

# REGISTRATION REPORT

## **Part A**

### **Risk Management**

Product code: BAS 762 02 F

Product name(s): Revydas / Brelyco

Chemical active substances:

Mefentrifluconazole, 100 g/L

Boscalid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**NATIONAL ASSESSMENT POLAND**

Applicant: BASF

Submission date: April 2021

MS Finalisation date: November 2021 (initial National Assessment)

April 2022 (final National Assessment)

### Version history

When	What
April 2021	Applicant initial dRR
November 2021	Initial zRMS assessment  In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and the product label are highlighted in grey, while not agreed use pattern <del>is struck through and shaded</del> .
April 2022	Final report (National Assessment after the commenting period)  Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are <b>highlighted in yellow</b> , while not agreed use pattern is <del>struck through and shaded</del> .

## Table of Contents

<b>1</b>	<b>Details of the application.....</b>	<b>5</b>
1.1	Application background .....	6
1.2	Letters of access .....	6
1.3	Justification for submission of tests and studies .....	6
1.4	Data protection claims .....	7
<b>2</b>	<b>Details of the authorisation decision .....</b>	<b>8</b>
2.1	Product identity .....	8
2.2	Conclusion.....	10
2.3	Substances of concern for national monitoring .....	10
2.4	Classification and labelling .....	11
2.4.1	Classification and labelling under Regulation (EC) No. 1272/2008 .....	11
2.4.2	Standard phrases under Regulation (EU) No. 547/2011 .....	11
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No. 1107/2009).....	12
2.5	Risk management .....	12
2.5.1	Restrictions linked to the PPP .....	12
2.5.2	Specific restrictions linked to the intended uses.....	12
2.6	Intended uses (only NATIONAL GAP).....	13
<b>3</b>	<b>Background of authorisation decision and risk management .....</b>	<b>16</b>
3.1	Physical and chemical properties (Part B, Section 2).....	16
3.2	Efficacy (Part B, Section 3).....	16
3.3	Efficacy data.....	16
3.3.1	Information on the occurrence or possible occurrence of the development of resistance .....	17
3.3.2	Adverse effects on treated crops.....	17
3.3.3	Observations on other undesirable or unintended side-effects .....	18
3.4	Methods of analysis (Part B, Section 5) .....	18
3.4.1	Analytical methods for the formulation.....	18
3.4.2	Analytical methods for residues .....	18
3.5	Mammalian toxicology (Part B, Section 6) .....	21
3.5.1	Acute toxicity .....	21
3.5.2	Operator exposure .....	21
3.5.3	Worker exposure .....	22
3.5.4	Bystander and resident exposure .....	22
3.6	Residues and consumer exposure (Part B, Section 7) .....	22
3.6.1	Residues.....	22
3.6.2	Consumer exposure .....	23
3.7	Environmental fate and behaviour (Part B, Section 8).....	25
3.7.1	Predicted environmental concentrations in soil (PEC <sub>soil</sub> ) .....	25
3.7.2	Predicted environmental concentrations in groundwater (PEC <sub>gw</sub> ) .....	25
3.7.3	Predicted environmental concentrations in surface water (PEC <sub>sw</sub> ).....	26
3.7.4	Predicted environmental concentrations in air (PEC <sub>air</sub> ).....	26
3.8	Ecotoxicology (Part B, Section 9) .....	27
3.8.1	Effects on terrestrial vertebrates .....	27
3.8.2	Effects on aquatic species.....	28
3.8.3	Effects on bees.....	28
3.8.4	Effects on other arthropod species other than bees .....	29
3.8.5	Effects on soil organisms.....	29
3.8.6	Effects on non-target terrestrial plants.....	30
3.8.7	Effects on other terrestrial organisms (Flora and Fauna) .....	30
3.9	Relevance of metabolites (Part B, Section 10) .....	30
<b>4</b>	<b>Conclusion of the national comparative assessment (Article 50 of Regulation (EC) No. 1107/2009).....</b>	<b>31</b>

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<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 authorisation .....31</b>
<b>Appendix 1</b>	<b>Copy of the product authorisation .....32</b>
<b>Appendix 2</b>	<b>Copy of the product label.....33</b>
<b>Appendix 3</b>	<b>Letter of access.....46</b>
<b>Appendix 4</b>	<b>Lists of data considered for national authorisation.....47</b>

# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

This document describes the acceptable use conditions required for the national registration of BAS 762 02 F, containing 100 g/L Mefentrifluconazole and 200 g/L Boscalid in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections B0-B10 and Part C and where appropriate in the national addendum. The information, data and assessments provided in Registration Report, Sections B includes assessment of further data or information as required at national level in accordance with the conclusions from EFSA (EFSA-Q-2016-00254, mandate 2012-0276, Pesticide risk assessment and peer review of BAS 750 F in accordance with Article 12 of Regulation (EC) No 1107/2009 (application for approval) and the legal deadline published in the register). It also includes assessment of data and information relating to BAS 762 02 F where that data has not been considered in the EU review. Assessments for the safe use of BAS 762 02 F have been made using endpoints agreed in the EU review of mefentrifluconazole and boscalid.

Appendix 1 of this document provides a copy of the final product authorization in Poland

Appendix 2 of this document is a copy of the approved product label for the in Poland

Appendix 3 not applicable for this formulation

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

## **1.1 Application background**

Applicant:

BASF Agro B.V., Arnhem (NL) – Freienbach Branch  
Huobstrasse 3  
8808 Pfäffikon SZ  
Switzerland

This application was submitted by:

BASF SE  
Carl-Bosch Straße 38  
67056 Ludwigshafen  
Germany

Agricultural Solutions  
P.O. Box 120  
67114 Limburgerhof  
Germany

Contact person:	Dr. Thomas Xxx
Tel. No.:	+49 (0)621 60-28184
Fax No.:	+49 (0)621 60-6628184
E-mail:	thomas.xxx@basf.com

Represented by:

BASF Polska Sp.z.o.o.  
A1. Jerozolimskie 142b  
03-305 Warszawa  
Poland

Contact person:	Monika Stepień-Zielinska
Tel.No.:	+48 22 5709-727
e-mail:	monika.stepien@basf.com

This application was submitted for the approval of BAS 762 02 F, an SC formulation containing 100.0 g/L mefentrifluconazole and 200.0 g/L boscalid for the use in oil seed rape, sunflower and wheat.

## **1.2 Letters of access**

Not relevant.

## **1.3 Justification for submission of tests and studies**

Testing is conducted according to the data requirements for the authorisation of plant protection products and is conducted in compliance with national and international animal welfare regulations. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Reasoning is provided in Section B documents.

Testing has been conducted in order to fulfil the data requirements for plant protection products and in order to demonstrate an acceptable use of the plant protection product.

#### **1.4 Data protection claims**

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

## 2 Details of the authorisation decision

### 2.1 Product identity

Product code	BAS 762 02 F
Product name in MS	Revydas
Authorisation number	Not yet assigned
Function	Fungicide
Applicant	BASF
Active substances (incl. content)	Mefentrifluconazole, 100.0 g/L Boscalid, 200.0 g/L
Formulation type	Suspension Concentrate [Code: SC]
Packaging	Please see the following tables; professional user
Co-formulants of concern for national authorisations	Not applicable
Restrictions related to identity	Further information is provided in Part B, Section 1
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

### Packaging

BAS 762 02 F is to be marketed in blow moulded high-density polyethylene (HDPE or f-HDPE) containers with a minimum wall thickness of 0.7 mm. They are sealed by either foil seals or a gasket, protected by a polyethylene screw cap.

**Table 2.1-1: Packaging information for 0.15 litre bxxxle**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 63 mm diameter x 92 mm
Opening	42 mm inner diameter
Closure	Screw cap
Seal	HF seal

**Table 2.1-2: Packaging information for 0.25 litre bxxxle**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 63 mm diameter x 126 mm
Opening	42 mm inner diameter
Closure	Screw cap
Seal	HF seal



**Table 2.1-3: Packaging information for 0.5 litre bxxxle**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 69 mm diameter x 185.5 mm
Opening	42 mm inner diameter
Closure	Screw cap
Seal	HF seal

**Table 2.1-4: Packaging information for 1 litre bxxxle**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 88.5 mm diameter x 234 mm
Opening	42 mm inner diameter
Closure	Screw cap
Seal	Induction sealed

**Table 2.1-5: Packaging information for 1 litre eco-bxxxle**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 88.5 mm diameter x 234 mm
Opening	54 mm inner diameter
Closure	Screw cap
Seal	Gasket

**Table 2.1-6: Packaging information for 5 litre container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Rectangular / approximately 190 mm x 140 mm x 313 mm
Opening	54 mm inner diameter
Closure	Screw cap
Seal	HF seal

**Table 2.1-7: Packaging information for 5 litre eco-container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Rectangular / approximately 185 mm x 136 mm x 313 mm
Opening	54 mm inner diameter
Closure	Screw cap
Seal	Gasket

**Table 2.1-8: Packaging information for 10 litre container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Rectangular / approximately 230 mm x 165 mm x 375 mm
Opening	54 mm inner diameter
Closure	Screw cap
Seal	Induction sealed

**Table 2.1-9: Packaging information for 10 litre eco-container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Rectangular / approximately 230 mm x 187 mm x 358 mm
Opening	54 mm inner diameter
Closure	Screw cap
Seal	Gasket

**Table 2.1-10: Packaging information for 20 litre eco-container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Rectangular / approximately 285 mm x 237 mm x 424 mm
Opening	52 mm inner diameter
Closure	Screw cap + valve
Seal	Gasket

**Table 2.1-11: Packaging information for 50 litre eco-container**

Type	Description
Material	HDPE or f-HDPE
Shape / size	Cylindrical / approximately 380 mm x 618 mm (d x h)
Opening	52 mm inner diameter
Closure	Screw cap + valve
Seal	Gasket

## 2.2 Conclusion

The evaluation of the application for BAS 762 02 F / Revydas / Brelyco resulted in the decision to grant the authorization.

All uses applied for were authorised except for the use in spring wheat, spring oilseed rape - due to no efficacy data; sunflower – due to no efficacy data from North-East EPPO zone and *Neopseudocercospora brassicae* in winter oilseed rape – due to no efficacy data from North-East EPPO zone. These uses can not be registered under article 33 of 1107/2009 regulation. Spring oilseed rape and sunflower are minor crops in Poland and can be registered under article 51 of 1107/2009 regulation.

## 2.3 Substances of concern for national monitoring

No further information required.



## 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 Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Chronic 2
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label** is formatted **bold**:

Hazard pictograms:	  GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	<b>H315: Causes skin irritation</b> <b>H317: May cause an allergic skin reaction</b> <b>H319: Causes serious eye irritation</b> <b>H411: Toxic to aquatic life with long lasting effects</b>
Precautionary statement(s):	<div>- General:</div> P101: If medical advice is needed, have product container or label at hand. <b>P102: Keep out of reach of children.</b> P103: Read carefully and follow all instructions <div>- Prevention:</div> P261: Avoid breathing mist. P264: Wash contaminated body parts thoroughly after handling P272: Contaminated work clothing should not be allowed out of the workplace. <b>P280: Wear protective gloves/clothing and eye/face protection</b> <div>- Response:</div> <b>P302 + P352:</b> IF ON SKIN (or hair): Wash with plenty of soap and water P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P337 + <b>P313</b> : If eye irritation persists: <b>Get medical advice/attention</b> <small>Call a POISON CENTER or physician.</small> P362 + P364: Take off contaminated clothing and wash it before reuse. P391: Collect spillage <div>- Storage</div> — <div>- Disposal</div> P501: Dispose of contents/container to hazardous or special waste collection point.
Additional labelling phrases:	To avoid risks to <b>human health</b> and the environment, comply with the instructions for use. [EUH401]
	Contains 2-methyl-4-isothiazolin-3-one (2682-20-4) and mefenfluconazole (1417782-03-6). May produce an allergic reaction. Contains Reaction mass of 5-chloro-2-methyl-4-iso-thiazolin-3-one and 2-methyl-2H-isothiazol-3-one and 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

### 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).
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### **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 authorisation of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
respective code if available	Wearing work wear and protective gloves (during mixing and loading) is required.
Worker protection:	
respective code if available	Wearing work wear is required.
Environmental protection	
	None proposed

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

None proposed.

### **2.5.2 Specific restrictions linked to the intended uses**

None proposed.

## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 2022-11

PPP (product name/code): Revydas / BAS 762 02 F  
Active substance 1: Mefentrifluconazole\*  
Active substance 2: Boscalid\*\*  
Safener: n.r.  
Synergist: n.r.  
Applicant: BASF  
Zone(s): central <sup>(d)</sup>  
Verified by MS: yes  
Field of use: fungicide

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 100 g/L <sup>(c)</sup>  
Conc. of as 2: 200 g/L <sup>(c)</sup>  
Conc. of safener: n.r. <sup>(c)</sup>  
Conc. of synergist: n.r. <sup>(c)</sup>  
Professional use: ☒  
Non-professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*								
Use- No. <sup>(e)</sup>	Member state(s)	Crop and / or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>	Overall conclusions								
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop / season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy	
Zonal uses (field or outdoor uses, certain types of protected crops)																						
1	PL	Oilseed Rape, F winter and spring (BRSNN)		<i>Sclerotinia sclerotiorum</i> (SCLESC) <i>Alternaria</i> spp. (ALTESP) <i>Erysiphe cruciferarum</i> (ERYSCR) <i>Neopseudocercospora</i> <i>brassicarum</i> (MYCOBR)	SP	BBCH 57-75	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 100* + 200** b) 100* + 200**	100-400	F	F is defined by latest application timing.	A	A	A	A	A	A	A	A	A BRSNW: SCLESC ALTESP ERYSCR
																						N BRSNS (possible registration under art. 51); BRSNW: MYCOBR)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15*							
Use -No. (e)	Membe r state(s)	Crop and / or situation  (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>	Overall conclusions							
					Metho d / Kind	Timing / Growth stage of crop & season	Max. numbe r a) per use b) per crop / season	Min. interval between applicatio ns (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/seaso n	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max			Phys-chem	Analytical methods	Toxicology	Residues	Fate & behaviour	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																					
2	PL	Sunflower (HELAN)	F	<i>Diaporthe helianthi</i> (DIAPHE) <i>Plenodomus lindquistii</i> (LEPTLI) <i>Sclerotinia sclerotiorum</i> (SCLESC) <i>Alternaria helianthi</i> (ALTEHE)	SP	BCH 31-69	a) 1 b) 2	7	a) 1,0 b) 2,0	a) 100* + 200** b) 200* + 400**	100 - 400	F	Maximum 2 applications per crop and season.  1st appl. BBCH 31-59 2nd appl. BBCH 61-69.  F is defined by latest application timing.	A	A	A	A	A	A	A	N (possible registrati on under art. 51)
3	PL	Wheat, (winter and spring) (TRZAW, TRZAS)	F	<i>Oculimacula yallundae</i> spp. - PSDCHE <i>Septoria tritici</i> - SEPTTR <i>Blumeria graminis</i> - ERYSGR	SP	BBCH 30 -49	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 100* + 200** b) 100* + 200**	100- 300	56	For eyespot control, application at BBCH 30-32	A	A	A	A	A	A	A	A TRZAW  N TRZAS

<b>Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)</b>	
None.	
<b>Minor uses according to Article 51 (zonal uses)</b>	
None.	
<b>Minor uses according to Article 51 (interzonal uses)</b>	
None.	

<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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
			15	Overall conclusions - explanation for the column 15 is below*

\* Explanation for column 15 “Overall conclusions”

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

## 3 Background of authorisation 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 a light beige liquid suspension with a moderate sweet odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a auto ignition temperature of 545 °C. In aqueous solution, it has a pH value of 6.0 - 8.0 at 24 °C. 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 contents nor the technical properties were changed. ~~The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE container is still ongoing and will be provided as soon as possible.~~ The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging materials.

The packaging proposed in the section 4 (HDPE and f-HDPE) are acceptable as a storage stability study at elevated temperature for 14 days and 2 years at ambient temperature was carried out in HDPE material and can be extrapolated to f-HDPE. Its technical characteristics are acceptable for an SC formulation.

The intended concentration of use is 0.25 % to 1.0 %.

BAS 762 02 F can be mixed in the tank together with Pictor Active (BAS 516 15 F), Biscaya (BAS 9165 1 I), Mospilan SG (BAS 9111 9 I), Avatar (BAS 9157 5 I), Mavrik Flol (BAS 9038 1 I), and Dash EC (BAS 160 00 S). Studies regarding the combination with these products were submitted and the application as tank mixture is acceptable.

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

The biological assessment dossier summarizes the biological activity of the plant protection product BAS 762 02 F containing the active substances mefentrifluconazole (100 g/L) and boscalid (200 g/L) on *Sclerotinia sclerotiorum*, *Alternaria* species, *Erysiphe cruciferarum* and *Neopseudocercospora brassicae* in oilseed rape, *Diaporthe helianthi*, *Plenodomus lindquistii*, *Sclerotinia sclerotiorum* and *Alternaria helianthi* in sunflower and *Oculimacula yallundae*, *Zymoseptoria tritici* and *Blumeria graminis* in wheat.

### 3.3 Efficacy data

The ratio justification has confirmed that the chosen ratio of 200 g ai/ha boscalid and 100 g ai/ha mefentrifluconazole provides the highest and the most consistent efficacy on the main pathogens of the oilseed rape, sunflower and wheat.

Two formulations of the product – BAS 762 02 F and BAS 762 00 F – have been included in the biological assessment dossier in order to justify the efficacy of the product. The comparability of both formulations has been confirmed with bridging trials.

The dose response of BAS 762 02 F has been demonstrated with altogether 138 trials conducted in the target crops in which the performances of the target dose rate and a reduced dose rates (60% of the target in the trials conducted in oilseed rape and sunflower trials, and 60-70% of the target in the trials carried out in wheat) were compared. In summary, according to the presented results, BAS 762 02 F at the targeted dose rate of 1,0 L/ha provided the optimum and most consistent control and should be considered as the minimum effective dose rate in oilseed rape, sunflower and wheat under a wide range of environmental conditions.

