

#### Consequences for authorisation

None

### 3.8.5 Effects on soil organisms

#### Earthworms

The potential risk of BAS 717 00 F, fluxapyroxad, difenoconazole and the relevant metabolites to earthworms and other non-target soil macro-organisms was assessed by the ZRMS comparing the maximum PEC<sub>soil</sub> values with NOEC or EC<sub>10</sub> values, to generate long-term TER values (TER<sub>lt</sub>).

All TER values for BAS 717 00 F, fluxapyroxad, difenoconazole and the relevant metabolites for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) were considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5.

**It can be concluded that BAS 717 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate**

Additionally, it was demonstrated in a field study that the application of BAS 717 00 F (75 g fluxapyroxad/L + 50 g difenoconazole/ha) in a tank mixture with BAS 700 04 F (300 g fluxapyroxad/L) at a rate of 10.4 L/ha BAS 717 00 F + 0.17 L/ha BAS 700 04 F did not result in sustaining adverse effects on a natural earthworm population after a period of one year.

### **Other organisms of the soil macro- and mesofauna**

TER values for other organisms of the soil macro- and mesofauna were calculated, taking into account the relevant toxicity data for fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) and calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  for chronic effects (as adopted from the risk assessment for earthworms) on other organisms of the soil macro- and mesofauna, 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 other organisms of the soil macro- and mesofauna due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### **Soil microbial activity**

Concentrations of fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) in soil were determined where effects on nitrogen mineralisation processes remained  $\leq 25\%$  and were compared to calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The comparison indicates no exceedance of the acceptability criterion  $\leq 25\%$  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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### **Consequences for authorisation**

None

### **3.8.6 Effects on non-target terrestrial plants**

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

## Consequences for authorisation

None

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Please refer to the core assessment.

### 3.9 Relevance of metabolites (Part B, Section 10)

The fluxapyroxad metabolite M700F002 is of no toxicological relevance in the groundwater. For further details please refer to the registration report of the zonal RMS PL.

## 4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance difenoconazole is approved as a candidate of substitution therefore a comparative assessment is foreseen.

The plant protection product Brivela contains the active substance Difenoconazole which is a candidate for substitution (CfS). It fulfills the P and T criteria

As a conclusion of the comparative assessment

From the efficacy point of view uses number 002, 003, and 004 from GAP table in 2.6 are suitable for substitution because there are enough alternative measures available for the control of the harmful organisms applied for without having significant economic or practical disadvantages. Sufficient alternatives remain available to minimise the occurrence of resistance and there are no adverse consequences for minor use authorizations.

### Comparative assessment of health risks

The plant protection products Netzschwefel Stulln (ZV3 050006-00), THIOVIT JET (ZV3 050498-00), Kumulus WG (ZV3 052273-00), Thiopron (ZV3 00A249-00), Property 180 SC (ZN1 007475-00) and Flexity (ZN1 025311-00) identified as alternatives for the uses 003 and/or 004 of Brivela are considered as safer or equal alternatives to the use of Brivela in wheat regarding the risk to health. For details see appendix 5.

### Comparative assessment of environmental risks

Tier 1 TER values resp. PEC/RAC ratios of Brivela were compared to a list of formulations with different active substances. A formulation was identified as a suitable alternative, if

- at least one TER value is 10 times higher or PEC/RAC ratio 10 times lower and thus indicates a significantly lower risk than that posed by Brivela, especially in an area of concern (i.e. where

Brivela TER values fall below the respective trigger and thus indicate a high risk to the environment), and

- there is no TER value 10 times lower or PEC/RAC ratio 10 times higher than that of Brivela, indicating a significantly higher risk than that posed by Brivela

The comparison of the tier 1-TER values resp. PEC/RAC ratios reveals that the alternative products with the active substances Sulphur, Pyriofenone, Metraferone, Proquinazid and Cyflufenamid as single active ingredient pose a significantly lower risk to the environment than Brivela.

The following products can be considered a significantly safer alternative to the use of Brivela in the respective crop regarding the risk to the environment:

**Table: Products with a significantly lower risk to the environment compared to Brivela**

Intended use	Suitable alternatives
003	Sulphur*
003	Talius
003	Property 180 SC
003	Vegas
003, 004	Flexity

\* "Sulphur" refers to all proposed products with sulfur as single a.i. (Netzschwefel Stulln, THIOVIT JET, Kumulus WG, Thiopron)

#### **Overall conclusion**

**According to the comparative assessment the use numbers 003 and 004 are suitable for substitution. From the efficacy point of view there are enough other ppp for a sufficient control available without having significant practical or economic impacts and other ppp are available having significant lower risk.**

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

Not relevant

## **Appendix 1 Copy of the product authorization (see Appendix 6)**

## **Appendix 2 Copy of the product label**

The submitted draft product label has been checked by the competent authority. The final version of the label is not displayed in the RR, because the label is the sole responsibility of the applicant and is therefore not finally checked by the competent authority. The applicant is requested to generate the product label in accordance with the authorisation granted by the competent authority.

### **Appendix 3 Letter of Access**

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



## **Appendix 4 Lists of data considered for national authorization**

Please consider the reference list in Part A of the zRMS. If applicable, additional references used for this authorisation are listed below or in Part B.

## Appendix 5 Comparative Assessment – original reports

### Stellungnahme des JKI zur vergleichenden Bewertung hinsichtlich zur Verfügung stehender alternativen Bekämpfungsmöglichkeiten

For the use no 002 to 004 are enough alternative control measures available to control the harmful organisms without having negative effects in agriculture.

The following alternatives are available listed in the following table:

#### Anwendung 001 (SEPTTR/ Weizen)

Mittel-Nr.	Mittelname	Wirkstoff/e	Aufwand	Bemerkung (Ende der Zulassung)
00A247-00	Tridex Flow	Mancozeb (0010) FRAC: undefined	3.00 l/ha	31.01.2021
004329-00	DOMARK 10 EC	Tetraconazole (0941) FRAC: G1	1.25 l/ha	31.12.2020
006462-00	Ampera	Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.50 l/ha	31.12.2022
006591-00	Osiris	Epoxiconazol (0875) FRAC: G1 CfS; Metconazol (0945) FRAC: G1 CfS	3.00 l/ha	30.04.2021
006778-00	Input Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.50 l/ha	31.07.2021
006798-00	Kantik	Fenpropidin (0881) FRAC: G2; Prochloraz (0631) FRAC: G1 CfS ; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
006912-00	EPOXION	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	31.12.2021
006934-00	Epoxion Top	Epoxiconazol (0875) FRAC: G1 CfS; Fenpropidin (0881) FRAC: G2	2.50 l/ha	31.12.2022
006937-00	Opus EC	Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	31.12.2021
007025-00	Eleando	Epoxiconazol (0875) FRAC: G1 CfS; Prochloraz (0631) FRAC: G1 CfS	3.00 l/ha	31.12.2025
007026-00	MAGNELLO	Difenoconazol (0865) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2025
007226-00	Cerix	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	3.00 l/ha	31.12.2025
007313-00	Viverda	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS; Pyraclostrobin (1013) FRAC: C3	2.50 l/ha	31.12.2024
007468-00	Rubric	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020
007566-00	Variano Xpro	Bixafen (1151) FRAC: C2 ; Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.75 l/ha	31.07.2021
007605-00	SEGURIS XTRA	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022

007905-00	Rubric XL	Azoxystrobin (0902) FRAC: C3 ; Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020
007969-00	Librax	Fluxapyroxad (1164) FRAC: C2 ; Metconazol (0945) FRAC: G1 CfS	2.00 l/ha	30.04.2021
008012-00	ADD-F2-004	Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022
008015-00	Mercury Pro	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	1.00 l/ha	31.05.2022
008127-00	MINISTER	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	0.75 l/ha	31.05.2022
008180-00	Priaxor	Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	1.50 l/ha	31.01.2021
008211-00	METACUR	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
008219-00	Ascra Xpro	Bixafen (1151) FRAC: C2 ; Fluopyram (1134) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
008235-00	Torero	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
008326-00	SEGURIS ERA	Isopyrazam (1156) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
008405-00	ELATUS PLUS	Benzovindiflupyr (1200) FRAC: C2 CfS	0.75 l/ha	02.03.2024
008406-00	ELATUS ERA	Benzovindiflupyr (1200) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
008930-00	Input Triple	Proquinazid (1053) FRAC: E1 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.07.2020
024216-00	Mirage 45 EC	Prochloraz (0631) FRAC: G1 CfS	1.20 l/ha	31.12.2022
024350-00	TRIDEX DG RAINCOAT	Mancozeb (0010) FRAC: undefined	2.13 kg/ha	31.01.2020
024487-00	CARAMBA	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
025273-00	Swing Gold	Dimoxystrobin (1028) FRAC: C3 CfS; Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	30.04.2020
025287-00	Proline	Prothioconazol (1035) FRAC: G1	0.80 l/ha	31.07.2021
025315-00	Fandango	Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
025625-00	Input Classic	Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.12.2022
025662-00	Prosaro	Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2020
025757-00	Champion	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	30.04.2020
026764-00	Aviator Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.25 l/ha	31.07.2021
026798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
026958-00	Adexar	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	30.04.2020
026979-00	Imbrex XE	Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	31.12.2023
026998-00	Skyway Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.25 l/ha	31.07.2021

027203-00	SEGURIS	Epoxiconazol (0875) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	30.04.2020
027413-00	Siltra Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
033924-00	Dithane NeoTec	Mancozeb (0010) FRAC: undefined	2.13 kg/ha	31.01.2020

### Anwendung 002 (PUCCRE/ Weizen)

Mittel-Nr.	Mittelname	Wirkstoff/e	Aufwand	Bemerkung (Ende der Zulassung)
00A150-00	AZOSHY	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
00A217-00	TEBKIN	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2021
004329-00	DOMARK 10 EC	Tetraconazole (0941) FRAC: G1	1.25 l/ha	31.12.2020
006341-00	Orius	Tebuconazol (0784) FRAC: G1 CfS	1.25 l/ha	31.12.2020
006400-00	Fezan	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2022
006462-00	Ampera	Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.50 l/ha	31.12.2022
006591-00	Osiris	Epoxiconazol (0875) FRAC: G1 CfS; Metconazol (0945) FRAC: G1 CfS	3.00 l/ha	30.04.2021
006778-00	Input Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.50 l/ha	30.09.2019
006798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
006912-00	EPOXION	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	31.12.2021
006934-00	Epoxion Top	Epoxiconazol (0875) FRAC: G1 CfS; Fenpropidin (0881) FRAC: G2	2.50 l/ha	31.12.2022
006937-00	Opus EC	Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	31.12.2021
007025-00	Eleando	Epoxiconazol (0875) FRAC: G1 CfS; Prochloraz (0631) FRAC: G1 CfS	3.00 l/ha	31.12.2025
007026-00	MAGNELLO	Difenoconazol (0865) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2025
007180-00	AZOXYSTAR	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
007226-00	Cerixax	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	3.00 l/ha	31.12.2025
007313-00	Viverda	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS; Pyraclostrobin (1013) FRAC: C3	2.50 l/ha	31.12.2024
007454-00	Soleil	Bromuconazol (0879) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.20 l/ha	31.12.2025
007468-00	Rubric	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020
007519-00	HELOCUR	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.08.2020
007566-00	Variano Xpro	Bixafen (1151) FRAC: C2 ; Fluoxastrobilin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.75 l/ha	31.07.2021
007605-00	SEGURIS XTRA	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022

007643-00	Comet	Pyraclostrobin (1013) FRAC: C3	1.25 l/ha	31.01.2021
007905-00	Rubic XL	Azoxystrobin (0902) FRAC: C3 ; Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020
007969-00	Librax	Fluxapyroxad (1164) FRAC: C2 ; Metconazol (0945) FRAC: G1 CfS	2.00 l/ha	30.04.2021
008012-00	ADD-F2-004	Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022
008015-00	Mercury Pro	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	1.00 l/ha	31.05.2022
008127-00	MINISTER	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	0.75 l/ha	31.05.2022
008180-00	Priaxor	Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	1.50 l/ha	31.01.2021
008211-00	METACUR	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
008219-00	Ascra Xpro	Bixafen (1151) FRAC: C2 ; Fluopyram (1134) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
008235-00	Torero	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
008326-00	SEGURIS ERA	Isopyrazam (1156) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
008405-00	ELATUS PLUS	Benzovindiflupyr (1200) FRAC: C2 CfS	0.75 l/ha	02.03.2024
008406-00	ELATUS ERA	Benzovindiflupyr (1200) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
008570-00	SINSTAR	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
008745-00	LEGADO	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
008967-00	Azbany	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
008990-00	GLOBAZTAR SC	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2022
024443-00	Pronto Plus	Spiroxamine (0914) FRAC: G2 ; Tebuconazol (0784) FRAC: G1 CfS	1.50 l/ha	31.12.2021
024487-00	CARAMBA	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
025090-00	AMISTAR	Azoxystrobin (0902) FRAC: C3	1.00 l/ha	31.12.2024
025273-00	Swing Gold	Dimoxystrobin (1028) FRAC: C3 CfS; Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	30.04.2020
025287-00	Proline	Prothioconazol (1035) FRAC: G1	0.80 l/ha	31.07.2019
025315-00	Fandango	Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
025625-00	Input Classic	Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.12.2022
025662-00	Prosaro	Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2020
025757-00	Champion	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	30.04.2020
026764-00	Aviator Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.25 l/ha	31.07.2021
026798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
026958-00	Adexar	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	30.04.2020
026979-00	Imbrex XE	Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	31.12.2023

026998-00	Skyway Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.25 l/ha	31.07.2021
027203-00	SEGURIS	Epoxiconazol (0875) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	30.04.2020
027413-00	Siltra Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
034028-00	Folicur	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2020

### Anwendung 003 (ERYSGR/ Weizen)

Mittel-Nr.	Mittelname	Wirkstoff/e	Aufwand	Bemerkung (Ende der Zu- lassung)
00A217-00	TEBKIN	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.08.2021
00A249-00	Thiopron	Schwefel (0184) FRAC: undefined / IRAC: UN	7.50 l/ha	31.12.2021
004329-00	DOMARK 10 EC	Tetraconazole (0941) FRAC: G1	1.25 l/ha	31.12.2020
006341-00	Orius	Tebuconazol (0784) FRAC: G1 CfS	1.25 l/ha	31.12.2020
006345-00	Leander	Fenpropidin (0881) FRAC: G2	0.75 l/ha	31.12.2022
006400-00	Fezan	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2022
006462-00	Ampera	Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.50 l/ha	31.12.2022
006778-00	Input Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.50 l/ha	31.07.2021
006798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
006912-00	EPOXION	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	31.12.2021
006934-00	Epoxion Top	Epoxiconazol (0875) FRAC: G1 CfS; Fenpropidin (0881) FRAC: G2	2.50 l/ha	31.12.2022
007226-00	Ceriox	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	3.00 l/ha	31.12.2025
007313-00	Viverda	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS; Pyraclostrobin (1013) FRAC: C3	2.50 l/ha	31.12.2024
007454-00	Soleil	Bromuconazol (0879) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	1.20 l/ha	31.12.2025
007468-00	Rubric	Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020
007475-00	PROPERTY 180 SC	Pyriofenone (1171) FRAC: B6	0.50 l/ha	31.12.2027
007519-00	HELOCUR	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.08.2020
007566-00	Variano Xpro	Bixafen (1151) FRAC: C2 ; Fluox- astrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.75 l/ha	31.07.2021
007605-00	SEGURIS XTRA	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022
007905-00	Rubric XL	Azoxystrobin (0902) FRAC: C3 ; Epoxiconazol (0875) FRAC: G1 CfS	1.00 l/ha	30.04.2020

007969-00	Librax	Fluxapyroxad (1164) FRAC: C2 ; Metconazol (0945) FRAC: G1 CfS	2.00 l/ha	30.04.2021
008012-00	ADD-F2-004	Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	1.00 l/ha	31.05.2022
008015-00	Mercury Pro	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	1.00 l/ha	31.05.2022
008211-00	METACUR	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
008219-00	Ascra Xpro	Bixafen (1151) FRAC: C2 ; Fluopyram (1134) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
008326-00	SEGURIS ERA	Isopyrazam (1156) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
008467-00	Microthiol WG	Schwefel (0184) FRAC: undefined / IRAC: UN	7.50 kg/ha	31.12.2021
008930-00	Input Triple	Proquinazid (1053) FRAC: E1 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.07.2020
024374-00	UNIX	Cyprodinil (0907) FRAC: D1 CfS	1.00 kg/ha	30.04.2021
024443-00	Pronto Plus	Spiroxamine (0914) FRAC: G2 ; Tebuconazol (0784) FRAC: G1 CfS	1.50 l/ha	31.12.2021
024487-00	CARAMBA	Metconazol (0945) FRAC: G1 CfS	1.50 l/ha	30.04.2021
025287-00	Proline	Prothioconazol (1035) FRAC: G1	0.80 l/ha	31.07.2021
025311-00	Flexity	Metrafenone (1040) FRAC: B6	0.50 l/ha	30.04.2021
025315-00	Fandango	Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
025609-00	Vegas	Cyflufenamid (1045) FRAC: unde- fined	0.375 l/ha	31.12.2020
025625-00	Input Classic	Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.12.2022
025662-00	Prosaro	Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2020
025678-00	TALIUS	Proquinazid (1053) FRAC: E1	0.25 l/ha	31.12.2022
026764-00	Aviator Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.25 l/ha	31.07.2021
026798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	2.00 l/ha	31.12.2023
026958-00	Adexar	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	30.04.2020
026979-00	Imbrex XE	Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	31.12.2023
026998-00	Skyway Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	1.25 l/ha	31.07.2021
027413-00	Siltra Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021
034028-00	Folicur	Tebuconazol (0784) FRAC: G1 CfS	1.00 l/ha	31.12.2020
050006-00	Netzschwefel Stulln	Schwefel (0184) FRAC: undefined / IRAC: UN	6.00 kg/ha	31.12.2020
050498-00	THIOVIT JET	Schwefel (0184) FRAC: undefined / IRAC: UN	6.00 kg/ha	31.12.2020
052273-00	Kumulus WG	Schwefel (0184) FRAC: undefined / IRAC: UN	6.00 kg/ha	31.12.2020

**Anwendung 004 (PSDCHE/ Weizen)**

Mittel-Nr.	Mittelname	Wirkstoff/e	Aufwand	Bemerkung (Ende der Zulassung)
007025-00	Eleando	Epoxiconazol (0875) FRAC: G1 CfS; Prochloraz (0631) FRAC: G1 CfS	3.00 l/ha	31.12.2025
007226-00	Cerixax	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	3.00 l/ha	31.12.2025
007313-00	Viverda	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS; Pyraclostrobin (1013) FRAC: C3	2.50 l/ha	31.12.2024
007969-00	Librax	Fluxapyroxad (1164) FRAC: C2 ; Metconazol (0945) FRAC: G1 CfS	2.00 l/ha	30.04.2021
008219-00	Ascra Xpro	Bixafen (1151) FRAC: C2 ; Fluopyram (1134) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
008930-00	Input Triple	Proquinazid (1053) FRAC: E1 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.07.2020
024374-00	UNIX	Cyprodinil (0907) FRAC: D1 CfS	1.00 kg/ha	30.04.2021
025287-00	Proline	Prothioconazol (1035) FRAC: G1	0.80 l/ha	31.07.2019
025311-00	Flexity	Metrafenone (1040) FRAC: B6	0.50 l/ha	30.04.2021
025315-00	Fandango	Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	1.50 l/ha	31.07.2021
025625-00	Input Classic	Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	1.25 l/ha	31.12.2022
025757-00	Champion	Boscalid (1023) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS	1.50 l/ha	30.04.2020
026764-00	Aviator Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.25 l/ha	31.07.2021
026958-00	Adexar	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	30.04.2020
026979-00	Imbrex XE	Fluxapyroxad (1164) FRAC: C2	2.00 l/ha	31.12.2023
027413-00	Siltra Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	1.00 l/ha	31.07.2021

Alternative nicht-chemische Verfahren werden auf Basis des Berichts „*Non-chemical pest control methods: A review of the literature to establish their efficacy and safety to workers, to inform the process of comparative assessment required by new pesticide legislation.- Defra Project Code: PS2809/348656, 2013.*“ bewertet.

Für bestimmte Blattkrankheiten kann durch den Anbau von resistenten Sorten, der Anpassung des Saatzeitpunktes und mehr Feldhygiene das Auftreten der Krankheiten vermindert, aber nicht vollständig verhindert werden. Einige Maßnahmen sind aber nicht geeignet, um z.B. die Erreger der Rostkrankheiten zu bekämpfen. Alternative nicht-chemischen Verfahren können praktische oder wirtschaftliche Nachteile nicht vollständig verhindern.

Für die Durchführung einer Integrierten Bekämpfungsstrategie ist somit eine Kombination von pflanzenbaulichen, nicht chemischen und chemischen Maßnahmen erforderlich.

