FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: BAS 765 00 F

Product name(s): Daxur

Chemical active substance(s):

Mefentrifluconazole, 100 g/L

Kresoxim-methyl, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: December 2020

MS Finalisation date: 03/11/2021

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2100368
12/2020	Submission to the Polish Ministry of Agriculture and Rural Development
02/2021	Submission to the evaluation unit: Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

Table of Contents

9 Ecotoxicology (KCP 10)

Review Comments:

This application was submitted by BASF Agro B.V. for approval of Daxur (BAS 765 00 F) a SC product containing 100 g/L Mefentrifluconazole and 150 g/L Kresoxim-methyl, as a fungicide in cereals.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	For Fusarium Head Blight control, only one application at BBCH 61-69.							
2	CZ	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35								
3	CZ	rye SECCW SECCS SECCE	F	Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35								
4	CZ	triticale TTLWI TTLSO	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	For Fusarium Head Blight control, only one application at BBCH 61-69.							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
5	HU	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 b) 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
6	HU	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35								
7	HU	rye SECCW SECCS SECCE		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.							
8	HU	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
9	PL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 b) 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
10	PL	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 69	a) 2 b) 2	14	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35								
11	PL	rye SECCW SECCS SECCE	F	Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 2 b) 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.							
12	PL	triticale TTLWI TTLSO	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 69	a) 2 b) 2	14*	a) 1.00 b) 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.							
13	RO	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 b) 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
14	RO	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35								
15	RO	rye SECCW SECCS SECCE		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.							
16	RO	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
17	SI	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 b) 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
18	SI	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35								
19	SI	rye SECCW		B. graminis - ERYSGR	Spraying	30 - 49	a) 1	14*	a) 0.60 - 1.00	a) 0.100 / 0.150	100 - 300	35	*if first application after BBCH 49; min.							

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
		SECCS SECCE		R. secalis - RHYNSE Puccinia recondita - PUCCRE			b) 1		b) 0.60 - 2.00	b) 0.200 / 0.300			21 days spray interval.							
20	SI	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
21	SK	wheat TRZAW, TRZAS TRZDU, TRZSP	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	Spraying	30 - 69	a) 2 b) 2	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
22	SK	barley HORVW HORVS	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35								

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
23	SK	rye SECCW SECCS SECCE		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval.							
24	SK	triticale TTLWI TTLSO		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.							
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (zonal uses)																				
5																				
6																				
Minor uses according to Article 51 (interzonal uses)																				
7																				
8																				

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

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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use

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

Remarks table:

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

9.1.1 Overall conclusions

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

9.1.1.1.1 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 kresoxim-methyl exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Drinking water risk assessment
Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 765 00 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 below 50 for kresoxim-methyl, a quantitative risk assessment for the proposed use pattern of BAS 765 00 F is not necessary.

Secondary poisoning and biomagnification
The log P_{OW} of both mefentrifluconazole and kresoxim-methyl was determined to be 3.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier1 risk assessment for earthworm- and fish-eating birds, the TER values for mefentrifluconazole and kresoxim-methyl are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and kresoxim-methyl was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion
It can be concluded that the risk to birds from application of BAS 765 00 F according to good agricultural practice is acceptable.

9.1.1.1.2 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 kresoxim-methyl exceed the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Drinking water risk assessment
Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 765 00 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 below 50 for kresoxim-methyl, a quantitative risk assessment for the proposed use pattern of BAS 765 00 F is not necessary.

Secondary poisoning and biomagnification
The log P_{OW} of both mefentrifluconazole and kresoxim-methyl was determined to be 3.4, which triggers an assessment of the potential risk from secondary poisoning. According to the tier1 risk assessment for earthworm- and fish-eating mammals, the TER values for mefentrifluconazole and kresoxim-methyl are both above the trigger value of 5 for acceptability of effects. The potential for bioaccumulation of both mefentrifluconazole and kresoxim-methyl was considered low in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion
It can be concluded that the risk to mammals from application of BAS 765 00 F according to good agricultural practice is acceptable.

9.1.1.1.3 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 kresoxim-methyl, the active substances in the formulation BAS 765 00 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).

Reference
US-EPA 2004. Overview of the ecological risk assessment process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances; Office of Pesticide Programs, Washington, D.C. 92 pp.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

The standard risk assessment for the active substances mefentrifluconazole and kresoxim-methyl indicate an acceptable risk for all groups of aquatic organisms following the intended uses of BAS 765 00 F in 'spring and winter cereals', if a 10 m vegetated buffer zone is considered.

The PEC/RAC ratios for the relevant metabolites of mefentrifluconazole and kresoxim-methyl are significantly below the trigger of 1 based on standard worst-case calculation; they are thus considered not to be of ecotoxicological relevance and well covered within the assessment of the parent compound.

The formulation risk assessment revealed an acceptable risk to aquatic organisms following the intended uses of BAS 765 00 F in 'spring and winter cereals'.

The standard and refined risk assessment provided for the fungicidal product BAS 765 00 F, the active substances mefentrifluconazole and kresoxim-methyl as well as their major metabolites demonstrate that the application of BAS 765 00 F in 'spring and winter cereals' according to good agricultural practice is of low risk to aquatic ecosystems, if 10 m non-sprayed, vegetated buffer zone is considered.

9.1.1.3 Effects on bees (KCP 10.3.1)

The risk to honey bees from the use of mefentrifluconazole, kresoxim-methyl and BAS 765 00 F was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (HQ) for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) [*OEPP/EPPO, 2010: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10 (3), Bulletin OEPP/EPPO Bulletin 40, 323–331*]. Furthermore, under Regulation (EC) No 1107/2009, no risk assessment scheme exists currently for chronic honey bee or honey bee larvae studies. In the absence of clear guidance (noted and agreed by member states) a preliminary risk assessment according to the current legal requirements (SANCO/10329/2002 and EPPO 2010) has been conducted.

The hazard quotients for BAS 765 00 F and the active substances mefentrifluconazole and kresoxim-methyl for acute oral and acute contact exposure of honey bees are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50. Additionally, the chronic TER for larvae and adult bees exceed the suggested trigger. Considering the very protective assumptions the risk can be considered acceptable.

Based on these results it can be concluded that low risk to honey bees is expected from applications of BAS 765 00 F according to the proposed uses. This is confirmed by a worst case assessment following EPPO (2010) for chronic adult and honey bee larvae.

No studies on chronic effects of the formulation to adult bees or to larvae were provided in the risk assessment to bees, although this is a data requirement set by the Commission Regulation (EU) 284/2013. Concerned Member States must decide on the consideration of data requirements on national level. For Poland, the deficiencies need to be fill by 31.12.2021.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002). The risk assessment for BAS 765 00 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 risk for non-target arthropods is expected from the use of BAS 765 00 F according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

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

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 765 00 F, mefentrifluconazole, kresoxim-methyl 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 765 00 F, mefentrifluconazole, kresoxim-methyl 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 765 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate.

Effects on soil microbial activity

The potential risk of BAS 765 00 F, mefentrifluconazole, kresoxim-methyl and the relevant metabolites to soil micro-organisms was assessed by comparing the maximum PEC_{soil} values with the maximum concentration with effects ≤ 25%.

For the formulation BAS 765 00 F, the active substances mefentrifluconazole, kresoxim-methyl 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 765 00 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

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

The toxicity of BAS 765 00 F to non-target terrestrial plants has been investigated by carrying out vegetative vigor and seedling emergence studies with up to six dicotyledonous and four monocotyledonous non-target plant species. Plants showed no sensitivity to pre- and post-emergence exposure at the highest concentration tested.

The risk assessment is 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 is calculated using the 90th percentile estimates in Appendix IV of ESCORT 2. For a single application to field crops, 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 765 00 F is used to calculate the maximum off-field predicted environmental rate ($PER_{off\text{-}field}$). The potential risk of BAS 765 00 F to non-target plants was assessed by comparing the calculated PER value to the ER_{50} 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 765 00 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 765 00 F applications are not required for the protection of terrestrial non-target plants.

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

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

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

Table 9.1-2: Critical use pattern of BAS 765 00 F grouped according to worst-case application

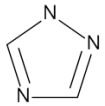
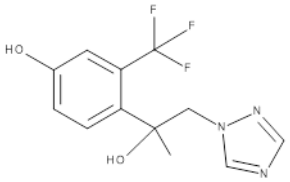
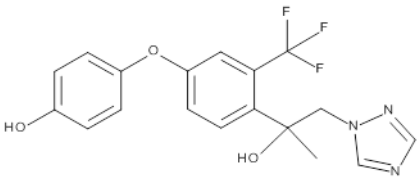
Grouping according to worst-case application				
Area	**Group**	**Intended uses**	**Relevant use parameters for grouping**	**Relevant parameter or value for sorting**
Birds & terrestrial vertebrates other than birds	Application rate	All intended uses	Risk assessments are based on the maximum application rate of 2 x 1.00 L formulation/ha (corresponding to 0.1 kg mefentrifluconazole/ha and 0.15 kg kresoxim-methyl/ha), with a 14-day application interval and BBCH 30-69	Maximum application rate = 2 x 1.00 L formulation/ha, with a 14-day application interval and BBCH 30-69
Aquatic organisms	Application rate	Spring and winter cereals	In the context of a risk envelope approach, the PEC values used for the risk assessment of mefentrifluconazole were calculated for single and twofold application with an application interval of 14 days, covering all proposed application scenarios.	Worst-case PEC values resulting from calculations for single and twofold application
	Application rate	Spring and winter cereals	In the context of a risk envelope approach, worst-case the PEC values for metabolites of mefentrifluconazole from single and twofold application in spring and winter cereals were used for the risk assessment.	Worst-case PEC values resulting from single and twofold application in spring and winter cereals
	Application rate	Spring and winter cereals	In the context of a risk envelope approach, worst-case the PEC values for metabolites of kresoxim-methyl from single and twofold application in spring and winter cereals were used for the risk assessment.	Worst-case PEC values resulting from single and twofold application in spring and winter cereals
	Application rate	Spring and winter cereals	In the context of a risk envelope approach, worst-case PEC for the formulation BAS 765 00 F resulting from the highest values for each	Worst-case PEC values resulting from the highest values for each scenario for each use

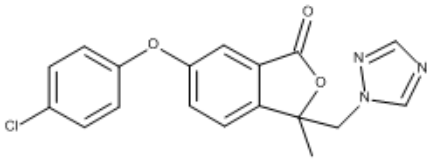
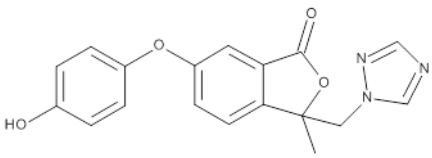
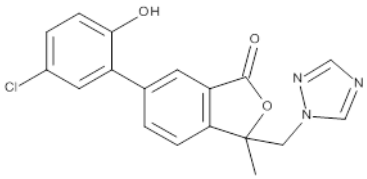
Grouping according to worst-case application				
Area	**Group**	**Intended uses**	**Relevant use parameters for grouping**	**Relevant parameter or value for sorting**
			scenario for each use were used for risk assessment.	
Bees. non-target plants	Application rate	All intended uses	Risk assessments are based on the maximum single application rate of 1 x 1.00 L/ha (corresponding to 0.1 kg mefentrifluconazole/ha and 0.15 kg kresoxim-methyl/ha)	Maximum single application rate = 1.00 L/ha
non-target arthropods, soil macro- and micro-organisms	Application rate	All intended uses	Risk assessments are based on the maximum application rate of 2 x 1.00 L/ha (corresponding to 0.1 kg mefentrifluconazole/ha and 0.15 kg kresoxim-methyl/ha)	Maximum application rate = 2 x 1.00 L/ha

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below (Table 9.1-3 and Table 9.1-4). The need for conducting a metabolite-specific risk assessment in the context of the evaluation of BAS 765 00 F is indicated in the tables.

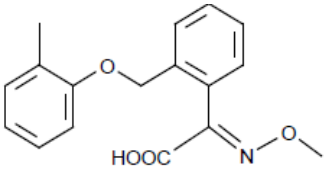
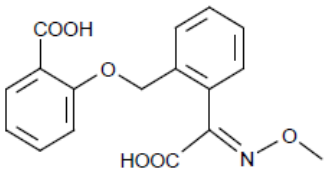
Table 9.1-3 Metabolites of mefentrifluconazole

Metabolite	Chemical structure	Molar mass [g mol-1]	Maximum observed occurrence in compartments [%]	Exposure assessment required due to
M750F001 (1,2,4-triazole)		69.1	Soil: 5.1[a] Water: 10.2 Sediment: 4.9 Total w/s system: 15.1	**Terrestrial** Metabolite relevant for RA: yes RA conducted: yes **Aquatic** Metabolite relevant for RA: yes RA conducted: yes
M750F003		287.2	Soil: 1.8 Water: 3.8 Sediment: 5.4 Total w/s system: 8.5	**Terrestrial** Metabolite relevant for RA: no RA conducted: no **Aquatic** Metabolite relevant for RA: yes RA conducted: yes
M750F005		379.3	Soil: not detected in soil Water: 32.2 (max. in aqueous photolysis study) Sediment: not detected in sediment Total w/s system: not detected in w/s study	**Terrestrial** Metabolite relevant for RA: no RA conducted: no **Aquatic** Metabolite relevant for RA: yes RA conducted: yes

Metabolite	Chemical structure	Molar mass [g mol-1]	Maximum observed occurrence in compartments [%]	Exposure assessment required due to
M750F006		355.8	Soil: not detected in soil Water: 30.7 (max. in aqueous photolysis study) Sediment: not detected in sediment Total w/s system: not detected in w/s study	**Terrestrial** Metabolite relevant for RA: no RA conducted: no **Aquatic** Metabolite relevant for RA: yes RA conducted: yes
M750F007		337.3	Soil: not detected in soil Water: 43.9 (max. in aqueous photolysis study) Sediment: not detected in sediment Total w/s system: not detected in w/s study	**Terrestrial** Metabolite relevant for RA: no RA conducted: no **Aquatic** Metabolite relevant for RA: yes RA conducted: yes
M750F008		355.8	Soil: not detected in soil Water: 7.3 (max. in aqueous photolysis study) Sediment: not detected in sediment Total w/s system: not detected in w/s study	**Terrestrial** Metabolite relevant for RA: no RA conducted: no **Aquatic** Metabolite relevant for RA: yes RA conducted: yes

[a] The metabolite was observed at a single time point above 5% in one soil (max. 5.1% at 90 d with subsequent decline – average of two replicates). For precautionary reasons, it was included in the exposure assessment for soil and groundwater

Table 9.1-4 Metabolites of kresoxim-methyl

Metabolite	Chemical structure	Molar mass (g/mol)	Maximum observed occurrence in compartments	Risk assessment required?
BF 490-1 acid of kresoxim-methyl		299.3	**Soil**: max. 84% after 3 days (aerobic laboratory degradation study) **Water**: max. 68.3% after 7 days (water / sediment study) **Sediment**: max. 17.5% after 14 days (water / sediment study) **Total water/sediment system:** max. 81.2% after 7 days (water / sediment study)	**Aquatic** Metabolite relevant for RA: yes RA conducted: yes **Terrestrial**: Metabolite relevant for RA: yes RA conducted: yes
BF 490-5 diacid of kresoxim-methyl		329.3	**Soil**: max. 4.3% * **Water**: not found **Sediment**: not found	**Aquatic** Metabolite relevant for RA: yes RA conducted: yes PEC_{sed}: yes (runoff and drainage) **Terrestrial**: Metabolite relevant for RA: yes RA conducted: yes

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with mefentrifluconazole and kresoxim-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

The selection of studies and endpoints for the risk assessment for mefentrifluconazole (Table 9.2-1) and kresoxim-methyl (Table 9.2-2) is in line with the results of the EU review process. Justifications are provided below.

Table 9.2-1: Mefentrifluconazole: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Mefentrifluconazole	Oral, 1 d Acute	LD_{50} = 816 mg/kg bw	EFSA Journal 2018;16(7):5379 [2014/1095701]
Anas platyrhynchos	Mefentrifluconazole	Oral, 1 d Acute	LDD_{50} > 2000 mg/kg bw	EFSA Journal 2018;16(7):5379 [2014/1095700]
Serinus canaria	Mefentrifluconazole	Oral, 1 d Acute	LD_{50} > 2860 mg/kg bw	EFSA Journal 2018;16(7):5379 [2015/1085493]
Colinus virginianus	Mefentrifluconazole	Dietary, 8d Short-term	LC_{50} = 6377 mg/kg diet LDD_{50} = 858 mg/kg bw/d	DAR (2017) [2014/1127963, amendment 2015/1223324]
Anas platyrhynchos	Mefentrifluconazole	Dietary, 8d Short-term	LC_{50} = 8347 mg/kg diet LDD_{50} = 1213 mg/kg bw/d	DAR (2017) [2014/1117035]
Colinus virginianus	Mefentrifluconazole	Dietary Reproductive toxicity	NOEL = 25.3 mg/kg bw/d	EFSA Journal 2018;16(7):5379 [2013/1281276]
Anas platyrhynchos	Mefentrifluconazole	Dietary Reproductive toxicity	NOEL = 80.5 mg/kg bw/d	EFSA Journal 2018;16(7):5379 [2015/7005819]
Endpoint used for acute risk assessment	**Mefentrifluconazole**	**Oral, 1d Acute**	**LD_{50} = 816 mg/kg bw**	**EFSA Journal 2018;16(7):5379 [2014/1095701]**
Endpoint used for reproductive risk assessment	**Mefentrifluconazole**	**Dietary Reproductive toxicity**	**NOEL = 25.3 mg/kg bw/d**	**EFSA Journal 2018;16(7):5379 [2013/1281276]**

Table 9.2-2: Kresoxim-methyl: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
Colinus virginianus	Kresoxim-methly	Oral, 1 d Acute	LD_{50} > 2150 mg/kg bw	EFSA Journal 2010;8(11):1891 [1993/10286]
Colinus virginianus	Kresoxim-methyl	Dietary Reproductive toxicity	NOEL = 51.7 mg/kg bw/d	EFSA Journal 2010;8(11):1891 [1994/10877]
Endpoint used for acute risk assessment	**Kresoxim-methyl**	**Oral, 1d Acute**	**LD_{50} (extrapolated) = 4059.2 mg/kg bw**	**Extrapolation of quail LD_{50} [1993/10286]**
Endpoint used for reproductive risk assessment	**Kresoxim-methyl**	**Dietary Reproductive toxicity – tier1**	**NOEL = 51.7 mg/kg bw/d**	**EFSA Journal 2010;8(11):1891 [1994/10877]**

Metabolites

Metabolites of mefentrifluconazole

According to the EFSA conclusion regarding the peer review of mefentrifluconazole (EFSA Journal 2018; 16(7): 5379), it was concluded that no specific risk assessment for birds and mammals for any of the mefentrifluconazole metabolites is necessary. Therefore, no risk assessment for metabolites is presented in this dossier.

Metabolites of kresoxim-methyl

According to the EFSA conclusion regarding the peer review of kresoxim-methyl (EFSA scientific report 2010; 8(11): 1891), the risk of the plant metabolites of kresoxim-methyl can be considered to be covered by the risk assessment of the active substance for both birds and mammals.

Formulation toxicity

No acute bird study with the formulation has been carried out. An acute oral rat study with BAS 765 00 F resulted in LD_{50} > 5000 mg formulation/kg bw with no mortality observed (BASF DocID 2019/2034513; see chapter 6.3 and Appendix 2 of chapter 6). Since the formulation shows no evidence of increased toxicity compared to the active substances (mefentrifluconazole LD_{50} > 2000 mg a.s./kg bw and kresoxim-methyl LD_{50} > 5000 mg a.s./kg bw), toxicity can reliably be predicted on the basis of the data for the active substances and no acute oral test with birds on the product is necessary according to EU Commission Regulation 284/2013.

9.2.1.1 Justification for new endpoints

Mefentrifluconazole

Acute – Not applicable. Endpoint is EU agreed.

Reproductive – Not applicable. Endpoint is EU agreed.

Kresoxim-methyl

Acute – Because no mortality or signs of toxicity occurred in the quail acute study (BASF DocID 1993/10286), the endpoint (LD_{50} > 2150 mg/kg bw) was extrapolated to LD_{50} = 4059.2 mg/kg bw.

Reproductive – Not applicable. Endpoint is EU agreed.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Proposed use pattern for the risk assessments

The proposed use pattern for the use in BAS 765 00 F is summarized in Table 9.2-3. The detailed use pattern table is presented at the beginning of the ecotoxicology chapter (section 9.1).

Table 9.2-3: Proposed use pattern

Crops as listed in GAP	Crop group [EFSA/2009/1438]	Application time [BBCH growth stage]	Number of applications	Application interval [d]	Application rate per treatment		
					Mefentrifluconazole [kg a.s./ha]	Kresoxim-methyl [kg a.s./ha]	BAS 765 00 F [L/ha]
Wheat, barley, rye, triticale[1)]	Cereals	30-69	2	14	0.1	0.15	1.0

[1)]Application scenario covers the worst-case for the specific crop group (EFSA/2009/1438) with regard to application rate and number of applications per season and BBCH stage.

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

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

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-4: Mefentrifluconazole: First-tier assessment of the acute and long-term risk for birds due to the use of BAS 765 00 F in cereals

Intended use		**Cereals**			
Active substance/product		mefentrifluconazole/BAS 765 00 F			
Application rate (kg/ha)		2 × 0.1			
Acute toxicity (mg/kg bw)		816			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small omnivorous bird	158.8	1.2	19.06	42.8
Reprod. toxicity (mg/kg bw/d)		25.3			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening Step	Small omnivorous bird	64.8	1.4 × 0.53	4.81	5.3
BBCH 30-39	Small omnivorous bird “lark”	5.4	1.4 × 0.53	0.40	63.1
BBCH ≥40	Small omnivoroud bird “lark”	3.3	1.4 × 0.53	0.245	103.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: Kresoxim-methyl: First-tier assessment of the acute and long-term risk for birds due to the use of BAS 765 00 F in cereals

Intended use		**Cereals**			
Active substance/product		kresoxim-methyl/BAS 765 00 F			
Application rate (kg/ha)		2 × 0.15			
Acute toxicity (mg/kg bw)		4059.2			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small omnivorous bird	158.8	1.2	28.58	142.0
Reprod. toxicity (mg/kg bw/d)		51.7			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening Step	Small omnivorous bird	64.8	1.4 × 0.53	7.21	7.2
BBCH 30-39	Small omnivorous bird “lark”	5.4	1.4 × 0.53	0.601	86.0
BBCH ≥40	Small omnivoroud bird “lark”	3.3	1.4 × 0.53	0.367	140.8

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Dietary risk assessment for combined effects of simultaneous exposure to several active ingredients

Combined acute toxicity

According to EFSA/2009/1438 section 2.5 this assessment is relevant for BAS 765 00 F because this formulation contains more than one active ingredient.

Following Appendix B (step 1) in EFSA/2009/1438, a surrogate LD_{50} = 1567.38 is calculated based on the assumption of dose additivity (Table 9.2-6). A combined acute risk assessment is not required if for one active ingredient the deviation between ‘tox per fraction (a.i.)’ and ‘tox per fraction (mix)’ is ≤10% as in that case the risk is covered by the assessment for that active ingredient. For BAS 765 00 F this does not apply because the deviation for both active ingredients is more than 10% (Table 9.2-6).

Table 9.2-6: Calculation of surrogate LD_{50} for the mixture of active ingredients

Active ingredient	Contrations a.i. in mixture [g/L]	Fraction a.i. in mixture	LD50 ai [mg/kg bw/d]	Fraction a.i./LD50 a.i.	Surrogate LD50 [mg/gw bw]	Tox per fraction (a.i.)	Deviation from tox per fraction (a.i.) and tox per fraction (mix) [%]
mefentrifluconazole	100	0.4	816	0.00049	1567.38	2040	30
kresoxim-methyl	150	0.6	4059.2	0.00015		6765.33	332

Since there are no experimental data on the acute toxicity of formulation BAS 765 00 F to birds (see justification in point 9.2.1), the surrogate LD_{50} = 1567.38 mg/kg bw will be the toxicity endpoint used in the risk assessment below.

Exposure and risk assessment for the combined active ingredients (virtual compound approach)

The potential exposure to the combined substances follows step 4 of Appendix B of EFSA/2009/1438. The maximum single application rate of formulation BAS 765 00 F in cereals is 1L product/ha (corresponding to 0.1 kg mefentrifluconazole/ha and 0.15 kg kresoxim-methly/ha); applying the concept for dose additivity to the exposure calculations results in a combined application rate of 0.25 kg virtual compound/ha.

The dietary TER acute value for the screening step presented in Table 9.2-6 is above the trigger of 10. Therefore, the acute risk to birds from combined effects of the two active ingredients in BAS 765 00 F is acceptable.

Table 9.2-7: **Virtual compound: First-tier assessment of the acute risk for birds due to the use of BAS 765 00 F in barley, wheat, rye and triticale (2 × 0.25 [kg a.s./ha]/cereals)**

Intended use		**Cereals**			
Active substance/product		BAS 765 00 F (virtual compound)			
Application rate (kg/ha)		2 × 0.25			
Acute toxicity (mg/kg bw)		1567.38			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small omnivorous bird	158.8	1.2	47.64	32.9

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Note that this virtual compound acute TER was calculated according to the concentration addition approach and thus gives the same vale as if calculated using the following equation:

$$\text{TER SUM acute} = \text{trigger}/((\text{trigger}/_{\text{TERsubstance1}}) + (\text{trigger}/_{\text{TERsubstance2}})).$$

In conclusion, the risk assessment approach for the combined toxicity of the active ingredients has resulted in a TER value at the screening step for the acute risk assessment above the trigger of 10 for acceptability of effects. Therefore, the acute dietary risk to birds from the proposed uses of BAS 765 00 F is acceptable.

Combined reproductive toxicity

As requested in the summary report of the Steering Committee of the Central Zone Harmonisation workshop in April 2015 and updated of October 2016, a long-term combination toxicity tier 1 risk assessment is presented. As proposed there, the calculations follow the concentration addition model. TER SUM acute values are covered by the virtual compound approach, so please see above for details (Table 9.2-7).

The combined reproductive TER value is calculated according to the following formula:

$$TER_{LTcombi} = trigger/((trigger/TERsubstance1) + (trigger/TERsubstance2))$$

An acceptable risk is expected when $TER_{LTcombi}$ > trigger.

Table 9.2-8: Combined reproductive toxicity: First-tier assessment of the long-term risk for birds due to the use of BAS 765 00 F in barley, wheat, rye and triticale (2 × 0.25 [kg a.s./ha]/cereals)

Crop scenario and/or indicator species		TER (tier1)[1)] mefentrifluconazole	TER (tier1)[1)] kresoxim-methyl	$TER_{LTcombi}$	Trigger
Reproductive - Screening Step					
Cereals	small omnivorous bird	5.3	7.2	**3.05**	5
Reproductive - Tier 1					
Cereals BBCH 30-39	Small omnivorous bird "lark"	63.1	86.0	36.4	5
Cereals BBCH ≥40	small omnivorous bird "lark"	103.3	140.8	59.58	5

TER values and scenarios shown in **bold** fall below the relevant trigger
[1)]reproductive TER values are presented in Table 9.2-4and Table 9.2-5.

The $TER_{LTcombi}$ values for tier 1 are all above the trigger value of 5. Thus, it can be concluded that the reproductive risk for birds for the combined exposure to the two active ingredients mefentrifluconazole and kresoxim-methyl in the formulation BAS 765 00 F according to good agricultural practices is low and acceptable.

9.2.2.2 Higher-tier risk assessment

A higher-tier risk assessment is not necessary. An acceptable acute and reproductive risk in cereals was shown either within the screening step or at first-tier risk assessment.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Leaf scenario

Since BAS 765 00 F is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

Table 9.2-9: Assessment of the risk for birds due to exposure to mefentrifluconazole and kresoxim-methyl via contaminated drinking water in puddles

Parameter	Mefentrifluconazole	Kresoxim-methyl	Comments
K_{oc} (geometric mean) [L/kg]	3455.59	302	EFSA Journal 2018; 16(7): 5379 EFSA Journal 2010; 8(11): 1891
DT_{50} (soil) [days]	200 (field)	1.0 (field)	
Number of applications	2	2	Chapter 9.1
Interval [days]	14	14	Chapter 9.1
MAF_m	1.95	1.00	$MAF_m = (1-e^{-nki}) / (1-e^{-ki})$ with k = $\ln(2)/DT_{50}$ (rate constant), n = number of applications and i = application interval [d]
Max use rate [g/ha]	100	150	
AR_{eff} [g/ha]	195.0	150	AR_{eff} = Application rate [g/ha] x MAFmean
LD_{50} [mg/kg bw]	816	4059.2	
Ratio (acute)	0.24	0.04	Ratio of AR_{eff} and LD_{50}
NO(A)EL [mg/kg bw/d]	25.3	51.7	
Ratio (repro)	7.71	2.90	Ratio of AR_{eff} and NO(A)EL
Trigger	3000	50	
Drinking water assessment required? [yes/no]	no	no	

The ratios for acute and reproductive endpoints do not exceed the relevant threshold value for either active ingredient, thus a quantitative drinking water risk assessment for the puddle scenario is not triggered.

In conclusion, the risk to birds via drinking water from the intended uses of BAS 765 00 F according to the proposed use pattern is acceptable.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of mefentrifluconazole is 3.4 (EFSA Journal 2018; 16(7): 5379) and thus does exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of kresoxim-methyl amounts to 3.4 (EFSA Journal 2010; 8(11): 1891) and thus does exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

Table 9.2-10: Assessment of the risk for earthworm-eating birds due to exposure to mefentrifluconazole and kresoxim-methyl via bioaccumulation in earthworms (secondary poisoning)

Parameter	Mefentrifluconazole	Kresoxim-methyl	comments
PEC_{soil} (mg/kg soil)	0.092 ($PEC_{accumulation}$)	0.007 (21-d twa PEC)	
P_{ow}	2350	2500	Mefentrifluconazole: BASF DocID 2013/1382370 Kresoxim-methyl: According to the EFSA conclusion (EFSA scientific report 2010, 8 (11): 1891) the log Pow is 3.40, which corresponds to a Kow of 2500
Koc (geometric mean) [L/kg]	3455.59	302	EFSA Journal 2018; 16(7): 5379 EFSA Journal 2010; 8(11): 1891
foc	0.02	0.02	Default
BCF_{worm}	0.42	5.11	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.04	0.04	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.04	0.04	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	25.3	51.7	
TER_{lt}	623.30	1377.61	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.2-11: Assessment of the risk for fish-eating birds due to exposure to mefentrifluconazole and kresoxim-methyl via bioaccumulation in fish (secondary poisoning)

Parameter	mefentrifluconazole	kresoxim-methyl	comments
PEC_{sw} (max.) (mg/L)	~~2.020~~ 4.048×10^{-3}	~~0.6758~~ 1.856×10^{-3}	Chapter 8.9, step 2 PECs
BCF_{fish}	385	220	EFSA Journal 2018; 16(7): 5379 EFSA Journal 2010; 8(11): 1891
BMF	--	--	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	~~0.778~~ 1.56	~~0.149~~ 0.41	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	~~0.124~~ 0.25	~~0.024~~ 0.065	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	25.3	51.7	
TER_{lt}	~~204.60~~ 101.2	~~2187.02~~ 795.4	

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Low potential for accumulation in animal tissue was concluded in the EU review of mefentrifluconazole (see EFSA Journal 2018;16(7):5379).

No evidence was found for potential of accumulation of kresoxim-methyl in animal tissue (see EFSA Journal 2010:8(11):1891).

Since the bioaccumulation potential of both mefentrifluconazole and kresoxim-methyl is low, no further assessment on biomagnification is required.

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

Not relevant.

9.2.4 Overall conclusions

It can be concluded that the risk to birds from application of BAS 765 00 F according to good agricultural practice is acceptable.

Review Comments:

The acute and chronic risks of BAS 765 00 F to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients and maximum residues occurring on food items. No acute toxicity test with the formulation was required.

All TER values exceed the relevant triggers indicating that BAS 765 00 F does not pose an unacceptable risk to birds following applications according to recommended use pattern.

Evaluation of exposing to birds through the drinking water demonstrated the acceptable risk. The potential risk of secondary poisoning is low.

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

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with mefentrifluconazole and kresoxim-methyl and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

The selection of studies and endpoints for the risk assessment of mefentrifluconazole (Table 9.3-1) and kresoxim-methyl (Table 9.3-2) is in line with the results of the EU review process. Justifications are provided below.

Table 9.3-1: Mefentrifluconazole: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Mefentrifluconazole	Oral, 1 d Acute	LD_{50} > 2000 mg a.s./kg bw	EFSA Journal 2018;16(7):5379 [2013/1149656]
Rat	BAS 765 00 F	Oral, 1 d Acute	LD_{50} > 5000 mg formulation/kg bw	not evaluated at EU level [2019/2034513]
Rat	Mefentrifluconazole	Dietary Reproductive toxicity Two-generation study	$NOEL_{Reproduction}$ = 200 mg a.s./kg bw/d $NOEL_{Parents}$ = 25 mg a.s./kg bw/d $NOEL_{Offspring}$ = 75 mg a.s./kg bw/d	EFSA Journal 2018;16(7):5379 [2014/1170754]
Rat	Mefentrifluconazole	Oral Developmental toxicity	$NOEL_{Maternal}$ = 150 mg a.s./kg bw $NOEL_{Developmental}$ = 400 mg a.s./kg bw/d	EFSA Journal 2018;16(7):5379 [2014/1170755]
Rabbit	Mefentrifluconazole	Oral Developmental toxicity	$NOEL_{Maternal}$ = 15 mg a.s./kg bw/d $NOEL_{Developmental}$ = 15 mg a.s./kg bw/d	EFSA Journal 2018;16(7):5379 [2014/1170757]
Endpoint used for acute risk assessment	**Mefentrifluconazole**	**Oral, 1 d Acute**	**LD_{50} > 2000 mg a.s./kg bw**	**EFSA Journal 2018;16(7):5379 [2013/1149656]**
Endpoint used for reproductive risk assessment	**Mefentrifluconazole**	**Dietary Reproductive toxicity – Tier 1**	**NOEL = 15 mg a.s./kg bw/d**	**EFSA Journal 2018;16(7):5379 [2014/1170757]**

Table 9.3-2: Kresoxim-methyl: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Kresoxim-methyl	Oral, 1 d Acute	LD_{50} > 5000 mg a.s./kg bw	EFSA Journal 2010;8(11):1891 [1993/10730]
Rat	Kresoxim-methyl	Dietary Reproductive toxicity Two-generation study	$NOAEL_{Reproduction}$ = 1500 mg/kg bw/d	1994/10950
			$NOAEL_{Offspring}$ = 100 mg a.s./kg bw/d $NOAEL_{Parents}$ = 100 mg a.s./kg bw/d	EFSA Journal 2010;8(11):1891 [1994/10950]
Rat	Kresoxim-methyl	Oral Prenatal Developmental toxicity	$NOAEL_{maternal/developmental}$ = 1000 mg a.s./kg bw/d	EFSA Journal 2010;8(11):1891 [1994/10833]
Rabbit	Kresoxim-methyl	Oral Prenatal Developmental toxicitiy	NOAELmaternal/developmental = 1000 mg a.s./kg bw/d	EFSA Journal 2010;8(11):1891 [1994/10980]
Endpoint used for acute risk assessment	**Kresoxim-methyl**	**Oral, 1 d Acute**	**LD_{50} > 5000 mg a.s./kg bw**	**EFSA Journal 2010;8(11):1891 [1993/10730]**
Endpoint used for reproductive risk assessment	**Kresoxim-methyl**	**Dietary Reproductive toxicity Two-generation study – Tier 1**	**NOAEL = 100 mg a.s./kg bw/d**	**EFSA Journal 2010;8(11):1891 [1994/10950]**

Metabolites

Metabolites of mefentrifluconazole and kresoxim-methyl

See section 9.21 in the bird chapter.

Formulation toxicity

For toxicological classification and labelling purposes, an acute oral toxicity study with BAS 765 00 F in rats was carried out according to the toxic class method described in OECD 423 (study BASF DocID 2019/2034513; see chapter 6.3 and Appendix 2 of chapter 6). No mortality occurred, resulting in LD_{50} > 5000 mg formulation/kg bw and indicating a low toxicity of the formulation and no increased toxicity compared to the active substance.

9.3.1.1 Justification for new endpoints

Mefentrifluconazole

Acute – Not applicable. Endpoint is EU agreed.

Reproductive – Not applicable. Endpoint is EU agreed.

Kresoxim-methyl

Acute – Not applicable. Endpoint is EU agreed.

Reproductive – Not applicable. Endpoint is EU agreed.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Proposed use pattern for the risk assessments

The proposed use pattern for the use in BAS 765 00 F is summarized in Table 9.3-3. The detailed use pattern table is presented at the beginning of the ecotoxicology chapter (section 9.1).

Table 9.3-3: Proposed use pattern

Crops as listed in the GAP	Crop group [EFSA/2009/1438]	Application time [BBCH growth stage]	Number of applications	Application interval [d]	Application rate per treatment		
					Mefentrifluconazole [kg a.s./ha]	Kresoxim-methyl [kg a.s./ha]	BAS 765 00 F [L/ha]
Wheat, barley, rye, triticale[1)]	Cereals	30-69	2	14	0.1	0.15	1.0

[1)]Application scenario covers the worst-case for the specific crop group (EFSA/2009/1438) with regard to application rate and number of applications per season and BBCH stage

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

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-4: Mefentrifluconazole: First-tier assessment of the acute and long-term risk for mammals due to the use of BAS 765 00 F in cereals

Intended use	**Cereals**				
Active substance/product	mefentrifluconazole/BAS 765 00 F				
Application rate (kg/ha)	2 × 0.1				
Acute toxicity (mg/kg bw)	2000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small herbivorous mammal	118.4	1.2	14.21	140.8
Reprod. toxicity (mg/kg bw/d)	15				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening Step	Small herbivorous mammal	48.3	1.4 × 0.53	3.58	**4.19**
BBCH ≥20	Small insectivorous mammal “shrew”	1.9	1.4 × 0.53	0.141	106.4
BBCH 30-39	Small omnivorous mammal “mouse”	3.9	1.4 × 0.53	0.289	51.8
BBCH ≥40	Small herbivorous mammal “vole”	21.7	1.4 × 0.53	1.61	9.3
BBCH ≥40	Small omnivorous mammal “mouse”	2.3	1.4 × 0.53	0.171	87.9

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: Kresoxim-methyl: First-tier assessment of the acute and long-term risk for mammals due to the use of BAS 765 00 F in cereals

Intended use	**Cereals**				
Active substance/product	Kresoxim-methyl/BAS 765 00 F				
Application rate (kg/ha)	2 × 0.15				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small herbivorous mammal	118.4	1.2	21.31	234.6
Reprod. toxicity (mg/kg bw/d)	100				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Screening Step	Small herbivorous mammal	48.3	1.4 × 0.53	5.38	18.60
BBCH ≥20	Small insectivorous mammal “shrew”	1.9	1.4 × 0.53	0.211	472.9
BBCH 30-39	Small omnivorous mammal “mouse”	3.9	1.4 × 0.53	0.434	230.4
BBCH ≥40	Small herbivorous mammal “vole”	21.7	1.4 × 0.53	2.415	41.4
BBCH ≥40	Small omnivorous mammal “mouse”	2.3	1.4 × 0.53	0.256	390.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Dietary risk assessment for combined effects of simultaneous exposure to several active ingredients

Combined acute toxicity

According to EFSA/2009/1438 section 2.5 this assessment is relevant for BAS 765 00 F because this formulation contains more than one active ingredient.

Following Appendix B (step 1) in EFSA/2009/1438, a surrogate LD_{50} = 3125.0 is calculated based on the assumption of dose additivity (Table 9.3-6). A combined acute risk assessment is not required if for one active ingredient the deviation between 'tox per fraction (a.i.)' and 'tox per fraction (mix)' is ≤10% as in that case the risk is covered by the assessment for that active ingredient. For BAS 765 00 F this does not apply because the deviation for both active ingredients is more than 10% (Table 9.3-6).

Table 9.3-6: Calculation of surrogate LD_{50} for the mixture of active ingredients

Active ingredient	Contrations a.i. in mixture [g/L]	Fraction a.i. in mixture	LD50 ai [mg/kg bw/d]	Fraction a.i./LD50 a.i.	Surrogate LD50 [mg/gw bw]	Tox per fraction (a.i.)	Deviation from tox per fraction (a.i.) and tox per fraction (mix) [%]
mefentrifluconazole	100	0.4	>2000	0.00020	3125.0	5000.0	60
kresoxim-methyl	150	0.6	>5000	0.00012		8333.3	167

There is a laboratory study on the acute toxicity of formulation BAS 765 00 F to rats, which resulted in an LD_{50} > 5000 mg/kg bw (see 9.3.1).

Appendix B of EFSA/2009/1438 recommends comparing the surrogate LD_{50} with the experimental LD_{50} from formulation testing and running the risk assessment with the lowest of the two results. However, Appendix B does not provide clear recommendations if for the comparison of the two LD_{50} values and for the calculations of the exposure scenarios only the content of the active ingredients should be considered, as the surrogate LD_{50} is based on toxicity and concentration of active ingredients while the experimental LD_{50} is based on all components of the formulation. Due to this lack of guidance in Appendix B, the most comprehensive approach is adopted by the notifier by presenting the two possible risk assessments, one for the virtual compound and another for the formulation.

Exposure and acute risk assessment for combined active ingredients (virtual compound approach)

The potential exposure to the combined substances follows step 4 of Appendix B of EFSA/2009/1438. The maximum application rate of the formulation BAS 765 00 F is 1.0 L/ha (corresponding to 0.1 kg/ha mefentrifluconazole and 0.15 kg/ha kresoxim-methly); applying the concept of dose additivity to the exposure calculations results in a combined application rate of 0.25 kg virtual compound/ha.

The dietary TER acute value for the screening and tier 1 step presented in Table 9.3-7 are above the trigger of 10.

Table 9.3-7: Virtual compound: First-tier assessment of the acute risk for mammals due to the use of BAS 765 00 F in cereals

Intended use		**Cereals**			
Active substance/product		BAS 765 00 F (virtual compound)			
Application rate (kg/ha)		2 × 0.25			
Acute toxicity (mg/kg bw)		3125.0			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small herbivorous mammal	118.4	1.2	35.52	88.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Exposure and acute risk assessment for combined active ingredients (formulation approach)

BAS 765 00 F is intended to be used in cereals with a maximum single application rate of 1 L product/ha. Considering the density of the formulation of 1.083 g/cm^3, this will result in an application rate of 1.083 kg BAS 765 00 F/ha.