The results obtained with altogether 210 efficacy trials (110 trials on oilseed rape, 76 trials on sunflower and 24 trials on wheat) proved that BAS 762 02 F is an efficient fungicide on *Sclerotinia sclerotiorum*, *Alternaria* species, *Erysiphe cruciferarum* and *Neopseudocercospora brassicae* in oilseed rape, *Diaporthe helianthi*, *Plenodomus lindquistii*, *Sclerotinia sclerotiorum* and *Alternaria helianthi* in sunflower and *Oculimacula yallundae*, *Zymoseptoria tritici* and *Blumeria graminis* in wheat. The importance of



double application was confirmed for *Plenodomus lindquistii* and *Alternaria helianthi* in sunflower.

The dose rate ranges, that are requested from either legal or marketing reasons in the countries of the South east zone (Hungary, Romania, Slovakia and Slovenia) and in the Czech Republic, have been justified.

Beside the efficacy of the product, the results demonstrated a yield increase after application of BAS 762 02 F and confirmed no negative impact of the product on the parameters such as thousand grain weight and oil content in oilseed rape and sunflower and thousand grain weight and hectoliter-weight in wheat. The results in sunflower demonstrated positive effect of the product on the reduction of broken stem and heads and increase of the green leaf area.

The submitted data confirm that BAS 762 02 F is a effective fungicide in the control of target pathogens. The following uses can not be accepted in Poland under article 33: spring wheat, spring oilseed rape - due to no efficacy data; sunflower – due to no efficacy data from North-East EPPO zone and *Neopseudocercospora brassicae* in winter oilseed rape – due to no efficacy data from North-East EPPO zone. Spring oilseed rape and sunflower are minor crops in Poland and can be registered under article 51.

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

Mefentrifluconazole, the first isopropanol azole, belongs, to the group of the sterol biosynthesis inhibitors (SBI), the subgroup of demethylation inhibitors (DMI, mode of action class G1), the chemical group of triazoles, which is classified with a medium resistance risk. There are big differences in the activity spectra of DMI fungicides. Generally, the cross resistance has to be anticipated between DMI fungicides active against the same fungus but there is no cross resistance known to other SBI classes. Mefentrifluconazole has shown to be highly active on many strains of *Zymoseptoria tritici*, which show lower sensitivity to other DMIs. The mefentrifluconazole molecule is more flexible in its structure than other DMIs and might therefore be able to bind even if the binding pocket shape is altered. This chemical constellation ensures a high degree of structural flexibility that is unique among the DMIs.

Boscalid belongs to the fungicide group succinate dehydrogenase inhibitors (SDHI, mode of action class C2), the chemical group of pyridine-carboxamides. FRAC describes the SDHI fungicides in general as medium to high-risk compounds. Out of the target species of this RRA, isolates with reduced SDHI sensitivity and mutations in the SDH genes have been found for *Zymoseptoria tritici* and *Sclerotinia sclerotiorum*.

The combined pathogen-fungicide analysis under unrestricted use led to the conclusion that the risk is not acceptable for *Zymoseptoria tritici*, *Blumeria graminis* f. sp. *tritici*, *Erysiphe cruciferarum*, *Alternaria* spp. (on oilseed rape) and DMIs under unrestricted use of DMIs. The risk is also not acceptable for all of the target pathogens of the Resistance Risk analysis and SDHIs under unrestricted use of SDHIs. Therefore, resistance management strategies have been presented.

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

No phytotoxicity was observed in the efficacy trials after the treatment with the maximum target dose rate of 1,0 L/ha of BAS 762 02 F.

Altogether 74 trials without disease or with the disease symptoms below the threshold (65 in oilseed rape, 8 in sunflower and 1 trial in wheat) were presented and demonstrated no statistically significant negative impact on yield and qualitative parameters such as the thousand grain weight and the oil content in oilseed rape and sunflower and the thousand grain weight and the hectolitre weight in wheat.

Germination tests confirmed that no impact on germination of harvested seeds after the foliar treatment with BAS 762 02 F should be expected.

### **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 and adjacent crops after the application of BAS 762 02 F.

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

### **3.4.1 Analytical methods for the formulation**

The analytical method AFL0995/01 was developed for the determination of the active substances mefentrifluconazole (BAS 750 F, Reg. No. 5834378) and boscalid (BAS 510 F, Reg. No. 300355) in the SC formulation BAS 762 02 F. With respect to the conditions described in the analytical method AFL0995/01, all validation parameters (identity, specificity, linearity, accuracy and precision) are acceptable. Therefore, this method is valid without restrictions in the tested concentration range and is applicable to determine the contents of mefentrifluconazole and boscalid in the SC formulation BAS 762 02 F.

Mefentrifluconazole contains  $\leq 0.5$  g/kg N,N-dimethylformamide (DMF), which is considered to be an impurity of toxicological concern (equivalent to  $\leq 51.6$  mg/L or 45.4 mg/kg DMF in the SC formulation BAS 762 02 F).

The analytical method AFL1010/01 was developed for the determination of DMF (Reg. No. 159267) in SC formulations containing mefentrifluconazole and validated for the determination of DMF in BAS 762 02 F. With respect to the conditions described in the analytical method AFL1010/01, all validation parameters (identity, specificity, linearity, accuracy and precision) are acceptable. Therefore, this method is valid without restrictions in the tested concentration range and is applicable to determine the contents of DMF in the SC formulation BAS 762 02 F.

Mefentrifluconazole contains  $\leq 1.0$  g/kg toluene, which is considered to be an impurity of toxicological concern (equivalent to  $\leq 103.1$  mg/L or 90.8 mg/kg toluene in the SC formulation BAS 762 02 F).

The analytical method AFL0948/03 was developed for the determination of toluene (Reg. No. 4005250) in SC formulations containing mefentrifluconazole and validated for the determination of toluene in BAS 762 02 F. With respect to the conditions described in the analytical method AFL0948/03, all validation parameters (identity, specificity, linearity, accuracy and precision) are acceptable. Therefore, this method is valid without restrictions in the tested concentration range and is applicable to determine the contents of toluene in the SC formulation BAS 762 02 F.

Mefentrifluconazole contains  $\leq 1.0$  g/kg 1,2,4-(1H)-triazole, which is considered to be an impurity of toxicological concern (equivalent to  $\leq 103.1$  mg/L or 90.8 mg/kg 1,2,4-(1H)-triazole in the SC formulation BAS 762 02 F).

The analytical method AFL0977/04 was developed for the determination of 1,2,4-(1H)-triazole (Reg. No. 87084) in formulations containing mefentrifluconazole and validated for the determination of 1,2,4-(1H)-triazole in BAS 762 02 F. With respect to the conditions described in the analytical method AFL0977/04, all validation parameters (identity, specificity, linearity, accuracy and precision) are acceptable. Therefore, this method is valid without restrictions in the tested concentration range and is applicable to determine the contents of 1,2,4-(1H)-triazole in the SC formulation BAS 762 02 F.

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

#### Mefentrifluconazole

The analytical methods developed for mefentrifluconazole (BAS 750 F) in plant and animal matrices were already submitted and evaluated in context of the previous process of Annex I Inclusion of mefentrifluconazole excepting of two new pre-authorization water methods, a new enforcement water method with its ILV, and a new enforcement body fluids method, which are submitted with the current dossier.

#### *Plant and plant products:*

The analytical method for determination of mefentrifluconazole in foodstuffs of plant origin (BASF Method L0076/09) is based on LC-MS/MS (using HPLC or UPLC) with an LOQ of 0.01 mg/kg. It was validated for a diverse range of representative plant matrices (all OECD crop groups). This method is used for data generation purposes.

An analytical LC-MS/MS method (L0295/01) based on QuEChERS was developed and validated, analyzing the parent compound with an LOQ of 0.01 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes. An independent laboratory validation (ILV) was carried out successfully. Therefore, this method can be used as enforcement method for BAS 750 F in plant matrices.

#### *Food of animal origin:*

An analytical LC-MS/MS method (L0272/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.01 mg/kg, for cow liver, kidney, muscle, fat, milk and cream and hen egg. This method based on LC-MS/MS determination is suitable for enforcement and data generation purposes.

An analytical GC-MS method (L0309/01) was developed and validated, analyzing the metabolite M750F022 with an LOQ of 0.01 mg/kg for animal matrices. This method based on GC-MS determination is suitable for enforcement purposes and data generation.

An independent laboratory validation (ILV) was carried out successfully for both methods (L0272/01 and L0309/01). The EU residue definition for BAS 750 F for monitoring purposes is parent only in food of animal origin.

#### *Soil*

An analytical LC-MS/MS method (L0214/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.002 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes and data generation. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

#### *Water*

BAS 750 F can be determined using BASF analytical method L0359/01 using LC/MS/MS with a limit of quantification of 30 ng/L. An independent laboratory validation (ILV) was carried out successfully in drinking and surface water. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

Beyond that, LC/MS/MS-based analytical methods APL0500/03 (determination of BAS 750 F in test water and mixing water with LOQ 0.001 mg/L) and L0631/01 (determination of BAS 750 F in tap water or M4-medium with LOQ 0.1 µg/L) were developed and validated.

#### *Air*

BAS 750 F in air can be determined (L0327/01) by sucking air through adsorption tubes (ORBOTM) for about 6 hours. The tube content is then extracted with acetonitrile and analysed by LC/MS-MS. The limit of quantification corresponded to a concentration of 0.01 ng/L air.

#### *Body Fluids*

An analytical method was developed and validated for the determination of BAS 750 F in body fluids (L0339/01) with a limit of quantification of 0.01 mg/L. Additionally, analytical method L0339/02 was successfully validated, allowing the determination of M750F015, M750F016 and M750F017 in body fluids with a LOQ of 0.01 mg/L.

#### *Honey*

Additionally, a residue study for the determination of BAS 750 F residues in honey has been performed (BASF DocID: 2020/2109990, Report Amendment N°1 DocID: 2021/2038566) and has been provided by Applicant. The study is a combination of residue analytics and a validation study in honey. Whole plant (no roots), inflorescences, pollen and honey specimens were analyzed for residues of BAS 750 F (Mefentrifluconazole) and for residues of the triazole metabolites: 1,2,4-Triazole (T), Triazolylalanine

(TA), Triazole lactic acid (TLA) and Triazole acetic acid (TAA) using BASF method L0170/03. The limit of quantification (LOQ) for all analytes was 0.050 mg/kg. The study is acceptable.

### Boscalid

The analytical methods for the determination of boscalid in foodstuff of plant and animal origin were evaluated in the previous process of inclusion in Annex I of Directive 91/414/EEC and during more recent evaluations performed by EFSA in the context of re-registration and MRL applications. All analytical methods are active substance data.

For the determination of boscalid in foodstuff of plant origin, a single residue method using LC-MS/MS (445/0) was evaluated and adequately validated with an LOQ of 0.05 mg/kg in high water (apple, onion, tomato, cabbage), high acid (grapes, strawberries), high oil (rape seed) and high starch content (carrot, dwarf bean) commodities (DAR 2002). In the frame of the Annex I renewal of boscalid, a new data generation method (535/1) was submitted which allows a LOQ of 0.01 mg/kg in high water (lettuce, tomato, onion), high acid (lemon), high oil (rape seed), high starch content (wheat grain) commodities. During review of the Maximum Residue Levels (MRLs) currently established at European level, it was pointed out that validated methods for enforcement of boscalid in hops, spices and herbal infusions are required. To close this data gap, a new method for determination of boscalid in such difficult plant matrices was developed and validated (L0076/01). The method is suitable for both, data generation and monitoring purposes.

Additionally, an already peer-reviewed enforcement method for plant matrices (based on the DFG S19 approach) exists and was considered fully valid for enforcement purposes (EFSA Reasoned Opinion, EFSA Journal 2014; 12(7): 3799). However, a new monitoring method based on the multi-residue QuEChERS approach was developed applying LC-MS/MS with a LOQ of 0.01 mg/kg in all plant matrices. An independent laboratory validation (ILV) for this method is not required, because a vast number of validated enforcement methods using the QuEChERS approach is available in the EURL (European Reference Laboratories for Residues of Pesticides) Data Pool.

The data shows that boscalid can be enforced in food of plant origin of all categories (high water, high acid, high oil, high protein/starch content and difficult matrices) with an LOQ of 0.01 mg/kg.

For food of animal origin, a peer reviewed LC-MS/MS method (471/0) exists with an LOQ of 0.01 mg/kg in eggs, milk and cream and 0.025 mg/kg in muscle, liver and kidney (DAR 2002). Two amendments to the study report are newly submitted which give information on stability, additionally report the second mass transition and address matrix effects. Also, a new ILV of method 471/0 was conducted to comply with the latest requirement of the SANCO guideline 825/00 rev. 8.1.

Besides, there exist the already peer-reviewed enforcement method for animal matrices (based on the DFG S19 approach) applying GC-ECD and GC-MS with a LOQ of 0.01 mg/kg in milk and 0.025 mg/kg in meat, fat, liver, kidney and eggs (DAR 2002). An ILV of this method was performed and confirmed the applicability of the method.

Analytical methods for the determination of boscalid residues in water, soil and air were submitted in the course of the previous Annex I inclusion process. For soil and sediment, a GC-MS method (408/1) with a LOQ of 0.01 mg/kg was evaluated and considered fully valid (DAR 2002). However, a new data generation method in soil (L0096/01) was submitted in the Annex I renewal process of boscalid. This method has the same LOQ of 0.01 mg/kg but uses LC MS/MS and allows direct determination of boscalid in soil extracts without any further sample clean-up.

Method no. 411 was validated for the determination of boscalid in tap water/leachate water and surface water with a LOQ of 0.05 µg/L and was evaluated as fully valid in the Annex I inclusion process (DAR 2002). A new enforcement method (L0127/01) was developed which has a lower LOQ of 0.03 µg/L. This method can also be used for the purpose of pre-registration data generation and is the proposed data generation method. An ILV of the method is available and confirms the suitability of the method.

For the determination of boscalid in air, analytical method no. 460 was already peer-reviewed and evaluated

as fully valid for monitoring purposes (DAR 2002). The method uses GC-MS for detection and has a LOQ of 1.5 µg/m<sup>3</sup>. A new LC-MS/MS method (L0336/01) enabling a lower LOQ of 0.0012 µg/m<sup>3</sup> was developed and submitted in the renewal process. A new method for determination of boscalid in body fluids was developed (L0342/01) with a limit of quantification of 0.01 mg/L in blood and urine samples.

### **3.5 Mammalian toxicology (Part B, Section 6)**

BAS 762 02 F is an SC product containing the active ingredients mefentrifluconazole and boscalid at concentrations of 100 g/L and 200 g/L, respectively. It is intended to be used for tractor-mounted applications to oilseed rape, sunflower and wheat.

Based on hazard properties of the product or the ingredients contained BAS 762 02 F is to be classified for toxicological hazards with Skin Irrit. 2; H315 “Causes skin irritation”, Eye Irrit. 2; H319 “Causes serious eye irritation” and H317 “May cause an allergic skin reaction”. Gloves, protective clothing and eye/face protection should be worn when handling the undiluted product.

Product and use-specific dermal absorption estimates for the active ingredients are available for the undiluted product and for the 1:400 dilution. These study-derived estimates are applicable for exposure estimations considering the maximum product application rate of 1 L/ha. Exposure estimations for the lower product application rate of 0.6 L/ha require a corresponding pro-rata increase of the dermal absorption estimate for the maximum in-use dilution of the product’s active ingredients by a factor of 1.67 (= 1.0/0.6). Comparative exposure calculations demonstrate that the higher dermal absorption estimate in combination with the lower product application rate, yields, if at all, decimal point differences in exposure estimates for the different application scenarios. Highest exposure estimates were almost always obtained at the maximum product application rate, except for the acute exposure estimation for operators, which was minimally higher at the low-application rate scenario (2.1% vs 1.9% of the AAOEL).

Dermal absorption estimates to be used in the non-dietary risk assessment are 0.031% and 1.8% for mefentrifluconazole and 0.026% and 0.86% for boscalid for the undiluted and spray-strength diluted (1:400) product, respectively. The relevant reference values for the non-dietary risk assessment (AOEL) are 0.035 mg/kg bw/day for mefentrifluconazole and 0.1 mg/kg bw/d for boscalid, to be used for longer-term exposure scenarios. For acute exposures, an AAOEL of 0.15 mg/kg bw has been derived for mefentrifluconazole. An AAOEL for boscalid is currently not assigned.

A toxicological relevance assessment for potential groundwater metabolites of mefentrifluconazole and boscalid was not required, because all concentrations are predicted to stay below 0.1 µg/L.

#### **3.5.1 Acute toxicity**

BAS 762 02 F is assessed to be of low acute toxicity by oral, dermal and inhalation routes not warranting classification for these endpoints. BAS 762 02 F is considered as skin and eye irritant (Skin Irrit. 2; H315, and Eye Irrit. 2; H319) and is classified as a skin sensitizer based on the product composition, thus requiring a classification with Skin Sens. 1, H317.

The acute classification of BAS 762 02 F was derived considering the product’s composition, in-vitro studies for assessment of skin and eye irritation, and on an acute oral toxicity study with the product.

#### **3.5.2 Operator exposure**

Operator exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874)]. The critical use of 2x1.0 L/ha BAS 762 02 F applied with tractor operated application systems was investigated. Based on EFSA model assumptions safe uses could be shown for operators wearing work wear during all operations and gloves during mixing/loading.

### 3.5.3 Worker exposure

Worker exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products (EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874)]. The critical use of 2x1.0 L/ha BAS 762 02 F was investigated. The relevant re-entry scenario investigated was crop inspection. Based on EFSA model assumptions safe uses could be shown for workers wearing work wear.

### 3.5.4 Bystander and resident exposure

Resident and bystander exposure and risk evaluations were performed following the EFSA guidance (2014) [European Food Safety Authority (2014) Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products. EFSA Journal 2014;12(10):3874 [55 pp.]. doi:10.2903/j.efsa.2014.3874]. The critical use of 2x1 L/ha BAS 762 02 F was investigated. Based on EFSA model assumptions safe uses could be shown for residents and bystanders.

## 3.6 Residues and consumer exposure (Part B, Section 7)

### 3.6.1 Residues

#### Mefentrifluconazole

The metabolism and residue studies of mefentrifluconazole (BAS 750 F) have been evaluated by the Rapporteur Member State (United Kingdom) and the EFSA in context of the Approval procedure (DAR and EFSA conclusion). Further MRLs for BAS 750 F were recently published in Europe.

BAS 762 02 F was not the representative formulation in the EU dossier of BAS 750 F. Therefore, additional studies in oilseed rape, sunflower and wheat are submitted to support the registration of the formulated product BAS 762 02 F.