**Stellungnahme zum Risiko der Resistenzbildung:**

Nach neuesten Erkenntnissen, die bei der Abschätzung des Resistenzrisikos im Januar 2020 noch nicht vorlagen, kann der Wirkstoff Difenconazol einen unverzichtbaren Beitrag zur Bekämpfung des pilzli-



chen Schaderregers *Zymoseptoria tritici* im Weizen leisten. Daher ist das Mittel aus Sicht des Resistenzmanagements zur Vermeidung von Fungizidresistenz für diese Anwendung unverzichtbar. Für die weiterhin aufgeführten Pathogene *Blumeria graminis*, *Puccinia recondita* und *Oculimacula yallundae* besteht die Notwendigkeit und das Gefährdungsrisiko nicht.

Die vergleichende Bewertung hat ergeben, dass Fungizide mit Wirkstoffen aus meistens 3 oder mehr MOAs (FRAC: C2, C3 und G1) als Alternativen zur Verfügung stehen. Diese Alternativen beinhalten auch Wirkstoffkombinationen, die die gleichen MOAs (FRAC: G1 und C2) haben wie das beantragte Mittel. Aufgrund der hohen Diversifikation bei *Zymoseptoria tritici* gibt es aber dennoch eindeutige Unterschiede zu den anderen Wirkstoffen dieser beiden MoAs G1 und C2 hinsichtlich des Risikos und der Bekämpfung von Isolaten mit Mutationen.

#### **Stellungnahme des Antragstellers:**

Aus Sicht des Antragstellers enthält das beantragte Pflanzenschutzmittel Brivela erstmalig die Wirkstoffkombination aus Difenconazol und Fluxapyroxad. Der Wirkstoff Difenconazol wurde bislang nicht zur Bekämpfung von *Zymoseptoria tritici* eingesetzt. Damit stellt er neben den hohen Wirkungsgraden im Rahmen des Resistenzmanagements ein unverzichtbares Element zur nachhaltigen Kontrolle dieser Pathogens dar. Auch wenn der Wirkstoff aus der Gruppe der Azole stammt, zeigen neueste Ergebnisse aus dem Jahr 2020 keine vollständige Kreuzresistenz mit anderen Wirkstoffen dieser chemischen Gruppe, sondern eine abweichende Reaktion bei den unterschiedlichen Zymoseptoria-Isolaten.

Aufgrund dieser Argumentation schlägt der Antragsteller vor, das Verfahren der vergleichenden Bewertung für die Anwendung *Zymoseptoria tritici* im Weizen zu beenden.

#### **Stellungnahme der Amtlichen Pflanzenschutzdienste:**

Die Amtlichen Pflanzenschutzdienste von Brandenburg, Rheinland-Pfalz, Hessen und Nordrhein-Westfalen haben ihre Einschätzung zum beantragten Mittel abgegeben.

Alle PSD haben zwar bisher keine eigenen Erkenntnisse mit dieser Wirkstoffkombination hinsichtlich Wirkung, Wirkungssicherheit und Verträglichkeit, doch stehen ihrer Meinung nach genügend Alternativen zur Verfügung.

Für fast alle PSD, außer dem Pflanzenschutzdienst des Landes Brandenburg, wird das Pflanzenschutzmittel für ein nachhaltiges Resistenzmanagement nicht benötigt. Es wird aber darauf hingewiesen, dass es wichtig sei, viele Azolwirkstoffe, insbesondere bei Kontrolle von Pilzpathogenen im Weizen, zur Verfügung zu haben.

Die Stellungnahmen der Amtlichen Pflanzenschutzdienste der Bundesländer und die Stellungnahme des Antragstellers wurden bei der abschließenden Entscheidungsfindung berücksichtigt.

#### **Schlussfolgerung**

Aus Sicht des Prüfbereichs Wirksamkeit bestehen für die folgenden Anwendungen vergleichbare Alternativen:

Anwendungsnummer	vergleichbar wirksame Alternativen liegen vor
001	nein
002	ja
003	ja
004	ja

11.03.2021

## **Stellungnahme des BfR zur vergleichenden Bewertung gesundheitlicher Risiken**

### **1 Gegenstand der Bewertung**

Zulassungsverfahren für das Pflanzenschutzmittel: Brivela  
Kenn-Nr.: ZV3 00A343-00/00  
Wirkstoff(e): Difenoconazole (0865), Fluxapyroxad (1164)

Mit Prüfauftrag vom 18.11.2020 und 29.01.2021 (BVL-Schreiben 200.22100.00A343-00/00.256860) wurde das BfR aufgefordert, basierend auf den Bewertungen des JKI und des UBA eine vergleichende Bewertung hinsichtlich der gesundheitlichen Risikobewertung für die beantragten Anwendungen des Mittels Brivela vorzunehmen.

Einer der beiden im Mittel enthaltenen Wirkstoffe, Difenoconazole, ist aufgrund von Umwelteigenschaften in der Verordnung (EU) 2015/408 als Substitutionskandidat (CfS) gelistet (PBT-Kriterien persistent und toxisch). Die Prüfung des BfR für Mittel mit CfS, die aufgrund von Umwelteigenschaften ersetzt werden sollen, hat das Ziel, sicherzustellen, dass die vom UBA identifizierten alternativen Mittel auch aus Sicht der gesundheitlichen Risikobewertung akzeptable Alternativen darstellen.

Gemäß dem Schreiben IV1.3/ZV300A343-00/00 des UBA vom 21.01.21 sind im Ergebnis der vergleichenden Bewertung in Hinblick auf die Umweltbewertung 8 Mittel als Alternativen identifiziert worden (basierend auf Tabelle 17 des UBA-Schreibens), von denen das Mittel Vegas mittlerweile jedoch nicht mehr zugelassen ist.

Im Rahmen der vergleichenden Bewertung wurden daher vom BfR nur die 7 verbleibenden Alternativen berücksichtigt.

Bei den beiden für das Mittel Brivela beantragten Anwendungen handelt es sich um Anwendungen in Weizen mit identischen Aufwandmengen, so dass keine Prüfung nach Anwendungsgebieten vorgenommen wurde.

### **2 Ergebnis**

Die Einschätzungen wurden auf Basis der vorliegenden Bewertungen vorgenommen, die z.T. noch auf der Basis der RL 91/414/EWG erstellt wurden und nicht mehr dem heutigen Stand von Wissenschaft und Technik entsprechen und nicht alle heute erforderlichen Prüfpunkte umfassen (z.B. Grundwasserbewertung). Eine Aktualisierung der Bewertungen zu den Alternativen wurde nicht durchgeführt.

**Tabelle: Ergebnis der vergleichenden Bewertung in Hinblick auf die gesundheitliche Risikobewertung**

Nr.	AWG	Kenn-Nr	Produktname	Wirkstoffe
1	-003	ZV3 050006-00 ZV3 050498-00 ZV3 052273-00 ZV3 00A249-00	Netzschwefel Stulln, THIOVIT JET, Kumulus WG, Thiopron	Schwefel (796,00 g/kg) Schwefel (800,00 g/kg) Schwefel (800,00 g/kg) Schwefel (825,00 g/l)
2	-003	ZN1 025678-00	Talius	Proquinazid 200 g/L
3	-003	ZN1 007475-00	Property 180 SC	Pyriofenone 180 g/L
5	-003, -004	ZN1 025311-00	Flexity	Metrafenone 300 g/L

Alternativen mit günstigeren gesundheitlichen Eigenschaften

Alternativen mit gleichwertigen gesundheitlichen Eigenschaften

Alternativen mit ungünstigeren gesundheitlichen Eigenschaften

Alle vom UBA identifizierten Alternativen sind Soloformulierungen, die nur einen Wirkstoff enthalten.

Im Ergebnis werden die Mittel **Netzschwefel Stulln**, **THIOVIT JET** und **Kumulus WG** mit dem Wirkstoff Schwefel aus Sicht der gesundheitlichen Risikobewertung grundsätzlich als günstiger im Vergleich zum Mittel Brivela beurteilt.

Das Mittel **Thiopron** mit dem Wirkstoff Schwefel sowie das Pyriofenone-haltige Mittel **Property 180 SC** und das Metrafenone-haltige Mittel **Flexity** werden grundsätzlich als gleichwertig beurteilt.

Das Mittel **Talius** mit dem Wirkstoff Proquinazid wird grundsätzlich als ungünstiger im Vergleich zum Mittel Brivela beurteilt.

### 3 Begründung

#### 3.1 Beantragtes Mittel

Das BfR hat sein Benehmen zur Zulassung des Mittels **ZV3 00A343-00/00 Brivela** am 18.01.2021 mit BfR-Benehmenserklärung 30-0302-03-11400298 erteilt. Im Ergebnis der Gefahrenbewertung wurde für das Mittel Brivela ein Einstufungs- und Kennzeichnungsvorschlag gemäß VO (EG) Nr. 1272/2008 mit Sens. Haut 1, H317; Lakt., H362 und den EUH208-Sätzen EUH208-0205 und -0098 (MIT, BIT) vergeben. Daraus resultiert das Signalwort „Achtung“.

Für eine sichere Anwendung sind für den Umgang mit dem unverdünnten Mittel Auflagen zum Tragen eines Pflanzenschutzanzugs, Handschuhen, einer Schürze sowie eines Gesichtsschutzes vergeben worden.

Im Hinblick auf die Risikobewertung für Verbraucher (Nahrung und Grundwasser) wurden im Rahmen der vorliegenden Bewertung des Mittels keine Datenlücken bzw. unannehmbaren Risiken identifiziert.

#### 3.2 Alternativen mit günstigeren oder gleichwertigen gesundheitlichen Eigenschaften

##### 3.2.1 Alternativen mit Schwefel

Die vom UBA identifizierten Alternativen mit dem Wirkstoff Schwefel können grundsätzlich als gleichwertig oder günstiger im Vergleich zum beantragten Mittel Brivela betrachtet werden. Der Wirkstoff Schwefel weist weniger kritische Eigenschaften auf als der zu ersetzende Wirkstoff Difenconazol und wurde in Annex IV der VO (EG) Nr. 396/2005 aufgenommen. Es sind keine toxikologischen Grenzwerte festgesetzt worden.

Für die drei Mittel **Netzschwefel Stulln**, **THIOVIT JET** und **Kumulus WG** Mittel war außer einem Gefahrenhinweis in Bezug auf die Austrocknung der Haut (EUH066) aus Sicht der gesundheitlichen Gefahrenbewertung kein Einstufungs- und Kennzeichnungsvorschlag gemäß Verordnung (EG) Nr. 1272/2008 erforderlich.

Hinsichtlich der zugeordneten Auflagen zur Anwendungssicherheit können die 3 Mittel auf Basis der bisherigen Bewertungen als günstiger im Verhältnis zu Brivela betrachtet werden.

Das Mittel **Thiopron** muss dagegen aus Sicht der gesundheitlichen Bewertung mit Sens. Haut 1, H317; Augenreiz. 2 H319 und dem EUH208-Satz EUH208-0098 eingestuft und gekennzeichnet werden (BfR-Benehmenserklärung 6-6112-10207549 vom 29.10.2018). Daraus resultiert das Signalwort „Achtung“. Die Auflagen für die Anwendung in Weizen sind identisch mit denen zu Brivela. Einige zusätzliche Auflagen betreffen Anwendungsgebiete, die nicht für Brivela beantragt sind.

Hinsichtlich der zugeordneten Auflagen zur Anwendungssicherheit ist das Mittel auf Basis der bisherigen Bewertung als gleichwertig zu Brivela anzusehen.

Im Hinblick auf die Risikobewertung für Verbraucher (Nahrung und Grundwasser) wurden im Rahmen der vorliegenden Bewertungen aller vier Mittel keine gravierenden Datenlücken bzw. unannehmbaren Risiken identifiziert (siehe Benehmenserklärungen 6-6112-7987092 vom 03.09.2014 zu Netzschwefel Stulln, 6-6112-7939852 vom 19.08.2014 zu Kumulus WG und 6-6112-7940420 vom 19.08.2014 zu Thiovit Jet und 6-6112-10207549 vom 29.10.2018 zu Thiopron).

### 3.2.2 Alternative mit Pyriofenone

Das Mittel **ZN1 007475-00/00 Property 180 SC** wurde vom BfR bereits 2013 auf Basis der Richtlinie 91/414/EWG bewertet (Benehmenserklärung 6-6112-7298421 vom 25.06.2013), die Zulassung in DE erfolgte jedoch erst 2017, nach der Neugenehmigung des Wirkstoffs am 01/02/2014. Eine Aktualisierung der BfR-Bewertung ist seitdem nicht erfolgt.

Im Ergebnis der RAC Opinion für den Wirkstoff Pyriofenone (CLH-O-0000001412-86-287/F vom 13.06.2019) muss der Wirkstoff, und daraus resultierend auch das Mittel Property 180 SC, mit Carc. 2, H351 gekennzeichnet werden. Daraus resultiert das Signalwort „Achtung“. Dies wurde vom BVL bereits umgesetzt. Die resultierenden Auflagen umfassen das Tragen eines Pflanzenschutzanzugs und von Handschuhen und sind damit geringer als für Brivela.

Im Hinblick auf die Risikobewertung für Verbraucher wurden im Rahmen der damaligen Bewertung des Mittels (6-6112-7298421 vom 25.06.2013) Datenlücken zu rückstandsanalytischen Methoden aufgezeigt. Im Hinblick auf die Risikobewertung für Verbraucher (Nahrung) wurden keine unannehmbaren Risiken identifiziert. Eine Bewertung von möglichen Einträgen von Metaboliten ins Grundwasser war zum damaligen Zeitpunkt nicht Bestandteil der Bewertung.

### 3.2.3 Alternative mit Metrafenone

Das Mittel **ZN1 025311-00/00 Flexity** wurde vom BfR bereits 2008 auf Basis der Richtlinie 91/414/EWG bewertet. Im Rahmen einer Formulierungsänderung wurde 2019 ein aktualisierter Einstufungs- und Kennzeichnungsvorschlag mitgeteilt (BfR-Bewertungsbericht 6-30-0302-03-10314241 vom 19.03.2019). Dementsprechend ist das Mittel mit Augenreiz. 2, H319 sowie dem EUH208-Satz zu 1,2-Benzisothiazol-3(2H)-on (CAS-Nr. 2634-33-5) zu kennzeichnen. Daraus resultiert das Signalwort „Achtung“.

Für einen sicheren Umgang bei der Ausbringung sind vergleichbare Auflagen wie für das Mittel Brivela nötig, jedoch keine Schürze.

Im Hinblick auf die Risikobewertung für Verbraucher (Nahrung) wurden keine unannehmbaren Risiken identifiziert (AL6-2501-2721718 / AL6-2501-2858130 vom 15.08.2006). Eine Bewertung von möglichen Einträgen von Metaboliten ins Grundwasser war zum damaligen Zeitpunkt nicht Bestandteil der Bewertung.

### 3.3 Alternativen mit ungünstigeren gesundheitlichen Eigenschaften

#### 3.3.1 Alternative mit Proquinazid

Das Benehmen des BfR für das Mittel **ZN1 025678-00/00 Talius** wurde bereits am 21.04.2011 auf Basis der Richtlinie 91/414/EWG erteilt. Im Rahmen der Bewertung des Erweiterungsantrages ZV1 025678-00/06 wurde der aktualisierte Einstufung und Kennzeichnungsvorschlag für das Mittel nach VO (EG) 1272/2008 mitgeteilt (BfR-Schreiben 6-6112-8983912 vom 20.09.2016). Danach ist das Mittel mit Hautreiz. 2 H315, Augenschäd. 1 H318 sowie Karz. 2, H351 zu kennzeichnen. Daraus resultiert das Signalwort „Gefahr“.

Für einen sicheren Umgang bei der Ausbringung sind vergleichbare Auflagen wie für das Mittel Brivela nötig, zusätzlich kommen jedoch auch noch Auflagen für das verdünnte Mittel hinzu.

Im Ergebnis der Gefahrenbewertung wird das Mittel eher ungünstig im Vergleich mit ZV3 00A343-00/00 Brivela eingeschätzt.

Im Hinblick auf die Risikobewertung für Verbraucher (Nahrung) wurden im Rahmen der damaligen Bewertung des Mittels (AL6-2501-6156757 vom 21.04.2011) keine gravierenden Datenlücken bzw. unannehmbaren Risiken identifiziert. Eine Bewertung von möglichen Einträgen von Metaboliten ins Grundwasser war zum damaligen Zeitpunkt nicht Bestandteil der Bewertung zu Anwendungen in Weizen.

### **Stellungnahme des UBA zur vergleichenden Bewertung gesundheitlicher Risiken**

UBA has conducted a comparative assessment regarding the risk of the product Brivela and of the proposed alternative products for the environment. According to Regulation (EC) No 1107/2009 Annex IV (2), a factor of at least 10 for the toxicity/exposure ratio (TER) of different plant protection products is considered as a significant difference in risk.

UBA has revised the potential alternatives of the active substances of these plant protection products and the overall characteristics of the products in the following stepwise approach.

1. Exclusion of products with critical ingredients equally as or even more critical than Difenoconazole
2. Exclusion of products with ingredients known for a low environmental risk
3. Selection of products with a high potential to be an alternative due to low environmental impact - proposed as alternatives for Brivela
  - Comparison of the environmental risk between Brivela and products with a single a.i.
  - Estimation of the environmental risk posed by formulations with more than one a.i.

## 1. Exclusion of products with ingredients equally as or even more critical than Difenoconazole

Some of the potentially alternative products for Brivela contain CfS themselves which show equivalent or even more critical properties from an environmental perspective as Difenoconazole. Products containing such active substances are *a priori* not considered significantly safer than Brivela and thus being no suitable alternative. Thus, a detailed comparison with the products containing the following active substances was omitted: Bromuconazole, Cyproconazole, Cyprodinil, Epoxiconazole, Isopyrazam, Metconazole, Prochloraz and Tebuconazole.

In consequence the following products were excluded from the comparative assessment with Brivela.

**Table 1: Products *a priori* not considered for comparative assessment**

Product No	Product Name	Active ingredients	Proposed for use No
00A217-00	TEBKIN	Tebuconazol (0784) FRAC: G1 CfS	002, 003
006341-00	Orius	Tebuconazol (0784) FRAC: G1 CfS	002, 003
006400-00	Fezan	Tebuconazol (0784) FRAC: G1 CfS	002, 003
007519-00	HELOCUR	Tebuconazol (0784) FRAC: G1 CfS	002, 003
034028-00	Folicur	Tebuconazol (0784) FRAC: G1 CfS	002, 003
006462-00	Ampera	Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	001, 002, 003
006591-00	Osiris	Epoxiconazol (0875) FRAC: G1 CfS; Metconazol (0945), FRAC: G1 CfS	001, 002
006798-00	Kantik	Fenpropidin (0881) FRAC: G2 ; Prochloraz (0631) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	001, 002, 003,
006912-00	EPOXION	Epoxiconazol (0875) FRAC: G1 CfS	001, 002, 003
006934-00	Epoxion Top	Epoxiconazol (0875) FRAC: G1 CfS; Fenpropidin (0881) FRAC: G2	001, 002, 003
006937-00	Opus EC	Epoxiconazol (0875) FRAC: G1 CfS	001, 002
007045-00	Eleando	Epoxiconazol (0875) FRAC: G1 CfS; Prochloraz (0631) FRAC: G1 CfS	001, 002, 004
007026-00	MAGNELLO	Difenoconazol (0865) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1 CfS	001, 002
007226-00	Cerix	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	001, 002, 003, 004
007313-00	Viverda	Boscalid (1043) FRAC: C2 ; Epoxiconazol (0875) FRAC: G1 CfS; Pyraclostrobin (1013) FRAC: C3	001, 002, 003, 004
007454-00	Soleil	Bromuconazol (0879) FRAC: G1 CfS; Tebuconazol (0784) FRAC: G1	002, 003

		CfS	
007468-00	Rubric	Epoxiconazol (0875) FRAC: G1 CfS	001, 002, 003
007605-00	SEGURIS XTRA	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	001,002, 003
007905-00	Rubric XL	Azoxystrobin (0902) FRAC: C3 ; Epoxiconazol (0875) FRAC: G1 CfS	001, 002, 003
007969-00	Librax	Fluxapyroxad (1164), FRAC: C2; Metconazol (0945) FRAC: G1 CfS;	001, 002, 003, 004
008012-00	AA-F2-004	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	001, 002, 003
008015-00	Mercury Pro	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	001, 002, 003
008127-00	MINISTER	Azoxystrobin (0902) FRAC: C3 ; Cyproconazol (0825) FRAC: G1 CfS	001, 002
008211-00	METACUR	Metconazol (0945) FRAC: G1 CfS	001, 002, 003
008326-00	SEGURIS ERA	Isopyrazam (1156) FRAC: C2 CfS; Prothioconazol (1035) FRAC: G1	001, 002, 003
044443-00	Pronto Plus	Spiroxamine (0914) FRAC: G2 ; Tebuconazol (0784) FRAC: G1 CfS	002, 003
024487-00	CARAMBA	Metconazol (0945) FRAC: G1 CfS	001, 002, 003
025273-00	Swing Gold	Dimoxystrobin (1028) FRAC: C3; Epoxiconazol (0875) FRAC: G1 CfS	001, 002
045662-00	Prosaro	Prothioconazol (1035) FRAC: G1 ; Tebuconazol (0784) FRAC: G1 CfS	001, 002, 003
025757-00	Champion	Boscalid (1023) FRAC: C2 ; Epoxi- conazol (0875) FRAC: G1 CfS	001, 002, 004
026958-00	Adexar	Epoxiconazol (0875) FRAC: G1 CfS; Fluxapyroxad (1164) FRAC: C2	001, 002, 003, 004
046998-00	Skyway Xpro	Bixafen (1151) FRAC: C2 ; Prothio- conazol (1035) FRAC: G1 ; Tebu- conazol (0784) FRAC: G1 CfS	001, 002, 003
027203-00	SEGURIS	Epoxiconazol (0875) FRAC: G1 CfS; Isopyrazam (1156) FRAC: C2 CfS	001, 002
024374-00	UNIX	Cyprodinil (0907) FRAC: D1 CfS	002, 003, 004
024216-00	Mirage 45 EC	Prochloraz (0631) FRAC: G1 CfS	001

After exclusion of the products in the table above the following products remain for the comparative assessment with Brivela for which Tier 1 TER-values resp. PEC/RAC ratios were used (for details refer to Annex "Comparative Assessment").