The dietary TER acute value for the screening step presented in Table 9.3-8 is above the trigger of 10.

Table 9.3-8: BAS 765 00 F: First-tier assessment of the acute risk for mammals due to the use of BAS 765 00 F in cereals

Intended use	**Cereals**				
Active substance/product	BAS 765 00 F				
Application rate (kg/ha)	2 × 1.083				
Acute toxicity (mg/kg bw)	> 5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Screening Step	Small herbivorous mammal	118.4	1.2	153.87	>32.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

In conclusion, the two risk assessment approaches (combined toxicity of the active ingredients and formulation toxicity) have resulted in TER values at the screening step above the trigger of 10 for acceptability of effects. Therefore, the acute dietary risk to mammals from the proposed uses of BAS 765 00 F in cereals is acceptable.

Combined reproductive toxicity

As requested in the summary report of the Steering Committee of the Central Zone Harmonisation workshop in April 2015 and updated of October 2016, a long-term combination toxicity tier 1 risk assessment is presented. As proposed there, the calculations follow the concentration addition model.

The combined TER value is calculated according to the following formula:

$$TER_{LTcombi} = trigger/((trigger/TERsubstance1) + (trigger/TERsubstance2))$$

An acceptable risk is expected when $TER_{LTcombi}$ > trigger.

Table 9.3-9: Combined reproductive toxicity: Screening and first-tier assessment of the long-term risk for mammals due to the use of BAS 765 00 F in cereals

Crop scenario and/or indicator species		TER (tier1)[1)] mefentrifluconazole	TER (tier1)[1)] kresoxim-methyl	$TER_{LTcombi}$	Trigger
Reproductive - Screening Step					
Cereals	small herbivorous mammal	4.19	18.6	**3.42**	5
Reproductive - Tier 1					
BBCH ≥20	Small insectivorous mammal “shrew”	106.4	472.9	86.86	5
BBCH 30-39	Small omnivorous mammal “mouse”	51.8	230.4	42.29	5
BBCH ≥40	Small herbivorous mammal “vole”	9.3	41.4	7.59	5
BBCH ≥40	Small omnivorous mammal “mouse”	87.9	390.6	71.75	5

TER values and scenarios shown in **bold** fall below the relevant trigger[1)]reproductive TER values are presented in Table 9.3-4and Table 9.3-5

The $TER_{LTcombi}$ values for tier 1 are all above the trigger value of 5. Thus, it can be concluded that the reproductive risk for mammals for the combined exposure to the two active ingredients mefentrifluconazole and kresoxim-methyl in the formulation BAS 765 00 F according to good agricultural practices is low and acceptable.

9.3.2.2 Higher-tier risk assessment

A higher-tier risk assessment is not necessary. An acceptable acute and reproductive risk in cereals was shown either within the screening step or at first-tier risk assessment.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

Table 9.3-10: Assessment of the risk for mammals due to exposure to mefentrifluconazole and kresoxim-methyl via contaminated drinking water in puddles

Parameter	Mefentrifluconazole	Kresoxim-methyl	Comments
K_{oc} (geometric mean) [L/kg]	3455.59	302	EFSA Journal 2018; 16(7): 5379
DT_{50} (soil) [days]	200	1.0	EFSA Journal 2010; 8(11): 1891
Number of applications	2	2	Chapter 9.1
Interval [days]	14	14	Chapter 9.1
MAF_m	1.95	1.00	$MAF_m = (1-e^{-nki}) / (1-e^{-ki})$ with $k = ln(2)/DT_{50}$ (rate constant), n = number of applications and i = application interval [d]
Max use rate [g/ha]	100	150	
AR_{eff} [g/ha]	195.0	150	AR_{eff} = Application rate [g/ha] x MAFmean
LD_{50} [mg/kg bw]	>2000	>5000	
Ratio (acute)	<0.10	<0.03	Ratio of AR_{eff} and LD_{50}
NO(A)EL [mg/kg bw/d]	15	100	
Ratio (repro)	13.00	1.50	Ratio of AR_{eff} and NO(A)EL
Trigger	3000	50	
Drinking water assessment required? [yes/no]	no	no	

The ratios for acute and reproductive endpoints do not exceed the relevant threshold value for either active ingredient, thus a quantitative drinking water risk assessment for the puddle scenario is not triggered.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of mefentrifluconazole is 3.4 (EFSA Journal 2018; 16(7): 5379) and thus does exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

The log P_{ow} of kresoxim-methyl amounts to 3.4 (EFSA Journal 2010; 8(11): 1891) and thus does exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

Table 9.3-11: Assessment of the risk for earthworm-eating mammals due to exposure to mefentrifluconazole and kresoxim-methyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

Parameter	Mefentrifluconazole	Kresoxim-methyl	comments
PEC_{soil} (mg/kg soil)	0.092 ($PEC_{accumulation}$)	0.007 (21-d twa PEC)	
P_{ow}	2350	2500	Mefentrifluconazole: BASF DocID 2013/1382370 Kresoxim-methyl: According to the EFSA conclusion (EFSA scientific report 2010, 8 (11): 1891) the log Pow is 3.40, which corresponds to a Kow of 2500
Koc (geometric mean) [L/kg]	3455.59	302	EFSA Journal 2018; 16(7): 5379 EFSA Journal 2010; 8(11): 1891
foc	0.02	0.02	Default
BCF_{worm}	0.42	5.11	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.12 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.04	0.04	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.05	0.05	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	15	100	
TER_{lt}	303.14	2185.82	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

Table 9.3-12: Assessment of the risk for fish-eating mammals due to exposure to mefentrifluconazole and kresoxim-methyl via bioaccumulation in fish (secondary poisoning) for the intended use in barley, wheat, rye and triticale (cereals)

Parameter	mefentrifluconazole	kresoxim-methyl	comments
PEC_{sw} (~~twa = 21 d;~~ max) (mg/L)	~~2.020~~ 4.048 × 10^{-3}	~~0.6758~~ 1.856 × 10^{-3}	Chapter 8.9, step 2 PECs
BCF_{fish}	385	220	EFSA Journal 2018; 16(7): 5379 EFSA Journal 2010; 8(11): 1891
BMF	--	--	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	~~0.778~~ 1.56	~~0.149~~ 0.41	$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	~~0.110~~ 0.222	~~0.021~~ 0.058	$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)	15	100	
TER_{lt}	~~135.83~~ 67.6	~~4736.64~~ 1724.1	

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Low potential for accumulation in animal tissue was concluded in the EU review of mefentrifluconazole (see EFSA Journal 2018;16(7):5379).

No evidence was found for potential for accumulation of kresoxim-methyl in animal tissue (see EFSA Journal 2010;8(11):1891).

Since the bioaccumulation potential of mefentrifluconazole and kresoxim-methyl is low, no further assessment on biomagnification is required**.**

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

Not relevant.

9.3.4 Overall conclusions

It can be concluded that the risk to mammals from application of BAS 765 00 F according to good agricultural practice is acceptable.

Review Comments:

The acute and chronic risks of BAS 765 00 F to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active ingredients and maximum residues occurring on food items.

All TER values exceed the relevant triggers indicating that BAS 765 00 F does not pose an unacceptable risk to mammals following applications according to recommended use pattern.

Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The potential risk of secondary poisoning is low.

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

According to the revised data requirements under regulation 1107/2009 (Commission Regulations (EU) 283/2013 and 284/2013 for the active ingredient and the plant protection products, respectively), the risk to terrestrial life-stages of amphibians and reptiles shall be addressed, yet toxicity testing is not required.

In general, information on the toxicity of chemicals to terrestrial life-stages of amphibians is scarce. However, in the cases where terrestrial life-stages of amphibians were tested in the same type of study as birds and mammals, the general pattern is that amphibians are less sensitive than the latter two taxa (see Table 12 and 13 in Fryday and Thompson, 2012). A review compiling data on 26 chemicals for birds, mammals and amphibians confirmed this pattern (Crane et al., 2016).

For reptiles, there is even less information available than for amphibians (see the review by Fryday and Thompson, 2009).

For the time being, 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 (US-EPA 2004).

References

Commission Regulation (EU) No 283/2013 setting out data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union: 1st March 2013.

Commission Regulation (EU) No 284/2013: setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union: 1st March 2013.

Crane, M., Finnegan, M., Weltje, L., Kosmala-Grzechnik, S., Gross, M. and Wheeler, J.R. 2016. Acute oral toxicity of chemicals in terrestrial life stages of amphibians: Comparisons to birds and mammals. Regulatory Toxicology and Pharmacology, 80: 335-341.

Fryday, S. and Thompson, H. 2009. Compared toxicity of chemicals to reptiles and other vertebrates. EFSA Supporting Publications, 6, EN-14: 169 pp.

Fryday, S. and Thompson, H. 2012. Toxicity of pesticides to aquatic and terrestrial life stages of amphibians and occurrence, habitat use and exposure of amphibian species in agricultural environments. EFSA Supporting Publications, 9, EN-343: 348 pp.

US-EPA 2004. Overview of the ecological risk assessment process in the Office of Pesticide Programs, U.S. Environmental Protection Agency: Endangered and Threatened Species Effects Determinations. Office of Prevention, Pesticides and Toxic Substances; Office of Pesticide Programs, Washington, D.C. 92 pp.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out using the formulation BAS 765 00 F, the active substances mefentrifluconazole and kresoxim-methyl and its major metabolites. Full details of these studies are provided in the EFSA conclusion of mefentrifluconazole (EFSA Journal 2018;16(7):5379), EFSA conclusion of kresoxim-methyl (EFSA Journal 2010;8 (11):1891) and the respective EU DAR, as well as in Appendix 2 of this document (new studies).

Except for a new acute study on toxicity of mefentrifluconazole to *Pimephales promelas* and a study on toxicity of M750F005 to *Oncorhynchus mykiss*, all studies conducted with the active substance mefentrifluconazole and its metabolites have already been submitted and evaluated during the Annex I inclusion process of mefentrifluconazole.

Effects on aquatic organisms of the product BAS 765 00 F were not evaluated previously as part of the EU assessment of the active substances. New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

Appropriate risk assessments for aquatic organisms for the active substance, its major metabolites and the formulated product BAS 765 00 F for the proposed use pattern are provided based on available toxicity data.

Full references to cited literature are given at the end of this document.

Mefentrifluconazole and metabolites

In Table 9.5-1 all endpoints relevant for the aquatic risk assessment of mefentrifluconazole and its relevant metabolites are listed.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – mefentrifluconazole and relevant metabolites

Species	Substance	Exposure System	Results	Reference / BASF DocID
Oncorhynchus mykiss	mefentrifluconazole	96 h, f	**LC_{50} = 0.532 mg a.s./L mm**	EFSA Journal 2018;16(7):5379 / 2014/1036951
Cyprinus carpio	mefentrifluconazole	96 h, f	LC_{50} = 1.126 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2015/1249071
Cyprinodon variegatus [1)]	mefentrifluconazole	96 h, ss	LC_{50} = 0.761 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2014/7002810
Danio rerio	mefentrifluconazole	96 h, s	LC_{50} = 0.906 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2015/1001581
~~*Pimephales promelas*~~	~~mefentrifluconazole~~	~~96 h, s~~	~~LC_{50} = 0.65 mg a.s./L mm~~	~~New study 2016/1155889~~
D. rerio (ELS study)	mefentrifluconazole	36 d, f	NOEC = 0.024 mg a.s./L_{nom} * NOEC = 0.027 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2014/1262160
C. variegatus [1)] (ELS study)	mefentrifluconazole	35 d, f	NOEC ≥ 0.160 mg a.s./L nom * NOEC ≥ 0.147 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2015/7000619
D. rerio (FSDT study)	mefentrifluconazole	69 d, f	NOEC ≥ 0.041 mg a.s./L nom * NOEC ≥ 0.045 mg a.s./L mm	EFSA Journal 2018;16(7):5379 / 2015/1099093
D. rerio (FLC study)	mefentrifluconazole	140 d, f	NOEC = 0.023 mg a.s./L nom * **NOEC = 0.022 mg a.s./L mm**	EFSA Journal 2018;16(7):5379 / 2016/1042889
O. mykiss BCF; 14 d uptake, 7 d depuration)	mefentrifluconazole	BCF_{KLg} (whole fish)	BCF_{KLg} = 385	EFSA Journal 2018;16(7):5379 / 2015/1122811
Daphnia magna	mefentrifluconazole	48 h, s	**EC_{50} = 0.944 mg a.s./L mm**	EFSA Journal 2018;16(7):5379 / 2013/1250866

Species	Substance	Exposure System	Results	Reference / BASF DocID
Americamysis bahia [1)]	mefentrifluconazole	48 h, f	LC_{50} = 1.53 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2014/7002845
Crassostrea virginica	mefentrifluconazole	96 h, f	EC_{50} = 0.947 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000021
D. magna	mefentrifluconazole	21 d, ss	NOEC = 0.010 mg a.s./L $_{nom}$ EC_{10} = 0.0175 mg a.s./L $_{nom}$ * NOEC = 0.0091 mg a.s./L $_{mm}$ **EC_{10} = 0.0161 mg a.s./L $_{mm}$**	EFSA Journal 2018;16(7):5379 / 2014/1098028
A. bahia [1)]	mefentrifluconazole	28 d, f	NOEC ≥ 0.0132 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2016/7001293
D. pulex	mefentrifluconazole	21 d, ss	NOEC = 0.0282 mg a.s./L $_{nom}$ EC_{10} = 0.0573 mg a.s./L $_{nom}$ * NOEC = 0.0276 mg a.s./L $_{mm}$ EC_{10} = 0.0567 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1003913
D. longispina	mefentrifluconazole	21 d, ss	NOEC = 0.0338 mg a.s./L $_{nom}$ EC_{10} = 0.0558 mg a.s./L $_{nom}$ * NOEC = 0.0342 mg a.s./L $_{mm}$ EC_{10} = 0.0564 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1003912 +2015/1251197
Geomean (NOEC / EC_{10} data for 4 crustacean species)	mefentrifluconazole	--	**$Geomean_{chronic}$ = 0.0287 mg a.s./L $_{mm}$**	Calculation considering NOEC / EC_{10} data based on mean measured concentrations
Chironomus dilutus (spiked sediment)	mefentrifluconazole	10 d, ss	NOEC = 7.08 mg a.s./kg dry sediment $_{mm}$ EC_{50} > 96 mg a.s./kg dry sediment $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000621
Hyalella azteca (spiked sediment)	mefentrifluconazole	10 d, ss	NOEC ≥ 100 mg a.s./kg dry sediment $_{mm}$ EC_{50} > 100 mg a.s./kg dry sediment $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000622
Leptocheirus plumulosus (spiked sediment)	mefentrifluconazole	10 d, s	NOEC ≥ 95 mg a.s./kg dry sediment $_{mm}$ EC_{50} > 95 mg a.s./kg dry sediment $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000623
C. riparius (spiked sediment)	mefentrifluconazole	28 d, s	**NOEC ≥ 1.158 mg a.s./kg dry sediment $_{im}$**	EFSA Journal 2018;16(7):5379 / 2014/1243181 +2017/1044236
C. dilutus (LC study; spiked sediment)	mefentrifluconazole	63 d, ss	NOEC = 5.7 mg a.s./kg dry sediment $_{mm}$ LC_{50} > 9.2 mg a.s./kg dry sediment $_{mm}$	EFSA Journal 2018;16(7):5379 / 2016/7006526
Pseudokirchneriella subcapitata [2)]	mefentrifluconazole	72 h, s	E_rC_{50} = 1.352 mg a.s./L $_{mm}$ E_yC_{50} = 0.777 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2013/1250865

Species	Substance	Exposure System	Results	Reference / BASF DocID
Skeletonema costatum [1), 2)]	mefentrifluconazole	72 h, s	**E_rC_{50} = 0.679 mg a.s./L $_{mm}$** E_yC_{50} = 0.479 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000620 + 2016/1292092 (Re-calculation)
Navicula pelliculosa [2)]	mefentrifluconazole	72 h, s	E_rC_{50} = 1.347 mg a.s./L $_{mm}$ E_yC_{50} = 0.671 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000618 + 2016/1292093 (Re-calculation)
Anabaena flos-aquae [2)]	mefentrifluconazole	72 h, s	E_rC_{50} & E_yC_{50} > 3.08 mg a.s./L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/7000617
Lemna gibba [2)]	mefentrifluconazole	7 d, s	**E_rC_{50}** & E_yC_{50} > **2.017 mg a.s./L $_{im}$**	EFSA Journal 2018;16(7):5379 / 2014/1001322 +2018/1220943
O. mykiss	1,2,4-triazole (Reg. No. 87084; M750F001)	96 h, s	LC_{50} = 498 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 1983/1000494
O. mykiss	M750F005 (Reg. No. 6003433)	96 h, s	LC_{50} > 5 mg/L $_{nom}$	New study 2019/1022695
O. mykiss	M750F006 (Reg. No. 5863469)	96 h, s	LC_{50} = 6.2 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2016/1128152
O. mykiss	M750F007 (Reg. No. 6003432)	96 h, s	LC_{50} > 7.2 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1001489
O. mykiss	1,2,4-triazole	28 d, ss	NOEC = 3.2 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 2002/1007850
D. magna	1,2,4-triazole	48 h, s	EC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 1995/1001851
D. magna	M750F003	48 h, s	EC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 2016/1289876
D. magna	M750F005	48 h, s	EC_{50} > 8.58 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1001490

Species	Substance	Exposure System	Results	Reference / BASF DocID
D. magna	M750F006	48 h, s	EC_{50} = 4.42 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1001492
D. magna	M750F007	48 h, s	EC_{50} > 10 mg/L $_{nom}$ * EC_{50} > 9.9 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1003915
D. magna	M750F008	48 h, s	EC_{50} > 8.07 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1001493
C. riparius	M750F003	28 d, s	NOEC ≥ 1.944 mg/kg dry sediment $_{im}$	EFSA Journal 2018;16(7):5379 / 2015/1003916+ 2017/1044237
P. subcapitata [2)]	1,2,4-triazole	72 h, s	E_rC_{50} = 22.5 mg/L$^{-3)}$ $_{mm}$	EFSA Journal 2018;16(7):5379 / 2001/1022266
P. subcapitata [2)]	M750F003	72 h, s	E_rC_{50} > 100 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 2016/1289875
P. subcapitata [2)]	M750F005	72 h, s	E_rC_{50} > 8.57 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1184816
P. subcapitata [2)]	M750F006	72 h, s	E_rC_{50} = 1.42 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1184815
P. subcapitata [2)]	M750F007	72 h, s	E_rC_{50} > 10 mg/L $_{nom}$	EFSA Journal 2018;16(7):5379 / 2015/1003914
P. subcapitata [2)]	M750F008	72 h, s	E_rC_{50} = 4.08 mg/L $_{mm}$	EFSA Journal 2018;16(7):5379 / 2015/1001491

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations; ELS = early life stage; LC = Life cycle; FLC = full life cycle; FSDT = fish sexual development test; BCF = Bioconcentration factor; **Bold** figures: Endpoint used in standard tier 1 risk assessment if more than one endpoint is available for the respective group or organism.

* In addition to the EU agreed endpoints (based on mean measured concentrations), the endpoints based on nominal concentrations are shown here since the measured concentrations were within ± 20% of nominal throughout the studies. For the risk assessment the mean measured endpoints are used.

1) Marine species

2) According to the EFSA Aquatic Guidance (EFSA, 2013) as well as according to the PRAPeR meeting (Sept 2015) endpoints based on growth rate are relevant for risk assessment of primary producers.

3) Considering the endpoint for the study on *P. subcapitata* using 1,2,4-triazole, there is a discrepancy in the value reported in the study report (*i.e.* DocID 2001/1022266), between the first EU evaluation (*i.e.* Annex I approval of epoxiconazole (EFSA, 2015), E_rC_{50} > 31 mg/L) and the endpoint reported in the Annex I approval of mefentrifluconazole (*i.e.* E_rC_{50} = 22.5 mg/L). For the risk assessment the EU agreed endpoint (E_rC_{50} > 22.5 mg/L, based on mean measured concentrations) is used.

Kresoxim-methyl and metabolites

In Table 9.5-2 all endpoints relevant for the aquatic risk assessment of kresoxim-methyl and its relevant metabolites are listed.

Table 9.5-2 Endpoints and effect values relevant for the risk assessment for aquatic organisms – kresoxim-methyl and relevant metabolites

Species	Substance	Exposure System	Results	Reference / BASF DocID
Oncorhynchus mykiss	kresoxim-methyl	96 h, s	0.15 < LC_{50} < 0.19 mg a.s./L measured at test termination	EFSA Journal, 8 (11): 1891, 2010 1992/10211 Amendment: 1993/11444
O. mykiss	kresoxim-methyl	96 h, f	**LC_{50} = 0.19 mg a.s./L** [1] **mean measured**	EFSA Journal, 8 (11): 1891, 2010 1995/5167
Lepomis macrochirus	kresoxim-methyl	96 h, s	LC_{50} = 0.62 mg a.s./L measured at test termination	EFSA Journal, 8 (11): 1891, 2010 1993/10483 Amendment: 1993/11442
L. macrochirus	kresoxim-methyl	96 h, f	LC_{50} = 0.499 mg a.s./L mean measured	EFSA Journal, 8 (11): 1891, 2010 1995/5168
Cyprinus carpio	kresoxim-methyl	96 h, s	0.247 < LC_{50} < 0.326 mg a.s./L mean measured	EFSA Journal, 8 (11): 1891, 2010 1993/10457 Amendment: 1993/11443
Cyprinodon variegatus	kresoxim-methyl	96 h, f	LC_{50} = 1.173 mg a.s./L [2] mean measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1996/5153
O. mykiss	kresoxim-methyl	28 d, f	**NOEC = 0.013 mg a.s./L mean measured**	EFSA Journal, 8 (11): 1891, 2010 1994/10921
P. promelas	kresoxim-methyl	32 d, f (ELS)	NOEC = 0.087 mg a.s./L [2] mean measured	EFSA Journal, 8 (11): 1891, 2010 1996/5155
Daphnia magna	kresoxim-methyl	48 h, s	**EC_{50} = 0.186 mg a.s./L nominal**	EFSA Journal, 8 (11): 1891, 2010 1993/10497
D. magna	kresoxim-methyl	48 h, f	EC_{50} = 0.332 mg a.s./L mean measured	EFSA Journal, 8 (11): 1891, 2010 1995/5169
Daphnia similis	kresoxim-methyl	24 h, s	EC_{50} = 1.510 mg a.s./L [2] nominal	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1991/10710

Species	Substance	Exposure System	Results	Reference / BASF DocID
Mysidopsis bahia	kresoxim-methyl	96 h, f	EC_{50} = 0.059 mg a.s./L [2)] mean measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1996/5151
Crassostrea virginica	kresoxim-methyl	96 h, f	EC_{50} = 0.015 mg a.s./L [2)] mean measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1996/5152
D. magna	kresoxim-methyl	21 d, ss	**NOEC = 0.032 mg a.s./L nominal**	EFSA Journal, 8 (11): 1891, 2010 1993/10335
D. magna	kresoxim-methyl	21 d, f	NOEC = 0.055 mg a.s./L mean measured	EFSA Journal, 8 (11): 1891, 2010 1996/5154
Ankistrodesmus bibraianus (syn. *P. subcapitata)*	kresoxim-methyl	72 h, s	**E_rC_{50} = 0.250 mg a.s./L nominal** E_yC_{50} = 0.0653 mg a.s./L [3)] nominal	EFSA Journal, 8 (11): 1891, 2010 1992/11598
Selenastrum capricornutum (syn. *P. subcapitata)*	kresoxim-methyl	120 h, s	E_bC_{50} = 0.0594 mg a.s./L initially measured	EFSA Journal, 8 (11): 1891, 2010 1995/5051
Navicula pelliculosa	kresoxim-methyl	120 h, s	E_yC_{50} = 0.0292 mg a.s./L [2)] initially measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1995/5048
Anabaena flos-aquae	kresoxim-methyl	120 h, s	E_yC_{50} > 0.0295 mg a.s./L [2)] initially measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1995/5050
Skeletonema costatum	kresoxim-methyl	120 h, s	E_yC_{50} > 0.0293 mg a.s./L [2)] initially measured	Final Addendum to the Assessment Report (Vol. 3, Annex B.9, revised, August 2010) 1995/5054
Outdoor mesocosm (multiple spray application) [4)]	kresoxim-methyl	ca. 6 mo, s	NOEC = 0.0067 mg a.s./L nominal NOEAEC = 0.333 mg a.s./L nominal	EFSA Journal, 8 (11): 1891, 2010 1995/11150
O. mykiss	BF 490-1	96 h, s	LC_{50} > 100 mg a.s./L nominal	EFSA Journal, 8 (11): 1891, 2010 1994/10621
D. magna	BF 490-1	48 h, s	EC_{50} > 100 mg a.s./L nominal	EFSA Journal, 8 (11): 1891, 2010 1994/10622
D. magna	BF 490-5	48 h, s	EC_{50} > 100 mg a.s./L nominal	EFSA Journal, 8 (11): 1891, 2010 2008/1037017

Species	Substance	Exposure System	Results	Reference / BASF DocID
P. subcapitata	BF 490-1	72 h, s	E_rC_{50} > 500 mg a.s./L nominal E_bC_{50} > 500 mg a.s./L nominal	EFSA Journal, 8 (11): 1891, 2010 1994/10616

s: static; ss: semi-static; f: flow-through
Bold figures: Endpoint used in standard tier 1 risk assessment if more than one endpoint is available for the respective group.
Abbreviations: ELS = early life stage; NO(E)AEC = No observed (ecologically) adverse effect concentration

1) This study is used for ETR calculations as it provides more reliable analytical measurements.
2) US (resp. Japan) specific studies, not required for registration in the EU; furthermore, a mesocosm study with a multitude of freshwater species is available.
3) Graphically determined.
4) Study was conducted with the solo-formulation BAS 490 02 F (containing 500 g kresoxim-methyl/kg, nominally); however, results are given in mg a.s./L.

Formulated product (BAS 765 00 F)

In Table 9.5-3 all endpoints relevant for the aquatic risk assessment of the formulated product BAS 765 00 F are listed.

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – BAS 765 00 F

Species	Substance	Exposure System	Results	Reference / BASF DocID
Oncorhynchus mykiss	BAS 765 00 F	96 h, s	LC_{50} = 1.08 mg/L $_{nom}$ LC_{50} = 0.747 mg/L_{mm}*	New study 2019/1050660
Daphnia magna	BAS 765 00 F	48 h, s	EC_{50} = 1.35 mg/L $_{nom}$	New study 2019/1050659
Pseudokirchneriella subcapitata	BAS 765 00 F	72 h, s	E_rC_{50} = 1.33 mg/L $_{nom}$ # E_yC_{50} = 0.396 mg/L $_{nom}$	New study 2019/10506658

s: static; nom: based on nominal concentrations

According to the EFSA Aquatic Guidance (EFSA, 2013) as well as according to the PRAPeR meeting (Sept 2015) endpoints based on growth rate are relevant for risk assessment of primary producers.

*based on less stable active substance: BAS 490 F

9.5.1.1 Justification for new endpoints

Mefentrifluconazole

In general, for mefentrifluconazole and its metabolites the EU agreed endpoints are used for the risk assessment. A new acute study on *P. promelas* conducted using the active substance is available.

Additionally, a new acute study on toxicity of M750F005 (metabolite of mefentrifluconazole) to fish is available. This study was conducted post Annex I inclusion for a different region. The study is provided to support the risk assessment of metabolites.

In line with the EFSA conclusion (EFSA Journal 2018;16(7):5379), the chronic endpoints for fish and invertebrates based on mean measured values are considered for the risk assessment. Additionally, the chronic endpoints for four crustacean species (NOEC for *A. bahia* and EC_{10} for *Daphnia spp.*) based on mean measured values were used for calculation of the geomean.

Kresoxim-methyl

All studies and endpoints for kresoxim-methyl and its metabolites are in line with the results of the EU review process.

9.5.2 Risk assessment

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

In accordance with the EFSA Aquatic GD, risk assessment for algae and aquatic plants was performed considering only the more relevant endpoint "growth rate" (E_rC_{50}).

According to the AGD, the risk to aquatic life-stages of amphibians shall be addressed. In general, regarding the aquatic risk assessment, several data analyses indicate that the risk assessment for aquatic organisms (and fish in particular) covers the risk assessment for aquatic phases of amphibians (Fryday S. and Thompson H., 2012, Weltje et al., 2013). Based on these extensive data reviews, it can be concluded that the acute and chronic risk to aquatic life stages of amphibians can be addressed by the currently requested and conducted risk assessment for fish and other aquatic organisms. This is also acknowledged in the Aquatic Guidance Document (EFSA, 2013).

Mefentrifluconazole

For mefentrifluconazole EU agreed endpoints are considered for the tier 1 risk assessment. Additionally, the higher tier Geomean-RAC of 2.87 µg a.s./L for aquatic crustacean (resulting from geometric mean calculations based on chronic NOEC/EC_{10} data for 4 crustacean species) is considered for the risk assessment for sake of completeness.

The relevant worst-case FOCUS Step 1 – 3 $PEC_{sw, sed}$ values for RAs covering the proposed use pattern and the resulting PEC/RAC ratios (ETR) for the active substance are presented in Table 9.5-4 and Table 9.5-5. For details please refer to Part B Section 8.

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for mefentrifluconazole for each organism group based on the worst-case FOCUS Step 1 - 3 calculations for single and twofold application of BAS 765 00 F in 'spring cereals'

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher-Plant**	**Higher-tier information**	**Group**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. rerio* (FLC Study)**	***D. magna***	***D. magna***	***S. costatum***	***L. gibba***	**$Geomean_{chronic}$ calculation - 4 crustacean species**	**Test species**	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	EC_{10}	E_rC_{50}	E_rC_{50}	Geomean	**Endpoint**	NOEC
(µg/L)		532	22	944	16.1	679	> 2017	28.7	**(µg/kg)**	≥ 1158
AF		100	10	100	10	10	10	10	**AF**	10
RAC (µg/L)		5.32	2.2	9.44	1.61	67.9	> 201.7	2.87	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**$PEC_{gl\text{-}sw\ max}$ (µg/L)**	**PEC/RAC (= ETR)**							**$PEC_{gl\text{-}sed\ max}$ (µg/kg)**	**PEC/RAC (= ETR)**
Step 1										
	13.728	**2.6**	**6.2**	**1.5**	**8.5**	0.2	< 0.07	**4.8**	420.381	**≤ 3.6**
Step 2										
N-Europe	2.216	0.4	**1.01**	0.2	**1.4**	--	--	0.8	72.548	≤ 0.6
S-Europe	4.048	0.8	**1.8**	0.4	**2.5**	--	--	**1.4**	135.574	**≤ 1.2**
Step 3										
D3 ditch	0.632	--	0.3	--	0.4	--	--	0.2	0.514	≤ 0.004
D4 pond	0.058	--	0.03	--	0.04	--	--	0.02	0.537	≤ 0.005
D4 stream	0.517	--	0.2	--	0.3	--	--	0.2	0.196	≤ 0.002
D5 pond	0.032	--	0.01	--	0.02	--	--	0.01	0.318	≤ 0.003
D5 stream	0.531	--	0.2	--	0.3	--	--	0.2	0.036	≤ 0.0003
R4 stream	0.418	--	0.2	--	0.3	--	--	0.1	2.842	≤ 0.02

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

For the intended single and twofold application of BAS 765 00 F in ‘spring cereals’ at 1x and 2x 100 g a.s./h, respectively, the calculated PEC/RAC ratios for mefentrifluconazole indicate an acceptable risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 - 3 $PEC_{sw, sed}$ values. Therefore, no further assessment is necessary.

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for mefentrifluconazole for each organism group based on the worst-case FOCUS Step 1 - 3 calculations for single and twofold application of BAS 765 00 F in 'winter cereals'

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Higher-Plant**	**Higher-tier information**	**Group**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. rerio* (FLC Study)**	***D. magna***	***D. magna***	***S. costatum***	***L. gibba***	**$Geomean_{chronic}$ calculation - 4 crustacean species**	**Test species**	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	EC_{10}	E_rC_{50}	E_rC_{50}	Geomean	**Endpoint**	NOEC
(µg/L)		532	22	944	16.1	679	> 2017	28.7	**(µg/kg)**	≥ 1158
AF		100	10	100	10	10	10	10	**AF**	10
RAC (µg/L)		5.32	2.2	9.44	1.61	67.9	> 201.7	2.87	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC $_{gl\text{-}sw\ max}$ (µg/L)**	**PEC/RAC (= ETR)**							**PEC $_{gl\text{-}sed\ max}$ (µg/kg)**	**PEC/RAC (= ETR)**
Step 1										
	13.728	**2.6**	**6.2**	**1.5**	**8.5**	0.2	< 0.07	**4.8**	420.381	**≤ 3.6**
Step 2										
N-Europe	2.216	0.4	**1.01**	0.2	**1.4**	--	--	0.8	72.548	≤ 0.6
S-Europe	4.048	0.8	**1.8**	0.4	**2.5**	--	-	**1.4**	135.574	**≤ 1.2**
Step 3										
D3 ditch	0.632	--	0.3	--	0.4	--	--	0.2	0.510	≤ 0.004
D4 pond	0.049	--	0.02	--	0.03	--	--	0.02	0.483	≤ 0.004
D4 stream	0.527	--	0.2	--	0.3	--	--	0.2	0.160	≤ 0.001
D5 pond	0.034	--	0.02	--	0.02	--	--	0.01	0.334	≤ 0.003
D5 stream	0.504	--	0.2	--	0.3	--	--	0.2	0.041	≤ 0.0004
R1 pond	0.102	--	0.05	--	0.06	--	--	0.04	1.361	≤ 0.01
R1 stream	0.454	--	0.2	--	0.3	--	--	0.2	2.116	≤ 0.02

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Higher-Plant	Higher-tier information	Group	Sed. dwell. prolonged
R3 stream	0.585	--	0.3	--	0.4	--	--	0.2	1.870	≤ 0.02
R4 stream	0.418	--	0.2	--	0.3	--	--	0.1	2.780	≤ 0.02

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

For the intended single and twofold application of BAS 765 00 F in ‘winter cereals’ at 1x and 2x 100 g a.s./h, respectively, the calculated PEC/RAC ratios for mefentrifluconazole indicate an acceptable risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 - 3 $PEC_{sw, sed}$ values. Therefore, no further assessment is necessary.

Refined risk assessment for mefentrifluconazole

The tier 1 ETR calculations (see above) demonstrate an acceptable risk for all groups of aquatic organisms following all proposed uses of BAS 765 00 F.
Furthermore, chronic data on additional crustacean species is available which allow for a refined risk assessment for aquatic crustacean, the most sensitive group of aquatic organisms.

Besides the standard aquatic invertebrate species *D. magna*, three additional crustacean species were tested chronically with mefentrifluconazole (*i.e. A. bahia*, *D. pulex* and *D. longispina*). The additional endpoint from the *A. bahia* study is an unbound NOEC (*i.e.* ≥ 0.0132 mg a.s./L).

The presented refinement follows the current recommendations as stated in the Minutes of the Network on Pesticide Steering Consultation for the corrigendum of the Aquatic guidance document (EFSA, 2016) as well as the EFSA Aquatic Guidance document (EFSA, 2013).

The Minutes state:" *…for using the geomean approach, the endpoints should be derived by highly comparable tests (toxicity estimates characterized by a* ***similar duration*** *of the tests, a* ***comparable measurement endpoint****, covering a* ***similar life stage*** *of the tested species)*."

- The EC_{10} values from the studies on *D. magna*, *D. pulex* and *D. longispina* are all derived from chronic studies over equal test durations (*i.e*. 21 days) and are based on the same effect parameter, *i.e.* effects on reproduction (most sensitive endpoint: number of offspring/parent). Daphnids were exposed at the same life stage (*i.e.* > 2 and < 24 h at test initiation).

- The exposure duration of the study on *A. bahia* deviates slightly from study durations for *D. magna* (*i.e*. 28 days). However, by including the NOEC derived from the study on *A. bahia* within the geometric mean calculation, the resulting geometric mean value is more conservative than if the endpoint was not included.

The EFSA Aquatic Guidance Document states that the geometric mean approach may be applied for a refined risk assessment, when toxicity data for a limited number of additional test species are available. All preconditions (considering daphnids and *A. bahia*) for using this approach that were set out in the EFSA Guidance (chapter 8.3.2 and 8.3.3) are fulfilled:

- *similar endpoints:*
  Endpoints are highly similar as recommendation of the Network on Pesticide Steering Consultation are fulfilled (see above).
- *species of the same taxonomic group:* aquatic crustaceans (aquatic insects, e.g. *Chironomus* proved to be less sensitive)
- *available data exceed the first-tier data requirements:*
  additional studies on *D. pulex*, *D. longispina* and *A. bahia*
- *most sensitive species should not be more than a factor of 100 below the geometric mean:*
  The study on *A. bahia* provides the lowest endpoint which is a factor of ~2 below the geometric mean of all four chronic species.
- *Less than 8 species tested:*
  4 different species
- *If the lowest toxicity value is higher than the Geomean-RAC value, it is acceptable to use the Geometric mean approach:*
  The *D. magna* EC_{10} of 16.1 µg a.s./L is ~5.5 times higher than the $RAC_{geomean}$ of 2.87 µg a.s./L.

Since, requirements of the EFSA AGD and the proposed corrigendum (Network on Pesticide Steering Consultation) are met, the presented geomean approach is considered adequate for refinement of the chronic risk assessment for aquatic crustaceans.

Table 9.5-6: Calculation of the geometric mean based on chronic toxicity data for aquatic invertebrates

Test species	Endpoint [#]	BASF DocID
D. magna	21 d EC_{10} = 0.0161 mg a.s./L	2014/1098028
A. bahia	28 d NOEC ≥ 0.0132 mg a.s./L	2016/7001293
D. pulex	21 d EC_{10} = 0.0567 mg a.s./L	2015/1003913
D. longispina	21 d EC_{10} = 0.0564 mg a.s./L	2015/1003912
Geomean	**$Geomean_{chronic}$ = 0.0287 mg a.s./L**	-

[#] The endpoints based on mean measured concentrations are used for the calculation.

The resulting NOEC/EC_{10} values for the four tested crustacean species can be used to calculate a geometric mean of 0.0287 mg a.s./L. Considering the standard chronic assessment factor of 10 this results in a **Geomean-$RAC_{chronic}$ of 2.87 µg a.s./L**.

Review Comments:

The standard RA for the mefentrifluconazole based on worst-case endpoint from laboratory study (16.1 µg a.s./L) demonstrate that applications of BAS 765 00 F in cereals according to good agricultural practice are of low risk to the aquatic ecosystem without any mitigation measures. Thus, the calculated geometric mean of 0.0287 mg a.s./L is treated as supplementary data.

Metabolites of mefentrifluconazole

The acute toxicity to fish of the metabolites M750F003, M750F005, and M750F008 has been estimated using a QSAR (ECOSAR version 1.11) during the Annex I inclusion process to avoid unnecessary vertebrate testing. The QSAR data for fish were assessed as valid in the DAR (please refer to Volume 3 B.9 (AS), Chapter B.9.12.) and using a QSAR model for metabolite risk assessment is in line with the proposed non-testing methods according to the EFSA Aquatic Guidance Document; specifically, to reduce vertebrate toxicity testing (please refer to Chapter 10.1 of the Aquatic GD). Furthermore, there is clear evidence from the available toxicity data for daphnia and algae that the metabolites are less toxic in comparison to the parent. This is further shown by the new available acute toxicity study on *O. mykiss* with M750F005 conducted for a different region post Annex I inclusion. The study shows a ~ 10 times lower toxicity of the metabolite M750F005 (i.e. LC_{50} > 5 mg/L) compared to the active substance and therewith confirming the QSAR calculations. Additionally, in some cases in the algae and daphnia studies, metabolites did not show any toxicity up to the solubility limit (in most cases metabolites are 10-times less toxic than the parent). Finally, comparing the available data for daphnia and algae to the QSAR predictions for these groups of organisms, confirms the appropriateness of the approach.

Similarly, for sediment dwellers, there is no indication of increased toxicity from the available data set.

Based on EFSA request during the EU review the aquatic risk assessment for metabolites of mefentrifluconazole was performed assuming a 10-times increased toxicity to fish. Similarly, 10-times increased toxicity to sediment dwellers was assumed. This approach is deemed overly conservative and scientifically not justified as discussed above.

Nevertheless, the risk assessment for metabolites is shown below assuming a 10-times increased toxicity to fish for M750F008 and similar toxicity in comparison to the parent compound for M750F003. For sediment dwelling organisms, similar toxicity in comparison to the parent compound is assumed for M750F001, M750F005, M750F006, M750F007, and M750F008.

In Table 9.5-7 the ETR ratios for aquatic organisms are given for the use of BAS 765 00 F in ‘spring and winter cereals’ and for each organism group for the relevant metabolites of mefentrifluconazole. Worst-case $PEC_{sw, sed}$ values from twofold application (covering single application) in ‘spring and winter cereals’ are used for risk assessment.