No new MRLs are proposed for BAS 750 F for oilseed rape, sunflower or wheat in this document.

~~According to the EFSA Journal 2018;16(7):5379 following data gap in residue area has been identified during the peer review process:~~

- ~~—Data or information addressing residue levels of mefentrifluconazole and its metabolites in pollen and in bee products for human consumption, obtained from primary and rotational crops.~~

~~In our opinion, the above data gap should also be fulfilled in this application to support the intended uses of BAS 762 02 F / Revydas.~~

The residue study for the determination of mefentrifluconazole residues in honey (BASF DocID: 2020/2109990, Report Amendment N°1 DocID: 2021/2038566) has been provided by Applicant and added to the Registration Report for BAS 762 02 F / Revydas. No residues (<0.05 mg/kg) of mefentrifluconazole and 1,2,4-Triazole (T), Triazolylalanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) were found in any honey samples collected at 67-69 BBCH (14 DALA).

Therefore, the data is sufficient for the registration of BAS 762 02 F / Revydas.

### Boscalid:

The metabolism and residue studies of boscalid have been evaluated by the Rapporteur Member State (Germany) in context of the Annex I inclusion procedure. Subsequent to the EU review of boscalid, evaluations of further uses have been made to establish revised EU MRLs for multiple crops (most recent EFSA opinions on MRLs, published in 2014: Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005; published in 2019: Reasoned opinion on the modification of the existing maximum residue level for boscalid in honey and published in 2020: EFSA (European Food Safety Authority), 2020. Reasoned opinion on the modification of the existing maximum residue level for boscalid in pomegranates).

The evaluations reviewed all the data relevant to establish MRLs for all supported uses and considered the dietary risk assessment with all uses presently registered.

The MRLs for boscalid are published in Annex III of Regulation (EC) No 396/2005, according to Reg. (EU) No 2021/590.

The present dossier supports the use of boscalid in oilseed rape, sunflower and wheat. Residue data supporting the safe use of BAS 762 02 F are included in this submission.

The residue levels found in the supervised field trials indicate that the existing EU MRLs of 0.8 mg/kg (wheat) and 1 mg/kg (oilseed rape and sunflower) will not be exceeded. Thus, the data show that the existing MRLs for boscalid in oilseed rape, sunflower and wheat are sufficient to cover also the target GAP.

## **3.6.2 Consumer exposure**

### Mefentrifluconazole

Dietary risk assessments for mefentrifluconazole (BAS 750 F) and the TDMs 1,2,4-T, TA, TLA and TAA were carried out based on the EFSA PRIMo model vers. 3.1.

The results of the IEDI calculations taking into account residues in food commodities of plant and animal origin, show that there is no chronic risk for consumers. Regarding the IESTI calculations, also no acute risk for consumers was identified.

**BAS 750 F:** Assessments of the potential chronic dietary consumer risk resulting from exposure to residues mefentrifluconazole were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) and the current EU MRLs values laid down in Regulation (EU) 2021/590.

The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2021/590 led to a utilisation of the ADI of 31% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Apples with 12% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.

A refined IESTI calculation was performed with the EFSA Pesticide Residues Intake Model (PRIMo 3.1) using an ARfD of 0.15 mg/kg bw/day and STMRs for oilseed rape, sunflower and wheat. For children, the highest ARfD utilization was 0.10% for consumption of wheat and second highest for sunflower seed (0.042%). For adults, the highest ARfD utilization was 0.06% for consumption of wheat.

The proposed uses of mefentrifluconazole and triazole derivative metabolites (TDMs) in the product BAS 762 02 F / Revydas do not represent unacceptable chronic and acute risks for the consumer.

Separate consumer risk assessments are performed for triazole derivative metabolites (TDMs): 1,2,4-T, TA, TAA and TLA.

1.2.4-T: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.3 to 48% of the ADI. The diet with the highest IEDI is "NL toddler" with 48% of the ADI. For this diet, the highest contributor is milk/cattle with 42% of the ADI. The diet with the second highest IEDI is "UK infant" with 30% of the ADI, in which also milk/cattle is the major contributor with 27% of the ADI.

For children, the highest ARfD utilization was 0.7% for consumption of wheat. For adults, the highest ARfD utilization was 0.4% for consumption of wheat as well.  
For processed commodities, the highest ARfD utilization for children was 0.6% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.2% for consumption of wheat / bread/pizza.

TA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.3 to 4% of the ADI. The diet with the highest IEDI is "NL toddler" with 4% of the ADI. For this diet, the highest contributor is maize/corn with 1% of the ADI. The diet with the second highest IEDI is "DK child" with 3% of the ADI, in which rye is the major contributor with 1% of the ADI.

For children, the highest ARfD utilization was 3% for consumption of wheat. For adults, the highest ARfD utilization was 2% for consumption of wheat as well.  
For processed commodities, the highest ARfD utilization for children was 1% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.9% for consumption of wheat / bread/pizza.

TLA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.0 to 1% of the ADI. The diet with the highest IEDI is "NL toddler" with 1% of the ADI. For this diet, the highest contributor is milk/cattle with 0.6% of the ADI. The diet with the second highest IEDI is "UK infant" with 0.5% of the ADI, in which also milk/cattle is the major contributor with 0.4% of the ADI.

For children, the highest ARfD utilization was 0.1% for consumption of wheat. For adults, the highest ARfD utilization was 0.06% for consumption of wheat as well.  
For processed commodities, the highest ARfD utilization for children was 0.1% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.03% for consumption of wheat / bread/pizza.

TAA: A long-term consumer intake concern was not identified for any of the diets incorporated in the EFSA model. In context of IEDI calculations the ADI utilization ranges from 0.0 to 1% of the ADI. The diet with the highest IEDI is "NL toddler" with 1% of the ADI. For this diet, the highest contributor is maize/corn with 0.6% of the ADI. The diet with the second highest IEDI is "DK child" with 0.9% of the ADI, in which rye is the major contributor with 0.4% of the ADI.

For children, the highest ARfD utilization was 1% for consumption of wheat. For adults, the highest ARfD utilization was 0.7% for consumption of wheat as well.  
For processed commodities, the highest ARfD utilization for children was 0.8% for consumption of wheat/milling (flour). For adults, the highest ARfD utilization was 0.3% for consumption of wheat / bread/pizza.

Boscalid:

The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2021/590 led to a utilisation of the ADI of 398% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinaches with 90% of the ADI.



The refined assessment of chronic risk is required as TMDI calculations exceeded 100% of the ADI. IEDI calculation has been performed with the STMRs values taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil.

The total chronic intake calculated accounted for 69% of the ADI (NL toddler) with apples (11%) as highest contributing commodity. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.

No ARfD was allocated, thus no acute risk assessment needs to be performed.

The IEDI utilization is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

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

Agreed endpoints from EFSA Journal 2018;16(7):5379 for mefentrifluconazole and its metabolites, as well as agreed endpoints from the EU Review Report (SANCO/3919/2007-rev.5), the Draft Assessment Report (2002), and its Addenda (2006) for boscalid, were used for the assessments in soil, groundwater, surface water, sediment and air for the intended use pattern. Degradation in soil of boscalid was described by geometric mean, not arithmetic mean values as in Monograph (2002).

All parameters and procedures relevant for the exposure assessment are provided in Part B of the core dossier.

All exposure calculation for mefentrifluconazole and its metabolites, as well as for boscalid, were carried out considering zonal and national requirements and appropriate worst-case application scenarios.

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

The PEC in soil have been assessed for mefentrifluconazole and its metabolite 1,2,4-triazole, as well as for boscalid, following the latest guidance of the FOCUS working groups on degradation kinetics, soil persistence models and groundwater scenarios. Calculations were carried out with consideration of appropriate worst-case application scenarios as well as substance-specific endpoints.

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.

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

Calculations for mefentrifluconazole and its metabolite 1,2,4-triazole, as well as for boscalid, were based on the latest guidance of the FOCUS groundwater working group. The simulations were performed with the models FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4, assuming worst-case application scenarios and considering all national relevant FOCUS scenarios parameterized for all relevant crops defined by the GAP.

For the metabolite of mefentrifluconazole, the leaching assessment was conducted at four Tiers. Tier 1 calculations were based on a single-compartment degradation model for 1,2,4-triazole. Tier 2 to Tier 4 PEC<sub>gw</sub> calculations implemented biphasic degradation (DFOP kinetics) considering different formation fractions for the metabolite. Further details on the assessment, and detailed results are presented in Section 8 of the Core dossier.

The 80<sup>th</sup> percentiles of the predicted annual leachate concentrations of mefentrifluconazole, as well as boscalid were clearly below 0.1 µg/L in all tested scenarios and models. PEC<sub>gw</sub> for 1,2,4-triazole were below 0.1 µg/L at Tier 2 to Tier 4 for all scenarios and models as well.

Predicted concentrations of boscalid in groundwater were far below the threshold concentration of 0.1 µg/L in all crops and scenarios indicating that no unacceptable leaching of this substance is expected after application of BAS 762 02 F according to the intended use pattern.

Overall, the leaching of unacceptable amounts of substances following application of mefentrifluconazole or boscalid to the various crops defined by the GAP is highly unlikely.

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

The PEC calculations in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) were performed for appropriate worst-case application scenarios for all relevant crops defined by the GAP. The assessment was carried out according to the latest guidance of the FOCUS working group on surface water scenarios in a stepwise approach, considering the pathways spray drift, drainage and runoff.

For mefentrifluconazole only calculations performed at Steps 1-3 were validated and agreed by the zRMS. While for metabolites 1,2,4-triazole and M750F003 calculations performed at Steps 1-2 were considered, while for metabolites M750F005, M750F006, M750F007 and M750F008 PEC<sub>sw/sed</sub> derived at Steps 1-3 were necessary to finalise the aquatic risk assessment.

Calculations performed at Step 4 for the parent and Step 3-4 for metabolites were not validated by the zRMS as being not necessary for purposes of the aquatic risk assessment (according to information available in area of ecotox section, for mefentrifluconazole and its metabolites acceptable risk could be concluded with Step 1-3 PEC<sub>sw/sed</sub> and for metabolites surface water exposure calculated at Step 1-2 was deemed sufficient).

Calculations for boscalid carried out at Step 1 to Step 3 were validated and agreed.

The software packages STEPS1-2 (version 3.2) for Step 1 and Step 2, FOCUS-SPIN version 2.2 and SWASH 5.3 in combination with MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 5.5.3 for Step 3 and SWAN 5.0.0 for Step 4 were used for the calculations.

At Step 2 of the assessment, the region regions “North Europe” and “South Europe” were taken into account. At Step 3, all national relevant FOCUS scenarios parameterized for the various crops defined by the GAP were selected for the simulations.

Additionally, PEC<sub>sw</sub> were calculated for the formulated product using Spray Drift Calculator.

Further details on the assessment as well as detailed results are presented in Part B, Section 8 of the Core dossier. The presented PEC<sub>sw</sub> and PEC<sub>sed</sub> values are suitable for subsequent ecotoxicological risk assessment.

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

Air is not a relevant exposure pathway for mefentrifluconazole according to EFSA (2018) due to low vapour pressure (<10<sup>-5</sup> Pa) and DT<sub>50</sub> in the atmosphere <2 days.

The vapour pressure at 20°C of the active substance boscalid is <10<sup>-5</sup> Pa. Hence, boscalid is regarded as non-volatile. Furthermore, DT<sub>50</sub> in the atmosphere is <2 days. Accordingly, air is not a relevant exposure pathway.

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

Following application of BAS 762 02 F no risk or unacceptable effects are expected for birds, mammals, non-target aquatic organisms, honey bees, non-target arthropods others than bees, non-target meso- and macrofauna, non-target higher plants and soil nitrogen transformation processes without the need for additional mitigation measures.

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

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

###### *Dietary risk assessment*

###### Exposure to active substances

In the screening step and/or tier1 risk assessment, all  $TER_A$  values and all  $TER_{LT}$  values for mefentrifluconazole and boscalid exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

###### Exposure to combined active substances

In the screening step of the acute assessment, the TER values for the combined active substances (virtual compound) exceed the trigger value for acceptability of effects. The combined reproductive risk assessment using the concentration addition model result in tier 1 TER values above the trigger of 5 for acceptability of effects.

###### *Drinking water risk assessment*

Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 762 02 F according to the proposed use pattern. Since the ratio of the effective application rate to the relevant endpoints is below the value of 3000 for mefentrifluconazole and for boscalid, a quantitative risk assessment for the proposed use pattern of BAS 762 02 F is not necessary.

###### *Secondary poisoning and biomagnification*

The log  $P_{ow}$  was 3.4 for mefentrifluconazole and 2.96 for boscalid, which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm- and fish-eating birds, the TER values for mefentrifluconazole and boscalid are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and boscalid was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

**It can be concluded that the risk to birds from application of BAS 762 02 F according to good agricultural practice is acceptable.**

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

###### *Dietary risk assessment*

###### Exposure to active substances

In the screening step and/or tier1 risk assessment, all  $TER_A$  values and all  $TER_{LT}$  values for mefentrifluconazole and boscalid exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

###### Exposure to combined active substances and to formulation

The two acute risk assessment approaches carried out (combined toxicity of the active substances as virtual compound and formulation toxicity) have resulted in acute TER values at the screening step above the trigger of 10 for acceptability of effects. The combined reproductive risk assessment using the

concentration addition model result in tier 1 TER values above the trigger of 5 for acceptability of effects.

#### *Drinking water risk assessment*

Following EFSA/2009/1438, the puddle scenario is the one relevant for mammals. Since the ratio of the effective application rate to the relevant endpoints is below the value of 3000 for mefentrifluconazole and for boscalid, a quantitative risk assessment for the proposed use pattern of BAS 762 02 F is not necessary.

#### *Secondary poisoning and biomagnification*

The log  $P_{ow}$  was 3.4 for mefentrifluconazole and 2.96 for boscalid, which triggers an assessment of the potential risk from secondary poisoning. According to the tier 1 risk assessment for earthworm-eating and fish-eating mammals, the TER values for mefentrifluconazole and boscalid are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and boscalid was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

**It can be concluded that the risk to mammals from application of BAS 762 02 F according to good agricultural practice is acceptable.**

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

In the EU, there is no requirement to test terrestrial amphibians or reptiles and there is also no guidance available on how to conduct risk assessments for these groups.

In the absence of toxicity data on mefentrifluconazole and boscalid, the active substances in the formulation BAS 762 02 F, and considering the lack of guidance for risk assessment, it is assumed that the risk assessments for birds and mammals are protective for terrestrial life-stages of amphibians and reptiles, an approach that is also used by US-EPA (2004).

### **3.8.2 Effects on aquatic species**

The risk assessment was performed in line with indications of EFSA (2013) with consideration of all FOCUS scenarios relevant for Poland.

The standard risk assessment for the active substances mefentrifluconazole and boscalid indicated an acceptable risk for all groups of aquatic organisms following the intended uses of BAS 762 02 F with no need for mitigation measures.

The PEC/RAC ratios for the relevant metabolites of mefentrifluconazole were significantly below the trigger of 1 based on standard worst-case calculation. For boscalid, no major metabolites (> 10% TAR) were formed in a sensitized water/sediment study; they are thus considered not to be of ecotoxicological relevance and well covered within the assessment of the parent compound.

The combined risk assessment revealed an acceptable risk to aquatic organisms from the mixture following the intended uses of BAS 762 02 F with no need for mitigation measures.

**The standard risk assessment provided for the fungicidal product BAS 762 02 F, the active substances mefentrifluconazole and boscalid as well as their major metabolites demonstrate that the proposed applications of BAS 762 02 F according to good agricultural practice are of low risk to aquatic ecosystems.**

### **3.8.3 Effects on bees**

The risk to honey bees from the use of mefentrifluconazole, boscalid and BAS 762 02 F was assessed using the maximum single application rate and the LD<sub>50</sub> values to calculate hazard quotients (HQ) for oral

exposure ( $Q_{HO}$ ) and contact exposure ( $Q_{HC}$ ) in line with indications of the current guidance document SANCO/10329/2002 rev. 2 final. The hazard quotients for BAS 762 02 F and the active substances mefentrifluconazole and boscalid for acute oral and acute contact exposure of honey bees are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50.

**Based on results of performed evaluation it can be concluded that low risk to honey bees is expected from applications of BAS 762 02 F according to the proposed uses. No adverse effects on adult bees, bee brood and bee colonies were observed in the tunnel study performed on flowering winter oilseed rape with BAS 762 02 F applied at 1.1 L/ha during the bee activity, confirming acceptable acute and chronic risk to bees from the intended uses of BAS 762 02 F.**

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

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002). The risk assessment for BAS 762 02 F is based on Tier I tests with the standard test species *A. rhopalosiphi* and *T. pyri*. The risk assessment is based on the worst-case application rate according to the proposed use pattern.

**Based on the results of the conducted first and higher tier risk assessments it can be concluded that low in- and off-field risk for non-target arthropods is expected from the use of BAS 762 02 F according to the proposed use pattern with no need for risk mitigation measures.**

#### 3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna), as well as 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).

##### *Effects on non-target soil meso- and macrofauna*

The potential risk of BAS 762 02 F, mefentrifluconazole, boscalid and the relevant metabolites to earthworms and other non-target soil macro-organisms was assessed by comparing the maximum  $PEC_{soil}$  values with NOEC or  $EC_{10}$  values, to generate long-term TER values ( $TER_{lt}$ ).

**All TER values for BAS 762 02 F, mefentrifluconazole, boscalid and the relevant metabolites for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5. This indicates that BAS 762 02 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate.**

##### *Effects on soil microbial activity*

The potential risk of BAS 762 02 F, mefentrifluconazole, boscalid and the relevant metabolites to soil micro-organisms was assessed by comparing the maximum  $PEC_{soil}$  values with the maximum concentration with effects  $\leq 25\%$ .

**For the formulation BAS 762 02 F, the active substances mefentrifluconazole and boscalid as well as their relevant metabolites, the maximum concentration with effects  $< 25\%$  (SANCO/10329/2002 trigger) are all above the maximum  $PEC_{soil}$  values. Therefore, it is concluded that the use of BAS 762 02 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.**

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

The toxicity of BAS 762 02 F to non-target terrestrial plants has been investigated by carrying out vegetative vigour and seedling emergence studies with up to six dicotyledonous and four monocotyledonous non-target plant species.