**Table 2: Products being a potential alternative for Brivela**

Product No	Product Name	Active ingredients	Proposed for use No
00A247-00	Tridex flow	Mancozeb (0010) FRAC: undefined	001
004329-00	DOMARCK 10 EC	Tetraconazol (0941) FRAC: G1	001, 003
026778-00	Input Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	001, 002, 003
007566-00	Variano Xpro	Bixafen (1151) FRAC: C2 ; Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	001, 002, 003
008180-00	Priaxor	Fluxapyroxad (1164) FRAC: C2 ; Pyraclostrobin (1013) FRAC: C3	001, 002
008219-00	Ascra Xpro	Bixafen (1151) FRAC: C2 ; Fluopyram (1134) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	001, 002, 003, 004
008235-00	Torero	Azoxystrobin (0902) FRAC: C	001, 002
008930-00	Input Triple	Proquinazid (1053) FRAC: E1 ; Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	001, 003, 004
024350-00	TRIDEX DG RAINCOAT	Mancozeb (0010) FRAC: undefined	001
025287-00	Proline	Prothioconazol (1035) FRAC: G1	001, 002, 003, 004
025315-00	Fandango	Fluoxastrobin (1034) FRAC: C3 ; Prothioconazol (1035) FRAC: G1	001, 002, 003, 004
025625-00	Input Classic	Prothioconazol (1035) FRAC: G1 ; Spiroxamine (0914) FRAC: G2	001, 002, 003, 004
026764-00	Aviator Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	001, 002, 003, 004
027413-00	Siltra Xpro	Bixafen (1151) FRAC: C2 ; Prothioconazol (1035) FRAC: G1	001, 002, 003, 004
008405-00	ELATUS PLUS	Benzovindiflupyr (1200) FRAC: C2 CfS	001, 002
008406-00	ELATUS ERA	Benzovindiflupyr (1200) FRAC: C2 CfS ; Prothioconazol (1035) FRAC: G1;	001, 002
026979-00	Imbrex XE	Fluxapyroxad (1164) FRAC: C2	001, 002, 003, 004
033924-00	Dithane Neo- Tec	Mancozeb (0010) FRAC: undefined	001
00A150-00	AZOSHY	Azoxystrobin (0902) FRAC: C3	002
007180-00	AZOXYSTAR	Azoxystrobin (0902) FRAC: C3	002
007643-00	Comet	Pyraclostrobin (1013) FRAC: C3	002
008570-00	SINSTAR	Azoxystrobin (0902) FRAC: C3	002



008745-00	LEGADO	Azoxystrobin (0902) FRAC: C3	002
008967-00	Azbany	Azoxystrobin (0902) FRAC: C3	002
008990-00	GLOBAZTAR SC	Azoxystrobin (0902) FRAC: C3	002
025090-00	AMISTAR	Azoxystrobin (0902) FRAC: C3	002
006345-00	Leander	Fenpropidin (0881) FRAC: G2	003
007475-00	Property 180 SC	Pyriofenone (1171) FRAC: B6	003
025311-00	Flexity	Metrafenone (1040) FRAC: B6	003, 004
025609-00	Vegas	Cyflufenamid (1045) FRAC: undefined	003
025678-00	TALIUS	Proquinazid (1053) FRAC: E1	003
00A249-00	Thiopron	Schwefel (0184) FRAC: undefined / IRAC: UN	003
050006-00	Netzschwefel Stulln	Schwefel (0184) FRAC: undefined / IRAC: UN	003
050498-00	THIOVIT Jet	Schwefel (0184) FRAC: undefined / IRAC: UN	003
052273-00	Kumulus WG	Schwefel (0184) FRAC: undefined / IRAC: UN	003

## 2. Exclusion of products with ingredients known for a low environmental risk

From the list provided by JKI products can be selected which contain active ingredients known for a low environmental impact. This applies for the chemical alternative Sulphur.

4 products with Sulphur as a.i. are proposed as alternatives for the intended use 003. The products THIOPRON, Netzschwefel Stulln, THIOVIT JET and Kumulus WG were all representative formulations for Sulphur Annex I Inclusion and have a joint risk assessment (EFSA Conclusion EPCO Manual E4 - rev. 4 (September 2005)). Thus, they are also assessed as a whole here. The comparison of their impacts on the environment reveals that they are less than that from Difenconazole. The Sulphur products are suitable alternatives to Brivela from an environmental perspective. For the respective results of the comparison please refer to the annex "Comparative assessment".

**Table 3: Products with Sulphur as a.i. - low risk**

Product No	Product Name	Active ingredients	Proposed for use No
00A249-00	Thiopron	Schwefel (0184) FRAC: undefined / IRAC: UN	003
050006-00	Netzschwefel Stulln	Schwefel (0184) FRAC: undefined / IRAC: UN	003
050498-00	THIOVIT Jet	Schwefel (0184) FRAC: undefined / IRAC: UN	003
052273-00	Kumulus WG	Schwefel (0184) FRAC: undefined / IRAC: UN	003

### 3. Selection of products with a high potential to be an alternative due to low environmental impact - proposed as alternatives for Brivela

Following the Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013 rev. 12, 10 October 2014), a stepwise approach of assessment for the environment was taken. Different approaches may be followed at Member State level, depending on the availability of e.g. national data bases on risks and risk mitigation measures. In this case the assessment focused on the specific criteria that resulted in Difenconazole being defined as candidate for substitution (persistence in soil, toxic to aquatic organisms) plus additional critical areas of risk i.e. chronic risk to birds and mammals).

Comparison of risks should be done on conceptually equivalent tiers of the risk assessment. The comparisons were therefore conducted with tier 1-TER values and PEC/RAC ratios. This approach implies that any generic risk mitigation measure will apply equally for all of the compared products, and that more specific characteristics of the active substances like residue dynamics are already taken into account in the first-tier calculation models. The calculations of the ratios between tier 1-level TER-values and PEC/RAC ratios of Brivela and alternative plant protection products were done on the basis of the Core Assessment report (CA) of the resp. zRMS and the German National Addendum (for aquatic and soil).

In the following the results of the comparison of alternative products with Brivela is documented. For the detailed comparison of and Tier 1-TER values and PEC/RAC ratios please refer to the annex of this statement.

#### A) Comparison of the environmental risk between Brivela and products with a single active ingredient

**Table 4: Products with Azoxystrobin as single a.i.**

ZA	Name	Azoxystrobin content	Proposed as alternative for use	Application rate
008235-00	Torero	250 g a.i./L	001, 002	2 x 250 g a.i./ha
00A150-00	AZOSHY	250 g a.i./L	002	2 x 250 g a.i./ha
007180-00	AZOXYSTAR	250 g a.i./L	002	2 x 250 g a.i./ha
008570-00	SINSTAR	250 g a.i./L	002	2 x 250 g a.i./ha
008745-00	LEGADO	250 g a.i./L	002	2 x 250 g a.i./ha
008967-00	Azbany	250 g a.i./L	002	2 x 250 g a.i./ha
008990-00	GLOBAZTAR SC	250 g a.i./L	002	2 x 250 g a.i./ha

025090-00	AMISTAR	250 g a.i./L	002	2 x 250 g a.i./ha
-----------	---------	--------------	-----	-------------------

As all formulations with azoxystrobin are used with the same application rate, the comparative assessment was based on one formulation (ZA 7180) and not conducted for each of the proposed alternatives.

The toxicity of Difenoconazole and Azoxystrobin is almost equivalent for all organism groups. The comparison of tier 1 TER values and PEC/RAC ratios reveals that the Azoxystrobin-containing products are no suitable alternative to Brivela.

**Table 5: Product with Prothioconazole as single a.i.**

ZA	Name	Prothioconazole content	Proposed as alternative for use	Application rate
025287-00	Proline	250 g a.i./L	001, 002, 003, 004	1-2 x 200 g a.i./L (3 x in the crop)

The toxicity of Prothioconazole-containing product Proline is in the same range as that of Brivela for most groups of organisms. However, the long-term risk for mammals posed by Prothioconazole is significantly (i.e. ten times) higher than from Difenoconazole and the risk to soil macro-organisms is high (TER=1.36 refined with field study). Proline is therefore not considered a suitable alternative to Brivela.

**Table 6: Products with Mancozeb as single a.i.**

ZA	Name	Mancozeb content	Proposed as alternative for use	Application rate
00A247-00	Tridex Flow	500 g a.i./L	001	3 x 1500 g a.i./ha
024350-00	TRIDEX DG RAINCOAT	750 g a.i./kg	001	3 x 1600 g a.i./ha
033924-00	Dithane Neo-Tec	750 g a.i./kg	001	3 x 1600 g a.i./ha

The two products Tridex DG Raincoat and Dithane NeoTec are used at equal application rates. Tridex Flow at slightly lower application rates. Thus, only Tridex Flow is considered for tier 1-TER calculations and comparison with Brivela.

In no field of risk assessment a significantly lower risk arises from the use of Tridex Flow. The long-term risk to mammals is significant higher and the risk to aquatic organisms is more than ten times higher than that of Brivela. Therefore Tridex Flow is not a suitable alternative for Brivela. Moreover, the approval of Mancozeb ended on 04.01.2021 and will not be renewed.

**Table 7: Products with Tetraconazole as single a.i.**

ZA	Name	Tetraconazole content	Proposed as alternative for use	Application rate
004329-00	DOMARK 10 EC	100 g a.i./L	001, 003	2 x 125 g a.i./ha

The toxicity of Domark 10 EC for aquatic organisms is more than 10 times lower than that of Brivela. Nevertheless Domark 10 EC is not a suitable alternative for Brivela as it shows a significant higher long-term toxicity for birds and mammals than Brivela.

**Table 8: Products with Benzovindiflupyr as a.i.**

ZA	Name	Benzovindiflupyr content	Proposed as alternative for use	Application rate
008405-00	ELATUS PLUS	100 g/L Benzovindiflupyr	001, 002	1 x 75 g a.i./ha
008406-00	ELATUS ERA	75 g/L Benzovindiflupyr 150 g/L Prothio.	001, 002	75 g Benzovindiflupyr/ha 150 g Prothioc./ha

The toxicity of Difenoconazole and Benzovindiflupyr is almost equivalent for all organism groups. Except, the toxicity of Benzovindiflupyr for aquatic organisms is significantly higher. Thus, ELATUS PLUS cannot be considered a suitable alternative to the application of Brivela. This holds true also for ELATUS ERA as the applicationrate of Benzovindiflupyr is the same for as for ELATUS ERA. In addition, the toxicity of ELATUS ERA is slightly worse due to Prothioconazole.

**Table 9: Product with Pyraclostrobin as single a.i**

ZA	Name	Pyraclostrobin content	Proposed as alternative for use	Application rate
007643-00	Comet	200 g a.i./L	002	2 x 250 g a.i./ha

The long-term risk to mammals is ten times higher for Comet than for Brivela and the risk for aquatic organisms is significantly higher using Comet. Thus, this product is no suitable alternative to the use of Brivela.

**Table 10: Product with Fluxapyroxad as single a.i**

ZA	Name	Fluxapyroxad content	Proposed as alternative for use	Application rate
046979-00	Imbrex XE	62.5 g/L	001, 002, 003, 004	2 x 125 g a.i./ha

The comparison of the toxicity of Brivela and Imbrex XE shows that the use of Imbrex XE is not significantly safer for the environment than Brivela. Imbrex XE is not a suitable alternative. One reason is that the Fluxapyroxad metabolite M700F002 is expected in groundwater in a concentration > 0.75µg/L and < 10 µg/L as for Fluxapyroxad of Brivela.

**Table 11: Product with Fenpropidin as single a.i.**

ZA	Name	Fenpropidin content	Proposed as alternative for use	Application rate
006345-00	Leander	750 g/L	003	562.5 g a.i./ha

In no field of risk assessment a significantly lower risk arises from the use of Leander. However, the risk to aquatic organisms is more than ten times higher than that of Brivela. Therefore Leander is not a suitable alternative for Brivela.

**Table 12: Product with Pyriofenone as single a.i.**

ZA	Name	Pyriofenone content	Proposed as alternative for use	Application rate
007574-00	Property 180 SC	180 g/L	003	2 x 90 g a.i./ha

In almost no field of risk assessment a significantly lower risk arises from the use of Property 180 SC. Except, the risk to aquatic organisms is more than ten times lower than that of Brivela. Therefore Property 180 SC could be a suitable alternative for Brivela.

**Table 13: Product with Metrafenone as single a.i.**

<b>ZA</b>	<b>Name</b>	<b>Metrafenone content</b>	<b>Proposed as alternative for use</b>	<b>Application rate</b>
025311-00	Flexity	300 g/L	003, 004	2 x 300 g a.i./ha

In almost no field of risk assessment a significantly lower risk arises from the use of Flexity. Except, the risk to aquatic organisms is more than ten times lower than that of Brivela. Therefore Flexity could be a suitable alternative for Brivela.

**Table 14: Product with Cyflufenamid as single a.i.**

<b>ZA</b>	<b>Name</b>	<b>Cyflufenamid content</b>	<b>Proposed as alternative for use</b>	<b>Application rate</b>
025609-00	Vegas	51,3 g/L	003	2 x 19.24 g a.i./ha

In almost all fields of risk assessment a significantly lower risk arises from the use of Vegas and the risk to aquatic organisms is more than ten times lower than that of Brivela. Therefore Vegas could be a suitable alternative for Brivela.

However, the metabolites NF 149 F1 and NF 149 F6 of Cyflufenamid can occur in groundwater at concentrations >0.1 µg/L but they are not ecotoxicological relevant.

**Table 15: Product with Proquinazid as single a.i.**

<b>ZA</b>	<b>Name</b>	<b>Proquinazid content</b>	<b>Proposed as alternative for use</b>	<b>Application rate</b>
025678-00	Talius	200 g/L	003	2 x 50 g a.i./ha

The toxicity of Talius is in the same range as that of Brivela for most groups of organisms. The acute toxicity for birds and mammals and that for soil macro-organisms is ten times lower. Therefore, Talius could be considered a suitable alternative to Brivela.

### B) Estimation of the environmental risk posed by formulations with more than one active ingredient

The JKI list provides further products as alternatives to the use of Brivela which contain two or more active ingredients. At least one of them has already be compared to Brivela under point A), so their risk profile is known. It can be judged roughly from the application rates whether the risk posed by them may be significantly lower than from Brivela.

**Table 16: Products with more than one active ingredient**

ZA	Name	Active ingredient content	Proposed as alternative for use	Application rate Estimation of risk
026778-00	Input Xpro	Bixafen 50 g/L Prothioconazole 100 g/L Spiroxamine 250 g/L	001, 002, 003	2 x 1.5 L/ha = 2 x 150 g P. + 75 g B. + 375 g Sp. /ha  Spiroxamine: 10 times more toxic for aquatic organisms than Difenconazole  Bixafen: High persistency  ➔ No suitable alternative
007566-00	Variano Xpro	Bixafen 40 g/L Fluoxastrobin 50 g/L Prothioconazole 100 g/L	001, 002, 003	2 x 1.75 L/ha = 2 x 175 g P. + 70 g B. + 87.5 g F. /ha  Fluoxastrobin and Bixafen: More toxic to aquatic organisms than Difenconazole  Bixafen: High persistency  ➔ No suitable alternative
008180-00	Priaxor	Fluxapyroxad 75 g/L ; Pyraclostrobin 150 g/L	001, 002	2 x 1.5 L/ha = 2 x 112.5 g F. + 225 g P.  Application rates equivalent to the respective monoformulations  Groundwater concentration of Fluxapyroxad metabolit M700F002: 3.238/2.818 µg/L  ➔ No suitable alternative
008219-00	Ascra Xpro	Bixafen 65 g/L Fluopyram 65 g/L Prothioconazole 130 g/L	001, 002, 003, 004	2 x 1.5 L/ha = 2 x 97.5 g B. + 97.5 g F. + 185 g P. /ha  Prothioconazole: Application rate not

				<p>much lower than in Proline</p> <p>Fluopyram: Higher chronic risk to birds and mammals than Difenoconazole</p> <p>Bixafen: High persistency</p> <p>➔ No suitable alternative</p>
008930-00	Input Triple	Proquinazid 40 g/L Prothioconazole 160 g/L Spiroxamine 200 g/L	001, 003, 004	<p>1 x 1.25 L/ha =                      50 g Proq. + 200 g Proth. + 250 g S. /ha</p> <p>Prothioconazole: Same application rate as with Proline</p> <p>Spiroxamine: High chronic risk to birds, mammals and 10 times more toxic for aquatic organisms than Difenoconazole</p> <p>➔ No suitable alternative</p>
025315-00	Fandango	Fluoxastrobin 100 g/L Prothioconazole 100 g/L	001, 002, 003, 004	<p>2 x 1.5 L/ha =                      2 x 150 g Fl. + 150 g Pro. /ha</p> <p>Fluoxastrobin: Higher long-term toxicity for mammals and significantly more toxic to aquatic organisms than Difenoconazole</p> <p>➔ No suitable alternative</p>
025625-00	Input Classic	Prothioconazole 160 g/L Spiroxamine 300 g/L	001, 002, 003, 004	<p>2 x 1.25 L/ha =                      2 x 200 g P. + 375 g S. /ha</p> <p>Prothioconazole: Same application rate as with Proline</p> <p>Spiroxamine: High chronic risk to birds, mammals and 10 times more toxic for aquatic organisms than Difenoconazole</p> <p>➔ No suitable alternative</p>
046764-00	Aviator Xpro	Bixafen 75 g/L Prothioconazole 150 g/L	001, 002, 003, 004	<p>2 x 1.25 L/ha =                      2 x 188 g P. + 94 g B. /ha</p> <p>Prothioconazole: Application rate not much lower than in Proline</p> <p>Bixafen: High persistency</p> <p>➔ No suitable alternative</p>



047413-00	Siltra Xpro	Bixafen 60 g/L Prothioconazole 200 g/L	001, 002, 003, 004	2 x 1.0 L/ha = 2 x 200 g P. + 60 g B. /ha  Prothioconazole: Same application rate as with Proline  Bixafen: high persistency  → No suitable alternative
-----------	-------------	--	-----------------------	---

None of the products in the table above proves to be a significantly safer alternative for the use of Brivela.

#### 4. Outcome of the comparative assessment

Tier 1 TER values resp. PEC/RAC ratios of Brivela were compared to a list of formulations with different active substances. A formulation was identified as a suitable alternative, if

- at least one TER value is 10 times higher or PEC/RAC ratio 10 times lower and thus indicates a significantly lower risk than that posed by Brivela, especially in an area of concern (i.e. where Brivela TER values fall below the respective trigger and thus indicate a high risk to the environment), and
- there is no TER value 10 times lower or PEC/RAC ratio 10 times higher than that of Brivela, indicating a significantly higher risk than that posed by Brivela

The comparison of the tier 1-TER values resp. PEC/RAC ratios reveals that the alternative products with the active substances Sulphur, Pyriofenone, Metraferone, Proquinazid and Cyflufenamid as single active ingredient pose a significantly lower risk to the environment than Brivela.