Table 9.5-7: **Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of mefentrifluconazole for each organism group based on worst-case FOCUS Step 1 - 2 calculations following twofold application of BAS 765 00 F in 'spring and winter cereals (covering all other intended uses)'**

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Algae**	**Group**	**Sed. dwell. prolonged**
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***P. subcapitata***	**Test species**	***C. riparius***
AF		100	10	100	10	**AF**	10
1,2,4-triazole (M750F001)							
Endpoint (µg/L)		LC_{50} 498000	NOEC 3200	EC_{50} > 100000	E_rC_{50} > 22500	**Endpoint (µg/kg)**	NOEC ≥ 1158 #
RAC (µg/L)		4980	320	> 1000	> 2250	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	2.154	0.0004	0.007	< 0.002	< 0.0001	1.783	≤ 0.02
M750F003							
Endpoint (µg/L)		LC_{50} 532 #	NOEC n.a.	EC_{50} > 100000	E_rC_{50} > 100000	**Endpoint (µg/kg)**	NOEC ≥ 1944
RAC (µ/L)		5.32	--	> 1000	> 10000	**RAC (µg/kg)**	≥ 194.4
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	2.872	0.5	--	< 0.003	< 0.0003	16.854	≤ 0.09
M750F005							
Endpoint (µg/L)		LC_{50} > 5000	NOEC n.a.	EC_{50} > 8580	E_rC_{50} > 8570	**Endpoint (µg/kg)**	NOEC ≥ 1158 #
RAC (µg/L)		>50	--	> 85.8	> 857	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	2.347	< 0.05	--	< 0.03	< 0.003	143.931	**≤ 1.2**
Step 2							
N-Europe	--	--	--	--	--	24.968	≤0.2
S-Europe	--	--	--	--	--	46.547	≤ 0.4

M750F006							
Endpoint (µg/L)		LC_{50} 6200	NOEC n.a.	EC_{50} 4420	E_rC_{50} 1420	**Endpoint (µg/kg)**	NOEC ≥ 1158 #
RAC (µg/L)		62	--	44.2	142	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	2.927	0.05	--	0.07	0.02	122.329	≤ **1.1**
Step 2							
N-Europe	--	--	--	--	--	21.220	≤ 0.2
S-Europe	--	--	--	--	--	39.560	≤ 0.3
M750F007							
Endpoint (µg/L)		LC_{50} > 7200	NOEC n.a.	EC_{50} > 10000	E_rC_{50} > 10000	**Endpoint (µg/kg)**	NOEC ≥ 1158 #
RAC (µg/L)		> 72	--	> 100	> 1000	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	4.655	< 0.06	--	< 0.05	< 0.005	160.566	≤ **1.4**
Step 2							
N-Europe	--	--	--	--	--	27.853	≤ 0.2
S-Europe	--	--	--	--	--	51.926	≤ 0.4
M750F008							
Endpoint (µg/L)		LC_{50} 53.2*	NOEC n.a.	EC_{50} > 8070	E_rC_{50} 4080	**Endpoint (µg/kg)**	NOEC ≥ 1158 #
RAC (µg/L)		0.532	--	> 80.7	408	**RAC (µg/kg)**	≥ 115.8
FOCUS Scenario	**PEC gl-max, sw (µg/L)**	**PEC/RAC ratio (= ETR)**				**PEC gl-sed max (µg/kg)**	**PEC/RAC (= ETR)**
Step 1							
	0.302	0.6	--	< 0.004	0.0007	32.129	≤ 0.3

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; ETR: Exposure-toxicity ratio; n.a. = no study available; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold**

The endpoint for the active substance is used since the toxicity of the metabolite is not expected to be greater than the active substance from supporting data.

* 10-fold higher toxicity compared to the active substance is assumed.

For the intended single and twofold application of BAS 765 00 F in ‘spring and winter cereals’, the calculated PEC/RAC ratios for the mefentrifluconazole metabolites indicate an acceptable risk for all groups of aquatic organisms based on worst-case FOCUS Step 1 - 2 assumptions. Therefore, no further assessment is necessary.

Kresoxim-methyl

The relevant global maximum FOCUS Step 1 - 4 PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios for kresoxim-methyl are presented in tables below.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for kresoxim-methyl for each organism group based on FOCUS Steps 1 - 3 calculations following twofold * application of BAS 765 00 F in 'spring cereals' (case 1 §)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***A. bibraianus***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}
(µg/L)		190	13	186	32	250
AF		100	10	100	10	10
RAC (µg/L)		1.9	1.3	1.86	3.2	25
FOCUS Scenario	**PEC gl, sw-max (µg/L)**	**PEC/RAC (= ETR)**				
Step 1						
	36.824	**19**	**28**	**20**	**12**	**1.5**
Step 2						
N-Europe	1.856	0.98	**1.4**	0.998	0.6	0.07
S-Europe	1.679	0.9	**1.3**	0.9	0.5	0.07
Step 3						
D3 ditch	0.951 +	--	0.7	--	--	--
D4 pond	0.044	--	0.03	--	--	--
D4 stream	0.778 +	--	0.6	--	--	--
D5 pond	0.046	--	0.04	--	--	--

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
D5 stream	0.799 [+]	--	0.6	--	--	--
R4 stream [$]	1.782	0.9	**1.4**	0.96	0.6	0.07

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

* Worst-case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

[§] Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

[+] Maximum concentration calculated for single application scenario.

[$] In this scenario, FOCUS Step 3 PEC values were higher than those calculated in FOCUS Step 2. Therefore, ETR calculations are provided for all organisms.

For the intended twofold application of BAS 765 00 F in ‘spring cereals’ (case 1) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable acute and chronic risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 – 3 $PEC_{sw,}$ values, except for the chronic risk to fish for the R4 stream scenario. Therefore, additional Step 4 calculations are provided in Table 9.5-9.

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for kresoxim-methyl based on FOCUS Step 4 calculations and chronic toxicity data for fish with mitigation of spray drift and run-off for twofold * application of BAS 765 00 F in 'spring cereals' (case 1 §)

Intended use		spring cereals (case 1 §)	
Active substance		kresoxim-methyl	
Application rate (g a.s./ha)		2 × 150	
Nozzle reduction	**No-spray buffer (m)**	5	10
	Vegetated filter strip (m)	--	10
None	R4 stream	1.782	0.805
RAC (µg/L) 1.3 (*O. mykiss*)		**PEC/RAC ratio**	
None	R4 stream	**1.4**	0.6

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.
§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

For the intended twofold application of BAS 765 00 F in 'spring cereals' (Case 1) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable chronic risk to fish based on tier 1 toxicity data and worst-case FOCUS Step 4 $PEC_{sw,}$ value, if 10 m vegetated buffer zone is considered.

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for kresoxim-methyl for each organism group based on FOCUS Steps 1 - 3 calculations following twofold * application of BAS 765 00 F in 'spring cereals' (case 2 §)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***A. bibraianus***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}
(µg/L)		190	13	186	32	250
AF		100	10	100	10	10
RAC (µg/L)		1.9	1.3	1.86	3.2	25
FOCUS Scenario	**PEC gl, sw-max (µg/L)**	**PEC/RAC (= ETR)**				
Step 1						
	36.824	**19**	**28**	**20**	**12**	**1.5**
Step 2						
N-Europe	1.856	0.98	**1.4**	0.998	0.6	0.07
S-Europe	1.679	0.9	**1.3**	0.9	0.5	0.07
Step 3						
D3 ditch	0.951 +	--	0.7	--	--	--
D4 pond	0.033 +	--	0.03	--	--	--
D4 stream	0.778 +	--	0.6	--	--	--
D5 pond	0.033 +	--	0.03	--	--	--
D5 stream	0.799 +	--	0.6	--	--	--
R4 stream $	1.771	0.9	**1.4**	0.95	0.6	0.07

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

* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

+ Maximum concentration calculated for single application scenario.

$ In this scenario, FOCUS Step 3 PEC values were higher than those calculated in FOCUS Step 2. Therefore, ETR calculations are provided for all organisms.

For the intended twofold application of BAS 765 00 F in 'spring cereals' (Case 2) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable acute and chronic risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 – 3 $PEC_{sw,}$ values, except for the chronic risk to fish for the R4 stream scenario. Therefore, additional Step 4 calculations are provided in Table 9.5-11.

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for kresoxim-methyl based on FOCUS Step 4 calculations and chronic toxicity data for fish with mitigation of spray drift and run-off for twofold * application of BAS 765 00 F in 'spring cereals' (case 2 §)

Intended use		spring cereals (case 2 §)	
Active substance		kresoxim-methyl	
Application rate (g a.s./ha)		2 × 150	
Nozzle reduction	**No-spray buffer (m)**	5	10
	Vegetated filter strip (m)	--	10
None	R4 stream	1.771	0.799
RAC (µg/L) 1.3 (*O. mykiss*)		**PEC/RAC ratio**	
None	R4 stream	**1.4**	0.6

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

* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

For the intended twofold application of BAS 765 00 F in 'spring cereals' (Case 2) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable chronic risk to fish based on tier 1 toxicity data and worst-case FOCUS Step 4 $PEC_{sw,}$ value, if 10 m vegetated buffer zone is considered.

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for kresoxim-methyl for each organism group based on FOCUS Steps 1 - 3 calculations following twofold * application of BAS 765 00 F in 'winter cereals' (case 1 §)

Group			**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species			***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***A. bibraianus***
Endpoint			LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}
(µg/L)			190	13	186	32	250
AF			100	10	100	10	10
RAC (µg/L)			1.9	1.3	1.86	3.2	25
FOCUS Scenario	**PEC gl, sw-max (µg/L)**		**PEC/RAC (= ETR)**				
Step 1							
	36.824		**19**	**28**	**20**	**12**	**1.5**
Step 2							
N-Europe	1.856		0.98	**1.4**	0.998	0.6	0.07
S-Europe	1.679		0.9	**1.3**	0.9	0.5	0.07
Step 3							
D3 ditch	0.951 +	-	--	0.7	--	--	--
D4 pond	~~0.033~~ +	0.044	--	0.03	--	--	--
D4 stream	0.793 +	-	--	0.6	--	--	--
D5 pond	~~0.033~~ +	0.049	--	~~0.03~~ 0.04	--	--	--
D5 stream	0.759 +	-	--	0.6	--	--	--
R1 pond	~~0.124~~	0.183	--	0.1	--	--	--
R1 stream	~~1.396~~	1.401	--	**1.1**	--	--	--

Group			Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
R3 stream	~~1.626~~	1.629	--	**1.3**	--	--	--
R4 stream [$]	~~1.797~~	1.809	0.9	**1.4**	1.97	0.6	0.07

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

* Worst-case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

[§] Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

[+] Maximum concentration calculated for single application scenario.

[$] In this scenario, FOCUS Step 3 PEC values were higher than those calculated in FOCUS Step 2. Therefore, ETR calculations are provided for all organisms.

For the intended twofold application of BAS 765 00 F in ‘winter cereals’ (Case 1) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable acute and chronic risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 – 3 $PEC_{sw,}$ values, except for the chronic risk to fish for the R1, R3 and R4 stream scenarios. Therefore, additional Step 4 calculations are provided in Table 9.5-13.

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for kresoxim-methyl based on FOCUS Step 4 calculations and chronic toxicity data for fish with mitigation of spray drift and run-off for twofold * application of BAS 765 00 F in 'winter cereals' (case 1 §)

Intended use **Active substance** **Application rate (g a.s./ha)**		winter cereals (case 1 §) kresoxim-methyl 2 × 150	
Nozzle reduction	**No-spray buffer (m)**	5	10
	Vegetated filter strip (m)	--	10
None	R1 stream	1.401	0.637
None	R3 stream	1.629	0.743
None	R4 stream	1.809	0.816
RAC (µg/L) 1.3 (*O. mykiss*)		**PEC/RAC ratio**	
None	R1 stream	**1.1**	0.5
None	R3 stream	**1.3**	0.6
None	R4 stream	**1.4**	0.6

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

* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

For the intended twofold application of BAS 765 00 F in 'winter cereals' (Case 1) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable chronic risk to fish based on tier 1 toxicity data and worst-case FOCUS Step 4 $PEC_{sw,}$ value, if 10 m vegetated buffer zone is considered.

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for kresoxim-methyl for each organism group based on FOCUS Steps 1 - 3 calculations following twofold * application of BAS 765 00 F in 'winter cereals' (case 2 §)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**
Test species		***O. mykiss***	***O. mykiss***	***D. magna***	***D. magna***	***A. bibraianus***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}
(µg/L)		190	13	186	32	250
AF		100	10	100	10	10
RAC (µg/L)		1.9	1.3	1.86	3.2	25
FOCUS Scenario	**PEC gl, sw-max (µg/L)**	**PEC/RAC (= ETR)**				
Step 1						
	36.824	**19**	**28**	**20**	**12**	**1.5**
Step 2						
N-Europe	1.856	0.98	**1.4**	0.998	0.6	0.07
S-Europe	1.679	0.9	**1.3**	0.9	0.5	0.07
Step 3						
D3 ditch	0.951 +	--	0.7	--	--	--
D4 pond	0.033 +	--	0.03	--	--	--
D4 stream	0.793 +	--	0.6	--	--	--
D5 pond	0.033 +	--	0.03	--	--	--
D5 stream	0.759 +	--	0.6	--	--	--
R1 pond	0.124	--	0.1	--	--	--
R1 stream	1.396	--	**1.1**	--	--	--

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae
R3 stream	1.626	--	**1.3**	--	--	--
R4 stream [$]	1.797	0.95	**1.4**	0.97	0.6	0.07

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

* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

+ Maximum concentration calculated for single application scenario.

$ In this scenario, FOCUS Step 3 PEC values were higher than those calculated in FOCUS Step 2. Therefore, ETR calculations are provided for all organisms.

For the intended twofold application of BAS 765 00 F in ‘winter cereals’ (Case 2) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable acute and chronic risk to all groups of aquatic organisms based on tier 1 toxicity data and worst-case FOCUS Step 1 – 3 $PEC_{sw,}$ values, except for the chronic risk to fish for the R1, R3 and R4 stream scenarios. Therefore, additional Step 4 calculations are provided in Table 9.5-11.

Table 9.5-15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for kresoxim-methyl based on FOCUS Step 4 calculations and chronic toxicity data for fish with mitigation of spray drift and run-off for twofold * application of BAS 765 00 F in 'winter cereals' (case 2 §)

Intended use		winter cereals (case 1 §)	
Active substance		kresoxim-methyl	
Application rate (g a.s./ha)		2 × 150	
Nozzle reduction	**No-spray buffer (m)**	5	10
	Vegetated filter strip (m)	--	10
None	R1 stream	1.396	0.635
None	R3 stream	1.626	0.742
None	R4 stream	1.797	0.811
RAC (µg/L) 1.3 (*O. mykiss*)		**PEC/RAC ratio**	
None	R1 stream	**1.1**	0.5
None	R3 stream	**1.3**	0.6
None	R4 stream	**1.4**	0.6

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

* Worst case PEC values are used for ETR calculations. Risk assessment for the single application is covered by the calculations for the twofold application scenario unless otherwise stated.

§ Case 1 and Case 2 refer to different parameter combinations (for details please refer to Part B, Section 8).

For the intended twofold application of BAS 765 00 F in 'winter cereals' (Case 2) at 2x 150 g a.s./ha, covering also the single application, the calculated PEC/RAC ratios for kresoxim-methyl indicate an acceptable chronic risk to fish based on tier 1 toxicity data and worst-case FOCUS Step 4 $PEC_{sw,}$ value, if 10 m vegetated buffer zone is considered.

Metabolites of kresoxim-methyl

The kresoxim-methyl metabolite BF 490-5 has been detected in soil at levels above 5% and has therefore been checked for its ecotoxicological potential. As daphnids have been shown to be of similar sensitivity as fish to the parent compound and the main metabolite BF 490-1, and in order to avoid unnecessary testing, only a study on *Daphnia magna* has been performed. The absence of toxic effects confirms the low ecotoxicological potential and does not warrant any further testing (please refer to the DAR, Vol.3, Annex B.9.2.6, part 1, revised in August 2010).

In Table 9.5-16 the ETR ratios for aquatic organisms are given for the use of BAS 765 00 F in 'spring and winter cereals' and for each organism group for the relevant metabolites of kresoxim-methyl. Worst-case PEC_{sw} values from twofold application (covering single application) in 'spring and winter cereals' are used for risk assessment.

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of kresoxim-methyl for each organism group based on worst-case FOCUS Step 1 calculations following twofold application of BAS 765 00 F in 'spring and winter cereals (covering all other intended uses)'

Test species		***O. mykiss***	***D. magna***	***P. subcapitata***
AF		100	100	10
			BF 490-1	
Endpoint (µg/L)		LC_{50} > 100000	EC_{50} > 100000	E_rC_{50} > 500000
RAC (µg/L)		> 1000	> 1000	> 50000
FOCUS	**PEC $_{gl\text{-}max}$ (µg/L)**	PEC/RAC ratio		
Step 1	155.243	< 0.2	< 0.2	< 0.003
			BF 490-5	
Endpoint (µg/L)		LC_{50} -	EC_{50} > 100000	E_rC_{50} -
RAC (µg/L)		-	> 1000	-
FOCUS	**PEC $_{gl\text{-}max}$ (µg/L)**	PEC/RAC ratio		
Step 1	4.504	-	< 0.005	-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration

For the intended single and twofold application of BAS 765 00 F in 'spring and winter cereals', the calculated PEC/RAC ratios for the kresoxim-methyl metabolites indicate an acceptable risk for all groups of aquatic organisms based on worst-case FOCUS Step 1 assumptions. Therefore, no further assessment is necessary.

Formulation risk assessment

A mixture toxicity risk assessment for the formulated product BAS 765 00 F, which is presented below, was conducted in accordance with the EFSA Aquatic GD. In the following the concentration addition (CA) model is used. To determine the respective formulation effect, EFSA proposes to calculate the model deviation ratio (MDR), which divides the calculated mixture toxicity ($EC_{x\ mix\text{-}CA}$) by the measured mixture toxicity ($EC_{x\ PPP}$). If the MDR is between 0.2 and 5 the observed and calculated mixture toxicities are considered in agreement. Respective MDR calculations are presented in Table 9.5-17.

Table 9.5-17: Comparison of the measured toxicity of the formulated product BAS 765 00 F and the calculated formulation toxicity based on the data for the active substances mefentrifluconazole and kresoxim-methyl

Test Species	Test system	Endpoint	Measured toxicity of the active substances (EC / LC_{50}) [µg a.s./L]		Measured toxicity of BAS 765 00 F (ECx_{ppp}) [µg product/L]	Calculated mixture toxicity [µg product/L] *	MDR
O. mykiss	acute	96 h LC_{50}	Mefentrifluconazole	532	1080 (248 µg a.s./L) 747	1115 (256 µg a.s./L)	1.0
			Kresoxim-methyl	190			1.49
D. magna	acute	48 h EC_{50}	Mefentrifluconazole	944	1350 (310 µg a.s./L)	1195 (274 µg a.s./L)	0.9
			Kresoxim-methyl	186			
P. subcapitata	--	72 h E_rC_{50}	Mefentrifluconazole	1352	1330 (305 ug a.s./L)	1617 (371 µg a.s./L)	1.2
		72 h E_rC_{50}	Kresoxim-methyl	250			

MDR = model deviation ratio (calculated toxicity / measured toxicity)

* The theoretical mixture toxicity of the formulation was re-calculated assuming concentration addition based on the measured toxicity data of the active substances, their nominal contents within the formulation (*i.e.* 100 g mefentrifluconazole/L and 150 g kresoxim-methyl/L) and the product density of 1.09 g/cm^3.

The calculated MDR values are between 0.9 and ~~1.2~~ 1.4 for all organisms, indicating that the formulation does not cause synergistic or antagonistic toxicity compared to the active substances but instead follows the expected toxicity for all groups of aquatic organisms (*i.e.* the CA model provides a reliable estimate of the toxicity of the given mixture). Furthermore, based on the calculations it can be concluded that chronic studies on fish and invertebrates using the formulations are not required, since the product is not by a factor ≥10 acutely more toxic than the active substances.

With regard to the mixture risk assessment, the EFSA Aquatic GD further states that if the toxicity of the mixture is largely explained by the toxicity of a single active substance and the CA model provides a reliable estimate of the toxicity of the given mixture, a sufficient protection level might be achieved by simply basing the risk assessment on the toxicity data for that "single driver". Whether one a.s. is driving the toxicity of the given mixture can be verified by the "Toxic Unit (TU)" approach. The EFSA Aquatic GD states that if more than 90% of the sum of toxic units calculated for the formulation comes from a single a.s., the risk assessment is sufficiently addressed by the risk assessment for the active substances. TU calculations for BAS 765 00 F are presented in Table 9.5-18.

Table 9.5-18: Toxic Unit calculations for BAS 765 00 F based on the content of the active substances mefentrifluconazole and kresoxim-methyl in the formulated product and the toxicity of the active substances

Group	Test substance	Test system	Nominal content of a.s. in BAS 765 00 F [g/L]	Measured toxicity of the a.s. ($LC_{50a.s.}$ / $EC_{xa.s.}$ / $NOEC_{a.s.}$) [µg a.s./L]	Toxic Unit (TU)	Toxic Unit [%]
Fish, acute	Mefentrifluconazole	96 h LC_{50} *O. mykiss*	100	532	187970	19.23
	Kresoxim-methyl	96 h LC_{50} *O. mykiss*	150	190	789474	80.77
SUM TU					977444	
Fish, prolonged +	Mefentrifluconazole	36 d NOEC *D. rerio*	100	27 [1)]	3703704	68.24
	Kresoxim-methyl	32 d NOEC *O. mykiss*	150	87 [2)]	1724138	31.76
SUM TU					5427842	
Invertebrate, acute	Mefentrifluconazole	48 h EC_{50} *D. magna*	100	944	105932	11.6
	Kresoxim-methyl	48 h EC_{50} *D. magna*	150	186	806452	88.4
SUM TU					912384	
Invertebrate, prolonged	Mefentrifluconazole	21 d EC10 *D. magna*	100	16.1	6211180	56.99
	Kresoxim-methyl	21 d NOEC *D. magna*	150	32	4687500	43.01
SUM TU					15676511	
Algae	Mefentrifluconazole	72 h E_rC_{50} *P. subcapitata*	100	1330	73964	11.0
	Kresoxim-methyl	72 h E_rC_{50} *P. subcapitata*	150	250	600000	89.0
SUM TU					673964	

+ Since no comparable species are available, the lowest chronic fish endpoints for each active ingredient are used as a worst-case approach.

1) For comparability reasons (similar duration and life stage), the ELS study in *D. rerio* (slightly higher endpoint than *D. rerio* FFLC study) was used for mefentrifluconazole to obtain a calculated mixture toxicity endpoint. ELS studies are also the current data requirement in the EU.

2) For comparability reasons (similar duration and life stage), the only available ELS study in *P. promelas* was used for kresoxim-methyl to obtain a calculated mixture toxicity endpoint. ELS studies are also the current data requirement in the EU.

Based on "Toxic Unit (TU)" calculations for aquatic organisms it is shown that for fish, aquatic invertebrates, and algae none of the active substances solely accounts for the toxicity of the formulated product BAS 765 00 F.

For algae no single driver of the toxicity could be identified. However, in line with the EFSA Aquatic Guidance Document (2013; Chapter 10.3.7), a mixture toxicity risk assessment is not required in this case, because all ETRs of the active substance risk assessment for algae are below 0.5 (*i.e*. ETR trigger/n; n=number of active substances).

For acute risk to fish and aquatic invertebrates, mixture RA according to EFSA Aquatic Guidance Document (2013) can be based on measured mixture toxicity ($EC_{xmix\text{-}CA,}$ see Table 9.5-17) since the mixture composition in the formulation is sufficiently similar to the mixture composition at the PEC_{mix} ($ECx_{mix\text{-}CA}$ [a.s. in PPP]/$ECx_{mix\text{-}CA}$ [a.s. in PEC_{mix}] = 0.8 - 1.2). For chronic risk to fish and aquatic invertebrates, mixture RA according to the EFSA Aquatic Guidance Document (2013) should be based on calculated mixture toxicity ($NOEC_{mix\text{-}CA,}$ see Table 9.5-17) as no chronic data is available for the formulation and no synergism is indicated (see Table 9.5-17). Thus, an additional mixture toxicity RA is provided below. ETR calculations use the worst-case FOCUS Step 1-3 PEC_{mix} values resulting from the highest values for each FOCUS scenario (see Table 9.5-20). Respective calculations of $ETR_{mix\text{-}CA}$ for BAS 765 00 F are presented in Table 9.5-19 to Table 9.5-20.

Table 9.5-19: Aquatic organisms: acceptability of risk ($PEC_{mix,\ max}$/RAC < 1) for the formulation BAS 765 00 F based on worst-case FOCUS Step 1 – 3 calculations in 'spring cereals' (covering all intended uses)

Group		**Fish, acute**	**Fish, prolonged**	**Invertebrate, acute**	**Invertebrate, prolonged**
Test species		***O. mykiss***	***P. promelas* / *D. rerio* ***	***D. magna***	***D. magna***
Endpoint (µg a.s./L)		$LC_{50\ PPP}$ ~~247.7~~ 171	$NOEC_{mix\text{-}CA}$ 46	$EC_{50\ PPP}$ 309.6	$EC_{10}/NOEC_{mix\text{-}CA}$ 23
AF		100	10	100	10
RAC (µg a.s./L)		~~2.477~~ 1.71	4.6	3.096	2.3
FOCUS Scenario	**$PEC_{sw\ mix,\ max}$ (µg sum a.s./L)**	**PEC_{mix}/RAC ratio (= ETR)**			
Step 1					
	50.754	~~20~~ **29.3**	**11**	**16**	**22**
Step 2					
N-Europe	4.072	~~1.6~~ **2.35**	**0.9**	**1.3**	**1.8**
S-Europe	5.743	~~2.3~~ **3.32**	**1.2**	**1.9**	**2.5**
Step 3					
D3 ditch	1.583	~~0.6~~ 0.9	0.3	0.5	0.7
D4 pond	0.102	~~0.04~~ 0.6	0.02	0.03	0.04
D4 stream	1.295	~~0.5~~ 0.75	0.3	0.4	0.6
D5 pond	0.078	~~0.03~~ 0.45	0.02	0.03	0.03
D5 stream	1.330	~~0.5~~ 0.8	0.3	0.4	0.6
R4 stream	2.220	~~0.9~~ **1.3**	0.5	0.7	0.97
Step 4 (10+10)					
R4 stream	0.986	0.6	-	-	-

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

* For comparability reasons (similar duration), the ELS study in *D. rerio* (slightly higher endpoint than *D. rerio* FFLC study) was used for mefentrifluconazole and the only available ELS study in *P. promelas* was used for kresoxim-methyl to obtain a calculated mixture toxicity endpoint. ELS studies are also the current data requirement in the EU.

For the intended application of BAS 765 00 F in 'spring cereals' (covering all intended uses), the calculated PEC/RAC ratios indicate that the acute and chronic risk to fish and invertebrates is acceptable.

Table 9.5-20: Aquatic organisms: acceptability of risk ($PEC_{mix,\ max}$/ RAC < 1) for the formulation BAS 765 00 F based on worst-case FOCUS Step 1 – 3 calculations in 'winter cereals' (covering all intended uses)

Group		Fish, acute	Fish, prolonged	Invertebrate, acute	Invertebrate, prolonged
Test species		***O. mykiss***	***P. promelas* / *D. rerio****	***D. magna***	***D. magna***
Endpoint		$LC_{50\ PPP}$	$NOEC_{mix\text{-}CA}$	$EC_{50\ PPP}$	$EC_{10}/NOEC_{mix\text{-}CA}$
(µg a.s./L)		~~247.7~~ 171	46	309.6	23
AF		100	10	100	10
RAC (µg a.s./L)		~~2.477~~ 1.71	4.6	3.096	2.3
FOCUS Step / Scenario	**$PEC_{sw\ mix,\ max}$ (µg sum a.s./L)**	**PEC_{mix}/RAC ratio (= ETR)**			
Step 1					
	50.754	~~20~~ **29.3**	**11**	**16**	**22**
Step 2					
N-Europe	4.072	~~1.6~~ **2.35**	**0.9**	**1.3**	**1.8**
S-Europe	5.743	~~2.3~~ **3.32**	**1.2**	**1.9**	**2.5**
Step 3					
D3 ditch	1.583	~~0.6~~ 0.9	0.3	0.5	0.7
D4 pond	0.093	~~0.04~~ 0.05	0.02	0.03	0.04
D4 stream	1.320	~~0.5~~ 0.8	0.3	0.4	0.6
D5 pond	0.083	~~0.03~~ 0.05	0.02	0.03	0.04
D5 stream	1.263	~~0.5~~ 0.7	0.3	0.4	0.5
R1 pond	~~0.287~~ 0.285	~~0.1~~ 0.2	0.06	0.09	0.1
R1 stream	~~1.875~~ 1.855	~~0.8~~ **1.1**	0.4	0.6	0.8
R3 stream	~~2.233~~ 2.214	~~0.9~~ **1.3**	0.5	0.7	0.97
R4 stream	~~2.247~~ 2.227	~~0.9~~ **1.3**	0.5	0.7	0.97
Step 4 (10+10)					
R1 stream	0.843	0.5	-	-	-
R3 stream	0.979	0.6	-	-	-
R4 stream	0.981	0.6	-	-	-

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

* For comparability reasons (similar duration), the ELS study in *D. rerio* (slightly higher endpoint than *D. rerio* FFLC study) was used for mefentrifluconazole and the only available ELS study in *P. promelas* was used for kresoxim-methyl to obtain a calculated mixture toxicity endpoint. ELS studies are also the current data requirement in the EU.

For the intended application of BAS 765 00 F in 'winter cereals' (covering all intended uses), the calculated PEC/RAC ratios indicate that the acute and chronic risk to fish and invertebrates is acceptable.

Residue data in fish

Mefentrifluconazole

The log P_{ow} of the active substance mefentrifluconazole was determined to be 3.34. In the BCF study (BASF DocID 2015/1122811) the steady state after exposure of *O. mykiss* to mefentrifluconazole at a nominal exposure level of 0.01 mg/L, was reached after 2.6 days. After exposure termination, radioactivity levels in fish tissues decreased rapidly with a half-life of *ca.* 0.59 days. After 7 days in clean water the whole-body residues in fish had declined to 3% of the mean steady state concentration (CF_{ss}). The BCF_{KLg} (lipid content and growth corrected) was determined to be 385.

Despite the relatively high lipophilicity of mefentrifluconazole, it is concluded that there is no risk of bioaccumulation due to the low accumulation and rapid excretion of the active substance from fish. Thus, residues of mefentrifluconazole in fish are of no concern and no accumulation in the food chain is to be expected.

Kresoxim-methyl

The log P_{ow} of the active substance kresoxim-methyl was determined to be 3.4 (BASF DocID 1990/10570). A bioaccumulation study in fish was performed (BASF DocID 1994/10725). The bioconcentration factor for whole fish was 220 and elimination was rapid. Due to the rapid excretion of the active substance from fish it is concluded that there is no risk of bioaccumulation in food chains.

For details please refer to the Draft Assessment Report of kresoxim-methyl (DAR, Vol.3, Annex B.9, part 1, revised in March 2010).

Thus, residues of the active substances as contained in BAS 765 00 F in fish are of low concern and no accumulation in the food chain is to be expected.

9.5.3 Overall conclusions

The standard and refined risk assessment provided for the fungicidal product BAS 765 00 F, the active substances mefentrifluconazole and kresoxim-methyl as well as their major metabolites demonstrate that the application of BAS 765 00 F in 'spring and winter cereals' according to good agricultural practice is of low risk to aquatic ecosystems, if 10 m vegetated buffer zone is considered.

Review Comments:
The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). The risk assessment was based on the worst case PEC values and the results of laboratory toxicity testing.
The standard RAs for the active substances (worst-case endpoints from laboratory studies): mefentrifluconazole and kresoxim-methyl, their metabolites and the formulated product demonstrate that applications of BAS 765 00 F in cereals according to good agricultural practice are of low risk to the aquatic ecosystem with appropriate mitigation measures (for R scenarios: 10 m no-spray buffer and 10 m vegetated filter strip).

References

EFSA (2013) EFSA Scientific Opinion. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7): 3290.

Fryday, S. and Thompson, H. 2012. Toxicity of pesticides to aquatic and terrestrial life stages of amphibians and occurrence, habitat use and exposure of amphibian species in agricultural environments. EFSA Supporting Publications, 9, EN-343: 348 pp.

European Commission (2013) Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with the Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

Weltje, L., P. Simpson, M. Gross, M. Crane & J. R. Wheeler (2013) Comparative acute and chronic sensitivity of fish and amphibians: a critical review of data. Environmental Toxicology and Chemistry, 32, 984-994.

Appendix:

Table 9.5-21: PEC $_{mix}$ values based on worst-case FOCUS Step 1 – 3 calculations considering the active substances mefentrifluconazole and kresoxim-methyl after application of BAS 765 00 F in 'winter cereals' and 'spring cereals' (covering all intended uses)

FOCUS Scenario	Mefentrifluconazole PEC a.i. [µg/L]	Kresoxim-methyl PEC a.i. [µg/L]	PECmix [µg/L]
'Spring cereals' (Case 1, 2) [1)]			
Step 1			
	13.728	36.824	50.754
Step 2			
N-Europe	2.216	1.856	4.072
S-Europe	4.048	1.679	5.743
Step 3			
D3 ditch	0.632	0.951[+]	1.583
D4 pond	0.058	0.044 (0.033)	0.102[#]
D4 stream	0.517	0.778 [+]	1.295
D5 pond	0.032	0.046 (0.033)	0.078[#]
D5 stream	0.531	0.799 [+]	1.330
R4 stream	0.418	1.782 (1.771)	2.220[#]
'Winter cereals' (Case 1, 2) [1)]			
Step 1			
	13.728	63.824	50.754
Step 2			
N-Europe	2.216	1.856	4.072
S-Europe	4.048	1.679	5.743
Step 3			
D3 ditch	0.632	0.951 [+]	1.583
D4 pond	0.049	0.033 (0.033)[+]	0.093
D4 stream	0.527	0.793 [+]	1.320
D5 pond	0.034	0.033 (0.033) [+]	0.083
D5 stream	0.504	0.759 [+]	1.263
R1 pond	0.102	0.124 (0.124)	0.287
R1 stream	0.454	1.396 (1.396)	1.875
R3 stream	0.585	1.626 (1.626)	2.233
R4 stream	0.418	1.797 (1.797)	2.247

[1)] Case 2 values are shown in brackets.
[2)] Tier 2 FOCUS Step 3 PEC values for D2 ditch scenario are shown in brackets and used for refinement of the risk assessment. For details please refer to Part B, Section 8.
[+] Maximum concentration calculated for single application scenario.
[#] Worst-case from Case 1 and Case 2 values.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Acute contact and oral toxicity studies on honey bees have been carried out with the active substances mefentrifluconazole (BAS 750 F) and kresoxim-methyl (BAS 490 F). Furthermore, a chronic oral toxicity study on honey bees, a single exposure and a repeated exposure toxicity study on honey bee larvae as well as bumble bee acute contact and oral toxicity studies were performed the active substance mefentrifluconazole. Full details of these studies are provided in the respective EU documents.

For kresoxim-methyl acute honey bee larvae and oral chronic adult toxicity studies are provided, both studies were tested with the solo-formulation BAS 490 02 F (50% kresoxim-methyl).

For BAS 765 00 F, acute contact and oral toxicity studies on honey bees are available.

All studies are listed in Table 9.6-1, Table 9.6-2 and Table 9.6-3 New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

Table 9.6-1: Endpoints and effect values for mefentrifluconazole relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera (adults)	mefentrifluconazole	acute oral	LD_{50} (48 h) > 100 µg a.s./bee	EFSA Journal 2018;16(7):5379 2015/1128674
Apis mellifera (adults)	mefentrifluconazole	acute contact	LD_{50} (48 h) > 100 µg a.s./bee	EFSA Journal 2018;16(7):5379 2015/1128674
Apis mellifera (adults)	mefentrifluconazole	chronic	LDD_{50} (10 d) > 110.5 µg a.s./bee/day NOED (10 d) ≥ 110.5 µg a.s./bee/day	EFSA Journal 2018;16(7):5379 2013/1235086
Apis mellifera (larvae)	mefentrifluconazole	single exposure	NOED (8 d) = 29.7 µg a.s./larva LD_{50} (8 d) = 43.9 µg a.s./larva	EFSA Journal 2018;16(7):5379 2013/1235087
Apis mellifera (larvae)	mefentrifluconazole	repeated exposure	NOED (21 d) ≥ 50.1 µg a.s./larva ED_{50} (21 d) > 50.1 µg a.s./larva	Draft Assessment Report (DAR) of mefentrifluconazole (Apr. 2017), Vol. 3, B.9 2014/1327676 #
Apis mellifera (larvae)	mefentrifluconazole	repeated exposure	NOED (22 d) = 25 µg a.s./larva ED_{50} (22 d) > 50 µg a.s./larva	EFSA Journal 2018;16(7):5379 2017/1045562

Species	Substance	Exposure System	Results	Reference
Bombus terrestris (adults)	mefentrifluconazole	acute oral	LD_{50} (96 h) > 195.4 µg a.s./bumblebee	EFSA Journal 2018;16(7):5379 2014/1275250
Bombus terrestris (adults)	mefentrifluconazole	acute contact	LD_{50} (96 h) > 200.0 µg a.s./bumblebee	EFSA Journal 2018;16(7):5379 2014/1275250

[#] According to the Draft Assessment Report (DAR) of mefentrifluconazole (April 2017), Vol. 3, B.9, the study is not reliable

Table 9.6-2: Endpoints and effect values for kresoxim-methyl relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera (adults)	kresoxim-methyl	acute oral	LD_{50} (48 h) > 111.0 µg a.s./bee	EFSA Journal 2010;8(11):1891 2008/1010702
Apis mellifera (adults)	kresoxim-methyl	acute contact	LD_{50} (48 h) > 100.0 µg a.s./bee	EFSA Journal 2010;8(11):1891 2008/1010702
Apis mellifera (adults)	kresoxim-methyl (tested as BAS 490 02 F) [1)]	chronic	LD_{50} (10 d) = 124.1 µg a.s./bee/day NOED (10 d) = 72.7 µg a.s./bee/day	new study 2014/1111117
Apis mellifera (larvae)	kresoxim-methyl (tested as BAS 490 02 F) [1)]	single exposure	LD_{50} (72 h) > 50.0 µg a.s./larva NOED (72 h) ≥ 50.0 µg a.s./larva	new study 2014/1111118

[1)] Study conducted with the kresoxim-methyl solo-formulation BAS 490 02 F, containing 50% (w/w) kresoxim-methyl.

Table 9.6-3: Endpoints and effect values of BAS 765 00 F relevant for the risk assessment for bees

Species	Product	Exposure System	Results	Reference
Apis mellifera (adults)	BAS 765 00 F	acute oral	LD_{50} (48 h) > 750 µg/bee (corresponding to > 173.5 µg total a.s./bee)	not EU evaluated 2019/2034549
Apis mellifera (adults)	BAS 765 00 F	acute contact	LD_{50} (48 h) > 750 µg/bee (corresponding to > 173.5 µg total a.s./bee)	not EU evaluated 2019/2034549

9.6.1.1 Justification for new endpoints

Effects of the formulation BAS 765 00 F on honey bees were not evaluated as part of the EU assessment of the active substances mefentrifluconazole or kresoxim-methyl. Hence, all relevant data and assessments considering this formulation are provided here and are considered adequate.

To address data requirements according to Commission Regulation 283/2013 and 284/2013 additional information on chronic and developmental toxicity to honeybees is provided for kresoxim-methyl. A honey bee larvae study and a chronic toxicity study on adult honey bees have been conducted with the solo-formulation BAS 490 02 F (50% kresoxim-methyl) as surrogate for the active substance.

All chronic studies on bees which were previously not evaluated on EU level, were checked for their potential to calculate $L/EC_{10/20}$ values in accordance with Commission Regulations (EU) 283/2013 and 248/2013, respectively. If a calculation was possible, the $L/EC_{10/20}$ are provided in the corresponding study summary in Appendix 2. However, since these values are not relevant for the risk assessment, they are not listed in chapter 9.6.1.

Review comments:
According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): The Applicant should provide chronic test on bees and evaluation of effects on honey bee development with either formulated product. The chronic studies were not performed, therefore, for Poland, the deficiencies need to be fulfilled by 31.12.2021. Concerned Member States must decide on the consideration of data requirements on national level.

9.6.2 Risk assessment

The evaluation of the risk for bees 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) and the EPPO 2010 risk assessment scheme (*OEPP/EPPO, 2010: Environmental risk assessment scheme for plant protection products, Chapter 10: Honey bees, PP 3/10 (3), Bulletin OEPP/EPPO Bulletin 40, 323–331*). The EFSA bee guidance document (EFSA Journal 2013; 11(7):3295) was not used as it has not been adopted by the Standing Committee on Plants, Animals, Food and Feed at the time of application.

The application of BAS 765 00 F is envisioned in various cereals. The following risk assessment is based on the highest maximum single application rate of 1.0 L BAS 765 00 F/ha (equivalent to 100 g mefentrifluconazole/ha and 150 g kresoxim-methyl/ha; see Section 9 Chapter 9.1 for details).

It should be noted that all intended crops (barley, rye, triticale and wheat) are not considered bee attractive (USDA 2017). Therefore, the following risk assessment is considered worst-case.

9.6.2.1 Hazard quotients for bees

The risk to honey bees from the use of mefentrifluconazole, kresoxim-methyl and BAS 765 00 F was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (HQ) for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) (OEPP/EPPO, 2010: Chapter 10: Honey bees, PP 3/10 (3)) as follows.

$$\text{Hazard Quotient (HQ)} = \frac{\text{Maximum application rate [g/ha]}}{\text{Acute LD}_{50}\ [\mu\text{g/bee}]}$$

A hazard quotient of less than 50 indicates a low risk to honey bees colonies in the field (see Table 9.6-4 and Table 9.6-6).

Table 9.6-4: First-tier assessment of the risk for bees due to the use of mefentrifluconazole as contained in BAS 765 00 F according to the proposed use pattern

Intended use	Cereals		
Active substance	mefentrifluconazole		
Application rate (g a.s./ha)	2 x 100		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 100.0	100	< 1
Contact toxicity	> 100.0		< 1

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure.

Table 9.6-5: First-tier assessment of the risk for bees due to the use of kresoxim-methyl as contained in BAS 765 00 F according to the proposed use pattern

Intended use	Cereals		
Active substance	kresoxim-methyl		
Application rate (g a.s./ha)	2 x 150		
Test design	**LD_{50} (lab.) (µg a.s./bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 111.0	150	< 1.4
Contact toxicity	> 100.0		< 1.5

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure.

Table 9.6-6: First-tier assessment of the risk for bees due to the use of BAS 765 00 F according to the proposed use pattern

Intended use	cereals		
Product	BAS 765 00 F		
Application rate (L/ha)	2 x 1.0		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	> 750	1090 [1)]	< 1.5
Contact toxicity	> 750		< 1.5

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure.
1) Taking into account a single application of 1.0 L product/ha and the density of BAS 765 00 F of 1.09 g/cm^3.