The risk assessment was based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field areas, as non-target plants are non-crop plants located outside the treated area. The amount of spray drift reaching off-crop habitats was calculated using the 90<sup>th</sup> percentile estimates in Appendix IV of ESCORT 2. For a single application to field crops and vegetables < 50 cm, 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). The highest single application rate of BAS 762 02 F was used to calculate the maximum off-field predicted environmental rate (PER<sub>off-field</sub>). The potential risk of BAS 762 02 F to non-target plants was assessed by comparing the calculated PER value to the ER<sub>50</sub> values in order to generate TER values (TER).

Based on the results of the greenhouse trials, the TER values for all tested plant species were above the standard trigger of 5.

**Based on the risk assessment it can be concluded that BAS 762 02 F poses no unacceptable risk to non-target plants if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 762 02 F applications are not required for the protection of terrestrial non-target plants.**

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

Not relevant.

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

The metabolites of mefentrifluconazole were not predicted to occur in groundwater at concentrations exceeding 0.1 µg L<sup>-1</sup>. Therefore, no assessment of the relevance of these metabolites is required.

No metabolites of boscalid were considered relevant for the groundwater assessment (chapter 8.8.2 in Part B, Section 8). Assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000–rev.10 was therefore not required.

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

Not required.

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

## **Appendix 1    Copy of the product authorisation**



## Appendix 2 Copy of the product label

### Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, pozostałości, toksykologii i istotności toksykologicznej metabolitów, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym kolorem.

Zakres zmian jest następujący:

### Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008r. nie jest wymagane.
2. Okres ważności: **2 lata w opakowaniach wykonanych z HDPE na podstawie wyników 2-letnich badań stabilności.** 2-letnie badania stabilności są w toku. ~~Możliwe jest wydanie zgody warunkowo, na podstawie zaakceptowanych wyników 14 dniowego badania przyspieszonego starzenia w temperaturze 54°C środka przechowywanego w opakowaniach wykonanych z HDPE (Xxx, M. 2019; 2019/2073795).~~ Zgodnie z zapisami wytycznej Ministerstwa Rolnictwa i Rozwoju Wsi w sprawie zasad zatwierdzania opakowań środków ochrony roślin z dnia 18/10/2021 możliwa jest ekstrapolacja wyników badań stabilności wykonanych dla środka przechowywanego w HDPE na f-HDPE. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisów nazw grup chemicznych, do których przyporządkowano substancje czynne oraz ich zawartości (zawartości substancji czynnych wyrażone w procentach obliczono w oparciu o gęstość środka ochrony roślin 1.136 g/ml zgodnie z danymi zawartymi w punkcie 1.2.1 dokumentu C).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego potwierdzono zgodność łącznego stosowania środka ochrony roślin BAS 762 02 F / Revydas ze środkami: Pictor Active (BAS 516 15 F), Biscaya (BAS 9165 1 I), Mospilan SG (BAS 9111 9 I), Avatar (BAS 9157 5 I), Mavrik Flol (BAS 9038 1 I) i Dash EC (BAS 160 00 S).

### Sekcja skuteczność:

1. Na podstawie przedłożonych przez wnioskodawcę badań możliwa jest rejestracja środka BAS 762 02 F / Revydas / Brelyco do zwalczania zgnilizny txxxzikowej, czerni krzyżowych, mączniaka kapustnych w rzepaku ozimym oraz łamliwości źdźbła zbóż i traw, septoriozy paskowanej liści pszenicy i mączniaka prawdziwego zbóż i traw w pszenicy ozimej w trybie art. 33 rozporządzenia 1107/2009.
2. Tabela GAP uwzględnia rejestrację środka w rzepaku ozimym do ochrony przed plamistością pierścieniową kapustnych. Powyższe zastosowanie wykreślono z etykiety środka z uwagi na brak badań skuteczności wykonanych w strefie EPPO północno-wschodniej (jedynie 5 badań dla tego zastosowania pochodzi z Francji).
3. Tabela GAP uwzględnia rejestrację środka w pszenicy jarej, rzepaku jarym oraz słoneczniku w trybie art. 33 rozporządzenia 1107/2009. Z uwagi na brak jakichkolwiek badań skuteczności wykonanych w pszenicy jarej oraz w rzepaku jarym, a także brak badań skuteczności środka ze strefy EPPO północno-wschodniej dla słonecznika, nie można zarejestrować tych upraw w trybie artykułu 33. Z uwagi na to, że rzepak jary, oraz słonecznik są wpisane na listę upraw małoobszarowych w rozporządzeniu Ministra Rolnictwa i Rozwoju Wsi z dnia 18 września 2019 r. zmieniającym rozporządzenie w sprawie zastosowań małoobszarowych środka ochrony roślin, zgodnie z przedłożoną etykietą, można zarejestrować te dwie uprawy w trybie art. 51 rozporządzenia 1107/2009.
4. Wprowadzono poprawną nazwę choroby pszenicy: łamliwość źdźbła zbóż i traw.
5. Biorąc pod uwagę wyniki badań skuteczności środka w zwalczaniu czerni krzyżowych i mączniaka kapustnych w rzepaku ozimym oraz łamliwości źdźbła i mączniaka prawdziwego w pszenicy ozimej (średnia skuteczność mieszcząca się w zakresie 60-80%) wprowadzono zapis o średnim poziomie zwalczania wyżej wymienionych chorób.
6. Uzupełniono zapisy dla strategii zarządzania odpornością.
7. Zawężono termin stosowania środka w pszenicy ozimej w ochronie przed łamliwością źdźbła do BBCH 30-32 – jest to właściwy czas na stosowanie fungicydów w ochronie pszenicy przed tą chorobą, co także znajduje odzwierciedlenie w przeprowadzonych badaniach skuteczności środka BAS 762 02 F / Revydas / Brelyco.

### Sekcja metody analityczne:

Brak uwag.

**Sekcja toksykologia i istotność toksykologiczna metabolitów:**

1. W części dotyczącej klasyfikacji zagrożeń odpowiednia fraza (P280) została zmodyfikowana w celu odzwierciedlenia wyników toksyczności ostrej. Dodano zwrot P337+P313<sup>3</sup>, pozostałe zwroty wskazujące środki ostrożności – reagowanie są zawarte w części pierwsza pomoc.
2. W części dotyczącej Środków bezpieczeństwa dla osób wykonujących zabiegi agrochemiczne, odpowiedni zapis został zmodyfikowany i stanowi wypadkową klasyfikacji zagrożeń oraz szacowania NDE.
3. Powyższe komentarze dotyczą propozycji etykiet dla śr Revydas oraz środka równoległego Brelyco.

**Sekcja pozostałości:**

Brak uwag.

**Sekcja los i zachowanie w środowisku:**

Brak uwag.

**Sekcja ekotoksykologia:**

1. Dopisano zwrot P501.
2. Zmieniono szerokość standardowej strefy ochronnej wymaganej w celu ochrony organizmów wodnych (z 3 na 1 metr).

Posiadacz zezwolenia:

BASF Agro B.V. Arnhem (NL), Oddział w Freienbach, Huobstrasse 3, 8808 Pfäffikon Sz, Konfederacja Szwajcarska, tel.: +41 0 44 781 99 11, fax: +41 0 44 781 99 12

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

BASF Polska Sp. z o.o., Al. Jerozolimskie 142B, 02-305 Warszawa, tel.: 22 570 99 99, fax: 22 570 97 92,

e-mail: [poczta@basf.com](mailto:poczta@basf.com)

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: ...

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin: .....

## REVYDAS

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Mefentriflukonazol (substancja z grupy triazoli) –

**100g/l (8,80 %w/w)**

Boskalid (substancja z grupy karboksamidów) –

**200g/l (17,61 %w/w)**

**Zezwolenie MRiRW nr R-**

**/ 22 z dnia**

**2022 r.**



**Uwaga**

H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H319	Działa drażniąco na oczy.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.

EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261 P280	Nie wdychać mgły lub par. <del>Stosować rękawice ochronne/odzież ochronną.</del>
P333+P313 311	Stosować rękawice ochronne/odzież ochronną/ ochronę oczu/ochronę twarzy W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P337+P313 311	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362+P364	Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach

## OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny do rozcieńczania wodą, o działaniu układowym, do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami grzybowymi.

## STOSOWANIE ŚRODKA

Środek do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

### Rzepak ozimy

*Zgnilizna txxxzikowa, czerń krzyżowych (średni poziom zwalczania), mączniak kapustnych (średni poziom zwalczania), plamistość pierścieniowa kapustnych*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, wiosną od fazy, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe kwiatostanów bocznych do końca fazy, gdy 50% łuszczyn osiąga typową wielkość (BBCH 57-75).

Liczba zabiegów: 1

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

### Pszenica ozima

~~Łamliwość podstawy źdźbła,~~ *Łamliwość źdźbła zbóż i traw (średni poziom zwalczania), septorioza paskowana liści pszenicy, mączniak prawdziwy zbóż i traw (średni poziom zwalczania)*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do widocznych pierwszych ości (BBCH 30-49). W przypadku zwalczania łamliwości źdźbła zabieg wykonać od początku fazy strzelania w źdźbło do fazy drugiego kolanka (BBCH 30-32).

Liczba zabiegów: 1

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

## STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

### Rzepak jary

*Zgnilizna txxxzikowa, czerń krzyżowych, mączniak kapustnych, plamistość pierścieniowa kapustnych*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, wiosną od fazy, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe kwiatostanów bocznych do końca fazy, gdy 50% łuszczyń osiąga typową wielkość (BBCH 57-75).

Liczba zabiegów: 1

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

## **Słonecznik**

*Plamistość łodyg słonecznika, czarna plamistość łodyg słonecznika, zgnilizna txxxzikowa słonecznika, alternarioza słonecznika*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od fazy widocznego pierwszego międzywęźla do końca fazy kwitnienia (większość kwiatów przekwita, a kwiaty brzeżne opadają) (BBCH 31-69)

Liczba zabiegów: 2

**Pierwszy zabieg** wykonać do fazy gdy pomiędzy przylistkami widoczne są brzeżne kwiaty kwiatostanów, ale kwiatostan jest nadal zamknięty BBCH 31-59

**Drugi zabieg** wykonać od początku fazy kwitnienia gdy brzeżne kwiaty wyciągają się i widoczne są kwiaty z zewnętrznej części kwiatostanu (1/3 kwiatostanu) BBCH 61-69

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

## **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

rzepak i słonecznik: nie dotyczy

pszenica: 56 dni

Środek zawiera następujące substancje czynne:

mefentriflukonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - SBI, grupa FRAC G). W grupie inhibitorów biosyntezy steroli, substancja należy do podgrupy inhibitorów demetylacji (DMI, grupa FRAC G1/3) oraz boskalid z grupy karboksamidów (fungicydy inhibitory dehydrogenazy bursztynianowej - SDHI, grupa FRAC C2/7).

W ramach strategii antyodpornościowej należy ograniczyć liczbę zabiegów z udziałem środków grzybobójczych zawierających ~~środki grzybobójcze zawierające~~ substancje czynne z grupy FRAC G1/3 i/lub z grupy FRAC C2/7 ~~z tych grup należy stosować maksymalnie w dwóch zabiegach w sezonie na danej plantacji rzepaku~~. Revydas może być stosowany 1 raz na plantacjach rzepaku i pszenicy oraz maksymalnie 2 razy na plantacjach słonecznika. Ponadto zaleca się stosować środek głównie w zabiegach zapobiegawczych (profilaktycznie), wyłącznie w zalecanej dawce, zgodnie z zaleceniami zamieszczonym na etykiecie oraz należy stosować środek przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania.

Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed użyciem wstrząsnąć zawartością opakowania.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

## ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

## ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1,3 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

## WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku połknięcia: niezwłocznie zasięgnij porady lekarza – pokaż opakowanie lub etykietę.

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

Posiadacz zezwolenia:

BASF Agro B.V. Arnhem (NL), Oddział w Freienbach, Huobstrasse 3, 8808 Pfäffikon Sz, Konfederacja Szwajcarska, tel.: +41 0 44 781 99 11, fax: +41 0 44 781 99 12

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

BASF Polska Sp. z o.o., Al. Jerozolimskie 142B, 02-305 Warszawa, tel.: 22 570 99 99, fax: 22 570 97 92, e-mail: [poczta@basf.com](mailto:poczta@basf.com)

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin: ...

Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin: .....

## BRELYCO

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Mefentriflukonazol (substancja z grupy triazoli) –

**100g/l (8,8 %w/w)**


Boskalid (substancja z grupy karboksamidów)

**200g/l (17,61 %w/w)**

**Zezwolenie MRiRW nr R-**

**/ 22 z dnia**

**2022 r.**

	
<b>Uwaga</b>	
H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H319	Działa drażniąco na oczy.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261	Nie wdychać mgły lub par.
P280	<del>Stosować rękawice ochronne/odzież ochronną.</del>
P333+P313	Stosować rękawice ochronne/odzież ochronną/ ochronę oczu/ochronę twarzy
311	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P337+P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
311	Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
P362+P364	Zebrać wyciek.
P391	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach
P501	odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach

### OPIS DZIAŁANIA

FUNGICYD w formie koncentratu w postaci stężonej zawiesiny do rozcieńczania wodą, o działaniu układowym, do stosowania zapobiegawczego i interwencyjnego w ochronie przed chorobami grzybowymi.

## STOSOWANIE ŚRODKA

Środek do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

### Rzepak ozimy

*Zgnilizna txxxzikowa, czerń krzyżowych (średni poziom zwalczania), mączniak kapustnych (średni poziom zwalczania), ~~plamistość pierścieniowa kapustnych~~*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, wiosną od fazy, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe kwiatostanów bocznych do końca fazy, gdy 50% łuszczyn osiąga typową wielkość (BBCH 57-75).

Liczba zabiegów: 1

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

### Pszenica ozima

*~~Łamliwość podstawy źdźbła,~~ Łamliwość źdźbła zbóż i traw (średni poziom zwalczania), septorioza paskowana liści pszenicy, mączniak prawdziwy zbóż i traw (średni poziom zwalczania)*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do widocznych pierwszych ości (BBCH 30-49). W przypadku zwalczania łamliwości źdźbła zabieg wykonać od początku fazy strzelania w źdźbło do fazy drugiego kolanka (BBCH 30-32).

Liczba zabiegów: 1

Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

## STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOObszarowych

**Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik**

### Rzepak jary

*Zgnilizna txxxzikowa, czerń krzyżowych, mączniak kapustnych, plamistość pierścieniowa kapustnych*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, wiosną od fazy, gdy widoczne są pojedyncze nadal zamknięte pąki kwiatowe kwiatostanów bocznych do końca fazy, gdy 50% łuszczyn osiąga typową wielkość (BBCH 57-75).

Liczba zabiegów: 1

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

### Słonecznik

*Plamistość łodyg słonecznika, czarna plamistość łodyg słonecznika, zgnilizna txxxzikowa słonecznika, alternarioza słonecznika*

**Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,0 l/ha**

**Termin stosowania:** środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od fazy widocznego pierwszego międzywęźla do końca fazy kwitnienia (większość kwiatów przekwita, a kwiaty brzeżne opadają) (BBCH 31-69)

Liczba zabiegów: 2

**Pierwszy zabieg** wykonać do fazy gdy pomiędzy przylistkami widoczne są brzeżne kwiaty kwiatostany, ale kwiatostan jest nadal zamknięty BBCH 31-59



**Drugi zabieg** wykonać od początku fazy kwitnienia gdy brzeżne kwiaty wyciągają się i widoczne są kwiaty z zewnętrznej części kwiatostanu (1/3 kwiatostanu) BBCH 61-69

Zalecana ilość wody: 100-400 l/ha

Zalecane opryskiwanie: drobnokropliste

## ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

rzepak i słonecznik: nie dotyczy

pszenica: 56 dni

Środek zawiera następujące substancje czynne:

mefentriflukonazol z grupy triazoli (fungicydy inhibitory biosyntezy steroli - SBI, grupa FRAC G). W grupie inhibitorów biosyntezy steroli, substancja należy do podgrupy inhibitorów demetylacji (DMI, grupa FRAC G1/3) oraz boskalid z grupy karboksamidów (fungicydy inhibitory dehydrogenazy bursztynianowej - SDHI, grupa FRAC C2/7).

W ramach strategii antyodpornościowej należy ograniczyć liczbę zabiegów z udziałem środków grzybobójczych zawierających środki grzybobójcze zawierające substancje czynne z grupy FRAC G1/3 i/lub z grupy FRAC C2/7 z tych grup należy stosować maksymalnie w dwóch zabiegach w sezonie na danej plantacji rzepaku. Revydas może być stosowany 1 raz na plantacjach rzepaku i pszenicy oraz maksymalnie 2 razy na plantacjach słonecznika. Ponadto zaleca się stosować środek głównie w zabiegach zapobiegawczych (profilaktycznie), wyłącznie w zalecanej dawce, zgodnie z zaleceniami zamieszczonym na etykiecie oraz należy stosować środek przemiennie ze środkami grzybobójczymi zawierającymi substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania.

Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie:

Nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.

## SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed użyciem wstrząsnąć zawartością opakowania.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

## **ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

## **ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości  $\geq 1$  m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.

W przypadku połknięcia: niezwłocznie zasięgnij porady lekarza – pokaż opakowanie lub etykietę.

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W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

## **Appendix 3 Letter of access**

Not relevant.