The following products can be considered a significantly safer alternative to the use of Brivela in the respective crop regarding the risk to the environment:

**Table 17: Products with a significantly lower risk to the environment compared to Brivela**

Intended use	Suitable alternatives
003	Sulphur*
003	Talius
003	Property 180 SC
003	Vegas
003, 004	Flexity

\* "Sulphur" refers to all proposed products with sulfur as single a.i. (Netzschwefel Stulln, THIOVIT JET, Kumulus WG, Thiopron)

➤ **Comparative assessment – comparison of tier 1 TER values resp. PEC/RAC ratios**

- Tier 1-TER value is ten times higher (or PEC/RAC ratio is ten times lower) in comparison to Brivela
- Tier 1-TER value is ten times lower (or PEC/RAC ratio is ten times higher) in comparison to Brivela

- Birds and mammals, acute risk: TER screening assessment (no area of concern)
- Birds and mammals, long-term risk: tier 1 TER from relevant critical scenario
- Aquatic organisms: Ratio  $PEC_{SW}/RAC$ .  $PEC_{SW}$  according to Driftox (1 m distance to the field margin without drift reducing techniques), resp. maximum  $PEC_{sw}$  for Run-off/Drainage if necessary (EXPOSIT, 0 m buffer zone),  $RAC$  = lowest acute or chronic endpoint divided by the respective SF
- Chronic risk to soil macro-organisms: Endpoint divided by  $PEC_{soil}$  (according to national addendum)

**A. Comparison of monoformulations**

Field of risk assessment	TER Brivela	TER Sulphur-products LoEP 2005	TER Azoxystrobin products ZA 7180	TER Prothioconazole ZA 025287	TER Mancozeb (ZV1 024350)	TER Tetraconazole ZA 4329	TER Proquinazid ZA 025678	TER Pyraclostrobin ZV1 7643	TER Fluxapyroxad ZV1 026979
Birds, acute risk (screening step)	210 (Fluxap.) >29.3 (Difenocon.) 67 (MixTox)	8	41	>123 Desthio: >246  (SANCO)	Tier 1: >79	Tier 1: 13 (a.i.) >21 (Prep.)  (SANCO)	>505 EFSA	>45.8	155
<b>Birds, long-term risk</b>	Screening: 8.7 (Fluxap.) 3.8 (Difenocon.)  Tier 1: 45 (Difenocon)	Not relevant	Screening: 9.1	13 Desthio: 4.9  (SANCO)	Tier 1: 2.2 / 3.6 Refinement possible	Tier 1: 0.5/ 1.2 (SANCO)  Tier 2: 1.1/12.5 refinement possible	5.2 EFSA	10.2	>6.4

	7.3 (MixTox)								
Aquatic organisms (most sensitive endpoint), acute PEC/RAC		Not applicable	Drift: 3.08/1.38 = 2.23 Run-off: 1.86/1.38 = 1.35 Drainage: 0.93/1.38 = 0.67			Drift: 10.85/11 = 0.99 (preparation)  No more risk through run-off or drainage			
<b>Aquatic organisms (most sensitive endpoint), chronic risk</b>	Difenocon.: Drift: 0.69/0.36 = 1.92 Run-off: 0.10/0.36 = 0.28 Drainage: 0.01/0.36 = 0.028  PEC/RAC Drift - Brivela: = 2.32	Not applicable		1 Desthio: Drift: 0.83/0.33 = 2.52 Run-off: 0.57/0.33 = 1.73 Drainage: 0.21/0.33 = 0.64	Drift: 14.8/0.22 = 67  Run-off and Drainage not relevant	Drift: 1.54/26 = 0.06 (a.i.)  No more risk through run-off or drainage	Drift: 0.47/0.18 = 2.6 Run-off: 0.03/0.18 = 0.17 Drainage: < 0.03/0.18 = < 0.17	Drift: 3.09/0.295 = 10.5 Run-off: 0.28/0.295 = 0.95 Drainage: 0.10/0.295 = 0.34	Drift: 1.82/2.9 = 0.62 Run-off: 0.76/2.9 = 0.26 Drainage: 0.05/2.9 = 0.017
Mammals, acute risk (Screening step)	150 (Fluxap.) 164 (Difenocon.) 9.1 (MixTox)  Tier 1 worst case: 26 (MixTox)	> 10	141	121 Desthio: 87 (SANCO)	Tier 1: 58	Tier 1: 32 (a.i.) 5.8 (Prep) (SANCO)	>>1000	>154 (a.i.) >3 (prepar.)  Tier 2 : 8.9 (prepar.)	>109
<b>Mammals,</b>	Screening: 3.5 (Fluxap.)	Not relevant	Screening: 3.6	Tier 1: 0.6/15 (ear-	Tier 1: 1.6	Tier 1: 0.07 – 0.8	12.5 EFSA	0.39	2.5

<b>long-term risk</b>	9.0 (Difenocon.)  Tier 1: 7.7 (Fluxa.) 20 (Difenocon.) 5.6 (MixTox)		Tier 1: 7.3	ly/late) Refined: >6.6  Desthio: 0.1/3.7 (early/late) Refined: >5.5  (SANCO)	Refined: 8.6	Tier 2: 1.6 – 16.1  Refinement possible		Tier 2: 2.4 (vole) – 27.3 (shrew)	Tier 1: 5.5 (vole) 64.8 (shrew)
Non-target arthropods	No risk	32	No risk	No risk	Risk Management.: NT 102 (75% + 3m)	No risk		No risk	No risk
Soil macro-organisms, chronic risk	<i>Eisenia</i> : 144 (Fluxap.) 4.85 (Difenoc.) 30 (Brivela)  Other organisms less susceptible	Not relevant	<i>Eisenia</i> : 15.2 (preparation)  Other organisms less susceptible	Desthio: 1.36  Refined with field study	<i>Eisenia</i> : >5	TERacute = 66 no longterm test	>300 (TALI-US)	<i>Eisenia</i> : 4.1 (product) Field study for refinement  <i>Folsomia</i> : 17 (prepar.)	<i>Eisenia</i> : ≥34 (product) Field study for refinement  <i>Folsomia</i> : 5 (prepar.)
Soil micro-organisms (MoS)	No risk	Not relevant	No risk	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate
Concentrations of relevant metabolites in ground water	1.03 µg/L Fluxapyroxad Metab. <i>M700F002</i> - ecotox. not relevant	Not relevant	R234886 > 0.1 µg/L but considered as non-relevant in groundwater	no	no	no	No	no	FOCUS PELMO 5.5.3 For the metabolites <i>M700F001</i> and <i>M700F002</i> after direct leaching a groundwater concentration of ≥ 0.75 µg/L cannot be excluded - ecotox. not rele-

									vant
--	--	--	--	--	--	--	--	--	------

Field of risk assessment	TER Brivela	TER Fenpropidin ZA 6345	TER Pyriofenone ZN 7475	TER Metrafenone ZA 025311	TER Benzovindiflupyr ZV1 8405	TER Benzovindiflup. + Prothioconazole ZV1 8406	TER Cyflufenamid ZA5609
Birds, acute risk (screening step)	210 (Fluxap.) >29.3 (Difenocon) 67 (MixTox)	91 EFSA	> 116 EFSA	125 SANCO	Screening: 110	Screening: <u>110</u> (Benz.) <u>84</u> (Proth.)	>1000 (SANCO)
Birds, long-term risk	Screening: 8.7 (Fluxap.) 3.8 (Difenocon.)  Tier 1: 45 (Difenocon.) 7.3 (MixTox)	7.9 EFSA	21.7 EFSA	14 SANCO	Screening: 9.7	Tier 1: <u>≥117</u> (Benz.) <u>&gt;38</u> (Desthio.) <u>&gt;183</u> (Proth.)	≥112 (SANCO)
Aquatic organisms (most sensitive endpoint), acute, PEC/RAC							
Aquatic organisms (most sensitive endpoint), chronic risk PEC/RAC	Difenocon.: Drift: 0.69/0.36 = 1.92 Run-off: 0.10/0.36 = 0.28 Drainage: 0.01/0.36 = 0.028	Drift: 5.48/0.1 = 54.8 Run-off: 0.18/0.1 = 1.8 Drainage: 0.03/0.1 = 0.3	Drift: 1.8/9.0 = 0.16 Run-off: 0.16/9.0 = 0.02 Drainage: 0.02/9.0 = 0.002	Drift: 1.46/22.5 = 0.07 Run-off: 1.43/22.5 = 0.06 Drainage: 0.01/22.5 = 0.0004	Drift: 0.69/0.095 = 7.26 Run-off: 0.07/0.095 = 0.74 Drainage: 0.01/0.95 = 0.11		Drift: 0.289/2.4 = 0.12 Run-off: 0.11/2.4 = 0.005 Drainage: 0.01/2.4 = 0.004

	PEC/RAC Drift - Brivela: = 2.32						
Mammals, acute risk  (Screening step)	150 (Fluxap.) 164 (Difenocon.) 9.1 (MixTox)  Tier 1 worst case: 26 (MixTox)	63 EFSA	156 EFSA	169 SANCO	Screening: 6.2 (12.7 Prep.)  Tier 1: ≥18	Tier 1: ≥17.9 (Benz.) ≥402 (Desthio.)	≥1000 (SANCO)
<b>Mammals, long-term risk</b>	Screening: 3.5 (Fluxap.) 9.0 (Difenocon.)  Tier 1: 7.7 (Fluxa.) 20 (Difenocon.) 5.6 (MixTox)	6.2	10.5	8.2 SANCO	Screening: 3.5  Tier 1: ≥7.9	Tier 1: ≥7.9 (Benz.) ≥6.4 (Desthio.) ≥5.7 (Proth.)	≥6.8 (SANCO)
Non-target arthropods	No risk	NT 102 (75% Driftreduction)	No risk	No risk			
Soil macro-organisms, chronic risk	<i>Eisenia</i> : 144 (Fluxap.) 4.85 (Difenocon.) 30 (Brivela)  Other organisms less susceptible	<i>Eisenia</i> : 40	<i>Eisenia</i> : 88 (a.i)	<i>Eisenia</i> : 4.3 (preparation)	<i>Eisenia</i> : 44 (38 prep.)  <i>Folsomia</i> : 65 (prep.)	<i>Eisenia</i> : 2.2 (Benz.) 4.4 (Prothio.)	<i>Eisenia</i> : 27
Soil micro-organisms (MoS)	No risk	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	No effects at application rates >> intended rate	
Concentrations of relevant metabo-	1.03 µg/L Fluxapyroxad Metab.	>0.1 µg/L <i>CGA289267 (RO 15-6045)</i>		no			Metabolites <i>NF 149 F1</i> and <i>NF 149 F6</i>

lites in ground water	M700F002 - ecotox. not relevant	Refined with field lysimeter					> 0.1 µg/l in groundwater - ecotoxicol. not relevant
-----------------------	---------------------------------	------------------------------	--	--	--	--	--

**B. Comparison of formulations with more than one active substance**

Field of risk assessment	TER Brivela	TER Input Xpro (ZV1 6778) Bixafen Prothioconazole Spiroxamine	TER Fandango (ZV1 025315) Prothioconazole Fluoxastrobin
Birds, acute risk (screening step)	210 (Fluxap.) >29.3 (Difenocon.) 67 (MixTox)	140 (Bixafen) 6.7 (Spiroxamine) 70 (Prothio.) 70 (Desthio.) 5.9 (TERmix)  Tier 1 Spiroxamine: 35 TERmix: 30	>89
<b>Birds, long-term risk</b>	Screening: 8.7 (Fluxap.) 3.8 (Difenocon)  Tier 1: 45 (Difenocon.) 7.3 (MixTox)	8.3 (Bixafen) 0.1 (Spiroxamine) 10.8 (Prothio.) 2.1 (Desthio.) 5.9 (TERmix)  Tier 1: 8.2 (Desthio.) 0.4 – 2.2 (Spiroxamine)	Desthio.: 3.6/4.4 Refined: 8.7/22  (SANCO)
Aquatic organisms (most sensitive endpoint), acute, PEC/RAC			
<b>Aquatic organisms (most sensitive endpoint), chronic risk PEC/RAC</b>	Difenocon.: Drift: 0.69/0.36 = 1.92 Run-off: 0.10/0.36 = 0.28	Drift: Bixafen: 1.18/0.45 = 2.6 Spiroxamine: 6.4/0.2 = 32 Prothio.: 2.0/1.8 = 1.1	Fluoxastrobin Drift: 0.55/0.122 = 4.5 Run-off: 2.2



	Drainage: $0.01/0.36 = 0.028$  PEC/RAC Drift - Brivela: $= 2.32$	Runoff: Bixafen: $0.24/0.46 = 0.52$ Spiroxamine: $1.09/0.2 = 5.45$ Prothio.: $0.52/1.8 = 0.55$ Desthio.: $0.45/0.33 = 1.36$	Drainage: 2.3
Mammals, acute risk  (Screening step)	150 (Fluxap.) 164 (Difenocon.) 9.1 (MixTox)  Tier 1 worst case: 26 (MixTox)	469 (Bixafen) 8.6 (Spiroxamine) 291 (Prothio.) 105 (Desthio.) 27 (Input Xpro)  Tier 1 Spiroxamine: 25 - 197	>42 (preparation)
<b>Mammals, long-term risk</b>	Screening: 3.5 (Fluxap.) 9.0 (Difenocon.)  Tier 1: 7.7 (Fluxap.) 20 (Difenocon.) 5.6 (MixTox)	12.9 (Bixafen) 1.7 (Spiroxamine) 17.8 (Prothio.) 1.9 (Desthio.) 27 (Input Xpro)  Tier 2 Desthio.: 19.4 Tier 2 Spiroxamine: 6.7 – 10.2	Desthio.: 0.8 Refined: 2.4  (SANCO)
Non-target arthropods	No risk		No risk
Soil macro-organisms, chronic risk	<i>Eisenia</i> : 144 (Fluxap.) 4.85 (Difenocon.) 30 (Brivela)  Other organisms less susceptible	<i>Eisenia</i> : 62 (Bixafen) >10 (Spiroxamine) 313 (Prothio.) 1.05 (Desthio.) 2.8 (Input Xpro)  Other organisms less susceptible, except <i>Collembola</i> : 4.8 (Bixafen)	<i>Eisenia</i> : Fluoxastrobin: 13.8

Soil micro-organisms (MoS)	No risk		No effects at application rates >> intended rate
Concentrations of relevant metabolites in ground water	1.03 µg/L Fluxapyroxad Metab. M700F002 . eco-tox. not relevant	Not relevant	Not relevant

## **Appendix 6 Copy of the product authorization**

See below



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

**Dr. Birgit Schreiber**  
Referentin

BASF SE  
E-APE/NDT, Li 556  
Speyerer Straße 2  
67117 Limburgerhof

TELEFON +49 (0)30 18444-22209  
TELEFAX +49 (0)30 18444-20099  
E-MAIL [birgit.schreiber@bvl.bund.de](mailto:birgit.schreiber@bvl.bund.de)

IHR ZEICHEN  
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.00A343-00/00.256860  
(bitte bei Antwort angeben)

DATUM 15. Juli 2021

### **ZV3 00A343-00/00**

**Brivela**

### **Zulassungsverfahren für Pflanzenschutzmittel**

Bescheid

Das oben genannte Pflanzenschutzmittel

mit den Wirkstoffen:           75 g/l           Fluxapyroxad  
  50 g/l           Difenoconazol

Zulassungsnummer:           00A343-00

Versuchsbezeichnungen:     BAS-71700-F-0-SC

Antrag vom:                     12. Dezember 2018

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

### **Zulassungsende**

Die Zulassung endet am 31. Dezember 2022.

### **Festgesetzte Anwendungsgebiete bzw. Anwendungen**

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

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
00A343-00/00-002	Braunrost (Puccinia recondita)	Winterweichweizen	
00A343-00/00-001	Septoria-Blattdürre (Septoria tritici)	Winterweichweizen	

### 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 278 der Verordnung vom 19. Juni 2020 (BGBl. I S. 1328), festgesetzt:

(NW470)

Etwaige Anwendungsflüssigkeiten, Granulate und deren Reste 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 Difenoconazol und Fluxapyroxad 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.

(SS110-1)

Beim Umgang mit dem unverdünnten Mittel sind Schutzhandschuhe (Pflanzenschutz) zu tragen.

#### Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsaufgaben zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS2101)

Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z.B. Gummistiefel) tragen

beim Umgang mit dem unverdünnten Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS530)

Gesichtsschutz tragen beim Umgang mit dem unverdünnten Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

(SS610)

Gummischürze tragen beim Umgang mit dem unverdünnten Mittel.

Begründung:

Aufgrund der Einstufung und Kennzeichnung des Mittels (vgl. Bundesanzeiger: "Bekanntmachung über die Ableitung von gefahrenbasierten Kennzeichnungsauflagen zur Anwendungssicherheit im Zulassungsverfahren für Pflanzenschutzmittel nach Inkrafttreten der CLP-Verordnung für Gemische (BVL 15/02/13) vom 23. September 2015" (BAnz AT 19.10.2015 B2)).

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:

Verpackungsart	Verpackungsmaterial	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Flasche	HDPE	1		0,15	1,00	l
Flasche	HDPE, fluoriert	1		0,15	1,00	l
Kanister	HDPE	1		1,00	20,00	l
Kanister	HDPE	1		50,00		l
Kanister	HDPE, fluoriert	1		1,00	20,00	l
Kanister	HDPE, fluoriert	1		50,00		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:

Kennzeichnungsaufgaben:

(EB001-2)

SP 1: Mittel und/oder dessen Behälter nicht in Gewässer gelangen lassen. (Ausbringungsgeräte nicht in unmittelbarer Nähe von Oberflächengewässern reinigen./Indirekte Einträge über Hof- und Straßenabläufe verhindern.)

(NW262)

Das Mittel ist giftig für Algen.

(NW264)

Das Mittel ist giftig für Fische und Fischnährtiere.

(NW265)

Das Mittel ist giftig für höhere Wasserpflanzen.

(SB001)

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

(SB005)

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

(SB010)

Für Kinder unzugänglich aufbewahren.

(SB111)

Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit ([www.bvl.bund.de](http://www.bvl.bund.de)) zu beachten.

(SB166)

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

(SF245-02)

Es ist sicherzustellen, dass behandelte Flächen/Kulturen erst nach dem Abtrocknen des Pflanzenschutzmittelbelages wieder betreten werden.

(SS206)

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

(WMFC2)

Wirkungsmechanismus (FRAC-Gruppe): C2

(WMFG1)

Wirkungsmechanismus (FRAC-Gruppe): G1

Siehe anwendungsbezogene Kennzeichnungsaufgaben 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 Wirkstoffnamen zuzuordnen.

### **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:

(S1)            Achtung

Gefahrenpiktogramme:

(GHS07)        Ausrufezeichen

(GHS09)        Umwelt

Gefahrenhinweise (H-Sätze):

(H317)



Kann allergische Hautreaktionen verursachen.

(H362)

Kann Säuglinge über die Muttermilch schädigen.

(H410)

Sehr giftig für Wasserorganismen mit langfristiger Wirkung.

(EUH 208-0098)

Enthält 1,2-Benzisothiazol-3(2H)-on. Kann allergische Reaktionen hervorrufen.

(EUH 208-0205)

Enthält 2-Methyl-2H-isothiazol-3-on. Kann allergische Reaktionen hervorrufen.

(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.

(P260)

Staub/Rauch/Gas/Nebel/Dampf/Aerosol nicht einatmen.

(P263)

Berührung während Schwangerschaft und Stillzeit vermeiden.

(P270)

Bei Gebrauch nicht essen, trinken oder rauchen.

(P280)

Schutzhandschuhe/Schutzkleidung/Augenschutz/Gesichtsschutz tragen.

(P302+P352)

BEI BERÜHRUNG MIT DER HAUT: Mit viel Wasser/... waschen.

(P308+P313)

BEI Exposition oder falls betroffen: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen.

(P362+P364)

Kontaminierte Kleidung ausziehen und vor erneutem Tragen waschen.

(P391)

Verschüttete Mengen aufnehmen.

(P501)

Inhalt/Behälter ... zuführen.

**Abgelehnte Anwendungsgebiete bzw. Anwendungen**

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

<b>Anwendungsnummer</b>	<b>Schadorganismus/ Zweckbestimmung</b>	<b>Pflanzen/-erzeugnisse/ Objekte</b>	<b>Verwendungszweck</b>
00A343-00/00-003	Echter Mehltau (Erysiphe graminis)	Winterweichweizen	
00A343-00/00-004	Halmbruchkrankheit (Pseudocercospora herpotrichoides)	Winterweichweizen	

**Hinweise****Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:**

(NB6641)

Das Mittel wird bis zu der höchsten durch die Zulassung festgelegten Aufwandmenge oder Anwendungskonzentration, falls eine Aufwandmenge nicht vorgesehen ist, als nicht bienengefährlich eingestuft (B4).

(NN1001)

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

(NN1002)

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

### **Weitere Hinweise und Bemerkungen**

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 beim Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Braunschweig einzulegen.