Commission Regulation (EU) No 284/2013 lists conditions under which testing of the formulated product is required. In accordance with the requirements set out in points 8.3.1 and 8.3.2 of Part A of the Annex to Regulation (EU) No 283/2013, formulated product testing is needed if the product contains more than one active substance and if the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the toxicity of the active substances. For BAS 765 00 F, acute honey bee endpoints are available for all active substances and the end use product. This data can be used to check the decisive second condition, i.e. whether the formulated product shows unexpected toxicity, while only in this case additional studies with the formulated product would be needed to examine the potential chronic risk to adult bees and other honey bee life stages. If the acute endpoint of the product study shows expected toxicity in comparison to the calculated endpoint derived from the acute studies with the active substances, then the chronic studies of the active substances can be used to predict the endpoint of the formulated product adequately (see Table 9.6-8).

The comparison of the acute endpoint obtained with the formulated product and the active substance endpoints, under consideration of the model deviation ratio (MDR), is shown in Table 9.6-7. If the MDR is between 0.2 and 5, the observed and calculated mixture toxicities are considered in agreement. Comparing the acute toxicity of the active substances with the acute toxicity of the formulated product BAS 765 00 F, no indication for unpredicted product toxicity is given (MDR of 0.61 and 0.58 for acute oral and acute contact data, respectively). Therefore, the chronic product toxicity can be predicted by the measured endpoints of the chronic active-substance studies.

Furthermore, repeated exposure of adult honey bees and immature life stages within the hive is realistic for active substances but not for the formulated product (formulants have different phys.-chem. properties). Therefore, data on the active substances cover the risk of BAS 765 00 F and no chronic/larvae data for the product is needed for the risk assessment.

Table 9.6-7: Measured acute-toxicity of BAS 765 00 F and calculated mixture-toxicity comparison and presentation of the model deviation ratio (MDR)

Test organisms (Species)	Test type & endpoint	Measured toxicity of the a.s. [µg a.s./bee]		Measured toxicity of BAS 765 00 F ($LD_{50\ PPP}$) [µg product/bee]	Calculated mixture toxicity ($EC_{x\ mix\text{-}CA}$) [µg mixture/bee] 1)	MDR ($EC_{x\ mix\text{-}CA}$ / ECx_{PPP})
honey bee (*Apis mellifera*)	acute oral, 48 h LD_{50}	mefentrifluconazole	> 100	> 750 (> 173.5 µg total a.s./bee)	> 459.7 (> 106.3 µg total a.s./bee)	> 0.61
		kresoxim-methyl	> 111.0			
	acute contact, 48 h LD_{50}	mefentrifluconazole	> 100	> 750 (> 173.5 µg total a.s./bee)	> 432.4 (> 100.0 µg total a.s./bee)	> 0.58
		kresoxim-methyl	> 100			

PPP = Plant Protection Product; CA = concentration addition; MDR = model deviation ratio

1) The theoretical formulation toxicity of the product was re-calculated based on the measured toxicity data of the active substances and their nominal content within the formulation (i.e. 100 g mefentrifluconazole/L and 150 g kresoxim-methyl/L) and a product density of 1.081 g/cm^3 from the study.

Table 9.6-8: Measured chronic toxicity endpoints and calculated mixture toxicity for the honey bee (*Apis mellifera*) of the mixture of mefentrifluconazole(100 g/L) and kresoxim-methyl (150 g/L) in the product BAS 765 00 F

Test system	Endpoint	Toxicity of the a.s.		Calculated mixture toxicity ($EC_{x\ mix\text{-}CA}$) [µg mixture/bee] 3)
Chronic adult	LD_{50}	mefentrifluconazole kresoxim-methyl 2)	> 110.5 µg a.s./bee/day 124.1 µg a.s./bee/day	511.4 corresponding to 118.3 µg total a.s./bee
	NOED	mefentrifluconazole kresoxim-methyl 2)	**≥ 110.5 µg a.s./bee/day** **72.7 µg a.s./bee/day**	364.2 corresponding to **84.2 µg total a.s./bee**
Single/repeated exposure larvae 1)	L/ED_{50}	mefentrifluconazole kresoxim-methyl 2)	> 50.0 µg a.s./larva > 50.0 µg a.s./larva	216.2 corresponding to 50 µg total a.s./larva
	NOED	mefentrifluconazole kresoxim-methyl 2)	**25.0 µg a.s./larva** **≥ 50.0 µg a.s./larva**	154.4 corresponding to **35.7 µg total a.s./larva**

Values in **bold** are used in the risk assessment.

1) For kresoxim-methyl, results of the single exposure larvae study are considered, i.e. the 8 d LD_{50} and the 8 d NOED.

2) Study done with the representative solo-formulation for kresoxim-methyl BAS 490 02 F.

3) The theoretical formulation toxicity of the product was re-calculated based on the measured toxicity data of the active substances and their nominal content within the formulation (i.e. 100 g mefentrifluconazole/L and 150 g kresoxim-methyl/L) and a density of BAS 765 00 F of 1.09 g/cm^3.

Under Regulation (EC) No 1107/2009, no adopted risk assessment scheme currently exists for chronic honey bee or honey bee larvae studies. Nevertheless, additional studies were carried out with mefentrifluconazole (BAS 750 F) and kresoxim-methyl (BAS 490 F, tested as BAS 490 02 F). For mefentrifluconazole, chronic toxicity study on honey bees resulted in a NOED ≥ 110.5 µg a.s./bee/day. The NOED derived from the repeated exposure study on honey bee larvae is 25 µg a.s./larva. For kresoxim-methyl, chronic toxicity study on honey bees resulted in a NOED of 72.7 µg a.s./bee/day. The NOED derived from the single exposure study on honey bee larvae is ≥ 50 µg a.s./larva. In the absence of clear guidance (noted and agreed by member states) a preliminary risk assessment according to the current legal requirements (SANCO/10329/2002 and EPPO 2010) has been conducted and is presented below.

As already mentioned above, it should be noted that all intended crops (barley, rye, triticale and wheat) are not considered bee attractive (USDA 2017). Therefore, the following risk assessment underlies an unrealistic worst-case assumption.

For the **chronic risk assessment for adult honey bees and honey bee larvae**, the revised EPPO scheme (2010) suggests calculating the ratio between the NOEL (oral) and the exposure. This approach has been originally proposed for seed treatments, but can be directly applied to foliar applications as well. For adult bees, the exposure is assessed through the amount of residues that may be ingested by a bee in one day. The ratio between the NOEL (= NOED in µg a.s./bee/day) and the exposure (also in µg a.s./bee/day) is then calculated as follows:

$$TER_{chronic,adult} = \frac{NOED_{oral}[\mu g\ a.s./bee/day]}{Amount\ of\ residues\ ingested\ by\ a\ bee\ in\ one\ day\ [\mu g\ a.s./bee/day]}$$

For the risk assessment the exposure of larvae is estimated as the amount of residues that may be ingested by the larvae during their complete larval stage (feeding period of five days) as a worst case assumption. For larvae, the ratio between the NOEL (in µg a.s./larva) and the exposure (residues ingested over the five-day feeding period in µg a.s./larva) is calculated by the following equation:

$$TER_{chronic,larvae} = \frac{NOEL_{oral}[\mu g\ a.s./larva]}{Amount\ of\ residues\ ingested\ by\ a\ larva\ [\mu g\ a.s./larva]}$$

Following EPPO (2010) the expected worst-case residue consumption of larvae and adult bees was calculated. For mefentrifluconazole and kresoxim-methyl, no specific RUD values are reported in the external EFSA supporting publication on residues in bee relevant matrices (EFSA 2017). Therefore, overall RUD residue values for spray applications have been used for exposure estimation as reported in EFSA (2017). In order to be protective, we suggest using the 3rd Quantile data which are well above the more realistic median values. Expected residues in nectar and pollen are calculated using the maximum single application of BAS 765 00 F (100 g mefentrifluconazole/ha and 150 g kresoxim-methyl/ha; see Table 9.6-9).

Table 9.6-9: Residue values of the active substances in pollen and nectar

	3rd quartile RUD	Expected residues based on proposed GAP
Pollen		
mefentrifluconazole (Application rate 100 g a.s./ha)	63.7 mg a.s./kg [1)]	6.37 mg a.s./kg
kresoxim-methyl (Application rate 150 g a.s./ha)	63.7 mg a.s./kg [1)]	9.56 mg a.s./kg
Nectar		
mefentrifluconazole (Application rate 100 g a.s./ha)	3.99 mg a.s./kg [1)]	0.4 mg a.s./kg
kresoxim-methyl (Application rate 150 g a.s./ha)	3.99 mg a.s./kg [1)]	0.6 mg a.s./kg

1) Overall RUD values from EFSA supporting publication on residues in bee relevant matrices (EFSA 2017).

To calculate the expected consumption of the relevant matrixes EPPO 2010 refers to a review by Rortais *et al. (2005).* For adult honey bees, only nectar consumption is relevant as adult bees do not consume pollen. In Rortais *et al. (2005)* the maximum amount of sugar an adult bee consumes per day is given as 128 mg/bee/day. Based on nectar sugar concentration of 30% this corresponds to a total consumption of approximately 426.7 mg/bee/day, which can be considered an unrealistic worst-case scenario. In the absence of clear guidance, the nectar sugar concentration was taken from Rortais *et al*. (2005), which cite a range of sugar concentrations in nectars between 5-80% specifically mentioning 40% as representative in bee attractive crops. This range suggests that 30% sugar concentration can be considered conservative for crop plants, which is well supported by the literature (Pamminger *et al*. 2019). For honey bee larvae Rortais *et al.* (2005) gives a maximum of 59.4 mg sugar/5days, which corresponds to a nectar consumption of 196.7 mg/5days based on 30% sugar concentration in nectar. In addition to their nectar requirements honey bee larvae consume up to 2 mg pollen/5days (Babendreier *et al*. 2004). It is to be noted that the pollen consumption values mentioned in Rortais *et al.* (2005) based on a citation of Babendreier *et al*. (2004) are not the values which are mentioned in the original publication Babendreier *et al*. (2004).

To calculate the residue intake of mefentrifluconazole(BAS 750 F), kresoxim-methyl (BAS 490 F) and BAS 765 00 F by adult honey bees and honey bee larvae, the consumed amounts of pollen and nectar are multiplied with relevant measured residue in nectar and pollen after application of BAS 765 00 F (see Table 9.6-10 to Table 9.6-12). The calculated chronic TER values are given in Table 9.6-13 to Table 9.6-15. These TERs are compared to the trigger of 1 as proposed in the revised EPPO scheme (2010). **Given the protective worst-case assumptions underlying this risk assessment (detailed above), as well as the fact that all calculated TERs far exceed the suggested trigger by at least a factor of 155, it can be concluded that the risk for chronic adult and developmental exposure to honey bees can be considered acceptable.**

Table 9.6-10: Total residue intake for adult honey bees and larvae following exposure to BAS 750 F according to the proposed uses

Honey bee stage	Adult	Larva (over 5 days)
Residue in pollen	6.37 mg a.s./kg (= 0.00637 µg a.s./mg)	6.37 mg a.s./kg (= 0.00637 µg a.s./mg)
Pollen consumption	0	2 mg/larva
Residue intake through pollen	0 µg a.s./bee/day	0.01 µg a.s./larva
Residue in nectar	0.4 mg a.s./kg (= 0.0004 µg a.s./mg)	0.4 mg a.s./kg (= 0.0004 µg a.s./mg)
Nectar consumption	426.7 mg/bee/day	198 mg/larva
Residue intake through nectar	0.17 µg a.s./bee/day	0.08 µg a.s./larva
Total residue intake	**0.17 µg a.s./bee/day**	**0.09 µg a.s./larva**

Table 9.6-11: Total residue intake for adult honey bees and larvae following exposure to BAS 490 F according to the proposed uses

Honey bee stage	Adult	Larva (over 5 days)
Residue in pollen	9.56 mg a.s./kg (= 0.00956 µg a.s./mg)	9.56 mg a.s./kg (= 0.00956 µg a.s./mg)
Pollen consumption	0	2 mg/larva
Residue intake through pollen	0 µg a.s./bee/day	0.02 µg a.s./larva
Residue in nectar	0.6 mg a.s./kg (= 0.0006 µg a.s./mg)	0.6 mg a.s./kg (= 0.0006 µg a.s./mg)
Nectar consumption	426.7 mg/bee/day	198 mg/larva
Residue intake through nectar	0.26 µg a.s./bee/day	0.12 µg a.s./larva
Total residue intake	**0.26 µg a.s./bee/day**	**0.14 µg a.s./larva**

Table 9.6-12: Total residue intake for adult honey bees and larvae following exposure to BAS 765 00 F according to the proposed uses

Honey bee stage	Adult	Larva (over 5 days)
Residue in pollen	15.93 mg total a.s./kg (= 0.01593 µg total a.s./mg)	15.93 mg total a.s./kg (= 0.01593 µg total a.s./mg)
Pollen consumption	0	2 mg/larva
Residue intake through pollen	0 µg total a.s./bee/day	0.03 µg total a.s./larva
Residue in nectar	1 mg total a.s./kg (= 0.001 µg total a.s./mg)	1 mg total a.s./kg (= 0.001 µg total a.s./mg)
Nectar consumption	426.7 mg/bee/day	198 mg/larva
Residue intake through nectar	0.43 µg total a.s./bee/day	0.2 µg total a.s./larva
Total residue intake	**0.43 µg total a.s./bee/day**	**0.23 µg total a.s./larva**

Table 9.6-13: Chronic risk to adult bees and larvae following the use of BAS 750 F in cereals using TER approach

Honey bee stage	Exposure route	NOED	Worst case residue intake	TER_{ch}	Trigger value
Adult	Oral	≥ 110.5 µg a.s./bee/day	0.17 µg a.s./bee/day	≥ 650	1
Larvae	Oral	25.0 µg a.s./larva	0.09 µg a.s./larva	278	1

TER values shown in **bold** are below the proposed trigger.

Table 9.6-14: Chronic risk to adult bees and larvae following the use of BAS 490 F in cereals using TER approach

Honey bee stage	Exposure route	NOED	Worst case residue intake	TER_{ch}	Trigger value
Adult	Oral	72.7 µg a.s./bee/day	0.26 µg a.s./bee/day	280	1
Larvae	Oral	≥ 50.0 µg a.s./larva	0.14 µg a.s./larva	≥ 357	1

TER values shown in **bold** are below the proposed trigger.

Table 9.6-15: Chronic risk to adult bees and larvae following the use of BAS 765 00 F in cereals using TER approach

Honey bee stage	Exposure route	NOED*	Worst case residue intake	TER_{ch}	Trigger value
Adult	Oral	84.2 µg total a.s./bee/day	0.43 µg a.s./bee/day	196	1
Larvae	Oral	35.7 µg total a.s./larva	0.23 µg a.s./larva	155	1

* Calculated value by concentration addition (Finney); considering the portion of the active substance in relation to the sum of substances within the mixture (see Table 9.6-8).

The underlying assumptions of the presented risk assessment according to EPPO (2010) for chronic adult bees and honey bee larvae largely comply with the proposals presented in the EFSA bee guidance document:

- in both approaches product testing would not be required if the MDR is between 0.2 and 5
- in both approaches the chronic adult and larvae endpoints are set into relation to exposure which is based on pollen and nectar consumption.
- in both approaches the assumed amount of pollen and nectar consumption and the relevant time-frame is identical as it is based on the same literature references.
- the RUD values used from the EFSA supporting publication 2017 are based on a review and quality evaluation of available residue studies. The request of EFSA for the supporting publication was the limited availability of residue data at the time of the finalization of the EFSA bee guidance document. The EFSA supporting publication 2017 reflects therefore the current knowledge status.
- the possibility to refine exposure by using a time-weighted-average factor is a common refinement option for risk assessment of non-target organisms which is also mentioned in the EFSA bee guidance document.

However, in some respects this proposal deviates from the EFSA bee guidance document. Main differences lie in the endpoints and triggers used. In the EFSA bee guidance document it is proposed to use the LDD_{50} endpoint for chronic adult and the NOED for honey bee larvae. At the same time the proposed chronic adult trigger in the EFSA bee guidance document for the ETR (exposure toxicity ratio) based on LDD_{50} is 0.03, corresponding to a TER trigger (toxicity exposure ratio) of 33.3. The ETR trigger for the larvae risk assessment in the EFSA bee guidance document is 0.2 (corresponding to a TER trigger of 5). In EPPO 2010 the proposed TER trigger is 1 based on NOED endpoint for the chronic adult and the larvae risk assessment.

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

Not relevant.

9.6.3 Effects on bumble bees

For bumble bees no specific data requirement exists under regulation (EC) No 1107/2009. Nevertheless, to support the application an acute oral and contact study was conducted with the active substance mefentrifluconazole. The oral and contact LD_{50} were determined to be > 195.4 µg a.s./bumble bee and > 200.0 µg a.s./bumble bee, respectively. Both endpoints exceed the acute endpoints for honey bees suggesting that mefentrifluconazole poses no unacceptable risk to bumblebees at the proposed use rate.

9.6.4 Effects on solitary bees

No reliable and validated testing methods for solitary bees are currently available and no specific data requirement exists under regulation (EC) No 1107/2009. The EFSA bee guidance document (EFSA Journal 2013; 11(7):3295) has not been adopted at the time of application. Therefore, no studies with solitary bees have been performed.

9.6.5 Overall conclusions

The hazard quotients for BAS 765 00 F and the active substances mefentrifluconazole and kresoxim-methyl 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 the available information it can be concluded that no unacceptable risk to honey bees is expected from applications of BAS 765 00 F according to the proposed uses. This is confirmed by a risk assessment following EPPO (2010) for chronic exposure to adult honey bees and repeated exposure to honey bee larvae.

Review comments:

The evaluation of the acute risk for bees 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). Additionally, the chronic risk assessment was performed based on the revised EPPO scheme (2010).

For formulation BAS 765 00 F the worst-case exposure scenario was used (1.0 L product/ha). The risk assessment performed for substances mefentrifluconazole and kresoxim-methyl and the formulated product BAS 765 00 F is agreed by the zRMS.
All hazard quotients calculated are lower than 50, indicating that the acute oral and contact risk to bees is acceptable according to the proposed use pattern of BAS 765 00 F.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): The Applicant should provide chronic test on bees and evaluation of effects on honey bee development with either formulated product. The chronic studies were not performed, therefore, for Poland, the deficiencies need to be fulfilled by 31.12.2021. Concerned Member States must decide on the consideration of data requirements on national level.

References

Babendreier, D., Kalberer, N., Romeis, J., Fluri, P., & Bigler, F. (2004). Pollen consumption in honey bee larvae: a step forward in the risk assessment of transgenic plants. Apidologie, 35(3), 293-300.

Pamminger, T., Becker, R., Himmelreich, S., Schneider, C. W., & Bergtold, M. (2019). The nectar report:

quantitative review of nectar sugar concentrations offered by bee visited flowers in agricultural and non-agricultural landscapes. *PeerJ, 7*, e6329.

Rortais, A., Arnold, G., Halm, M. P., & Touffet-Briens, F. (2005). Modes of honey bees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie, 36(1), 71-83.

United States Department of Agriculture [USDA], (2017). Attractiveness of agricultural crops to pollinating bees for the collection of nectar and/or pollen. [Online]. United States Department of Agriculture, Washington, DC (2017). Assessed: January 2019.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

The toxicity of BAS 765 00 H to non-target arthropods has been investigated by carrying out Tier I tests on *Aphidius rhopalosiphi* and *Typhlodromus pyri*. All studies are listed in Table 9.7-1. New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

Table 9.7-1: Endpoints and effect values for BAS 765 00 H relevant for the risk assessment for non-target arthropods

Species	Product	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	BAS 765 00 H	laboratory test glass plates 2D exposure	LR_{50} > 2.0 L/ha Corrected mortality: 2.8% at .0125 L/ha 1.0% at 0.25 L/ha 2.8% at 0.5 L/ha 4.5% at 1.0 L/ha 11.5% at 2.0 L/ha	not EU evaluated 2019/2034600
Aphidius rhopalosiphi (adults)	BAS 765 00 H	laboratory test glass plates 2D exposure	LR_{50} > 2.0 L/ha Corrected mortality: 2.7% at .0125 L/ha 0.0% at 0.25 L/ha 17.5% at 0.5 L/ha 20.0% at 1.0 L/ha 27.5% at 2.0 L/ha	not EU evaluated 2019/2034598

9.7.1.1 Justification for new endpoints

Effects of BAS 765 00 H on non-target arthropods other than bees were not evaluated as part of the EU assessment of the active substances mefentrifluconazole and kresoxim-methyl. Hence, all relevant data and assessments considering this formulation are provided here and are considered adequate.

9.7.2 Risk assessment

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002).

9.7.2.1 Risk assessment for in-field exposure

The application of BAS 765 00 H is envisioned in cereals. The following risk assessment is based on the worst-case field application rate of 2 × 1.0 L/ha (see Section 9 Chapter 9.1 for details).

The in-field exposure (Predicted Environmental Rate, PER) is calculated according to the ESCORT 2 Guidance Document using the following equation:

$$\mathrm{PER_{in-field}} = \text{Application rate [L/ha]} * \text{MAF}$$

Default foliar and soil MAF values following multiple applications are given in the ESCORT 2 Guidance Document and are the following for BAS 765 00 H and its application scheme.

MAF (leaf substrate) = 1.7
MAF (soil) = 1.9

As a pre-emergence or early post-emergence application is not intended for the use of BAS 765 00 H (see Section 9 Chapter 9.1 for details), the MAF (soil) will not be considered in the following risk assessment. Thus, the $\mathrm{PER_{in\text{-}field}}$ is 1.7 L/ha.

The potential risk for non-target arthropods exposed in-field to BAS 765 00 H was assessed by calculating the hazard quotient (HQ = exposure/toxicity, see Table 9.7-2) for tier I standard laboratory studies according to the formula:

$$\mathrm{HQ_{in\text{-}field}} = \frac{\mathrm{PER_{in\text{-}field}\ [L/ha]}}{\mathrm{LR_{50}\ [L/ha]}}$$

For higher tier laboratory studies risk is acceptable if the $\mathrm{PER_{in\text{-}field}}$ is below the relevant endpoint (see Table 9.7-2).

Table 9.7-2: First-tier assessment of the in-field risk for non-target arthropods due to the use of BAS 765 00 H according to the proposed use pattern

Intended use	Cereals		
Product	BAS 765 00 H		
Application rate (L/ha)	2 x 1.0		
MAF	1.7 (vegetation)		
Test species	**Tier I**		
	LR_{50} (lab.) [L/ha]	**$PER_{in\text{-}field}$ [L/ha]**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 2.0	1.7	< 0.85
Aphidius rhopalosiphi	> 2.0		< 0.85

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient.

9.7.2.2 Risk assessment for off-field exposure

Exposure of non-target arthropods living in off-field areas to BAS 765 00 H will mainly be due to spray drift from field applications. Off-field areas are assumed to be densely vegetated and thus spray drift is unlikely to reach bare ground. Therefore, evaluation of exposure via soil residues in off-field areas was not considered. Off-field foliar PER values were calculated from in-field foliar PER values in conjunction with drift values listed in Appendix IV of the ESCORT 2 guidance document:

$$PER_{off\text{-}field} = \frac{\text{maximum } PER_{in\text{-}field} * (\%\ drift/100)}{\text{vegetation distribution factor}}$$

A vegetation distribution or dilution factor is included in the equation when calculating PER values from toxicity endpoints derived from two-dimensional studies (Table 9.7-3). A dilution factor of 10 is recommended by ESCORT 2.

For 2 applications of BAS 765 00 H in field crops, the drift value at 1 m distance is 2.38% of the application rate (82nd percentile drift). The drift factor (% drift/100) is therefore 2.38/100 = 0.0238.

Table 9.7-3: $PER_{off\text{-}field}$ values following application of BAS 765 00 H

Study type [Exposure scenario]	Maximum $PER_{in\text{-}field}$ [L/ha]	Drift factor [% drift/100]	Vegetation distribution factor	$PER_{off\text{-}field}$ [L/ha]
2D	1.7	0.0238	10	0.004
3D			--	0.04

To assess the potential risk of BAS 765 00 H to off-field non-target arthropods (see Table 9.7-4), the $PER_{off\text{-}field}$ (Table 9.7-3) is compared to the toxicity endpoints of tier I standard laboratory studies according to the following equation:

$$HQ_{off\text{-}field} = \frac{PER_{off\text{-}field}\ [L/ha]}{LR_{50}\ [L/ha]} * \text{correction factor}$$

ESCORT 2 recommends a correction factor of 10 for Tier I and 5 for higher Tier data in the off-field risk assessment to account for extrapolation from testing just few representative species to the species diversity expected in off-field areas.

Table 9.7-4: First-tier assessment of the off-field risk for non-target arthropods due to the use of BAS 765 00 H according to the proposed use pattern

Intended use	cereals				
Product	BAS 765 00 H				
Application rate (L/ha)	2 x 1.0				
MAF	1.7 (vegetation)				
vdf	10 (2D exposure) / - (3D exposure)				
Test species	**Tier I**				
	LR_{50} (lab.) [L/ha]	**Drift rate (%)**	**$PER_{off-field}$ [L/ha]**	**CF**	**$HQ_{off-field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	> 2.0	2.38	0.004	10	< 0.02
Aphidius rhopalosiphi	> 2.0				< 0.02

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient.

9.7.2.3 Additional higher-tier risk assessment

Not relevant

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Based on the results of the conducted first-tier risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of BAS 765 00 H according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

Review Comments:

Based on the results of the conducted Tier 1 risk assessment it can be concluded that low risk for non-target arthropods is expected from the use of BAS 765 00 F according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

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

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with mefentrifluconazole (BAS 750 F), kresoxim-methyl (BAS 490 F) and relevant metabolites. Full details of these studies are provided in the respective EU documents.
For kresoxim-methyl, chronic studies on earthworm and collembola with the representative solo-formulation BAS 490 02 F are available. Furthermore, studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with BAS 765 00 F. All studies are listed in Table 9.8-1, Table 9.8-2 and Table 9.8-3

New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

Table 9.8-1: Endpoints and effect values of mefentrifluconazole and metabolites relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance/metabolite	Exposure System	Results	Reference
Acute #				
Eisenia fetida	mefentrifluconazole	Mixed into substrate 14 d 10% peat content	LC_{50} > 1000 mg/kg dry soil $LC_{50\ CORR}$ = 500 mg/kg dry soil *	Draft Assessment Report (DAR) of mefentrifluconazole, Vol. 3, B.9 2015/1003342
Chronic				
Eisenia fetida	mefentrifluconazole	Mixed into substrate 56 d 10% peat content	NOEC = 8.0 mg/kg dry soil EC_{10} = 5.3 mg/kg dry soil $NOEC_{CORR}$ = 4.0 mg/kg dry soil * **$EC_{10\ CORR}$= 2.65 mg/kg dry soil ***	EFSA Journal 2018;16(7):5379 2013/1235075
Eisenia fetida	Metabolite, Reg. No. 87 084 1,2,4-triazole	Mixed into substrate 56 d 10% peat content	**NOEC ≥ 1.0 mg/kg dry soil**	EFSA Journal 2018;16(7):5379 2004/1041154
Folsomia candida	mefentrifluconazole	Mixed into substrate 28 d 5% peat content	**NOEC ≥ 400 mg/kg dry soil** **$NOEC_{CORR}$ ≥ 200 mg/kg dry soil ***	EFSA Journal 2018;16(7):5379 2013/1235081
Folsomia candida	Metabolite, Reg. No. 87 084 1,2,4-triazole	Mixed into substrate 28 d 10% peat content	**NOEC = 1.8 mg/kg dry soil**	EFSA Journal 2018;16(7):5379 2002/1007851

Species	Substance/metabolite	Exposure System	Results	Reference
Hypoaspis aculeifer	mefentrifluconazole	Mixed into substrate 14 d 5% peat content	**NOEC ≥ 1000 mg/kg dry soil** **NOEC $_{CORR}$ ≥ 500 mg/kg dry soil** *	EFSA Journal 2018;16(7):5379 2013/1235082
Hypoaspis aculeifer	Metabolite, Reg. No. 87 084 1,2,4-triazole	Mixed into substrate 14 d 5% peat content	**NOEC = 171 mg/kg dry soil**	EFSA Journal 2018;16(7):5379 2014/1326895

Values shown in **bold** are used for the risk assessment
Acute studies listed for reference only but not used in the risk assessment according to Commission Regulation (EU) 283/2013.
* Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

Table 9.8-2: Endpoints and effect values of kresoxim-methyl and metabolites relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance/metabolite	Exposure System	Results	Reference
Acute #				
Eisenia fetida	kresoxim-methyl	Mixed into substrate 14 d 10% peat content	LC_{50} > 937 mg a.s./kg dry soil $LC_{50\ CORR}$ > 469 mg a.s./kg dry soil *	EFSA Journal 2010;8(11):1891 1992/11722
Eisenia fetida	Metabolite, Reg. No. 262 451 BF 490-1 (490M01)	Mixed into substrate 14 d 10% peat content	LC_{50} > 1000 mg/kg dry soil	EFSA Journal 2010;8(11):1891 1994/10811
Eisenia fetida	Metabolite, Reg. No. 286 404 BF 490-5 (490M05)	Mixed into substrate 14 d 10% peat content	LC_{50} > 1000 mg/kg dry soil	EFSA Journal 2010;8(11):1891 2008/1010608
Chronic				
~~*Eisenia fetida*~~	~~kresoxim-methyl (tested as BAS 490 02 F)~~ 1)	~~Mixed into substrate 56 d 10% peat content~~	~~NOEC = 13.5 mg a.s./kg dry soil NOEC$_{CORR}$ = 6.75 mg a.s./kg dry soil* EC_{10} = 27.4 mg a.s./kg dry soil **$EC_{10\ CORR}$ = 13.7 mg a.s./kg dry soil**~~	~~not EU-evaluated 2013/1132495~~
~~*Folsomia candida*~~	~~kresoxim-methyl (tested as BAS 490 02 F)~~ 1)	~~Mixed into substrate 28 d 5% peat content~~	~~**NOEC ≥ 500 mg a.s./kg dry soil** NOEC$_{CORR}$ ≥ 250 mg a.s./kg dry soil~~	~~not EU-evaluated 2013/1132497~~

Endpoints in **bold** will be used in the risk assessment.
Acute studies listed for reference only but not used in the risk assessment according to Commission Regulation (EU) 283/2013.
* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.
1) Study conducted with the kresoxim-methyl solo-formulation BAS 490 02 F, containing 50% (w/w) kresoxim-methyl.

Table 9.8-3: Endpoints and effect values of BAS 765 00 F relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Product	Exposure System	Results	Reference
Chronic				
Eisenia andrei	BAS 765 00 F	Mixed into substrate 56 d 10% peat content	NOEC = 170 mg/kg dry soil (equivalent to 15.7 mg mefentrifluconazole and 23.6 mg kresoxim-methyl/kg dry soil [1)]) EC_{10} = 178 mg/kg dry soil (equivalent to 16.5 mg mefentrifluconazole and 24.7 mg kresoxim-methyl/kg dry soil [1)]) $NOEC_{CORR}$ = 19.7 mg total a.s./kg dry soil [1) *] **$EC_{10\ CORR}$ = 20.6 mg total a.s./kg dry soil [1) *]**	not EU evaluated 2019/2034565
Folsomia candida	BAS 765 00 F	Mixed into substrate 28 d 5% peat content	**NOEC ≥ 918 mg/kg dry soil (equivalent to 84.9 mg mefentrifluconazole and 127.4 mg kresoxim-methyl/kg dry soil)** EC_{10} > 918 mg/kg dry soil (equivalent to 84.9 mg mefentrifluconazole and 127.4 mg kresoxim-methyl/kg dry soil) $NOEC_{CORR}$ ≥ 106.2 mg total a.s./kg dry soil [1) **] $EC_{10\ CORR}$ > 106.2 mg total a.s./kg dry soil [1) **]	not EU evaluated 2019/2034592
Hypoaspis aculeifer	BAS 765 00 F	Mixed into substrate 14 d 5% peat content	**NOEC ≥ 918 mg/kg dry soil (equivalent to 84.9 mg mefentrifluconazole and 127.4 mg kresoxim-methyl/kg dry soil)** EC_{10} > 918 mg/kg dry soil (equivalent to 84.9 mg mefentrifluconazole and 127.4 mg kresoxim-methyl/kg dry soil) $NOEC_{CORR}$ ≥ 106.2 mg total a.s./kg dry soil [1) **] $EC_{10\ CORR}$ > 106.2 mg total a.s./kg dry soil [1) **]	not EU evaluated 2019/2034595

Values shown in **bold** are relevant for the conclusion of the risk assessment.

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002 due to the log P_{ow} > 2 of mefentrifluconazole.

** Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

[1)] Endpoint based on sum/content of active substances (nominal) and taking into account a density of BAS 765 00 F of 1.081 g/cm^3.

9.8.1.1 Justification for new endpoints

Effects of the formulation BAS 765 00 F on earthworms and other non-target soil organisms (meso- and macrofauna) were not evaluated as part of the EU assessment of the active substances mefentrifluconazole or kresoxim-methyl. Hence, all relevant data and assessments considering this formulation are provided here and are considered adequate.

~~For kresoxim-methyl, a chronic earthworm study (BASF DocID 2013/1132495) and a chronic collembola study (BASF DocID 2013/1132497) have been performed with the solo formulation BAS 490 02 F, containing 50% kresoxim-methyl. These studies are used as surrogate for the active substance and were not evaluated as part of the EU assessment of kresoxim-methyl. However, all relevant data and assessments based on active substance content considering this formulation are provided here and are considered adequate.~~

The endpoints for *Folsomia* and *Hypoaspis* were corrected in the EFSA conclusion for mefentrifluconazole. This is not in accordance with the current guidance (EPPO scheme 2002) because the tests were conducted with a substrate carbon content of 5%. EFSA proposed the correction in its technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology (EFSA supporting publication 2015: EN 924. 62 pp.). However, this correction is not justified by specific data and is not adopted by all member states. Therefore, both values are given in the following risk assessment and the conclusion are based on the non-corrected values.

All chronic studies on earthworms, collembolans and soil mites after guidelines OECD 222, OECD 232 and OECD 226, respectively, were checked for their potential to calculate $EC_{10/20}$ values. If a calculation was possible, the $EC_{10/20}$ are provided in the corresponding study summary in Appendix 2 and the EC_{10} is listed in Chapter 9.8.1.

In the risk assessment, both NOEC and EC_{10} values (if available) are used for TER calculation. ~~The conclusion, however, will be based on the EC_{10} if reliable. If the EC_{10} is not reliable or could not be calculated, the NOEC is considered the relevant endpoint for the risk assessment.~~

9.8.2 Risk assessment

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

For substances with log P_{ow} values > 2 and a high content of organic material in the artificial soil (*i.e.* 10% peat), the resulting endpoints have to be corrected by a soil factor of 2 (f_{oc}) in the risk assessment in order to address lower contents of organic material in natural field soil.

The log P_{ow} values of the mefentrifluconazole metabolite 1,2,4-triazole is < 2. Therefore, the endpoints are not corrected. The endpoints of active substances mefentrifluconazole and kresoxim-methyl were corrected (10% peat content), due to a log P_{ow} >2.

9.8.2.1 First-tier risk assessment

The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for kresoxim-methyl and its metabolites BF 490-1 and BF 490-5. In contrast, multi-annual accumulation needs to be considered for mefentrifluconazole and its relevant metabolite 1,2,4-triazole.

The potential risk of BAS 765 00 F, mefentrifluconazole, kresoxim-methyl and 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}, Table 9.8-4 to Table 9.8-6).

The TER was calculated as follows:

$$\mathbf{TER} = \frac{\mathbf{Endpoint\ [mg/kg\ dry\ soil]}}{\mathbf{PEC_{soil}\ [mg/kg\ dry\ soil]}}$$

Table 9.8-4: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of mefentrifluconazole as contained in BAS 765 00 F according to the proposed use pattern

Intended use	2 x 100 g mefentrifluconazole/ha in cereals		
Chronic effects on earthworms			
Active substance/metabolite	**Endpoint (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
mefentrifluconazole	*$NOEC_{CORR}$ = 4.0* $EC_{10\ CORR}$ = 2.65	0.092 *	*43.5* 28.8
Metabolite, Reg. No. 87 084 1,2,4-triazole	NOEC ≥ 1.0	< 0.001 *	1000
Chronic effects on other soil meso- and macrofauna			
Active substance/metabolite	**Endpoint (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
Collembola (*Folsomia candida*)			
mefentrifluconazole	NOEC ≥ 400 *$NOEC_{CORR}$ ≥ 200*	0.092 *	≥ 4348 *≥ 2174*
Metabolite, Reg. No. 87 084 1,2,4-triazole	NOEC = 1.8	< 0.001 *	1800
Soil mite (*Hypoaspis aculeifer*)			
mefentrifluconazole	NOEC ≥ 1000 *$NOEC_{CORR}$ ≥ 500*	0.092 *	≥ 10870 *≥ 5435*
Metabolite, Reg. No. 87 084 1,2,4-triazole	NOEC = 171	< 0.001 *	171000

TER values in **bold** are below the trigger.

~~Endpoints and TER in *italics* are not relevant for the conclusion of the risk assessment.~~

* $PEC_{soil,\ accu}$.

Table 9.8-5: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of kresoxim-methly as contained in BAS 765 00 F according to the proposed use pattern

Intended use	2 x 150 g kresoxim-methyl/ha in cereals		
Chronic effects on earthworms			
Active substance	**Endpoint (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
kresoxim-methyl (tested as BAS 490 02 F) [1)]	*NOEC = 13.5* *$NOEC_{CORR}$ = 6.75* *EC_{10} = 27.4* *$EC_{10\ CORR}$ = 13.7*	0.04	*338* *169* *685* *343*
Chronic effects on other soil meso- and macrofauna			
Active substance	**Endpoint (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
Collembola (*Folsomia candida*)			
kresoxim-methyl (tested as BAS 490 02 F) [1)]	NOEC ≥ 500 *$NOEC_{CORR}$ ≥ 250*	0.04	≥ 12500 *≥ 6250*

TER values in **bold** are below the trigger.
Endpoints and TER in *italics* are not relevant for the conclusion of the risk assessment.
[1)] Study conducted with the kresoxim-methyl solo-formulation BAS 490 02 F, containing 50% (w/w) kresoxim-methyl.

Table 9.8-6: First-tier assessment of the chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of BAS 765 00 F according to the proposed use pattern

Intended use	2 x 1.0 L BAS 765 00 F/ha in cereals		
Chronic effects on earthworms			
Product	**Endpoint (mg a.s./kg dry soil)**	**PEC_{soil} (mg a.s./kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
total a.s. in BAS 765 00 F	*NOEC = 39.3* [1)] *$NOEC_{CORR}$ = 19.7* [1)] *EC_{10} = 41.2* [1)] $EC_{10\ CORR}$ = 20.6 [1)]	0.132 [2)]	*298* *149* *312* 156
Chronic effects on other soil meso- and macrofauna			
Product	**Endpoint (mg a.s./kg dry soil)**	**PEC_{soil} (mg a.s./kg dry soil)**	**TER_{lt} (criterion TER ≥ 5)**
Collembola (*Folsomia candida*)			
total a.s. in BAS 765 00 F	NOEC ≥ 212.3 [1)] *$NOEC_{CORR}$ ≥ 106.2* [1)] *EC_{10} > 212.3* [1)] *$EC_{10\ CORR}$ > 106.2* [1)]	0.132 [2)]	≥ 1608 *≥ 805* *> 1608* *> 805*
Soil mites (*Hypoaspis aculeifer*)			
total a.s. in BAS 765 00 F	NOEC ≥ 212.3 [1)] *$NOEC_{CORR}$ ≥ 106.2* [1)] *EC_{10} > 212.3* [1)] *$EC_{10\ CORR}$ > 106.2* [1)]	0.132 [2)]	≥ 1608 *≥ 805* *> 1608* *> 805*

TER values in **bold** are below the trigger.

Endpoints and TER in *italics* are not relevant for the conclusion of the risk assessment.

1) Endpoint based on sum of active substances (nominal) and taking into account a density of BAS 765 00 F of 1.081 g/cm^3.

2) Based on the sum of the worst-case active substance PEC_{soil} values ($PEC_{soil\ accu}$ for mefentrifluconazole).

9.8.2.2 Higher tier risk assessments

Not relevant.

9.8.3 Overall conclusions

All TER values for BAS 765 00 F, the active substances mefentrifluconazole, kresoxim-methyl (as sum of active substances in the formulation) and 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 765 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use pattern.

Review Comments:

The long-term risks of BAS 765 00 F to soil meso- and macro-organisms were assessed from toxicity exposure ratios between toxicity endpoints and maximum PEC_{soil}. The relevant predicted environmental concentration in soil (PEC_{soil}) for risk assessment covering the proposed use pattern was taken from Part B Section 8 (Environmental Fate).

Safe use of BAS 765 00 F in cereals were confirmed based on TER_{LT} calculations for formulation, active substances and their metabolites.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on the effects on soil microorganisms have been carried out with the active substances mefentrifluconazole, kresoxim-methyl (tested as BAS 490 02 F) and their relevant metabolites. Full details of these studies are provided in the respective EU documents. Furthermore, studies on the effects on soil microorganisms have been carried out with BAS 765 00 F.

New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

All studies are listed in Table 9.9-1, Table 9.9-2 and Table 9.9-3.

Table 9.9-1: Endpoints and effect values of mefentrifluconazole and relevant metabolites relevant for the risk assessment for soil microorganisms

Endpoint	Substance/metabolite	Exposure System	Results	Reference
N-mineralization	mefentrifluconazole	28 d, aerobic loamy sand	Nitrate formation rate at 2.53 mg/kg dry soil +2.1%	EFSA Journal 2018;16(7):5379 2015/1108623
	Metabolite, Reg. No. 87 084 1,2,4-triazole	28 d, aerobic sandy loam	Nitrate formation rate at 0.333 mg/kg dry soil +8.3%	EFSA Journal 2018;16(7):5379 2000/1021861
C-mineralization [1)]	mefentrifluconazole	28 d, aerobic loamy sand	CO_2 formation rate or O_2 consumption at 2.53 mg/kg dry soil -1.1%	EFSA Journal 2018;16(7):5379 2015/1108621

+ = stimulation, - = inhibition

1) Carbon transformation studies are listed for reference only but are not used in the risk assessment according to Commission Regulation (EU) No 283/2013.

