

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

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 2020/2094698
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1, 4	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP triticale TTLWI, TTLSO	F	<i>B. graminis</i> - <i>ERYSGR</i> <i>Zymoseptoria tritici</i> - <i>SEPTTR</i> <i>Puccinia triticina</i> - <i>PUCCRT</i> <i>Puccinia striiformis</i> - <i>PUCCST</i> <i>P. tritici-repentis</i> - <i>PYRNTR</i> <i>Fusarium sp.</i> - <i>FUSASP</i> <i>Puccinia recondita</i> - <i>PUCCRE</i> <i>Septoria spp.</i> <i>SEPTSP</i>	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A - 0.15 ^B b) 0.2 ^A - 0.3 ^B	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.	
2	CZ	barley HORVW HORVS	F	<i>B. graminis</i> - <i>ERYSGR</i> <i>Pyrenophora teres</i> - <i>PYRNTE</i> <i>R. secalis</i> - <i>RHYNSE</i> <i>P. hordei</i> - <i>PUCCHD</i>	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray interval.	
3	CZ	rye SECCW SECCS SECCE	F	<i>B. graminis</i> - <i>ERYSGR</i> <i>R. secalis</i> - <i>RHYNSE</i> <i>Puccinia recondita</i> - <i>PUCCRE</i>	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray interval.	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
5, 8	PL	wheat TRZAW, TRZAS TRZDU, TRZSP triticale TTLWI TTL SO	F	<i>B. graminis</i> - ERYSGR <i>Zymoseptoria tritici</i> - SEPTTR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUCCST <i>P. tritici-repentis</i> - PYRNTR <i>Fusarium sp.</i> – FUSASP <i>Puccinia recondita</i> - PUCCRE <i>Septoria spp.</i> SEPTSP	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 1.00 b) 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	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	PL	barley HORVW HORVS	F	<i>B. graminis</i> - ERYSGR <i>Pyrenophora teres</i> - PYRNTE <i>R. secalis</i> - RHYNSE <i>P. hordei</i> - PUCCHD	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 1.00 b) 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray interval.	
7	PL	rye SECCW SECCS SECCE	F	<i>B. graminis</i> - ERYSGR <i>R. secalis</i> - RHYNSE <i>Puccinia recondita</i> - PUCCRE	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 1.00 b) 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray interval.	
9, 12	HU, SK, SI, RO	wheat TRZAW, TRZAS TRZDU, TRZSP triticale TTLWI TTL SO	F	<i>B. graminis</i> - ERYSGR <i>Zymoseptoria tritici</i> - SEPTTR <i>Puccinia triticina</i> - PUCCRT <i>Puccinia striiformis</i> - PUCCST <i>P. tritici-repentis</i> - PYRNTR <i>Fusarium sp.</i> – FUSASP <i>Puccinia recondita</i> - PUCCRE <i>Septoria spp.</i> SEPTSP	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	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	HU, SK, SI, RO	barley HORVW HORVS	F	<i>B. graminis</i> - ERYSGR <i>Pyrenophora teres</i> - PYRNTE <i>R. secalis</i> - RHYNSE	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha	Conclusion Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
				<i>P. hordei - PUCCHD</i>									interval.	
11	HU, SK, SI, RO	rye SECCW SECCS SECCE	F	<i>B. graminis - ERYSGR</i> <i>R. secalis - RHYNSE</i> <i>Puccinia recondita - PUCCRE</i>	Spraying	BBCH 30-69	a) 2 b) 2	14	a) 0.60 - 1.00 b) 0.60 - 2.00	a) 0.1 ^A -0.15 ^B b) 0.2 ^A - 0.3 ^B	100 / 300	35	*if first application after BBCH 49; min. 21 days spray interval.	

* 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

^A Mefentrifluconazole

^B Kresoxim-methyl

Explanation for column 15 “Conclusion”

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

Table 8.1-2: Assessed (critical) uses during approval of mefentrifluconazole concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.*	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					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		
1	EU28	Cereals	F	Septoria tritici - SEPTTR further control claims are currently under evaluation	Foliar spray	30-69	2	14	a) 1.50 b) 3.00	150 g as/ha 300 g as/ha	100-300	35	

* 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

Table 8.1-3: Assessed (critical) uses during approval of kresoxim-methyl concerning the Section Environmental Fate

As stated in the EFSA Conclusion for kresoxim-methyl (EFSA Journal 2010;8(11):1891)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					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 as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	Northern & Southern Europe	Cereals (wheat, barley, rye, triticale)	F	<i>P. herpotrichoides</i> (<i>Erysiphe graminis</i>), <i>Septoria, spp.</i> , <i>Puccinia</i> <i>spp.</i> (<i>Fusarium spp</i>), <i>R.</i> <i>secalis</i> , <i>P. teres</i>	Foliar spray	BBCH 25- 69	a) 2 b) 2	21	-	125 ^A	200-400	35	
2	Northern & Southern Europe	Apples, pears	F	<i>Venturia inequalis</i> , <i>Podosphaera</i> <i>leucotricha</i>	Foliar spray	BBCH 53- 79	a) 1-4 b) 1-4	7-10	-	100-125 ^B	200-1800	35	Rate increases with plant growth: 100 + 100 + 125 + 125
3	Northern & Southern Europe	Grapes	F	<i>Guignardia bidwellii</i> , <i>Phomopsis viticola</i> , <i>Pseudopeziza</i> <i>tracheiphila</i> , <i>Uncinula</i> <i>necator</i>	Foliar spray	BBCH 19- 81	a) 1-3 b) 1-3	8-14	-	100-150 ^B	150-1600	35	Rate increases with plant growth: 100 + 120 + 150

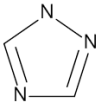
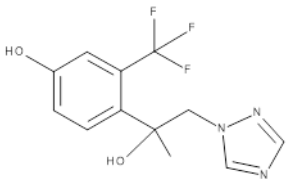
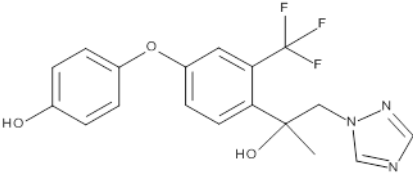
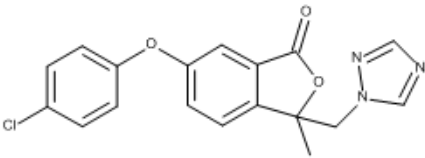
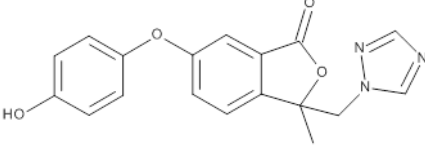
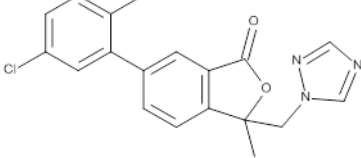
* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

^A Kresoxim-methyl in product BAS 494 04 F

^B Kresoxim-methyl in product BAS 490 02 F

8.2 Metabolites considered in the assessment

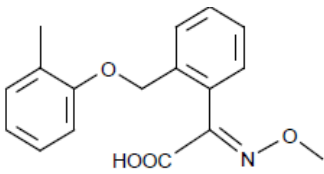
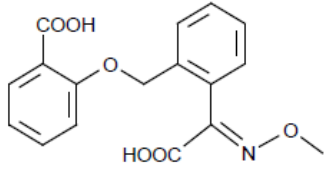
Table 8.2-1: Metabolites of mefentrifluconazole potentially relevant for exposure assessment*

Metabolite	Molar mass [g mol ⁻¹]	Chemical structure	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	PEC _{soil} : yes ^a PEC _{gw} : yes ^a PEC _{sw} : yes PEC _{sed} : yes
M750F003	287.2		Soil: 1.8 Water: 3.8 Sediment: 5.4 Total w/s system: 8.5	PEC _{soil} : no PEC _{gw} : no PEC _{sw} : yes PEC _{sed} : 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	PEC _{soil} : no PEC _{gw} : no PEC _{sw} : yes PEC _{sed} : yes
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	PEC _{soil} : no PEC _{gw} : no PEC _{sw} : yes PEC _{sed} : 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	PEC _{soil} : no PEC _{gw} : no PEC _{sw} : yes PEC _{sed} : 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	PEC _{soil} : no PEC _{gw} : no PEC _{sw} : yes PEC _{sed} : 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

* All information provided in this chapter was previously evaluated in the frame of the EU review of mefentrifluconazole (BAS 750F) and were summarized from the EFSA Conclusion on the active substance [EFSA (European Food Safety Authority), 2018. *Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (Mefentrifluconazole)*. EFSA Journal 2018;16(7):5379, 32 pp. doi:10.2903/j.efsa.2018.5379]. More detailed information were collected from the DAR, when necessary. [European Commission / RMS UK, Co-RMS AT and FR (2018): *Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. BAS 750F (Mefentrifluconazole)*].

Table 8.2-2: Metabolites of kresoxim-methyl potentially relevant for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments	Exposure 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)	PEC _{gw} : yes PEC _{soil} : yes PEC _{sw} : yes PEC _{sed} : yes, due to maximum occurrence in sediment >10%
BF 490-5 diacid of kresoxim-methyl	329.3		Soil: max. 4.3% * Water: not found Sediment: not found	PEC _{gw} : yes PEC _{soil} : yes PEC _{sw} : yes (runoff and drainage) PEC _{sed} : yes (runoff and drainage)

* A maximum occurrence of 5.1% was found in an aerobic degradation study with BF 490-1 applied (single event >5%). From this value, 4.3% were calculated when relating the maximum observed occurrence to the parent kresoxim-methyl. This low level of formation does not usually trigger further consideration, however, the metabolite was assessed in all compartments in accordance with the EFSA Conclusion (2010).

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Mefentrifluconazole and its metabolites

Table 8.3-1: Summary of aerobic degradation rates for mefentrifluconazole - laboratory studies

Mefentrifluconazole, laboratory studies, dark aerobic conditions							
Soil Soil type ^a	pH	t. [°C] / MWH C [%]	DT ₅₀ /DT ₉₀ [d] Trigger endpoints, not normalised	DT ₅₀ [d] Modelling endpoints normalised to 20 °C pF2/10kPa ^d	χ ² error (trigger / modelling)	Kinetic model (trigger / modelling)	Evaluated on EU level
Li10 loamy sand (tr)	6.1 ^b	20/40	>1000/>1000 α: 0.0656, β: 8.43	477.1	0.3 / 1.6	FOMC / SFO	Yes, EFSA (2018)
Indiana Loam (tr)	5.8 ^b	20/40	>1000/>1000 α: 0.0762, β: 21.13	366	0.8 / 1.2	FOMC / SFO	Yes, EFSA (2018)
LUFA 5M loamy sand (cp and tr)	7.2 ^b	20/40	525/1870 cp α: 0.0844, β: 12.9 tr k1: 1.2E-1, k2: 1.2E-3, g: 6.6E-2	252	0.3 / 1.4	FOMC cp label, DFOP tr label / SFO	Yes, EFSA (2018)
New Jersey Loam (cp and tr)	6.9 ^c	20/40	488/>1000 cp k1: 1.7E-1, k2: 2.9E-3, g: 1.1E-1 tr α: 0.229, β: 24.2	134	0.8 / 2.6	DFOP cp label, FOMC tr label / SFO	Yes, EFSA (2018)
New Jersey Loam (tf)	6.4 ^b	20/40	434/>1000 α: 0.249, β: 28.5	104	1.2 / 2.4	FOMC / SFO	Yes, EFSA (2018)
Geometric mean New Jersey				118			
Geometric mean all soils (if not pH dependent) ^e				268 ^f			
pH dependence				No			

^a Label designations: chlorophenyl (cp), triazole (tr), trifluoromethylphenyl (tf)

^b Measured in CaCl₂ solution

^c Measured in water

^d Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^e In the geometric mean calculations, the geometric mean value of the New Jersey soil results was considered (i.e. the 'geometric mean all soils (if not pH dependent)' is calculated from the following DT₅₀ values: 477.1, 366, 252 and 118)

^f For PEC calculation DT₅₀ values from the field study were used

Table 8.3-1: Summary of aerobic degradation rates for mefentrifluconazole - laboratory studies

Mefentrifluconazole, laboratory studies, dark aerobic conditions							
Soil type ^a	pH	t. [°C] / MWH C [%]	DT ₅₀ /DT ₉₀ [d] Trigger endpoints, not normalised	DT ₅₀ [d] Modelling endpoints normalised to 20 °C pF2/10kPa ^d	χ ² error (trigger / modelling)	Kinetic model (trigger / modelling)	Evaluated on EU level

Table 8.3-2: Summary of aerobic degradation rates for 1,2,4-triazole - laboratory studies

M750F001 (1,2,4-triazole), laboratory studies, dark aerobic conditions, metabolite applied as parent.									
Soil type	pH ^a	t. [°C] / MWH C [%]	k ₁ /k ₂ /g	DT ₅₀ fast phase/DT ₅₀ slow phase[d]	f. f. k _f / k _{dp}	DT ₅₀ [d] 20 °C pF2/10kPa ^b	St. (χ ²)	Method of calculation	Evaluate d on EU level
Sandy loam	6.4	20°C / 40 %	0.77 / 0.01 / 0.683	0.9/59.2	-	-	-	DFOP	Yes, CRD (2014) EFSA (2018)
Loamy sand	5.8	20°C / 40 %	0.46 / 2.8E-3 / 0.580	1.5/247.6	-	-	-	DFOP	Yes, CRD (2014) EFSA (2018)
Silt loam	6.7	20°C / 40 %	0.87 / 0.03 / 0.443	0.8/20.6	-	-	-	DFOP	Yes, CRD (2014) EFSA (2018)
Geometric mean				1.0/67.1 / 0.569 ^c				DFOP	Yes, CRD (2014) EFSA (2018)
pH dependence						No			

^a Measured in CaCl₂ solution

^b Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^c For PEC calculation DT₅₀ values from the field study were used

8.3.1.2 Kresoxim-methyl and its metabolites

Table 8.3-3: Summary of aerobic degradation rates for kresoxim-methyl - laboratory studies

Kresoxim-methyl, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	T (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	χ ² (%)	Kinetic model	Reference
Bruch West (dataset 2)	Sandy loam	7.82	20	40	0.555	1.844	0.457	9.85	SFO	EFSA Conclusion (2010)
Bruch West (dataset 4)	Sandy loam	7.8	20	40	0.475	1.577	0.368	8.48	SFO	EFSA Conclusion (2010)
Geomean Bruch West					0.51		0.41			EFSA Conclusion (2010)
Holly Springs (dataset 3)	Sandy loam	6.4	20	75% of 0.33 bar	3.11 ^A	10.32	1.85	10.87	FOMC	EFSA Conclusion (2010)
Geometric mean (n=2)					1.26		0.87			
pH-dependency					No					

^A SFO-DT₅₀ back calculated from the bi-phasic DT₉₀ 10.32/3.32

Table 8.3-4: Summary of aerobic degradation rates for BF 490-1 - laboratory studies

BF 490-1, Laboratory studies, aerobic conditions											
Soil name	Soil type	pH (CaCl ₂)	T (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	f.f. k _{dp} /k _f	DT ₅₀ (d) 20°C pF2/10kPa	χ ² (%)	Kinetic model	Reference
Bruch West (dataset 2)	Sandy loam	7.2	20	40	46.2	153.4	0.89	38.1	13.33	SFO	EFSA Conclusion (2010)
Bruch West (dataset 4)	Sandy loam	7.8	20	40	36.4	120.9	0.90	28.2	7.13	SFO	EFSA Conclusion (2010)
Geomean Bruch West					41	-	-	32.8 ^B			EFSA Conclusion (2010)
Holly Springs (dataset 3)	Sandy loam	6.4	20	75% of 0.33 bar	58.9	195.9	0.94	35.05	8.10	SFO	EFSA Conclusion (2010)
Borris (dataset 5) ^A	Sand	5.3	20	40	51	169	-	47.4	8.73	SFO	EFSA Conclusion (2010)
Langvad (dataset 7) ^A	Sandy loam	5.8	20	40	85.7	274.5	-	59.2	4.10	SFO	EFSA Conclusion (2010)
Karup (dataset 6) ^A	Sand	4.6	20	40	22.8 ^C	287.6	-	5.5 and 117.5 (SFO: fast and slow phases)		DFOP	EFSA Conclusion (2010)
LUFA 2.1 ^A	Sand	5.2	20	41	48	159	-	36.6	6.4	SFO	EFSA Conclusion (2010)
LUFA 3A ^A	Loam	7.3	20	42	36	119	-	23.0	5.0	SFO	EFSA Conclusion (2010)
Speyrer Wald ^A	Loamy sand	5.7	20	41	77	256	-	54.9	5.2	SFO	EFSA Conclusion (2010)
Payette ^A	Loam	6.3	20	41	32	106.24	-	27.8	2.7	SFO	EFSA Conclusion (2010)
Geometric mean (n=11) ^C					50.9	-	-	40.8			
pH-dependency					-						

^A BF 490-1 applied as test item

^B The geometric mean DT₅₀ of the Bruch West soil was included in the calculation of the normalized overall geometric mean

^C The DT₅₀ of soil Karup was not included in the calculation of the not-normalized geometric mean

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1 Anaerobic degradation in soil (KCP 9.1.1.1)

8.4.1.1 Mefentrifluconazole

Table 8.4-1: Summary of anaerobic degradation rates for mefentrifluconazole - laboratory studies

Mefentrifluconazole, laboratory studies, dark anaerobic conditions							
Soil type	pH ^a	t. [°C] / MWHC [%]	DT ₅₀ / DT ₉₀ [d]	DT ₅₀ [d] 20 °C ^b	St. (χ^2)	Kinetic model	Evaluated on EU level
Li10 loamy fine sand (tr)	6.1	20 / flooded	349 / >1000	Not calculated	3.51	SFO	Yes, EFSA (2018)
LUFA 5M sandy loam (tr)	7.2	20 / flooded	- / - ^c	-	-	-	Yes, EFSA (2018)
Indiana loam (tr)	5.6	20 / flooded	390 / >1000	Not calculated	2.8	SFO	Yes, EFSA (2018)
New Jersey loam (cp) (tr) ^d	6.6	20 / flooded	899 / >1000	Not calculated	2.8	SFO	Yes, EFSA (2018)

^a Measured in CaCl₂ solution

^b Normalised using a Q10 of 2.58

^c No discernible decline for BAS 750 F was observed, therefore kinetics were not investigated

^d Data treated as 4 replicates, 2 from each radiolabel

No major metabolites were detected under anaerobic conditions.