Mit freundlichen Grüßen  
im Auftrag

gez. Dr. Martin Streloke  
Abteilungsleiter

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

### **Anlage**

## Anlage 1 zugelassene Anwendung: 00A343-00/00-001

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Septoria-Blattdürre (*Septoria tritici*)

Pflanzen/-erzeugnisse/Objekte: Winterweichweizen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwenderkategorie:	Beruflich
Stadium der Kultur:	30 bis 49
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:	
-	1,5 l/ha in 200 bis 300 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

(WW709)

Bei wiederholten Anwendungen des Mittels oder von Mitteln derselben Wirkstoffgruppe können Wirkungsminderungen eintreten oder eingetreten sein. Um Resistenzbildungen vorzubeugen, das Mittel möglichst im Wechsel mit Mitteln aus anderen Wirkstoffgruppen verwenden.

#### 2.3 Wartezeiten

56 Tage Freiland: Weizen

### 3 Anwendungsbezogene Anwendungsbestimmungen

(NW609-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr.

205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.

5 m

Begründung:

Das o. g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bestimmend für die Bewertung des Risikos ist hier die NOEC für *Pimephales promelas* von 3,6 µg/L (bezogen auf den Wirkstoff Difenconazol). Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist die o. g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des o. g. Mittels in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

## Anlage 1 zugelassene Anwendung: 00A343-00/00-002

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Braunrost (*Puccinia recondita*)

Pflanzen/-erzeugnisse/Objekte: Winterweichweizen

Verwendungszweck:

### 2 Kennzeichnungsauflagen

#### 2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Ackerbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwenderkategorie:	Beruflich
Stadium der Kultur:	30 bis 49
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:	
-	1,5 l/ha in 200 bis 300 l Wasser/ha

#### 2.2 Sonstige Kennzeichnungsauflagen

- keine -

#### 2.3 Wartezeiten

56 Tage Freiland: Weizen

### 3 Anwendungsbezogene Anwendungsbestimmungen

(NW609-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mindestens mit unten genanntem Abstand erfolgen. Dieser Abstand muss nicht eingehalten werden, wenn die Anwendung mit einem Gerät erfolgt, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Unabhängig davon ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten. Zuwiderhandlungen können mit einem Bußgeld bis zu 50.000 Euro geahndet werden.

5 m

Begründung:

Das o. g. Pflanzenschutzmittel weist ein hohes Gefährdungspotenzial für aquatische Organismen, insbesondere Fische auf. Bestimmend für die Bewertung des Risikos ist hier die NOEC für *Pimephales promelas* von 3,6 µg/L (bezogen auf den Wirkstoff Difenoconazol). Ausgehend von den geltenden Modellen zur Abdrift (hier: EVA 3) und einem Sicherheitsfaktor von 10 ist die o. g. Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des o. g. Mittels in Oberflächengewässer zu gewährleisten. Weitere Informationen hierzu sind dem Registration Report, Part B, nationales Addendum zu entnehmen (Sektion 9, Kapitel 9.5).

## Anlage 2 nicht zugelassene Anwendung: 00A343-00/00-003

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Echter Mehltau (*Erysiphe graminis*)

Pflanzen/-erzeugnisse/Objekte: Winterweichweizen

Verwendungszweck:

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und  
Kleingartenbereich: Nein

Anwenderkategorie: Beruflich

Stadium der Kultur: 30 bis 49

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:

- 1,5 l/ha in 200 bis 300 l Wasser/ha

### 3 Begründung

Vergleichende Bewertung

Die Prüfung nach Art. 50 Abs. 1 Buchst. a bis d der Verordnung (EG) Nr. 1107/2009 wurde durchgeführt. Danach ist für ein Pflanzenschutzmittel, das einen Substitutionskandidaten enthält, keine Zulassung zu erteilen bzw. die Verwendung zu beschränken, wenn die vergleichende Bewertung der Risiken und des Nutzens gemäß Anhang IV der Verordnung ergibt, dass für die im Antrag genannte Verwendung bereits ein zugelassenes Pflanzenschutzmittel existiert, das für die Gesundheit von Mensch oder Tier oder für die Umwelt deutlich sicherer ist und keine signifikanten praktischen oder ökonomischen Nachteile für die landwirtschaftliche Praxis aufweist. Die hier beantragte Anwendung ist daher abzuweisen.

Begründung:

Von Seiten der Wirksamkeit stehen genügend Alternativen für die Bekämpfung des Schaderegens ohne signifikante praktische oder ökonomische Nachteile für die landwirtschaftliche Praxis zur Verfügung. Die Bewertung der Auswirkungen auf die Gesundheit von Mensch und Tier sowie der Umwelt zeigt, dass es sichere Alternativen gibt. Für weitere Details verweise ich auf die ausführlichen Stellungnahmen der zuständigen Bewertungsbehörden. Auswirkungen auf geringfügige Verwendungen sind nicht zu befürchten.



## Anlage 2 nicht zugelassene Anwendung: 00A343-00/00-004

### 1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Halmbruchkrankheit (Pseudocercospora herpotrichoides)

Pflanzen/-erzeugnisse/Objekte: Winterweichweizen

Verwendungszweck:

### 2 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Ackerbau

Anwendungsbereich: Freiland

Anwendung im Haus- und Kleingartenbereich: Nein

Anwenderkategorie: Beruflich

Stadium der Kultur: 30 bis 32

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

Maximale Zahl der Behandlungen

- in dieser Anwendung: 1

- für die Kultur bzw. je Jahr: 1

Anwendungstechnik: spritzen

Aufwand:

- 1,5 l/ha in 200 bis 300 l Wasser/ha

### 3 Begründung

Vergleichende Bewertung

Die Prüfung nach Art. 50 Abs. 1 Buchst. a bis d der Verordnung (EG) Nr. 1107/2009 wurde durchgeführt. Danach ist für ein Pflanzenschutzmittel, das einen Substitutionskandidaten enthält, keine Zulassung zu erteilen bzw. die Verwendung zu beschränken, wenn die vergleichende Bewertung der Risiken und des Nutzens gemäß Anhang IV der Verordnung ergibt, dass für die im Antrag genannte Verwendung bereits ein zugelassenes Pflanzenschutzmittel existiert, das für die Gesundheit von Mensch oder Tier oder für die Umwelt deutlich sicherer ist und keine signifikanten praktischen oder ökonomischen Nachteile für die landwirtschaftliche Praxis aufweist. Die hier beantragte Anwendung ist daher abzuweisen.

Begründung:

Von Seiten der Wirksamkeit stehen genügend Alternativen für die Bekämpfung des Schaderregers ohne signifikante praktische oder ökonomische Nachteile für die landwirtschaftliche Praxis zur Verfügung. Die Bewertung der Auswirkungen auf die Gesundheit von Mensch und Tier sowie der Umwelt zeigt, dass es sichere Alternativen gibt. Für weitere Details verweise ich auf die ausführlichen Stellungnahmen der zuständigen Bewertungsbehörden. Auswirkungen auf geringfügige Verwendungen sind nicht zu befürchten.



# DRAFT REGISTRATION REPORT

## Part B

### Section 8

#### Environmental Fate

Detailed summary of the risk assessment

Product code: -

Product name(s): Brivela

Chemical active substances:

Fluxapyroxad 75 g/L

Difenoconazole 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ADDENDUM – GERMANY

(authorisation)

(ZV3 00A343-00/00)

Applicant: BASF

Submission date: 12.12.2018

MS Finalisation date: January 2021

## Version history

<b>When</b>	<b>What</b>
2021	NA by UBA

## Table of Contents

<b>8</b>	<b>Fate and behaviour in the environment (KCP 9).....</b>	<b>5</b>
8.1	Critical GAP and overall conclusions.....	6
8.1.1	Table of critical GAPS .....	6
8.1.2	Overall conclusion .....	8
8.1.2.1	Predicted environmental concentrations in soil (PEC <sub>soil</sub> ) .....	8
8.1.2.2	Predicted environmental concentrations in groundwater (PEC <sub>gw</sub> ) .....	8
8.1.2.3	Predicted environmental concentrations in surface water (PEC <sub>sw</sub> ).....	9
8.1.2.4	Fate and behaviour in air.....	9
8.1.3	Grouping of intended uses for risk assessment.....	9
8.2	Metabolites considered in the assessment.....	10
8.3	Rate of degradation in soil (KCP 9.1.1).....	10
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1) .....	10
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	10
8.4	Field studies (KCP 9.1.1.2).....	10
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). 10	
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2) .....	10
8.5	Mobility in soil (KCP 9.1.2) .....	10
8.5.1	Adsorption and desorption in soil (KCP 9.1.2.1).....	10
8.5.2	Column leaching (KCP 9.1.2.1).....	10
8.5.3	Lysimeter studies (KCP 9.1.2.2).....	11
8.5.4	Field leaching studies (KCP 9.1.2.3) .....	11
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3).....	11
8.6.1	Water/sediment study (KCP 9.2.2) .....	11
8.7	Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....	12
8.7.1	Justification of new endpoints .....	12
8.7.2	Active substances and relevant metabolite(s) .....	12
8.7.2.1	PEC <sub>soil</sub> .....	13
8.8	Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....	14
8.8.1	Justification of new endpoints .....	14
8.8.2	Active substances and relevant metabolite(s) (KCP 9.2.4.1) Direct Leaching into groundwater .....	14
8.8.3	Additional field test (KCP 9.2.4.2) .....	15
8.8.4	Groundwater contamination by bank filtration due to surface water exposure via runoff and drainage.....	15
8.8.4.1	Fluxapyroxad and its metabolites .....	15
8.8.4.2	Difenoconazole and its metabolites .....	16
8.9	Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) .....	17
8.9.1	Justification of new endpoints .....	17
8.9.2	PEC <sub>sw</sub> after exposure by spray drift and volatilization with subsequent deposition.....	17
8.9.2.1	Fluxapyroxad and its metabolites .....	17
8.9.2.2	Difenoconazole and its metabolites .....	18
8.9.3	PEC <sub>sw</sub> after exposure by surface runoff and drainage .....	18

8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....	19
8.11	Classification and labelling.....	19
8.11.1	GHS Classification and labelling.....	19
8.11.2	National labelling and conditions of use.....	19
<b>Appendix 1</b>	<b>21</b>	
	<b>List of data submitted by the applicant and relied on .....</b>	<b>21</b>

## **8 Fate and behaviour in the environment (KCP 9)**

The exposure assessment of the plant protection product Brivela in its intended uses is documented in detail in the core assessment of the plant protection product Brivela dated from 06/12/2019 performed by Poland. This national addendum has been produced to support a national decision on the authorisation of the product Brivela in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for Brivela including risk mitigation measures.





- \* 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

- |                       |   |   |
|-----------------------|---|---|
| <b>Remarks table:</b> | <ul style="list-style-type: none"> <li>(1) Numeration necessary to allow references</li> <li>(2) Use official codes/nomenclatures of EU</li> <li>(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)</li> <li>(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</li> <li>(5) Scientific names <u>and</u> 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</li> <li>(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench<br/>                 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</li> </ul> | <ul style="list-style-type: none"> <li>(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</li> <li>(8) The maximum number of application possible under practical conditions of use must be provided</li> <li>(9) Minimum interval (in days) between applications of the same product.</li> <li>(10) For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</li> <li>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</li> <li>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</li> <li>(13) PHI - minimum pre-harvest interval</li> <li>(14) Remarks may include: Extent of use/economic importance/restrictions</li> </ul> |
|-----------------------|---|---|

## 8.1.2 Overall conclusion

### 8.1.2.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)

PEC<sub>soil</sub> was calculated for the active substance Fluxapyroxad considering a soil depth of 1 cm. Due to the slow degradation of the active substance Fluxapyroxad in soil the accumulation potential of Fluxapyroxad was considered. Therefore PEC<sub>soil</sub> used for risk assessment comprises background concentration in soil (PEC<sub>accu</sub>) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC<sub>act</sub>.

PEC<sub>soil</sub> was calculated for the active substance Difenoconazole considering a soil depth of 1 cm. Due to the slow degradation of the active substance Difenoconazole in soil the accumulation potential of Difenoconazole was considered. Therefore PEC<sub>soil</sub> used for risk assessment comprises background concentration in soil (PEC<sub>accu</sub>) considering a tillage depth of 20 cm (arable crop) or 5 cm (permanent crops) and the maximum annual soil concentration PEC<sub>act</sub>.

The PEC<sub>soil</sub> values for the active substances were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Brivela in Germany.

### 8.1.2.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)

#### Direct leaching into groundwater

As indicated in the core assessment results of modelling with FOCUS PELMO / PEARL show that the active substances Fluxapyroxad and Difenoconazole and their soil metabolites M700F001, CGA 205375 and CGA 71019 (1,2,4-triazole) are not expected to penetrate into groundwater at concentrations of  $\geq 0.1 \mu\text{g/L}$  in the intended uses of Brivela in Germany according to use No. 001-004 in the scenario Hamburg.

For the metabolite M700F002 of Fluxapyroxad concentrations of  $\geq 0.1 \mu\text{g/L}$  in groundwater cannot be excluded. For the assessment of the relevance of metabolite M700F002 of active substance Fluxapyroxad please refer to the results of the core assessment, Part B, section 10.

Triazol is considered as relevant metabolite according to the definition of the guidance document on the assessment of the relevance of metabolites in groundwater (2003) .

1,2,4-Triazol is formed as metabolite of several active substances of plant protection products, which are used in different crops against a wide range of crop deceases. It is therefore possible that several 1,2,4-triazol forming active substances will be applied onto the same agricultural field in the same year and season, which may result in a summation of groundwater entries of 1,2,4-triazol from different active substances.

The higher tier assessment of the groundwater risk for 1,2,4-triazole is based on monitoring studies (listed in Appendix 1) conducted by member companies on behalf of the TDMG (Triazole Derivatives Metabolite Group). The available studies do not indicate entries of 1,2,4-triazole into the groundwater  $>0.1 \mu\text{g/L}$  if the azole fungicides are applied in terms of good agricultural practice for cereals .

#### Consequences for authorization:

none

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

According modelling with EXPOSIT 3, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substances Fluxapyroxad and Difenoconazole due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

#### Consequences for authorization:

The authorization of the plant protection product Brivela is linked with following labelling:

Use No. 001-004                      NG --

#### 8.1.2.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition was estimated with the model EVA 3 using drift data by Rautmann and Ganzelmeier.

Surface water exposure including effects of risk mitigation via surface runoff and drainage was estimated using the model EXPOSIT 3.

The results of the specific national exposure assessment for the active substances were used in the ecotoxicological risk assessment.

#### 8.1.2.4 Fate and behaviour in air

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

The vapour pressure at 20 °C of the active substance Difenoconazole is  $< 10^{-5}$  Pa. Hence the active substance Difenoconazole is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Difenoconazole due to volatilization with subsequent deposition was not 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 Brivela 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	001, 002, 003, 004	1.5 L/ha 80% Spring application	

## **8.2 Metabolites considered in the assessment**

Please refer to the core assessment.

## **8.3 Rate of degradation in soil (KCP 9.1.1)**

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

### **8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)**

Please refer to the core assessment.

### **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)**

Please refer to the core assessment.

### **8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)**

Please refer to the core assessment.

## **8.5 Mobility in soil (KCP 9.1.2)**

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

### **8.5.1 Adsorption and desorption in soil (KCP 9.1.2.1)**

Please refer to the core assessment.

### **8.5.2 Column leaching (KCP 9.1.2.1)**

Please refer to the core assessment.

### 8.5.3 Lysimeter studies (KCP 9.1.2.2)

Please refer to the core assessment.

### 8.5.4 Field leaching studies (KCP 9.1.2.3)

Please refer to the core assessment.

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

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

### 8.6.1 Water/sediment study (KCP 9.2.2)

Please refer to the core assessment

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

<b>Active substance</b>	Fluxapyroxad
<b>Accumulation potential in sediment</b>	yes ( $DT_{90, \text{whole system}} > 1$ year, see core assessment)
<b>Accumulation factor (SFO)</b> $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	4.47 based on $DT_{50, \text{whole system}} = 1000$ (maximum, see core assessment, Part B, Section 8, chapter 8.6.1), $t = 365$ d

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

<b>Active substance</b>	Difenoconazole
<b>Accumulation potential in sediment</b>	yes ( $DT_{90, \text{whole system}} > 1$ year, see core assessment)
<b>Accumulation factor (SFO)</b> $f_{\text{accu}} = e^{-kt}/(1 - e^{-kt})$	0.81 based on $DT_{50, \text{whole system}} = 315$ (maximum, see core assessment, Part B, Section 8, chapter 8.6.1), $t = 365$ d

## 8.7 Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

Results of PEC<sub>soil</sub> calculation for Brivela and its intended for uses in wheat according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 8, chapter 8.7. In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>1</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a K<sub>Foc</sub> < 500, whereas a soil layer depth of 1 cm is applied for active substances with a K<sub>Foc</sub> > 500. A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment.

### 8.7.1 Justification of new endpoints

Not applicable as no new endpoints used.

### 8.7.2 Active substances and relevant metabolite(s)

The PEC<sub>soil</sub> calculations were performed with ESCAPE 2.0 based on the input parameters as presented in the tables below.

**Table 8.7-1: Input parameters for active substances and relevant metabolite(s) for PEC<sub>soil</sub> calculation**

Compound	ratio Molecular weight (g/mol)	Max. occurrence (%)	DT <sub>50</sub> (days) EU endpoint	DT <sub>50</sub> (days) updated endpoint
Fluxapyroxad		-	PEC <sub>soil</sub> accu: DFOP, 21.6/ 1000d, g= 0.3502	
Metabolite M700F00	0.462 (176.1/381.13)	12.1	10 d (non-normalised worst case laboratory studies)	
Metabolite M700F002	0.425 (162.0/381.13)	70.5	FOMC: 39.2 d (field, worst case, non- normalised,) alpha 2.4056; beta 117.5	
Difenoconazole			265	
Metabolite CGA 205375	0.862	11.9	152	
Metabolite CGA 71019	0.170	23	K1 0.0632=DT50 10.9d K2 0.002= DT50 346.6 days g 0.5732, DFOP	

Due to the slow degradation of Fluxapyroxad in soil (DT<sub>90</sub> > 365 d, field data) the accumulation potential of Fluxapyroxad needs to be considered. Therefore an accumulated soil concentration (PEC<sub>accu</sub>) is used for

<sup>1</sup> 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

risk assessment that comprises background concentration in soil ( $PEC_{bkgd}$ ) and the maximum annual soil concentration  $PEC_{act}$ .

Due to the slow degradation of Difenoconazole in soil ( $DT_{90} > 365$  d, field data) the accumulation potential of Difenoconazole 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 $PEC_{soil}$

The calculated  $PEC_{soil}$  used for German risk assessment for Fluxapyroxad and Difenoconazole as well as for the formulation Brivela are summarised in Table 8.7-2.

**Table 8.7-2: Results of  $PEC_{soil}$  calculation for the intended use in wheat used for German risk assessment**

<b>Plant protection product:</b>		Brivela				
<b>Use:</b>		001-004				
<b>Number of applications/interval:</b>		1				
<b>Application rate (g/ha):</b>		Brivela: (1.5 L/ha, rel. density 1.074) 1611 Fluxapyroxad: 113 Difenoconazole: 75				
<b>Crop interception (%):</b>		80				
<b>Active substance/ formulation</b>	<b>Soil relevant ap- plication rate (g/ha)</b>	<b>Soil depth<sub>act</sub> (cm)</b>	<b><math>PEC_{act}</math> (mg/kg)</b>	<b>Tillage depth (cm)</b>	<b><math>PEC_{bkgd}</math> (mg/kg)</b>	<b><math>PEC_{accu} =</math> <math>PEC_{act} +</math> <math>PEC_{bkgd}</math> (mg/kg)</b>
product Brivela	322.2	1 2.5	2.1480 0.8592	-	-	-
Fluxapyroxad	22.6	1	0.1507	20	0.0159	0.1666
Metabolite M700F001	1.26	2.5	0.0034		-	-
Metabolite M700F002	6.77	2.5	0.0181		-	-
Difenoconazole	15	1	0.1000	20	0.0031	0.1031
Metabolite CGA 205375	1.54	1	0.0103	20	0.0001	0.0104
Metabolite CGA 71019	0.58	2.5	0.0015	20	0.001	0.0016

## 8.8 Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) (KCP 9.2.4)

Results of the PEC<sub>gw</sub> calculation of Fluxapyroxad and Difenconazole for the intended uses of Brivela in wheat according to EU assessment using FOCUS PELMO/PEARL are given in the core assessment, part B, section 8, chapter 8.8.

Risk assessment for groundwater for authorisation of plant protection products in Germany 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. The latter pathway was not addressed neither by core assessment nor for EU assessment of the active substances.