Table 9.9-2: Endpoints and effect values of kresoxim-methyl and relevant metabolites relevant for the risk assessment for soil microorganisms

Endpoint	Substance/metabolite	Exposure System	Results	Reference
N-mineralization	kresoxim-methyl (tested as BAS 490 02 F) [1)]	28 d, aerobic sandy loam and clay sand	Nitrate formation rate at 2.0 mg/kg dry soil +5.1% (sandy loam) -2.5% (clay sand)	EFSA Journal 2010;8(11):1891 1993/11452
	Metabolite, Reg. No. 262 451 BF 490-1 (490M01)	42 d, aerobic loamy sand	Nitrate formation rate at 2.0 mg/kg dry soil -11.3%	EFSA Journal 2010;8(11):1891 1993/10899
	Metabolite, Reg. No. 286 404 BF 490-5 (490M05)	28 d, aerobic loamy sand	Nitrate formation rate at 0.42 mg/kg dry soil -1.2%	EFSA Journal 2010;8(11):1891 2008/1010665
C-mineralization [2)]	kresoxim-methyl (tested as BAS 490 02 F) [1)]	28 d, aerobic sandy loam and clay sand	O_2 consumption at 2.0 mg/kg dry soil +1.5% (sandy loam) +2.5% (clay sand)	EFSA Journal 2010;8(11):1891 1993/11471
	Metabolite, Reg. No. 262 451 BF 490-1 (490M01)	28 d, aerobic loamy sand	O_2 consumption at 2.0 mg/kg dry soil -3.8%	EFSA Journal 2010;8(11):1891 1993/10900
	Metabolite, Reg. No. 286 404 BF 490-5 (490M05)	28 d, aerobic loamy sand	O_2 consumption at 0.42 mg/kg dry soil -3.1%	EFSA Journal 2010;8(11):1891 2008/1010664

+ = stimulation, - = inhibition

1) Study was conducted with the kresoxim-methyl solo-formulation BAS 490 02 F (50% kresoxim-methyl).

2) Carbon transformation studies are listed for reference only but are not used in the risk assessment according to Commission Regulation (EU) No 283/2013.

Table 9.9-3: Endpoints and effect values of BAS 765 00 F relevant for the risk assessment for soil microorganisms

Endpoint	Product	Exposure System	Results	Reference
N-mineralization	BAS 765 00 F	28 d, aerobic loamy sand	Nitrate formation rate at 32.43 mg/kg dry soil (equivalent to 3.0 mg mefentrifluconazole and 4.5 mg kresoxim-methyl/kg dry soil) [1)] +16.8%	not EU evaluated 2019/2034555

+ = stimulation, - = inhibition

1) Calculated, based on the nominal content of the a.s. and taking into account a density of BAS 765 00 F of 1.081 g/cm^3.

9.9.1.1 Justification for new endpoints

Effects on soil microbial activity of BAS 765 00 F were not evaluated as part of the EU review of mefentrifluconazole or kresoxim-methyl. Therefore, all relevant data and assessments are provided here and are considered adequate.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant predicted environmental concentrations in soil (PEC_{soil}) for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see Section 9 Chapter 9.8).

The potential risk of BAS 765 00 F, mefentrifluconazole, kresoxim-methyl and relevant metabolites to soil micro-organisms was assessed by comparing the maximum PEC_{soil} values with the maximum concentration with effects ≤ 25 % (see Table 9.9-4, Table 9.9-5 and Table 9.9-6).

Table 9.9-4: Assessment of the risk for effects on soil micro-organisms due to the use of mefentrifluconazole as contained in BAS 765 00 F according to the proposed use pattern

Intended use	cereals		
Active substance	mefentrifluconazole		
Application rate (g a.s./ha)	2 x 100		
N-mineralization			
Active substance/metabolite	**Max. conc. with effects ≤ 25 % (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**Risk acceptable?**
mefentrifluconazole	> 2.53 (at 28 d)	0.092 *	yes
Metabolite, Reg. No. 87 084 1,2,4-triazole	> 0.333 (at 28 d)	< 0.001 *	yes

* $PEC_{soil, accu}$

Table 9.9-5: Assessment of the risk for effects on soil micro-organisms due to the use of kresoxim-methyl as contained in BAS 765 00 F according to the proposed use pattern

Intended use	cereals		
Active substance	kresoxim-methyl		
Application rate (g a.s./ha)	2 x 150		
N-mineralization			
Active substance/metabolite	**Max. conc. with effects ≤ 25 % (mg/kg dry soil)**	**PEC_{soil} (mg/kg dry soil)**	**Risk acceptable?**
kresoxim-methyl (tested as BAS 490 02 F) [1)]	> 2.0 (at 28 d)	0.04	yes
Metabolite, Reg. No. 262 451 BF 490-1 (490M01)	> 2.0 (at 42 d)	0.053	yes
Metabolite, Reg. No. 286 404 BF 490-5 (490M05)	> 0.42 (at 28 d)	0.004	yes

[1)] Study was conducted with the kresoxim-methyl solo-formulation BAS 490 02 F (50% kresoxim-methyl).

Table 9.9-6: Assessment of the risk for effects on soil micro-organisms due to the use of BAS 765 00 F according to the proposed use pattern

Intended use	cereals		
Product	BAS 765 00 F		
Application rate (L/ha)	2 x 1.0		
N-mineralization			
Product	**Max. conc. with effects ≤ 25 % (mg a.s./kg dry soil)**	**PEC_{soil} (mg a.s./kg dry soil)**	**Risk acceptable?**
total a.s. in BAS 765 00 F	> 7.5 (at 28 d) [1)]	0.132 [2)]	yes

[1)] Endpoint based on the sum of the active substances.
[2)] Based on the sum of the worst-case active substance PEC_{soil} values ($PEC_{soil, accu}$ for mefentrifluconazole).

9.9.3 Overall conclusions

For the formulation BAS 765 00 F, the active substances mefentrifluconazole and kresoxim-methyl as well as for the 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 765 00 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

Review Comments:

BAS 765 00 F had no significant effect on soil micro-organisms at 32.43 mg product/kg dry soil (7.5 mg sum a.s./kg dry soil). This is approximately 57 times higher than the maximum PEC_{soil} of 132 mg product as sum of a.s./kg dry soil following the worst-case application to OSR. This supports the conclusion that under field conditions, use of BAS 765 00 F at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

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

9.10.1 Toxicity data

Vegetative vigor and seedling emergence studies have been conducted with BAS 765 00 F (see Table 9.10-1).

New data submitted with this application are listed in Appendix 1 and summarized in Appendix 2.

Table 9.10-1: Endpoints and effect values of BAS 765 00 F relevant for the risk assessment for non-target terrestrial plants

Species	Product	Exposure System	Results	Reference
Greenhouse				
Daucus carota d (carrot) *Lactuca sativa* d (lettuce) *Brassica oleracea* d (cabbage) *Brassica napus* d (oilseed rape) *Glycine max* d (soybean) *Solanum lycopersicum* d (tomato) *Allium cepa* m (onion) *Lolium multiflorum* m (ryegrass) *Triticum aestivum* m (wheat) *Zea mays* m (corn)	BAS 765 00 F	21 d Seedling emergence	ER_{50} emergence > 1.0 L/ha ER_{50} plant height > 1.0 L/ha ER_{50} plant weight > 1.0 L/ha	not EU evaluated 2019/2034603
Daucus carota d (carrot) *Lactuca sativa* d (lettuce) *Brassica oleracea* d (cabbage) *Brassica napus* d (oilseed rape) *Glycine max* d (soybean) *Solanum lycopersicum* d (tomato) *Allium cepa* m (onion) *Lolium multiflorum* m (ryegrass) *Triticum aestivum* m (wheat) *Zea mays* m (corn)	BAS 765 00 F	21 d Vegetative vigor	ER_{50} plant height > 1.0 L/ha ER_{50} plant weight > 1.0 L/ha	not EU evaluated 2019/2034607 amendment 2020/2080765

m: monocotyledonous; d: dicotyledonous;

9.10.1.1 Justification for new endpoints

Effects on non-target plants of BAS 765 00 F were not evaluated as part of the initial Annex I inclusion or the Annex I renewal process of mefentrifluconazole or kresoxim-methyl. Hence, all relevant data and assessments considering this formulation are provided here and are considered adequate.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

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

The risk assessment is 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 application of BAS 765 00 F is envisioned in cereals. The following risk assessment is based on the worst-case field application rate of 2 x 1.0 L BAS 765 00 F/ha (see Section 9 Chapter 9.1 for details).

The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates in Appendix IV of ESCORT 2. Only a single application was considered, because factors like plant growth will reduce residues per unit area between multiple applications. The predicted rate reaching the off-crop environment ($PER_{off\text{-}field}$) is calculated as:

$$PER_{off\text{-}field} = \text{maximum single application rate (L/ha)} * (\%\ \text{drift}/100)$$

For a single application to field crops (i.e.), 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the field (worst-case scenario). The highest single application rate of BAS 765 00 F is 1.0 L product/ha. The maximum off-field predicted environmental rate ($PER_{off\text{-}field}$) is thus calculated to be 0.0277 L product/ha.

The potential risk of BAS 765 00 F to non-target plants was assessed by comparing the calculated PER value to the ER_{50} values in order to generate the toxicity exposure ratio (TER) as follows.

$$TER = \frac{\text{Endpoint [L/ha]}}{PER_{off-field}\ \text{[L/ha]}}$$

The results of the risk assessment are presented in Table 9.10-2.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of BAS 765 00 F according to the proposed use pattern

Intended use	cereals			
Product	BAS 765 00 F			
Application rate (L/ha)	2 x 1.0			
MAF	n/a			
Test species	**ER_{50} (L/ha) [1)]**	**Drift rate (%)**	**$PER_{off\text{-}field}$ (L/ha)**	**TER criterion: TER ≥ 5**
Daucus carota d (carrot) *Lactuca sativa* d (lettuce) *Brassica oleracea* d (cabbage) *Brassica napus* d (oilseed rape) *Glycine max* d (soybean) *Solanum lycopersicum* d (tomato) *Allium cepa* m (onion) *Lolium multiflorum* m (ryegrass) *Triticum aestivum* m (wheat) *Zea mays* m (corn)	> 1.0	2.77	0.0277	> 36

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio.
1) Worst case endpoint derived from vegetative vigor and seedling emergence.

9.10.2.3 Higher-tier risk assessment

Not relevant

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Based on the risk assessment it can be concluded that BAS 765 00 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 765 00 F applications are not required for the protection of terrestrial non-target plants.

Review Comments:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002).

Based on the risk assessment it can be concluded that the proposed use of BAS 765 00 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 765 00 F applications are not required.

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

Not relevant.

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

Plant protection products have to be classified for their acute and chronic environmental hazard according to (EC) No 1272/2008 (CLP). Classification is based primarily on data of the product itself if adequate acute and chronic data is available. When aquatic toxicity data for the formulated product is not available for all three trophic levels, the summation method is additionally performed, meaning that the content of substances classified with a specific category are added to derive a classification for the product.

For BAS 765 00 F acute data (LC/EC_{50}) is available for all trophic levels. Regarding chronic toxicity, adequate data are only available for algae, thus chronic classification will be based on the summation method using data on the active substance. The active substance mefentrifluconazole (BAS 750 F) is not legally classified within the EU. Hence, chronic classification will be based on the lowest aquatic chronic toxicity endpoint (*i.e.* EC_{10} for *D. magna*). In contrast, the active substance kresoxim-methyl (BAS 490 F) is legally classified within the EU with H400 (Aquatic Acute 1) and H410 (Aquatic Chronic 1) according to Annex VI of (EC) No 1272/2008 (CLP). It should be noted that no M-factor is listed in Annex VI of (EC) No 1272/2008 (CLP). Therefore, the M-factor was determined based on the available data. Table 9.13-1 shows the relevant data for classification purposes.

Table 9.13-1: Ecotoxicology/Environment data relevant for classification of BAS 765 00 F

Substance tested	Study Type (duration)	Findings	Triggered classification and labelling	Reference
Acute (short-term) aquatic hazard				
BAS 765 00 F	*Oncorhynchus mykiss* (96 h)	96 h LC_{50} = ~~1.08~~ 0.747 mg/L (mm)	~~No~~ aquatic acute hazard cat. 1	2019/1050660
BAS 765 00 F	*Daphnia magna* (48 h)	48 h EC_{50} = 1.35 mg/L	No aquatic acute hazard cat.	2019/1050659
BAS 765 00 F	*Pseudokirchneriella subcapitata* (72 h)	72 h E_rC_{50} = 1.33 mg/L	No aquatic acute hazard cat.	2019/1050658
		72 h E_rC_{10} = 0.275 mg/L	No aquatic acute hazard cat.	
Chronic (long-term) aquatic hazard				
Mefentrifluconazole [1)]	*Daphnia magna* (21 d)	21 d EC_{10} = 0.0175 mg/L [2)]	Aquatic chronic hazard cat. 1 (H410), M=1	2014/1098028
Mefentrifluconazole [1)]	Biodegradation	not readily biodegradable	--	2014/71239574
Kresoxim-methyl [3)]	*Oncorhynchus mykiss* (28 d)	28 d NOEC = 0.013 mg/L	Aquatic chronic hazard category 1, M=1 [4)]	Regulation (EC) No. 1272/2008, Annex VI 1994/10921
Kresoxim-methyl [3)]	Biodegradation	not readily biodegradable	--	EFSA Journal, 8 (11): 1891, 2010 1993/10083

1) Nominal contents within the formulated product: **100 g mefentrifluconazole/L (9.17% (w/w)).**
2) In accordance with the ECHA: Guidance on the Application of the CLP Criteria Version 5.0 – July 2017, the EC_{10} is preferred over the NOEC for chronic aquatic toxicity.
3) Nominal contents within the formulated product: **150 g kresoxim-methyl/L (13.76% w/w).**
4) No M-factor is listed in the legal classification of kresoxim-methyl in Annex VI of Regulation (EC) No. 1272/2008 (CLP). Therefore, the M-factor was determined based on the lowest chronic endpoint for the active substance from a study on *Oncorhynchus mykiss*. Please note that the study on the green algae *Ankistrodesmus bibraianus* (BASF DocID 1992/11598) is considered not valid for classification purposes.

Based on the lowest acute aquatic toxicity endpoint obtained with BAS 765 00 F no aquatic hazard category is given according to (EC) No 1272/2008 (CLP).

Regarding chronic classification, mefentrifluconazole (a.s. content of 9.17% w/w within the product) and kresoxim-methyl (a.s. content of 13.76% w/w within the product) are considered for the summation method in the 1st equation and 2nd equation according to CLP, yielding a value which is above the trigger of 25%. Hence, BAS 765 00 F is classified with aquatic chronic hazard category 2 (H411). Chronic classification of BAS 765 00 F using the summation method is summarized in Table 9.13-2.

Table 9.13-2: Chronic classification of BAS 765 00 F using the summation method according to (EC) No 1272/2008

Chronic classification of BAS 765 00 F						
Formulation component				Result (% Content x M-Factor)		
Name	Chronic Category	M-Factor	Content in BAS 765 00 F [% w/w]			
Mefentrifluconazole	1	1	~~9.17~~ 9.52	~~9.17~~ 9.52		
Kresoxim-methyl	1	1	~~13.76~~ 15.22	~~9.17~~ 15.22		
1st equation	SUM *(M x Chronic 1)*			~~22.93~~ 24.74	< 25%	
Mefentrifluconazole	1	1	10 x ~~9.17~~ 9.52	~~91.7~~ 95.2		
Kresoxim-methyl	1	1	10 x ~~13.76~~ 152.2	~~137.6~~ 152.2		
2nd equation	SUM *((M x 10 x Chronic 1) + Chronic 2)*			~~229.3~~ 247.4	≥ 25%	**BAS 765 00 F: Aquatic Chronic Hazard Category 2**

Additionally, three co-formulants are classified for their acute and chronic environmental hazard:

- H400 – sum is 0.18%;
- H410 – sum is 0.08%;
- H412 – sum 0.92 / 1.1%

Conclusion

Based on the data obtained with the product and the lowest chronic aquatic toxicity endpoints of the active substance within the formulated product the following classification and labelling is proposed for BAS 765 00 F: ~~**aquatic chronic hazard category 2 (H411)**~~ H410 according to GHS following Regulation (EC) No 1272/2008.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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	Owner
~~KCP 10.2.1/1~~	~~xxxxxxxxxx~~	~~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~~	~~BASF~~
KCP 10.2.1/2	xxxxxxxxxxx	2019	Reg.No. 6003433 (metabolite of BAS 750 F) - Acute toxicity study in the rainbow trout (Oncorhynchus mykiss) 2019/1022695 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	BASF
KCP 10.2.1/3	xxxxxxxxxxx	2020	BAS 765 00 F - Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a static 96-hour test 2019/1050660 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	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	Owner
KCP 10.2.1/4	Eckenstein, H.	2020	BAS 765 00 F – Effect on Daphnia magna in a static 48-Hour Immobilization Test 2019/1050659 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	BASF
KCP 10.2.1/5	Eckenstein, H.	2020	BAS 765 00 F - Effect on Pseudokirchneriella subcapitata in a 72-hour algal growth Inhibition test 2019/1050658 IES - Innovative Environmental Services Ltd., Witterswil, Switzerland yes Unpublished	No	BASF
KCP 10.3.1.1.1/1	Franke, M.	2019	Acute toxicity of BAS 765 00 F to the honeybee Apis mellifera L. under laboratory conditions 2019/2034549 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.3.1.1.2/1	Franke, M.	2019	Acute toxicity of BAS 765 00 F to the honeybee Apis mellifera L. under laboratory conditions 2019/2034549 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	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	Owner
KCP 10.3.1.2/1	Ruhland, S.	2015	Chronic toxicity of BAS 490 02 F to the honeybee (Apis mellifera L.) under laboratory conditions 2014/1111117 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.3.1.3/1	Kleebaum, K.	2015	Acute toxicity of BAS 490 02 F to honeybee larvae Apis mellifer L. under laboratory conditions (in vitro) 2014/1111118 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.3.2.1/1	Fallowfield, L.	2019	A rate-Response laboratory tet to determine the effects of BAS 765 00 F on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) 2019/2034600 Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom yes Unpublished	No	BASF
KCP 10.3.2.1/2	Stevens, J.	2019	A rate-Response laboratory study to determine the effects of BAS 765 00 F on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) 2019/2034598 Mambo-Tox Ltd., Southampton SO16 7NP, United Kingdom yes Unpublished	No	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	Owner
KCP 10.4.1.1/1	Friedrich, S.	2020	Effects of BAS 765 00 F on the reproduction of the earthworm Eisenia andrei in artificial soil 2019/2034565 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
~~KCP 10.4.1.1/2~~	~~Friedrich, S.~~	~~2013~~	~~Sublethal toxicity of BAS 490 02 F to the earthworm Eisenia fetida in artificial soil~~ ~~2013/1132495~~ ~~BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.~~ ~~yes~~ ~~Unpublished~~	~~No~~	~~BASF~~
~~KCP 10.4.2.1/1~~	~~Friedrich, S.~~	~~2013~~	~~Effects of BAS 490 02 F on the reproduction of the collembolan Folsomia candida~~ ~~2013/1132497~~ ~~BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep.~~ ~~yes~~ ~~Unpublished~~	~~No~~	~~BASF~~
KCP 10.4.2.1/2	Friedrich, S.	2020	Effects of BAS 765 00 F on the reproduction of the collembolan Folsomia candida 2019/2034592 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	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	Owner
KCP 10.4.2.1/3	Schulz, L.	2020	Effects of BAS 765 00 F on the reproduction of the predatory mite Hypoaspis aculeifer 2019/2034595 BioChem agrar GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.5/1	Persdorf, M.	2019	Effects of BAS 765 00 F on the activity of soil microflora (Nitrogen transformation test) 2019/2034555 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Machern OT Gerichshain, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.6.2/1	Maleck, A.	2020	Effect of BAS 765 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2019/2034607 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 10.6.2/2	Maleck, A.	2020	Final Report - Amendment No. 1 - Effect of BAS 765 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2020/2080765 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	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	Owner
KCP 10.6.2/3	Maleck, A.	2020	Effects of BAS 765 00 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions 2019/2034603 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

BAS 765 00 F is a new product, no already evaluated product data are available.

The following tables are to be completed by MS

List of data submitted by the applicant and not 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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

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	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

Review Comment:

In order to provide sufficient detail, where appropriate, the following studies summaries have been adapted by the zRMS. Details were taken directly from the full studies reports provided in the dossier. zRMS text is highlighted in grey. The comments on individual studies are provided in grey comment boxes.

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

No further studies were conducted.

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

No further studies were conducted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

No further studies were conducted.

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

No further studies were conducted.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No further studies were conducted.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.1.1 Study 1

Comments of zRMS:	The study was not crucial for finalization of the risk assessment, thus was not evaluated by zRMS.

Reference:	CP 10.2.1/1
Report	BAS 750 F - Acute toxicity study in the fathead minnow (Pimephales promelas), [redacted] report No EU-805877, EU-18F0741/11E200 BASF DocID 2016/1155889 Authority registration No
Guideline(s):	EC 440/2008 C.1, OECD 203, EPA 72-1, EPA 850.1075
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a 96-hour static acute toxicity laboratory study, fathead minnows were exposed to a dilution water control and to nominal concentrations of 4.6, 10, 22, 46 and 100% of a saturated solution of BAS 750 F (corresponding to mean measured concentrations of 0.0916, 0.204, 0.462, 0.941 and 2.2 mg a.s./L) in groups of 10 animals in stainless steel aquaria containing 20 L water. Fish were observed for survival and symptoms of toxicity directly after start of exposure and 1, 6, 24, 48, 72 and 96 hours after start of exposure.

The biological results are based on mean measured concentrations of the test item. After 96 hours of exposure, no mortality was observed in the dilution water control and the test item concentrations of up to and including 0.462 mg a.s./L. At the two highest tested concentrations, all fish were dead after 96 hours of exposure. No sub-lethal effects were found at any of the test concentrations after 96 hours.

In a static acute toxicity study with fathead minnow the LC_{50} (96 h) of BAS 750 F was determined to be 0.65 mg a.s./L based on mean measured concentrations. The NOEC (96 h) was determined to be 0.462 mg a.s./L (mean measured).

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 750 F (Reg. no.: 583 437 8); batch no. COD-001740; purity: 98.8% (± 1.0%).

B. STUDY DESIGN

Test species: Fathead minnow (*Pimephales promelas*), approx. 4 month old; mean body length: 2.8 cm (2.4 cm – 3.4 cm); mean wet weight: 0.24 g (0.12 g – 0.40 g); supplied by in-house culture; no feeding from approx. 48 h bevor test start.

Test design: Static (96 h); 5 test item concentrations plus a dilution water control, 2 replicates per treatment; 10 fish per aquarium (loading 0.1 g fish/L); assessment of mortality and sub-lethal effects within 1, 6, 24, 48, 72 and 96 hours after start of exposure.

Endpoints: LC_{50}, NOEC, mortality and sub-lethal effects.

Test concentrations: Control (dilution water), 4.6, 10, 22, 46 and 100% of a saturated solution of BAS 750 F (nominal), corresponding to mean measured concentrations of 0 (control), 0.0916, 0.204, 0.462, 0.941 and 2.20 mg a.s./L.

Test conditions: 20 L stainless steel aquaria, test volume: 20 L; dilution water: non-chlorinated charcoal filtered drinking water mixed with deionized water; hardness: 1.04 mmol $CaCO_3$/L; temperature: 24.1 – 24.6 °C; pH 8.1 – 8.4; oxygen content: 6.9 mg/L – 8.4 mg/L; conductivity: 248 µS/cm; photoperiod 16 h light : 8 h dark; light intensity: 114 – 431 Lux; no aeration; no feeding.

Analytics: Analytical verification of test item concentrations was conducted at start, 48 h and 96 h of exposure using a HPLC-method with MS detection.

Statistics: Descriptive statistics; probit method based on Finney for determination of LC50.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of mefentrifluconazole (BAS 750 F) in test water were determined according to the analytical method APL0500/03. The validation of the analytical method is described in the study report. The analytical method APL0500/03 was slightly modified with respect to the chromatographic conditions to determine BAS 750 F in test water. Stock solutions were prepared by weighing about 50 mg test item into 100 mL acetonitrile. Calibration standards, ranging from 0.0002 mg/L to 0.004 mg/L, were prepared from intermediate solutions in test water/acetonitrile/formic acid mixture (80:20:0.1, v/v/v) by diluting with the same solvent mixture. The determination was performed by reversed phase UHPLC with MS detection. The limit of quantification (LOQ) was 0.001 mg/L and the limit of detection (LOD) was set to 0.002 mg/L. Details on measured fortification samples and obtained procedural recoveries for mefentrifluconazole are given in the table below.

Table A 1: Procedural recoveries for mefentrifluconazole

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Test water	0.001	5	106	4.3
Test water	5.0	5	103	1.8

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of BAS 750 F concentrations was conducted in each test item concentration at the beginning of the test, after 48 h and at the end of the exposure. The mean measured concentrations of the test item were < LoQ (Limit of quantification), 0.0916, 0.204, 0.462, 0.941 and 2.20 mg a.s./L. The analyzed contents of BAS 750 F ranged from 97% to 105% of overall mean measured concentrations at test initiation, from 93% to 103% after 48 h and from 95% to 103% of overall mean measured concentrations at test termination. The following biological results are based on mean measured concentrations.

Biological results: After 96 hours of exposure, no mortality was observed in the dilution water control and at test item concentrations of up to and including 0.462 mg a.s./L. At the two highest tested concentrations, all fish were dead after 96 hours of exposure. No sub-lethal effects were found at any of the test concentrations after 96 hours. The results are summarized in Table A 2.

Table A 2: Acute toxicity (96 h) of BAS 750 F to fathead minnow (*Pimephales promelas*)

Concentration [% saturated solution] (nominal)	**Control**	**4.6**	**10**	**22**	**46**	**100**
Concentration [mg a.s./L] (mean measured)	**0**	**0.0916**	**0.204**	**0.462**	**0.941**	**2.2**
Mortality [%] (96 h)	0	0	0	0	100	100
Symptoms (after 96 h)	none	none	none	none	n.d.	n.d.
Endpoints [mg BAS 750 F/L] (mean measured)						
LC_{50} (96 h)	**0.65** (95% confidence limits: 0.577 – 0.731)					
NOEC (96 h)	0.462					

n.d. = not determined; all fish dead

Validity criteria according to OECD 203 (2019)	Obtained in this study
In the control(s) (dilution water control, solvent control), the mortality should not exceed 10% (or one fish, if fewer than 10 control fish are tested) at the end of the exposure	0%
The dissolved oxygen concentration must have been at least 60% of the air saturation value throughout the test	> 60% (6.9 – 8.4 mg/L)
Analytical measurement of test concentrations is compulsory (see § 24)	Analysis of each test concentrations. at 0, 48 and 96 hours after test start.

All validity criteria were met.

III. CONCLUSION

In a static acute toxicity study with fathead minnow the LC_{50} (96 h) of BAS 750 F was determined to be 0.65 mg a.s./L based on mean measured concentrations. The NOEC (96 h) was determined to be 0.462 mg a.s./L (mean measured).

A 2.2.1.2 Study 2

Comments of zRMS:	During the EU review the aquatic risk assessment for metabolites of mefentrifluconazole was performed assuming a 10-times increased toxicity to fish. In Applicant opinion this approach was deemed overly conservative and scientifically not justified. Thus, new study was provided to support the risk assessment of metabolites. The study was conducted to OECD guideline 203 and according to the principles of GLP. In the definitive test all validity criteria were met. The study is considered to be reliable and suitable for the risk assessment.

Reference:	CP 10.2.1/2
Report	Reg.No. 6003433 (metabolite of BAS 750 F) - Acute toxicity study in the rainbow trout (Oncorhynchus mykiss), xxxxxxxxxxx 2019 report No EU-12F0396/18E020, EU-867193 BASF DocID 2019/1022695 Authority registration No
Guideline(s):	EC 440/2008 C.1 Acute Toxicity for Fish, OECD 203
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a 96-hour static acute toxicity laboratory study, rainbow trout (*Oncorhynchus mykiss*) were exposed to a water and solvent control and to a nominal concentration of 5 mg M750F005/L in groups of 10 animals in aquaria containing 20 L water. Fish were observed for survival and symptoms of toxicity 1, 6, 24, 48, 72 and 96 hours after start of exposure.

The biological results are based on nominal concentrations of the test item. No mortality occurred in the controls and in the test item. No additional adverse effects or abnormal behavior were observed in any of the test treatments.

In a 96-h static acute toxicity study with rainbow trout the LC_{50} (96 h) for M750F005 was determined to be > 5 mg/L based on nominal concentration. The NOEC was determined to be ≥ 5.0 mg/L based on nominal concentration.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: M750F005, metabolite of BAS 750 F (Reg. No. 6003433), batch no. L87-34, purity: 96.9%;

B. STUDY DESIGN

Test species: Rainbow trout (*Oncorhynchus mykiss*), approx. 3.5 months old, mean body length 4.8 (4.3 – 5.5) cm, mean body weight 0.89 (0.5 – 1.49) g; supplied by ´Forellenzucht Trostadt GbR', Trostadt, Germany.

Test design: Static system (96 hours); 1 replicate per treatment; 10 fish per replicate (loading about 0.45 g fish/L); assessment of survival and symptoms of toxicity after 1, 6, 24, 48, 72 and 96 hours.

Endpoints: LCx and NOEC based on mortality and sublethal effects.

Test concentrations: Water control, solvent control (DMF), 5 mg M750F005/L (nominal).

Test conditions: ~24 L stainless steel aquaria (38.5x23.5x29 cm); test volume 20 L, dilution water: non-chlorinated charcoal-filtered municipal water mixed with deionized water; temperature: 11.9 – 12.3°C; pH 7.9 – 8.3; oxygen content: 7.9 – 10.4 mg/L; total hardness about 1 mmol/L (dilution water); acid capacity about 2.5 mmol/L (dilution water); photoperiod: 16 hours light : 8 hours dark; no aeration; no feeding.

Analytics: Analytical verification of the test item concentrations was performed using an LC-method with MS/MS detection.

Statistics: No statistical analysis was carried out since no lethality was observed up to the highest tested concentration.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of M750F005 (metabolite of BAS 750 F) in test water were determined according to the analytical method L0359/01. The validation of the analytical method is described in another study (BASF Doc-ID: 2017/1066523). Fortification solutions for the high residue level (5 mg/L) were prepared by dilution of the stock solution with acetonitrile and solutions for the LOQ and 10 x LOQ fortifications were prepared by further dilution with acetonitrile/water (50/50, v/v) The determination was performed by HPLC-method with MS/MS detection.. The limit of quantification (LOQ) was 0.03 µg/L and the limit of detection (LOD) was set to 0.009 µg/L. To check on potential matrix effects quality control samples were prepared at LOQ measurement concentration level. The sample was prepared routinely with untreated test medium solution and compared to solvent standards. The recovery values of all replicates of the quality control sample were all in an acceptable range, therefore no significant matrix effect has been identified. Details on measured fortification samples and obtained procedural recoveries for M750F005 are given in the table below.

Table A 3: Procedural recoveries for mefentrifluconazole

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Test water	0.03	3	95.7	1.6
Test water	0.3	3	94.0	0.6
Test water	5000	3	98.3	1.1

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentrations was conducted in the test item group at the beginning and at the end of the test. The analytically detected concentration was initially 88.4% of the nominal value and 88.0% at the end of the test. The biological results are based on nominal concentrations.

Biological results: No mortality occurred in the controls and in the treatment. No additional adverse effects or abnormal behavior were observed in the test treatment. The results are summarized in Table A 4.

Table A 4: Acute toxicity (96 h) of M750F005 to rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] (nominal)	Water Control	Solvent Control	5
Mortality [%] (96 h)	0	0	0
Symptoms (after 96 h) #	none	none	none
	Endpoints [mg M750F005/L] (nominal)		
LC_{50} (96 h)	> 5 (confidence interval: n.d.)		
NOEC (96 h)	≥ 5		

n.d. not determined

Validity criteria according to OECD 203 (2019)	Obtained in this study
In the control(s) (dilution water control, solvent control), the mortality should not exceed 10% (or one fish, if fewer than 10 control fish are tested) at the end of the exposure	0%
The dissolved oxygen concentration must have been at least 60% of the air saturation value throughout the test	> 60% (7.9 – 10.4 mg/L)
Analytical measurement of test concentrations is compulsory (see § 24)	Analysis of each test concentrations. at 0 and 96 hours after test start.

All validity criteria were met.

III. CONCLUSION

In a 96-h static acute toxicity study with rainbow trout the LC_{50} (96 h) for M750F005 was determined to be > 5 mg/L based on nominal concentration. The NOEC was determined to be ≥ 5.0 mg/L based on nominal concentration.

A 2.2.1.3 Study 3

Comments of zRMS:	The study was conducted to OECD guideline 203 (2019) and according to the principles of GLP. In the definitive test all validity criteria were met. The study is considered to be reliable and suitable for the risk assessment. Results refer to nominal concentrations: LC_{50} = 1.08 mg/L (0.108 mg BAS 750 F and 0.162 mg BAS 490 F) Results refer to mean measured concentrations: LC_{50} = 0.078 mg BAS 750 F/L and 0.112 mg BAS 490 F/L LC_{50} = 0.747 mg BAS 765 F/L (based on less stable active substance: BAS 490 F/L)

Reference:	CP 10.2.1/3
Report	BAS 765 00 F - Acute toxicity to rainbow trout (Oncorhynchus mykiss) in a static 96-hour test, xxxxxxxxxxxxxxx., 2020 report No 862755, 20190141 BASF DocID 2019/1050660 Authority registration No
Guideline(s):	EC 440/2008 C.1, OECD 203 (2019)
Deviations:	No
GLP:	yes (certified by Swiss Federal Office of Public Health, Berne, Switzerland),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a static acute toxicity laboratory study, juvenile rainbow trout were exposed to the test item BAS 765 00 F at nominal concentrations of 0.15, 0.33, 0.73, 1.60 and 3.51 mg/L and a dilution water control in groups of 7 animals per aquarium. Fish were observed for survival and symptoms of toxicity after 2 and 4 hours and in the morning and afternoon at 1, 2, 3 and 4 days of the exposure

The biological results are based on nominal concentrations of the test item. In the control and the test item concentrations up to and including nominal 0.73 mg/L all fish survived until the end of the test and no visible abnormalities were observed in the test fish. In the two highest test concentrations (1.60 and 3.51 mg/L), the fish showed abnormal swimming behavior, specifically hypoactivity, corkscrew swimming and convulsions as well as abnormal ventilator behavior, in this case hyperventilation. By the morning observation on day 2, all fish in these concentrations had died.

In a static acute toxicity study with rainbow trout, the LC_{50} (96 h) of BAS 765 00 F was determined to be 0.108 mg/L based on nominal concentrations. The NOEC was 0.73 mg/L (nominal).

I. MATERIAL AND METHODS

A. MATERIALS

Test item:	BAS 765 00 F, batch no. FD-190128-0007; content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species:	Rainbow trout (*Oncorhynchus mykiss* Walb.); juvenile fish; mean body length 5.5 ± 0.23 cm; mean body weight 1.34 ± 0.18 g; supplied by "Fish breeding farm Störk", Bad Saulgau, Germany.
Test design:	Static system (96 hours); 7 fish per aquarium (loading: 0.67 g fish/L); assessment of mortality and symptoms of toxicity after 2 and 4 hours and in the morning and afternoon at 1, 2, 3 and 4 days of the exposure.
Endpoints:	LC_{50}, NOEC, mortality and sub-lethal effects.
Test concentrations:	0 (control), 0.15, 0.33, 0.73, 1.60 and 3.51 mg BAS 765 00 F/L (nominal).
Test conditions:	20-L glass aquaria, test volume: 14 L, reconstituted test medium; temperature: 13°C; pH 7.4; oxygen saturation: 8.8 - 9.8 mg/L; total hardness: 125 mg $CaCO_3$/L; alkalinity: 0.4 mmol/L; light intensity: 958 – 990 lux; photoperiod: 16 h light: 8 h dark with a 30-min transition period; slight aeration, no feeding.
Analytics:	Analytical verification of concentrations of the a.s. BAS 750 F and BAS 490 F contained in the test item BAS 765 00 F was conducted using HPLC methods with MS/MS detection (method no. L0361/01 and L0361/03, respectively).
Statistics:	Descriptive statistics. The LC50-value for 96 hours was determined as a geometric mean value of the two consecutive test concentrations with 0 and 100% mortality. The NOEC and LOEC were calculated by Fishers Exact Binomial Test with Bonferroni Correction.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 750 F and BAS 450 F (contained in the test item BAS 765 00 F) in reconstituted test medium were determined according to the analytical method no. L0361/01 and L0361/03, respectively. The validation of the analytical methods is described in the study report. The original analytical methods are fully validated in separate studies (BASF DocID 2017/1065621 for BAS 750 F, BASF DocID 2019/1039564 for BAS 490 F). For procedural recoveries, 10 mL of untreated test water was fortified with the test item. The samples (10 mL) were diluted to 20 mL with water / acetonitrile / formic acid (600/400/2, v/v/v, = solvent mixture 1). Further dilution steps were carried out with test water / solvent mixture 1 (1/1, v/v), in order to dilute the samples into the linear calibration range. The determination was performed by HPLC with MS/MS detection. The limit of quantification (LOQ) for BAS 750 F and BAS 490 F was 0.00141 and 0.00211 mg/L, respectively, and the limit of detection (LOD) was set to 0.00005 mg/L for both analytes. For the assessment of potential matrix effects, matrix-matched calibration standards were used. For both active substances, the storage time did not exceed 30 days. The mean recoveries of BAS 750 F and BAS 490 F ranged from 77.8% to 98.7% for both analytes and fortification levels tested. Details on measured fortification samples and obtained procedural recoveries for BAS 750 F and BAS 490 F are given in Table A 5.

Table A 5: Procedural recoveries for BAS 750 F and BAS 490 F

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Recovery Data of BAS 750 F in Matrix, Mass Transition m/z 398 → 70.1 (Quantifier)				
Reconstituted test medium	0.00141	5	77.8	1.5
Reconstituted test medium	0.389	5	91.2	1.4
Recovery Data of BAS 490 F in Matrix, Mass Transition m/z 314 → 116 (Quantifier)				
Reconstituted test medium	0.00211	5	80.3	18.7
Reconstituted test medium	0.582	5	98.7	9.7

Table AI-9 Results for Test Samples – Analysis of BAS 750 F (based on Quantifier m/z 398→70.1)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 765 00 F [mg/L]	Nominal Concen-tration of BAS 750 F c_{nom} [mg/L]	Measured Concen-tration of BAS 750 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 750 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	F1	Control	Control	n.d.	4	< LOQ	n.a.
	F4	0.15	0.0138	0.231	52	0.0120	86.9
	F7	0.33	0.0304	0.203	135	0.0275	90.6
	F10	0.73	0.0672	0.288	202	0.058	86.6
	F13	1.60	0.147	0.390	402	0.157	106
	F16	3.51	0.323	0.298	1002	0.298	92.3
1/24	F34	3.51	0.323	0.270	1002	0.271	83.8
2/48	F31	1.60	0.147	0.277	402	0.111	75.6
4/96	F19	Control	Control	n.d.	4	< LOQ	n.a.
	F20 (a)	Control	Control	n.d.	4	< LOQ	n.a.
	F21 (a)	Control	Control	n.d.	4	< LOQ	n.a.
	F22	0.15	0.0138	0.139	52	0.00723	52.3
	F23 (a)	*0.15*	*0.0138*	*0.131*	*52*	*0.00682*	*49.4*
	F24 (a)	*0.15*	*0.0138*	*0.132*	*52*	*0.00689*	*49.9*
					mean	**0.00698**	**50.5**
	F25	0.33	0.0304	0.173	102	0.0177	58.1
	F26 (a)	*0.33*	*0.0304*	*0.164*	*135*	*0.0221*	*72.6*
	F27 (a)	*0.33*	*0.0304*	*0.163*	*135*	*0.0219*	*72.2*
					mean	**0.0206**	**67.6**
	F28	0.73	0.0672	0.225	202	0.0454	67.5
	F29 (a)	*0.73*	*0.0672*	*0.211*	*202*	*0.0426*	*63.3*
	F30 (a)	*0.73*	*0.0672*	*0.212*	*202*	*0.0428*	*63.7*
					mean	**0.0436**	**64.8**
	F37	1.60	0.147	0.272	402	0.109	74.3
	F40	3.51	0.323	0.264	1002	0.265	81.9

n.d. = not detected, below lowest calibration standard
n.a. = not applicable
(a) = retain sample
LOD: 0.2 µg BAS 750 F /L
LOQ: 1.41 µg BAS 750 F /L
The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

Table AI-10 Results for Test Samples – Analysis of BAS 490 F (based on Quantifier m/z 314→116)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 765 00 F [mg/L]	Nominal Concen-tration of BAS 490 F c_{nom} [mg/L]	Measured Concen-tration of BAS 490 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 490 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	F1	Control	Control	n.d.	4	< LOQ	n.a.
	F4	0.15	0.0207	0.382	52	0.0199	96.3
	F7	0.33	0.0454	0.370	135	0.0501	110
	F10	0.73	0.101	0.446	202	0.0902	89.7
	F13	1.60	0.220	0.567	402	0.228	103
	F16	3.51	0.483	0.452	1002	0.453	93.8
1/24	F34	3.51	0.483	0.469	1002	0.467	97.1
2/48	F31	1.60	0.220	0.436	402	0.175	79.6
4/96	F19	Control	Control	n.d.	4	< LOQ	n.a.
	F20 (a)	Control	*Control*	*n.d.*	*4*	*< LOQ*	*n.a.*
	F21 (a)	Control	*Control*	*n.d.*	*4*	*< LOQ*	*n.a.*
	F22	0.15	0.0207	0.120	52	0.00624	30.2
	F23 (a)	*0.15*	*0.0207*	*0.175*	*52*	*0.00908*	*44.0*
	F24 (a)	*0.15*	*0.0207*	*0.137*	*52*	*0.00712*	*34.5*
					mean	**0.00748**	**36.2**
	F25	0.33	0.0454	0.226	135	0.0306	67.4
	F26 (a)	*0.33*	*0.0454*	*0.216*	*135*	*0.0292*	*64.2*
	F27 (a)	*0.33*	*0.0454*	*0.246*	*135*	*0.0333*	*73.2*
					mean	**0.0310**	**68.3**
	F28	0.73	0.101	0.287	202	0.058	57.7
	F29 (a)	*0.73*	*0.101*	*0.290*	*202*	*0.0585*	*58.2*
	F30 (a)	*0.73*	*0.101*	*0.297*	*202*	*0.0599*	*59.6*
					mean	**0.0588**	**58.5**
	F37	1.60	0.220	0.439	402	0.176	80.1
	F40	3.51	0.483	0.385	1002	0.386	79.8

n.d. = not detected, below lowest calibration standard
n.a. = not applicable
(a) = retain sample
LOD: 0.2 µg BAS 490 F /L
LOQ: 2.11 µg BAS 490 F /L
The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

II. RESULTS AND DISCUSSION

Analytical measurements: The measured concentrations of the active ingredient BAS 750 F in the analyzed test medium samples from the start of the exposure period ranged between 86.9% and 106% of the nominal values; the active ingredient BAS 490 F ranged between 89.7% and 110%, demonstrating the correct dosage of the test item BAS 765 00 F. During the exposure period, the concentrations of both active ingredients decreased. For the active ingredient BAS 750 F, the range at the end of the test or the respective time point when all fish were dead was 50.5% to 83.8%. For the active ingredient BAS 490 F at the end of

the test or the respective time point when all fish were dead, the range was 36.2% to 97.1% of the nominal. For both active ingredients, the lower dosages had lower recovery values. As the correct dosage of the test item at the start of the test was shown, the reported biological results are based on nominal concentrations.