8.4.1.2 Kresoxim-methyl

Table 8.4-2: Summary of anaerobic degradation rates for kresoxim-methyl - laboratory studies

Kresoxim-methyl, Laboratory studies, anaerobic conditions									
Soil name	Soil type	pH (CaCl ₂)	T (°C)	MWHC (%)	DT ₅₀ (d) 20°C pF2/10kPa	DT ₉₀ (d) 20°C pF2/10kPa	χ^2 (%)	Kinetic model	Reference
Bruch West	Sandy loam	7.5	20	40	0.294	0.978	9.08	SFO	EFSA Conclusion (2010), DAR revised (2010)

Table 8.4-3: Summary of anaerobic degradation rates for BF 490-1 - laboratory studies

BF 490-1, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	T (°C)	MWHC (%)	DT ₅₀ (d) 20°C pF2/10kPa	DT ₉₀ (d) 20°C pF2/10kPa	f.f. k _{ap} /k _f	χ^2 (%)	Kinetic model	Reference
Bruch West	Sandy loam	7.5	20	40	395.7	> 1000	0.9251	5.73	SFO	EFSA Conclusion (2010)

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

8.4.2.1 Mefentrifluconazole and its metabolites

Table 8.4-4: Summary of aerobic degradation rates for mefentrifluconazole - field studies

Mefentrifluconazole, field studies									
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH ^a	Depth [cm]	DT ₅₀ [d] Actual Trigger, k1/k2/g where appropriate	DT ₉₀ [d] Actual Trigger	DT ₅₀ [d] Norm ^b . Modelling	St. (χ^2)	Method of calculation	Evaluated on EU level
Sandy loam	Bogense, Denmark	6.4	0-50	185.5	616.1	96.5	9.2 / 9.4	SFO / SFO	Yes, EFSA (2018)
Loamy sand	Lentzke, East Germany	5.4	0-50	350.6	>1000	184.0	8.9 / 9.0	SFO / SFO	Yes, EFSA (2018)
Silt loam	Goch- Nierswalde, West Germany	6.5	0-50	267.6	889.1	146.7	16.2 /17.5	SFO / SFO	Yes, EFSA (2018)
Silty clay loam	Stotzheim, France	7.4	0-50	145.4 ^c / 262.1 ^d 2.027E-2 / 2.17E-3 / 0.3389	870.2	128.6	8.4 / 6.2	DFOP / SFO	Yes, EFSA (2018)
Silty clay loam	Poggio Renatico, Italy	7.6	0-50	846.6	>1000	610.8	9.4 / 8.5	SFO / SFO	Yes, EFSA (2018)
Loamy sand	Utrera, Spain	7.4	0-50	200.5 ^c / 292.6 ^d 9.477E-2 / 2.087E- 3/0.2401	971.6	313.0	6.3 / 14.2	DFOP / SFO	Yes, EFSA (2018)
Geometric mean (if not pH dependent)						200.0			
pH dependence				No					

^a Measured in CaCl₂ solution

^b Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT_{50matrix}

^c Overall value

^d Calculated Value: Overall DegT₉₀/3.32

Table 8.4-5: Summary of aerobic degradation rates for 1,2,4-triazole - field studies: trigger endpoints

M750F001 (1,2,4-triazole) , Field studies – Trigger endpoints										
Soil type	Location	pH^a	Depth [cm]	DT₅₀ [d] actual	DT₉₀ [d] actual	St. (χ²)	DT₅₀ [d] Norm^b	f. f. k_f / k_{dp}	Method of calculation	Evaluated on EU level
Silt loam	Germany	6.4	0-30	7.8	366.7	15.2	See table Table 8.4-6 for normalised endpoints	-	FOMC	Yes, CRD (2014) ^c EFSA (2018)
Silty clay loam	Italy	7.6	0-40	21.2	207.4	10.7		-	DFOP	Yes, CRD (2014) ^c EFSA (2018)
Sandy loam	UK	7.4	0-40	6.8	109.3	17.8		-	DFOP	Yes, CRD (2014) ^c EFSA (2018)
Loam	Spain	5.8	0-30	28.1	717.6	13.3		-	DFOP	Yes, CRD (2014) ^c EFSA (2018)
Geometric mean (if not pH dependent)										
Arithmetic mean								-		
pH dependence					No					

^a Measured in CaCl₂ solution

^b Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT_{50matrix}

Table 8.4-6: Summary of aerobic degradation rates for 1,2,4-triazole - field studies: modelling endpoints

M750F001 (1,2,4-triazole) , Field studies – Modelling endpoints									
Soil type	Location	pH ^a	Depth [cm]	DT₅₀ [d] Fast phase (k1)	DT₅₀ [d] Slow phase (k2)	'g'	St. (χ²)	Method of calculation	Evaluated on EU level
Silt loam	Germany	6.4	0-30	2.5 (0.277)	70.7 (9.8E-3)	0.655	18.8	DFOP	Yes, CRD (2014) EFSA (2018)
Silty clay loam	Italy	7.6	0-40	1.4 (0.495)	59.8 (0.116)	0.364	10.6	DFOP	Yes, CRD (2014) EFSA (2018)
Sandy loam	UK	7.4	0-40	0.5 (1.386)	25.1 (0.028)	0.458	18.1	DFOP	Yes, CRD (2014) EFSA (2018)
Loam	Spain	5.8	0-30	4.6 (0.151)	126.0 (5.5E-3)	0.489	12.7	DFOP	Yes, CRD (2014) EFSA (2018)
Geometric mean				1.68	60.5			DFOP	
Arithmetic mean						0.489			

^a Measured in CaCl₂ solution

8.4.2.2 Kresoxim-methyl and its metabolites

Triggering endpoints

**Table 8.4-7: Summary of aerobic degradation rates for kresoxim-methyl - field studies:
Triggering endpoints**

Kresoxim-methyl, Field studies – Triggering endpoints								
Soil type	Location	pH	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	χ^2 (%)	Method of calculation	Reference
For all field trials					< 1 ^A			EFSA Conclusion (2010)

^A The dissipation of kresoxim-methyl was very fast so that a meaningful evaluation of the dissipation rate of the parent and formation fractions to BF 490-1 was not possible.

Table 8.4-8: Summary of aerobic degradation rates for BF 490-1 - field studies: Triggering endpoints

BF 490-1, Field studies – Triggering endpoints								
Soil type (German or USDA classification)	Location	pH (H ₂ O)	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	χ^2 (%)	Method of calculati on	Reference
Sandy silty loam (bare)	Germany, Niederhofen	7.2	25	14.1	47.0	17.8	SFO	EFSA Conclusion (2010), DAR revised (2010)
Clayey loamy sand (bare)	Germany, Birkenheide	5.5	25	7.3	24.2	2.3	SFO ^A	EFSA Conclusion (2010), DAR revised (2010)
Sandy loam (bare)	Germany, Oberding	7.3	25	37.4	124.1	16.5	SFO	EFSA Conclusion (2010), DAR revised (2010)
Sandy silty loam (bare)	Germany, Brockhausen	7.5	25	4.9	16.2	6.2	SFO ^A	EFSA Conclusion (2010), DAR revised (2010)
Loamy sand (bare)	United States, New York	5.9	15	12.8	126.7	16.4	FOMC	EFSA Conclusion (2010), DAR revised (2010)
Silty loam (bare)	United States, Oregon	5.9	15	7.7	50.8	14.3	FOMC	EFSA Conclusion (2010), DAR revised (2010)
Sandy loam (bare)	United States, California	7.1	30	7.6	25.2	6.7	SFO	EFSA Conclusion (2010), DAR revised (2010)
Sandy loam (bare)	Canada, Nova Scotia	5.3	15	18.0	59.9	22.4	SFO	EFSA Conclusion (2010), DAR revised (2010)
Loam (bare)	Canada, Ontario	7.4	30	2.9	53.8	10.1	DFOP	EFSA Conclusion (2010), DAR revised (2010)
Sandy loam (bare)	Canada, British Columbia	6.1	30	29.8	283.9	6.9	DFOP	EFSA Conclusion (2010), DAR revised (2010)
Maximum (n=10)				37.4				

^A Bi-phasic models not evaluated due to limited number of data points

For metabolite BF 490-5, calculations of DT₅₀ for non-normalized field data were not performed. PEC_{soil} for BF 490-5 were calculated using the normalized DT₅₀ values (DAR revised, 2010).

Modelling endpoints

Table 8.4-9: Summary of aerobic degradation rates for kresoxim-methyl - field studies: Modelling endpoints

Kresoxim-methyl, Field studies – Modelling endpoints							
Soil type	Location	pH	Depth (cm)	DT ₅₀ (d) 20°C, pF2	χ^2 (%)	Kinetic	Reference
For all field trials, used in modelling				1			EFSA Conclusion (2010)

Table 8.4-10: Summary of aerobic degradation rates for BF 490-1 - field studies: Modelling endpoints

BF 490-1, Field studies – Modelling endpoints ^A							
Soil type (German or USDA classification)	Location	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) 20°C, pF2	χ^2 (%)	Kinetic	Reference
Sandy silty loam (bare)	Germany, Niederhofen	7.2	25	10.8	17.9	SFO	EFSA Conclusion (2010)
Clayey loamy sand (bare)	Germany, Birkenheide	5.5	25	4.7	0.7	SFO	EFSA Conclusion (2010)
Sandy loam (bare)	Germany, Oberding	7.3	25	25.5	15	SFO	EFSA Conclusion (2010)
Sandy silty loam (bare)	Germany, Brockhausen	7.5	25	3.6	5.8	SFO	EFSA Conclusion (2010)
Loamy sand (bare)	United States, New York	5.9	15	11.5	16.4	SFO	EFSA Conclusion (2010)
Silty loam (bare)	United States, Oregon	5.9	15	8.3	16.9	SFO	EFSA Conclusion (2010),
Sandy loam (bare)	United States, California	7.1	30	9.2	6.7	SFO	EFSA Conclusion (2010)
Sandy loam (bare)	Canada, Nova Scotia	5.3	15	12.4	25	SFO	EFSA Conclusion (2010)
Loam (bare)	Canada, Ontario	7.4	30	6.8	22.4	SFO	EFSA Conclusion (2010)
Sandy loam (bare)	Canada, British Columbia	6.1	30	8.1	5.2	SFO	EFSA Conclusion (2010)
Geometric mean (n=10)				8.8			
pH-dependency				No			

^A The dissipation of kresoxim-methyl was very fast so that a meaningful evaluation of the dissipation rate of the parent and formation fractions to BF 490-1 was not possible.

Table 8.4-11: Summary of aerobic degradation rates for BF 490-5 - field studies: Modelling endpoints

BF 490-5, Field studies – Modelling endpoints								
Soil type (USDA classification)	Location	pH (H ₂ O)	Depth (cm)	DT ₅₀ (d) 20°C, pF2	f.f. ^A (-)	χ ² (%)	Kinetic	Reference
Loamy sand (bare)	United States, New York	5.9	7	3.5	0.61	19.7	SFO	EFSA Conclusion (2010)
Silty loam (bare)	United States, Oregon	5.9	7	3.7	0.50	12.2	SFO	EFSA Conclusion (2010)
Sandy loam (bare)	Canada, Nova Scotia	5.3	7	3.9	0.61	18.3	SFO	EFSA Conclusion (2010)
Sandy loam (bare)	Canada, British Columbia	6.1	7	1.0	0.32	23.9	SFO	EFSA Conclusion (2010)
Maximum (n=4)				3.9	0.61			
Geometric mean (n=4)				2.7				
Arithmetic mean (n=4)				-	0.51			
pH-dependency				No				

^A From metabolite BF 490-1.

8.4.3 Soil accumulation testing (KCP 9.1.1.2.2)

Mefentrifluconazole

A terrestrial field accumulation study with mefentrifluconazole is ongoing. Study design and related information are presented in the DAR [*European Commission / RMS UK, Co-RMS AT and FR (2018): Draft Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009. BAS 750F (Mefentrifluconazole) - Volume 3 – B.8 (AS)*].

Kresoxim-methyl

No soil accumulation studies were performed or triggered.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Mefentrifluconazole and its metabolites

Soil Type (USDA)	OC %	Soil pH (measured in water)	K _d [mL g ⁻¹]	K _{doc} [mL g ⁻¹]	K _F [mL g ⁻¹]	K _{Foc} [mL g ⁻¹]	1/n	Evaluated on EU level
Indiana loam	1.22	5.7	-	-	48.46	3972.29	0.95	Yes, EFSA (2018)
New Jersey loam	1.00	6.8	-	-	35.61	3560.75	0.96	Yes, EFSA (2018)
Obhiro loam	3.40	6.9	-	-	126.14	3709.90	1.01	Yes, EFSA (2018)
Fiorentino Poggio Renatico 1 loam	1.00	8.2	-	-	31.43	3143.03	0.92	Yes, EFSA (2018)
La Gironda Sandy clay loam	1.22	8.3	-	-	24.53	2010.28	0.94	Yes, EFSA (2018)
Li10 Loamy sand	0.95	6.9	-	-	36.34	3824.78	1.02	Yes, EFSA (2018)
LUFA 5M Sandy loam	1.10	7.4	-	-	35.83	3251.56	1.00	Yes, EFSA (2018)
LUFA 2.1 sand	0.60	6.5	-	-	29.59	4930.94	1.00	Yes, EFSA (2018)
Geometric mean (if not pH dependent)					39.93	3455.59		
Arithmetic mean (if not pH dependent)							0.975	
pH dependence			No					

Table 8.5-1: Summary of soil adsorption/desorption for 1,2,4-triazole

M750F001 (1,2,4-triazole)								
Soil Type	OC %	Soil pH ^a	K_d [mL g⁻¹]	K_d_{oc} [mL g⁻¹]	K_F [mL g⁻¹]	K_{Foc} [mL g⁻¹]	1/n	Evaluated on EU level
Silty clay	0.70	8.8	-	-	0.833	120	0.897	Yes, CRD (2014) EFSA (2018)
Clay loam	1.74	6.9	-	-	0.748	43	0.827	Yes, CRD (2014) EFSA (2018)
Silty clay loam	0.70	7.0	-	-	0.722	104	0.922	Yes, CRD (2014) EFSA (2018)
Sandy loam	0.81	6.9	-	-	0.720	89	1.016	Yes, CRD (2014) EFSA (2018)
Geometric mean						83		
Arithmetic mean					0.756	89	0.916	
pH dependence			No					

^a Measured in CaCl₂ solution

Table 8.5-2: Summary of soil adsorption/desorption for the aquatic metabolites of mefentrifluconazole

Estimated adsorption coefficients for the aquatic metabolites of mefentrifluconazole ^a								
Metabolite name	OC %	Soil pH	K _d [mL g ⁻¹]	K _{doc} [mL g ⁻¹]	K _F [mL g ⁻¹]	K _{oc} [mL g ⁻¹]	1/n	Evaluated on EU level
M750F003	n.a.	n.a.	-	-	-	597.6	n.a.	Yes, EFSA (2018)
M750F005	n.a.	n.a.	-	-	-	7863	n.a.	Yes, EFSA (2018)
M750F006	n.a.	n.a.	-	-	-	4919	n.a.	Yes, EFSA (2018)
M750F007	n.a.	n.a.	-	-	-	3938	n.a.	Yes, EFSA (2018)
M750F008	n.a.	n.a.	-	-	-	17240	n.a.	Yes, EFSA (2018)
pH dependence			n.a.					

n.a. not available

^a Adsorption coefficients (K_{oc}) were estimated for metabolites of BAS 750 F that occurred in studies with BAS 750 F in aqueous systems. QSAR method implemented in the KocWIN (EPISuite) tool was used.