## Appendix 4 Lists of data considered for national authorisation

### 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	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/1	Xxx, D.	2017	Additional investigations of the metabolism of 14C-BAS 510 F in beans 2017/1143721 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.2.2/1	xxx, C., Xxx, J.	2019	The Metabolism of [14C-pyridin]- BAS 510 F (Reg. No. 300355) in Laying Hens 2019/1077444 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report never submitted before	BASF
KCA 6.2.2/2	xxx, N., Xxx, J.	2019	Further investigation of metabolite M510F65 (identified in hen metabolism study 773275) 2019/1075236 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report never submitted before	BASF
KCA 6.3.1/1	Xxx, H.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of BAS 762 00 F under field conditions in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and 2019/1016882 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/2	Xxx, H.	2020	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 2020/2006193 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.3.1/3	Xxx, H.	2021	Final Report- Amendment No. 1 Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 2021/2001354 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.3.2/1	Xxx, O.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F under field conditions in Northern and Southern Europe, season 2018 2018/1205796 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.3.2/2	Xxx, O.	2020	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 2019/2075093 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.2/3	Xxx, O.	2020	Amendment No. 1: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 2020/2108977 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.3.3/1	Xxx, H.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in wheat after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F under field conditions in Germany, Poland, Southern France, Spain, The Netherla 2019/1016888 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.10	Xxx, M.	2021	Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018 BASF DocID 2020/2109990 yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.10	Xxx, M.	2021	Amendment N°1 to final report Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018 BASF DocID 2021/2038566 yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.9/1	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_TMDI 2021/2001331 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 6.9/2	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_IEDI 2021/2001332 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/3	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_IESTI_core C 2021/2001333 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/4	Anonymous	2021	TA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001334 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/5	Anonymous	2021	TAA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001335 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/6	Anonymous	2021	TLA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001336 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/7	Anonymous	2021	124T_EFSA_PRIMo_rev3.1_IED_IESTI_core C 2021/2001337 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/8	Anonymous	2021	BAS 510 F_EFSA_PRIMo_rev3.1_TMD 2021/2001884 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF



<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 6.9/9	Anonymous	2021	BAS 510 F_EFSA_PRIMo_rev3.1_IED 2021/2001885 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.9/10	Xxx Xxx, A.	2021	Supplemental document - 1,2,4-T, TA, TAA, TLA - Derivation of input values for the livestock dietary burden and the risk assessments for formulation BAS 762 02 F 2021/2001338 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 2.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.2.1/1	Xxx, J.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039586 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2/1	Xxx, J.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039586 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.3.1/1	Xxx, J.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039586 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.3.3/1	Xxx, J.	2019	Determination of physico-chemical properties according to UN Transport Regulation and Directive 94/37/EC (Regulation (EC) No. 440/2008) 2019/1039586 consilab Gesellschaft fuer Anlagensicherheit mbH, Frankfurt/Main, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.4.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.5.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.5.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.6.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.7.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.7.4/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.7.5/1	Xxx, M.	2022	Physical and Chemical Properties of BAS 762 02 F: Storage stability for up to 156 weeks at 25°C in HDPE packs - 104 week report – 2022/2002995 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 2.8.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.8.3.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.8.3.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.8.5.1.1/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.8.5.1.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 2.8.7.2/1	Xxx, M.	2019	Physical and chemical properties of BAS 762 02 F including low temperature stability (7 days at 0°C) and accelerated storage stability (14 days at 54°C) 2019/2073795 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 2.9.1/1	Xxx, C.	2019	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 762 02 F 2019/2037577 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 2.9.2/1	Xxx, C.	2019	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 762 02 F 2019/2037577 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 4.2/1	Xxx, C.	2019	Effectiveness of procedures for cleaning application equipment and protective clothing BAS 762 02 F 2019/2044222 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 4.3/1	Anonymous	2021	Safety data sheet - Revydas 2021/2004277 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 4.4/1	Xxx, B.	2019	BAS 762 02 F EU Performance Test Packaging made of HDPE 2019/1039588 BASF SE, Ludwigshafen, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.5/1	Anonymous	2021	Safety data sheet - Revydas 2021/2004277 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 5.1/1	Xxx, G.	2017	Validation of analytical method APL0500/03 for the determination of BAS 750 F (Reg.No. 5834378) and its metabolite M750F007 (Reg.No. 6003432) in M4-Medium, OECD-water and mixing water by LC/MS 2017/1064882 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with BAS 765 00 F. evaluation is ongoing	BASF
KCP 5.1/2	Xxx, E.	2016	BAS 750 F - Acute toxicity study in the fathead minnow (Pimephales promelas) 2016/1155889 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> Nov 2019.	BASF
KCP 5.1/3	Xxx, M.	2017	Validation of BASF Method L0361/01 for the determination of pesticides in water by LC-MS/MS 2017/1065621 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 773 01 H (Butisan Avant; R-9/2017) from 23 <sup>rd</sup> February 2017.	BASF
KCP 5.1.1/1	Xxx, A.	2019	AFL0995/01: Determination of the Active Ingredients Boscalid and Mefentrifluconazole in BAS 762 02 F and Aqueous Solutions of BAS 762 02 F by HPLC and UPLC 2019/2034432 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/2	Xxx, A.	2019	Validation of the Analytical Method AFL0995/01: Determination of the Active Ingredients Boscalid and Mefentrifluconazole in BAS 762 02 F and Aqueous Solutions of BAS 762 02 F by HPLC and UPLC 2019/2034429 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.1.1/3	Xxx, D.	2020	Analytical Method AFL 1010/01 - Determination of Dimethylformamide in Formulations containing Mefentrifluconazole (BAS 750 F) 2020/2028497 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Data/study report submitted before with BAS 765 00 F Daxur. Evaluation is ongoing	BASF
KCP 5.1.1/4	Xxx, D.	2020	Validation of the Analytical Methode AFL1010/01: "Determination of Dimethylformamide in Formulations containing Mefentrifluconazole (BAS 750 F)" 2020/2032727 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.1.1/5	Xxx, A.	2020	Additional Validation of the Analytical Method AFL1010/01: "Determination of Dimethylformamide in Formulations containing Mefentrifluconazole (BAS 750 F)" 2020/2085538 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before	BASF
KCP 5.1.1/6	Xxx, M.	2017	Analytical method AFL0948/01 - Determination of Toluene in formulations containing Mefentrifluconazole (BAS 750 F) 2017/1077926 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/7	Xxx, M.	2017	Validation of the analytical method AFL0948/01: Determination of Toluene in formulations containing Mefentrifluconazole (BAS 750 F) 2017/1078235 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with BAS 765 00 F Daxur. evaluation is ongoing	BASF
KCP 5.1.1/8	Xxx, M.	2020	Analytical Method AFL0948/03 - Determination of Toluene in Formulations containing Mefentrifluconazole (BAS 750 F). 2020/2080925 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 5.1.1/9	Xxx, M.	2020	Additional Validation to the Analytical Method AFL0948/03: Determination of Toluene in Formulations containing Mefentrifluconazole (BAS 750 F) 2020/2085856 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.1.1/10	Xxx, D.	2018	Analytical method AFL0977/01 - Determination of the impurity Reg.No. 87084 in formulations containing Mefentrifluconazole 2018/1144189 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 5.1.1/11	Xxx, D.	2018	Validation of the Analytical Method AFL0977/01: Determination of the impurity Reg.No. 87084 in Formulations containing Mefentrifluconazole 2018/1144190 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with BAS 765 00 F Daxur. evaluation is ongoing	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1/12	Xxx, A.	2020	AFL0977/04: Determination of the impurity Reg.No. 87084 in Formulations containing Mefentrifluconazole 2020/2037327 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 5.1.1/13	Xxx, A.	2020	Additional Validation to the Analytical Method AFL0977/04: Determination of the impurity Reg.No. 87084 in Formulations containing Mefentrifluconazole 2020/2080849 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.1.2/1	Xxx, A., Xxx, C.	2007	Validation of BASF method No. 535/1 in plant matrices 2006/1039427 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Data/study report submitted before. Data protection starts with BAS 500 06 F (Comet 200 EC; R-155/2015) from 25 <sup>th</sup> September 2015.	BASF
KCP 5.2/1	Xxx, M.	2017	Validation of analytical method L0359/01 for the determination of BAS 750 F and its metabolites M750F003, M750F005, M750F006 (Reg.No.5863469), M750F007 (Reg.No.6003432) and M750F008 (Reg.No.6010286) in drinking and surface water by LC-MS/MS 2017/1066523 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> October 2019.	BASF
KCP 5.2/2	Xxx, T.	2017	Independent laboratory validation (IVL) of method L0359/01 for the determination of BAS 750 F and its metabolites M750F005, M750F006, M750F007 and M750F008 in drinking water and surface water by LC-MS/MS 2017/1066522 EAG Laboratories PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> October 2019	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/3	Xxx, N.	2019	Validation of BASF Analytical Method L0339/02 for the determination of M750F015, M750F016 and M750F017 in body fluids 2019/1046404 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> October 2019	BASF
IIA 4.3/7	Xxx, M.	2021	Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under semi-field conditions in Germany, 2018 BASF DocID 2020/2109990 yes Unpublished	No	Yes	Data/study report never submitted before	BASF
IIA 4.3/8	Xxx, M.	2021	Amendment N°1 to final report Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under semi-field conditions in Germany, 2018 BASF DocID 2021/2038566 yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.2/4	Xxx, N.	2015	Validation of the analytical method QuEChERS for the determination of BAS 510 F (Boscalid) in foodstuff of plant origin 2015/1114667 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/5	Xxx, R.	2015	Validation of BASF analytical method number L0076/01 for the determination of BAS 510 F (Boscalid) in hops, spices and herbal infusions 2015/1091103 Battelle UK Ltd., Chelmsford Essex CM2 5LB, United Kingdom yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/6	Xxx, F.	2001	The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2000/1017223 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/7	Xxx, F.	2004	Report amendment No. 1: The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2003/1021922 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/8	Xxx, J.	2015	Report Amendment No.2: The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2015/1174463 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/9	Xxx, H., Xxx, A.	2015	Independent laboratory validation of the BASF method L0041/01 (471/0) for the determination of BAS 510 F (Boscalid) and metabolite M510F01 in animal matrices 2015/1114666 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/10	Xxx, H.	2015	Amendment No. 1 - Independent laboratory validation of the BASF method L0041/01 (471/0) for the determination of BAS 510 F (Boscalid) and metabolite M510F01 in animal matrices 2015/1251211 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/11	Xxx, M.	2009	Validation of analytical method L0096/01: Determination of Boscalid Reg.No. 300355 in soil using HPLC/MS-MS 2008/1084832 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/12	Xxx, M.	2015	Report amendment no. 1 - Validation of analytical method L0096/01: Determination of Boscalid Reg.No. 300355 in soil using HPLC/MS-MS 2015/1174527 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/13	Xxx D.	2013	Validation of an Analytical Method for Determination of Residues of M510F47 and M510F49 in Soil 2013/1415720 Eurofins Agrosience Services yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 5.2/14	Xxx, H.	2009	Validation of analytical method L0127/1 for the determination of BAS 510 F (Boscalid) residues in surface water and groundwater 2008/1086809 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/15	Xxx, T.	2015	Report Amendment No. 1 to final report: Validation of analytical method L0127/1 for the determination of BAS 510 F (Boscalid) residues in surface water and groundwater 2015/1174526 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/16	Xxx, M.	2016	Independent laboratory validation (ILV) of the BASF method L0127 for the determination of Boscalid (BAS 510 F) and two of its metabolites M510F47 (Reg.No. 107371) and M510F49 (Reg.No. 391572) in surface water and groundwater 2016/1112645 Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/17	Xxx, T.	2015	Validation of analytical method L0127/02 for the determination of M510F47 (Reg.No. 107371) and M510F49 (Reg.No. 391572) in surface and groundwater 2015/1109588 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/18	Xxx, M.	2016	Validation of analytical method L0336/01: Determination of BAS 510 F (Boscalid) in Air 2016/1037754 Eurofins Agrosience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/19	Xxx, S., Xxx, S.	2016	Validation of BASF analytical method L0342/01 for the determination of BAS 510 F (Boscalid) and its metabolite M510F01 in body fluids 2016/1193046 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 5.2/20	Xxx, H.	2010	Standard stability of BAS 510 F in methanol / acetate buffer solution 2010/1046613 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/21	Xxx, T.	2015	Comparative analysis of extraction procedures on Boscalid (BAS 510 F) originating from a field accumulation and dissipation study in Northern Italy 2015/1109589 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 6/1	Xxx, D.	2021	BAS 762 02 F BAD C-Zone 2020/2109659 BASF SE Agricultural Solutions no Unpublished	No	No	Not applicable	BASF
KCP 6.1/1	Xxx, M.	2020	Justification of the co-formulated mixture BAS 762 02 F for oilseed rape, sunflower and cereals 2020/2106608 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.2/1	Anonymous	2020	Dossier Trial Data Reports: BAS 762 02 F - Efficacy trials in oilseed rape (162 trials) 2020/2109355 <none> yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.2/2	Anonymous	2020	Dossier Trial Data Reports: BAS 762 02 F - Efficacy trials in sunflower (84 trials) 2020/2109356 <none> yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.2/3	Anonymous	2020	Dossier Trial Data Reports: BAS 762 02 F - Efficacy trials in wheat (25 trials) 2020/2109357 <none> yes Unpublished	No	Yes	Data/study report never submitted before	BASF

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KCP 6.2/4	Anonymous	2021	Additional trial reports (13 trials) 2021/2029135 <none> yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.3/1	Xxx, G.	2020	BAS 762 02 F - Resistance Risk Analysis 2020/2082886 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.4.4/1	Xxx, A., Xxx, A.	2020	Germination trials with harvested grains from wheat treated with BAS 762 00 F 2020/2006395 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.5.1/1	Xxx, L.	2019	Cultivation of different crops in substrate treated with BAS 762 02 F (Succeeding crops study) 2019/1028202 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 6.5.2/1	Xxx, A.	2020	Effect of BAS 762 02 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2020/1000745 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.6/1	Xxx, C.	2019	Effectiveness of procedures for cleaning application equipment and protective clothing BAS 762 02 F 2019/2044222 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/2	Xxx, C.	2019	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 762 02 F 2019/2037577 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 6.6/3	Anonymous	2020	Dossier Trial Data Reports: BAS 762 02 F - Water volume testing in oilseed rape (3 trials) 2020/2109358 <none> yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 6.6/4	Anonymous	2020	BAS 762 02 F: Summary report on comparison of regions 2020/2109359 <none> no Unpublished	No	No	Not applicable	BASF
KCP 6.6/5	Anonymous	2015	GEP Certificate: Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria - 2015 2015/1143221 Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria no Unpublished	No	No	Not applicable	BASF
KCP 6.6/6	Xxx, P.	2009	GEP Certificate: Zkusebni stanice Nechanice, s.r.o., Nechanice, Czech Republic 2009/1127609 Zkusebni stanice Nechanice s.r.o., Nechanice, Czech Republic no Unpublished	No	No	Not applicable	BASF
KCP 6.6/7	Anonymous	2016	GEP Certificate: Oseva Pro s.r.o., odstepny zavod Vyzkumny ustav olejnin Opava, Czech Republic 2016/1274861 OSEVA Pro s.r.o., Opava, Czech Republic no Unpublished	No	No	Not applicable	BASF