The risk assessment for groundwater of the pathway direct leaching after soil passage follows the recommendation of the Ground Water Work Group of FOCUS as provided by the Commission Services (Sanco/13144/2010, version 3, 10 October 2014) as also done by the zRMS in the core assessment.

Risk assessment for groundwater for the pathway surface runoff and drainage into an adjacent ditch with subsequent bank filtration into the groundwater are estimated using the model EXPOSIT 3 stipulating also risk mitigation measures, if applicable.

### 8.8.1 Justification of new endpoints

Not applicable as no new endpoints used.

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

Results of the groundwater modelling in the core assessment show that the active substances Fluxapyroxad and Difenconazole and their soil metabolites M700F001, CGA205375 and CGA71019 are not expected to penetrate into groundwater at concentrations of  $\geq 0.1 \mu\text{g/L}$  in the groundwater Scenario Hamburg relevant for authorisation in Germany in the intended uses of Brivela in wheat. That result covers the groundwater risk assessment for the intended uses of Brivela in Germany in wheat according to use No.001-004.

For the metabolite M700F002 of Fluxapyroxad concentrations of  $\geq 0.1 \mu\text{g/L}$  in groundwater cannot be excluded.

Max. concentration of M700F002 given in CA for winter cereals for the scenario Hamburg, Application on 1st May,  $1 \times 113 \text{ g a.s. ha}^{-1}$ , BBCH 30, calculated with PELMO 5.5.3

Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth [ $\mu\text{g L}^{-1}$ ]		
	Fluxapyroxad	M700F001	M700F002
Hamburg	<0.001	0.090	1.033

For the assessment of the relevance of metabolite M700F002 of Fluxapyroxad please refer to the results of the core assessment, Part B, section 10.

#### Consequences for authorisation:

None



### 8.8.3 Additional field test (KCP 9.2.4.2)

Several azole active substances can be applied on a same field. Considering that 1,2,4-triazole can be formed from most of these azole active substances, an exceedance of the regulatory limit of 0.1 µg/L cannot be excluded. In order to ensure that the regulatory limit in groundwater is not exceeded for 1,2,4-triazole, all applicants of azole-based products were requested to submit results of a groundwater monitoring for the metabolite 1,2,4-triazole according to § 36 paragraph 5 PflSchG.

The higher tier assessment of the groundwater risk for 1,2,4-triazole is based on monitoring studies (listed in Appendix 1) conducted by member companies on behalf of the TDMG (Triazole Derivatives Metabolite Group). The available studies do not indicate entries of 1,2,4-triazole into the groundwater >0.1 µg/L if the azole fungicides are applied in terms of good agricultural practice for cereals.

### 8.8.4 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.

**Table 8.8-1: Input parameters related to application of Brivela for PEC<sub>gw</sub> and PEC<sub>sw</sub> calculations with EXPOSIT 3**

Use No.	001-004		
Crop	wheat		
Application rate (g as/ha)	Fluxapyroxad: 113 Difenoconazole: 75		
Number of applications/interval (d)	1		
Crop interception (%)	80		

#### 8.8.4.1 Fluxapyroxad and its metabolites

**Table 8.8-2: Input parameters for Fluxapyroxad used for PEC<sub>gw</sub> calculations with EXPOSIT 3**

Parameter	Fluxapyroxad	Reference
K <sub>Foc</sub>	728	
DT <sub>50</sub> soil (d)	370	
Solubility in water (mg/L)	3.4	
Mobility class	1	
Reduction by bank filtration	100%	

The soil metabolites of Fluxapyroxad 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.

#### **PEC<sub>gw</sub> of Fluxapyroxad and its metabolites due to bank filtration**

As the reduction by bank filtration is assumed to be 100 % for Fluxapyroxad, no calculation is necessary.

According modelling with EXPOSIT 3, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substance Fluxapyroxad due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded .

#### **Consequences for authorization:**

The authorization of the plant protection product Brivela is linked with following labeling:

Use No. 001-004                      NG---

#### **8.8.4.2              Difenoconazole and its metabolites**

**Table 8.8-3:              Input parameters for Difenoconazole used for PEC<sub>gw</sub> calculations with EX-  
POSIT 3**

<b>Parameter</b>	<b>Difenoconazole</b>	<b>Reference</b>
K <sub>Foc</sub>	3759.4	
DT <sub>50</sub> soil (d)	265	
Solubility in water (mg/L)	15	
Mobility class	1	
Reduction by bank filtration	100%	

According modelling with EXPOSIT 3, groundwater contamination at concentrations  $\geq 0.1 \mu\text{g/L}$  by the active substance Difenoconazole due to surface runoff and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

#### **Consequences for authorization:**

The authorization of the plant protection product Brivela is linked with following labeling:

Use No. 001-004                      NG ---

## 8.9 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

Risk mitigation measures for the intended uses of plant protection products in Germany due to exposure of surface water consider the two routes of entry (i) spray drift and volatilization with subsequent deposition and (ii) runoff, drainage separately.

Surface water exposure including effects of risk mitigation via spray drift and volatilization with subsequent deposition is estimated with the model EVA. Surface water exposure including effects of risk mitigation via surface runoff and drainage is estimated using the model EXPOSIT.

### 8.9.1 Justification of new endpoints

Not applicable as no new endpoints used.

### 8.9.2 PEC<sub>sw</sub> after exposure by spray drift and volatilization with subsequent deposition

The calculation of PEC<sub>sw</sub> 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 90<sup>th</sup> percentile of the drift values. For multiple applications, lower percentiles of the drift values for each application are applied, resulting in an overall 90<sup>th</sup> percentile of drift probabilities. Only one volatilization event following the last use of pesticide is generally considered.

**Table 8.9-1: Input parameters for Brivela related to the application used for PEC<sub>sw</sub> calculations with EVA 3**

Use No.:	001-004	
Number of applications/ interval:	1	
Application rate (g a.s./ha)	Fluxapyroxad: 113 Difenoconazole: 75	

#### 8.9.2.1 Fluxapyroxad 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 Fluxapyroxad is < 10<sup>-5</sup> Pa. Hence the active substance Fluxapyroxad is regarded as non-volatile. Therefore exposure of surface water by the active substance Fluxapyroxad 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 summarised below.

**Table 8.9-2: Input parameters for Fluxapyroxad used for the PEC<sub>sw</sub> calculations with EVA 3**

Parameter	Fluxapyroxad	Reference
Vapour pressure (Pa)	not required since no v/d	LoEP
Solubility in water (mg/L)	not required since no v/d	

DissT <sub>50</sub> water (d)	FOMC DT90/ 3.32=79.5	SFO (worst case) see LoEP (2012)
DegT <sub>50</sub> water/sediment study, total system (d)	1000	SFO (worst case) see LoEP (2012)

For PEC<sub>sw/sed</sub> due to spray drift and volatilization with subsequent deposition for Fluxapyroxad please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

### 8.9.2.2 Difenoconazole 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 Difenoconazole is < 10<sup>-5</sup> Pa. Hence the active substance Difenoconazole is regarded as non-volatile. Therefore exposure of surface water by the active substance Difenoconazole due to volatilization with subsequent deposition does not need to be considered.

**Table 8.9-3: Input parameters for Difenoconazole used for the PEC<sub>sw</sub> calculations with EVA 3**

Parameter	Difenoconazole	Reference
Vapour pressure (Pa)	not required since no v/d	LoEP
Solubility in water (mg/L)	not required since no v/d	
DissT <sub>50</sub> water (d)	2	SFO (worst case) see LoEP (2010)
DegT <sub>50</sub> water/sediment study, total system (d)	315	SFO (worst case) see LoEP (2010)

For PEC<sub>sw/sed</sub> due to spray drift and volatilization with subsequent deposition for Difenoconazole please refer to national Addendum Germany, Part B, Section 9, chapter 9.5.

### 8.9.3 PEC<sub>sw</sub> after exposure by surface runoff and drainage

The concentration of the active substance Fluxapyroxad and Difenoconazole in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3. The input parameters for Brivela related to the application used for PEC<sub>sw</sub> calculations with Exposit 3 are summarised in Table 8.8-1.

The substance specific input parameters used for modelling surface water exposure via runoff and drainage in an adjacent ditch with EXPOSIT 3 are summarised in chapter 8.8.4 of this document.

For PEC<sub>sw/sed</sub> 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 and conditions of use**

**Table 8.11-1 Mandatory conditions of use according to § 36 (1) PflSchG**




## Appendix 1

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Ver- te- brate study Y/N	Owner
KCA 7.5	Miles, B.	2014	Retrospective Survey of 1,2,4-Triazole in Groundwater Samples from Monitoring Sites in Areas with High Levels of Triazole Fungicide Usage. Final report. BASF DocID 2014/1113530 GLP: N Published: N	N	TDMG
KCA 7.5	Naeb, O., Liss, D.	2014	Hydrogeological Characterisation of Groundwater Monitoring Wells for 1,2,4-Triazole in Germany. Final report. SGS INSTITUT FRESENIUS Study No. IF-2515712-1. GLP: N Published: N	N	TDMG
KCA 7.5	Naeb, O., Liss, D.	2018	Groundwater Monitoring for 1,2,4-Triazole in prominent sugar beet and cereal areas in the lower Rhine valley in Germany. Final report. BASF DocID 2018/1059312 GLP: Y Published: N	N	TDMG
KCA 7.5	Naeb, O., Koslik, M., Liss, D.	2018	Groundwater Monitoring for 1,2,4-Triazole in prominent sugar beet and cereal areas in the lower Rhine valley in Germany. Selection of Groundwater Monitoring Sites and Characterisation of the Monitoring Sites. Final report. BASF DocID 2018/1059311 GLP: N Published: N	N	TDMG
KCA 7.5	Naeb, O., Koslik, M.	2018	1,2,4-Triazole - Hydrogeological Characterisation of Groundwater Monitoring Wells for 1,2,4-Triazole in Germany. Final report. SGS INSTITUT FRESENIUS Study No. IF-12/02265870-CHR-S Syngenta DocID: CGA071019_10041 GLP: N Published: N	N	TDMG
KCA 7.5	Penning H.,Schmidt C.	2013	Analysis of groundwater monitoring samples from selected areas of Germany for 1,2,4-Triazole. BASF DocID 2013/1164781 GLP: Y Published: N	N	TDMG
KCA 7.5	Resseler, H., Naeb, O., Liss, D.	2018	1,2,4-Triazole - Hydraulic Connection between Groundwater Monitoring Wells for 1,2,4-Triazole and Agricultural fields in Germany. Final report. Syngenta Report No. HR-01-2017 Syngenta DocID: CA469_10077 GLP: N Published: N	N	TDMG
KCA	Schelling, D.	2015	Storage stability of 1,2,4-Triazole (Reg.no. 87084) in surface	N	TDMG

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Ver- te- brate study Y/N</b>	<b>Owner</b>
7.5			water and groundwater (approx. -18°C). BASF DocID 2015/1098623 GLP: Y Published: N		
KCA 7.5	Schneider, M., Liss, D., Naeb, O.	2017	Groundwater Monitoring for 1,2,4-Triazole in Cereal Areas in Germany. SGS INSTITUT FRESENIUS Study No. IF-16/03714032 GLP: Y Published: N	N	TDMG
KCA 7.5	Schneider, M.	2014	Farmer Interviews Application of 1,2,4-Triazole Containing Products in the Years 2008 – 2012 in 5 Regions in Germany. Report No IF-2515712-interviews. GLP: N Published: N	N	TDMG
KCA 7.5	Stahl, F.	2018	Residue Analysis of Chloridazon Metabolite B in Groundwater. BASF DocID 2018/1068468 GLP: Y Published: N	N	TDMG



**DRAFT REGISTRATION REPORT**

**Part B**

**Section 9**

**Ecotoxicology**

Detailed summary of the risk assessment

Product code: ZV3 00A343-00/00

Product names: Brivela

Chemical active substances:

Fluxapyroxad, 75 g/L or g/kg

Difenoconazole, 50 g/L or g/kg

Central Zone

Zonal Rapporteur Member State: Poland

National Addendum

Germany

(authorisation)

Applicant: BASF

Submission date: 12/11/2018

MS Finalisation date: January 2021

## Version history

<b>When</b>	<b>What</b>
01/2020	Draft NA by UBA (commenting phase)
01/2021	NA after commenting phase

## Table of Contents

<b>9</b>	<b>Ecotoxicology (KCP 10)</b> .....	<b>5</b>
9.1	Critical GAP and overall conclusions.....	6
9.1.1	Overall conclusions.....	8
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).....	8
9.1.1.2	Effects on aquatic organisms (KCP 10.2).....	8
9.1.1.3	Effects on bees (KCP 10.3.1).....	9
9.1.1.4	Effects on arthropods other than bees (KCP 10.3.2) .....	9
9.1.1.5	Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5).....	9
9.1.1.6	Effects on non-target terrestrial plants (KCP 10.6) .....	10
9.1.1.7	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7).....	11
9.1.2	Consideration of metabolites .....	11
9.2	Effects on birds (KCP 10.1.1).....	11
9.2.1	Risk assessment for spray applications.....	11
9.2.2	Overall conclusions.....	11
9.3	Effects on terrestrial vertebrates other than birds (KCP 10.1.2).....	11
9.3.1	Risk assessment for spray applications.....	11
9.3.2	Overall conclusions.....	11
9.4	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) .....	12
9.5	Effects on aquatic organisms (KCP 10.2).....	12
9.5.1	Toxicity data .....	12
9.5.2	Risk assessment .....	12
9.5.2.1	Exposure of surface water bodies .....	12
9.5.2.2	Consideration of Metabolites.....	16
9.5.3	Overall conclusions.....	17
9.6	Effects on bees (KCP 10.3.1).....	17
9.7	Effects on arthropods other than bees (KCP 10.3.2) .....	18
9.7.1	Toxicity data .....	18
9.7.2	Risk assessment .....	18
9.7.3	Overall conclusions.....	19
9.8	Effects on non-target soil meso- and macrofauna (KCP 10.4) .....	19
9.8.1	Toxicity data .....	19
9.8.2	Risk assessment .....	19
9.8.2.1	First-tier risk assessment.....	20
9.8.2.2	Higher-tier risk assessment.....	21
9.8.3	Overall conclusions.....	22
9.9	Effects on soil microbial activity (KCP 10.5).....	22
9.9.1	Toxicity data .....	22
9.9.2	Risk assessment .....	22
9.9.3	Overall conclusions.....	23
9.10	Effects on non-target terrestrial plants (KCP 10.6) .....	23
9.10.1	Toxicity data .....	23

9.10.2	Risk assessment .....	23
9.10.3	Overall conclusions.....	24
9.11	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7).....	25
9.12	Monitoring data (KCP 10.8) .....	25
9.13	Classification and Labelling .....	25
9.13.1	National labelling and conditions of use.....	25
<b>Appendix 1</b>	<b>Detailed evaluation of the new studies .....</b>	<b>26</b>

## **9 Ecotoxicology (KCP 10)**

The risk assessment of the plant protection product Brivela in its intended uses in spring and winter cereals is documented in detail in the core assessment of the plant protection product Brivela dated from 29.04.2020 performed by zRMS Poland.

This national addendum has been produced to support a national decision on the authorisation of the product Brivela in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for Brivela including risk mitigation measures.

The zRMS pointed out that Member States shall pay particular attention to:

- The risk for aquatic organisms: Conditions of authorisation shall include risk mitigation measures, where appropriate.

## 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	15-21						
														Application				Application rate		
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)	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	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
<b>Intended uses in Germany</b>																				
001-004	DE	Wheat winter and spring (TRZAW, TRZAS, TRZDU, TRZSP)	F	Septoria tritici, Puccinia recondita, Erysiphe graminis, Pseudocercospora herpotrichoides	SP	001-003: BBCH 30-49 004: BBCH 30-32	a) 1 b) 1	n.a.	a) 1.5 b) 1.5	a) fluxapyroxad: 0.113 + difenoconazole: 0.075 b) fluxapyroxad: 0.113 + difenoconazole: 0.075	200-300			A	A	R	A	A	A	A

\* 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
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/m<sup>3</sup> 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)

#### Birds

In his assessment, zRMS has concluded on an acceptable risk for birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### Terrestrial vertebrates other than birds

In his assessment, zRMS has concluded on an acceptable risk for terrestrial vertebrates other than birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### Terrestrial vertebrate wildlife

Not yet considered.

#### Consequences for authorisation

None

### 9.1.1.2 Effects on aquatic organisms (KCP 10.2)

Risk ratios of predicted environmental versus regulatory acceptable concentrations (PEC/RAC) for aquatic organisms were calculated. Calculated exposure concentrations in surface water bodies, according to the intended uses of the product Brivela in spring and winter wheat were considered in the exposure term. The regulatory acceptable concentration (RAC) is obtained by division of the relevant toxicity data for fluxapyroxad and difenoconazole by an assessment factor of 10 for chronic effects on aquatic organisms. The calculated risk ratios do achieve the acceptability criterion on  $PEC/RAC \leq 1$  for aquatic organisms, as derived from the prescriptions in 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 Brivela in spring and winter wheat according to the label.

#### Consequences for authorisation

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

#### Labelling requirements according to § 36 (3) PflSchG

NW 262	Difenoconazole: <i>S. subspicatus</i> $E_bC_{50} = 0.032 \text{ mg a.s./L } [\leq 1 \text{ mg/L}]$ Fluxapyroxad: <i>P. subcapitata</i> $E_rC_{50} = 0.7 \text{ mg a.s./L } [\leq 1 \text{ mg/L}]$
--------	--



NW 264	Difenoconazole: <i>O. mykiss</i> LC <sub>50</sub> = 0.65 mg a.s./L [ $\leq$ 10 mg/L], <i>P. promelas</i> NOEC = 0.0036 mg a.s./L [ $\leq$ 1 mg/L] <i>M. bahia</i> EC <sub>50</sub> = 0.15 mg a.s./L [ $\leq$ 10 mg/L], <i>D. magna</i> NOEC = 0.0056 mg a.s./L [ $\leq$ 1 mg/L] Fluxapyroxad: <i>C. carpio</i> LC <sub>50</sub> = 0.29 mg a.s./L [ $\leq$ 10 mg/L], <i>P. promelas</i> NOEC = 0.0359 mg a.s./L [ $\leq$ 1 mg/L] <i>C. virginica</i> EC <sub>50</sub> = 1.1 mg a.s./L [ $\leq$ 10 mg/L], <i>D. magna</i> NOEC = 0.5 mg a.s./L [ $\leq$ 1 mg/L]
NW 265	Fluxapyroxad: <i>Lemna gibba</i> 7 d E <sub>r</sub> C <sub>10</sub> = 0.69 mg/L [ $\leq$ 1 mg/L]

**Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (uses 001 - 004)**

NW 470	
NW 609	Drift-reduction technique– corresponding buffer zone: conv. – 5 m;

**9.1.1.3 Effects on bees (KCP 10.3.1)**

Please refer to the risk assessment for honey bees provided in the core assessment.

**9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)**

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  (standard 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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

**Consequences for authorisation**

None

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

**Earthworms**

TER values for earthworms were calculated, taking into account the relevant toxicity data for fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) and calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5 with

regard to fluxapyroxad and Brivela (BAS 717 00 F), but do not achieve the acceptability criterion  $TER \geq 5$  for chronic effects of difenoconazole on earthworms.

It was, however, demonstrated in a field study that the application of BAS 717 00 F (75 g fluxapyroxad/L + 50 g difenoconazole/ha) in a tank mixture with BAS 700 04 F (300 g fluxapyroxad/L) at a rate of 10.4 L/ha BAS 717 00 F + 0.17 L/ha BAS 700 04 F did not result in sustaining adverse effects on a natural earthworm population after a period of one year. Thus, it can be concluded that the risk for earthworms due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label is acceptable.

### **Other organisms of the soil macro- and mesofauna**

TER values for other organisms of the soil macro- and mesofauna were calculated, taking into account the relevant toxicity data for fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) and calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  for chronic effects (as adopted from the risk assessment for earthworms) on other organisms of the soil macro- and mesofauna, 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 other organisms of the soil macro- and mesofauna due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### **Soil microbial activity**

Concentrations of fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) in soil were determined where effects on nitrogen mineralisation processes remained  $\leq 25\%$  and were compared to calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The comparison indicates no exceedance of the acceptability criterion  $\leq 25\%$  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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### **Consequences for authorisation**

None

#### **9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)**

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### **Consequences for authorisation**

None

### **9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)**

Please refer to the core assessment.

### **9.1.2 Consideration of metabolites**

Please refer to the Core Assessment.

### **9.2 Effects on birds (KCP 10.1.1)**

Please refer to the Core Assessment.

#### **9.2.1 Risk assessment for spray applications**

Please refer to the Core Assessment.

#### **9.2.2 Overall conclusions**

In his assessment, zRMS has concluded on an acceptable risk for birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### **Consequences for authorisation**

None

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

Please refer to the Core Assessment.