8.5.2 Kresoxim-methyl and its metabolites

Table 8.5-3: Summary of soil adsorption/desorption for kresoxim-methyl

Kresoxim-methyl							
Soil name	Soil type	OC (%)	pH	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Reference
Speyer 2.1	Sand	0.70	6.1	2.60	372	0.97	EFSA Conclusion (2010)
Speyer 2.2	Loamy sand	2.29	6.0	7.74	338	0.99	EFSA Conclusion (2010)
Speyer 2.3	Sandy loam	1.20	6.2	3.62	301	0.95	EFSA Conclusion (2010)
Limburgerhof	Clayey loam	2.70	7.5	5.92	219	0.99	EFSA Conclusion (2010)
Geometric mean (n=4)					302	-	
Arithmetic mean (n=4)					308	0.975	
pH-dependency					No		

Table 8.5-4: Summary of soil adsorption/desorption for BF 490-1

BF 490-1							
Soil name	Soil type	OC (%)	pH (H ₂ O)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Reference
Germany, Speyer 2.1	Sandy loam	0.90	6.8	<0.1	19.3	n.a. ^A	EFSA Conclusion (2010)
Germany, Speyer 2.2	Sandy loam	2.60	6.7	0.62	24	0.94	EFSA Conclusion (2010)
Germany, Speyer 2.3	Loamy sand	1.00	7.3	<0.1	24.16	n.a. ^A	EFSA Conclusion (2010)
Germany, Lihof Bruch Ost	Clayey loam	3.27	8.5	0.55	17	0.91	EFSA Conclusion (2010)
United States, Red River Valley	Clay	1.80	6.5	0.79	44	0.81	EFSA Conclusion (2010)
United States, Fuquay-Varina	Loamy sand	0.64	5.7	0.44	69	0.84	EFSA Conclusion (2010)
United States, Savoy	Loam	2.61	6.3	0.87	33	0.76	EFSA Conclusion (2010)
Netherlands, PBK	Loam	2.1	7.1	0.37	17	0.95	EFSA Conclusion (2010)
Netherlands, PWK	Sandy loam	1.4	7.3	0.29	21	0.95	EFSA Conclusion (2010)
Netherlands, ORD	Sand	1.3	5.4	1.08	83	0.93	EFSA Conclusion (2010)
Netherlands, OZP	Sand	1.4	6.4	0.67	48	0.93	EFSA Conclusion (2010)
Netherlands, CHD	Sand	3.0	5.4	3.28	109	0.94	EFSA Conclusion (2010)
Netherlands, CHV	Loamy sand	2.8	6.3	1.77	63	0.94	EFSA Conclusion (2010)
Netherlands, PHS	Sand / loamy sand	1.9	6.2	0.51	27	0.95	EFSA Conclusion (2010)
Netherlands, MBO	Sandy loam	1.4	6.1	0.24	17	0.97	EFSA Conclusion (2010)
Denmark, Jydevad	Coarse sand _B	1.4	6.23	0.47	33.6	0.95	EFSA Conclusion (2010)
Denmark, Borris	Coarse sand _B	1.3	6.05	0.46	35.4	0.92	EFSA Conclusion (2010)
Denmark, Flakkebjerg	Sandy loam ^B	1.63	6.25	0.59	36.2	0.96	EFSA Conclusion (2010)
Denmark, Karup	Coarse sand _B	1.68	5.9	0.47	28.0	0.94	EFSA Conclusion (2010)
Denmark, Langvad	Loamy clay ^B	1.31	6.95	0.30	22.9	0.93	EFSA Conclusion (2010)
Lysimeter (Speyerer Wald)	Sand	0.70	7.8	0.2116	30.2	0.912	EFSA Conclusion (2010)
Median (n=21)					30.2	-	EFSA Conclusion (2010)
Median (n=19)					-	0.94	EFSA Conclusion (2010)
Arithmetic mean (n=19)						0.92	EFSA Conclusion (2010)
Lower level of K _{foc} pH-relationship (K _{f,oc,ba} value; used for PEC _{gw} and PEC _{sw} calculation)					23.1		EFSA Conclusion (2010)
pH-dependency		Yes. The K _{oc} -pH-relationship can be described by a sigmoidal curve with a K _{f,oc} under very acid conditions (K _{f,oc,ac}) of 1231.2 mL/g and a K _{f,oc,ba} of 23.1 mL/g for basic soils.					

^A Not analyzed

^B Danish soil classification

Table 8.5-5: Summary of soil adsorption/desorption for BF 490-5

BF 490-5							
Soil name	Soil type	OC (%)	pH (CaCl₂)	K_f (mL/g)	K_{foc} (mL/g)	1/n (-)	Reference
LUFA 2.1	Sand	0.68	5.2	0.034	5.05	0.914	EFSA Conclusion (2010)
Speyerer Wald	Loamy sand	0.62	5.7	0.036	5.82	0.933	EFSA Conclusion (2010)
Payette, Idaho	Sandy loam	1.33	6.3	0.016	1.21	0.792	EFSA Conclusion (2010)
LUFA 3A	Loam	2.73	7.3	0.032	1.19	0.776	EFSA Conclusion (2010)
Geometric mean (n=4)					2.6		
Arithmetic mean (n=4)					3.32	0.854	
pH-dependency					No		

8.5.3 Column leaching (KCP 9.1.2.1)

Mefentrifluconazole

Column leaching studies were not performed for mefentrifluconazole and its metabolites.

Kresoxim-methyl

Column leaching studies of kresoxim-methyl and metabolite were evaluated during the Annex I inclusion. No additional studies have been performed. A summary of the reviewed data is provided below.

Four column leaching studies were performed with kresoxim-methyl, first one with the active substance (fresh and aged residues) and three studies with formulations.

- A great portion of the applied radioactivity was eluted out of the laboratory columns. BF 490-1 was shown to be the predominant component in the percolates.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Mefentrifluconazole

Lysimeter studies were not performed for mefentrifluconazole and its metabolites as based on PEC_{gw} calculations no leaching is expected.

Kresoxim-methyl

A lysimeter study with three outdoor lysimeters was performed in Limburgerhof (Germany) according to German guidelines with an undisturbed cropped soil core (1.2 m depth, 1 m² surface). The soil was loamy sand-sand of pH = 5.7 - 6.8 with an organic carbon content of 0.14 - 0.94% in the profile. Application was made in April-May in the first year onto winter barley (growth stages 30/31 and 49/51) and in the second year onto winter wheat (in one lysimeter only, same growth stage). Two applications were made per year amounting to 300 g/ha/year. The study duration was three years with average annual rainfall of 813.2, 824.5, 874.5 mm (years 1, 2, 3) and average annual leachate volumes of 195.7 to 243.1 mm.

- During the three-year lysimeter study, 0.67% to 1.05% of the accumulated applied radioactivity was detected in the leachate. The concentrations of kresoxim-methyl recorded in the leachate were < 0.01 µg/L. The concentrations of metabolite BF 490-1 recorded in the leachate were in the ranges 0.018 - 0.04 µg/L (leaching during the first year of the study) and 0.003 - 0.012 µg/L (leaching during the second year of the study).
- Further evaluations of the lysimeter study confirmed the absence of the metabolite BF 450-5 at levels exceeding 0.1 µg/L in the lysimeter leachate (Kresoxim-methyl. Addendum Confirmatory Data 2014). These evaluations also supported the statement that two unidentified peaks in the leachate samples do not correspond to metabolites individually exceeding the trigger value of 0.1 µg/L.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Mefentrifluconazole

Field leaching studies were not performed for Mefentrifluconazole and its metabolites as based on PEC_{gw} calculations no leaching is expected.

Kresoxim-methyl

During a field leaching / monitoring study on the possible leaching of kresoxim-methyl and BF 490-1 into groundwater, several representative fields in the Netherlands were investigated over 2 to 3 years. The application intensity was high, covering a worst-case situation. 3.6% of the analyzed samples (in total 730) showed concentrations above the limit of quantification of 0.05 µg/L and 1.8% above 0.1 µg/L.

None of these findings can be attributed to leaching, rather than to direct contamination of sampling equipment. Further findings can be explained by direct entry through damaged measuring points, applications outside the label recommendations and by the harvesting technique.

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

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

8.6.1 Mefentrifluconazole and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of mefentrifluconazole

Mefentrifluconazole distribution (max. sediment 75.7% after 28 days)											
Persistence endpoints											
Water / sediment system	pH water phase	pH sediment ^a	t. °C	DT ₅₀ /DT ₉₀ whole system	St. (χ^2)	DT ₅₀ /DT ₉₀ water	St. (χ^2)	DT ₅₀ /DT ₉₀ sediment	St. (χ^2)	Kinetic model	Evaluated on EU level
Berghäuser Altrhein ^c	7.4, 8.4 ^d	7.1, 7.0 ^d	20	122.2/444.0	2.0	6.6 ^g /21.9	6.4	224.8/746.7	4.0	DFOP FOMC SFO	Yes, EFSA (2018)
Ranschgraben ^c	7.3, 7.1 ^d	5.2, 6.0 ^d	20	213.1/785.6	1.3	7.9 ^g /26.2	6.7	395.6/>1000	1.0	HS FOMC SFO	Yes, EFSA (2018)
Modeling endpoints											
Water / sediment system	pH water phase	pH sediment ^a	t. °C	Modeling DegT ₅₀ whole system ^e	St. (χ^2)	Modeling DisT ₅₀ water ^f	St. (χ^2)	Modeling DisT ₅₀ sediment ^f	St. (χ^2)	Method of calculation	Evaluated on EU level
Berghäuser Altrhein ^{c)}	7.4, 8.4 ^d	7.1, 7.0 ^d	20	125.5	2.8	6.6 ^g	6.4	224.8	4.0	SFO FOMC	Yes, EFSA (2018)
Ranschgraben ^c	7.3, 7.1 ^d	5.2, 6.0 ^d	20	212.8	2.7	7.9 ^g	6.7	395.6	1.0	SFO FOMC	Yes, EFSA (2018)
Geometric mean at 20°C ^b				163.4		7.2		298.2			

^a Measured in CaCl₂ solution

^b Normalised using a Q10 of 2.58

^c Residues from the three different label experiments (chlorophenyl-, triazole- and trifluoromethylphenyl-label) were considered as replicates

^d pH at field sampling from two different sampling events

^e Degradation rate

^f Dissipation rate

^g Calculated as DT₅₀ = DT₉₀/3.32

Table 8.6-2: Summary of observed metabolites

Compound Observed in...	Maximum observed occurrence in compartments [%]	Evaluated on EU level
M750F001 (1,2,4-triazole) Water/sediment system	Max in total system: 15.1% after 100 days Max in water: 10.2% after 100 days Max in sediment: 4.9% after 100 days kinetic formation fraction (kf/kdp): not calculated No DT ₅₀ was derived from parent studies	Yes, EFSA (2018)
M750F003 Water/sediment system	Max in total system: 8.5% (mean of replicates) after 100 days Max in water: 3.8% after 100 days Max in sediment: 5.4% after 100 days kinetic formation fraction (kf/kdp): not calculated No DT ₅₀ was derived from parent studies	Yes, EFSA (2018)
M750F005 Aqueous photolysis study	Max in water: 32.2% after 6 days	Yes, EFSA (2018)
M750F006 Aqueous photolysis study	Max in water: 30.7% after 9 days	Yes, EFSA (2018)
M750F007 Aqueous photolysis study	Max in water: 43.9% after 15 days	Yes, EFSA (2018)
M750F008 Aqueous photolysis study	Max in water: 7.3% after 13 days	Yes, EFSA (2018)

8.6.2 Kresoxim-methyl and its metabolites

Table 8.6-3: Summary of degradation in water/sediment of kresoxim-methyl

Kresoxim-methyl (Distribution: max. sediment 11.3% AR after 1 d in Krempe system*)								
Water / sediment system	pH water/ sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	DissT ₅₀ sed. (d)	Reference
Krempe	7.7/ 7.1	1.26	4.19	SFO, $\chi^2=7.2$	-	-	-	EFSA Conclusion (2010), DAR revised (2010)
Ohlau	7.8/ 6.3	1.36	4.51	SFO, $\chi^2=4.7$	-	-	-	EFSA Conclusion (2010), DAR revised (2010)

* The value is calculated as difference between the %TAR in total system and the %TAR in water for the parent compound (values in original study).

Table 8.6-4: Summary of observed metabolites

BF 490-1 Water/sediment system	max. water 68.3% after 7 d (Ohlau system); max. sediment 17.5% after 14 d (Krempe system); max. whole system 81.2% after 7 d (Ohlau system)	EFSA Conclusion (2010), DAR revised (2010)
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Table 8.6-5: Summary of degradation in water/sediment of BF 490-1

BF 490-1								
Water / sediment system	pH water/ sed.	DissT ₅₀ whole syst. (d)	DissT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	DissT ₅₀ sed. (d)	Reference
Krempe	7.7/ 7.1	468.6	1556.8	SFO ^A , $\chi^2=0.7$	-	-	-	EFSA Conclusion (2010), DAR revised (2010)
Ohlau	7.8/ 6.3	452.1	1501.7	SFO ^A , $\chi^2=2.5$	-	-	-	EFSA Conclusion (2010), DAR revised (2010)

^A Fitted from maximum onwards

Table 8.6-6: Summary of degradation of BF 490-1 in a natural water photolysis study

BF 490-1, natural water photolysis study					
Natural water system	pH	T (°C)	DT ₅₀ (d)	Kinetic, Fit	Reference
Kleiner Waldsee pond water	8.0	20	18.2	SFO, $\chi^2=3.85$	EFSA Conclusion (2010), DAR revised (2010)
DT ₅₀ for modelling ^A			36.4*		EFSA Conclusion (2010), DAR revised (2010)

^A According to photolysis study: under real conditions of a clear summer day the half life would be approximately twice as long.

* For modelling, the rounded value of 36 days was applied (as in EFSA Conclusion).

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

zRMS Comments:	<p>The submitted reports were accepted. Calculations of PEC_s for active substances, their metabolites and formulation for cereals were accepted. The endpoints used for PECs assessment were agreed at the EU level. The interception of 80% was accepted.</p> <p>The maximum PEC_s values for active substances and their metabolites and formulation are presented in following table:</p> <table><tr><td>Crop</td><td colspan="2">Winter and Spring cereals</td></tr><tr><td>Use No. in GAP table</td><td colspan="2">1 – 12</td></tr><tr><td>Compound</td><td>PECs ini mg/kg soil</td><td>PECs accum mg/kg soil</td></tr><tr><td><u>Mefentrifluconazole</u></td><td>0.053</td><td>0.092</td></tr><tr><td>1,2,4-triazole</td><td>0.0005</td><td>< 0.001</td></tr><tr><td>Kresoxim-methyl</td><td>0.040</td><td>nr</td></tr><tr><td>BF 490-1</td><td>0.053</td><td>nr</td></tr><tr><td>BF 490-5</td><td>0.004</td><td>nr</td></tr><tr><td>Formulation</td><td>0.289</td><td>nr</td></tr></table> <p>nr – not relevant</p> <p>These PECs values will be used in further risk assessment.</p>	Crop	Winter and Spring cereals		Use No. in GAP table	1 – 12		Compound	PECs ini mg/kg soil	PECs accum mg/kg soil	<u>Mefentrifluconazole</u>	0.053	0.092	1,2,4-triazole	0.0005	< 0.001	Kresoxim-methyl	0.040	nr	BF 490-1	0.053	nr	BF 490-5	0.004	nr	Formulation	0.289	nr
Crop	Winter and Spring cereals																											
Use No. in GAP table	1 – 12																											
Compound	PECs ini mg/kg soil	PECs accum mg/kg soil																										
<u>Mefentrifluconazole</u>	0.053	0.092																										
1,2,4-triazole	0.0005	< 0.001																										
Kresoxim-methyl	0.040	nr																										
BF 490-1	0.053	nr																										
BF 490-5	0.004	nr																										
Formulation	0.289	nr																										

8.7.1 Justification for new endpoints

Mefentrifluconazole

EU agreed endpoints were used for PEC_{soil} calculations for mefentrifluconazole [EFSA, 2018] and for its metabolite 1,2,4-triazole [(CRD (2014): Triazole Derived Metabolite: 1,2,4-Triazole. Proposed revision to DT50 Summary, Scientific Evaluation and Assessment July 2011, revised September 2011 (after comments from MS and EFSA) and further revised January 2013 (minor clarifications added post-commenting)]. All relevant endpoints for 1,2,4-triazole were included in the EFSA Conclusion on the active substance mefentrifluconazole as well.