Biological results: In the control and the test item concentrations up to and including nominal 0.73 mg/L all fish survived until the end of the test and no visible abnormalities were observed in the test fish. In the two highest test concentrations (1.60 and 3.51 mg/L), the fish showed abnormal swimming behavior, specifically hypoactivity, corkscrew swimming and convulsions as well as abnormal ventilator behavior, in this case hyperventilation. By the morning observation on day 2, all fish in these concentrations had died. The results are summarized in Table A 6.

Table A 6: Acute toxicity (96 h) of BAS 765 00 F on rainbow trout (*Oncorhynchus mykiss*)

Concentration [mg/L] (nominal)	**Control**	**0.15**	**0.33**	**0.73**	**1.60**	**3.51**
Concentration [mg/L] (mean measured)	**--**	**n.d.**	**n.d.**	**n.d.**	**n.d.**	**n.d.**
Mortality [%]	0	0	0	0	100	100
Symptoms [1)]	none	none	none	none	n.d.	n.d.
Endpoints [mg BAS 765 00 F/L]						
	nominal			**mean measured**		
LC_{50} (96 h)	1.08 (95% confidence limits: n.d.)			n.d. (95% confidence limits: n.d.)		
NOEC (96 h)	0.73			n.d.		

n.d. = not determined / all animals dead

Validity criteria:

Validity criteria according to OECD 203 (2019)	**Obtained in this study**
In the control(s) (dilution water control, solvent control), the mortality should not exceed 10% (or one fish, if fewer than 10 control fish are tested) at the end of the exposure	0%
The dissolved oxygen concentration must have been at least 60% of the air saturation value throughout the test	≥ 83%
Analytical measurement of test concentrations is compulsory (see § 24)	Analysis of each test conc. at test initiation (0 h) and after 96 h plus the highest conc. at 24 h and the second highest conc. at 48 h when all fish were dead;

All validity criteria were met.

III. CONCLUSION

In a static acute toxicity study with rainbow trout, the LC_{50} (96 h) of BAS 765 00 F was determined to be ~~0.108~~ 1.08 mg/L based on nominal concentrations. The NOEC was 0.73 mg/L (nominal).

A 2.2.1.4 Study 4

Comments of zRMS:	The study was conducted to OECD guideline 202 and according to the principles of GLP. In the definitive test all validity criteria were met. The study is considered to be reliable and suitable for the risk assessment. Based on analytical measurements the BAS 750 F was stable during the test and mean measured concentrations of BAS 490 F was above 80%. Thus, results refer to nominal concentrations: EC_{50} = 0.135 mg/L (0.0135 mg BAS 750 F and 0.02025 mg BAS 490 F)

Reference:	CP 10.2.1/4
Report	BAS 765 00 F – Effect on *Daphnia magna* in a static 48-Hour Immobilization Test, Eckenstein, H., 2020 report No 862754, 20190140 BASF DocID 2019/1050659
Guideline(s):	OECD 202, SANCO/3029/99 rev. 4
Deviations:	No
GLP:	yes (certified by Swiss Federal Office of Public Health, Berne, Switzerland)
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a 48-hour static acute toxicity laboratory study, water flea neonates were exposed to the test item BAS 765 00 F at nominal concentrations of 0 (control), 0.50, 0.90, 1.6, 2.9 and 5.2 mg/L in 4 replicates per concentration, containing 5 daphnids each. Daphnids were observed for immobility 24 hours and 48 hours after start of exposure.

The biological results are based on the nominal concentrations of the test item. After 48 hours of exposure, no immobilized test organisms were determined in the control and up to and including the test item concentration of 0.90 mg/L. At the concentration of 1.6 mg/L, 80% of the daphnids were found to be immobile. In addition, adverse effect (daphnids with reduced swimming activity compared to the control animals) was noted at the four remaining mobile test animals. At the both highest concentrations (2.9 and 5.2 mg/L) all daphnids were found to be immobile, as already observed after 24 hours of exposure.

In a 48-hour static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 765 00 F was 1.35 mg/L based on nominal concentrations. The NOEC was determined to be 0.90 mg/L (nominal).

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007; content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Water flea (*Daphnia magna* STRAUS), neonates collected from in-house culture, < 24 hours old at test initiation.

Test design: Static system (48 hours), 5 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility after 24 and 48 hours.

Endpoints: NOEC, EC_{50} based on immobility of daphnids.

Test concentrations: 0 (control), 0.50, 0.90, 1.6, 2.9 and 5.2 mg BAS 765 00 F/L (nominal).

Test conditions: 100-mL glass vessels, test volume 50 mL, dilution water: "M7" (Elendt medium); pH 7.80; oxygen content: 8.2 - 8.5 mg/L; temperature: 22°C; photoperiod: 16 h light : 8 h dark, no feeding, no aeration.

Analytics: Analytical verification of concentrations of the a.s. BAS 750 F and BAS 490 F contained in the test item BAS 765 00 F was conducted using HPLC methods with MS/MS detection (method no. L0361/01 and L0361/03 for BAS, respectively).

Statistics: Descriptive statistics; The 48-hour EC_{50} and the 95% confidence limits was calculated by Trimmed Spearman-Karber procedure. For the determination of the 48-hour NOEC, the immobilization of the daphnia at the test concentrations were compared to the control by Step-down Cochran-Armitage test procedure (one-sided greater, $\alpha = 0.05$).

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 750 F and BAS 490 F (contained in the test item BAS 765 00 F) in M7 medium were determined according to the analytical method L0361/01 and L0361/03, respectively. The validation of the analytical methods is described in the study report. The original analytical methods are fully validated in separate studies (BASF DocID 2017/1065621 for BAS 750 F, BASF DocID 2019/1039564 for BAS 490 F). For procedural recoveries, 10 mL of untreated test water was fortified with the test item. The samples (10 ml) were diluted to 20 mL with water / acetonitrile / formic acid (600/400/2, v/v/v, = solvent mixture 1). Further dilution steps were carried out with test water / solvent mixture 1 (1/1, v/v), in order to dilute the samples into the linear calibration range. The determination was performed by HPLC with MS/MS detection. The limit of quantification (LOQ) for BAS 750 F and BAS 490 F was 0.0046 and 0.00688 mg/L, respectively, and the limit of detection (LOD) was set to 0.00002 and 0.00006 mg/L, respectively. For the assessment of potential matrix effects, matrix-matched calibration standards were used. The maximum storage period between sampling and analysis was 20 days. The mean recoveries ranged from 90.4% to 104% for BAS 750 F and between 80.3% to 105% for BAS 490 F. Details on measured fortification samples and obtained procedural recoveries are given in Table A 7.

Table A 7: Procedural recoveries for BAS 750 F and BAS 490 F

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Recovery Data of BAS 750 F in Matrix, Mass Transition m/z 398 → 70.1 (Quantifier)				
M7 medium	0.00460	3	90.4	2.2
M7 medium	0.575	3	104	1.1
Recovery Data of BAS 490 F in Matrix, Mass Transition m/z 314 → 116 (Quantifier)				
M7 medium	0.00688	3	80.3	6.1
M7 medium	0.860	3	105	17.5

Table AI-10 Results for Test Samples – Analysis of BAS 750 F (based on Quantifier m/z 398→70.1)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 765 00 F [mg/L]	Nominal Concen-tration of BAS 750 F c_{nom} [mg/L]	Measured Concen-tration of BAS 750 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 750 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	D1	0	0	n.d.	20	< LOD	n.a.
	D4	0.50	0.0461	0.437	100	0.0437	94.9
	D7	0.90	0.0829	0.389	200	0.0778	93.9
	D10	1.6	0.147	0.324	400	0.130	88.1
	D13	2.9	0.267	0.299	800	0.239	89.5
	D16	5.2	0.479	0.232	2000	0.465	97.0
2/48	D19	0	0	*	20	< LOQ	n.a.
	D22	0.50	0.0461	0.458	100	0.0458	99.4
	D25	0.90	0.0829	0.375	200	0.0750	90.5
	D28	1.6	0.147	0.343	400	0.137	93.0
	D31	2.9	0.267	0.295	800	0.236	88.5
	D34	5.2	0.479	0.229	2000	0.458	95.7

n.d. = not detected, below lowest calibration standard
n.a. = not applicable
* a small peak occurred with area counts < 30 % of the LOQ
LOD: 0.2 µg BAS 750 F /L
LOQ: 4.60 µg BAS 750 F /L
The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

Table AI-11 Results for Test Samples – Analysis of BAS 490 F (based on Quantifier m/z 314→116)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 765 00 F [mg/L]	Nominal Concen-tration of BAS 490 F c_{nom} [mg/L]	Measured Concen-tration of BAS 490 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 490 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	D1	0	0	n.d.	20	< LOD	n.a.
	D4	0.50	0.0689	0.609	100	0.0609	88.4
	D7	0.90	0.124	0.518	200	0.104	83.7
	D10	1.6	0.220	0.441	400	0.176	80.0
	D13	2.9	0.399	0.486	800	0.389	97.5
	D16	5.2	0.716	0.299	2000	0.599	83.7
2/48	D19	0	0	*	20	< LOQ	n.a.
	D22	0.50	0.0689	0.581	100	0.0581	84.4
	D25	0.90	0.124	0.458	200	0.0916	74.0
	D28	1.6	0.220	0.429	400	0.172	77.9
	D31	2.9	0.399	0.350	800	0.280	70.1
	D34	5.2	0.716	0.251	2000	0.501	70.0

n.d. = not detected, below lowest calibration standard
n.a. = not applicable
* a small peak occurred with area counts < 30 % of the LOQ
LOD: 0.6 µg BAS 490 F /L
LOQ: 6.88 µg BAS 490 F /L
The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

II. RESULTS AND DISCUSSION

Analytical measurements: Analytical verification of test item concentrations was conducted in each concentration at the beginning and at the end of the test. The analyzed contents of BAS 750 F ranged from 88.1% to 97.0% of nominal at test initiation and from 88.5 to 99.4% at test termination. The analyzed contents of BAS 490 F ranged from 80.0% to 97.5% at test initiation and from 70.0% to 84.4% at test termination.
The biological results are based on nominal concentrations as the correct dosage of the test item at the start of the test was shown.

Biological results: After 48 hours of exposure, no immobilized test organisms were determined in the control and up to and including the test item concentration of 0.90 mg/L. At the concentration of 1.6 mg/L, 80% of the daphnids were found to be immobile. In addition, adverse effect (daphnids with reduced swimming activity compared to the control animals) was noted at the four remaining mobile test animals. At the both highest concentrations (2.9 and 5.2 mg/L) all daphnids were found to be immobile, as already observed after 24 hours of exposure. For results see Table A 8.

Table A 8: Effects of BAS 765 00 F on *Daphnia magna* immobility

Concentration [mg/L] (nominal)	**Control**	**0.50**	**0.90**	**1.60**	**2.90**	**5.20**
Immobility (24 h) [%]	0	0	0	70	100	100
Immobility (48 h) [%]	0	0	0	80	100	100
Endpoints [mg BAS 765 00 F/L] (nominal)						
EC_{50} (48 h)	1.35 (95% confidence limits: 1.21 - 1.50)					
NOEC (48 h)	0.90					

Validity criteria according to OECD 202 (2004)	**Obtained in this study**
In the control, including the control containing the solubilising agent, not more than 10% of the daphnids should have been immobilised. (Not more than 10% of the control daphnids should show immobilisation or other signs of disease or stress, for example, discoloration or unusual behaviour such as trapping at surface of water.)	0%
The dissolved oxygen concentration at the end of the test should be ≥ 3 mg/L in control and test vessels.	8.2 - 8.4 mg/L

All validity criteria were met.

III. CONCLUSION

In a 48-hour static acute toxicity study with *Daphnia magna* the EC_{50} of BAS 765 00 F was 1.35 mg/L based on nominal concentrations. The NOEC was determined to be 0.90 mg/L (nominal).

A 2.2.1.5 Study 5

Comments of zRMS:	The study was conducted to OECD guideline 201 and according to the principles of GLP. In the definitive test all validity criteria were met. The study is considered to be reliable and suitable for the risk assessment. Based on analytical measurements the BAS 750 F was stable during the test and mean measured concentrations of BAS 490 F was above 83%. Thus, results refer to nominal concentrations: E_rC_{50} = 1.33 mg/L (0.133 mg BAS 750 F and 0.2 mg BAS 490 F)

Reference:	CP 10.2.1/5
Report	BAS 765 00 F - Effect on *Pseudokirchneriella subcapitata* in a 72-hour algal growth Inhibition test, Eckenstein, H., 2020 report No 862753, 20190139 BASF DocID 2019/1050658 Authority registration No
Guideline(s):	OECD 201, SANCO 3029/99 Rev.4
Deviations:	No
GLP:	yes (certified by Swiss Federal Office of Public Health),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a 72-hour static acute toxicity laboratory study, the effect of BAS 765 00 F on the growth of the green alga *Pseudokirchneriella subcapitata* was investigated. The following concentrations were applied: 0.032, 0.10, 0.32, 1.0 and 3.2 mg BAS 765 00 F/L (nominal). Assessment of growth was conducted 24 h, 48 h and 72 h after test initiation.
The biological results are based on nominal concentrations of the test item.

After 72 hours significant inhibitory effects on growth rate and yield have been observed at concentrations including and above 0.10 mg test item/L. No morphological effects on algae were observed in the control and in any of the test item concentrations tested.

In a 72-hour algae test with *Pseudokirchneriella subcapitata*, the E_rC_{50} for BAS 765 00 F was determined to be 1.33 mg/L, the E_yC_{50} was 0.396 mg/L based on nominal concentrations.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007; content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Unicellular fresh water green alga, *Pseudokirchneriella subcapitata* (Reinsch) Korshikov (syn. *Selenastrum capricornutum* Prinz), SAG 61.81; in-house culture; stock obtained from "Sammlung von Algenkulturen" Göttingen, Germany.

Test design: Static system; test duration 72 hours; 5 test concentrations, each with 5 replicates per test item concentration plus a control with 10 replicates; daily assessment of growth via fluorescence measurement.

Endpoints: EC_{10}, EC_{20} and EC_{50} with respect to growth rate and yield after exposure over 72 hours.

Test concentrations: 0 (control), 0.032, 0.10, 0.32, 1.0 and 3.2 mg BAS 765 00 F/L (nominal).

Test conditions: 75-mL Erlenmeyer glass flasks; test volume: 30 mL; test medium: AAP medium; pH 7.3 - 7.4 at test initiation and pH 7.5 - 7.9 at test termination; temperature: 22.2°C - 22.4°C; initial cell densities 5 x 10^3 cells/mL; continuous light at 4710 - 5220 lux; continuous shaking at 125 rpm.

Analytics: Analytical verification of concentrations of the a.s. BAS 750 F and BAS 490 F contained in the test item BAS 765 00 F was conducted using HPLC methods with MS/MS detection (method no. L0361/01 and L0361/03 for BAS, respectively).

Statistics: Descriptive statistics; 72-hour EC_x values for the inhibition of average growth rate and yield and their 95% confidence intervals were calculated by Probit Analysis using linear maximum likelihood regression. For the determination of the LOEC and NOEC, the average growth rate and yield at the test concentrations were compared to the control values by Williams t-test and Welch t-test with Bonferroni-Holm-adjustment, where appropriate.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 750 F and BAS 490 F (contained in the test item BAS 765 00 F) in AAP medium were determined according to the analytical method L0361/01 and L0361/03, respectively. The validation of the analytical methods is described in the study report. The original analytical methods are fully validated in separate studies (BASF DocID 2017/1065621 for BAS 750 F, BASF DocID 2019/1039564 for BAS 490 F). For procedural recoveries, 10 mL of untreated test water was fortified with the test item. The samples (10 ml) were diluted to 20 mL with water / acetonitrile / formic acid (600/400/2, v/v/v, = solvent mixture 1). Further dilution steps were carried out with test water / solvent mixture 1 (1/1, v/v), in order to dilute the samples into the linear calibration range. The determination was performed by HPLC with MS/MS detection. The limit of quantification (LOQ) for BAS 750 F and BAS 490 F was 0.0003 and 0.0004 mg/L, respectively and the limit of detection (LOD) was set to 0.00005 mg/L for both analytes. For the assessment of potential matrix effects, matrix matched calibration standards were used. BAS 750 F is stable in different test media from ecotoxicological tests for at least 90 days (BASF DocID 2017/1115731). Since the retain samples confirmed the values for the first set of samples, the storage stability for that period is also confirmed. For BAS 490 F, the non-aged samples showed recoveries in the range of 89.4% to 101% of the nominal concentrations, confirming the storage stability for 73 days. Since the retain samples confirmed the values for the first set of samples, the storage stability for a period 104 days is also confirmed for BAS 490 F. The mean recoveries ranged from 81.5% to 101% for BAS 750 F and from 92.6% to 96.0% for BAS 490 F. Details on measured fortification samples and obtained procedural recoveries are given in Table A 9.

Table A 9: Procedural recoveries for BAS 750 F and BAS 490 F

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Recovery Data of BAS 750 F in Matrix, Mass Transition m/z 398 → 70.1 (Quantifier)				
AAP medium	0.000296 / 0.000278	2/3	81.5	5.0
AAP medium	0.370 / 0.371	2/3	101	6.0
Recovery Data of BAS 490 F in Matrix, Mass Transition m/z 314 → 116 (Quantifier)				
AAP medium	0.000442 / 0.000416	2/3	92.6	9.5
AAP medium	0.553 / 0.554	2/3	96.0	4.0

Table AI-9 Results for Test Samples – Analysis of BAS 750 F (based on Quantifier m/z 398→70.1)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 765 00 F [mg/L]	Nominal Concen-tration of BAS 750 F c_{nom} [mg/L]	Measured Concen-tration of BAS 750 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 750 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	A1	Control	Control	n.d.	2	< LOQ	n.a.
	A4	0.032	0.00295	0.235	12	0.00282	95.8
	A7	0.10	0.00921	0.253	31	0.00773	83.9
	A10	0.32	0.0295	0.217	135	0.0294	99.7
	A13	1.0	0.0921	0.255	336	0.0859	93.3
	A16	3.2	0.295	0.237	1092	0.259	87.8
3/72	A19	Control	Control	n.d.	2	< LOQ	n.a.
	A20	Control	Control	(b)	2	< LOQ	n.a.
	A21	Control	Control	(b)	2	< LOQ	n.a.
	A22	0.032	0.00295	0.209	12	0.00251	85.3
	A23 (a)	*0.032*	*0.00295*	*0.203*	*12*	*0.00244*	*82.8*
	A24 (a)	*0.032*	*0.00295*	*0.199*	*12*	*0.00239*	*81.1*
					mean	**0.00245**	**83.1**
	A25	0.10	0.00921	0.227	31	0.00694	75.4
	A26 (a)	*0.10*	*0.00921*	*0.255*	*31*	*0.00780*	*84.6*
	A27 (a)	*0.10*	*0.00921*	*0.257*	*31*	*0.0079*	*85.5*
					mean	**0.00783**	**81.8**
	A28	0.32	0.0295	0.209	135	0.0283	96.0
	A31	1.0	0.0921	0.245	336	0.0823	89.4
	A32 (a)	*1.0*	*0.0921*	*0.246*	*336*	*0.0826*	*89.7*
	A33 (a)	*1.0*	*0.0921*	*0.252*	*336*	*0.0847*	*92.0*
					mean	**0.0832**	**90.4**
	A34	3.2	0.295	0.267	1092	0.291	98.8

n.d. = not detected, below lowest calibration standard
n.a. = not applicable
(a) retain sample
(b) a small peak occurred at the retention time of the analyte; the corresponding concentration was below the LOQ
LOD: 0.1 µg BAS 750 F /L
LOQ: 0.3 µg BAS 750 F /L
The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

Table AI-10 Results for Test Samples – Analysis of BAS 490 F (based on Quantifier m/z 314→116)

Sampling Day / Age of Sample [day/ hours]	IES Sample ID	Nominal Concen-tration of BAS 764 00 F [mg/L]	Nominal Concen-tration of BAS 490 F c_{nom} [mg/L]	Measured Concen-tration of BAS 490 F x [µg/L]	Sample Preparation Factor F	Determined Concen-tration of BAS 490 F c [mg/L]	% of Nominal Concen-tration [%]
0/0	A1	Control	Control	n.d.	2	< LOQ	n.a.
	A4	0.032	0.00441	0.332	12	0.00398	90.3
	A7	0.10	0.0138	0.442	31	0.01375	98.1
	A10	0.32	0.0441	0.327	135	0.0443	101
	A13	1.0	0.138	0.404	336	0.136	98.7
	A16	3.2	0.441	0.361	1092	0.394	89.4
3/72	A19	Control	Control	n.d.	2	< LOQ	n.a.
	A20	Control	Control	(b)	2	< LOQ	n.a.
	A21	Control	Control	(b)	2	< LOQ	n.a.
	A22	0.032	0.00441	0.298	12	0.00357	81.0
	A23 (a)	*0.032*	*0.00441*	*0.260*	*12*	*0.00312*	*70.9*
	A24 (a)	*0.032*	*0.00441*	*0.257*	*12*	*0.00309*	*70.1*
					mean	**0.00326**	**74.0**
	A25	0.10	0.0138	0.273	31	0.0833	60.5
	A26 (a)	*0.10*	*0.0138*	*0.314*	*31*	*0.00961*	*69.8*
	A27 (a)	*0.10*	*0.0138*	*0.344*	*31*	*0.0105*	*76.3*
					mean	**0.0101**	**68.8**
	A28	0.32	0.0441	0.323	135	0.0437	99.2
	A31	1.0	0.138	0.352	336	0.118	85.9
	A32 (a)	*1.0*	*0.138*	*0.312*	*336*	*0.105*	*76.3*
	A33 (a)	*1.0*	*0.138*	*0.333*	*336*	*0.112*	*81.3*
					mean	**0.112**	**81.2**
	A34	3.2	0.441	0.419	1092	0.458	104

n.d. = not detected, below lowest calibration standard

n.a. = not applicable

(a) retain sample

(b) a small peak occurred at the retention time of the analyte; the corresponding concentration was below the LOQ

LOD: 0.1 µg BAS 490 F /L

LOQ: 0.3 µg BAS 490 F /L

The tabulated values of the samples represent rounded results obtained by calculation using the exact data.

II. RESULTS AND DISCUSSION

Analytical measurements:
The measured concentrations of the test item BAS 765 00 F were based on the active substances BAS 750 F and BAS 490 F. At the start of the test, the measured concentrations of BAS 750 F in the test media ranged between 83.9 and 99.7% of the nominal values and between 81.8 and 98.8%at the end of the test. The measured concentrations of BAS 490 F in the test media ranged between 89.4 and 101% of the nominal values at the start and between 68.8 and 104% at the end of the test.
The biological results are based on nominal concentrations as the correct dosage of the test item at the start of the test was shown.

Biological results: The test item had a significant inhibitory effect on the inhibition of growth rate of the algae after the test period of 72-hours starting at the test item concentration of 0.10 mg/L (Welch t-test, one-sided smaller, $\alpha = 0.05$). The yield of the algae after 72 hours of incubation was statistically significantly reduced starting at the test item concentration of 0.10 mg/L (Welch t-test, one-sided smaller, $\alpha = 0.05$). No morphological effects on algae were observed in the control and in any of the test item concentrations tested. The effects on algal growth rate and yield are summarized in Table A 10.

Table A 10: Effect of BAS 765 00 F on the growth of green alga *Pseudokirchneriella subcapitata*

Concentration [mg/L] (nominal)	**Control**	**0.032**	**0.10**	**0.32**	**1.0**	**3.2**
Inhibition in 72 h (growth rate) [%]	0.0	0.4	1.1	9.4	44.1	74.1
Inhibition in 72 h (yield) [%]	0.0	2.3	5.6	38.1	89.7	98.2
Endpoints [mg BAS 765 00 F/L] (nominal)						
NOE_rC (72 h)	0.032					
E_rC_{50} (72 h)	1.330 (95% confidence limits: 1.298 - 1.364)					
E_rC_{20} (72 h)	0.472 (95% confidence limits: 0.453 - 0.490)					
E_rC_{10} (72 h)	0.275 (95% confidence limits: 0.260 - 0.289)					
NOE_yC (72 h)	0.032					
E_yC_{50} (72 h)	0.396 (95% confidence limits: 0.383 - 0.411)					
E_yC_{20} (72 h)	0.208 (95% confidence limits: 0.197 - 0.219)					
E_yC_{10} (72 h)	0.149 (95% confidence limits: 0.138 – 0.159)					

Validity criteria according to OECD 201 (2011)	**Obtained in this study**
The biomass in the control cultures should have increased exponentially by a factor of at least 16 within the 72-hour test period. This corresponds to a specific growth rate of 0.92/day (for species in Annex 2 of OECD 201)	154
The mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures must not exceed 35%.	13%
The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures must not exceed 7% in tests with *Pseudokirchneriella subcapitata* and *Desmodesmus subspicatus*. For other less frequently tested species, the value should not exceed 10%.	0.8%

All validity criteria were met.

III. CONCLUSION

In a 72-hour algae test with *Pseudokirchneriella subcapitata*, the E_rC_{50} for BAS 765 00 F was determined to be 1.33 mg/L, the E_yC_{50} was 0.396 mg/L based on nominal concentrations.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

No further studies have been conducted

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

Not necessary.

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.1.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 213 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	CP 10.3.1.1.1/1
Report	Acute toxicity of BAS 765 00 F to the honeybee Apis mellifera L. under laboratory conditions, Franke, M., 2019 report No 862757, 1948BAA0072 BASF DocID 2019/2034549 Authority registration No
Guideline(s):	OECD 213 (1998), OECD 214 (1998)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In an oral toxicity dose-response test, honey bees (worker bees of *Apis mellifera* L.) were exposed to BAS 765 00 F. The toxicity of the test product was determined at nominal concentrations of 46.9, 93.8, 187.5, 375.0 and 750.0 µg BAS 765 00 F/bee which were equivalent to the actual uptake. Additionally, honey bees were treated with BAS 152 11 I (dimethoate) as reference item at nominal concentrations of 0.086, 0.123, 0.175 and 0.250 µg dimethoate/bee or with an aqueous sucrose solution as control. Assessment of bee mortality and behavioral effects was done after 4, 24 and 48 hours.

After 48 hours, no mortality occurred in the control group fed with pure sucrose solution. In the test item treatment, no statistically significant mortality was observed after oral consumption of ≤ 750.0 µg BAS 765 00 F/bee, after 48 hours. Mortality of 13.3% was observed at the dose rate of 750.0 µg BAS 765 00 F/bee, whereas the lower dose rates of ≤ 375.0 µg BAS 765 00 F/bee revealed no mortality on honey bees, after 48 hours.

In an oral toxicity study with BAS 765 00 F on honey bees, the LD_{50} value (48 h) was estimated to be > 750.0 µg BAS 765 00 F/bee, corresponding to > 173.5 µg total a.s./bee.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: *Apis mellifera* L. (honey bee), adult worker bees (3 - 5 weeks old); derived from a healthy and queen-right colony; collected in the morning of use without anesthesia; source: in-house hives.

Test design: In a 48-hour dose-response test, adult worker bees of *Apis mellifera* were exposed orally to BAS 765 00 F via food (sucrose solution). The following treatment groups were set up: 5 concentrations of the test item, 1 untreated control and 4 doses of the reference item) with 3 replicates per treatment and 10 bees per replicate. Assessment of bee mortality and behavioral effects was done after 4, 24 and 48 hours.

Endpoint: Mortality (LD_{50})

Reference item: BAS 152 11 I (dimethoate, 429.0 g/L analyzed (nominal 400 g/L)).

Test concentrations: Untreated control: sucrose solution (50% (w/v)).
Test item:

Nominal doses of BAS 765 00 F [µg/bee]		Consumed doses of BAS 765 00 F [µg/bee]	
based on product	based on total a.s.	based on product	based on total a.s.
46.9	10.8	46.9	10.8
93.8	21.7	93.8	21.7
187.5	43.4	187.5	43.4
375.0	86.7	375.0	86.7
750.0	173.5	750.0	173.5

	Reference item (nominal): 0.086, 0.123, 0.175 and 0.25 µg dimethoate/bee in an aqueous sucrose solution (50% (w/v)).
Test conditions:	Temperature: 23.8°C - 24.8°C; relative humidity: 56% - 75%, photoperiod: 24 h darkness. Food: 50% (w/v) aqueous sucrose solution.
Analytics:	No analytical verification of the test item is required according to current data test guideline. Hence, no analytical verification of the product was conducted.
Statistics:	Descriptive statistics; Fisher's Exact Binominal Test with Bonferroni-Holm Correction for mortality data (one-sided greater, $\alpha = 0.05$).

II. RESULTS AND DISCUSSION

After 48 hours, no mortality occurred in the control group fed with pure sucrose solution. In the test item treatment, no statistically significant mortality was observed after oral consumption of ≤ 750.0 µg BAS 765 00 F/bee, after 48 hours (Fisher's Exact Binomial Test with Bonferroni-Holm Correction for mortality data, one-sided greater, α = 0.05). Mortality of 13.3% was observed at the dose rate of 750.0 µg BAS 765 00 F/bee, whereas the lower dose rates of ≤ 375.0 µg BAS 765 00 F/bee revealed no mortality on honey bees, after 48 hours. The results are summarized in Table A 11.

Table A 11 Toxicity of BAS 765 00 F to *Apis mellifera* (honey bee) in an oral toxicity test

Treatment group	**Uptake of test item**		**Mortality [%]**		
	[µg product/bee]	**[µg a.s./bee] 1)**	**4 h**	**24 h**	**48 h**
Control	--	--	0.0	0.0	0.0
BAS 765 00 F	46.9	10.8	0.0	0.0	0.0
	93.8	21.7	0.0	0.0	3.3
	187.5	43.4	0.0	0.0	0.0
	375.0	86.7	0.0	0.0	0.0
	750.0	173.5	0.0	6.7	13.3
	Endpoint (nominal)				
	[µg a.s./bee] 1)		**[µg BAS 765 00 F/bee]**		
LD_{50} (48 h)	> 173.5		> 750.0		

1) Based on the sum of both active substances.

The LD_{50} value (24 h) for the reference item in the oral toxicity test was determined to be 0.125 µg a.s./bee (95% confidence limits: 0.108 – 0.141 µg a.s./bee) - based on actual consumption.

Validity criteria:

Validity criteria according to OECD 213 (1998)	**Obtained in this study**
Control mortality ≤ 10%	0%
LD_{50} (24 h) of the reference item should be in the specified range 0.10 - 0.35 µg a.s./bee	0.125 µg a.s./bee

All validity criteria were met.

III. CONCLUSION

In an oral toxicity study with BAS 765 00 F on honey bees, the LD_{50} value (48 h) was estimated to be > 750.0 µg BAS 765 00 F/bee, corresponding to > 173.5 µg total a.s./bee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.1.2.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 214 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	CP 10.3.1.1.2/1
Report	Acute toxicity of BAS 765 00 F to the honeybee Apis mellifera L. under laboratory conditions, Franke, M., 2019 report No 862757, 1948BAA0072 BASF DocID 2019/2034549 Authority registration No
Guideline(s):	OECD 213 (1998), OECD 214 (1998)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a contact toxicity dose-response test, honey bees (worker bees of *Apis mellifera* L.) were exposed to BAS 765 00 F. The toxicity of the test product was determined at nominal concentrations of 46.9, 93.8, 187.5, 375.0 and 750.0 µg BAS 765 00 F/bee. Additionally, honey bees were treated with BAS 152 11 I (dimethoate) as reference item at concentrations of 0.106, 0.141, 0.188 and 0.250 µg dimethoate/bee (nominal). Furthermore, bees were treated with deionized water as untreated control and with deionized water + 1% (v/v) wetting agent (Tween®80) as tween control. Assessment of bee mortality and behavioral effects was done after 4, 24, and 48 hours.

After 48 hours of contact exposure, no mortality occurred in the control groups either treated with deionized water or tween solution. In the test item treatment, no mortality was observed after thoracic application of ≤ 750.0 µg BAS 765 00 F/bee, after 48 hours.

In a contact toxicity study with BAS 765 00 F on honey bees, the LD_{50} value (48 h) was estimated to be > 750.0 µg BAS 765 00 F/bee, corresponding to > 173.5 µg total a.s./bee.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: *Apis mellifera* L. (honey bee), adult worker bees (3 - 5 weeks old); derived from a healthy and queen-right colony; collected in the morning of use without anesthesia; source: in-house hives.

Test design: In a 48-hour dose-response test, adult worker bees of *Apis mellifera* were exposed to five concentrations of BAS 765 00 F in an appropriate carrier (deionized water + 1% (v/v) wetting agent (Tween®80)) placed on the dorsal bee thorax. The following treatment groups were set up: 5 concentrations of the test item, 1 untreated control (deionized water), 1 tween control (deionized water + 1% (v/v) wetting agent (Tween®80)) and 4 doses of a reference item) with 3 replicates per treatment and 10 bees per replicate. Assessment of bee mortality and behavioral effects was done after 4, 24, and 48 hours.

Endpoint: Mortality (LD_{50}).

Reference item: BAS 152 11 I (dimethoate, 429.0 g/L analyzed (nominal 400 g/L)).

Test concentrations: Untreated control (deionized water);
Tween control (deionized water + 1% (v/v) wetting agent (Tween®80));
Test item:

Nominal doses of BAS 765 00 F [µg/bee]	
based on product	based on total a.s.
46.9	10.8
93.8	21.7
187.5	43.4
375.0	86.7
750.0	173.5

Reference item: 0.106, 0.141, 0.188 and 0.250 µg dimethoate/bee

Test conditions: Temperature: 23.8°C - 24.8°C; relative humidity: 56% - 75%, photoperiod: 24 h darkness. Food: 50% (w/v) aqueous sucrose solution.

Analytics: No analytical verification of the test item is required according to current data test guideline. Hence, no analytical verification of the product was conducted.

Statistics: Descriptive statistics; Fisher's Exact Binomial Test with Bonferroni-Holm Correction for mortality data (one-sided greater, $\alpha = 0.05$).

II. RESULTS AND DISCUSSION

After 48 hours of contact exposure, no mortality occurred in the control groups either treated with deionized water or tween solution. In the test item treatment, no mortality was observed after thoracic application of ≤ 750.0 µg BAS 765 00 F/bee, after 48 hours. The results are summarized in Table A 12.

Table A 12 Toxicity of BAS 765 00 F to *Apis mellifera* (honey bee) in a contact toxicity test

Treatment		**Mortality [%]**		
[µg BAS 765 00 F/bee]	**[µg a.s./bee] [1)]**	**4 h**	**24 h**	**48 h**
Water control	--	0.0	0.0	0.0
Tween control	--	0.0	0.0	0.0
46.9	10.8	0.0	0.0	0.0
93.8	21.7	0.0	0.0	0.0
187.5	43.4	0.0	0.0	0.0
375.0	86.7	0.0	0.0	0.0
750.0	173.5	0.0	0.0	0.0
	Endpoint (nominal)			
LD_{50} (48 h)	**[µg a.s./bee] [1)]**		**[µg BAS 765 00 F/bee]**	
	> 173.5		> 750.0	

[1)] Based on sum of both active substances.

The LD_{50} value (24 h) for the reference item in the contact toxicity test was determined to be 0.163 µg a.s./bee (95% confidence limits: 0.149 – 0.178 µg a.s./bee).

Validity criteria:

Validity criteria according to OECD 214 (1998)	**Obtained in this study**
Control mortality ≤ 10%	0.0% (both controls)
LD_{50} (24 h) of the reference item should be in the specified range 0.10 - 0.30 µg a.s./bee	0.163 µg a.s./bee

All validity criteria were met.

III. CONCLUSION

In a contact toxicity study with BAS 765 00 F on honey bees, the LD_{50} value (48 h) was estimated to be > 750.0 µg BAS 765 00 F/bee, corresponding to > 173.5 µg total a.s./bee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

~~Based on the acute toxicity data for honeybees there is no indication for a considerable increase in toxicity of BAS 765 00 F. The acute formulation endpoint (based on µg a.s./bee) is less than a factor of 5 more toxic than the summed endpoints of the active substances) and toxicity can be predicted based on the data of the active substances. Hence, in accordance with Commission Regulation (EU) 283/2013 and Reg. 284/2013 no study was conducted with BAS 765 00 F but reference is made to the data of the active substances. For kresoxim-methyl (BAS 490 F, tested as BAS 490 02 F) a study on chronic toxicity to bees is summarized below. For mefentrifluconazole (BAS 750 F) EU agreed endpoints are used.~~

A 2.3.1.2.1 Study 1

Comments of zRMS:	The kresoxim-methyl was included to Annex 1 based on "old" data requirements. For this reason, in order to allow carried out a risk assessment in accordance with the EPPO scheme, the applicant submitted an additional study for BAS 490 02 F. As no studies on chronic effects of the formulation BAS 765 00 F to adult bees were provided, zRMS evaluated BAS 490 02 F study as supplementary data. The study is considered to be reliable and suitable for the risk assessment.

Reference:	CP 10.3.1.2/1
Report	Chronic toxicity of BAS 490 02 F to the honeybee (Apis mellifera L.) under laboratory conditions, Ruhland, S., 2015 report No EU-141048050B,EU-702200,14 10 48 050 B BASF DocID 2014/1111117 Authority registration No
Guideline(s):	Current ring test protocol of the AG-Bienenschutz (2014), CEB No. 230 (2012), Decourty et al. (2005), OECD 213 (1998), Suchail et al. (2001)
Deviations:	Yes No analytical verification of the test substance was conducted. Study was conducted before an agreed test guideline requesting analytical verification was available. However, the results of the reference item indicate that correct exposure and study is considered acceptable for use in the risk assessment.
GLP:	Yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Supplementary
Duplication (if vertebrate study)	No

Executive Summary

In a 10-day chronic oral toxicity test, 1 - 4 days old worker honey bees (*Apis mellifera carnica* P.) were exposed to a daily application of BAS 490 02 F diluted in the bee food (50% (w/v) aqueous sucrose solution). The chronic toxicity of the test item was determined at nominal doses of 25.0, 50.0, 100.0, 200.0 and 400.0 µg a.s./bee/day (effective doses were 27.4, 48.4, 72.7, 128.8 and 203.2 µg a.s./bee/day), corresponding to concentrations of 0.642, 1.284, 2.568, 5.136 and 10.271 g a.s./kg, respectively. Additionally, honey bees were treated with Dimethoate EC 400 as reference item at nominal doses ranging from 27.3 to 5.9 ng a.s./bee/day. Untreated diet served as a control. Assessments of bee mortality and behavioral effects were done daily over the 10 days test period.

In the chronic toxicity test, the control group showed a mean mortality of 1.7% after 10 days of testing. In the test item group, bees showed mortalities between 1.7% and 95.0%. The two highest concentrations showed 53.3% and 95% mortality, which are statistically significant increased compared to the control group.

In a 10-day chronic toxicity feeding study with BAS 490 02 F, the LD_{50} and LC_{50} were determined to be 124.1 µg consumed a.s./bee/day and 4.996 g a.s./kg food, respectively. The NOED was determined to be 72.7 µg consumed a.s./bee/day, corresponding to a NOEC of 2.568 g a.s./kg food.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 490 02 F, batch no. 02583524UO, content of a.s.: kresoxim-methyl (BAS 490 F; Reg. No. 242 009): 50.2% (50.0% nominal).

B. STUDY DESIGN

Test species: Honey bee (*Apis mellifera* L. spp. *carnica*); 1-4 day old bees; obtained from healthy and queen-right colonies; source: Bienenfarm Kern GmbH, Leipzig, Germany.

Test design: 10-day chronic oral feeding test in the laboratory (dose response test). The honey bees were provided daily with 5 doses of test item treated sugar solutions (50% (w/v) aqueous sucrose solution). 10 treatment groups were set up: 5 doses of the test item, 1 untreated control group (50% (w/v) aqueous sucrose solution) and 4 doses of the reference item with 3 replicates per dose, each consisting of 20 bees per replicate. Assessments of bee mortality and behavioral effects were done daily over the 10 days test period.

Endpoint: Mortality

Reference item: Dimethoate 400 EC (BAS 152 11 I), 400.0 g/L dimethoate (nominal).

Test concentrations: Control: untreated diet (50% (w/v) aqueous sucrose solution),
Test item: 25.0, 50.0, 100.0, 200.0 and 400.0 µg a.s./bee/day (corresponding to concentrations of 0.642, 1.284, 2.568, 5.136 and 10.271 g a.s./kg food).
Reference item: 5.9, 9.8, 16.4 and 27.3 ng dimethoate/bee/day (corresponding to concentrations of 0.152, 0.253, 0.421 and 0.702 mg a.s./kg food).

Test conditions: Temperature: 32.6°C – 33.1°C,
Relative humidity: 55.5% – 62.0%
Photoperiod: constant darkness (except during assessments)
Food: 50% (w/v) aqueous sucrose solution.

Analytics: No analytical verification of the test item was conducted.

Statistics: Descriptive statistics; Fisher's Exact Binomial test with Bonferroni Correction for mortality data (one-sided greater, $\alpha = 0.05$); Logit analysis using linear maximum likelihood regression for calculation of the LD_{50}/LC_{50} value for the test item.