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KCP 6.6/8	Xxx, P.	2016	GEP Certificate: Zemedelska Zkusebni Stanice Kujavy s.r.o., Kujavy Czech Republic - 2016 2016/1350608 Zemedelska Zkusebni Stanice Kujavy s.r.o., Kujavy, Czech Republic no Unpublished	No	No	Not applicable	BASF
KCP 6.6/9	Xxx, P.	2016	GEP Certificate: Zkusebni stanice Kluky, spol. s r.o., Czech Republic - 2016 2016/1350647 Zkusebni stanice Kluky spol. s.r.o., Kluky, Czech Republic no Unpublished	No	No	Not applicable	BASF
KCP 6.6/10	Xxx, P.	2016	GEP Certificate: Ing. Jitka Mareckova, Zkusebni stanice Krasne Udoli Touzim, Czech Republic 2016/1352929 <none> no Unpublished	No	No	Not applicable	BASF
KCP 6.6/11	Xxx, P.	2016	GEP Certificate - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic - 2017 2017/1156065 ZST - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic no Unpublished	No	No	Not applicable	BASF
KCP 6.6/12	Xxx, P.	2016	GEP Certificate: Zemedelsky Vyzkumny Ustav Kromeriz s.r.o., Poland 2016 2017/1192567 Zemedelsky Vyzkumny Ustav Kromeriz s.r.o., Kromeriz, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/13	Xxx, P.	2018	GEP Certificate - ADW Agro As Krahulov Czech Republic - 2018 2019/2046744 ADW Agro A.s., Krahulov, Czech Republic no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/14	Xxx, P.	2018	Rozhodnuti InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic 2019/2055093 InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic no Unpublished	No	No	Not applicable	BASF
KCP 6.6/15	Xxx, N.	2013	GEP Certificate - Aarhus University (diseases and pests), Slagelse, Denmark 2014-2019 2014/1321454 University of Aarhus, Slagelse, Denmark no Unpublished	No	No	Not applicable	BASF
KCP 6.6/16	Xxx, N.	2013	GEP Certificate - Agronova - Gefion Field trials, Soro, Denmark, 2014 2014/1327452 Agronova - Gefion Field Trials, Soro, Denmark no Unpublished	No	No	Not applicable	BASF
KCP 6.6/17	Anonymous	2013	GEP Certificate: Agrolab A/S, Field Trials, Middelfart, Denmark, 2014 2014/1327634 Agrolab A/S, Middelfart, Denmark no Unpublished	No	No	Not applicable	BASF
KCP 6.6/18	Xxx, A.	2015	GEP Certificate: SynTech Research France SAS 2015/1093415 SynTech Research, La Chapelle de Guinchay, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/19	Anonymous	2016	GEP Certificate - Staphyt, Inchy-en-Artois, France - 2016 2016/1346288 Staphyt Sarl, Inchy en Artois, France no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/20	Anonymous	2016	GEP Certificate: Antedis, Beauvais France - 2016 2016/1350387 Antedis, Beauvais, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/21	Xxx, A.	2019	GEP Certificate: Antedis, Beauvais France - 2019-2021 2019/1078913 Antedis, Beauvais, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/22	Xxx, A.	2017	GEP Certificate - BASF France SAS Ecully France - 2017 2017/1023856 BASF Agro SAS, Ecully, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/23	Xxx, A.	2019	GEP Certificate: BASF France SAS, Ecully, France, 2019 2019/1054949 BASF France SAS, Ecully, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/24	Xxx, A.	2017	GEP Certificate: Eurofins Agrosiences Services - France - 2017-2019 2017/1140795 Eurofins Agrosience Services France (Alsace), Saint Pierre, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/25	Xxx, A.	2019	GEP Certificate - Eurofins Agro Sciences France, FR valid from 24/02/2019 to 23/02/2024 2020/2000003 Eurofins Agrosience Service France, Benfeld, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/26	Xxx, A.	2018	GEP Certificate: SynTech Research France SAS, 2018 2018/1128731 SynTech Research, La Chapelle de Guinchay, France no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/27	Xxx, A.	2018	GEP Certificate: Agrolis Consulting, Isle-sur-la-Sorgue, France 2018-2020 2018/1186469 Agrolis Consulting, Isle-Sur-La-Sorgue, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/28	Xxx, A.	2018	GEP Certificate: Centrexpe Eurl - Angerville - France - 2018-2020 2018/1219542 EURL Centrexpe, Angerville, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/29	Xxx, A.	2018	GEP Certificate - Astria 64 Castetis France - 2018-2023 2019/2053492 Astria 64 Sarl, Castetis, France no Unpublished	No	No	Not applicable	BASF
KCP 6.6/30	Xxx, H.	2013	GEP Certificate: BASF SE Agrarzentrum Limburgerhof, Germany, 2013 2013/1412362 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 6.6/31	Xxx, W.	2018	GEP Certificate - BASF SE Agrarzentrum Limburgerhof Germany - 2018 2018/1238674 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 6.6/32	Xxx J.	2019	GEP Certificate - Hetterich Fieldwork GbR Schwarzach - Germany 2019/2041586 Hetterich Fieldwork GbR, Schwarzach, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/33	Anonymous	2011	GEP Certificate - SynTech Research Hungary Kft. - Taplanszentkereszt - HU 2011 2011/1291596 SynTech Research Hungary Kft., Taplanszentkereszt, Hungary no Unpublished	No	No	Not applicable	BASF
KCP 6.6/34	Anonymous	2012	GEP Certificate: BASF Hungaria Kft, Budapest, Hungary 2012/1136722 BASF Hungaria Kft., Budapest, Hungary no Unpublished	No	No	Not applicable	BASF
KCP 6.6/35	Xxx, T.	2017	GEP Certificate - BASF Hungaria Kft - Budapest - Hungaria - 2017 2017/1077283 BASF Hungaria Kft., Budapest, Hungary no Unpublished	No	No	Not applicable	BASF
KCP 6.6/36	Xxx, M.	2016	GEP Certificate - SynTech Research Hungary Kft. Szombathely Hungary - 2016 2016/1350307 SynTech Research Hungary Kft., Szombathely, Hungary no Unpublished	No	No	Not applicable	BASF
KCP 6.6/37	Xxx, T.	2017	GEP Certificate - Agrofil-SZMI Kft. Pieski Hungary - 2017 2017/1190271 Agrofil-SZMI Kft., Pieski, Hungary no Unpublished	No	No	Not applicable	BASF
KCP 6.6/38	Xxx, M.	2014	GEP Certificate: SGS Hungaria Kft., Budapest, Hungary 2019/2039376  no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/39	Xxx, R.	2014	GEP Certificate: SIA Agrolab Baltic, Cesis, Latvia, 2014 2014/1327636 SIA Agrolab Baltic, Cesis, Latvia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/40	Xxx, R.	2019	GEP Certificate: SIA Agrolab Baltic Fungicide+Insecticide, Riga, Latvia, 2018 2019/1076012 SIA Agrolab Baltic, Riga, Latvia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/41	Xxx, R.	2016	GEP Certificate - Latvijas Augu aizsardzibas petniecias centrs, Riga, LV 2016/1350437 Latvian State Centre of Plant Protection, Riga, Latvia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/42	Xxx Xxx, E.	2013	GEP certificate - Lithuanian Institute of Agriculture, Akademija Lithuania - 2013-2019 2013/1418041 Lithuanian Institute of Agriculture, Akademija, Lithuania no Unpublished	No	No	Not applicable	BASF
KCP 6.6/43	Xxx, T.	2010	GEP Certificate - Uniwersytet Technologiczno - Przyrodniczy im. Jana i Jędrzeja Śniadeckich - Wydział Rolnictwa i Biotechnologii - Katedra Fitopatologii i Mikologii Molekularnej, Bydgoszcz, Poland 2010/1226832 <none> no Unpublished	No	No	Not applicable	BASF
KCP 6.6/44	Xxx, D.	2010	GEP Certificate - Institute of Plant Protection - National Research Institute in Poznan - Sosnowice Branch - Pesticide Efficacy Testing Department, Poland 2010/1226834 <none> no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/45	Xxx, T.	2011	GEP Certificate - Agrostat Sp. z.o.o., Poland 2011/1269203 Agrostat Sp. z o.o., Poznan, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/46	Xxx, T.	2011	GEP Certificate - BASF Polska Sp. z.o.o., Warsaw, Poland 2011/1269204 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/47	Anonymous	2011	GEP Certificate - Institut of Plant Protection - National Research Institute - Department of Plant Protection Products - Team for Fungicide Investigation, Poznan, Poland 2011/1269209 Institute of Plant Protection - National Research Institute, Poznan, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/48	Xxx, T.	2016	GEP Certificate - SGS Polska Sp. zo.o Warswa Poland - Translation 2016/1350127 SGS Polska Sp. zo.o., Warsaw, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/49	Anonymous	2017	GEP Certificate: Biotek Agriculture Polska Sp. z o.o., Olawa, Poland - 2017 2017/1230363 Biotek Agriculture Polska, Olawa, Poland no Unpublished	No	No	Not applicable	BASF
KCP 6.6/50	Anonymous	2018	GEP Certificate: AGRECO Sp. z o.o., Wroclaw, Poland 2018 2018/1181238 AGRECO Sp. z o.o., Wroclaw, Poland no Unpublished	No	No	Not applicable	BASF

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KCP 6.6/51	Xxx, E.	2015	GEP Certificate: S.C. Eurofins Agroscience Services SRL, Timisoara, Romania, 2015 2015/1174500 Eurofins Agroscience Services SRL, Timisoara, Romania no Unpublished	No	No	Not applicable	BASF
KCP 6.6/52	Xxx, D.	2016	GEP Certificate - S.C. BASF SRL Calarasi Romania - 2016 2016/1135081 S.C. BASF SRL, Calarasi, Romania no Unpublished	No	No	Not applicable	BASF
KCP 6.6/53	Xxx, B.	2016	GEP Certificate: FYSE s.r.o., Kolare, Slovakia, 2016 2016/1056229 FYSE s.r.o., Kolare, Slovakia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/54	Xxx, B.	2016	GEP Certificate - Gernerprodukt Valice OVD, Rimavska Sobota, Slovakia 2016 - Translation 2016/1273733 Gernerprodukt Valice OVD, Rimavska Sobota, Slovakia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/55	Xxx, B.	2016	GEP Certificate - UKSUP - Ustredny Kontrolny a Skusobny Ustav Polnohospodarsky, Kosice, Slovakia 2016 2016/1352907 UKSUP - Ustredny Kontrolny a Skusobny Ustav Polnohospodarsky, Kosice, Slovakia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/56	Anonymous	2017	GEP Certificate - Berberis s.r.o., Boliarov, Slovakia 2017/1224930 Berberis s.r.o., Boliarov, Slovakia no Unpublished	No	No	Not applicable	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.6/57	Anonymous	2017	GEP Certificate - NPPC - Vyskumny ustav rastlinnej vyroby Piestany, Piestany, Slovakia 2017 2017/1226421 VURV - Vyskumny Ustav Rastlinnej Vyroby Piestany, Piestany, Slovakia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/58	Xxx, P.	2018	GEP Certificate - CVRV - Vyskumno-slachtitelska stanica Viglas-Pstrusa, Detva, Slovakia 2018 2018/1127784 CVRV - Vyskumno-slachtitelska stanica Viglas-Pstrusa, Detva, Slovakia no Unpublished	No	No	Not applicable	BASF
KCP 6.6/59	Anonymous	2015	GEP Certificate: Husec AB - Bjaerred - Sweden 2015/1284713 HUSEC AB, Bjaerred, Sweden no Unpublished	No	No	Not applicable	BASF
KCP 6.6/60	Anonymous	2016	GEP Certificate - Agrolab Sverige AB - Eslov - Sweden - 2016 2016/1354368 Agrolab Sverige AB, Eslov, Sweden no Unpublished	No	No	Not applicable	BASF
KCP 6.6/61	Anonymous	2013	GEP Certificate: BASF plc, United Kingdom, 2013 2013/1060882 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	No	Not applicable	BASF
KCP 6.6/62	Anonymous	2018	GEP Certificate: BASF plc, United Kingdom, 2018 2018/1015310 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.6/63	Anonymous	2016	GEP Certificate: RSK ADAS Limited UK 2016-2018 2016/1346468 RSK ADAS Ltd., Boxworth Cambridge CB23 4NN, United Kingdom no Unpublished	No	No	Not applicable	BASF
KCP 6.6/64	Anonymous	2018	GEP Certificate: RSK ADAS Limited UK 2018-2023 2018/1106019 RSK ADAS Ltd., Boxworth Cambridge CB23 4NN, United Kingdom no Unpublished	No	No	Not applicable	BASF
KCP 7.1.1/1	Xxx, S., Xxx, S.	2019	BAS 762 02 F - Acute oral toxicity study in rats 2019/2034516 Bioassay - Labor fuer biologische Analytik GmbH, Heidelberg, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report never submitted before	BASF
KCP 7.1.4/1	Xxx, A.	2019	BAS 762 02 F in vitro skin irritation and corrosion Turnkey Testing Strategy 2019/2034428 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 7.1.5/1	Xxx, A.	2019	BAS 762 02 F in vitro eye irritation test (EIT) in reconstructed human cornea 2019/2034409 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 7.1.5/2	Xxx T.	2019	BAS 762 02 F: Isolated chicken eye test method for identifying (i) chemicals inducing serious eye damage and (ii) chemicals not requiring classification for eye Irritation or serious eye damage 2019/2040543 Phycher Bio Developpement, Martillac, France yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3/1	Xxx, S.	2019	14C-BAS 750 F in BAS 762 02 F - Study of Penetration through human Skin in vitro 2019/2038144 BASF SE, Ludwigshafen, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 7.3/2	Xxx, S., Xxx, A.	2020	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873]] - For Study BASF DocID 2019/2038144 2020/2097030 BASF SE, Ludwigshafen, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 7.3/3	Xxx, S.	2019	14C-BAS 510 F in BAS 762 02 F - Study of Penetration through human skin in vitro 2019/2040354 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 7.3/4	Xxx, S.	2020	Excel file using "efs24873-sup-0001-supinfo_1.xlsx" (version 3) to support dermal absorption calculations according to EFSA Guidance on Dermal Absorption [EFSA Journal 2017;15(6):4873]] 2020/2110168 BASF SE, Ludwigshafen, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.1.1.1/1	Xxx, I.-C.	2008	Boscalid (BAS 510 F): Study on soil degradation and long-term sorption in soil 2008/1013108 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data Protection starts with BAS 516 04 F (Bellis; R-48/2011) from 26 <sup>th</sup> June 2011.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.1.1.2.2/1	Xxx, C., Xxx, H., Xxx, T.	2009	Accumulation behaviour of BAS 510 F in soil under field conditions over several years after application onto vegetables 2009/1070939 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data Protection starts with BAS 516 04 F (Bellis; R-48/2011) from 26 <sup>th</sup> June 2011.	BASF
KCP 9.1.3/1	Xxx Xxx, E.	2021	Predicted environmental concentrations of BAS 750 F – mefentrifluconazole and its metabolite in soil following application to various crops in Europe 2020/2108239 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.1.3/2	Xxx Xxx, E.	2021	Predicted environmental concentrations of BAS 510 F - Boscalid in soil following application to various crops in Europe 2020/2108245 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.2.4/1	Xxx Xxx, T.	2021	Predicted environmental concentrations of BAS 750 F – mefentrifluconazole and its metabolite in groundwater following application to various crops in Europe 2020/2108240 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.2.4/2	Xxx Xxx, T.	2021	Predicted environmental concentrations of BAS 510 F - Boscalid in groundwater following application to various crops in Central Europe 2020/2108246 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5/1	xxx, M.	2021	Predicted environmental concentrations of BAS 750 F – mefentrifluconazole and its metabolites in surface water and sediment following application to various crops in Europe 2020/2108241 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.2.5/2	Xxx Xxx, E.	2021	Predicted environmental concentrations of BAS 510 F - Boscalid in surface water and sediment following application to various crops in Central and Northern Europe 2020/2108247 knoell Germany GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 9.2.5/3	xxx, S.	2022	Accumulation of predicted environmental concentrations of BAS 510 F - boscalid in sediment following application to cereals, oilseed rape and sunflower in Europe 2022/2017799 BASF SE Agricultural Solutions, Ecology and Environmental Analytics, Germany no Unpublished	No	No	Not applicable	BASF
KCP 10.2/1	xxx, G.	2015	Report Amendment No.1 - Chronic toxicity of BAS 750 F (Reg.No. 5834378) to Daphnia longispina in a 21 day semi-static test 2015/1251197 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with context of BAS 750 F first approval	BASF
KCP 10.2/2	xxx, K., xxx, B.	2017	Report Amendment 1: Chronic toxicity of Reg.No. 5834378 to the non-biting midge Chironomus riparius - A spiked sediment study 2017/1044236 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with context of BAS 750 F first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/3	xxx, K., xxx, B.	2017	Amendment No. 1: Chronic toxicity of Reg.No. 5924326 (M750F003; metabolite of BAS 750 F) to the non-biting midge Chironomus riparius - A spiked sediment study 2017/1044237 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before with context of BAS 750 F first approval	BASF
KCP 10.2/4	xxx, H.	2018	Amendment No. 1: BAS 750 F (Reg.No. 5834378) - Lemna gibba CPCC 310, Growth inhibition test 2018/1220943 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.2.1/1	Xxx, E.	2016	BAS 750 F - Acute toxicity study in the fathead minnow (Pimephales promelas) 2016/1155889 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> November 2019	BASF
KCP 10.2.1/2	xxx, A.	2019	Reg.No. 6003433 (metabolite of BAS 750 F) - Acute toxicity study in the rainbow trout (Oncorhynchus mykiss) 2019/1022695 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study report submitted before. Data protection starts with BAS 751 00 F (Balaya; R-174/2019) from 30 <sup>th</sup> November 2019	BASF
KCP 10.2.1/3	xxx, B.	2019	BAS 762 02 F - Acute Toxicity to Rainbow trout (Oncorhynchus mykiss) in a static 96-Hour Test 2019/1050663 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	Yes	Data/study report never submitted before	BASF

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCP 10.2.1/4	xxx, H.	2019	BAS 762 02 F - Effect on Daphnia magna in a static 48-Hour Immobilization Test 2019/1050662 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.2.1/5	xxx, H.	2020	BAS 762 02 F - Effect on Pseudokirchneriella subcapitata in a 72-hour algal growth Inhibition test 2019/1050661 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.1.1.1/1	xxx, K.	2019	BAS 762 02 F: Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions 2019/1061115 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.1.1.2/1	xxx, K.	2019	BAS 762 02 F: Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions 2019/1061115 Eurofins Agrosience Services GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.1.2/1	xxx, S.	2015	Chronic toxicity of BAS 510 01 F to the honeybee (Apis mellifera L.) under laboratory conditions 2014/1083455 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.2/2	xxx D.	2021	Chronic toxicity of BAS 762 02 F to the honey bee <i>Apis mellifera</i> L. under laboratory conditions 2020/2032682 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.1.3/1	xxx, S.	2014	Effect of Reg.No. 300355 (BAS 510 F) on survival and development of honey bee brood ( <i>Apis mellifera</i> ), using an in vitro rearing method 2013/1275399 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 10.3.1.3/2	xxx, K.	2017	Repeated exposure of honey bee ( <i>Apis mellifera</i> ) larvae in BAS 510 F (Boscalid) under laboratory conditions (in vitro) 2017/1000161 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before. Data protection starts with BAS 517 01 F (Empartis; R-140/2020) from 5 <sup>th</sup> November 2020.	BASF
KCP 10.3.1.3/3	xxx K.	2021	Repeated exposure of honey bee ( <i>Apis mellifera</i> L.) larvae to BAS 762 02 F under laboratory conditions 2020/2032683 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.1.5/1	xxx A.	2021	Effects of BAS 762 02 F on the honeybee <i>Apis mellifera</i> L. under semi-field conditions (tunnel test) with additional assessments on colony and brood development 2021/2001936 BioChem agrar Labor für biologische und chemische Analytik GmbH yes Unpublished	No	Yes	Data/study report never submitted before	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1/1	xxx U.	2019	Effects of BAS 762 02 F on the predatory mite Typhlodromus pyri Scheuten in a laboratory test 2019/1061533 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.3.2.1/2	xxx, U.	2019	Effects of BAS 762 02 F on the parasitic wasp Aphidius rhopalosiphi (DESTEFANI-PEREZ) in a laboratory test 2019/1061532 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.4.1.1/1	xxx, S.	2014	Sublethal toxicity of BAS 510 F (Boscalid) to the earthworm Eisenia fetida in artificial soil 2014/1083454 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 10.4.1.1/2	xxx, S.	2020	Effects of BAS 762 02 F on the reproduction of the earthworm Eisenia xxxi in artificial soil 2020/1000741 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.4.2.1/1	xxx, S.	2014	Effects of BAS 510 F (Boscalid) on the reproduction of the collembolan Folsomia candida 2014/1083456 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before. Data protection starts with BAS 510 01 F (Cantus; R-111/2018) from 30 <sup>th</sup> May 2018.	BASF
KCP 10.4.2.1/2	xxx, S.	2020	Effects of BAS 762 02 F on the reproduction of the collembolan Folsomia candida 2020/1000742 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4.2.1/3	xxx, L.	2020	Effects of BAS 762 02 F on the reproduction of the predatory mite Hypoaspis aculeifer 2020/1000743 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.5/1	xxx, M.	2019	Effects of BAS 762 02 F on the activity of soil microflora (Nitrogen transformation test) 2019/1061116 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.6.2/1	Xxx, A.	2020	Effect of BAS 762 02 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2020/1000745 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCP 10.6.2/2	Xxx, A.	2020	Effect of BAS 762 02 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions 2020/1000744 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report never submitted before	BASF