#### **9.3.1 Risk assessment for spray applications**

Please refer to the Core Assessment.

The risk assessment for terrestrial vertebrates other than birds for the intended uses of the product Brivela indicates an acceptable acute and long-term risk for terrestrial vertebrates other than birds based on the screening and first tier risk assessment step for the active substances fluxapyroxad and difenoconazole as well as applying the concept of concentration additivity of toxicity for mixtures.

#### **9.3.2 Overall conclusions**

In his assessment, zRMS has concluded on an acceptable risk for terrestrial vertebrates other than birds in the screening and first tier assessment. No specific risk mitigation measures are required on national level.

#### **Consequences for authorisation**

None

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

Not yet considered.

## **9.5 Effects on aquatic organisms (KCP 10.2)**

### **9.5.1 Toxicity data**

Please refer to the Core Assessment.

### **9.5.2 Risk assessment**

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

#### **9.5.2.1 Exposure of surface water bodies**

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 fluxapyroxad and difenoconazole 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. Fluxapyroxad and difenoconazole both have respective vapour pressures of  $< 10^{-5}$  Pa and are therefore classified as non-volatile. Hence, deposition following volatilisation can be disregarded in the exposure assessment. The model input parameters for fluxapyroxad and difenoconazole are provided in the Environmental Fate section.

##### *Selection of relevant toxicity endpoint*

Please refer to the core assessment.

Several ecotoxicological endpoints are available to assess the risk of the active substances fluxapyroxad and difenoconazole and the product Brivela. 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.

**Table 9.5-1: Selection of decision-relevant assessment scenario based on ratios of RAC values for substances and their respective numerical shares in the product**

Substance	Sensitive species	Effect value (µg/L)	AF	RAC (µg/L)	Fraction of compd. in product	RAC/ fraction-compd.
Fluxapyroxad	<i>C. carpio</i>	290 (LC <sub>50</sub> )	100	2.9	0.075	38.7
	<i>P. promelas</i>	35.9 (NOEC)	10	3.59		47.9
Difenoconazole	<i>A. bahia</i>	150 (EC <sub>50</sub> )	100	1.5	0.05	30
	<i>P. promelas</i>	3.6 (NOEC)	10	0.36		7.2
	<i>A. bahia</i>	4.6 (EC <sub>10</sub> )	10	0.46		9.2
Brivela (BAS 717 00 F)	<i>C. carpio</i>	LC <sub>50</sub> = 1900 µg prod/L <sub>mm</sub>	100	19.0	1	19.0

RAC: regulatory acceptable concentration; AF: Assessment factor

Fish represents the most sensitive species with regard to the toxicity of difenoconazole and fluxapyroxad and there is no indication of synergistic or antagonistic toxicity based on acute formulation data (please refer to Chapter 9.5.2 of the core assessment B 9).

**Table 9.5-2: Assessment of the risk for aquatic organisms due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 - 004) – exposure to entries of difenoconazole and fluxapyroxad via spray drift, considering risk mitigation measures**

<b>Intended use:</b>		001 – 004						
<b>Active substance/product:</b>		Difenoconazole						
<b>Application parameters:</b>		1 × 75 g a.s./ha						
<b>DisT<sub>50</sub> water phase (SFO):</b>		2.0 d						
<b>Scenario, drift percentile:</b>		Arable crops, 90 %-ile						
<b>PEC type:</b>		actual						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC <sub>sw,i</sub> ; conventional and drift-reducing technique			
	(%)	(µg/L)	(%)	(µg/L)	0 % red.	50 % red.	75 % red.	90 % red.
					(µg/L)			
1	2.77%	0.693	-/-	-/-	0.693	0.346	0.173	0.069
5	0.57%	0.143	-/-	-/-	0.143	0.071	0.036	0.014
<b>Endpoint (µg/L) and AF:</b>		NOEC = 3.6 µg/L ( <i>P. promelas</i> ), AF = 10						
<b>RAC<sub>i</sub> (µg/L):</b>		0.36						
Buffer zone (m)					PEC <sub>i</sub> /RAC <sub>i</sub> ratio			
1					1.924	0.962	0.481	0.192
5					0.396	0.198	0.099	0.040

<b>Active substance/product:</b>		Fluxapyroxad						
<b>Application parameters:</b>		1 × 113 g a.s./ha						
<b>DisT50 water phase (SFO):</b>		79.5 d						
<b>Scenario, drift percentile:</b>		Arable crops, 90 %-ile						
<b>PEC type:</b>		actual						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PEC <sub>sw</sub> ; conventional and drift-reducing technique			
	(%)	(µg/L)	(%)	(µg/L)	0 % red.	50 % red.	75 % red.	90 % red.
1	2.77%	1.043	-/-	-/-	1.043	0.522	0.261	0.104
5	0.57%	0.215	-/-	-/-	0.215	0.107	0.054	0.021
<b>Endpoint (µg/L) and AF:</b>		NOEC = 35.6 µg/L ( <i>P. promelas</i> ), AF = 10						
<b>RAC (µg/L):</b>		3.56						
Buffer zone (m)					PEC <sub>i</sub> /RAC <sub>i</sub> ratio			
1					0.291	0.145	0.073	0.029
5					0.060	0.030	0.015	0.006
<b>Risk mitigation measures:</b>			NW609 - conv. technique: 5 m buffer zone					

PEC: predicted environmental concentration; AF: Assessment factor; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

### Risk assessment for sediment-dwelling organisms

A separate risk assessment for sediment-dwelling organisms due to exposure via spray drift has to be considered for difenoconazole, as > 90% (trigger: > 10%) of the substance partitions to the sediment after 14 days and the chronic toxicity testing on *Daphnia* delivers a NOEC of 0.0056 mg a.s./L (trigger: < 0.1 mg a.s./L).

The sediment-dwelling organism *Chironomus riparius* has been tested in a water-sediment system with a water-spiked design. From this test, a NOEC of 0.015 mg a.s./L is reported in the List of Endpoints of difenoconazole (EFSA Journal 2011;9(1):1967). Due to the lower chronic toxicity endpoints assessed for *Daphnia magna* and *P. promelas*, the risk for sediment-dwelling organisms due to exposure to difenoconazole via the water phase is assumed to be covered by the risk assessment presented above.

An additional water-sediment test with *Chironomus riparius* in a sediment-spiked design (Eckenstein, H., 2014, A 2.2.2.4) has been submitted by the applicant and was evaluated by zRMS Poland (please refer to Chapter 9.5.1, Table 9.5-2 and Chapter A 2.2.2.4 of the core assessment). A NOEC of 8.2 mg a.s./kg dry sediment is derived from this study. A PEC<sub>sed</sub> of 0.015 mg/kg sed is calculated for the worst case application pattern of 1 × 75 g difenoconazole/ha (uses 001 – 004) using the drift model “EVA3” mentioned above in combination with the following sediment exposure parameters: K<sub>f,oc</sub> of 3760 mL/g, DegT<sub>50</sub> of 315 d in the water/sediment system and 99.8 % partition in sediment. Furthermore, multi-annual accumulation of the substance in the sediment and an assessment factor of 10 are considered. The resulting PEC<sub>sed</sub>/RAC<sub>sed</sub> ratio amounts to a value of 0.018 (TER = 546) and points out an acceptable risk for sediment dwelling organisms without further requirement for risk mitigation.

In conclusion, the risk for sediment dwelling organisms is covered by the risk assessment for fish, which shows a higher sensitivity to the toxicity of difenoconazole.

## Exposure of surface water bodies via run-off or drainage

### Exposure assessment

The concentrations of the active substances fluxapyroxad and difenoconazole in an adjacent ditch due to surface run-off or drainage are calculated using the model EXPOSIT 3.02. 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).

Since the chronic endpoints for fish and invertebrates are similar and the K<sub>foc</sub> of difenoconazole is relatively high, it has been checked for this exposure pathway whether the consideration of invertebrate endpoints is decisive in this case.

**Table 9.5-3: Assessment of the risk for aquatic organisms due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 - 004) – exposure to entries of fluxapyroxad and difenoconazole via run-off or drainage, considering risk mitigation measures**

<b>Intended use:</b>	001 – 004	
<b>Active substance:</b>	a) Fluxapyroxad (DT <sub>50,soil</sub> = 370 d) b) Difenoconazole (DT <sub>50,soil</sub> = 265 d)	
<b>Application parameters:</b>	a) 1 × 113 g a.s./ha, 80 % interception b) 1 × 75 g a.s./ha, 80 % interception	
<b>Endpoint (µg/L) and AF:</b>	a) NOEC = 35.6 µg/L ( <i>P. promelas</i> ), AF = 10 b) NOEC = 3.6 µg/L ( <i>P. promelas</i> ), AF = 10	
<b>RAC (µg/L):</b>	a) 3.56 b) 0.36	
<b>Run-off</b>		
<b>Buffer zone (m)</b>	<b>PEC<sub>i</sub> (µg/L) (Run-off)</b>	<b>PEC<sub>i</sub>/RAC<sub>i</sub> ratio</b>
0	a) 0.16	a) 0.044
	b) 0.05	b) 0.14
5	a) 0.14	a) 0.039
	b) 0.04	b) 0.11
<b>Drainage</b>		
<b>Time of application</b>	<b>PEC<sub>i</sub> (µg/L)</b>	<b>PEC<sub>i</sub>/RAC<sub>i</sub> ratio</b>
Spring/summer	a) 0.003	a) 0.0008
	b) 0.002	b) 0.006
Autumn/winter	a) 0.01	a) 0.002
	b) 0.007	b) 0.019
<b>Risk mitigation measures:</b>	None	

PEC: predicted environmental concentration; AF: Assessment factor; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

**Table 9.5-4: Assessment of the risk for aquatic organisms due to the use of Brivela (BAS 717 00 F) in spring and winter wheat uses 001 - 004) – exposure to entries of difenoconazole via run-off or drainage, considering risk mitigation measures**

<b>Intended use:</b>	001 – 004	
<b>Active substance:</b>	Difenoconazole (DT <sub>50,soil</sub> = 265 d)	
<b>Application parameters:</b>	1 × 75 g a.s./ha, 80 % interception	
<b>Endpoint (µg/L) and AF:</b>	NOEC = 4.6 µg/L ( <i>A. bahia</i> ), AF = 10	
<b>RAC (µg/L):</b>	0.46	
<b>Run-off</b>		
<b>Buffer zone (m)</b>	<b>PEC<sub>i</sub> (µg/L) (Gesamtaustrag)</b>	<b>PEC<sub>i</sub>/RAC<sub>i</sub> ratio</b>
0	0.10	0.22
5	0.09	0.20
<b>Drainage</b>		
<b>Time of application</b>	<b>PEC<sub>i</sub> (µg/L)</b>	<b>PEC<sub>i</sub>/RAC<sub>i</sub> ratio</b>
Spring/summer	0.002	0.004
Autumn/winter	0.007	0.015
<b>Risk mitigation measures:</b>	None	

PEC: predicted environmental concentration; AF: Assessment factor; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

### 9.5.2.2 Consideration of Metabolites

Please refer to the core assessment. The aquatic risk of the metabolites is covered by the respective assessment for difenoconazole and fluxapyroxad.



### 9.5.3 Overall conclusions

Risk ratios of predicted environmental versus regulatory acceptable concentrations (PEC/RAC) for aquatic organisms were calculated. Calculated exposure concentrations in surface water bodies, according to the intended uses of the product Brivela in spring and winter wheat were considered in the exposure term. The regulatory acceptable concentration (RAC) is obtained by division of the relevant toxicity data for fluxapyroxad and difenoconazole by an assessment factor of 10 for chronic effects on aquatic organisms. The calculated risk ratios do achieve the acceptability criterion  $PEC/RAC \leq 1$  for aquatic organisms, as derived from the prescriptions in 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 Brivela in spring and winter wheat according to the label.

### Consequences for authorisation

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

**Table 9.5-5 Labelling requirements according to § 36 (3) PflSchG**

NW 262	Difenoconazole: <i>S. subspicatus</i> $E_bC_{50} = 0.032 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$ Fluxapyroxad: <i>P. subcapitata</i> $E_rC_{50} = 0.7 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$
NW 264	Difenoconazole: <i>O. mykiss</i> $LC_{50} = 0.65 \text{ mg a.s./L} [\leq 10 \text{ mg/L}]$ , <i>P. promelas</i> $NOEC = 0.0036 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$ <i>M. bahia</i> $EC_{50} = 0.15 \text{ mg a.s./L} [\leq 10 \text{ mg/L}]$ , <i>D. magna</i> $NOEC = 0.0056 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$ Fluxapyroxad: <i>C. carpio</i> $LC_{50} = 0.29 \text{ mg a.s./L} [\leq 10 \text{ mg/L}]$ , <i>P. promelas</i> $NOEC = 0.0359 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$ <i>C. virginica</i> $EC_{50} = 1.1 \text{ mg a.s./L} [\leq 10 \text{ mg/L}]$ , <i>D. magna</i> $NOEC = 0.5 \text{ mg a.s./L} [\leq 1 \text{ mg/L}]$
NW 265	Fluxapyroxad: <i>Lemna gibba</i> 7 d $E_rC_{10} = 0.69 \text{ mg/L} [\leq 1 \text{ mg/L}]$

**Table 9.5-6 Mandatory conditions of use according to § 36 (1) PflSchG for the protection of aquatic organisms (uses 001 - 004)**

NW 470	
NW 609	Drift-reduction technique– corresponding buffer zone: conv. – 5 m;

### 9.6 Effects on bees (KCP 10.3.1)

Please refer to the risk assessment for honey bees provided in the core assessment.

## 9.7 Effects on arthropods other than bees (KCP 10.3.2)

### 9.7.1 Toxicity data

Please refer to the Core Assessment.

### 9.7.2 Risk assessment

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) and in consideration of the recommendations of the guidance document ESCORT 2 is documented in the core assessment. For authorisation in Germany, a modified off-field risk assessment is relevant that takes into account the possible additional exposure route via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.<sup>1</sup>

#### *Exposure assessment*

Exposure levels of Brivela (BAS 717 00 F) in terrestrial off-field habitats due to spray drift and volatilisation with subsequent deposition are calculated using the model EVA3 (see chapter on effects on aquatic organisms for further explanations).

To extrapolate from exposure in a 2-dimensional toxicity test system to exposure in 3-dimensional field vegetation structures, a 2D/3D correction factor analogous to the ESCORT 2 ‘vegetation distribution factor’ (vdf) is applied in the risk assessment for national authorisations in Germany. This factor is derived from experimental data on spray drift deposits on meadows and hedgerows<sup>2</sup> and recalculated quotients of theoretically expected vs. measured residues. While several quotients were found to be lower than the ESCORT 2 vdf of 10, a 2D/3D correction factor of 5 was considered to appropriately define the required realistic worst case for a risk assessment.

**Table 9.7-1: Assessment of the risk for non-target arthropods in off-field habitats due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 - 004), considering risk mitigation measures**

<b>Active substance/product:</b>		Brivela (BAS 717 00 F)						
<b>Intended use:</b>		001 – 004						
<b>Application parameters:</b>		1 × 1.5 L prod/ha						
<b>MAF:</b>		1						
<b>Scenario, drift percentile:</b>		Arable crops, 90 %-ile						
<b>2D/3D correction factor:</b>		5						
Buffer zone (m)	Spray drift		Deposition following volatilisation		PER <sub>off-field</sub> ; conventional and drift-reducing technique			
	(%)	(g/ha)	(%)	(g/ha)	0 % red.	50 % red.	75 % red.	90 % red.
	(g/ha)							
1	2.77%	0.008	-/-	-/-	0.008	0.004	0.002	0.001
5	0.57%	0.002	-/-	-/-	0.002	0.001	0.000	0.000

<sup>1</sup> Schulte et al., UWSF (5) 261-266 (1999), Bewertungskriterien des Umweltbundesamtes: Auswirkungen von Pflanzenschutzmitteln auf terrestrische Arthropoden.

<sup>2</sup> Koch H, Weißer P and Landfried M (2003): Effect of drift potential on drift exposure in terrestrial habitats. Nachrichtenblatt Deut. Pflanzenschutzd., 55, 181-188.

<b>Endpoint (g/ha):</b>	LR <sub>50</sub> > 3.6 L prod/ha (formulation BAS 717 00 F, <i>T. pyri</i> , <i>A. rhopalosiphi</i> ) *			
<b>TER acceptability criterion:</b>	10			
<b>Buffer zone (m)</b>	<b>TER</b>			
1	433	866	1733	4332
5	2105	4211	8421	21053
<b>Risk mitigation measures:</b>	none			

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

\* Reproduction was not tested. However, the EU assessment of fluxapyroxad and difenoconazole indicates that mortality delivers the more sensitive endpoint for both a.s. and thus, the risk assessment based on the LR<sub>50</sub> (mortality) is acceptable in the present case.

### 9.7.3 Overall conclusions

TER values for non-target arthropods in off-field habitats were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  (standard 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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### Consequences for authorisation

None

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

### 9.8.1 Toxicity data

Please refer to the Core Assessment.

A submitted field study with earthworms (Schulz, L. 2015) was not considered necessary for the risk assessment by zRMS UK and therefore not evaluated in the core assessment. However, this study is relevant for the German risk assessment for earthworms as documented below. In this study a tank mixture of BAS 700 04 F (300 g fluxapyroxad/L) + BAS 717 00 F (75 g fluxapyroxad/L + 50 g difenoconazole/ha) was applied on arable land in Germany. About one year after application the maximum rate of 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha had no adverse effects on single species, ecological groups and total earthworm abundance and biomass (please refer to the summary in the Appendix of this National Addendum).

### 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).

### Exposure assessment

In the German exposure assessment, the considered soil layer depth is based on experimental data.<sup>3</sup> Generally, a soil layer depth of 2.5 cm is applied in the calculation for active substances with a  $K_{f,oc} < 500$ , whereas a soil layer depth of 1 cm is applied for active substances with a  $K_{f,oc} > 500$  which is the case for Fluxapyroxad and Difenoconazole. A soil bulk density of 1.5 g/cm<sup>3</sup> is assumed as in the core assessment.

## 9.8.2.1 First-tier risk assessment

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from National Addendum Germany, Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-2. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for fluxapyroxad, difenoconazole and for the difenoconazole metabolites CGA205375 and CGA71017 (1,2,4-triazole).

**Table 9.8-1: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 - 004)**

Intended use	001 – 004		
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	$PEC_{soil}$ (mg/kg dw)	$TER_{it}$ (criterion $TER \geq 5$ )
Fluxapyroxad	NOEC <sub>corr</sub> = 24.0 mg/kg sdw (10% peat) <sup>#</sup>	0.1666 *	144
Metabolite M700F001	NOEC $\geq$ 5.33 mg/kg sdw (5% peat)	0.0034	> 1000
Metabolite M700F002	NOEC $\geq$ 2.56 mg/kg sdw (5% peat)	0.0181	141
Difenoconazole	NOEC = 0.5 mg/kg sdw (5% peat)	0.1031 *	<b>4.85</b>
Metabolite CGA 205375	NOEC <sub>corr</sub> = 4.8 mg/kg sdw (10% peat) <sup>#</sup>	0.0104 *	462
Metabolite CGA 71019	NOEC = 1.0 mg/kg sdw <sup>##</sup>	0.0016 *	625
Brivela (BAS 717 00 F)	NOEC = 70 mg prod/kg sdw EC <sub>10</sub> = 69.7 mg prod/kg sdw (5% peat)	2.1480	33 32
(total) a.s. in Brivela (BAS 717 00 F)	NOEC = 8.1 mg a.s./kg sdw (5% peat) <sup>1)</sup>	0.2697 * <sup>2)</sup>	30
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg dw)	$PEC_{soil}$ (mg/kg dw)	$TER_{it}$ (criterion $TER \geq 5$ )
Fluxapyroxad	NOEC $\geq$ 500 mg/kg sdw (5% peat), <i>F. candida</i>	0.1666 *	> 1000

<sup>3</sup> 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

	EC <sub>10</sub> > 1000 mg/kg sdw (5% peat), <i>H. aculeifer</i>		> 1000
Metabolite M700F002	NOEC ≥ 1000 mg/kg sdw (5% peat), <i>F. candida</i>	0.0181	> 1000
Difenoconazole	NOEC <sub>corr</sub> = 250 mg/kg sdw (10% peat), <i>F. candida</i> #	0.1031 *	> 1000
Metabolite CGA 205375	NOEC <sub>corr</sub> = 1.2 mg/kg sdw (10% peat), <i>F. candida</i> #	0.0104 *	115
Metabolite CGA 71019	NOEC = 1.8 mg/kg sdw, <i>F. candida</i> ##	0.0016 *	> 1000
Brivela (BAS 717 00 F)	NOEC ≥ 96 mg prod/kg sdw (5% peat), <i>F. candida</i>	2.1480	45
	NOEC ≥ 1000 mg prod/kg sdw (5% peat), <i>H. aculeifer</i>		466
(total) a.s. in Brivela (BAS 717 00 F)	NOEC ≥ 11.2 mg a.s/kg sdw (5% peat), <i>F. candida</i> <sup>1)</sup>	0.2697 * <sup>2)</sup>	42
	NOEC ≥ 115.8 mg a.s/kg sdw (5% peat), <i>H. aculeifer</i> <sup>1)</sup>		429

TER values shown in bold fall below the relevant trigger.