Kresoxim-methyl

No deviation from EU agreed endpoints given in the EFSA Conclusion (2010), the Draft Assessment Report (DAR, revised 2010), DAR Final Addendum (2010) and the Addendum on Confirmatory Data (2014).

8.7.2 Active substance(s) and relevant metabolite(s)

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

Use No.	1-12
Crops in GAP	Wheat, barley, rye, triticale
BBCH stage	30-69
Application rate (g/ha)	Mefentrifluconazole: 100 / 100 Kresoxim-methyl: 150 / 150
Number of applications / interval (d)	2 / 14
Crop interception (%)	80
Amount reaching the soil surface per application (g/ha)	Mefentrifluconazole: 20 / 20 Kresoxim-methyl: 30 / 30
Depth of soil layer (relevant for plateau concentration) [cm]	5 / 20 (mixing depth for annual crops)
Models used for calculation	Mefentrifluconazole: <ul style="list-style-type: none"> • Excel for parent • ESCAPE 2.0 for metabolite Kresoxim-methyl: <ul style="list-style-type: none"> • ESCAPE 2.0

Table 8.7-2: Input parameters for mefentrifluconazole and its metabolite for PEC_{soil} calculations

Compound	Mefentrifluconazole	1,2,4-triazole	Value in accordance to EU endpoint y/n Reference
Molecular weight [g mol ⁻¹]	397.8	69.1	Yes EFSA (2018)
Max. occurrence [%]	- ^a	5.1 (DAT 90, laboratory, dark aerobic conditions)	Yes EFSA (2018)
DT ₅₀ [d]	846.6* (SFO, worst case from field studies, non-normalized, n = 6)	10.968 (fast) 346.574 (slow) (DFOP ^b , worst case from field studies (28.1), non-normalized, n = 4)**	Yes * EFSA (2018) **CRD (2014)

DAT = days after treatment

^a Not relevant for parent substance

^b Corresponding DFOP parameters: k₁ of 0.0632d⁻¹, k₂ of 0.002 d⁻¹ and g of 0.5732

Table 8.7-3: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Formation fraction (-)	DT ₅₀ (d)	K _{foc} (mL/g)	Reference
Kresoxim-methyl	313.3	-	1.0 (conservative assumption)	302 (geomean, n=4)	EFSA Conclusion (2010)
BF 490-1	299.3	84	37.4 (SFO, maximum normalized field studies, SFO DT ₅₀ , n=10)	23.1 (lowest value from sigmoidal function)	EFSA Conclusion (2010)
BF 490-5	329.3	61 (from BF 490-1, maximum, n=4)	3.9 (SFO, maximum of normalized field studies, SFO DT ₅₀ , n=4)	2.6 (geomean, n=4)	EFSA Conclusion (2010)

8.7.2.1 Mefentrifluconazole and its metabolites

Comments of zRMS:	The submitted report was accepted. In PECs assessment the active substance $DT_{50} = 846.6$ d was used. An accumulation concentration was assessed. Mefentrifluconazole. PECs = 0.053 mg a.s./kg soil 1,2,4-triazole. PECs < 0.001 mg/kg soil
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Reference:	CP 9.1.3/1
Report	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its metabolites in soil, groundwater, surface water and sediment following application to cereals Europe considering endpoints according to Focus, Mendez Gutierrez A., 2018 report No EU-CALC-2247 2018/1099933 Authority registration No
Guideline(s):	Focus Groundwater (2014) GG for Tier 1 Focus GW Assessments v 2.2, FOCUS Kinetics (2006) SANCO/10058/2005 version 1.1 of Dec. 2014, FOCUS Surface Water Report SANCO/4802/2001 rev. 2, FOCUS (2015): Generic guidance for FOCUS surface water scenarios v 1.4, FOCUS (2007a): Landscape And Mitigation Factors In Aquatic Risk Assessment. Vol. 1, FOCUS (2007b): Landscape And Mitigation Factors In Aquatic Risk Assessment. Vol. 2, FOCUS Air (2008) SANCO/10553/2006 Rev. 2 June 2008
Deviations:	No
GLP:	No, not compulsory to PEC reports
Acceptability:	Yes

Table 8.7-4: PEC_{soil} for mefentrifluconazole following application of 2 x 100 g a.s. ha⁻¹ to cereals

PEC_{soil} [mg kg ⁻¹]		Multiple applications	
		Actual	TWA
Initial		0.053	-
Short term	24h	0.053	0.053
	2d	0.053	0.053
	4d	0.053	0.053
Long term	7d	0.053	0.053
	14d	0.052	0.053
	21d	0.052	0.053
	28d	0.052	0.052
	50d	0.051	0.052
	100d	0.049	0.051
Plateau concentration (20 cm) after 10 years		0.039	
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		0.092	

PEC_{soil} of metabolite

Only global maximum values are reported, which can be considered as worst-case estimates of short-term and long-term exposure.

Table 8.7-5: PEC_{soil} for metabolite 1,2,4-triazole following application of 2 x 100 g a.s. ha⁻¹ to cereals

PEC_{soil} [mg kg ⁻¹]	Multiple applications
Initial	<0.001
Plateau concentration (20 cm) after 10 years	<0.001
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)	<0.001

8.7.2.2 Kresoxim-methyl and its metabolites

Comments of zRMS:	<p>The submitted report was accepted.</p> <p>In PECs assessment the active substance $DT_{50} = 37.4$ d was used.</p> <p>An accumulation concentration was assessed.</p> <p>Kresoxim-methyl. PECs = 0.040 mg a.s./kg soil</p> <p>BF 490-1. PECs = 0.053 mg/kg soil</p> <p>BF 490-5. PECs = 0.004 mg/kg soil</p>
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Reference:	CP 9.1.3/2
Report	<p>Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals</p> <p>Kiener T., 2020</p> <p>report No CALC-2412 (BASF SE)</p> <p>BASF DocID 2020/2036242</p> <p>Authority registration No</p>
Guideline(s):	<p>FOCUS Kinetics (2006) SANCO/10058/2005 v 2.0</p> <p>FOCUS (2014) Generic guidance for FOCUS Kinetics, v 1.1</p> <p>FOCUS Groundwater (2000) Sanco/321/2000</p> <p>FOCUS Groundwater (2009) Sanco/13144/2010 v3 of 2014</p> <p>FOCUS Groundwater (2014) GG for Tier 1 FOCUS GW Assessments, v 2.2</p> <p>FOCUS Surface Water (2001) SANCO/4802/2001-rev.2 final (May 2003)</p> <p>FOCUS (2015) Generic guidance for FOCUS surface water scenarios, v1.4</p>
Deviations:	No
GLP:	No, not compulsory for PEC reports.
Acceptability:	Yes

Table 8.7-6: PEC_{soil} for kresoxim-methyl on cereals

PEC_{soil} (mg/kg) / Time *		Cereals – 2× 150 g/ha	
		5 cm soil depth	
		$PEC_{soil,act}$ [mg/kg]	$PEC_{soil, twa}$ [mg/kg]
Initial		0.040	–
Short term	24h	0.020	0.030
	2d	0.010	0.025
	4d	0.003	0.018
Long term	7d	<0.001	0.011
	14d	<0.001	0.006
	21d	<0.001	0.007
	28d	<0.001	0.005
	50d	<0.001	0.003

	100d	<0.001	0.001
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* Time: days after maximum concentration ($PEC_{soil,act}$) or time interval ($PEC_{soil,twa}$)

Table 8.7-7: PEC_{soil} for BF 490-1 on cereals

PEC _{soil} (mg/kg) / Time *		Cereals – 2× 150 g/ha	
		5 cm soil depth	
		PEC _{soil,act} [mg/kg]	PEC _{soil,tna} [mg/kg]
Initial		0.053	–
Long term	21d	0.037	0.047

* Time: days after maximum concentration (PEC_{soil,act}) or time interval (PEC_{soil,tna})

Table 8.7-8: PEC_{soil} for BF 490-5 on cereals

PEC _{soil} (mg/kg) / Time *		Cereals – 2× 150 g/ha	
		5 cm soil depth	
		PEC _{soil,act} [mg/kg]	PEC _{soil,tna} [mg/kg]
Initial		0.004	–
Long term	21d	0.003	0.003

* Time: days after maximum concentration (PEC_{soil,act}) or time interval (PEC_{soil,tna})

8.7.2.3 PEC_{soil} of BAS 765 00 F

The application rate in g/ha of the product BAS 765 00 F was calculated by multiplying the application rate of the product of 1.0 L product/ha with the product density of 1083 g/L. Maximum PEC_{soil} for a single application to cereals were calculated assuming a soil layer depth of 5 cm, a soil bulk density of 1.5 g/cm³ and 80% crop interception.

Table 8.7-9: PEC_{soil} (formulation) following single application of BAS 765 00 F

Crop	Crop interception (%)	Application rate (g/ha)	Formulation PEC _{soil} (mg/kg) 5 cm
Cereals (Use 1-12)	80	1083	0.289

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

<p>zRMS Comments:</p>	<p>The submitted reports with PEC_{gw} assessment were accepted.</p> <p>All used endpoints were agreed at the EU level. For 1,2,4-triazole the endpoints were also agreed at the EU level (EFSA, 2018).</p> <p>The recommended FOCUS models were used: FOCUS PELMO, FOCUS PEARL and FOCUS MACRO.</p> <p>Calculations of PEC_{GW} for active substances and its relevant metabolite were provided with PUF = 0.</p> <p>The winter and spring cereals and multiple application were taken into consideration. The application dates used in modeling differ from recommended in AppDate tool. This deviation does not affect final PEC_{gw} results.</p> <p>Mefentrifluconazole. A tiered approach was used in PEC_{gw} assessment and it was accepted. At Tier 2 the biphasic degradation of 1,2,4-triazole was implemented for PEC_{gw} modeling in accordance with FOCUS Groundwater guidance.</p> <p>The 80th percentiles PEC_{GW} values for active substance and 1,2,4-triazole were below the trigger value of 0.1 µg/L in Tier 2 to 4 modeling.</p> <p>Kresoxim-methyl. The 80th percentiles of the predicted annual leachate concentrations of kresoxim-methyl and its both metabolites were below 0.1 µg/L in all tested scenarios.</p>
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8.8.1 Justification for new endpoints

Mefentrifluconazole

EU agreed endpoints were used in PEC_{gw} calculations for mefentrifluconazole (EFSA, 2018) and for its metabolite 1,2,4-triazole (CRD, 2014, EFSA, 2018).

Kresoxim-methyl

No deviation from EU agreed endpoints given in the EFSA Conclusion (2010), the Draft Assessment Report (DAR, revised 2010), DAR Final Addendum (2010) and the Addendum on Confirmatory Data (2014).

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

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

Use No.	1-12
Crop (according to GAP)	Wheat, barley, rye, triticale
FOCUS crop (for modelling)	Winter cereals, spring cereals
BBCH stage	30-69
Application rate (g/ha)	Mefentrifluconazole ^a : 150 / 150 Kresoxim-methyl: 150 / 150
Number of applications / interval (d)	2 / 14
Absolut application date	Specific*
Crop interception (%)	80 / 80
Amount reaching the soil surface per application (g/ha)	Mefentrifluconazole: 20 / 20 Kresoxim-methyl: 30 / 30
Total yearly soil load (g/ha)	Mefentrifluconazole: 40 Kresoxim-methyl: 60
Frequency of application	Annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

* Application dates used in EU assessment of mefentrifluconazole

. ^a For mefentrifluconazole an application rate of 150 g a.s. ha⁻¹ instead of 100 g a.s. ha⁻¹ was considered in context of a risk envelope approach across different formulations

Table 8.8-2: Application dates used for groundwater risk assessment

FOCUS crop	FOCUS Scenario	Application dates (absolute)	
		1 st application	2 nd application
Winter cereals	Châteaudun	1-May (121) [#]	15-May (135) [#]
	Hamburg	1-May	15-May
	Jokioinen	1-June	15-June
	Kremsmünster	1-May	15-May
	Okehampton	1-May	15-May
	Piacenza	15-March	29-March
	Porto	15-March	29-March
	Sevilla	15-March	29-March
	Thiva	15-March	29-March
Spring cereals	Chateaudun	7-April (97) [#]	21-April (111) [#]
	Hamburg	29 -April	13-May
	Jokioinen	15 -June	29-June
	Kremsmünster	29-April	13-May
	Okehampton	29-April	13-May
	Porto	7-April	21-April

[#] Julian day as input for MACRO

8.8.2.1 Mefentrifluconazole and its metabolites

Comments of zRMS:	<p>The submitted report was accepted. In PECgw assessment the tiered approach was considered. The PECgw assessment was conducted with recommended FOCUS groundwater models.</p> <p>Mefentrifluconazole. PECgw < 0.1 µg/L 1,2,4-triazole. PECgw < 0.1 µg/L</p>
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Reference:	9.2.4.1/1
Report	<p>Predicted environmental concentrations of BAS 750F and its metabolite M750F001 (1,2,4-triazole) in groundwater following application of BAS 750F to cereals using geometric mean Koc for both compounds,</p> <p>Szegedi, K., 2017 report No EU-CALC-2247 2017/1219165 Authority registration No</p>
Guideline(s):	<p>FOCUS Groundwater Scenarios (2000) Sanco/321/2000 rev. 2, FOCUS Groundwater (2014) Sanco/13144/2010 v. 3, FOCUS Groundwater (2014) Generic Guidance for Tier 1 v. 2.2, FOCUS Degradation Kinetics (2006) SANCO/10058/2005 v. 1.1 (December 2014)</p>
Deviations:	No
GLP:	No, not compulsory to PEC reports
Acceptability:	Yes

For mefentrifluconazole an application rate of 150 g a.s. ha⁻¹ instead of 100 g a.s. ha⁻¹ was considered in context of a risk envelope approach across different formulations.

PEC_{gw} assessment was performed for the metabolite 1,2,4-triazole at four different tiers. Tier 1 does not include the characteristic biphasic behavior of the compound: only the slow degrading compartment was considered. Additionally, the default worst case formation percentage of 100% of 1,2,4-triazole from BAS 750F was considered. The characteristic biphasic behavior of the compound was implemented in Tier 2 calculations. according to FOCUS degradation kinetics (2014). However, still the default worst case formation percentage of 100% of 1,2,4-triazole from BAS 750F was considered, which makes these scenarios overly conservative. Although already Tier 2 shows safe use, Tier 3 and Tier 4 calculations were performed with more appropriate estimated formation fractions (in addition to biphasic degradation) to provide more realistic estimation on the leaching potential of 1,2,4-triazole as a metabolite of BAS 750F.