II. RESULTS AND DISCUSSION

In the chronic toxicity test, the control group showed a mean mortality of 1.7% after 10 days of testing. In the test item group, bees showed mortalities between 1.7% and 95.0%. The two highest concentrations showed 53.3% and 95% mortality, which are statistically significant increased compared to the control group (Fisher's Exact Binomial test with Bonferroni Correction, α = 0.05, one-sided greater)
In the test item group, the food consumption ranged between 19.8 and 42.6 mg solution per bee and day which is 50.8% to 109.5% of the expected amount (control: on average 46.7 mg/bee/day = 119.9%).
The LD_{50} was determined to be 124.1 µg consumed a.s./bee/day and the LC_{50} was determined to be 4.996 g a.s./kg food. The NOED was determined to be 72.7 µg consumed a.s./bee/day and the NOEC was 2.568 g a.s./kg food, respectively. The results are summarized in Table A 13.

Table A 13 Mean cumulative mortality of honey bees exposed to BAS 490 02 F in a 10-day chronic oral toxicity test

Treatment group	Dosage [µg a.s./bee/day		Cumulative mean mortality [%]		Behavioral abnormalities [1]
	nominal	consumed	absolute	corrected	
Control	--	--	1.7	--	0 out of 59
BAS 490 02 F	25.0	27.4	1.7	0.0	0 out of 59
	50.0	48.4	1.7	0.0	0 out of 59
	100.0	72.7	8.3	6.8	0 out of 55
	200.0	128.8	53.3 *	52.5	0 out of 28
	400.0	150.9	95.0 *	94.9	0 out of 3
		Endpoints		**10 days**	
Test item doses		**LD_{50}** [1] [µg consumed a.s./bee/day]		124.1 (114.9 – 134.1)	
		NOED [3] [µg consumed a.s./bee/day]		72.7	
Test item concentrations		**LC_{50}** [1] [g a.s./kg food]		4.996 (4.502 – 5.543)	
		NOEC [3] [g a.s./kg food]		2.568	
Reference item		**LD_{50}** [4] [ng consumed a.s./bee/day]		11.5 (10.8 – 12.3)	
		LC_{50} [4] [mg a.s./kg food]		0.477 (0.443 – 0.513)	

negative values are treated as "0"; corrected: corrected mortality (according to SCHNEIDER-ORELLI 1947).

* Statistically significant difference in pairwise comparison between treatment and untreated control (Fisher`s Exact Binomial Test with Bonferroni Correction; α = 0.05; one sided greater)

1) Number of bees with behavioral abnormalities referring to the number of remaining bees.

2) Median lethal dose/concentration (and 95 % CL / lower-upper) was calculated by using Logit analysis (linear max. likelihood regression

3) Fisher's Exact Binomial Test with Bonferroni Correction (one-sided greater, α = 0.05).

4) Median lethal dose/concentration (and 95 % CL / lower-upper) was calculated by using Probit/Weibull analysis (linear max. likelihood regression).

For the reference item the LD_{50} was determined to be 11.5 ng consumed a.s./bee/day, the LC_{50} was 0.477 mg a.s./kg food, respectively. The highest reference dosage tested in the study was 27.3 ng a.s./bee/day (actual consumption on average per day: 17.6 ng a.s./bee), which caused a mean mortality of 95%.

Validity criteria:

Validity criteria according to OECD 245 (2017)	**Obtained in this study**
Control mortality from ≤ 15% at D10 across all replicates	1.7% untreated control
Reference item mortality ≥ 50% on D10	95%

All validity criteria were met.

III. CONCLUSION

In a 10-day chronic toxicity feeding test with BAS 490 02 F the LD_{50} was determined to be 124.1 µg consumed a.s./bee/day and the LC_{50} was determined to be 4.996 g a.s./kg food. The NOED was determined to be 72.7 µg consumed a.s./bee/day and the NOEC was 2.568 g a.s./kg food, respectively.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Based on the acute toxicity data for honey bees there is no indication for a considerable increase in toxicity of BAS 765 00 F. The acute formulation endpoints (based on µg a.s./bee) is less than a factor of 5 more toxic than the summed endpoints of the active substances) and toxicity can be predicted based on the data of the active substances. Hence, in accordance with Commission Regulation (EU) 283/2013 and Reg. 284/2013 no study was conducted with BAS 765 00 F but reference is made to the data of the active substances. For kresoxim-methyl (BAS 490 F, tested as BAS 490 02 F), a study on toxicity to honey bee larvae is summarized below. For mefentrifluconazole (BAS 750 F), EU agreed endpoints are used.

A 2.3.1.3.1 Study 1

Comments of zRMS:	The kresoxim-methyl was included to Annex 1 based on "old" data requirements. For this reason, in order to allow carried out a risk assessment in accordance with the EPPO scheme, the applicant submitted an additional study for BAS 490 02 F. As no studies on effects of the formulation BAS 765 00 F to larvae were provided, zRMS evaluated BAS 490 02 F study as supplementary data. The study is considered to be valid.

Reference:	CP 10.3.1.3/1
Report	Acute toxicity of BAS 490 02 F to honeybee larvae Apis mellifer L. under laboratory conditions (in vitro), Kleebaum, K., 2015 report No EU-141048063B,EU-702199,14 10 48 063 B BASF DocID 2014/1111118 Authority registration No
Guideline(s):	OECD 237 (2013) Honey bee (Apis mellifera) larval toxicity test single exposure
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Supplementary
Duplication (if vertebrate study)	No

Executive Summary

In a single feeding toxicity test, four-day old (D4) honey bee larvae (*Apis mellifera* L.) were exposed to one application of BAS 490 02 F diluted in the larvae food. Synchronized 1st larval stage (L1) honey bee larvae were fed with a single application of BAS 490 02 F diluted in larvae food at doses of 10.0, 20.0, 30.0, 40.0 and 50.0 µg a.s./larva (corresponding to 20.0, 40.0, 60.0, 80.1 and 100.1 µg product/larva). The concentrations of test item in the diet were 0.303, 0.607, 0.910, 1.213 and 1.516 g a.s./kg food. Untreated diet served as a control. Furthermore, dimethoate at a dose rate of 8.8 µg/larva served as reference item treatment. All treatment groups and controls contained larvae from three different bee colonies. Assessments of larval mortality were done 24, 48, 72 and 96 hours after start of the treatment. Additionally, other observations such as small body size or large quantities of remaining food after 72 and 96 hours (on Day 7 and D8) was noted.

After 72 hours (D7) the control group showed a mortality of 11.1% and 13.9% after 96 hours (D8). In the test item group, none of the larvae fed with 10.0, 20.0, 30.0, 40.0 and 50.0 µg a.s./larva revealed statistically significantly higher mortality in comparison to the control group after 72 hours (D7). On D8 the highest test item dose of 50.0 µg a.s./larvae revealed a statistically, significant difference in mortality compared to the control treatment. Nevertheless, less than 50% of the larvae responded, so no LD/LC_{50} could be determined. In the reference item treatment group of 8.8 µg dimethoate/larva a mortality of 83.3% on D7 and 88.9% (corrected by control mortality: 81.3% and 87.1%, respectively) on D8 was determined. Analytical determination of samples taken at the day of application from stock solution via HPLC with UV-detection resulted in a concentration of 16.276 mg/mL (recovery rate: 97%). Control mortality was ≤ 15%, corrected mortality in the reference item dose of 8.8 µg a.s./larva was ≥ 50% and the analytical verification of active substance concentration in the test item stock solution was within ± 20% of the nominal concentration. Thus, the study can be regarded as valid.

In an acute larval toxicity test with BAS 490 02 F, the NOED (72 h and 96 h) was ≥ 50.0 and 40.0 µg a.s./larva and the corresponding NOEC (72 h and 96 h) was ≥ 1.516 and 1.213 g a.s./kg food. Accordingly, the LD_{50} (72 h) was determined to be > 50.0 µg a.s./larva, which is equivalent to a LC_{50} (72 h) of > 1.516 g a.s./kg food. The LD_{50} (96 h) was determined to be > 50.0 µg a.s./larva, which is equivalent to a LC_{50} (96 h) of > 1.516 g a.s./kg food.

I. MATERIALS AND METHODS

A. MATERIALS

Test item: BAS 490 02 F, batch no.: 02583524U0; content of active substance: kresoxim-methyl (BAS 490 F, Reg. No. 242 009): nominal: 50.0%; analyzed: 50.2%

B. STUDY DESIGN

Test species: *Apis mellifera carnica* L. (honey bee), synchronized first instar larvae (L1, one day old); derived from three healthy and queen-right colonies; source: Bienenfarm Kern GmbH, 04249 Leipzig, Germany.

Test design: One day old honey bee larvae (D1) of *Apis mellifera* L. were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates 3 day before start of the treatment. After this in a 72-hour (D7)/96 hour (D8) acute test, the 4 day old (D4) larvae were exposed to a single application of BAS 490 02 F diluted in the larvae food (aqueous sugar solution mixed with royal jelly). In total, 7 treatment groups were set up: 5 doses of the test item, 1 untreated control group and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate. After the day of application additional feeding of the larvae took place 24 (D5) and 48 hours later (D6). Assessments of larval mortality were done after 24, 48, 72 and 96 hours (respectively D5, D6, D7, D8). Additionally, other observations as small body size or large quantities of remaining food after 72 and 96 hours (on D7 and D8) were noted. In an analytical phase of the study the concentration of the active substance in the test item stock solution (based on water) was determined.

Endpoints: Mortality, quantitative observations: body size, remaining food.

Reference item: Dimethoate tech. (analyzed purity: 99.8% w/w).

Test doses: Control: untreated diet containing 50% aqueous sugar solution with 50% royal jelly

Nominal dose/concentration of BAS 490 02 F	
Doses [µg a.s./larva]	**Concentrations [g a.s./kg food]**
10.0	0.303
20.0	0.607
30.0	0.910
40.0	1.213
50.0	1.516

Reference item: treated diet with a dose of 8.8 µg dimethoate/larva (corresponding concentration: 0.267 g a.s./kg food).

Test conditions: Temperature: 34.2°C – 34.8°C
Relative humidity: 86% – 100%
Photoperiod: darkness (except during assessments)
Food: 50% aqueous sugar solution and 50% royal jelly.

Analytics: Analytical determination of the active substance in aqueous sugar solution via in-house developed HPLC method with UV-detection.

Statistics: Descriptive statistics; Fisher's Exact Binomial test with Bonferroni Correction for mortality data (one-sided greater, $\alpha = 0.05$) and No Observed Effect Level.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 490 F (contained in BAS 490 02 F) in aqueous sugar solution were determined using the method described within the study report. The validation of the analytical method is described in the study report. The determination was conducted by an in-house developed method using reversed phase-high performance liquid chromatography (HPLC) with UV-detection. The method was validated with test medium spiked with test item at approximately 50% of the nominal test concentration (8414 mg a.s./L) and at the nominal test concentration (16837 mg a.s./L). The sample was allowed to reach room temperature and was analyzed after dilution with factor 1500 with dilution medium. The determination was performed by HPLC with UV-detection. The limit of quantification (LOQ) was 8414 mg/L. The limit of detection (LOD) is not reported. Matrix effects were not taken into account, since the dilution factor (with dilution medium) of the measuring solutions of specimens and validation solutions was 1500. Thus, the influence of the original matrix solution is regarded as negligible using UV-detection. Details on measured fortification samples and obtained procedural recoveries for BAS 490 F are given in Table A 14.

Table A 14 Procedural recoveries for BAS 490 F in aqueous sugar solution

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Aqueous sugar solution	8414	5	100	0.5
Aqueous sugar solution	16837	5	101	0.5

II. RESULTS AND DISCUSSION

The concentration of active substance in the test item base stock solution was 97% of the nominal concentration and therefore within the parameters defined in the study plan. In larval toxicity test, the control group showed a mortality of 11.1% after 72 hours (D7) and 13.9% after 96 hours (D8). In the test item group, none of the larvae fed with 10.0, 20.0, 30.0, 40.0 and 50.0 µg a.s./larva revealed statistically significantly higher mortality in comparison to the control group after 72 hours (D7). On D8 the highest test item dose of 50.0 µg a.s./larvae revealed a statistically, significant difference in mortality compared to the control treatment (Fisher's Exact Binomial test with Bonferroni Correction, one-sided greater, $\alpha = 0.05$). Nevertheless, less than 50% of the larvae responded, so no LD/LC_{50} could be determined. The results are summarized in Table A 15.

Table A 15 Toxicity of BAS 490 02 F to *Apis mellifera* (honey bee) in an acute larval toxicity test

Dosage [µg a.s./larva]	**Concentration [g a.s./kg food]**	**D7 mortality [%]**		**D8 mortality [%]**	
		absolute	**corrected** [1)]	**absolute**	**corrected** [1)]
Control	Control	11.1	--	13.9	--
10.0	0.303	11.1	0.0	13.9	0.0
20.0	0.607	16.7	6.3	16.7	3.2
30.0	0.910	8.3	0.0	11.1	0.0
40.0	1.213	11.1	0.0	11.1	0.0
50.0	1.516	27.8	18.8	41.7*	32.3
Endpoints		**[D7]**		**[D8]**	
LD_{50} [µg a.s./larva]		> 50.0		> 50.0	
NOED [µg a.s./larva] [2)]		≥ 50.0		40.0	
LC_{50} [g a.s./kg food]		> 1.516		> 1.516	
NOEC [g a.s./kg food] [2)]		≥ 1.516		1.213	

negative values are set to "0"

* Statically significant difference in pairwise comparison between treatment and untreated control (Fisher`s Exact Binomial Test with Bonferroni Correction; α=0.05; one sided greater)

1) Corrected for control mortality according to Schneider-Orelli (1947).

2) Fisher`s Exact Binomial Test with Bonferroni Correction; α=0.05; one sided greater.

In the reference item treatment group of 8.8 µg dimethoate/larva a mortality of 83.3% on D7 and 88.9% (corrected by control mortality: 81.3% and 87.1%, respectively) on D8 was determined.

Validity criteria:

Validity criteria according to OECD 237 (2013)	**Obtained in this study**
Control mortality from D4 to D7 ≤ 15% across all replicates	11.1% untreated control
Effects of the reference item: Dimethoate: larval mortality ≥ 50% on D7 across all replicates	dimethoate: 83.3%

All validity criteria were met.

III. CONCLUSION

In an acute larval toxicity test with BAS 490 02 F, the NOED (72 h and 96 h) was ≥ 50.0 and 40.0 µg a.s./larva and the corresponding NOEC (72 h and 96 h) was ≥ 1.516 and 1.213 g a.s./kg food. Accordingly, the LD_{50} (72 h) was determined to be > 50.0 µg a.s./larva, which is equivalent to a LC_{50} (72 h) of > 1.516 g a.s./kg food. The LD_{50} (96 h) was determined to be > 50.0 µg a.s./larva, which is equivalent to a LC_{50} (96 h) of > 1.516 g a.s./kg food.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

As BAS 765 00 F poses no unacceptable risk to honey bees, further studies are not necessary.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

As BAS 765 00 F poses no unacceptable risk to honey bees, further studies are not necessary.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

As BAS 765 00 F poses no unacceptable risk to honey bees, further studies are not necessary.

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.3 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

A 2.3.3.1 Study 1

Comments of zRMS:	The study follows the guideline specified by Blümel *et al.* (2000) and according to the principles of GLP. No deviations were noted and all validity criteria were met. The study is acceptable for the risk assessment purposes.

Reference:	CP 10.3.2.1/1
Report	A rate-Response laboratory test to determine the effects of BAS 765 00 F on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae), Fallowfield, L., 2019 report No 862759, BASF-19-8 BASF DocID 2019/2034600 Authority registration No
Guideline(s):	Bluemel et al. (2000)
Deviations:	No
GLP:	yes (certified by Department of Health of the Government of the United Kingdom, United Kingdom),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a rate-response laboratory study, protonymphs of the mite *Typhlodromus pyri* (Acari: Phytoseiidae) were exposed to dried residues of BAS765 00 F on glass plates. The test item was applied at application rates of 125, 250, 500, 1000 and 2000 mL BAS 765 00 F/ha. Additionally, the reference item BAS 152 11 I (dimethoate) was applied at a rate equivalent to 15 mL BAS 152 11 I/ha and a purified water control was set up. All substances were applied in 200 L water/ha. Endpoint for the study was mortality, which was assessed at 1 and 7 days after treatment (DAT).

After 7 days there was 4.0% mortality in the control, compared with 6.7%, 5.0%, 6.7%, 8.3% and 15.0% mortality in the 125, 250, 500, 1000 and 2000 mL BAS 765 00 F/ha treatment rates, respectively. When adjusted for the control treatment deaths, the corrected mortalities were 2.8%, 1.0%, 2.8%, 4.5% and 11.5% in the five respective test item treatments. Statistically, only the 2000 BAS 765 00 F/ha treatment rate differed significantly from the control.

In a laboratory study with BAS 765 00 F, the LR_{50} for *Typhlodromus pyri* was > 2000 mL BAS 765 00 F/ha in 200 L water/ha.

I. MATERIALS AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190218-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: *Typhlodromus pyri* Scheuten (predatory mite); protonymphs < 24 hours old; source: in-house culture.

Test design: Exposure of mites to air-dried residues on treated glass plates. Seven treatment groups (5 application rates of test item, a purified water control and a reference item) with 5 replicates of 20 mites in the control and 3 replicates of 20 mites per treatment group. Assessments of mite mortality were made at 1 and 7 days after treatment (DAT). Fresh untreated food was provided daily.

Endpoints: Mortality (LR_{50}).

Reference item: BAS 152 11 I (dimethoate, nominal 400 g/L, measured 429.0 g/L).

Test rates: Untreated control: purified water
Test item:

Nominal application rates of BAS 765 00 F		
Based on the product BAS 765 00 F [mL/ha]	Based on the a.s. BAS 750 F [g/ha]	Based on the a.s. BAS 490 F [g/ha]
125	12.5	18.75
250	25	37.5
500	50	75
1000	100	150
2000	200	300

Reference item: BAS 152 11 I was applied at an application rate of 15 mL BAS 152 11 I/ha. All substances were applied in 200 L water/ha.

Test conditions: Temperature: 24.8 – 25.9°C; relative humidity: 60 - 71%; photoperiod: 16 h light : 8 h dark; light intensity: 430-1050 lux; food: pollen from almond (*Prunus* sp.) and apple (*Malus* sp.) (1:1, v/v) and occasionally freshly-collected pollen of bean (*Vicia faba* L.*)*.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics. The mortality data in each test-item treatment were compared to that in the control using Chi2 2x2 Test with Bonferroni Correction ($\alpha = 0.05$, one-sided, > control).

II. RESULTS AND DISCUSSION

After 7 days there was 4.0% mortality in the control, compared with 6.7%, 5.0%, 6.7%, 8.3% and 15.0% mortality in the 125, 250, 500, 1000 and 2000 mL BAS 765 00 F/ha treatment rates, respectively. When adjusted for the control treatment deaths, the corrected mortalities were 2.8%, 1.0%, 2.8%, 4.5% and 11.5% in the five respective test item treatments. Statistically, only the 2000 BAS 765 00 F/ha treatment rate differed significantly from the control (Chi^2 2x2 Test with Bonferroni Correction, $\alpha = 0.05$, one-sided, > control). The results are summarized in Table A 16.

Table A 16 Effects on *Typhlodromus pyri* exposed to BAS 765 00 F under worst-case laboratory conditions

Treatment	Rate [1] [mL/ha]	Mortality [2] [%]	Corrected Mortality [3] [%]
Control	--	4.0	--
BAS 765 00 F	125	6.7	2.8
	250	5.0	1.0
	500	6.7	2.8
	1000	8.3	4.5
	2000	15.0 *	11.5
		Endpoint [mL BAS 765 00 F/ha]	
LR_{50}		> 2000	

* Treatments differing statistically significantly from the control (Chi2 2x2 Test with Bonferroni Correction, $\alpha = 0.05$, one-sided, > control).
[1] Application rate in 200 L water/ha.
[2] Mortality after 7 days of exposure to BAS 765 00 F on glass plates.
[3] Corrected mortality according to Abbott (1925).

In the reference item treatment, 93.3% mortality (93.1% corrected) was observed at 7 DAT.

Validity criteria:

Validity criteria according to Bluemel et al (2000)	Obtained in this study
Control mortality ≤ 20% on day 7	4.0%
Corrected mortality in the reference group 50-100% on day 7	93.1%

All validity criteria were met.

III. CONCLUSION

In a laboratory study with BAS 765 00 F, the LR_{50} for *Typhlodromus pyri* was > 2000 mL BAS 765 00 F/ha in 200 L water/ha.

A 2.3.3.2 Study 2

Comments of zRMS:	The study follows the guideline specified by Mead-Briggs M. *et al.* (2000) and according to the principles of GLP. No deviations were noted and all validity criteria were met. The study is acceptable for the risk assessment purposes.

Reference:	CP 10.3.2.1/2
Report	A rate-Response laboratory study to determine the effects of BAS 765 00 F on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae), Stevens, J., 2019 report No 862761, BASF-19-7 BASF DocID 2019/2034598 Authority registration No
Guideline(s):	Mead-Briggs M. et al. (2000)
Deviations:	No
GLP:	yes (certified by Department of Health of the Government of the United Kingdom, United Kingdom),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a worst-case laboratory study, adults of the wasp *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) were exposed to dried residues of BAS 765 00 F on glass plates. The test item was applied at application rates of 125, 250, 500, 1000 and 2000 mL BAS 765 00 F/ha. Additionally, the reference item BAS 152 65 I (dimethoate) was applied at a rate equivalent to 0.1 mL BAS 152 65 I/ha and a purified water control was set up. All substances were applied in 200 L spray solution/ha. Wasp mortality was assessed after 2, 24 and 48 hours of exposure.

At 48 h, there was 7.5% mortality in the control treatment, compared with 10.0%, 7.5%, 17.5%, 20.0% and 27.5% mortality in the 125, 250, 50, 1000 and 2000 mL BAS 765 00 F/ha treatment rates, respectively. When adjusted for the control treatment deaths, the corrected mortality in the respective test item treatments was 2.7%, 0.0%, 10.8%, 13.5% and 21.6%. None of the results for the treatment rates differed significantly from the control.

In a laboratory study with *Aphidius rhopalosiphi* the LR_{50} was > 2000 mL BAS 765 00 F/ha in 200 L water/ha.

I. MATERIALS AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190218-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: *Aphidius rhopalosiphi* (parasitoids); adults less than 48 h old; source: in-house culture.

Test design: Exposure of the wasps to air-dried residues on treated glass plates. Seven treatment groups (5 application rates of test item, a purified water control and a reference item) and 4 replicates of 10 wasps per treatment. Assessment of mortality was done at 2, 24 and 48 hours after test initiation.

Endpoint: Mortality (LR_{50}).

Reference item: BAS 152 65 I (dimethoate, nominal 400 g/L, analyzed 417.0 g/L).

Test rates: Untreated control: purified water
Test item:

Nominal application rates of BAS 765 00 F		
Based on the product BAS 765 00 F [mL/ha]	Based on the a.s. BAS 750 F [g/ha]	Based on the a.s. BAS 490 F [g/ha]
125	12.5	18.75
250	25	37.5
500	50	75
1000	100	150
2000	200	300

Reference item: BAS 152 65 I was applied at an application rate of 0.1 mL BAS 152 11 I/ha. All substances were applied in 200 L spray solution/ha.

Test conditions: Temperature: 20.4 - 20.9°C; relative humidity: 69 - 76%; photoperiod: 16 h light : 8 h dark; light intensity: 907 - 980 lux; food: 1:3 (v/v) solution of honey and water.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics. The mortality data in each test-item treatment were compared to that in the control using multiple sequentially-rejective Fisher Test after Bonferroni-Holm (one-sided, > control, $\alpha = 0.05$). Regression analysis of the results was not deemed appropriate, due to the outcome of the bioassay. The LR_{50} was extrapolated from the data.

II. RESULTS AND DISCUSSION

At 48 h, there was 7.5% mortality in the control treatment, compared with 10.0%, 7.5%, 17.5%, 20.0% and 27.5% mortality in the 125, 250, 50, 1000 and 2000 mL BAS 765 00 F/ha treatment rates, respectively. When adjusted for the control treatment deaths, the corrected mortality in the respective test item treatments was 2.7%, 0.0%, 10.8%, 13.5% and 21.6%. None of the results for the treatment rates differed statistically significantly from the control (multiple sequentially-rejective Fisher Test after Bonferroni-Holm, one-sided, > control, $\alpha = 0.05$). The results are summarized in Table A 17.

Table A 17 Effects on *Aphidius rhopalosiphi* exposed to BAS 765 00 F under worst-case laboratory conditions after 48 hours of exposure

Treatment	Rate [mL/ha] [1)]	Mortality [%] [2)]	Corrected mortality [%] [3)]
Control	--	7.5	--
BAS 765 00 F	125	10.0	2.7
	250	7.5	0.0
	500	17.5	10.8
	1000	20.0	13.5
	2000	27.5	21.6
	Endpoint [mL BAS 765 00 F/ha]		
LR_{50}	> 2000		

1) Rate in terms of mL BAS 765 00 F/ha.
2) Mortality after 48 h of exposure to BAS 765 00 F on treated glass plates. The results for individual test item treatments were compared to the control using multiple sequentially-rejective Fisher Test after Bonferroni-Holm (one-sided, > control, $\alpha = 0.05$).
3) Corrected mortality according to Abbott (1925).

In the reference item treatment, 100% mortality was observed at 48 h.

Validity criteria:

Validity criteria according to Mead-Briggs M. et al. (2009)	Obtained in this study
Control mortality < ~~10%~~ 13% (48 h)	7.5%
Corrected mortality in the reference item group 50 - 100% (48 h)	100%

All validity criteria were met.

III. CONCLUSION

In a laboratory study with *Aphidius rhopalosiphi* the LR_{50} was > 2000 mL BAS 765 00 F/ha in 200 L water/ha.

A 2.3.4 KCP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

As BAS 765 00 F poses no unacceptable risk to non-target arthropods, further studies are not necessary.

A 2.3.5 KCP 10.3.2.3 Semi-field studies with non-target arthropods

As BAS 765 00 F poses no unacceptable risk to non-target arthropods, further studies are not necessary.

A 2.3.6 KCP 10.3.2.4 Field studies with non-target arthropods

As BAS 765 00 F poses no unacceptable risk to non-target arthropods, further studies are not necessary.

A 2.3.7 KCP 10.3.2.5 Other routes of exposure for non-target arthropods

As BAS 765 00 F poses no unacceptable risk to non-target arthropods, further studies are not necessary.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.1.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 222 (2016) and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment.

Reference:	CP 10.4.1.1/1
Report	Effects of BAS 765 00 F on the reproduction of the earthworm Eisenia andrei in artificial soil, Friedrich, S., 2020 report No 862747, 1948TEC0056 BASF DocID 2019/2034565 Authority registration No
Guideline(s):	OECD 222 (2016)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effects of BAS 765 00 F on mortality, biomass development and reproduction of *Eisenia andrei* (Annelida: Oligochaeta) were investigated in an extended laboratory study over 56 days. Eight test item concentrations (9.0, 16.2, 29.2, 52.9, 94.5, 170, 306 and 551 mg BAS 765 00 F/kg dry soil) were incorporated into the soil (10% peat) with 4 replicates per treatment (each containing 10 worms). An untreated control with 8 replicates was included. The reference item was tested in a separate study. Assessment of worm mortality, body weight, and feeding activity was carried out after 28 days; assessment of reproduction (number of juveniles) was carried out after 56 days.

BAS 765 00 F did not show any statistically significant effects on mortality and body weight. The mortality of adult worms ranged between 0 - 2.5% in the test item treated groups and was 0% in the control group. The weight change of adult worms was 22.8 - 27.6% in the test item treated groups and 24.6 % in the control group. The feeding activity in all test item treated groups was comparable to the control. The reproduction rate was significantly different compared to the control at concentrations of 306 and 551 mg BAS 765 00 F/kg dry soil. No pathological symptoms and no further effects on behavior of the worms were observed.

In a 56-day earthworm reproduction study with BAS 765 00 F, the NOEC for mortality and biomass was determined to be greater than or equal to 551 mg BAS 765 00 F/kg dry soil. The NOEC for reproduction was determined to be 170 mg BAS 765 00 F/kg dry soil. The EC_{10}, EC_{20} and EC_{50} values for reproduction were calculated to be 178, 234 and 394 mg BAS 765 00 F/kg dry soil, respectively.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: *Eisenia andrei*; adult worms with clitellum and weight of 309 – 495 mg, approximately 4 months old; source: in-house culture.

Test design: In a 56-day test, adults of *Eisenia andrei* were exposed to 8 concentrations of the test item in treated artificial soil according to OECD 222 (10% peat). In total, 9 treatment groups were set up (8 concentrations of the test item and 1 untreated control group) with 4 replicates for the test item treatments and 8 replicates for the control, 10 adult worms per replicate. Assessment of worm mortality, behavioral effects and weight change was done after 28 days of exposure. After an additional 28 days (56 days after application), reproduction (number of juveniles) was assessed.

Endpoints: Mortality (LC_{50}, NOEC), weight change (NOEC), feeding activity and reproduction (number of juveniles, ($EC_{50/20/10}$, NOEC)).

Reference item: Maypon Flow (Carbendazim, SC 500). The effects of the reference item were investigated in a separate study.

Test concentrations: Untreated control
Test item:

Nominal concentrations of BAS 765 00 F			
Based on the product BAS 765 00 F [mg/kg dry soil	Based on total a.s. [mg/kg dry soil]	Based on the a.s. BAS 750 F [mg/kg dry soil]	Based on the a.s. BAS 490 F [mg/kg dry soil]
9.0	2.1	0.8	1.2
16.2	3.7	1.5	2.2
29.2	6.7	2.7	4.0
52.5	12.1	4.9	7.3
94.5	21.8	8.7	13.1
170	39.3	15.7	23.6
306	70.8	28.3	42.5
551	127.4	51.0	76.5

Reference item: Maypon Flow was applied at concentrations of 5 and 10 mg product/kg dry soil.

Test conditions: Artificial soil according to OECD 222 with 10% peat; pH: 5.92 - 5.96 at test initiation, pH 5.60 - 5.84 at test termination; water content: 56.0 - 56.2% of its maximum water holding capacity (WHC) at test initiation and 54.7% - 55.7% of WHC at test termination, temperature: 19.2 - 21.8°C; photoperiod: 16 hours light : 8 hours dark, light intensity: 570 lux, feeding with horse manure.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics; Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for mortality ($\alpha = 0.05$, one-sided greater), Dunnett-t-test for weight change and Williams-t-test for reproduction ($\alpha = 0.05$, one-sided smaller), 3-parametric normal cumulative distribution function (CDF) for calculation of EC_x values.

II. RESULTS AND DISCUSSION

BAS 765 00 F did not show any statistically significant effects on mortality and body weight. The mortality of adult worms ranged between 0 - 2.5% in the test item treated groups and was 0% in the control group. The weight change of adult worms was 22.8 - 27.6% in the test item treated groups and 24.6% in the control group. The feeding activity in all test item treated groups was comparable to the control. The reproduction rate was statistically significantly different compared to the control at concentrations of 306 and 551 mg BAS 765 00 F/kg dry soil (Williams-t-test, $\alpha = 0.05$, one-sided smaller). No pathological symptoms and no further effects on behavior of the worms were observed. The results are summarized in Table A 18.

Table A 18 Effects of BAS 765 00 F on *Eisenia andrei* in a 56-day reproduction study

BAS 765 00 F [mg/kg dry soil]	**Control**	**9.0**	**16.2**	**29.2**	**52.5**	**94.5**	**170**	**306**	**551**
Mortality (day 28) [%]	0.0	0.0	0.0	0.0	2.5	0.0	0.0	0.0	2.5
Weight change (day 28) [%]	24.6	25.2	23.3	26.0	27.6	22.8	27.1	24.6	24.1
Number of juveniles (day 56)	381.1	384.5	377.8	349.3	370.0	358.8	331.8	249.0*	108.8*
Reproduction (day 56) [% of control]	100	100.9	99.1	91.6	97.1	94.1	87.0	65.3	28.5
Endpoints [mg BAS 765 00 F/kg dry soil]									
NOEC (day 28)	≥ 551								
NOEC (day 56)	170								
LC_{50} (day 28) [2)]	> 551								
EC_{10} [1)] (day 56)	178 (95% confidence limits: 157 - 200)								
EC_{20} [1)] (day 56)	234 (95% confidence limits: 213 - 255)								
EC_{50} [1)] (day 56)	394 (95% confidence limits: 376 - 414)								

* Statistically significantly different from control (Williams-t-test for reproduction, $\alpha = 0.05$, one-sided smaller)
1) Based on 3-parametric normal cumulative distribution function.
2) Based on estimation of data.

In a separate study the reference item Maypon Flow (carbendazim, SC 500), the number of juveniles was reduced by 58 and 99% at concentrations of 5 and 10 mg product/kg dry soil (mean number of juveniles = 71.3 and 1.5) after 8 weeks of test duration when compared to control (mean number of juveniles = 169).

Validity criteria:

Validity criteria according to OECD 222 (2016)	**Obtained in this study**
Adult mortality in the control ≤ 10%	0.0%
Number of juveniles per control replicate ≥ 30 (with 10 adults per replicate)	292 to 438
Coefficient of variation of reproduction in the control ≤ 30%	12.4%

All validity criteria were met.

III. CONCLUSION

In a 56-day earthworm reproduction study with BAS 765 00 F, the NOEC for mortality and biomass was determined to be greater than or equal to 551 mg BAS 765 00 F/kg dry soil. The NOEC for reproduction was determined to be 170 mg BAS 765 00 F/kg dry soil. The EC_{10}, EC_{20} and EC_{50} values for reproduction were calculated to be 178, 234 and 394 mg BAS 765 00 F/kg dry soil, respectively.

A 2.4.1.1.2 Study 2

Comments of zRMS:	The study was not crucial for finalization of the risk assessment, thus was not evaluated by zRMS.

Reference:	CP 10.4.1.1/2
Report	Sublethal toxicity of BAS 490 02 F to the earthworm Eisenia fetida in artificial soil, Friedrich, S., 2013 report No EU-131048144S,EU-702201,13 10 48 144 S BASF DocID 2013/1132495 Authority registration No
Guideline(s):	OECD 222 (2004)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effects of BAS 490 02 F on mortality, biomass development and reproduction of the earthworm *Eisenia fetida* were investigated in a 56-day extended laboratory study. Five application rates (15.0, 27.0, 48.6, 87.5 and 157.5 mg BAS 490 02 F/kg dry soil) were incorporated into the soil (10% peat) with four replicates per treatment (each containing 10 worms). An untreated control with 8 replicates was included. The toxic reference item was tested in a separate study. Assessment of adult worm mortality and biomass development was carried out after 28 days, assessment of reproduction rate (number of juveniles) was carried out after 56 days.

BAS 490 02 F did not show any statistically significant effect on mortality. The mortality of adult worms ranged between 0 and 2.5 % in the treatment groups and was 0 % in the control group. Statistically significant effects on worm weight of *Eisenia fetida* were determined at the highest tested concentration of 157.5 mg test item/kg dry soil. The weight change of adult worms was about 28.0 – 37.2 % in the treatment group and 34.9 % in the control group.

The reproduction rate was statistically significantly different compared to the control at the concentrations of 48.6, 87.5 and 157.5 mg test item/kg dry soil. No behavioral abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control.

In a 56-day reproduction study with BAS 490 02 F, no statistically significant effects on growth of earthworms (*Eisenia fetida*) were observed up to a rate of 87.5mg BAS 490 02 F/kg dry soil. The NOEC for reproduction was 27 mg BAS 490 02 F/kg dry soil.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 490 02 F, batch no. 02583524U0; content of a.s.: kresoxim-methyl (BAS 490 F, Reg. No. 242 009) 50 % (50.2 % analyzed).

B. STUDY DESIGN

Test species: Earthworm (*Eisenia fetida*), adult worms (with clitellum and weight of 271 - 436 mg), approximately 3 months old; source: "W. Neudorff GmbH KG" followed by in-house culture.

Test design: 56-day test in treated artificial soil according to OECD 222 (10% peat). Different concentrations of the test item were incorporated into the soil. 6 treatment groups (5 test item rates, control) were set up with 8 replicates for the control and 4 replicates for the test item group, each with 10 worms. Assessment of worm mortality, behavioral effects and weight change was done after 28 days of exposure, after additional 28 days (56 days after application) the reproduction rate was determined.

Endpoints: Mortality, weight change, feeding activity and reproduction rate.

Toxic reference item: Nutdazim 50 FLOW (carbendazim, SC 500). The effects of the reference item were investigated in a separate study.

Test concentrations: Control, 15.0, 27.0, 48.6, 87.5 and 157.5 mg BAS 490 02 F/kg dry soil.

Test conditions: Artificial soil according to OECD 222 (with a content of peat: 10%); pH 5.89 - 5.93 at test initiation, pH 5.71 - 5.74 at test termination; water content at test initiation: 55.5% - 55.6% of maximum water holding capacity (WHC), 54.5% - 55.3% of maximum WHC at test termination; temperature: 18.0°C - 22.0°C; photoperiod: 16 hours light : 8 hours dark; light intensity: 530 lux; feeding with horse manure.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics. Fisher's Exact test for mortality (α = 0.05, one-sided greater), Williams t-test for weight change and reproduction (α = 0.05, one-sided smaller).

II. RESULTS AND DISCUSSION

BAS 490 02 F did not show any statistically significant effect on mortality. The mortality of adult worms ranged between 0 and 2.5% in the treatment groups and was 0 % in the control group. Statistically significant effects on worm weight of *Eisenia fetida* were determined at the highest tested concentration of 157.5 mg test item/kg dry soil (Williams-t-test, $\alpha = 0.05$, one-sided smaller). The weight change of adult worms was about 28.0 - 37.2% in the treatment group and 34.9% in the control group. The reproduction rate was statistically significantly different compared to the control at the concentrations of 48.6, 87.5 and 157.5 mg test item/kg dry soil (Williams-test, $\alpha = 0.05$, one-sided smaller). No behavioral abnormalities were observed in any of the treatment groups. The feeding activity in all the treated groups was comparable to the control. The results are summarized in Table A 19.

Table A 19 Effects of BAS 490 02 F on earthworm (*Eisenia fetida*) in a 56-day reproduction study

BAS 490 02 F [mg/kg dry soil]	**Control**	**15.0**	**27.0**	**48.6**	**87.5**	**157.5**
Mortality (28 d) [%]	0	0	0	2.5	0	2.5
Weight change (28 d) [%]	34.9	36.4	31.3	37.2	29.9	28.0 *
Number of juveniles (56 d)	120.4	123.3	104.0	85.8 *	52.3 *	15.3 *
Reproduction (56 d) [% of control]	100	102.4	86.4	71.2	43.4	12.7
	Endpoints [mg BAS 490 02 F/kg dry soil]					
$NOEC_{weight\ change}$ (28 d)	87.5					
$NOEC_{reproduction}$ (56 d)	27					
$EC_{10,reproduction}$ (56 d) [1)]	27.4					
$EC_{20,reproduction}$ (56 d) [1)]	38.4					
$EC_{50,reproduction}$ (56 d) [1)]	73.1					

* = statistically significantly different compared to the control (Williams-t-test, $\alpha = 0.05$, one-sided smaller)
1) based on estimation of the data

In a separate study the reference item Maypon Flow (carbendazim, SC 500), the number of juveniles was reduced by 72.7 and 98.8% at concentrations of 5 and 10 mg product/kg dry soil (mean number of juveniles = 23 and 1) after 8 weeks of test duration when compared to control (mean number of juveniles = 93).

Validity criteria:

Validity criteria according to OECD 222 (2016)	**Obtained in this study**
Adult mortality in the control ≤ 10%	0.0%
Number of juveniles per control replicate ≥ 30 (with 10 adults per replicate)	91 to 162
Coefficient of variation of reproduction in the control ≤ 30%	18.6%

All validity criteria were met.

III. CONCLUSION

In a 56-day reproduction study with BAS 490 02 F, no statistically significant effects on growth of earthworms (*Eisenia fetida*) were observed up to a rate of 87.5mg BAS 490 02 F/kg dry soil. The NOEC for reproduction was 27 mg BAS 490 02 F/kg dry soil.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

As BAS 765 00 F does not pose an unacceptable risk to earthworms, further studies are not necessary.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.1.1 Study 1

Comments of zRMS:	The study was not crucial for finalization of the risk assessment, thus was not evaluated by zRMS.

Reference:	CP 10.4.2.1/1
Report	Effects of BAS 490 02 F on the reproduction of the collembolan Folsomia candida, Friedrich, S., 2013 report No EU-131048147S,EU-702203,13 10 48 147 S BASF DocID 2013/1132497 Authority registration No
Guideline(s):	ISO 11267 (1999), OECD 232 (2009)
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effects of BAS 490 02 F on mortality and reproduction of the Collembola *Folsomia candida* were investigated in a chronic laboratory study over 28 days according to OECD 232 and ISO 11267. Five application rates (62.5, 125, 250, 500 and 1000 mg BAS 490 02 F/kg dry soil) were incorporated into the soil (5% peat). For the control, the soil was left untreated. 4 replicates were prepared for the test item treatments and 8 replicates for the control, each containing 10 collembolans. Assessments of reproduction (number of juveniles), behavior and mortality were carried out after 28 days.

A mortality of 2.5% was observed in the control group compared to 0.0% - 2.5% mortality in the test item treatments. No statistically significant effect on mortality was observed at any test item concentration. No statistically significant effects on the number of juveniles compared to the control group were recorded at any concentration tested. The mean reproduction in the untreated control reached 1128 juveniles. The mean reproduction rates in the test item treatments ranged from 1091 - 1167 juveniles. Differences between the behavior of the collembolans in the control and the test item treatment groups could not be observed.

In a 28-day collembolan reproduction study with BAS 490 02 F the NOEC based on mortality and reproduction was determined to be ≥ 1000 mg BAS 490 02 F/kg dry soil. The LC_{50} and EC_{50} values could not be calculated, by from the results it can be concluded that the LC_{50} and EC_{50} are > 1000 mg BAS 490 02 F/kg dry soil.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 490 02 F, batch No. 002583524U0; content of a.s.: kresoxim-methyl (BAS 490 F; Reg. No. 242 009): 50.0% (nominal), 50.2% (analyzed); density: 1.3 g/cm³.