\* PEC<sub>soil,accu</sub> (= PEC<sub>soil,act</sub> + PEC<sub>soil,bkgd</sub>) instead of PEC<sub>soil,act</sub> due to DT<sub>50</sub> > 365 d (multi-annual accumulation in soil) of the respective compounds

# Corrected endpoint due to a P<sub>ow</sub> < 2 and 10% peat

## No endpoint correction for the metabolite CGA 71019 (1,2,4-triazole) due to a log P<sub>ow</sub> < 2

<sup>1)</sup> Endpoint based on sum of active substances (nominal) and taking into account a density of BAS 717 00 F of 1.079 g/cm<sup>3</sup>.

<sup>2)</sup> Based on the sum of the worst-case active ingredient PEC<sub>soil</sub> values.

An acceptable risk for earthworms and soil mesofauna due to exposure with fluxapyroxad and Brivela (BAS 717 00 F) has been demonstrated for all intended uses 001 – 004. However, the chronic risk due to exposure with difenoconazole is only acceptable for soil mesofauna, but not for earthworms as demonstrated by the TER value below the trigger of 5. Therefore, a higher-tier risk assessment is required.

### 9.8.2.2 Higher-tier risk assessment

The applicant submitted an earthworm field study conducted with a tank mixture of BAS 700 04 F (300 g fluxapyroxad/L) + BAS 717 00 F (75 g fluxapyroxad/L + 50 g difenoconazole/ha) by Schulz, L. (2015). This study was not evaluated by zRMS Poland as it was not considered necessary for the intended uses assessed in the core assessment as all TER values was greater than 5. However, the study is taken into account for risk assessment in this national addendum, because a soil layer depth of 1 cm based on experimental data is considered for PEC<sub>soil</sub> calculation in the German exposure assessment for soil resulting in TER <5 as stated above.

The tank mixture was applied at rates of 2.6 L/ha, 5.2 L/ha and 10.4 L/ha BAS 717 00 F together with a fixed application rate of 0.17 L/ha BAS 700 04 F. The potential for multi-annual accumulation of the active substances difenoconazole (DT<sub>50,soil</sub> = 265 d) and fluxapyroxad (DT<sub>50,soil</sub> = 370 d) was not addressed in the study. However, the highest test application rate of 10.4 L/ha BAS 717 00 F in the field study is considered acceptable to cover the intended field application rate of 1 × 1.5 L prod/ha Brivela (BAS 717 00 F) even under consideration of multi-annual accumulation. Since no dose response and no treatment related effects were observed one year after application for total earthworm abundance and biomass, an acceptable risk to earthworms due to the use of Brivela (BAS 717 00 F) can be concluded for all intended uses.

### **9.8.3 Overall conclusions**

#### **Earthworms**

TER values for earthworms were calculated, taking into account the relevant toxicity data for fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) and calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  for chronic effects on earthworms, according to Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2.5 with regard to fluxapyroxad and Brivela (BAS 717 00 F), but do not achieve the acceptability criterion  $TER \geq 5$  for chronic effects of difenoconazole on earthworms.

It was, however, demonstrated in a field study that the application of BAS 717 00 F (75 g fluxapyroxad/L + 50 g difenoconazole/ha) in a tank mixture with BAS 700 04 F (300 g fluxapyroxad/L) at a rate of 10.4 L/ha BAS 717 00 F + 0.17 L/ha BAS 700 04 F did not result in sustaining adverse effects on a natural earthworm population after a period of one year. Thus, it can be concluded that the risk for earthworms due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label is acceptable.

#### **Other organisms of the soil macro- and mesofauna**

TER values for other organisms of the soil macro- and mesofauna were calculated, taking into account the relevant toxicity data for fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) and calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 5$  for chronic effects (as adopted from the risk assessment for earthworms) on other organisms of the soil macro- and mesofauna, 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 other organisms of the soil macro- and mesofauna due to the intended use of Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

#### **Consequences for authorisation**

None

### **9.9 Effects on soil microbial activity (KCP 10.5)**

#### **9.9.1 Toxicity data**

Please refer to the Core Assessment.

#### **9.9.2 Risk assessment**

The evaluation of the risk for soil microorganisms 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).

##### *Exposure assessment*

The relevant  $PEC_{soil}$  for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

**Table 9.9-1: Assessment of the risk for effects on soil micro-organisms due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 -004)**

Intended use	001 – 004		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC <sub>soil</sub> (mg/kg dw)	Risk acceptable?
Fluxapyroxad	2.01 (at 28 d)	0.1666 *	yes
Metabolite M700F001	0.37 (at 28 d)	0.0034	yes
Metabolite M700F002	1.0 (at 28 d)	0.0181	yes
Difenoconazole	16.7 (at 28 d)	0.1031 *	yes
Metabolite CGA 205375	0.22 (at 28 d)	0.0104 *	yes
Metabolite CGA 71019	0.353 (at 28 d)	0.0016 *	yes
Brivela (BAS 717 00 F)	51.84 (at 28 d)	2.1480	yes
(total) a.s. in Brivela (BAS 717 00 F)	6.0 (at 28 d) <sup>1)</sup>	0.2697 * <sup>2)</sup>	yes

\* PEC<sub>soil,accu</sub> (= PEC<sub>soil,act</sub> + PEC<sub>soil,bkgd</sub>) instead of PEC<sub>soil,act</sub> due to DT<sub>50</sub> > 365 d (multi-annual accumulation in soil) of the respective compounds

<sup>1)</sup> Endpoint based on sum of active substances (nominal) and taking into account a density of BAS 717 00 F of 1.079 g/cm<sup>3</sup>.

<sup>2)</sup> Based on the sum of the worst-case active ingredient PEC<sub>soil</sub> values.

### 9.9.3 Overall conclusions

Concentrations of fluxapyroxad, difenoconazole as well as for the product Brivela (BAS 717 00 F) in soil were determined where effects on nitrogen mineralisation processes remained ≤ 25 % and were compared to calculated exposure concentrations in soil, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. 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 Brivela (BAS 717 00 F) in spring and winter wheat according to the label.

### Consequences for authorisation

None

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

### 9.10.1 Toxicity data

Please refer to the Core Assessment.

### 9.10.2 Risk assessment

A risk assessment according to the recommendations of the “Guidance Document on Terrestrial Ecotoxicology” (SANCO/10329/2002) is documented in the core assessment. For authorisation in Germany, a modified off-field risk assessment is relevant that takes into account the possible additional exposure route

via volatilisation with subsequent deposition and addresses the availability of specific national risk mitigation measures.<sup>4</sup>

For the basic toxicity data set with values for 6 plant species, an acceptability criterion  $TER \geq 10$  is used in the risk assessment for national authorisations in Germany. This takes account for the lack of information on chronic effects from the standard tests as well as the great diversity of the plant realm, for which the test species stand as representatives. Due to a tendency towards large fields and intensive farming, plant bio-coenoses in the German agricultural landscape typically have to be considered as highly vulnerable; hence, a high level of safety is required in the risk assessment to ensure that the legally defined protection goal is met.

**Table 9.10-1: Assessment of the risk for non-target terrestrial plants due to the use of Brivela (BAS 717 00 F) in spring and winter wheat (uses 001 - 004), considering risk mitigation measures**

<b>Active substance/product:</b>		Brivela (BAS 717 00 F)						
<b>Intended use:</b>		001 – 004						
<b>Application parameters:</b>		1 × 1.5 L prod/ha						
<b>MAF:</b>		1						
<b>Scenario, drift percentile:</b>		Arable crops, 90 %-ile						
<b>Interception (off-crop):</b>		0 %						
<b>Buffer zone (m)</b>	<b>Spray drift</b>		<b>Deposition following volatilisation</b>		<b>PER<sub>off-field</sub>; conventional and drift-reducing technique</b>			
	<b>(%)</b>	<b>(g/ha)</b>	<b>(%)</b>	<b>(g/ha)</b>	<b>0 % red.</b>	<b>50 % red.</b>	<b>75 % red.</b>	<b>90 % red.</b>
					<b>(g/ha)</b>			
1	2.77%	0.042	-/-	-/-	0.042	0.021	0.010	0.004
5	0.57%	0.009	-/-	-/-	0.009	0.004	0.002	0.001
<b>Endpoint (g/ha):</b>		ER <sub>50</sub> > 8.0 L prod/ha (formulation BAS 717 00 F, SE, VV)						
<b>TER acceptability criterion:</b>		10						
<b>Buffer zone (m)</b>					<b>TER</b>			
1					193	385	770	1925
5					936	1871	3743	9357
<b>Risk mitigation measures:</b>			None					

PER: predicted environmental rate; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger

### 9.10.3 Overall conclusions

TER values for non-target terrestrial plants were calculated, taking into account the relevant toxicity data for Brivela (BAS 717 00 F) and calculated exposure concentrations in off-field habitats, according to the intended uses of the product Brivela (BAS 717 00 F) in spring and winter wheat. The calculated TER values do achieve the acceptability criterion  $TER \geq 10$  for effects on non-target plants, according to agreed EU Guidance in Document SANCO/10329/2002 rev 2 (as modified by specific German guidance) that insofar amends Commission Regulation (EU) No 546/2011, Annex, Part I C, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Brivela (BAS

<sup>4</sup> Füll et al., UWSF (11) 145-149 (1999), Prüfanforderungen des Umweltbundesamtes zur Bewertung der Auswirkungen von Pflanzenschutzmitteln auf terrestrische Pflanzen.



717 00 F) in spring and winter wheat according to the label.

### Consequences for authorisation

None

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

Please refer to the core assessment.

#### 9.12 Monitoring data (KCP 10.8)

Please refer to the core assessment.

#### 9.13 Classification and Labelling

##### 9.13.1 National labelling and conditions of use

**Table 9.13-1 Labelling requirements according to § 36 (3) PflSchG**

NW 262	Difenoconazole: <i>S. subspicatus</i> E <sub>b</sub> C <sub>50</sub> = 0.032 mg a.s./L [≤ 1 mg/L] Fluxapyroxad: <i>P. subcapitata</i> E <sub>r</sub> C <sub>50</sub> = 0.7 mg a.s./L [≤ 1 mg/L]
NW 264	Difenoconazole: <i>O. mykiss</i> LC <sub>50</sub> = 0.65 mg a.s./L [≤ 10 mg/L], <i>P. promelas</i> NOEC = 0.0036 mg a.s./L [≤ 1 mg/L] <i>M. bahia</i> EC <sub>50</sub> = 0.15 mg a.s./L [≤ 10 mg/L], <i>D. magna</i> NOEC = 0.0056 mg a.s./L [≤ 1 mg/L] Fluxapyroxad: <i>C. carpio</i> LC <sub>50</sub> = 0.29 mg a.s./L [≤ 10 mg/L], <i>P. promelas</i> NOEC = 0.0359 mg a.s./L [≤ 1 mg/L] <i>C. virginica</i> EC <sub>50</sub> = 1.1 mg a.s./L [≤ 10 mg/L], <i>D. magna</i> NOEC = 0.5 mg a.s./L [≤ 1 mg/L]
NW 265	Fluxapyroxad: <i>Lemna gibba</i> 7 d E <sub>r</sub> C <sub>10</sub> = 0.69 mg/L [≤ 1 mg/L]

**Table 9.13-2 Mandatory conditions of use according to § 36 (1) PflSchG (uses 001 - 004)**

NW 470	
NW 609	Drift-reduction technique– corresponding buffer zone: conv. – 5 m;

## Appendix 1 Detailed evaluation of the new studies

Please refer to the core assessment.

One study was not considered relevant by zRMS UK and therefore not evaluated in the core assessment. However, the study is relevant for the German assessment.

### KCP 10.4.1.2 Earthworms - field studies

Comments of RMS DE:	Study is considered valid and acceptable and is used in the evaluation.
---------------------	---

Reference:	KCP 10.4.1.2
Report	Schulz, L.; 2015, Effects of BAS 700 04 F plus 717 00 F on earthworms under field conditions 13 10 48 005 F ICS- No. 90929
Guideline(s):	ISO/CD 11268-3 (1999), Kula et al. (2006) - Technical Recommendations for the Update of the ISO Earthworm Field Test Guideline (ISO 11268-3)
Deviations:	Not specified
GLP:	Yes
Acceptability:	Yes
Original study evaluation revised by zRMS	No

### Objective

The objective of this field study was to investigate potential effects and the potential recovery of field populations of earthworms after the application of the test item BAS 700 04 F plus BAS 717 00 F. Therefore, a field experiment lasting about one year was performed and the potential effects of the test item with regard to species composition, biomass and abundance were compared to an untreated control and to a reference item (toxic standard; Nutdazim 50 FLOW®).

### Materials and methods

The study design was based on the ISO guidance document (ISO 11268-3, 1999: Soil quality – Effects of pollutants on earthworms, Part 3: Guidance on the determination of effects in field situations (Anonymous, 1999)). The following recommendations were taken into account: KULA et al. (2006): Technical recommendations for the update of the ISO earthworm field test guideline (ISO 11268-3).

The trial was placed on arable land near Machern in Saxony/Germany. The test item is a tankmix of BAS 700 04 F plus BAS 717 00F. BAS 700 04 F (fluxapyroxad (BAS 700 F) 300.0 g/L (nominal)) and BAS 717 00 F (fluxapyroxad (BAS 700 F) 75.0 g/L (nominal), difenoconazole (BAS 9150 F) 50.0 g/L (nominal)) were applied once at rates of 0.17 L BAS 700 04 F/ha + 2.6 L BAS 717 00 F/ha, 0.17 L BAS 700 04 F/ha + 5.2 L BAS 717 00 F/ha and 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha corresponding to 0.246 kg, 0.441 kg and 0.831 kg fluxapyroxad/ha (nominal) and 0.130 kg, 0.260 kg and 0.520 kg difenoconazole/ha (nominal).

Nutdazim 50 FLOW® (carbendazim 500 g/L (nominal)) was applied in parallel to the test item once to the reference plots at a rate of 20 L/ha (nominally equivalent 10 kg carbendazim/ha). Tap water was applied to the control plots.

No measurable residues (< LOD) of the test item were determined in any of the soil samples of the control plots taken after application. In the plots treated with the test item, mean residue values of 73 - 110 % of the application rates were found in soil samples taken after application.

The results of spray target analyses confirmed that the test item was accurately applied to the assigned plots at application. Mean residue values of 88 - 120 % of the application rates were found.

Therefore, all mean recoveries were in the recommended range of 50 - 150 %.

Twenty plots, each 10 m x 10 m, were arranged in a 5 x 4 formation, each plot surrounded by a 2 m wide path between the plots. The set-up was a randomised block design. The assignment of the treatment groups to the plots was based on the results of a pre-sampling. The pre-sampling was conducted to determine the density, diversity and homogeneity of earthworm populations at the site. Defined areas were sampled to assess earthworm populations before application and three times after application, i.e. about 1, 5 and 12 months after application.

Earthworms were sampled from four 0.125 m<sup>2</sup> sampling areas per plot per sampling occasion by combining hand sorting with formalin extraction in the excavated hole.

## Results and discussions

The mean earthworm abundance in the control plots was 653.5 ind./m<sup>2</sup> at pre-sampling, 453.0 ind./m<sup>2</sup> at 1<sup>st</sup> sampling, 412.0 ind./m<sup>2</sup> at 2<sup>nd</sup> sampling and 375.0 ind./m<sup>2</sup> at 3<sup>rd</sup> sampling.

Earthworm species found in the plots of the field site at pre-sampling were the endogeic species *Aporrectodea caliginosa* (64.2 % of total earthworms) and *Aporrectodea rosea* (10.8 % of total earthworms), the epigeic species *Lumbricus castaneus* (0.1 % of total earthworms), as well as the anecic species *Lumbricus terrestris* (20.9 % of total earthworms) and *Aporrectodea longa* (0.3 % of total earthworms). The presence of the dominant species *Aporrectodea caliginosa* and *Lumbricus terrestris* representing different ecological groups indicated the suitability of the field site.

The toxic reference item reduced total earthworm abundance by 93.3 % at 1<sup>st</sup> sampling, 85.7 % at 2<sup>nd</sup> sampling and 66.1 % at 3<sup>rd</sup> sampling. *Lumbricus terrestris* was the most sensitive species and was reduced in total abundance by 99.0 %, 92.3 % and 69.9 % on these sampling dates.

The total earthworm biomass was reduced by the reference item by 95.7 % at 1<sup>st</sup> sampling, 89.7 % at 2<sup>nd</sup> sampling and 55.3 % at 3<sup>rd</sup> sampling. The total biomass of *Lumbricus terrestris* was reduced by 99.3 % at 1<sup>st</sup> sampling, 96.3 % at 2<sup>nd</sup> sampling and 71.8 % at 3<sup>rd</sup> sampling.

Surface monitoring on days 1-3 after application showed that there was no acute primary effect on earthworms by BAS 700 04 F plus BAS 717 00 F. No alive, moribund or dead earthworms were found on the soil surface neither in the test item nor in the control monitoring areas.

No statistically significant reductions in total earthworm abundance and biomass could be observed for all application rates tested up to a rate of 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha about 1, 5 and 12 months after application.

Furthermore, no statistically significant reductions in abundance and biomass of endogeic earthworms and the endogeic earthworm species *Aporrectodea caliginosa* and *Aporrectodea rosea* could be observed for all test item application rates about 1, 5 and 12 months after application.

Transient statistically significant reductions could be observed for the abundance of anecic earthworms and the abundance of the anecic earthworm species *Lumbricus terrestris* at 0.17 L BAS 700 04 F/ha + 2.6 L BAS 717 00 F/ha and 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha about 1 month after application (1<sup>st</sup> sampling). The biomass of both taxa was not statistically significantly reduced on this sampling date.

At all following sampling occasions (about 5 and 12 months after application) no statistically significant reductions in abundance and biomass of anecic earthworms and in abundance and biomass of *Lumbricus*

*terrestris* could be observed for both test item treatment groups.

At an application rate of 0.17 L BAS 700 04 F/ha + 5.2 L BAS 717 00 F/ha statistically significant reductions in juvenile anecic abundance and juvenile abundance of *Lumbricus terrestris* could be observed about 12 months after application (3<sup>rd</sup> sampling). However, no initial effects were found 1 and 5 months after application. The juvenile biomass of both taxa was not statistically significantly reduced in this treatment group throughout the whole test period. Since juvenile anecic abundance and juvenile abundance of *Lumbricus terrestris* were not statistically significantly reduced at the highest tested application rate of 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha about 5 and 12 months after application (2<sup>nd</sup> and 3<sup>rd</sup> sampling), the observed reductions in juvenile anecic abundance and juvenile abundance of *Lumbricus terrestris* at an application rate of 0.17 L BAS 700 04 F/ha + 5.2 L BAS 717 00 F/ha are considered as not test item related.

### Validity criteria

All validity criteria were met.

The mean abundance of earthworms of the test field at trial start was 656.1 ind./m<sup>2</sup>, thus fulfilling the guideline recommendation (60 ind./m<sup>2</sup> for arable soils).

At least one representative of endogeic and anecic earthworms was present at the field site in a sufficient number (>10 % of total earthworms or 10- 15 ind./m<sup>2</sup>), with abundances of 420.9 ind./m<sup>2</sup> for *Aporrectodea caliginosa* (endogeic) and 137.2 ind./m<sup>2</sup> for *Lumbricus terrestris* (anecic; pre-sampling values).

In the reference item treatment group the total earthworm abundance and biomass was reduced by 93.3 % and 95.7 % at 1<sup>st</sup> sampling (about 1 month after application), respectively, fulfilling the guideline recommendation (reduction of the earthworm abundance and / or biomass of > 50 % compared to the control).

### Conclusion

The current study meets all criteria required for a valid earthworm field study as required by the available guidance for earthworm field studies (ISO 11268-3, 1999; KULA et al., 2006). It can be concluded that the application of BAS 700 04 F plus BAS 717 00 F tested at application rates of 0.17 L BAS 700 04 F/ha + 2.6 L BAS 717 00 F/ha, 0.17 L BAS 700 04 F/ha + 5.2 L BAS 717 00 F/ha and 0.17 L BAS 700 04 F/ha + 10.4 L BAS 717 00 F/ha had no adverse effects on single species, ecological groups and total earthworm abundance and biomass about one year after application.