Table 8.8-3: Input parameters for mefentrifluconazole and metabolite for PEC_{gw} calculations

Compound	Mefentrifluconazole	1,2,4-triazole	Value in accordance to EU endpoint y/n Reference
Molecular weight [g mol ⁻¹]	397.8	69.1	Yes EFSA (2018)
Water solubility [mg L ⁻¹] (20°C)	0.81	7.00 x 10 ⁵	Yes EFSA (2018)
Saturated vapor pressure [Pa] (20°C)	3.2 x 10 ⁻⁶	1.0 x 10 ⁻¹⁰	Yes EFSA (2018)
DT _{50,soil} [d]	200 (geometric mean of field studies, normalized, n = 6)	fast phase (DFOP): 1.68 slow phase (DFOP): 60.5 (geometric mean of field studies studies, normalized, n = 4) g (proportion of the fast pool): 0.489 (arithmetic mean, n = 4)	Yes EFSA (2018)
Transformation rate (PELMO)	Tier 1: To 1,2,4-triazole: 0.0034657 To sink: 0 Tier 2: To 1,2,4-triazole (fast phase): 0.0016947 To 1,2,4-triazole (slow phase): 0.0017710 To sink: 0 Tier 3: To 1,2,4-triazole (fast phase): 0.00110158 To 1,2,4-triazole (slow phase): 0.00115114 To sink: 0.00121301 Tier 4: To 1,2,4-triazole (fast phase): 0.00067790 To 1,2,4-triazole (slow phase): 0.00070840 To sink: 0.00207944	Tier 1: To sink: 0.011457 Tier 2-4: To sink (fast phase): 0.412588 To sink (slow phase): 0.011457	Calculated
K _{f,oc} [mL g ⁻¹]	3455.6 * (geometric mean; n = 8)	83 ** (geometric mean; n = 4)	Yes * EFSA (2018) **CRD (2014)
K _{f,om} [mL g ⁻¹]	2004.4 * (geometric mean; n = 8)	48 ** (geometric mean; n = 4)	Yes * EFSA (2018) **CRD (2014)
Freundlich exponent 1/n	0.975 (arithmetic mean; n = 8)	0.916 (arithmetic mean; n = 4)	Yes EFSA (2018))

Table 8.8-3: Input parameters for mefentrifluconazole and metabolite for PEC_{gw} calculations

Compound	Mefentrifluconazole	1,2,4-triazole	Value in accordance to EU endpoint y/n Reference
Plant Uptake [-]	0	0	Yes EFSA (2018)
Formation fraction	- ^a	Tier 1:1 Tier 2: Fast phase: 0.489 Slow phase: 0.511 Tier 3: Fast phase: 0.489*0.65 Slow phase: 0.511*0.65 Tier 4: Fast phase: 0.489*0.4 Slow phase: 0.511*0.4	Yes DAR (2018) EFSA (2018)

^a Not relevant for parent substance

Tier 1

Table 8.8-4: PEC_{gw} for mefentrifluconazole and metabolite on winter cereals – multiple application (2 x 150 g ha⁻¹), Tier 1

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Winter cereals	Châteaudun	<0.001	0.020
		Hamburg	<0.001	0.095
		Jokioinen	<0.001	0.035
		Kremsmünster	<0.001	0.065
		Okehampton	<0.001	0.094
		Piacenza	<0.001	0.052
		Porto	<0.001	0.053
		Sevilla	<0.001	<0.001
		Thiva	<0.001	0.013
PELMO 5.5.3	Winter cereals	Châteaudun	<0.001	0.013
		Hamburg	<0.001	0.105
		Jokioinen	<0.001	0.044
		Kremsmünster	<0.001	0.070
		Okehampton	<0.001	0.097
		Piacenza	<0.001	0.062
		Porto	<0.001	0.083
		Sevilla	<0.001	<0.001
		Thiva	<0.001	0.005
MACRO 5.5.4	Winter cereals	Châteaudun	<0.001	0.025

Table 8.8-5: PEC_{gw} for mefentrifluconazole and metabolite on spring cereals – multiple application (2 x 150 g ha⁻¹), Tier 1

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Spring cereals	Châteaudun	<0.001	0.016
		Hamburg	<0.001	0.109
		Jokioinen	<0.001	0.034
		Kremsmünster	<0.001	0.067
		Okehampton	<0.001	0.090
		Porto	<0.001	0.056
PELMO 5.5.3	Spring cereals	Châteaudun	<0.001	0.009
		Hamburg	<0.001	0.093
		Jokioinen	<0.001	0.031
		Kremsmünster	<0.001	0.061
		Okehampton	<0.001	0.082
		Porto	<0.001	0.071
MACRO 5.5.4	Spring cereals	Châteaudun	<0.001	0.027

Tier 2

Table 8.8-6: PEC_{gw} for mefentrifluconazole and metabolite on winter cereals – multiple application (2 x 150 g ha⁻¹), Tier 2

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Winter cereals	Châteaudun	<0.001	0.010
		Hamburg	<0.001	0.049
		Jokioinen	<0.001	0.018
		Kremsmünster	<0.001	0.033
		Okehampton	<0.001	0.048
		Piacenza	<0.001	0.027
		Porto	<0.001	0.027
		Sevilla	<0.001	<0.001
		Thiva	<0.001	0.007
PELMO 5.5.3	Winter cereals	Châteaudun	<0.001	0.007
		Hamburg	<0.001	0.054
		Jokioinen	<0.001	0.023
		Kremsmünster	<0.001	0.036
		Okehampton	<0.001	0.050
		Piacenza	<0.001	0.032
		Porto	<0.001	0.043
		Sevilla	<0.001	<0.001
		Thiva	<0.001	0.003
MACRO 5.5.4	Winter cereals	Châteaudun	<0.001	0.005

Table 8.8-7: PEC_{gw} for mefentrifluconazole and its metabolite on spring cereals – multiple application (2 x 150 g ha⁻¹), Tier 2

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Spring cereals	Châteaudun	<0.001	0.008
		Hamburg	<0.001	0.056
		Jokioinen	<0.001	0.017
		Kremsmünster	<0.001	0.035
		Okehampton	<0.001	0.046
		Porto	<0.001	0.029
PELMO 5.5.3	Spring cereals	Châteaudun	<0.001	0.005
		Hamburg	<0.001	0.048
		Jokioinen	<0.001	0.016
		Kremsmünster	<0.001	0.032
		Okehampton	<0.001	0.042
		Porto	<0.001	0.037
MACRO 5.5.4	Spring cereals	Châteaudun	<0.001	0.006

Tier 3

Table 8.8-8: PEC_{gw} for mefentrifluconazole and metabolite on winter cereals – multiple application (2 x 150 g ha⁻¹), Tier 3

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Winter cereals	Châteaudun	<0.001	0.004
		Hamburg	<0.001	0.021
		Jokioinen	<0.001	0.007
		Kremsmünster	<0.001	0.014
		Okehampton	<0.001	0.021
		Piacenza	<0.001	0.012
		Porto	<0.001	0.011
		Sevilla	<0.001	0.000
		Thiva	<0.001	0.002
PELMO 5.5.3	Winter cereals	Châteaudun	<0.001	0.004
		Hamburg	<0.001	0.032
		Jokioinen	<0.001	0.013
		Kremsmünster	<0.001	0.021
		Okehampton	<0.001	0.030
		Piacenza	<0.001	0.019
		Porto	<0.001	0.026
		Sevilla	<0.001	0.000
		Thiva	<0.001	0.002
MACRO 5.5.4	Winter cereals	Châteaudun	<0.001	0.003

Table 8.8-9: PEC_{gw} for mefentrifluconazole and its metabolite on spring cereals – multiple application (2 x 150 g ha⁻¹), Tier 3

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Spring cereals	Châteaudun	<0.001	0.003
		Hamburg	<0.001	0.024
		Jokioinen	<0.001	0.007
		Kremsmünster	<0.001	0.015
		Okehampton	<0.001	0.020
		Porto	<0.001	0.012
PELMO 5.5.3	Spring cereals	Châteaudun	<0.001	0.003
		Hamburg	<0.001	0.028
		Jokioinen	<0.001	0.009
		Kremsmünster	<0.001	0.018
		Okehampton	<0.001	0.025
		Porto	<0.001	0.022
MACRO 5.5.4	Spring cereals	Châteaudun	<0.001	0.003

Tier 4

Table 8.8-10: PEC_{gw} for mefentrifluconazole and metabolite on winter cereals – multiple application (2 x 150 g ha⁻¹), Tier 4

Model	Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth [$\mu\text{g L}^{-1}$]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Winter cereals	Châteaudun	<0.001	0.002
		Hamburg	<0.001	0.012
		Jokioinen	<0.001	0.004
		Kremsmünster	<0.001	0.008
		Okehampton	<0.001	0.012
		Piacenza	<0.001	0.007
		Porto	<0.001	0.006
		Sevilla	<0.001	0.000
		Thiva	<0.001	0.001
PELMO 5.5.3	Winter cereals	Châteaudun	<0.001	0.002
		Hamburg	<0.001	0.017
		Jokioinen	<0.001	0.007
		Kremsmünster	<0.001	0.012
		Okehampton	<0.001	0.017
		Piacenza	<0.001	0.011
		Porto	<0.001	0.014
		Sevilla	<0.001	0.000
		Thiva	<0.001	0.001
MACRO 5.5.4	Winter cereals	Châteaudun	<0.001	0.001

Table 8.8-11: PEC_{gw} for mefentrifluconazole and its metabolite on spring cereals – multiple application (2 x 150 g ha⁻¹), Tier 4

Model	Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth [µg L ⁻¹]	
			Mefentrifluconazole	1,2,4-triazole
PEARL 4.4.4	Spring cereals	Châteaudun	<0.001	0.002
		Hamburg	<0.001	0.014
		Jokioinen	<0.001	0.004
		Kremsmünster	<0.001	0.008
		Okehampton	<0.001	0.012
		Porto	<0.001	0.007
PELMO 5.5.3	Spring cereals	Châteaudun	<0.001	0.002
		Hamburg	<0.001	0.015
		Jokioinen	<0.001	0.005
		Kremsmünster	<0.001	0.010
		Okehampton	<0.001	0.014
		Porto	<0.001	0.012
MACRO 5.5.4	Spring cereals	Châteaudun	<0.001	0.002

The 80th percentiles of the predicted annual leachate concentrations of mefentrifluconazole were clearly below 0.1 µg L⁻¹ in all tested scenarios. PEC_{gw} for the metabolite 1,2,4-triazole are slightly above 0.1 µg L⁻¹ for only one scenario (Hamburg) at Tier 1, but below 0.1 µg L⁻¹ in all tested scenarios at Tiers 2-4.

Hence, the leaching of unacceptable amounts of the parent substance or the metabolite following application of mefentrifluconazole to the crops intended in the GAP is highly unlikely.

8.8.2.2 Kresoxim-methyl and its metabolites

Comments of zRMS:	<p>The submitted report was accepted.</p> <p>The PEC_{gw} assessment was conducted with recommended FOCUS groundwater models.</p> <p>Kresoxim-methyl. PEC_{gw} < 0.1 µg/L</p> <p>BF 490-1 and BF 490-5. PEC_{gw} < 0.1 µg/L</p>
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Reference:	CP 9.2.4.1/2
Report	<p>Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals</p> <p>Kiener T., 2020</p> <p>Report No CALC-2412 (BASF SE)</p> <p>BASF DocID 2020/2036242</p> <p>Authority registration No</p>
Guideline(s):	<p>FOCUS Kinetics (2006) SANCO/10058/2005 v 2.0</p> <p>FOCUS (2014) Generic guidance for FOCUS Kinetics, v 1.1</p> <p>FOCUS Groundwater (2000) Sanco/321/2000</p> <p>FOCUS Groundwater (2009) Sanco/13144/2010 v3 of 2014</p> <p>FOCUS Groundwater (2014) GG for Tier 1 FOCUS GW Assessments, v 2.2</p> <p>FOCUS Surface Water (2001) SANCO/4802/2001-rev.2 final (May 2003)</p> <p>FOCUS (2015) Generic guidance for FOCUS surface water scenarios, v1.4</p>
Deviations:	No
GLP:	No, not compulsory for PEC reports.
Acceptability:	Yes

Table 8.8-12: Input parameters related to kresoxim-methyl and its metabolites for PEC_{gw} calculations

Compound	Kresoxim-methyl	BF 490-1	BF 490-5	Reference
Molecular weight (g/mol)	313.3	299.3	329.31	EFSA Conclusion (2010)
Water solubility (mg/L)	2.0 (20°C)	90.1	100	EFSA Conclusion (2010)
Saturated vapour pressure (Pa)	2.3×10^{-6} (20°C)	1.0×10^{-9} (default)	1.0×10^{-9} (default)	EFSA Conclusion (2010)
DT ₅₀ in soil (d)	1.0 (conservative assumption)	8.8 (geomean field studies, normalized to pF2 and 20°C, n=10)	2.7 (geomean field studies, normalized to pF2 and 20°C, n=4)	EFSA Conclusion (2010)
Formation fraction	-	0.84 from parent* (worst case from laboratory studies)	0.51 from BF 490-1 (arithmetic mean from field studies, n = 4)	EFSA Conclusion (2010)
Transformation rate in PELMO (d ⁻¹)	0.11090 to sink 0.58224 to BF 490-1	0.038596 to sink 0.040171 to BF 490-5	0.256721 to sink	calculated

Compound	Kresoxim-methyl	BF 490-1	BF 490-5	Reference
Conversion factor in MACRO	-	0.802	0.536***	calculated
$K_{\text{foc}} / K_{\text{fom}}$ (mL/g)	308 / 178.7 (arithmetic mean, n=4)	23.1 / 13.4 (lowest value from sigmoidal function, n=21)	3.32 / 1.9 (arithmetic mean, n=4)	EFSA Conclusion (2010)
1/n	0.975 (arithmetic mean, n=4)	0.940 (median, n=19)	0.854 (arithmetic mean, n=4)	EFSA Conclusion (2010)
Plant uptake factor	0	0	0	-
Soil adsorption option	pH-independent	pH-independent	pH-independent	-

* Formation fraction unavailable, maximum occurrence used.

** pH-independence assumed as worst case assumption, actual pH-dependency not considered.

*** Since MACRO can only handle a single metabolite, it was assumed that BF 490-5 is formed directly from the parent. The conversion factor for BF 490-5 was calculated as follows:

$$\text{CONV}_{\text{BF490-5}} = \text{FormationFraction}_{\text{BF490-1}} \times \text{FormationFraction}_{\text{BF490-5}} \times \text{MolarMass}_{\text{BF490-5}} / \text{MolarMass}_{\text{Parent}}$$

Table 8.8-13: PEC_{gw} for kresoxim-methyl and its metabolites (with FOCUS PEARL 4.4.4) – spring and winter cereals, $2 \times (14\text{d})$ 150 g/ha

Crop	FOCUS Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)		
		Kresoxim-methyl	BF 490-1	BF 490-5
Spring cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	0.015	0.007
	Jokioinen	<0.001	0.010	0.009
	Kremsmünster	<0.001	0.010	0.003
	Okehampton	<0.001	0.012	0.004
	Porto	<0.001	0.001	<0.001
Winter cereals	Châteaudun	<0.001	0.001	<0.001
	Hamburg	<0.001	0.012	0.006
	Jokioinen	<0.001	0.006	0.005
	Kremsmünster	<0.001	0.010	0.004
	Okehampton	<0.001	0.016	0.007
	Piacenza	<0.001	0.007	0.003
	Porto	<0.001	0.001	0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-14: PEC_{gw} for kresoxim-methyl and its metabolites (with FOCUS PELMO 5.5.3) – spring and winter cereals, 2 × (14d) 150 g/ha

Crop	FOCUS Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Kresoxim-methyl	BF 490-1	BF 490-5
Spring cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	0.006	0.002
	Jokioinen	<0.001	0.011	0.012
	Kremsmünster	<0.001	0.010	0.003
	Okehampton	<0.001	0.014	0.006
	Porto	<0.001	0.002	0.001
Winter cereals	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	0.007	0.003
	Jokioinen	<0.001	0.009	0.007
	Kremsmünster	<0.001	0.011	0.004
	Okehampton	<0.001	0.015	0.008
	Piacenza	<0.001	0.006	0.005
	Porto	<0.001	0.003	0.002
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-15: PEC_{gw} for kresoxim-methyl and its metabolites (with FOCUS MACRO 5.5.4) – spring and winter cereals, 2 × (14d) 150 g/ha

Crop	FOCUS Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Kresoxim-methyl	BF 490-1	BF 490-5
Spring cereals	Châteaudun	<0.001	<0.001	<0.001
Winter cereals	Châteaudun	<0.001	<0.001	<0.001

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

zRMS Comments:	The submitted PEC _{sw} and PEC _{sed} calculations were accepted.																														
	All used endpoints for active substances and their metabolites were agreed at the EU level.																														
	The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3 and Step 4. The multiple application in winter and spring cereals was considered. The mitigation measures were proposed.																														
	D1 and D2 scenarios are not relevant for Central Zone and were not taken into consideration.																														
	The application dates were accepted.																														
	Mefentrifluconazole. A tiered approach was used in PEC _{sw} assessment and it was accepted.																														
	The following mitigation measures were taken into consideration:																														
	<ul style="list-style-type: none">• vegetated filter strips of 10 m and 20 m with 10 m and 20 m of non sprayed buffer strips, respectively;• drift reduction of mefentrifluconazole using no spray buffer zones of 5 m, 10 m and 20 m;• drift mitigation of 50% drift-reduction nozzles at edge-of-field and in combination with a 5 m buffer zone.																														
	The max PEC _{sw} for Central Zone and Poland with relevant mitigation measure are presented in the table below.																														
	<table><tr><th>Crop</th><th>Application rate g a.s./ha</th><th>Vegetative strip (m)</th><th>No spray buffer (m)</th><th>Central Zone Max PEC_{sw} (µg/l)</th><th>Poland* Max PEC_{sw} (µg/l)</th></tr><tr><td rowspan="2">Winter cereals</td><td rowspan="2">2 x 100</td><td>10</td><td>10</td><td>0.410 D6 ditch</td><td>0.206 R1 stream</td></tr><tr><td>20</td><td>20</td><td>0.410 D6 ditch</td><td>0.108 R1 stream</td></tr><tr><td rowspan="2">Spring cereals</td><td rowspan="2">2 x 100</td><td>10</td><td>10</td><td>0.192 D4 stream</td><td>0.206 R1 stream</td></tr><tr><td>20</td><td>20</td><td>0.192 D4 stream</td><td>0.192 D4 stream</td></tr></table>						Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC _{sw} (µg/l)	Poland* Max PEC _{sw} (µg/l)	Winter cereals	2 x 100	10	10	0.410 D6 ditch	0.206 R1 stream	20	20	0.410 D6 ditch	0.108 R1 stream	Spring cereals	2 x 100	10	10	0.192 D4 stream	0.206 R1 stream	20	20	0.192 D4 stream
Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC _{sw} (µg/l)	Poland* Max PEC _{sw} (µg/l)																										
Winter cereals	2 x 100	10	10	0.410 D6 ditch	0.206 R1 stream																										
		20	20	0.410 D6 ditch	0.108 R1 stream																										
Spring cereals	2 x 100	10	10	0.192 D4 stream	0.206 R1 stream																										
		20	20	0.192 D4 stream	0.192 D4 stream																										

* in case of spring cereals in Poland, the R1 scenario from winter cereals was considered

Metabolites of mefentrifluconazole were also taken into consideration. The max PEC_{sw} (Step 2) and PEC_{sed} (Step 2 and Step 3, if relevant) for multiple application are presented in the table below:

Metabolite	Winter and Spring cereals	
	Max PEC _{sw} µg/L	Max PEC _{sed} µg/kg
1,2,4-triazole	0.357	0.295
M750F003	0.492	2.881
M750F005	0.339	Winter cereals 0.901* R4 stream Spring cereals 0.945* R4 stream
M750F006	0.457	Winter cereals 0.809* R4 stream Spring cereals 0.849* R4 stream
M750F007	0.747	Winter cereals 0.748* R4 stream Spring cereals 0.784* R4 stream
M750F008	0.60 (single)	Winter cereals 0.748* R4 stream Spring cereals 0.887* R4 stream

* - Step 3 values

Kresoxim-methyl. Two cases of DT₅₀: conservative of 1.0 d and the lowest of 1.36 d were considered.