B. STUDY DESIGN

Test species: Collembola *(Folsomia candida)*, age: 9 - 12 days; source: in-house culture.

Test design: 28-day test in treated artificial soil according to OECD 232 and ISO 11267; different concentrations of the test item were homogenously mixed into artificial soil (5% peat) and filled in glass vessels before collembolans were introduced on top of the soil. 6 treatment groups (5 test item concentrations, control) were set up with 4 replicates for the test item treatments and 8 replicates for the control, each containing 10 collembolans.
Assessment of adult mortality and reproduction and behavioral effects was carried out after 28 days.

Endpoints: Mortality and reproduction rate after 28 days (NOEC, LC_{50}, EC_{50}).

Reference item: Boric acid (100% analyzed) The effects of the reference item were investigated in a separate study.

Test concentrations: Control, 62.5, 125, 250, 500 and 1000 mg BAS 490 02 F/kg dry soil.

Test conditions: Artificial soil according to OECD 232 (with a reduced peat content of 5%); pH 5.98 - 6.05 at test initiation, pH 5.75 - 5.77 at test termination; water content at test initiation 58.0 - 58.3% of maximum water holding capacity (WHC) and 56.9 - 57.6% of maximum WHC at test termination; temperature: 18.3°C – 21.9°C; photoperiod: 16 h light : 8 h dark; light intensity: 520 lux; food: 2 mg dry yeast at the start of the test and on day 14.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics; Fisher-Exact Binominal Test for mortality ($\alpha = 0.05$, one-sided greater), Williams t-test for reproduction ($\alpha = 0.05$, one-sided smaller).

II. RESULTS AND DISCUSSION

A mortality of 2.5% was observed in the control group compared to 0.0% - 2.5% mortality in the test item treatments. No statistically significant effect on mortality was observed at any test item concentration (Fisher`s Exact Binominal Test, $\alpha = 0.05$).

No statistically significant effects (Williams-t-test, $\alpha = 0.05$, one-sided smaller) on the number of juveniles compared to the control group were recorded at any concentration tested.

The mean reproduction in the untreated control reached 1128 juveniles. The mean reproduction rates in the test item treatments ranged from 1091 - 1167 juveniles. Differences between the behavior of the collembolans in the control and the test item treatment groups could not be observed.

The results are summarized in Table A 20.

Table A 20 Effect of BAS 490 02 F on Collembola (*Folsomia candid*) in a 28-day reproduction study

BAS 490 02 F [mg/kg dry soil]	**Control**	**62.5**	**125**	**250**	**500**	**1000**
Mortality (day 28) [%]	2.5	2.5	0.0	2.5	0.0	2.5
No. of juveniles (day 28)	1128	1110	1167	1091	1129	1117
Reproduction in [%] of control (day 28)	100	98	104	97	100	99
	Endpoints [mg BAS 490 02 F/kg dry soil]					
NOEC	≥ 1000					
LC_{50} [1)]	> 1000					
EC_{50} [1)]	> 1000					

No statistically significant differences compared to the control were calculated (Fisher's Exact Binomial Test with Bonferroni Correction for mortality, $\alpha = 0.05$, one-sided greater; Williams-t-test for reproduction; $\alpha = 0.05$, one-sided smaller)
[1)] based on estimation of the data

Validity criteria:

Validity criteria according to OECD 232 (2016)	**Obtained in this study**
Mean adult mortality in the control ≤ 20%	2.5%
Mean number of juveniles per control replicate ≥ 100	1128
Coefficient of variation of reproduction in the control ≤ 30%	13.8%

All validity criteria were met.

III. CONCLUSION

In a 28-day collembolan reproduction study with BAS 490 02 F the NOEC based on mortality and reproduction was determined to be ≥ 1000 mg BAS 490 02 F/kg dry soil. The LC_{50} and EC_{50} values could not be calculated, by from the results it can be concluded that the LC_{50} and EC_{50} are > 1000 mg BAS 490 02 F/kg dry soil.

A 2.4.2.1.2 Study 2

Comments of zRMS:	The study was conducted to OECD guideline 232 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment

Reference:	CP 10.4.2.1/2
Report	Effects of BAS 765 00 F on the reproduction of the collembolan Folsomia candida, Friedrich, S., 2020 report No 862748, 2048TCC0001 BASF DocID 2019/2034592 Authority registration No
Guideline(s):	OECD 232 (2016)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effects of BAS 765 00 F on mortality and reproduction of the Collembola *Folsomia candida* were investigated in a chronic laboratory study over 28 days according to OECD 232. The test item was mixed into artificial soil at concentrations of 15.0, 27.0, 48.6, 87.4, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil. For the control treatment, the soil was left untreated. 4 replicates were prepared for the treatment groups and 8 replicates for the control, each containing 10 collembolans. Assessments of mortality, reproduction (number of juveniles) and behavior were carried out 28 days after treatment.

No statistically significant effect on parental mortality was found for any concentration tested. Mortality rates of 0.0% - 5.0% were recorded in the test item treatment groups. In the control the mortality rate was 3.8%. No statistically significant effects on the number of juveniles compared to the control were recorded at any concentration tested. The mean number of juveniles counted 28 days after introduction of the parental collembolans into the test vessels was 1116 in the control and 1127, 1121, 1102, 1084, 1088, 1100, 1143 and 1103 at concentrations of 15.0, 27.0, 48.6, 87.4, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil., respectively.

In a 28-day *Folsomia candida* reproduction study, LC_{50} and all EC_x values are > 918 mg BAS 765 00 F/kg dry soil, the highest tested concentration. The NOEC for mortality and reproduction was determined to be ≥ 918 mg BAS 765 00 F/kg dry soil.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Collembola *(Folsomia candida)*, age: 9 - 12 days; source: in-house culture.

Test design: 28-day test in treated artificial soil according to OECD 232; different concentrations of the test item were homogenously mixed into artificial soil (5% peat) and filled in glass vessels before collembolans were introduced on top of the soil. 9 treatment groups (8 test item concentrations, control) were set up with 4 replicates for the test item treatments and 8 replicates for the control, each containing 10 collembolans. Assessment of adult mortality, reproduction and behavioral effects was carried out after 28 days.

Endpoints: Mortality and reproduction rate after 28 days (NOEC, LC_{50}, EC_{10}, EC_{20}, EC_{50}).

Reference item: Boric acid (100.8% analyzed) The effects of the reference item were investigated in a separate study.

Test concentrations: Untreated control
Test item:

Nominal concentrations of BAS 765 00 F			
Based on the product BAS 765 00 F [mg/kg dry soil]	Based on total a.s. [mg/kg dry soil]	Based on the a.s. BAS 750 F [mg/kg dry soil]	Based on the a.s. BAS 490 F [mg/kg dry soil]
15.0	3.5	1.4	2.1
27.0	6.2	2.5	3.7
48.6	11.2	4.5	6.7
87.4	20.2	8.1	12.1
157	36.4	14.6	21.8
283	65.5	26.2	39.3
510	118	47.2	70.8
918	212	84.9	127.4

Reference item: Boric acid was applied at concentrations of 44, 67, 100, 150 and 225 mg/kg dry soil.

Test conditions: Artificial soil according to OECD 232 (with a peat content of 5%); pH 6.06 - 6.11 at test initiation, pH 5.80 - 5.86 at test termination; water content at test initiation 57.8 - 58.0% of maximum water holding capacity (WHC) and 56.4 - 57.1% of maximum WHC at test termination; temperature: 19.3 - 21.0°C; photoperiod: 16 h light : 8 h dark; light intensity: 610 lux; food: 2 mg dry yeast at the start of the test and on day 14.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics; Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for mortality (α = 0.05, one-sided greater), Dunnett-t-test for reproduction (α = 0.05, one-sided smaller).

II. RESULTS AND DISCUSSION

No statistically significant effect (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm, α = 0.05, one-sided greater) on parental mortality was found for any concentration tested. Mortality rates of 0.0% - 5.0% were recorded in the test item treatment groups. In the control the mortality rate was 3.8%. No statistically significant effects (Dunnett-t-test, α = 0.05, one-sided smaller) on the number of juveniles compared to the control were recorded at any concentration tested. The mean number of juveniles counted 28 days after introduction of the parental collembolans into the test vessels was 1116 in the control and 1127, 1121, 1102, 1084, 1088, 1100, 1143 and 1103 at concentrations of 15.0, 27.0, 48.6, 87.4, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil., respectively. The results are summarized in Table A 21.

Table A 21 Effect of BAS 765 00 F on Collembola (*Folsomia candid*) in a 28-day reproduction study

BAS 765 00 F [mg/kg dry soil]	**Control**	**15.0**	**27.0**	**48.6**	**87.4**	**157**	**283**	**510**	**918**
Mortality (day 28) [%]	3.8	2.5	2.5	2.5	2.5	0.0	5.0	5.0	5.0
Mean no. of juveniles (day 28)	1116	1127	1121	1102	1084	1088	1100	1143	1103
Reproduction in [%] of control (day 28)	100	101	100	99	97	98	99	102	99
	Endpoints [mg BAS 765 00 F/kg dry soil]								
$NOEC_{mortality/reproduction}$ (28 d)	≥ 918								
$LOEC_{mortality/reproduction}$ (28 d)	> 918								
LC_{50} (28 d) [1)]	> 918								
$EC_{10,reproduction}$ (28 d) [1)]	> 918								
$EC_{20,reproduction}$ (28 d) [1)]	> 918								
$EC_{50,reproduction}$ (28 d) [1)]	> 918								

No statistically significant differences compared to the control (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for mortality, α = 0.05, one-sided greater; Dunnett-t-test for reproduction, α = 0.05, one-sided smaller)
Calculations were performed with unrounded values
[1)] Due to negligible effects and lacking dose response the values were estimated to be above the highest test concentration

In a separate study, the EC_{50} (reproduction) of the reference item boric acid was calculated to be 103 mg/kg dry soil.

Validity criteria:

Validity criteria according to OECD 232 (2016)	**Obtained in this study**
Mean adult mortality in the control ≤ 20%	3.8%
Mean number of juveniles per control replicate ≥ 100	1116
Coefficient of variation of reproduction in the control ≤ 30%	12.0%

All validity criteria were met.

III. CONCLUSION

In a 28-day *Folsomia candida* reproduction study, LC_{50} and all EC_x values are > 918 mg BAS 765 00 F/kg dry soil, the highest tested concentration. The NOEC for mortality and reproduction was determined to be ≥ 918 mg BAS 765 00 F/kg dry soil.

A 2.4.2.1.3 Study 3

Comments of zRMS:	The study was conducted to OECD guideline 226 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment

Reference:	CP 10.4.2.1/3
Report	Effects of BAS 765 00 F on the reproduction of the predatory mite Hypoaspis aculeifer, Schulz, L., 2020 report No 862749, 2048THC0001 BASF DocID 2019/2034595 Authority registration No
Guideline(s):	2004/10/EC of 11 February 2004, OECD 226 (2016)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effects of BAS 765 00 F on mortality and reproduction of the predatory mite *Hypoaspis aculeifer* were investigated in a chronic laboratory study over 14 days. The test item was mixed into artificial soil at concentrations of 15, 27, 49, 87, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil. For the control treatment, the soil was left untreated. 8 replicates and 4 replicates were prepared for the control and test item treatment groups, respectively, each containing 10 adult soil mites (females). Assessments of adult mortality and reproduction effects were carried out after 14 days of exposure.

Mortality rates of 0.0 - 5.0% were recorded in the test item treatment groups. In the control group the mortality rate was 5.0%. The observed mortality rates for adult mites in the test item treatment groups compared to control were not statistically significant up to and including 918 mg BAS 765 00 F/kg dry soil. Differences in the behavior and the morphology of the mites between the control and the test item treatment groups could not be observed. Reproduction rates in the 15, 27, 49, 87, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil were 344.5, 345.0, 346.0, 318.3, 319.8, 334.0, 317.0 and 306.5 juveniles, respectively. The mean reproduction in the control reached 309.5 juveniles. The test item showed no statistically significant adverse effects on reproduction up to and including 918 mg BAS 765 00 F/kg dry soil.

In a 14-day *Hypoaspis aculeifer* reproduction study with BAS 765 00 F, the LC_{50}, EC_{10}, EC_{20} and EC_{50} were determined to be > 918 mg BAS 765 00 F/kg dry soil. The NOEC for mortality and for reproduction was determined to be ≥ 918 mg BAS 765 00 F/kg dry soil, the highest concentration tested.

I. MATERIALS AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Predatory mites (*Hypoaspis aculeifer)*, adults with an age difference of 2 days; source: in-house culture.

Test design: 14-day chronic laboratory test in treated artificial soil according to OECD 226. Different concentrations of the test item were mixed homogenously into artificial soil and used to fill vessels after which mites were introduced on top of the soil; 9 treatment groups (8 test item concentrations, control); 4 replicates for each test item treatment and 8 replicates for the control group, each containing 10 mites. Feeding of mites with *Tyrophagus putrescentiae* (SCHRANK) at the beginning and *ad libitum* in the course of the test. Assessments of adult mortality and reproduction effects were carried out after 14 days of exposure.

Endpoints: Mortality (LC_{50}, NOEC, reproduction rate (number of juveniles, $EC_{50/20/10}$, NOEC).

Reference item: Dimethoate (98.8% ± 0.5% analyzed). The effects of the reference item were investigated in a separate study.

Test concentrations: Untreated control,
Test item:

Nominal concentrations of BAS 765 00 F			
Based on the product BAS 765 00 F [mg/kg dry soil]	Based on total a.s. [mg/kg dry soil]	Based on the a.s. BAS 750 F [mg/kg dry soil]	Based on the a.s. BAS 490 F [mg/kg dry soil]
15	3.5	1.4	2.1
27	6.2	2.5	3.7
49	11.2	4.5	6.7
87	20.2	8.1	12.1
157	36.4	14.6	21.8
283	65.5	26.2	39.3
510	117.9	47.2	70.8
918	212.3	84.9	127.4

Test conditions: Artificial soil according to OECD 226 (5% peat); pH 6.2 at test initiation, pH 5.8 - 6.0 at test termination; water content at study initiation 46.81 - 49.70% of maximum water holding capacity and 45.20 - 49.72% of maximum WHC at test termination; temperature: 20.0 - 21.1°C; photoperiod: 16 h light : 8 h dark, light intensity: 531 lux.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics; Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm ($\alpha = 0.05$, one-sided greater) for mortality, Dunnett-t-test for reproduction ($\alpha = 0.05$, one-sided smaller).

II. RESULTS AND DISCUSSION

Mortality rates of 0.0 - 5.0% were recorded in the test item treatment groups. In the control group the mortality rate was 5.0%. The observed mortality rates for adult mites in the test item treatment groups compared to control were not statistically significant up to and including 918 mg BAS 765 00 F/kg dry soil (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm, $\alpha = 0.05$, one-sided greater). Differences in the behavior and the morphology of the mites between the control and the test item treatment groups could not be observed. Reproduction rates in the 15, 27, 49, 87, 157, 283, 510 and 918 mg BAS 765 00 F/kg dry soil were 344.5, 345.0, 346.0, 318.3, 319.8, 334.0, 317.0 and 306.5 juveniles, respectively. The mean reproduction in the control reached 309.5 juveniles. The test item showed no statistically significant adverse effects on reproduction up to and including 918 mg BAS 765 00 F/kg dry soil (Dunnett-t-test, $\alpha = 0.05$, one-sided smaller). The results are summarized in Table A 22.

Table A 22: Effects of BAS 765 00 F on predatory mite (*Hypoaspis aculeifer)* in a 14-day reproduction study

BAS 765 00 F [mg/kg dry soil]	**Control**	**15**	**27**	**49**	**87**	**157**	**283**	**510**	**918**
Mortality (day 14) [%]	5.0	0.0	5.0	5.0	2.5	5.0	5.0	0.0	2.5
No. of juveniles (day 14)	309.5	344.5	345.0	346.0	318.3	319.8	334.0	317.0	306.5
Reproduction in [%] of control (day 14)	100	111	111	112	103	103	108	102	99
	Endpoints [mg BAS 765 00 F/kg dry soil]								
$NOEC_{mortality/reproduction}$ (14 d)	≥ 918								
$LOEC_{mortality/reproduction}$ (14 d)	> 918								
LC_{50} (14 d) [1)]	> 918								
$EC_{10,reproduction}$ (14 d) [1)]	> 918								
$EC_{20,reproduction}$ (14 d) [1)]	> 918								
$EC_{50,reproduction}$ (14 d) [1)]	> 918								

No statistically significant differences compared to the control (Multiple Sequentially-rejective Fisher Test after Bonferroni-Holm for mortality, $\alpha = 0.05$, one-sided greater; Dunnett-t-test for reproduction, $\alpha = 0.05$, one-sided smaller)
Calculations were performed with unrounded values
1) Based on estimation of data.

In a separate GLP study, the EC_{50} (reproduction) of the reference item dimethoate was calculated to be 6.3 mg dimethoate/kg dry soil.

Validity criteria:

Validity criteria according to OECD 226 (2016)	Obtained in this study
Mean adult mortality in the control ≤ 20%	5.0%
Mean number of juveniles per control replicate ≥ 50	309.5
Coefficient of variation of reproduction in the control ≤ 30%	10.1%

All validity criteria were met.

III. CONCLUSION

In a 14-day *Hypoaspis aculeifer* reproduction study with BAS 765 00 F, the LC_{50}, EC_{10}, EC_{20} and EC_{50} were determined to be > 918 mg BAS 765 00 F/kg dry soil. The NOEC for mortality and for reproduction was determined to be ≥ 918 mg BAS 765 00 F/kg dry soil, the highest concentration tested.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

As BAS 765 00 F does not pose an unacceptable risk to non-target soil meso- and macro-organisms other than earthworms, further studies are not necessary.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment

Reference:	CP 10.5/1
Report	Effects of BAS 765 00 F on the activity of soil microflora (Nitrogen transformation test), Persdorf, M., 2019 report No 862746 2019/2034555 Authority registration No
Guideline(s):	OECD 216 (2000)
Deviations:	No
GLP:	yes (certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

The effect of BAS 765 00 F on nitrogen transformation was tested in a lucerne-enriched loamy sand soil. BAS 765 00 F was applied to samples of the soil in the laboratory at nominal application rates of 6.49 mg BAS 765 00 F/kg dry soil (equivalent to 4.5 L BAS 765 00 F/ha) and 32.43 BAS 765 00 F/kg dry soil (equivalent to 22.5 L BAS 765 00 F/ha). The treated soils and untreated control soils were incubated at approx. 20°C in the dark for 28 days. Triplicate samples of each treatment were removed for analysis of NH_4-nitrogen and NO_3-nitrogen, 0, 7, 14 and 28 days after application.

No adverse effects of BAS 765 00 F on nitrogen transformation in soil could be observed at both test concentrations (6.49 mg BAS 765 00 F/kg dry soil and 32.43 mg BAS 765 00 F/kg dry soil) after 28 days (time interval 0-28). Only negligible deviations from the control of +11.3% (test concentration 6.49 mg BAS 765 00 F/kg dry soil) and +16.8% (test concentration 32.43 mg BAS 765 00 F/kg dry soil) were measured at the end of the 28-day incubation period (time interval 0-28).

Exposure of BAS 765 00 F in a field soil up to a test concentration of 32.43 mg BAS 765 00 F/kg dry soil, equivalent to a field application rate of 22.5 L BAS 765 00 F/ha, caused no adverse effects (deviation from control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO_3-N- production) at the end of the 28-day incubation period (time interval 0-28).

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test soil: Biologically active agricultural soil: loamy sand (DIN 4220) soil: pH 6.1 (H_2O), 1.46% C_{org}, microbial mass: 3.68% of C_{org}, WHC: 38.36 g/100 g dry soil.

Test design: Determination of the N-transformation (NO_3-nitrogen-production) in soil enriched with lucerne meal (concentration in the soil 0.5%). Comparison of test item treated soil with a non-treated soil. NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen formed from the nitrification process was determined using an Autoanalyzer. Sampling scheme: 0, 7, 14 and 28 days after treatment. Sub-samples (3 replicates) were withdrawn from the bulk batches and subjected to the measurement.

Test rates: Control (untreated),
Test item:

Nominal concentrations of BAS 765 00 F			
Based on the product BAS 765 00 F [mg/kg dry soil]	Based on total a.s. [mg/kg dry soil]	Based on the a.s. BAS 750 F [mg/kg dry soil]	Based on the a.s. BAS 490 F [mg/kg dry soil]
6.49	1.5	0.6	0.9
32.43	7.5	3.0	4.5

Endpoints: Effects on the NO_3-nitrogen production after 7, 14 and 28 days of exposure.

Reference item: Dinoterb (purity: 99.28% (g/g) analyzed). The reference item was tested in a separate study at rates of 6.80, 13.60 and 27.2 mg dinoterb/kg dry soil.

Test conditions: Loamy sand soil: soil moisture 45% of its maximum water holding capacity (WHC), measured water content: 16.38 - 16.96 g/100 g dry soil, pH 5.7. Soil samples were incubated at 18.9 - 20.6°C in the dark.

Analytics: No analytical verification of the test item is required according to the current test guideline. Hence, no analytical verification was conducted.

Statistics: Descriptive statistics.

II. RESULTS AND DISCUSSION

No adverse effects of BAS 765 00 F on nitrogen transformation in soil could be observed at both test concentrations (6.49 mg BAS 765 00 F/kg dry soil and 32.43 mg BAS 765 00 F/kg dry soil) after 28 days (time interval 0-28). Only negligible deviations from the control of +11.3% (test concentration 6.49 mg BAS 765 00 F/kg dry soil) and +16.8% (test concentration 32.43 mg BAS 765 00 F/kg dry soil) were measured at the end of the 28-day incubation period (time interval 0-28). The results are summarized in Table A 23 and Table A 24.

Table A 23 Effects of BAS 765 00 F on soil micro-organisms (nitrogen transformation) for the intervals 0-7, 0-14 and 0-28

Soil (days)	Control	6.49 mg BAS 765 00 F/kg dry soil		32.43 mg BAS 765 00 F/kg dry soil	
	NO_3–N [mg/kg dry soil] [2)]	NO_3–N [mg/kg dry soil] [2)]	% Deviation from control [1)]	NO_3–N [mg/kg dry soil] [2)]	% Deviation from control [1)]
Loamy sand (0 - 7 d)	28.80	28.27	-1.9	33.67	+16.9
Loamy sand (0 - 14 d)	39.97	47.00	+17.6	48.77	+22.0
Loamy sand (0 - 28 d)	58.97	65.63	+11.3	68.87	+16.8

1) Based on NO_3-nirogen production; - = inhibition; + = stimulation

2) Measured values sampling day "x" - measured values sampling day 0, mean of 3 replicates.

Table A 24 Effects of BAS 765 00 F on soil micro-organisms (nitrogen transformation) for the intervals 0-7, 0-14 and 0-28

Soil (days)	Control	6.49 mg BAS 765 00 F/kg dry soil		32.43 mg BAS 765 00 F/kg dry soil	
	NO_3–N [mg/kg dry soil/d] [2)]	NO_3–N [mg/kg dry soil/d] [2)]	% Deviation from control [1)]	NO_3–N [mg/kg dry soil/d] [2)]	% Deviation from control [1)]
Loamy sand (0 - 7 d)	4.11	4.04	-1.9	4.81	+16.9
Loamy sand (0 - 14 d)	2.86	3.36	+17.6	3.48	+22.0
Loamy sand (0 - 28 d)	2.11	2.34	+11.3	2.46	+16.8

1) Based on NO_3-nirogen production; - = inhibition; + = stimulation

2) Daily rates not given in the study report but recalculated based on the data listed in Table A 23

In a separate study the reference item dinoterb produced a stimulation of nitrogen transformation of +34.2% at 13.60 mg/kg dry soil determined 28 days after application.

Validity criteria:

Validity criteria according to OECD 216 (2000)	Obtained in this study
Coefficient of variation in the control for NO_3-N ≤ 15%	max. 4.5% (loamy sand)

All validity criteria were met.

III. CONCLUSION

Exposure of BAS 765 00 F in a field soil up to a test concentration of 32.43 mg BAS 765 00 F/kg dry soil, equivalent to a field application rate of 22.5 L BAS 765 00 F/ha, caused no adverse effects (deviation from control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO_3-N- production) at the end of the 28-day incubation period (time interval 0-28).

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

Tests on non-target plants have been conducted. The data point is covered by Appendix 2.6.2 (KCP 10.6.2).

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.2.1 Study 1

Comments of zRMS:	The study was conducted to OECD guideline 227 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment

Reference:	CP 10.6.2/1
Report	Effect of BAS 765 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions, Maleck, A., 2020 report No 862751, AC/BASF/19/27 BASF DocID 2019/2034607 Authority registration No
Guideline(s):	OECD 227 Terrestrial Plant Test: Vegetative Vigour Test (July 2006), EPA 850.4150 (2012)
Deviations:	No
GLP:	yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und fuer Verbraucherschutz, Potsdam, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Comments of zRMS:	The Final Report Amendment No. 1 dated on 18 May 2020 replaces the Final Report dated on 06 Jan 2020. The reason of the Final Report - Amendment No. 1 was to introduce a correction to the final report.

Reference:	CP 10.6.2/2
Report	Effect of BAS 765 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions, Maleck, A., 2020 report No 862751, AC/BASF/19/27 BASF DocID 2020/2080765 Authority registration No
Guideline(s):	EPA 850.4150 - Vegetative Vigour (2012), OECD 227 July 2006
Deviations:	No
GLP:	yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und fuer Verbraucherschutz, Potsdam, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a vegetative vigor test, six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soybean, tomato) and four species of monocotyledonous plants (onion, ryegrass, wheat, corn) were exposed to BAS 765 00 F to evaluate the phytotoxic potential. BAS 765 00 F was applied post-emergence at growth stage BBCH 12-14 in a limit test with a rate of 1.0 L BAS 765 00 F/ha. After application, the plants were cultivated for 21 days under greenhouse conditions. Assessment of plant survival and phytotoxicity was done 7, 14 and 21 days after treatment (DAT) and assessment of plant length and shoot dry weight was done at study termination (21 DAT).

All control plants remained healthy throughout the entire trial period. No control mortality was observed. No negative impact of the application of 1.0 L BAS 765 00 F/ha at BBCH 12-14 on plant survival, plant length, dry biomass production and plant phytotoxicity was found for all tested species.

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that BAS 765 00 F applied post emergence at BBCH 12-14 with a rate of 1.0 L/ha did not cause effects to plant phytotoxicity, plant survival, plant length and plant dry biomass for all tested plant species. The NOER for plant survival, plant length, dry biomass and plant phytotoxicity of all tested plant species is equal or higher than the tested rate of 1.0 L BAS 765 00 F/ha. The ER_{50} for all plant species is > 1.0 L BAS 765 00 F/ha.

I. MATERIAL AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Carrot (*Daucus carota*), lettuce (*Lactuca sativa*), cabbage (*Brassica oleracea* var. *capitata f. alba*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), tomato (*Solanum lycopersicum*), onion (*Allium cepa*), ryegrass (*Lolium multiflorum*), wheat (*Triticum aestivum*) and corn (*Zea mays*).

Test design: Greenhouse study; limit test; 2 treatment groups (1 test item rate, control); 5 replicates per treatment, 1 - 3 pots/replicate, each pot with 2 - 6 plants per pot; post-emergence application at growth stage BBCH 12-14 using a laboratory spray system at a mean output volume of 273 L/ha (CV of 0.77% for all tested plant species); assessment of plant survival and phytotoxicity was done 7, 14 and 21 days after treatment (DAT); assessment of plant length and shoot dry weight was done 21 DAT.

Endpoints: Survival, phytotoxicity, plant length and shoot dry weight (NOER, ER_{50}).

Test rates: Control (tap water) and 1.0 L BAS 765 00 F/ha.

Test conditions: Daily average temperature: 24.4 - 28.2°C; daily mean relative humidity: 53.8 - 70.2%; photoperiod: day length ≥ 16 hours; additional light supply automatically for 16 hours in maximum when indoor illumination was less than 300 µmol.

Analytics: Analytical verification of the a.s. BAS 750 H present in application solutions prepared from the test item BAS 765 00 H was conducted using a HPLC method with MS/MS detection (method no. L0361/01).

Statistics: Descriptive statistics. Depending on outcomes of pretesting sequences the limit concentration of BAS 765 00 F for survival, plant length and biomass was tested by pairwise comparison with the control. Metric data were tested by Two-sample t-test (Student t-test, one-sided smaller, p = 0.05). The NOER for phytotoxicity was estimated. Phytotoxicity values < 10% were considered as insignificant.

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 750 H (contained in BAS 765 00 H) in the spray solution were determined according to the analytical method L0361/01. The validation of the analytical method is described in the study report and the original analytical method is fully validated in a separate study (BASF DocID 2017/1065621). The method was adapted to perform the analysis in the given concentration range. Fortified samples were diluted in two steps by a total factor of 100000 using acetonitrile/water (20/80 v/v) + 0.1% formic acid. The injection volume was 10 µL. The determination was performed by LC with MS/MS detection. The limit of detection (LOD) was set to 10 mg/L. Due to the high total dilution factor (100000), no relevant matrix effects were expected for the LC-MS/MS determination of BAS 750 F. Frozen storage stability of the active substance BAS 750 F was demonstrated in a previous study for at least 90 ± 2 days for different water types (BASF DocID 2017/1115731). The actual storage period for the samples (56 days) was within the timeframe investigated in the related storage stability study. The mean recovery of BAS 750 H was 101% for both fortification levels tested. Details on measured fortification samples and obtained procedural recoveries for BAS 750 H are given in Table A 25.

Table A 25 Procedural recoveries for BAS 750 H

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Mass Transition: 399 m/z → 70 m/z				
Spray solution	285	5	101	2.96
Spray solution	437	5	101	4.91

II. RESULTS AND DISCUSSION

All control plants remained healthy throughout the entire trial period. No control mortality was observed. No negative impact of the application of 1.0 L BAS 765 00 F/ha at BBCH 12-14 on plant survival, plant length, dry biomass production and plant phytotoxicity was found for all tested species. The results are summarized in Table A 26 and Table A 27.

Table A 26 Effects of BAS 765 00 F on survival, phytotoxicity, plant height and plant dry weight 21 DAT

BAS 765 00 F [L/ha]	Carrot	Lettuce	Cabbage	Oilseed rape	Soybean	Tomato	Onion	Ryegrass	Wheat	Corn
Plant survival [%]										
Control	100	100	100	100	100	100	100	100	100	100
1.0	100	100	100	100	100	100	100	100	100	100
Phytotoxicity [%]										
Control	0	0	0	0	0	0	0	0	0	0
1.0	0	0	0	0	0	0	0	0	0	0
Plant length [% compared to control]										
Control	--	--	--	--	--	--	--	--	--	--
1.0	97.4	102.5	103.0	100.4	100.7	100.4	98.9	96.1	101.8	103.4
Plant dry weight [% compared to control]										
Control	--	--	--	--	--	--	--	--	--	--
1.0	102.2	99.0	100.8	98.5	100.8	98.1	100.1	102.4	102.2	103.3

Table A 27 NOER and ER_{50} of BAS 765 00 F for non-target plants 21 DAT

BAS 765 00 F [L/ha]	Carrot	Lettuce	Cabbage	Oilseed rape	Soybean	Tomato	Onion	Ryegrass	Wheat	Corn
Plant survival										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Phytotoxicity										
NOER [1)]	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50} [1)]	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Plant length										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Plant dry weight										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0

[1)] Estimated from assessment data

Validity criteria:

Validity criteria according to OECD 227	**Obtained in this study**
Seedling emergence is at least 70%	yes (80% to 100%)
In the controls:	
The plants do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations). Plants exhibit only normal variation in growth and morphology for that particular species	yes (0%)
Mean plant survival at least 90% for the duration of the study	yes (100%)
Environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source	yes

All validity criteria were met.

III. CONCLUSION

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that BAS 765 00 F applied post emergence at BBCH 12-14 with a rate of 1.0 L/ha did not cause effects to plant phytotoxicity, plant survival, plant length and plant dry biomass for all tested plant species. The NOER for plant survival, plant length, dry biomass and plant phytotoxicity of all tested plant species is equal or higher than the tested rate of 1.0 L BAS 765 00 F/ha. The ER_{50} for all plant species is > 1.0 L BAS 765 00 F/ha.

A 2.6.2.2 Study 2

Comments of zRMS:	The study was conducted to OECD guideline 208 and according to the principles of GLP. The study is considered to be reliable and suitable for the risk assessment. No phytotoxic symptoms could be observed for all tested species after pre-emergence application of 1.0 L BAS 765 00 F/ha.

Reference:	CP 10.6.2/3
Report	Effects of BAS 765 00 F on seedling emergence and seedling growth of ten species of terrestrial plants under greenhouse conditions, Maleck, A., 2020 report No 862750, AC/BASF/19/26 BASF DocID 2019/2034603 Authority registration No
Guideline(s):	OECD 208 (2006), EPA 850.4100 (2012)
Deviations:	No
GLP:	yes (certified by Land Brandenburg Ministerium der Justiz und fuer Europa und fuer Verbraucherschutz, Potsdam, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Executive Summary

In a seedling emergence test, six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soybean and tomato) and four species of monocotyledonous plants (onion, ryegrass, wheat and corn) were exposed to BAS 765 00 F. The test item was applied pre-emergence at an application rate of 1.0 L BAS 765 00 F/ha. Plants were cultivated under greenhouse conditions for 21 days (carrot and onion for 28 days). Assessments for seedling emergence, plant survival and phytotoxicity were done 7, 14 and 21 days after treatment (DAT) for all plants (14, 21 and 28 DAT for carrot and onion). Assessments for plant length and plant dry weight were done at study termination 21 DAT (for carrot and onion 28 DAT).

All emerged control plants remained healthy throughout the entire trial period. No control mortality was observed. The rate of emergence in the controls was > 70% for all tested plant species. Plant survival and plant length of all tested plant species were not influenced by pre emergence application of 1.0 L BAS 765 00 F/ha. No negative impact of BAS 765 00 F on seedling emergence and dry biomass production was found for lettuce, cabbage, oilseed rape, soybean, tomato, onion, ryegrass, wheat and corn. Significant reduction of plant emergence with 15% was detected for carrot after pre emergence application of 1.0 L BAS 765 00 F/ha. The dry biomass per replicate for carrot was reduced by 8%.

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that the fungicide BAS 765 00 F did not cause effects to plant survival and plant length of the tested plant species. The NOER for plant emergence, plant survival, plant length and biomass of all tested plant species is ≥ 1.0 L BAS 765 00 F/ha, except for plant emergence and biomass per replicate of carrot (NOER < 1.0 L BAS 765 00 F/ha). The ER_{50} is > 1.0 L BAS 765 00 F/ha for all tested plant species.

I. MATERIALS AND METHODS

A. MATERIALS

Test item: BAS 765 00 F, batch no. FD-190128-0007, content of a.s.: mefentrifluconazole (BAS 750 F, Reg. No. 5 834 378): 99.6 g/L analyzed (nominal 100.0 g/L) and kresoxim-methyl (BAS 490 F, Reg. No. 242 009): 148.9 g/L analyzed (nominal 150.0 g/L), density: 1.081 g/cm^3.

B. STUDY DESIGN

Test species: Carrot (*Daucus carota*), lettuce (*Lactuca sativa*), cabbage (*Brassica oleracea* var. *capitata f. alba*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), tomato (*Solanum lycopersicum*), onion (*Allium cepa*), ryegrass (*Lolium multiflorum*), wheat (*Triticum aestivum*) and corn (*Zea mays*).

Test design: Greenhouse study; limit test; 2 treatment groups (1 test item rate, control); 4 replicates per treatment, 1 - 2 pots/replicate, each pot with 5 - 10 seeds per pot; pre-emergence application shortly after seeding using a laboratory spray cabin at a mean output volume of 282 L/ha (CV of 0.84% for all tested plant species); assessment of seedling emergence, plant survival and phytotoxicity was done 7, 14 and 21 days after treatment (DAT) (carrot and onion 14, 21 and 28 DAT); assessment of plant length and shoot dry weight was done 21 DAT (for carrot and onion 28 DAT).

Endpoints: Seedling emergence, survival, phytotoxicity, plant length and plant dry weight (NOER, ER_{50})

Test rates: Control (tap water) and 1.0 L BAS 765 00 F/ha.

Test conditions: Daily average temperature: 23.4 - 29.2°C; daily mean relative humidity: 50.7 - 29.2%; photoperiod: day length ≥ 16 hours; additional light supply automatically for 16 hours in maximum when indoor illumination was less than 300 µmol.

Analytics: Analytical verification of the a.s. BAS 750 H present in application solutions prepared from the test item BAS 765 00 H was conducted using a HPLC method with MS/MS detection (method no. L0361/01).

Statistics: Descriptive statistics; Depending on outcomes of pretesting sequences the limit concentration of BAS 765 00 F for emergence, survival, plant length, and biomass was tested by pairwise comparison with the control. Metric data were tested by Two sample t-test (Student t-test, one sided smaller, p = 0.05) and quantal data were tested by Two-sample Fisher's Exact test (one-sided greater, p = 0.05).

C. DESCRIPTION OF THE ANALYTICAL PROCEDURES

Concentrations of BAS 750 H (contained in BAS 765 00 H) in the spray solution were determined according to the analytical method L0361/01. The validation of the analytical method is described in the study report. The original analytical method is fully validated in a separate study (BASF DocID 2017/1065621). The method was adapted to perform the analysis in the given concentration range. Fortified samples were diluted in two steps by a total factor of 100000 using acetonitrile/water (20/80 v/v) + 0.1% formic acid. The injection volume was 10 µL. The determination was performed by LC with MS/MS detection. The limit of detection (LOD) was set to 10 mg/L. Due to the high total dilution factor (100000), no relevant matrix effects were expected for the LC-MS/MS determination of BAS 750 F. Frozen storage stability of the active substance BAS 750 F was demonstrated in a previous study for at least 90 ± 2 days for different water types (BASF DocID 2017/1115731). The actual storage period for the samples (56 days) was within the timeframe investigated in the related storage stability study. Mean recoveries of BAS 750 H ranged from 97% to 98% for both fortification levels tested. Details on measured fortification samples and obtained procedural recoveries for BAS 750 H are given in Table A 28.

Table A 28 Procedural recoveries for BAS 750 H

Matrix	Fortification level (mg/L)	n	Mean (%)	RSD (%)
Mass Transition: 399 m/z → 70 m/z				
Spray solution	281	5	97	3.61
Spray solution	435	5	98	2.63

II. RESULTS AND DISCUSSION

All emerged control plants remained healthy throughout the entire trial period. No control mortality was observed. The rate of emergence in the controls was > 70% for all tested plant species. Plant survival and plant length of all tested plant species were not influenced by pre emergence application of 1.0 L BAS 765 00 F/ha. No negative impact of BAS 765 00 F on seedling emergence and dry biomass production was found for lettuce, cabbage, oilseed rape, soybean, tomato, onion, ryegrass, wheat and corn. Significant reduction of plant emergence with 15% was detected for carrot after pre emergence application of 1.0 L BAS 765 00 F/ha (Two-sample Fisher's Exact test, one-sided greater, p=0.05). The dry biomass per replicate for carrot was reduced by 8% (Student t-test, p=0.05). The results are summarized in Table A 29 and Table A 30.

Table A 29 Effect of BAS 765 00 F on seedling emergence, survival, phytotoxicity, plant length and plant dry weight 21 DAT (for carrot and onion 28 DAT)

BAS 765 00 F [L/ha]	Carrot [1)]	Lettuce	Cabbage	Oilseed rape	Soybean	Tomato	Onion [1)]	Ryegrass	Wheat	Corn
Seedling emergence [% compared to control]										
Control	100	100	100	100	100	100	100	100	100	100
1.0	85 *	105	103	106	100	103	106	87	94	100
Survival [%]										
Control	100	100	100	100	100	100	100	100	100	100
1.0	100	100	100	100	100	100	100	100	100	100
Phytotoxicity [%]										
Control	0	0	0	0	0	0	0	0	0	0
1.0	0	0	0	0	0	0	0	0	0	0
Plant length [% compared to control]										
Control	100	100	100	100	100	100	100	100	100	100
1.0	97.0	94.8	99.2	98.9	101.9	103.2	102.2	103.6	98.5	100.2
Plant dry weight [% compared to control]										
Control	100	100	100	100	100	100	100	100	100	100
1.0	92.3 *	96.8	105.0	98.0	102.3	102.4	102.5	94.5	91.5	99.2

* Statistically significant differences compared to control (for seedling emergence: Two-sample Fisher's Exact test, one-sided greater, p=0.05; for plant dry weight: Student t-test, p=0.05).

1) Carrot and onion 28 DAT

Table A 30 NOER and ER_{50} of BAS 765 00 F for non-target plants 21 DAT (for carrot and onion 28 DAT)

BAS 765 00 F [L/ha]	Carrot [1)]	Lettuce	Cabbage	Oilseed rape	Soybean	Tomato	Onion [1)]	Ryegrass	Wheat	Corn
Seedling emergence										
NOER	< 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Survival										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Phytotoxicity [2)]										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Plant length										
NOER	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0
Plant dry weight										
NOER	< 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0	≥ 1.0
ER_{50}	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0	> 1.0

1) Carrot and onion 28 DAT
2) Estimated from assessment data

Validity criteria:

Validity criteria according to OECD 208	Obtained in this study
Seedling emergence is at least 70% in the control	yes (80% to 100%)
Seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) in the control and control plants exhibit only normal variation in growth and morphology for that particular species	yes (0%)
Mean survival of emerged control seedlings at least 90% for the duration of the study	yes (100%)
Environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source	yes

All validity criteria were met.

III. CONCLUSION

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that the fungicide BAS 765 00 F did not cause effects to plant survival and plant length of the tested plant species. The NOER for plant emergence, plant survival, plant length and biomass of all tested plant species is ≥ 1.0 L BAS 765 00 F/ha, except for plant emergence and biomass per replicate of carrot (NOER < 1.0 L BAS 765 00 F/ha). The ER_{50} is > 1.0 L BAS 765 00 F/ha for all tested plant species.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

As BAS 765 00 F does not pose an unacceptable risk to non-target plants, further studies are not necessary.

A 2.6.4 KCP 10.6.4 Semi-field and field tests on non-target plants

As BAS 765 00 F does not pose an unacceptable risk to non-target plants, further studies are not necessary.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

Not relevant.

A 2.8 KCP 10.8 Monitoring data

Not relevant.