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review (BAS 750 F)**

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 6.1/1	xxx, B., Xxx Xxx, A.	2016	Storage Stability of BAS 750 F in plant matrices 2016/1112644 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.1/2	xxx, R.	2015	Freezer storage stability of Triazolyl lactic acid in plant samples 2015/7005764 ADPEN Laboratories Inc., Jacksonville FL, United States of America yes Unpublished	No	Yes	Data protection started with Dagonis (BAS 717 00F), Reg. No. R-36/2019, approved: 12.02.2019	BASF
KCA 6.1/3	Xxx Xxx, A., xxx, N.	2015	Storage stability of BAS 750 F in animal matrices 2015/1106711 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.1/4	xxx, N., xxx, I.	2015	Storage stability of Reg.No. 6011210 in animal matrices 2015/1106710 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.1/1	xxx, B.	2015	Metabolism of 14C-BAS 750 F in grape 2015/1073822 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.1/2	xxx, U.	2015	Metabolism of 14C LS 5834378 in wheat 2015/1001872 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.1/3	Xxx, J.	2015	Metabolism of 14C-BAS 750 F in soybean 2014/1224012 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.2/1	xxx, N.	2015	The metabolism of 14C-Reg. No 5834378 (BAS 750 F) in laying hens 2015/1001001 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.3/1	Xxx, J.	2015	The metabolism of [14C]-Reg. No. 5834378 (BAS 750 F) in lactating goats 2015/1078841 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.5/1	xxx, C., xxx, J.	2015	The metabolism of 14C-BAS 750 F in rainbow trout (Oncorhynchus mykiss) 2015/1106141 Fraunhofer-Institute for Molecular Biology and Applied Ecology, Schmallingenberg, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.1/1	Xxx, H.	2017	Study on the residue behaviour of BAS 750 F (Reg.No. 5834378) in oilseed rape after application of BAS 750 05 F under field conditions in Germany, United Kingdom and Italy, 2016 2017/1023368 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Submitted with BAS 750 11 F, evaluation ongoing.	BASF
KCA 6.3.1/2	Xxx, H.	2018	Residue of BAS 750 F (Mefentrifluconazole) in oilseed rape after application of BAS 750 05 F under field conditions in Germany, The Netherlands, Hungary, United Kingdom, Denmark, Southern France, Greece, Spain and Italy, 2017 2018/1086903 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Submitted with BAS 750 11 F, evaluation ongoing.	BASF

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KCA 6.3.2/1	xxx, S.	2017	Study on the residue behaviour of BAS 750 F (Reg. No. 5834378) on sunflower after treatment with BAS 750 05 F under field conditions in North and South Europe, season 2016 2017/1018091 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	Yes	Submitted with BAS 750 11 F, evaluation ongoing.	BASF
KCA 6.3.2/2	Xxx, O.	2018	Study on the residue behaviour of Mefentrifluconazole (BAS 750 F) on sunflower after treatment with BAS 750 05 F under field conditions in North and South Europe, season 2017 2018/1013070 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	Yes	Submitted with BAS 750 11 F, evaluation ongoing.	BASF
KCA 6.3.3/1	Xxx, H.	2015	Study on the residue behaviour of Reg.No. 5834378 (BAS 750 F) in wheat after application of EXP 5834378 F-AV (BAS 750 00 F) under field condition in Germany, The Netherlands, United Kingdom, Southern France, Greece, Italy and Spain, 2013 2014/1010809 Agro-Check Dr. Xxx & Xxx GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.3/2	xxx, E.	2015	Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to wheat in Northern and Southern Europe in 2014 2015/1099704 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.3/3	xxx, E.	2017	Report Amendment 1: Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to wheat in Northern and Southern Europe in 2014 2017/1141927 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.5.1/1	xxx, J.	2014	BAS 750 F: Hydrolysis at 90°C, 100°C and 120°C 2014/1170665 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.5.3/1	xxx, S.	2015	Determination of residues of BAS 750 F (Reg.No. 5834378) in wheat and its processed products after two applications of BAS 750 01 F in Germany, 2014 2014/1315283 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.5.3/2	xxx, L.	2016	Magnitude of the residue of BAS 750 F in soybean processed commodities following applications of BAS 750 01 F 2015/7005934 Landis International Inc., Valdosta GA, United States of America yes Unpublished	No	Yes	Submitted with BAS 750 11 F, evaluation ongoing.	BASF
KCA 6.6.1/1	xxx, W., xxx, U.	2015	Confined rotational crop study with 14C LS 5834378 2015/1001871 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2/1	xxx, T.	2015	Study on the residue behavior of BAS 750 F on the rotational crops: wheat, carrots or radish, broccoli or cauliflower and spinach or lettuce after one application of BAS 750 01 F to bare soil under field conditions, 2014-2015 2015/1106682 Agrologia SLU, Utrera, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/1	xxx, W	2015	Validation of BASF Method Number L0076/09 for the determination of BAS 750 F in citrus (whole fruit), coffee (grain), dry beans (seed), soybeans (grain), tomato (whole fruit), wheat (grain) and wheat (straw) using LC-MS/MS 2015/3001681 BASF SA, Guaratingueta, Brazil yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/2	xxx, C.	2015	Validation of the BASF analytical method L0272/01 for BAS 750 F in animal matrices 2015/1106707 CEMAS - CEM Analytical Services Ltd., Wokingham Berkshire RG41 2FD, United Kingdom yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/3	xxx, N., xxx, I.	2016	Validation of the BASF analytical method L0309/01: For the determination of M750F022 (Reg.No. 6011210) in animal matrices 2015/1106706 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/4	xxx, N.	2016	Determination of the fatty conjugates metabolites of M750F022 (Reg. No. 6011210) in animal matrices 2016/1001326 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/5	xxx, T.	2011	Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic acid by LC/DMS/MS/MS in plant materials 2012/1294644 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with Inovor (BAS 734 00 F), Reg. No. R-233/2017, approved: 21.11.2017	TDMG
KCP 5.1.2/6	xxx, P.	2009	Residue analytical method 01132 for the determination of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in/on milk, egg, muscle, fat, liver and kidney by HPLC-MS/MS (including amendment No. 1) 2010/1230632 Bayer CropScience AG, Monheim, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	TF
KCP 5.1.2/7	xxx, D.	2015	Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2015/1039006 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/8	xxx, D.	2016	Report Amendment No. 1: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2016/1030227 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/9	Xxx, M.	2016	Report Amendment No.2: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2016/1215646 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/10	xxx, D.	2016	Validation of method D1506/01: Determination of Mefentrifluconazole (BAS 750 F, Reg.No. 5834378) and its metabolites M750F003 (Reg.No. 5924326), M750F005, M750F006, M750F007 and M750F008 in surface and drinking water by LC-MS/MS 2015/7001125 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.1.2/11	Xxx, H.	2013	Validation of analytical method L0199/01 for the determination of 1,2,4-Triazole (Reg.No. 87084) in water by LC-MS/MS 2012/1297158 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/1	Xxx, S.	2015	Validation of the multi-residue method QuEChERS, BASF method number L0295/01, for the determination of BAS 750 F in different matrices of plant origin 2015/1106708 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/2	Xxx, S.	2015	Independent method validation (ILV) of the QuEChERS method for the determination of BAS 750 F in 5 plant matrices, using LC/MS/MS (BASF Method No. L0295/01) 2015/1240004 PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/3	xxx, B.	2015	Investigation of the extractability of BAS 750 F in samples from 14C plant metabolism studies 2014/1261057 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/4	xxx, C.	2015	Validation of the BASF analytical method L0272/01 for BAS 750 F in animal matrices 2015/1106707 CEMAS - CEM Analytical Services Ltd., Wokingham Berkshire RG41 2FD, United Kingdom yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/5	xxx, N., xxx, I.	2016	Validation of the BASF analytical method L0309/01: For the determination of M750F022 (Reg.No. 6011210) in animal matrices 2015/1106706 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/6	Xxx, S.	2015	Independent method validation (ILV) of a method for the determination of BAS 750 F in various foodstuffs of animal origin, using LC/MS/MS - (BASF Method No. L0272/01) 2015/1240005 PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/7	xxx, P.	2015	Independent method validation (ILV) of BASF method no. L0309/01 for the determination of the BAS 750 F diol metabolite in various foodstuffs of animal origin, using GC/MS 2015/1240006 PTRL Europe, Ulm, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/8	xxx, W., Xxx, J.	2015	Investigation of the extractability of BAS 750 F and M750F022 in samples from 14C animal metabolism studies 2015/1161960 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/9	xxx, D.	2015	Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2015/1039006 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/10	xxx, D.	2016	Report Amendment No. 1: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and its metabolites Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2016/1030227 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/11	Xxx, M.	2016	Report Amendment No.2: Validation of analytical method L0214/01 for the determination of BAS No. 750 F (Reg.No. 5834378) and metabolites of Reg.No. 5924326 and 1,2,4-Triazole (Reg.No. 87084) in soil by LC-MS/MS 2016/1215646 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/12	xxx, D.	2016	Validation of method D1506/01: Determination of Mefentrifluconazole (BAS 750 F, Reg.No. 5834378) and its metabolites M750F003 (Reg.No. 5924326), M750F005, M750F006, M750F007 and M750F008 in surface and drinking water by LC-MS/MS 2016/7010048 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/13	xxx, G.	2016	Independent laboratory validation of BASF analytical method D1506/01: Determination of BAS 750 F (Reg.No. 5834378) and its metabolites M750F003, M750F005, M750F006, M750F007 and M750F008 in surface and drinking water by LC-MS/MS 2015/7006199 Alliance Pharma Inc., Malvern PA, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/14	Xxx, M.	2015	Validation of analytical method L0327/01, for the determination of BAS 750 F in air by LC-MS/MS 2015/1111330 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 5.2/15	xxx, F.	2016	Validation of BASF Analytical Method No. L0339/01 for the determination of BAS 750 F in body fluids 2016/1148911 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 9.3/1	xxx, H.	2014	BAS 750 F - Determination of the ready biodegradability in the CO2-evolution test 2014/1239574 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

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KCP 10.1.1/1	Xxx, S.	2014	BAS 750 F - Acute toxicity in the bobwhite quail ( <i>Colinus virginianus</i> ) after single administration (LD50) 2014/1095701 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/2	Xxx, S.	2014	BAS 750 F - Acute toxicity in the mallard duck ( <i>Anas platyrhynchos</i> ) after single oral administration (LD50) 2014/1095700 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/3	Xxx, J.	2015	BAS 750 F - Acute toxicity in the canary ( <i>Serinus canaria</i> ) after single oral administration (LD50) 2015/1085493 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/4	Xxx, S.	2014	BAS 750 F - Avian dietary toxicity test in chicks of the bobwhite quail ( <i>Colinus virginianus</i> ) 2014/1127963 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/5	Xxx, S.	2014	BAS 750 F - Avian dietary toxicity test in ducklings of the mallard duck ( <i>Anas platyrhynchos</i> ) 2014/1117035 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/6	Xxx, J.	2015	Amendment No. 1 - BAS 750 F - Avian dietary toxicity test in chicks of the bobwhite quail ( <i>Colinus virginianus</i> ) 2015/1223324 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.1.1/7	xxx, J., xxx, K., xxx, L., B xxx xxx, M., xxx, S., xxx, T.	2014	BAS 750 F: A reproduction study with the Northern bobwhite 2013/1281276 Wildlife International Ltd., Easton MD, United States of America yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.1/10	xxx, K., xxx, D., xxx, A., xxx, L.	2015	BAS 750 F: A reproduction study with the mallard 2015/7005819 Wildlife International Ltd., Easton MD, United States of America yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.2/1	Xxx, S.	2013	BAS 750 F - Acute oral toxicity study in rats 2013/1149656 Bioassay - Labor fuer biologische Analytik GmbH, Heidelberg, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.2/2	Xxx, S.	2015	BAS 750 F - Two-generation reproduction toxicity study in Wistar rats - Administration via the diet 2014/1170754 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.2/3	Xxx, S.	2015	BAS 750 F - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage) 2014/1170755 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.1.2/4	Xxx, S.	2015	BAS 750 F - Prenatal developmental toxicity study in New Zealand white rabbits - Oral administration (gavage) 2014/1170757 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

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KCP 10.2/1	Xxx, E.	2014	BAS 750 F - Acute toxicity study in the rainbow trout (Oncorhynchus mykiss) 2014/1036951 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/2	Xxx, E.	2015	BAS 750 F - Acute toxicity study in the common carp (Cyprinus carpio) 2015/1249071 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/3	xxx, O.	2014	BAS 750 F: Acute toxicity to the sheepshead minnow, Cyprinodon variegatus, determined under static-renewal test conditions 2014/7002810 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/4	xxx, H.	2015	BAS 750 F (Reg.No. 5834378) - Zebrafish acute toxicity test 2015/1001581 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/5	Xxx, E.	2017	BAS 750 F - Life cycle toxicity test on the zebrafish (Danio rerio) in a flow through system 2016/1042889 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/6	Xxx, E.	2015	BAS 750 F - Early life-stage toxicity test on the zebrafish (Danio rerio) in a flow through system 2014/1262160 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/7	xxx, N.	2015	BAS 750 F: Early life-stage toxicity test with the sheepshead minnow, <i>Cyprinodon variegatus</i> , under flow-through conditions 2015/7000619 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/8	Xxx, E.	2015	BAS 750 F - Fish sexual development test on the zebrafish ( <i>Danio rerio</i> ) 2015/1099093 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/9	Xxx, E.	2015	14C-BAS 750 F (label: triazole-3(5)-C14) - Bioconcentration study in the rainbow trout ( <i>Oncorhynchus mykiss</i> ) 2015/1122811 BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/10	xxx, K.	2014	BAS 750 F (Reg.No. 5834378) - <i>Daphnia magna</i> , acute immobilization test 2013/1250866 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/11	xxx, A.	2014	BAS 750 F: Acute toxicity test with the saltwater mysid, <i>Americamysis bahia</i> , determined under flow-through test conditions 2014/7002845 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/12	xxx, A.	2015	BAS 750 F: Effect on new shell growth of the eastern oyster ( <i>Crassostrea virginica</i> ) 2015/7000021 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefenitrifluconazole first approval	BASF
KCP 10.2/13	xxx, G.	2014	Chronic toxicity of the BAS 750 F (Reg.No. 5834378) to <i>Daphnia magna</i> STRAUS in a 21 day semi-static test 2014/1098028 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefenitrifluconazole first approval	BASF
KCP 10.2/14	xxx, S.	2016	BAS 750 F: Life-cycle toxicity test of the saltwater mysid, <i>Americamysis bahia</i> , conducted under flow-through conditions 2016/7001293 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefenitrifluconazole first approval	BASF
KCP 10.2/15	Xxx, G.	2015	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to <i>Daphnia pulex</i> in a 21 day semi-static test 2015/1003913 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefenitrifluconazole first approval	BASF
KCP 10.2/16	Xxx, G.	2015	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to <i>Daphnia longispina</i> in a 21 day semi-static test 2015/1003912 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefenitrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/17	Xxx, G.	2015	Report Amendment No.1 - Chronic toxicity of BAS 750 F (Reg.No. 5834378) to Daphnia longispina in a 21 day semi-static test 2015/1251197 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/18	Xxx, R.	2015	BAS 750 F - 10-day toxicity test exposing midge (Chironomus dilutus) to a test substance applied to sediment under static-renewal conditions 2015/7000621 Smithers Viscient LLC, Wareham MA, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/19	Xxx, R.	2015	BAS 750 F - 10-Day toxicity test exposing freshwater amphipods (Hyaella azteca) to a test substance applied to sediment under static-renewal conditions 2015/7000622 Smithers Viscient LLC, Wareham MA, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/20	Xxx, R.	2015	BAS 750 F - 10-Day toxicity test exposing estuarine amphipods (Leptocheirus plumulosus) to a test substance applied to sediment under static conditions 2015/7000623 Smithers Viscient LLC, Wareham MA, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/21	xxx, K., xxx, L.	2015	Chronic toxicity of Reg.No. 5834378 to the non-biting midge Chironomus riparius - A spiked sediment study 2014/1243181 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/22	xxx, K., xxx, B.	2017	Report Amendment 1: Chronic toxicity of Reg.No. 5834378 to the non-biting midge Chironomus riparius - A spiked sediment study 2017/1044236 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/23	xxx, M.	2016	BAS 750 F - Life-cycle toxicity test exposing midges (Chironomus dilutus) to a test substance applied to sediment under static-renewal conditions following EPA test methods 2016/7006526 Smithers Viscient LLC, Wareham MA, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/24	xxx, K.	2014	BAS 750 F (Reg.No. 5834378) - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test 2013/1250865 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/25	xxx, A.	2015	BAS 750 F: Growth inhibition test with the marine diatom, Skeletonema costatum 2015/7000620 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/26	xxx, C.	2016	Recalculation of endpoints for the study Xxx A., 2015a (BASF DocID 2015/7000620): "BAS 750 F: Growth inhibition test with marine diatom, Skeletonema costatum" 2016/1292092 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/27	Xxx, A.	2015	BAS 750 F: Growth inhibition test with the freshwater diatom, Navicula pelliculosa 2015/7000618 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/28	Xxx, C.	2016	Recalculation of endpoints for the study by Xxx A., 2015b (BASF DocID 2015/7000618): BAS 750 F: Growth inhibition test with the freshwater diatom Navicula pelliculosa 2016/1292093 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 10.2/29	Xxx, A.	2015	BAS 750 F: Growth inhibition test with the cyanobacterium, Anabaena flos-aquae 2015/7000617 ABC Laboratories Inc., Columbia MO, United States of America yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/30	xxx, A.	2014	BAS 750 F (Reg.No. 5834378) - Lemna gibba CPCC 310 growth inhibition test 2014/1001322 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/31	xxx, H.	2018	Amendment No. 1: BAS 750 F (Reg.No. 5834378) - Lemna gibba CPCC 310, Growth inhibition test 2018/1220943 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/32	xxx, H.	1983	Report on the test for acute toxicity CGA 98032 to rainbow trout 1983/1000494 Ciba-Geigy AG, Basel, Switzerland no Unpublished	Yes	No	Not applicable	TDMG
KCP 10.2/33	Xxx, H.	2016	Reg.No. 5863469 (Metabolite of BAS 750 F, M750F006) - Rainbow trout, acute toxicity test 2016/1128152 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/34	Xxx, H.	2015	Reg.No. 6003432 (metabolite of BAS 750 F, M750F007) - Rainbow trout, acute toxicity test 2015/1001489 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/35	xxx, M., xxx, H.	2002	1,2,4-Triazole - Juvenile growth test, fish (Oncorhynchus mykiss) 2002/1007850 Bayer AG, Leverkusen, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	TDMG
KCP 10.2/36	xxx, G.	1995	Fluquinconazole technical material 100.8% w/w 1,2,4-Triazole: Acute toxicity to Daphnia magna 1995/1001851 Huntingdon Life Sciences Ltd., Huntingdon Cambridgeshire PE18 6ES, United Kingdom yes Unpublished	No	No	Not applicable	TDMG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/37	xxx, N.	2016	Acute toxicity of Reg.No. 5924326 /M750F003; metabolite of BAS 750 F) to Daphnia magna STRAUS in a 48 hour static test 2016/1289876 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/38	Xxx, H.	2015	Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) - Daphnia magna, acute immobilization test 2015/1001490 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/39	Xxx, H.	2015	Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - Daphnia magna, acute immobilization test 2015/1001492 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/40	xxx, K., xxx, N.	2015	Acute toxicity of Reg.No. 6003432 (M750F007; metabolite of BAS 750 F) to Daphnia magna STRAUS in a 48 hour static test 2015/1003915 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/41	Xxx, H.	2015	Reg.No. 6010286 (metabolite of BAS 750 F, M750F008) - Daphnia magna, acute immobilization test 2015/1001493 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/42	Xxx, K., Xxx, L.	2015	Chronic toxicity of Reg.No. 5924326 (M750F003; metabolite of BAS 750 F) to the non-biting midge <i>Chironomus riparius</i> - A spiked sediment study 2015/1003916 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/43	Xxx, K., xxx, B.	2017	Amendment No. 1: Chronic toxicity of Reg.No. 5924326 (M750F003; metabolite of BAS 750 F) to the non-biting midge <i>Chironomus riparius</i> - A spiked sediment study 2017/1044237 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/44	xxx, S.	2001	1,2,4-Triazole: A 96-hour toxicity test with the freshwater alga ( <i>Selenastrum capricornutum</i> ) 2001/1022266 Wildlife International Ltd., Easton MD, United States of America yes Unpublished	No	No	Not applicable	TDMG
KCP 10.2/45	Xxx, K.	2016	Effect of Reg.No. 5924326 (M750F003, metabolite of BAS 750 F) on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> 2016/1289875 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/46	Xxx, H.	2016	Reg.No. 6003433 (metabolite of BAS 750 F, M750F005) - <i>Pseudokirchneriella subcapitata</i> SAG 61.81 - Growth inhibition test 2015/1184816 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.2/47	Xxx, H.	2016	Reg.No. 5863469 (metabolite of BAS 750 F, M750F006) - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test 2015/1184815 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/48	Xxx, K.	2015	Effect of Reg.No. 6003432 (M750F007, metabolite of BAS 750 F) on the growth of the green alga Pseudokirchneriella subcapitata 2015/1003914 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.2/49	xxx, K.	2015	Reg.No. 6010286 (metabolite of BAS 750 F, M750F008) - Pseudokirchneriella subcapitata SAG 61.81 - Growth inhibition test 2015/1001491 Institute of Industrial Organic Chemistry, Pszczyna, Poland yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.3.1/1	xxx, M.	2015	Acute toxicity of BAS 750 F to the honeybee Apis mellifera L. under laboratory conditions 2015/1128674 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.3.1/2	xxx, K.	2015	Chronic toxicity of BAS 750 F (Reg.No. 5834378) to the honeybee Apis mellifera L. under laboratory conditions 2013/1235086 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1/3	Xxx, K.	2015	Acute toxicity of BAS 750 F to honeybee larvae (Apis mellifera L.) under laboratory conditions (in vitro) 2013/1235087 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.3.1/4	Xxx, S.	2015	BAS 750 F (Reg.No. 5834378) - Honey bee larvae test (repeated exposure, observation 21 days) under laboratory conditions (in vitro) - Non-GLP 2014/1327676 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCP 10.3.1/5	Xxx, S.	2017	Repeated exposure of honey bee (Apis mellifera) larvae to BAS 750 F under laboratory conditions (in vitro) 2017/1045562 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.3.1/6	xxx, K.	2015	Acute toxicity of BAS 750 F to the bumblebee Bombus terrestris L. under laboratory conditions 2014/1275250 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.3.1/7	xxx, S., xxx, T.	2008	Effects of BAS 490 F (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory 2008/1010702 Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with the EU-approval of Kresoxim-methyl	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4/1	Xxx, S.	2015	Acute toxicity of BAS 750 F to the earthworm <i>Eisenia fetida</i> in artificial soil with 10% peat 2015/1003342 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.4/2	Xxx, S.	2013	Sublethal toxicity of Reg.No. 5834378 (BAS 750 F) to the earthworm <i>Eisenia fetida</i> in artificial soil 2013/1235075 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.4/3	xxx, T., xxx, A.	2004	1,2,4-Triazole: Reproduction toxicity to the earthworm <i>Eisenia fetida</i> in artificial soil 2004/1041154 Bayer CropScience AG, Monheim, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	TDMG
KCP 10.4/4	Xxx, S.	2013	Effects of BAS 750 F on the reproduction of the collembolan <i>Folsomia candida</i> 2013/1235081 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.4/5	Xxx, T., Xxx, A.	2002	1,2,4-Triazole: Acute and reproduction toxicity to the collembolan species <i>Folsomia candida</i> according to the ISO guideline 11267 Soil quality - Inhibition of reproduction of collembola ( <i>Folsomia candida</i> ) by soil pollutants (1999) 2002/1007851 ECT Oekotoxikologie GmbH, Floersheim, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	TDMG