The following mitigation measures were taken into consideration:

- vegetated filter strips of 10 m with 10 m non sprayed buffer zone;
- drift reduction of kresoxim-methyl using no spray buffer zones of 5 m.

The max PEC_{sw} for Central Zone and Poland with relevant mitigation measure are presented in the table below.

Crop	Application rate g a.s./ha	Vegetative strip (m)	No spray buffer (m)	Central Zone Max PEC _{sw} (µg/l)	Poland*
Winter cereals	2 x 150	-	5	1.809 R4 stream	1.401 R1 stream
		10	10	0.816 R4 stream	0.637 R1 stream
Spring cereals	2 x 150	-	5	1.782 R4 stream	1.401 R1 stream
		10	10	0.805 R4 stream	0.637 R1 stream

Metabolites of kresoxim-methyl were also taken into consideration. The max PEC_{sw} and PEC_{sed} in Step 2 for multiple application are presented in the table below:

		Metabolite	Winter and Spring cereals	
			Max PEC _{sw} µg/L	Max PEC _{sed} µg/kg
		BF 490-1	17.593	4.058
		BF 490-5	0.331	0.011

ZRMS is of the opinion, that relevant mitigation measures will be proposed at the Member State level.

The drift exposure was reassessed by evaluator using the Drift Calculator in SWASH model:

Crop	Application rate g a.s./ha	No spray buffer (m)	Max PEC _{sw} (µg/l)
Winter and spring cereals	1083 g [prod]/ha equivalent to 1 L {prod/ha	10	1.00

The relevant mitigation measure will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

Mefentrifluconazole

At Steps 1-2 of the tiered assessment scheme, for mefentrifluconazole the whole system DT₅₀ of 163.4 days was used both for the water and sediment compartment according to current FOCUS guideline [*FOCUS (2006,2014): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 1.1 of December 2014, 440 pp*], whilst the List of Endpoints (DAR, 2018) gives a default of 1000 days for DT₅₀ in sediment. However, resulting STEP 1-2 PEC_{sw} and PEC_{sed} values show only a minor difference from corresponding values in the DAR.

During the evaluation of the active substance at EU level STEP 3 PEC_{sw} was estimated for the metabolites M750F005, M750F006, M750F007, and M750F008 based on PEC_{sw} of mefentrifluconazole, while only STEP 1-2 PEC_{sed} values were reported [*EFSA, 2018*]. In current dossier the applicant submitted STEP 3 PEC_{sw} and PEC_{sed} values for these metabolites calculated according to the FOCUS surface water generic guidance [*FOCUS 2015*].

All other endpoints used for PEC_{sw/sed} calculations for mefentrifluconazole and its metabolites were selected according to the EFSA Conclusion on the active substance [*EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (Mefentrifluconazole). EFSA Journal 2018;16(7):5379, 32 pp. doi:10.2903/j.efsa.2018.5379*].

Kresoxim-methyl

No deviation from EU agreed endpoints given in the EFSA Conclusion (2010), the Draft Assessment Report (DAR, revised 2010), DAR Final Addendum (2010) and the Addendum on Confirmatory Data (2014). Sorption of parent and BF 490-5 were now described by geometric mean.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for PEC_{SW/SED} calculations

Use No.	1-12
Crop (according to GAP)	Wheat, barley, rye, triticale
FOCUS crop (for modelling)	Spring and winter cereals*
BBCH stage	30-69
Application rate (g as/ha)	Mefentrifluconazole: 100 / 100 Kresoxim-methyl: 150 / 150
Number of applications / interval (d)	2 / 14
Application window (relevant for STEP 1 and 2 only)	NEU / SEU, Oct-Feb / Mar-May / June-Sep
Crop interception (relevant for STEP 1 and 2 only)	20 % ('average crop cover')
Application method	Spraying ('ground spray')
CAM (Chemical application method)	2 - Foliar linear
Soil depth (cm)	4
Models used for calculation	STEPS 1-2 in FOCUS v3.2 FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v.5.5.3, SWAN v5.0.0

* Step1-2 calculations were only done for winter cereals since the results for winter and spring cereals in Step1-2 are always identical if the input is identical.

The appropriate dates for the beginning and end of the application window for STEP3 and STEP4 calculations were selected relative to the emergence or harvest dates of winter and spring cereals.

The length of the application window that is required for the Pesticide Application Tool (PAT) to determine actual application dates was chosen to cover the whole application window as specified in the GAP considering the BBCH growth stage. For calculations of single and twofold application the same application window was applied.

For winter cereals, the start date of the application window at BBCH 30 was set to 15th March, 1st May and 1st June for the scenarios in South and Central Europe, respectively, except for the scenario D4 where the window start was set 4 days earlier to cover the 44-day period. For spring cereals, the start date of the application window at BBCH 30 was set to 28 days after emergence.

The last possible application date was set to 42 days before harvest for winter and spring cereals. The resulting length of the application windows were 44 to 80 days depending on crop and FOCUS scenario.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of BAS 765 00 F

Crop	FOCUS Scenario	Application window used in modeling	Application date(s) chosen by SWASH (PAT) [#]	
			1 st application date*	2 nd application date
Spring cereals	D1	02-Jun – 24-Jul	17-Jun-1982	02-Jul-1982
	D3	29-Apr – 09-Jul	04-May-1992	18-May-1992
	D4	24-May – 15-Jul	30-May-1985	04-Jul-1985
	D5	12-Apr – 08-Jun	14-Apr-1978	11-May-1978
	R4	12-Apr – 08-Jun	04-May-1984	27-May-1984
Winter cereals	D1	01-Jun – 15-Jul	17-Jun-1982	02-Jul-1982
	D2	01-May – 26-Jun	07-May-1986	23-May-1986
	D3	01-May – 04-Jul	04-May-1992	18-May-1992
	D4	27-May – 10-Jul	30-May-1985	04-Jul-1985
	D5	15-Mar – 03-Jun	08-Apr-1978	22-Apr-1978
	D6	15-Mar – 19-May	15-Mar-1986	09-Apr-1986
	R1	01-May – 19-Jun	02-May-1984	13-Jun-1984
	R3	15-Mar – 20-May	28-Mar-1980	11-Apr-1980
	R4	15-Mar – 03-Jun	04-May-1984	27-May-1984

[#] Pesticide Application Timing Calculator integrated in PRZM and MACRO

* For single applications, the same data as for the first application of the twofold application was always selected by PAT.

Global maxima from single and multiple applications and 21d TWA values are reported. Please refer to respective study reports for detailed results of PEC calculations.

8.9.2.1 Mefentrifluconazole and its metabolites

Comments of zRMS:	The submitted report was accepted. In PECsw assessment the EU agreed endpoints were used. The PECsw assessment was conducted with recommended FOCUS surface water models (Step 1& 2, Step 3 and Step 4). The mitigation measures were proposed: 5m, 10m, 20m of non-sprayed buffer zone and 10m and 20m of vegetative buffer zone.
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STEPS 1-2

Reference:	CP 9.2.5/1
Report	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its metabolites in soil, groundwater, surface water and sediment following application to cereals Europe considering endpoints according to Focus, Mendez Gutierrez A., 2018 report No EU-CALC-2247 BASF DocID 2018/1099933 Authority registration No
Guideline(s):	Focus Groundwater (2014) GG for Tier 1 Focus GW Assessments v 2.2, FOCUS Kinetics (2006) SANCO/10058/2005 version 1.1 of Dec. 2014, FOCUS Surface Water Report SANCO/4802/2001 rev. 2, FOCUS (2015): Generic guidance for FOCUS surface water scenarios v 1.4, FOCUS (2007a): Landscape And Mitigation Factors In Aquatic Risk Assessment. Vol. 1, FOCUS (2007b): Landscape And Mitigation Factors In Aquatic Risk Assessment. Vol. 2, FOCUS Air (2008) SANCO/10553/2006 Rev. 2 June 2008
Deviations:	No
GLP:	No, not compulsory to PEC reports
Acceptability:	Yes

STEPS 3-4

Reference:	CP 9.2.5/2
Report	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its aquatic metabolites in surface water and sediment following application to cereals in Europe, Liebig, E., 2019 report No CALC-2343 2019/2034636 Authority registration No
Guideline(s):	FOCUS Degradation Kinetics (2006) SANCO/10058/2005 version 1.1 of December 2014, FOCUS Surface Water Report SANCO/4802/2001 rev. 2, FOCUS Surface Water (2015) Generic Guidance for FOCUS Surface Water Scenarios v1.4
Deviations:	No
GLP:	No, not compulsory to PEC reports
Acceptability:	Yes

Table 8.9-3: Input parameters related to active substance mefentrifluconazole and its metabolites for PEC_{sw/sed} calculations

Compound	Mefentrifluconazole	1,2,4-triazole	M750F003	M750F005	M750F006	M750F007	M750F008	Value in accordance to EU endpoint Reference
Molecular weight [g mol ⁻¹]	397.8	69.1	287.2	379.3	355.8	337.3	355.8	Yes EFSA (2018)
Saturated vapor pressure [Pa] (20°C)	3.2 x 10 ⁻⁶	- ^a	- ^a	- ^a 2.3 x 10 ⁻⁰⁹	- ^a 4.5 x 10 ⁻⁰⁸	- ^a 3.7 x 10 ⁻¹¹	- ^a 2.7 x 10 ⁻¹³	Yes EFSA (2018)
Water solubility [mg L ⁻¹] (20°C)	0.81	700000	1000 (conservative estimate)	1000 (conservative estimate)	1000 (conservative estimate)	1000 (conservative estimate)	1000 (conservative estimate)	Yes EFSA (2018)
Diffusion coefficient in water [m ² d ⁻¹]	4.3 x 10 ⁻⁵	- ^a	- ^a	- ^a 4.3 x 10 ⁻⁵	- ^a 4.3 x 10 ⁻⁵	- ^a 4.3 x 10 ⁻⁵	- ^a 4.3 x 10 ⁻⁵	Default
Diffusion coefficient in air [m ² d ⁻¹]	0.43	- ^a	- ^a	- ^a 0.43	- ^a 0.43	- ^a 0.43	- ^a 0.43	Default
K _{f,oc} [mL g ⁻¹]	3455.6 (geometric mean; n = 8)	83 (geometric mean; n = 4)	597.6 (QSAR estimate)	7863 (QSAR estimate)	4919 (QSAR estimate)	3938(QSAR estimate)	17240 (QSAR estimate)	Yes EFSA (2018) CRD (2014)
Freundlich exponent 1/n	0.975 (arithmetic mean; n = 8)	- ^a	- ^a	- ^a 0.9 (default)	- ^a 0.9 (default)	0.9 (default)	0.9 (default)	Yes EFSA (2018)
Plant Uptake [-]	0	- ^a	- ^a	- ^a 0	- ^a 0	0	0	Yes EFSA (2018))
Wash-off factor from crop [1 mm ⁻¹]	0.05 (MACRO) 0.50 (PRZM)	- ^a	- ^a	- ^a 0.05 (MACRO) 0.50 (PRZM)	- ^a 0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	Default
DT ₅₀ soil [d]	200 (geometric mean of field trials, normalized, n = 6)	60.5 (geometric mean of field studies, slow phase DFOP, n = 4)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes EFSA (2018) CRD (2014)

Table 8.9-3: Input parameters related to active substance mefentrifluconazole and its metabolites for PEC_{sw/sed} calculations

Compound	Mefentrifluconazole	1,2,4-triazole	M750F003	M750F005	M750F006	M750F007	M750F008	Value in accordance to EU endpoint Reference
DT ₅₀ water [d]	163.4 (geometric mean, whole system, n = 2) (Step 1 - 2), 1000 (default) (Step 3)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes EFSA (2018))
DT ₅₀ sediment [d]	163.4 (geometric mean, whole system level P-1, n = 2)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes ^b EFSA (2018)
DT ₅₀ whole system [d]	163.4 (geometric mean, n = 2)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes EFSA (2018))
Maximum occurrence observed [%]	- ^c	Soil: 5.1 Total w/s system: 15.1	Soil: 1.8 Total w/s system: 8.5	Soil: 0.001 ^d Photolysis study: 32.2	Soil: 0.001 ^d Photolysis study: 30.7	Soil: 0.001 ^d Photolysis study: 43.9	Soil: 0.001 ^d Photolysis study: 7.3	Yes EFSA (2018))
Formation fraction [-]	- ^c	- ^e	- ^e	Soil: 0 ^f Water: 1 (default) Sediment: 1 (default)	Soil: 0 ^f Water: 1 (default) Sediment: 1 (default)	Soil: 0 ^f Water: 1 (default) Sediment: 1 (default)	Soil: 0 ^f Water: 1 (default) Sediment: 1 (default)	Yes EFSA (2018)

DAT = Days after treatment

^a Not required for Steps 1-2

^b At Steps 2 the whole system DT₅₀ of 163.4 days was used both for the water and sediment compartment according to current FOCUS guideline

^c Not relevant for parent substance

^d Metabolite not detected in soil, Step1-2 needs value >0

^e Not relevant

^f Metabolite not detected in soil

Table 8.9-4: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for mefentrifluconazole following single/multiple application of 100 g a.s. ha⁻¹ to winter cereals

Scenario FOCUS	Waterbody / Season	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	21 d – PEC _{sw, twa} [µg L ⁻¹]	Max. PEC _{sed} [µg kg ⁻¹]
Step 1					
-	-	13.728 multiple	-	11.725 multiple	420.381 multiple
Step 2					
Northern Europe	March-May	2.216 multiple	-	2.020 multiple	72.548 multiple
Southern Europe	March-May	4.048 multiple	-	3.772 multiple	135.574 multiple
Step 3					
D1	Ditch	1.034 multiple	Drift	0.736 multiple	13.700 multiple
D1	Stream	0.561 single	Drift	0.459 multiple	7.076 multiple
D2	Ditch	1.625 multiple	Drainage	0.796 multiple	14.54 multiple
D2	Stream	1.015 multiple	Drainage	0.458 multiple	8.005 multiple
D3*	Ditch	0.632 single	Drift	0.061 multiple	0.510 multiple
D4*	Pond	0.049 multiple	Drainage	0.041 multiple	0.483 multiple
D4*	Stream	0.527 single	Drift	0.016 multiple	0.160 multiple
D5*	Pond	0.034 multiple	Drift	0.030 multiple	0.334 multiple
D5*	Stream	0.504 single	Drift	0.003 multiple	0.041 multiple
D6	Ditch	0.635 single	Drift	0.094 multiple	0.939 multiple
R1*	Pond	0.102 multiple	Runoff	0.094 multiple	1.361 multiple
R1*	Stream	0.454 multiple	Runoff	0.038 multiple	2.116 multiple
R3*	Stream	0.585 single	Drift	0.038 multiple	1.870 multiple
R4*	Stream	0.418 single	Drift	0.058 multiple	2.780 multiple

* Scenario relevant for the central zone.

Table 8.9-5: FOCUS Steps 1, 2 and 3 PEC_{sw} and PEC_{sed} for mefentrifluconazole following single/multiple application of 100 g a.s. ha⁻¹ to spring cereals

Scenario FOCUS	Waterbody / Season	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	21 d – PEC _{sw, twa} [µg L ⁻¹]	Max. PEC _{sed} [µg kg ⁻¹]
Step 1^a					
-	-	13.728 multiple	-	11.725 multiple	420.381 multiple
Step 2^a					
Northern Europe	March-May	2.216 multiple	-	2.020 multiple	72.548 multiple
Southern Europe	March-May	4.048 multiple	-	3.772 multiple	135.574 multiple
Step 3					
D1	Ditch	1.130 multiple	Drift	0.794 multiple	14.490 multiple
D1	Stream	0.564 single	Drift	0.427 multiple	7.656 multiple
D3*	Ditch	0.632 single	Drift	0.061 multiple	0.514 multiple
D4*	Pond	0.058 multiple	Drainage	0.049 multiple	0.537 multiple
D4*	Stream	0.517 single	Drift	0.02 multiple	0.196 multiple
D5*	Pond	0.032 multiple	Drift	0.028 multiple	0.318 multiple
D5*	Stream	0.531 single	Drift	0.003 multiple	0.036 multiple
R4*	Stream	0.418 single	Drift	0.064 multiple	2.842 multiple

^a At Steps 1 and 2 only the crop winter cereals was considered, representing the worst-case in the context of a risk envelope approach

* Scenario relevant for the central zone

Table 8.9-6: FOCUS Step 4 PEC_{sw} for mefentrifluconazole following single/twofold application of 100 g a.s. ha⁻¹ to winter cereals

PEC _{sw} [µg L ⁻¹]	Scenario	Step 4					
Nozzle reduction	Vegetated filter strip [m]	None	None	None	None	10	20
	No-spray buffer [m]	Edge-of- field	5	10	20	10	20
None	D1 ditch	1.034 multiple	0.824 multiple	0.824 multiple	0.824 multiple	0.824 multiple	0.824 multiple
50%		0.824 multiple	0.824 multiple	-	-	-	-
None	D1 stream	0.561 single	0.517 multiple	0.517 multiple	0.517 multiple	0.517 multiple	0.517 multiple
50%		0.517 multiple	0.517 multiple	-	-	-	-
None	D2 ditch	1.625 multiple	1.625 multiple	1.625 multiple	1.625 multiple	1.625 multiple	1.625 multiple
50%		1.625 multiple	1.625 multiple	-	-	-	-
None	D2 stream	1.015 multiple	1.015 multiple	1.015 multiple	1.015 multiple	1.015 multiple	1.015 multiple
50%		1.015 multiple	1.015 multiple	-	-	-	-
None	D3 ditch*	0.632 single	0.171 single	0.091 single	0.047 single	0.091 single	0.047 single
50%		0.316 single	0.086 single	-	-	-	-
None	D4 pond*	0.049 multiple	0.048 multiple	0.046 multiple	0.044 multiple	0.046 multiple	0.044 multiple
50%		0.045 multiple	0.045 multiple	-	-	-	-
None	D4 stream*	0.527 single	0.193 single	0.158 multiple	0.158 multiple	0.158 multiple	0.158 multiple
50%		0.264 single	0.158 multiple	-	-	-	-
None	D5 pond*	0.034 multiple	0.030 multiple	0.022 multiple	0.018 multiple	0.022 multiple	0.018 multiple
50%		0.019 multiple	0.018 multiple	-	-	-	-
None	D5 stream*	0.504 single	0.184 single	0.098 single	0.072 multiple	0.098 single	0.072 multiple
50%		0.252 single	0.092 single	-	-	-	-
None	D6 ditch	0.635 single	0.410 multiple	0.410 multiple	0.410 multiple	0.410 multiple	0.410 multiple
50%		0.410 multiple	0.410 multiple	-	-	-	-
None	R1 pond*	0.102 multiple	0.100 multiple	0.098 multiple	0.096 multiple	0.044 multiple	0.023 multiple
50%		0.097 multiple	0.096 multiple	-	-	-	-
None	R1 stream*	0.454 multiple	0.454 multiple	0.454 multiple	0.454 multiple	0.206 multiple	0.108 multiple

Table 8.9-6: FOCUS Step 4 PEC_{sw} for mefentrifluconazole following single/twofold application of 100 g a.s. ha⁻¹ to winter cereals

PEC _{sw} [µg L ⁻¹]	Scenario	Step 4					
Nozzle reduction	Vegetated filter strip [m]	None	None	None	None	10	20
	No-spray buffer [m]	Edge-of- field	5	10	20	10	20
50%		0.454 multiple	0.454 multiple	-	-	-	-
None	R3 stream *	0.585 single	0.516 multiple	0.516 multiple	0.516 multiple	0.236 multiple	0.124 multiple
50%		0.516 multiple	0.516 multiple	-	-	-	-
None	R4 stream *	0.418 single	0.362 multiple	0.362 multiple	0.362 multiple	0.165 multiple	0.086 multiple
50%		0.362 multiple	0.362 multiple	-	-	-	-

* Scenario relevant for the central zone.

Table 8.9-7: FOCUS Step 4 PEC_{sw} for mefentrifluconazole following single/twofold application of 100 g a.s. ha⁻¹ to spring cereals

PEC _{sw} [µg L ⁻¹]	Scenario	Step 4					
Nozzle reduction	Vegetated filter strip [m]	None	None	None	None	10	20
	No-spray buffer [m]	Edge-of-field	5	10	20	10	20
None	D1 ditch	1.130 multiple	0.814 multiple	0.814 multiple	0.814 multiple	0.814 multiple	0.814 multiple
50%		0.814 multiple	0.814 multiple	-	-	-	-
None	D1 stream	0.564 single	0.510 multiple	0.510 multiple	0.510 multiple	0.510 multiple	0.510 multiple
50%		0.510 multiple	0.510 multiple	-	-	-	-
None	D3 ditch *	0.632 single	0.171 single	0.091 single	0.047 single	0.091 single	0.047 single
50%		0.316 single	0.086 single	-	-	-	-
None	D4 pond *	0.058 multiple	0.057 multiple	0.056 multiple	0.054 multiple	0.056 multiple	0.054 multiple
50%		0.055 multiple	0.054 multiple	-	-	-	-
None	D4 stream *	0.517 single	0.192 multiple	0.192 multiple	0.192 multiple	0.192 multiple	0.192 multiple
50%		0.258 single	0.192 multiple	-	-	-	-
None	D5 pond *	0.032 multiple	0.028 multiple	0.020 multiple	0.015 multiple	0.020 multiple	0.015 multiple
50%		0.017 multiple	0.016 multiple	-	-	-	-
None	D5 stream *	0.531 single	0.194 single	0.103 single	0.060 multiple	0.103 single	0.060 multiple
50%		0.265 single	0.097 single	-	-	-	-
None	R4 stream *	0.418 single	0.397 multiple	0.397 multiple	0.397 multiple	0.181 multiple	0.095 multiple
50%		0.397 multiple	0.397 multiple	-	-	-	-

* Scenario relevant for the central zone.

Metabolites of mefentrifluconazole

Table 8.9-8:: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for the metabolites of mefentrifluconazole following single/twofold application of mefentrifluconazole to winter and spring cereals (100 g a.s. ha⁻¹)

Scenario FOCUS	Season	Max PEC _{sw} [µg L ⁻¹]	Max PEC _{sed} [µg kg ⁻¹]
1,2,4-triazole			
Step 1	-	2.154 multiple	1.783 multiple
Step 2			
Northern Europe	Mar-May	0.357 multiple	0.295 multiple
Southern Europe	Mar-May	0.675 multiple	0.559 multiple
M750F003			
Step 1	-	2.872 multiple	16.854 multiple
Step 2			
Northern Europe	Mar-May	0.492 multiple	2.881 multiple
Southern Europe	Mar-May	0.920 multiple	5.434 multiple
M750F005			
Step 1	-	2.347 multiple	143.931 multiple
Step 2			
Northern Europe	Mar-May	0.339 multiple	24.968 multiple
Southern Europe	Mar-May	0.613 multiple	46.547 multiple
M750F006			
Step 1	-	2.927 multiple	122.329 multiple
Step 2			
Northern Europe	Mar-May	0.457 multiple	21.220 multiple
Southern Europe	Mar-May	0.830 multiple	39.560 multiple
M750F007			
Step 1	-	4.655 multiple	160.566 multiple
Step 2			

Table 8.9-8:: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for the metabolites of mefentrifluconazole following single/twofold application of mefentrifluconazole to winter and spring cereals (100 g a.s. ha⁻¹)

Scenario FOCUS	Season	Max PEC _{sw} [µg L ⁻¹]	Max PEC _{sed} [µg kg ⁻¹]
Northern Europe	Mar-May	0.747 multiple	27.853 multiple
Southern Europe	Mar-May	1.358 multiple	51.926 multiple
M750F008			
Step 1	-	0.302 multiple	32.129 multiple
Northern Europe	Mar-May	0.060 single	5.573 multiple
Southern Europe	Mar-May	0.063 multiple	10.390 multiple

STEP 3

Metabolite M750F005

Table 8.9-9: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F005 following single/ multiple application of 100 g a.s. ha⁻¹ to spring cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.017 multiple	Drainage	4.395 multiple
D1	stream	0.002 multiple	Drainage	1.980 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.046 multiple
D4	pond	<0.001 single + multiple	Drainage	0.134 multiple
D4	stream	<0.001 single + multiple	Drainage	0.010 multiple
D5	pond	0.001 multiple	Drainage	0.184 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
R4	stream	<0.001 single + multiple	Runoff	0.945 multiple

Table 8.9-10: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F005 following single/ multiple application of 100 g a.s. ha⁻¹ to winter cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.015 multiple	Drainage	4.012 multiple
D1	stream	0.002 multiple	Drainage	1.635 multiple
D2	ditch	0.016 multiple	Drainage	4.564 multiple
D2	stream	0.020 multiple	Drainage	2.767 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.045 multiple
D4	pond	<0.001 single + multiple	Drainage	0.129 multiple
D4	stream	<0.001 single + multiple	Drainage	0.010 multiple
D5	pond	0.001 multiple	Drainage	0.196 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
D6	ditch	<0.001 single + multiple	Drainage	0.174 multiple
R1	pond	0.003 multiple	Runoff	0.452 multiple
R1	stream	<0.001 single + multiple	Runoff	0.658 multiple
R3	stream	0.002 multiple	Runoff	0.634 multiple
R4	stream	<0.001 single + multiple	Runoff	0.901 multiple

Metabolite M750F006

Table 8.9-11: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F006 following single/ multiple application of 100 g a.s. ha⁻¹ to spring cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.021 multiple	Drainage	3.750 multiple
D1	stream	0.002 multiple	Drainage	1.686 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.040 multiple
D4	pond	<0.001 single + multiple	Drainage	0.116 multiple
D4	stream	<0.001 single + multiple	Drainage	0.009 multiple
D5	pond	0.001 multiple	Drainage	0.160 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
R4	stream	<0.001 single + multiple	Runoff	0.849 multiple

Table 8.9-12: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F006 following single/ multiple application of 100 g a.s. ha⁻¹ to winter cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.019 multiple	Drainage	3.432 multiple
D1	stream	0.002 multiple	Drainage	1.396 multiple
D2	ditch	0.019 multiple	Drainage	3.911 multiple
D2	stream	0.019 multiple	Drainage	2.327 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.039 multiple
D4	pond	<0.001 single + multiple	Drainage	0.112 multiple
D4	stream	<0.001 single + multiple	Drainage	0.008 multiple
D5	pond	0.001 multiple	Drainage	0.171 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
D6	ditch	<0.001 multiple	Drainage	0.149 multiple
R1	pond	0.003 multiple	Runoff	0.391 multiple
R1	stream	<0.001 single + multiple	Runoff	0.589 multiple
R3	stream	0.002 multiple	Runoff	0.565 multiple
R4	stream	<0.001 single + multiple	Runoff	0.809 multiple

Metabolite M750F007

Table 8.9-13: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F007 following single/ multiple application of 100 g a.s. ha⁻¹ to spring cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.023 multiple	Drainage	3.383 multiple
D1	stream	0.002 multiple	Drainage	1.520 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.036 multiple
D4	pond	<0.001 single + multiple	Drainage	0.106 multiple
D4	stream	<0.001 single + multiple	Drainage	0.008 multiple
D5	pond	0.001 multiple	Drainage	0.146 multiple
D5	stream	<0.001 single + multiple	Drift	0.003 multiple
R4	stream	<0.001 single + multiple	Runoff	0.784 multiple

Table 8.9-14: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F007 following single/ multiple application of 100 g a.s. ha⁻¹ to winter cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.021 multiple	Drainage	3.101 multiple
D1	stream	0.002 multiple	Drainage	1.260 multiple
D2	ditch	0.020 multiple	Drainage	3.537 multiple
D2	stream	0.018 multiple	Drainage	2.089 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.036 multiple
D4	pond	<0.001 single + multiple	Drainage	0.102 multiple
D4	stream	<0.001 single + multiple	Drainage	0.008 multiple
D5	pond	0.001 multiple	Drainage	0.156 multiple
D5	stream	<0.001 single + multiple	Drift	0.003 multiple
D6	ditch	<0.001 single + multiple	Drainage	0.136 multiple
R1	pond	0.003 multiple	Runoff	0.355 multiple
R1	stream	<0.001 single + multiple	Runoff	0.542 multiple
R3	stream	0.002 multiple	Runoff	0.521 multiple
R4	stream	<0.001 single + multiple	Runoff	0.748 multiple

Metabolite M750F008

Table 8.9-15: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F008 following single/ multiple application of 100 g a.s. ha⁻¹ to spring cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.009 multiple	Drainage	4.699 multiple
D1	stream	0.002 multiple	Drainage	2.126 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.048 multiple
D4	pond	<0.001 single + multiple	Drainage	0.138 multiple
D4	stream	<0.001 single + multiple	Drainage	0.011 multiple
D5	pond	<0.001 single + multiple	Drainage	0.190 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
R4	stream	<0.001 single + multiple	Runoff	0.931 multiple

Table 8.9-16: FOCUS Steps 3 PEC_{sw} and PEC_{sed} for M750F008 following single/ multiple application of 100 g a.s. ha⁻¹ to winter cereals

FOCUS scenario	Waterbody	Max. PEC _{sw} [µg L ⁻¹]	Dominant entry route	Max. PEC _{sed} [µg kg ⁻¹]
D1	ditch	0.008 multiple	Drainage	4.268 multiple
D1	stream	0.002 multiple	Drainage	1.748 multiple
D2	ditch	0.009 multiple	Drainage	4.851 multiple
D2	stream	0.018 multiple	Drainage	3.059 multiple
D3	ditch	<0.001 single + multiple	Drainage	0.048 multiple
D4	pond	<0.001 single + multiple	Drainage	0.134 multiple
D4	stream	<0.001 single + multiple	Drainage	0.010 multiple
D5	pond	<0.001 single + multiple	Drainage	0.202 multiple
D5	stream	<0.001 single + multiple	Drift	0.004 multiple
D6	ditch	<0.001 single + multiple	Drainage	0.185 multiple
R1	pond	0.002 multiple	Runoff	0.470 multiple
R1	stream	<0.001 single + multiple	Runoff	0.651 multiple
R3	stream	0.002 multiple	Runoff	0.630 multiple
R4	stream	<0.001 single + multiple	Runoff	0.887 multiple

8.9.2.2 Kresoxim-methyl and its metabolites

Comments of zRMS:	<p>The submitted report was accepted.</p> <p>In PECsw assessment the EU agreed endpoints were used.</p> <p>The PECsw assessment was conducted with recommended FOCUS surface water models (Step 1& 2, Step 3 and Step 4).</p> <p>The mitigation measures were proposed: 5m of non-sprayed buffer zone and 10m of vegetative buffer zone with 10 m non sprayed buffer zone.</p>
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Reference: CP 9.2.5/3

Report Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals

Kiener T., 2020

report No CALC-2412 (BASF SE)

BASF DocID 2020/2036242

Authority registration No

Guideline(s): FOCUS Kinetics (2006) SANCO/10058/2005 v 2.0
 FOCUS (2014) Generic guidance for FOCUS Kinetics, v 1.1
 FOCUS Groundwater (2000) Sanco/321/2000
 FOCUS Groundwater (2009) Sanco/13144/2010 v3 of 2014
 FOCUS Groundwater (2014) GG for Tier 1 FOCUS GW Assessments, v 2.2
 FOCUS Surface Water (2001) SANCO/4802/2001-rev.2 final (May 2003)
 FOCUS (2015) Generic guidance for FOCUS surface water scenarios, v1.4
 FOCUS (2007) Landscape and Mitigation factors in aquatic risk assessment, Vol. 1&2

Deviations: No

GLP: No, not compulsory for PEC reports.