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4/6	Xxx, L.	2014	Effects of BAS 750 F on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 2013/1235082 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.4/7	Xxx, L.	2014	CGA71019 - Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 2014/1326895 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	TDMG
KCP 10.5/1	Xxx, L.	2015	Effects of BAS 750 F (Reg.No. 5834378) on the activity of soil microflora (Nitrogen transformation test) 2015/1108623 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCP 10.5/2	xxx, W.	2000	The effects of CGA71019 on soil respiration and nitrification 2000/1021861 RCC Ltd., Itingen, Switzerland yes Unpublished	No	No	Not applicable	TDMG
KCP 10.5/3	Xxx, L.	2015	Effects of BAS 750 F (Reg.No. 5834378) on the activity of soil microflora (Carbon transformation test) 2015/1108621 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review (BAS 510 F)**

<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>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>
KCA 6.1/1	Xxx, H., Rabe, U.	2001	Metabolism of 14C-BAS 510 F in grapevine 2000/1014860 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.1/2	xxx, H., Xxx, C.	2001	Investigation of the stability of residues of BAS 510 F in plant matrices under normal storage conditions 2001/1015028 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.1/3	Xxx, F.	2001	Investigation of the stability of residues of BAS 510 F and M510F01 in sample materials of animal origin under usual storage conditions 2000/1017229 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.2.1/1	Xxx, H., xxx, U.	2001	Metabolism of 14C-BAS 510 F in grapevine 2000/1014860 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.2.1/2	xxx, R.	1999	Metabolism of BAS 510 F in lettuce 1999/11240 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.2.1/3	xxx, P.	2001	Metabolism of 14C-BAS 510 F in beans 2000/1014861 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.2/1	xxx, W., xxx, D.	2000	Nature of residues of 14C-BAS 510 F in laying hens 2000/5154 BASF Corporation Agricultural Products Center, Research Triangle Park NC 27709, United States of America yes Unpublished	Yes	No	Not applicable	BASF
KCA 6.2.3/1	xxx, H., xxx, E.	2000	14C-BAS 510 F - Absorption, distribution and excretion after repeated oral administration in lactating goats 2000/1012353 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCA 6.2.3/2	Xxx, E., Xxx, F.	2001	The metabolism of 14C - BAS 510 F in lactating goat 2000/1017221 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCA 6.2.3/3	Xxx, E.	2019	The Metabolism of 14C - BAS 510F in Lactating Goat 2019/2046268 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	Yes	Data/study submitted before in the context of Boscalid reregistration	BASF
KCA 6.2.5/1	xxx, S.	2000	Bioaccumulation and metabolism of (14C)-BAS 510 F in rainbow trout 2000/1017222 Inveresk Research, Tranent East Lothian EH33 2NE, United Kingdom yes Unpublished	Yes	No	Not applicable	BASF
KCA 6.5.1/1	xxx, J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C 1998/10878 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.3/1	xxx, S., xxx, P.	2001	The magnitude of BAS 510 F residues in canola seed processed fractions A BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with Efiflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.5.3/2	xxx, G.	2003	Determination of the residues of BAS 510 F and Epoxiconazole in winter wheat processing products following double application of BAS 549 KA F in Germany 2003/1000945 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.6.1/1	xxx, R., xxx, P.	2001	Confined rotational crop study with 14C-BAS 510 F 2000/1014862 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.6.1/2	xxx, R., xxx, P.	2002	Report amendment No. 1: Confined rotational crop study with 14C-BAS 510 F 2002/1004122 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with Efiflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/1	xxx, H., Xxx, C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000 2000/1014853 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2/2	xxx, H., Xxx, C.	2001	Report amendment No. 1 to final report: Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000 2001/1000989 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCA 6.6.2/3	Xxx, J.	2002	Cereal grains and soybean field rotational crop study for BAS 510 F 2002/5001341 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with Eflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/4	Xxx, J.	2002	Field rotational study for BAS 510 F on grasses, alfalfa and clover as livestock feed crops 2002/5002063 BASF Corp., Princeton NJ, United States of America yes Unpublished	No	Yes	Data protection started with Eflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/5	xxx, S., xxx, D.	2001	Limited rotational crop study for the use of BAS 510 F 2001/5000966 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with Eflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/6	xxx, S., xxx, P.	2002	Magnitude of the residue of BAS 510 F in peas and beans planted as rotational crops and of BAS 500 F in peas and beans when applied as a foliar spray 2001/5003311 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with Eflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2/7	xxx, R.	2003	Sugar beet, garden beet and turnip field rotational crop study for BAS 510 02 F residues 2002/5004273 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data protection started with Efiflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/8	Xxx, J.	2003	Study on the residue behavior of Boscalid (BAS 510 F) on succeeding crops after application of BAS 510 01 F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002 2003/1001358 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with Efiflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF
KCA 6.6.2/9	xxx, T., xxx, E.	2008	Study on the residue behavior of BAS 510 F on the rotational crop: Carrots, after the application to the soil of BAS 510 01 F under field conditions in France (South), Germany, Netherlands and Spain, 2007 2008/1036949 Agrologia SL, Palomares, Spain yes Unpublished	No	Yes	Data protection started with Efiflor 193 SC (BAS 664 00 F), Reg. No. R-101/2013, approved: 20.06.2013	BASF



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/1	xxx, H., Xxx, C.	2001	Determination of the stability of 205259 (BAS 480 F), 242009 (BAS 490 F), 285028 (BAS 505 F) and 300355 (BAS 510 F) in different solvents 2000/1014856 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/2	Xxx, F.	2001	The stability of BAS 510 F and the metabolites M510F01, M510F49, M510F51 and M510F53 in acetonitrile 2000/1017225 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/3	xxx, M.	2001	Investigations on the extractability of 14C-BAS 510 F residues from plant matrices 2001/1001739 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/4	Xxx, F.	2001	The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2000/1017223 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/5	Xxx, W.	1998	Validation of analytical method No. 408/1 GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction 1998/11314 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/6	Xxx, W.	1998	Validation of analytical method No. 411 - Determination of BAS 510 F ai residues in water 1998/10922 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/7	Xxx, C.	2003	Report amendment No. 1 to final report: Validation of analytical method No. 411 - Determination of BAS 510 F ai residues in water 2003/1000976 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/8	Xxx, C.	2001	Validation of analytical method No. 411/0 - GC/MS determination of BAS 510 F ai residues in surface water 2001/1008955 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/9	Xxx, C.	2003	Report amendment No. 1 to final report: Validation of analytical method No. 411/0 - GC/MS determination of BAS 510 F ai residues in surface water 2003/1000975 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.1.2/10	Xxx, H.	2009	Validation of analytical method L0127/1 for the determination of BAS 510 F (Boscalid) residues in surface water and groundwater 2008/1086809 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with Cantus (BAS 510 01 F), Reg.No. R-111/2018; approved: 30.05.2018	BASF
KCP 5.1.2/11	Xxx, F.	2004	Report amendment No. 1: The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2003/1021922 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection started with Cantus (BAS 510 01 F), Reg.No. R-111/2018 approved: 30.05.2018	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/1	xxx, R., xxx, S.	1999	Validation of DFG method S 19 for the determination of BAS 510 F in various plant materials 1999/11461 Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/2	xxx, N.	2001	Independent laboratory validation of a method of analysis for the determination of BAS 510 F in white cabbage, rape (seed), hop and lettuce 2000/1014886 Institut Fresenius Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/3	xxx, M.	2001	Investigations on the extractability of 14C-BAS 510 F residues from plant matrices 2001/1001739 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/4	xxx, P.	2001	Metabolism of 14C-BAS 510 F in beans 2000/1014861 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/5	Xxx, H., xxx, U.	2001	Metabolism of 14C-BAS 510 F in grapevine 2000/1014860 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/6	xxx, R., xxx, P.	2001	Confined rotational crop study with 14C-BAS 510 F 2000/1014862 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

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KCP 5.2/7	xxx, R.	1999	Metabolism of BAS 510 F in lettuce 1999/11240 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/8	xxx, T.	2001	Assessment and validation of the adapted multi-residue method DFG S19 for the determination of BAS 510 F and its metabolite M510F01 in animal matrices 2000/1017227 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/9	xxx, K.	2001	Independent laboratory validation of the adapted multi- residue method DFG S19 for the determination of BAS 510 F and its metabolite M510F01 in animal matrices (PTRL europe study No. P453G) 2000/1017226 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/10	Xxx, F.	2001	The validation of BASF method 471/0: The determination of BAS 510 F and the metabolite M510F01 in animal matrices 2000/1017223 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/11	Xxx, E., Xxx, F.	2001	The metabolism of 14C - BAS 510 F in lactating goat 2000/1017221 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 5.2/12	Xxx, W.	1998	Validation of analytical method No. 408/1 GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction 1998/11314 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

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KCP 5.2/13	Xxx, C.	2003	Report amendment No. 1 to final report: Validation of analytical method No. 408/1 GC-MS determination of BAS 510 F active ingredient residues in soil and sediment after methanol extraction 2003/1000977 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 5.2/14	xxx, W.	2000	Validation of analytical method 460: Determination of BAS 510 F (Reg.No. 300 355) in air by GC-MS 2000/1014992 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 9.3/1		1999	Determination of the biodegradability of BAS 510 F in the manometric respirometry test according to GLP, EN 45001 and ISO 9002 1999/10290 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.1.1/1	Xxx, S.	1999	BAS 510 F - Avian single-dose oral LD50 on the bobwhite quail (Colinus virginianus) 1999/11115 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.1/2	Xxx, S.	2000	1-generation reproduction study on the bobwhite quail (Colinus virginianus) by administration in the diet 2000/1017245 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF

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KCP 10.1.1/3	Xxx, S.	2000	Amendment No. 1: BAS 510 F - 1 Generation reproduction study in the bobwhite quail (Colinus virginianus) by administration in the diet 2000/1017168 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.1/4	Xxx, S.	2000	BAS 510 F - 1-Generation reproduction study on the mallard duck (Anas platyrhynchos L.) by administration in the diet 2000/1018527 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.2/1	xxx, J., xxx, C.	1998	BAS 510 F - Acute oral toxicity in rats 1998/10643 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.2/2	xxx, K.	2001	BAS 510 F - Two-generation reproduction toxicity study in Wistar rats - Continuous dietary administration 2001/1000117 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.2/3	xxx, K., xxx, J.	2000	BAS 510 F - Prenatal developmental toxicity study in Wistar rats - Oral administration (gavage) 2000/1015001 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.1.2/4	xxx, K., xxx, J.	2000	BAS 510 F - Prenatal developmental toxicity study in Himalayan rabbits. Oral administration (gavage) 2000/1013425 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF

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KCP 10.2/1	Xxx, S.	2001	Acute toxicity study on the rainbow trout ( <i>Oncorhynchus mykiss</i> WALBAUM 1792) in a static system (96 hours) 2001/1001726 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.2/2	Xxx, S.	1999	BAS 510 F - Early life-stage toxicity test on the rainbow trout ( <i>Oncorhynchus mykiss</i> WALBAUM 1792) 1999/11847 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	Yes	No	Not applicable	BASF
KCP 10.2/3	xxx, P.	2001	Effect of BAS 510 F on the immobility of <i>Daphnia magna</i> STRAUS in a 48 hour static, acute toxicity test 2000/1018537 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.2/4		2000	BAS 510 F - Determination of the chronic effect on the reproduction of the water flea <i>Daphnia magna</i> STRAUS 2000/1018539 BASF AG, Ludwigshafen/Rhein, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.2/5	xxx, P.	2001	Effects of BAS 510 F on the development of sediment dwelling larvae of <i>Chironomus riparius</i> in a water-sediment system 2000/1018538 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.2/6	Xxx, L.	2005	Chronic toxicity of Boscalid (BAS 510 F) to the non-biting midge <i>Chironomus riparius</i> exposed via spiked-sediment 2005/1022464 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF

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KCP 10.2/7	xxx, J.	2001	Effect of BAS 510 F on the growth of the green alga Pseudokirchneriella subcapitata 2000/1018524 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.3.1/1	xxx, D.	1999	Effect of Reg.No. 300 355 on the Honeybee (Apis mellifera L.) in laboratory trials 1999/10823 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.4/1	xxx, U.	1999	Acute toxicity (14 days) of BAS 510 F to the earthworm Eisenia fetida (Savigny 1826) in artificial Soil 1999/10816 IBACON GmbH yes Unpublished	No	No	Not applicable	
KCP 10.5/1	xxx, S.	2001	Assessment of the side effects of BAS 510 01 F on the activity of the soil microflora - Nitrogen turnover 2000/1018517 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.5/2	xxx, S.	2001	Report amendment No. 1 to study 20001059/01-ABMF: Assessment of the side effects of BAS 510 01 F on the activity of the soil microflora - Nitrogen turnover 2001/1014651 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Boscalid reregistration	BASF



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KCP 10.5/3	Xxx, S.	2001	Assessment of the side effects of BAS 510 01 F on the activity of the soil microflora - Short-term respiration 2000/1018516 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	No	Not applicable	BASF
KCP 10.5/4	Xxx, S.	2001	Report amendment No. 1 to study 20001059/02-ABMF: Assessment of the side effects of BAS 510 01 F on the activity of the soil microflora - Short-term respiration 2001/1014649 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Boscalid reregistration	BASF

**List of data submitted by the applicant and not relied on**

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**List of data relied on and not submitted by the applicant, but necessary for evaluation**

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