Acceptability: Yes

Table 8.9-17: Input parameters for kresoxim-methyl and its metabolites for PEC_{sw/sed} calculations at Steps 1–4 (only Steps 1–2 for metabolites)

Compound	Kresoxim-methyl	BF 490-1	BF 490-5	Reference
Molecular weight (g/mol)	313.3	299.3	329.31	EFSA Conclusion (2010)
Saturated vapour pressure (Pa)	2.3×10^{-6} (20°C)	not required for Step 1-2	not required for Step 1-2	EFSA Conclusion (2010)
Water solubility (mg/L)	2.0 (20°C)	90.1	100	EFSA Conclusion (2010)
Diffusion coefficient in water (m ² /d)	4.3×10^{-5} (default)	Not required for Step1+2	Not required for Step1+2	FOCUS recommendation
Diffusion coefficient in air (m ² /d)	0.43 (default)	Not required for Step1+2	Not required for Step1+2	FOCUS recommendation
K _{foc} (mL/g)	308 (arithmetic mean, n=4)	23.1 (lowest value from sigmoidal function, n=21)	3.32 (arithmetic mean, n=4)	EFSA Conclusion (2010)

Compound	Kresoxim-methyl	BF 490-1	BF 490-5	Reference
Freundlich exponent 1/n (-)	0.975 (arithmetic mean, n=4)	not required for Step 1-2	not required for Step 1-2	EFSA Conclusion (2010)
Plant uptake factor (-)	0	-	-	Worst case
Wash-Off factor from crop	0.05 l/mm (MACRO) 0.50 l/cm (PRZM)	Not required	Not required	FOCUS recommendation
DT _{50,soil} (d)	1.0 (conservative assumption)	8.8 (geomean field studies, normalized to pF2 and 20°C, n=10)	2.7 (geomean field studies, normalized to pF2 and 20°C, n=4)	EFSA Conclusion (2010)
DT _{50,water} (d) Step 2 and 3	Step 2: 1000 (default) Step 3: Case 1: 1000 (default) Case 2: 1.36 (slowest DT ₅₀ in whole system, n=2)	36 (from natural water photolysis study)	1000 (default)	EFSA Conclusion (2010)
DT _{50,sed} (d) Step 2 and 3	Step 2: 1.36 (slowest DT ₅₀ in whole system, n=2) Step 3: Case 1: 1.36 (slowest DT ₅₀ in whole system, n=2) Case 2: 1000 (default)	1000 (default)	1000 (default)	EFSA Conclusion (2010)
DT _{50,whole system} (d) Step 1	1.36 (slowest DT ₅₀ in whole system, n=2)	468.6 (slowest DT ₅₀ in whole system, n=2)	1000 (default)	EFSA Conclusion (2010)
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 11.3	Soil: 84 Total system: 81.2	Soil: 4.3 Total system: 0	EFSA Conclusion (2010)

PEC_{sw/sed}

Table 8.9-18: **FOCUS Step 1-4 PEC_{sw} and PEC_{sed} for kresoxim-methyl following multiple** applications of 150 g/ha to spring cereals - Case 1 - default / slowest DT50 (total system) of two systems**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	36.824	-	-	10.037	109.168
Step 2						
Northern Europe	Oct-Feb	1.856	-	-	1.270	3.873
	Mar-May	1.533	-	-	1.169	2.235
	Jun-Sep	1.533	-	-	1.169	2.235
Southern Europe	Oct-Feb	1.679	-	-	1.137	3.327
	Mar-May	1.679	-	-	1.137	3.327
	Jun-Sep	1.533	-	-	1.252	2.781
Step 3						
D1	ditch	1.363	02-Jul-1982	Spray drift	1.177	0.698
D1	stream	0.841*	17-Jun-1982	Spray drift	0.109*	0.233*
D3	ditch	0.951*	04-May-1992	Spray drift	0.157*	0.261*
D4	pond	0.044	04-Jul-1985	Spray drift	0.041	0.025
D4	stream	0.778*	30-May-1985	Spray drift	0.027	0.092
D5	pond	0.046	11-May-1978	Spray drift	0.044	0.031
D5	stream	0.799*	14-Apr-1978	Spray drift	0.009	0.039
R4	stream	1.782	15-May-1984	Runoff	0.36	0.491*
Step 4 – 5 m non-sprayed buffer zone						
D1	ditch	0.353	02-Jul-1982	Spray drift	0.305	0.184
D1	stream	0.307*	17-Jun-1982	Spray drift	0.04*	0.086*
D3	ditch	0.258*	04-May-1992	Spray drift	0.042*	0.072*
D4	pond	0.037	04-Jul-1985	Spray drift	0.039	0.022
D4	stream	0.284*	30-May-1985	Spray drift	0.005	0.033
D5	pond	0.04	11-May-1978	Spray drift	0.038	0.027
D5	stream	0.292*	14-Apr-1978	Spray drift	0.003	0.014
R4	stream	1.782	15-May-1984	Runoff	0.542	0.49

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 4 – 10 m non-sprayed vegetated buffer zone						
D1	ditch	0.184	02-Jul-1982	Spray drift	0.158	0.096
D1	stream	0.163*	17-Jun-1982	Spray drift	0.021*	0.046*
D3	ditch	0.137*	04-May-1992	Spray drift	0.022*	0.038*
D4	pond	0.027	04-Jul-1985	Spray drift	0.025	0.016
D4	stream	0.151*	30-May-1985	Spray drift	0.005	0.017
D5	pond	0.028	11-May-1978	Spray drift	0.027	0.019
D5	stream	0.155*	14-Apr-1978	Spray drift	0.002	0.007
R4	stream	0.805	15-May-1984	Runoff	0.164	0.22

* Maximum concentration results from single application

** Maximum of single and multiple calculations reported

Table 8.9-19: FOCUS Step 1-4 PEC_{sw} and PEC_{sed} for kresoxim-methyl following multiple applications of 150 g/ha to spring cereals - Case 2 - slowest DT50 (total system) of two systems / default**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	36.824	-	-	10.037	109.168
Step 2						
Northern Europe	Oct-Feb	1.856	-	-	1.270	3.873
	Mar-May	1.533	-	-	1.169	2.235
	Jun-Sep	1.533	-	-	1.169	2.235
Southern Europe	Oct-Feb	1.679	-	-	1.137	3.327
	Mar-May	1.679	-	-	1.137	3.327
	Jun-Sep	1.533	-	-	1.252	2.781
Step 3						
D1	ditch	0.962*	17-Jun-1982	Spray drift	0.432*	0.527
D1	stream	0.841*	17-Jun-1982	Spray drift	0.097*	0.236*
D3	ditch	0.951*	04-May-1992	Spray drift	0.124*	0.27
D4	pond	0.033*	30-May-1985	Spray drift	0.015*	0.016*
D4	stream	0.778*	30-May-1985	Spray drift	0.025	0.095
D5	pond	0.033*	14-Apr-1978	Spray drift	0.018*	0.019
D5	stream	0.799*	14-Apr-1978	Spray drift	0.008	0.041
R4	stream	1.771	15-May-1984	Runoff	0.357	0.538*
Step 4 – 5 m non-sprayed buffer zone						
D1	ditch	0.261*	17-Jun-1982	Spray drift	0.117*	0.144
D1	stream	0.307*	17-Jun-1982	Spray drift	0.035*	0.091*
D3	ditch	0.258*	04-May-1992	Spray drift	0.034*	0.071
D4	pond	0.028*	30-May-1985	Spray drift	0.013*	0.014*
D4	stream	0.284*	30-May-1985	Spray drift	0.009	0.034
D5	pond	0.028*	14-Apr-1978	Spray drift	0.016*	0.017
D5	stream	0.292*	14-Apr-1978	Spray drift	0.003	0.014
R4	stream	1.771	15-May-1984	Runoff	0.357	0.533

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 4 – 10 m non-sprayed vegetated buffer zone						
D1	ditch	0.138*	17-Jun-1982	Spray drift	0.062*	0.079
D1	stream	0.163*	17-Jun-1982	Spray drift	0.019*	0.052*
D3	ditch	0.137*	04-May-1992	Spray drift	0.018*	0.037
D4	pond	0.02*	30-May-1985	Spray drift	0.009*	0.01*
D4	stream	0.151*	30-May-1985	Spray drift	0.005	0.018
D5	pond	0.02*	14-Apr-1978	Spray drift	0.011*	0.012
D5	stream	0.155*	14-Apr-1978	Spray drift	0.002	0.008
R4	stream	0.799	15-May-1984	Runoff	0.162	0.237*

* Maximum concentration results from single application

** maximum of single and multiple calculations reported

Table 8.9-20: FOCUS Step 1-4 PEC_{sw} and PEC_{sed} for kresoxim-methyl following multiple applications of 150 g/ha to winter cereals- Case 1 - default / slowest DT50 (total system) of two systems**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	36.824	-	-	10.037	109.168
Step 2						
Northern Europe	Oct-Feb	1.856	-	-	1.270	3.873
	Mar-May	1.533	-	-	1.169	2.235
	Jun-Sep	1.533	-	-	1.169	2.235
Southern Europe	Oct-Feb	1.679	-	-	1.137	3.327
	Mar-May	1.679	-	-	1.137	3.327
	Jun-Sep	1.533	-	-	1.252	2.781
Step 3						
D1	ditch	1.363	02-Jul-1982	Spray drift	1.177	0.698
D1	stream	0.841*	17-Jun-1982	Spray drift	0.109*	0.233*
D2	ditch	0.962*	07-May-1986	Spray drift	0.834*	0.603*
D2	stream	0.85*	07-May-1986	Spray drift	0.718*	0.519*
D3	ditch	0.951*	04-May-1992	Spray drift	0.154*	0.259*
D4	pond	0.044	04-Jul-1985	Spray drift	0.042	0.025
D4	stream	0.793*	30-May-1985	Spray drift	0.029	0.098
D5	pond	0.049	22-Apr-1978	Spray drift	0.047	0.042
D5	stream	0.759*	08-Apr-1978	Spray drift	0.01	0.044
D6	ditch	0.955*	15-Mar-1986	Spray drift	0.366	0.367*
R1	pond	0.183	21-Jun-1984	Runoff	0.173	0.112
R1	stream	1.401	21-Jun-1984	Runoff	0.165	0.689
R3	stream	1.629	20-Apr-1980	Runoff	0.225	0.68
R4	stream	1.809	15-May-1984	Runoff	0.373	0.498
Step 4 – 5 m non-sprayed buffer zone						
D1	ditch	0.353	02-Jul-1982	Spray drift	0.304	0.23*
D1	stream	0.307*	17-Jun-1982	Spray drift	0.04*	0.159*
D2	ditch	0.261*	07-May-1986	Spray drift	0.226*	0.139
D2	stream	0.311*	07-May-1986	Spray drift	0.262*	0.166*
D3	ditch	0.258*	04-May-1992	Spray drift	0.042*	0.192*
D4	pond	0.038	04-Jul-1985	Spray drift	0.036	0.071*
D4	stream	0.29*	30-May-1985	Spray drift	0.01	0.035
D5	pond	0.042	22-Apr-1978	Spray drift	0.041	0.036
D5	stream	0.277*	08-Apr-1978	Spray drift	0.004	0.023*
D6	ditch	0.259*	15-Mar-1986	Spray drift	0.095	0.085

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
R1	pond	0.178	21-Jun-1984	Runoff	0.168	0.109
R1	stream	1.401	21-Jun-1984	Runoff	0.165	0.689
R3	stream	1.629	20-Apr-1980	Runoff	0.225	0.678
R4	stream	1.809	15-May-1984	Runoff	0.373	0.497
Step 4 – 10 m non-sprayed vegetated buffer zone						
D1	ditch	0.183	02-Jul-1982	Spray drift	0.158	0.096
D1	stream	0.163*	17-Jun-1982	Spray drift	0.021*	0.046*
D2	ditch	0.138*	07-May-1986	Spray drift	0.12*	0.088*
D2	stream	0.165*	07-May-1986	Spray drift	0.139*	0.102*
D3	ditch	0.137*	04-May-1992	Spray drift	0.022*	0.038*
D4	pond	0.027	04-Jul-1985	Spray drift	0.025	0.016
D4	stream	0.154*	30-May-1985	Spray drift	0.005	0.018
D5	pond	0.03	22-Apr-1978	Spray drift	0.029	0.026
D5	stream	0.147*	08-Apr-1978	Spray drift	0.002	0.008
D6	ditch	0.137*	15-Mar-1986	Spray drift	0.049	0.054*
R1	pond	0.081	21-Jun-1984	Runoff	0.077	0.05
R1	stream	0.637	21-Jun-1984	Runoff	0.075	0.233
R3	stream	0.743	20-Apr-1980	Runoff	0.104	0.268
R4	stream	0.816	15-May-1984	Runoff	0.17	0.223

* Maximum concentration results from single application

** maximum of single and multiple calculations reported

Table 8.9-21: **FOCUS Step 1-4 PEC_{sw} and PEC_{sed} for kresoxim-methyl following multiple** applications of 150 g/ha to winter cereals - Case 2 - slowest DT50 (total system) of two systems / default**

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Step 1	---	36.824	-	-	10.037	109.168
Step 2						
Northern Europe	Oct-Feb	1.856	-	-	1.270	3.873
	Mar-May	1.533	-	-	1.169	2.235
	Jun-Sep	1.533	-	-	1.169	2.235
Southern Europe	Oct-Feb	1.679	-	-	1.137	3.327
	Mar-May	1.679	-	-	1.137	3.327
	Jun-Sep	1.533	-	-	1.252	2.781
Step 3						
D1	ditch	0.962*	17-Jun-1982	Spray drift	0.432*	0.528
D1	stream	0.841*	17-Jun-1982	Spray drift	0.097*	0.236*
D2	ditch	0.962*	07-May-1986	Spray drift	0.456*	0.53
D2	stream	0.85*	07-May-1986	Spray drift	0.397*	0.407*
D3	ditch	0.951*	04-May-1992	Spray drift	0.122*	0.269
D4	pond	0.033*	30-May-1985	Spray drift	0.015*	0.016*
D4	stream	0.793*	30-May-1985	Spray drift	0.028	0.102
D5	pond	0.033*	08-Apr-1978	Spray drift	0.018*	0.026
D5	stream	0.759*	08-Apr-1978	Spray drift	0.01	0.046
D6	ditch	0.955*	15-Mar-1986	Spray drift	0.223*	0.353
R1	pond	0.124	21-Jun-1984	Runoff	0.053	0.082
R1	stream	1.396	21-Jun-1984	Runoff	0.164	0.802
R3	stream	1.626	20-Apr-1980	Runoff	0.224	0.755
R4	stream	1.797	15-May-1984	Runoff	0.37	0.564*
Step 4 – 5 m non-sprayed buffer zone						
D1	ditch	0.261*	17-Jun-1982	Spray drift	0.117*	0.145
D1	stream	0.307*	17-Jun-1982	Spray drift	0.035*	0.091*
D2	ditch	0.261*	07-May-1986	Spray drift	0.124*	0.14
D2	stream	0.311*	07-May-1986	Spray drift	0.145*	0.15*
D3	ditch	0.258*	04-May-1992	Spray drift	0.033*	0.071
D4	pond	0.028*	30-May-1985	Spray drift	0.013*	0.014*
D4	stream	0.29*	30-May-1985	Spray drift	0.01	0.036
D5	pond	0.028*	08-Apr-1978	Spray drift	0.016*	0.022
D5	stream	0.277*	08-Apr-1978	Spray drift	0.004	0.016
D6	ditch	0.259*	15-Mar-1986	Spray drift	0.06*	0.095*

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Date of max. PEC _{sw}	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
R1	pond	0.124	21-Jun-1984	Runoff	0.053	0.08
R1	stream	1.396	21-Jun-1984	Runoff	0.164	0.795
R3	stream	1.626	20-Apr-1980	Runoff	0.224	0.736
R4	stream	1.797	15-May-1984	Runoff	0.37	0.561*
Step 4 – 10 m non-sprayed vegetated buffer zone						
D1	ditch	0.138*	17-Jun-1982	Spray drift	0.062*	0.08
D1	stream	0.163*	17-Jun-1982	Spray drift	0.019*	0.051*
D2	ditch	0.138*	07-May-1986	Spray drift	0.065*	0.073
D2	stream	0.165*	07-May-1986	Spray drift	0.077*	0.08*
D3	ditch	0.137*	04-May-1992	Spray drift	0.018*	0.037
D4	pond	0.02*	30-May-1985	Spray drift	0.009*	0.01*
D4	stream	0.154*	30-May-1985	Spray drift	0.005	0.019
D5	pond	0.02*	08-Apr-1978	Spray drift	0.011*	0.016
D5	stream	0.147*	08-Apr-1978	Spray drift	0.002	0.008
D6	ditch	0.137*	15-Mar-1986	Spray drift	0.032*	0.051*
R1	pond	0.05	21-Jun-1984	Runoff	0.021	0.033
R1	stream	0.635	21-Jun-1984	Runoff	0.075	0.271
R3	stream	0.742	20-Apr-1980	Runoff	0.103	0.291
R4	stream	0.811	15-May-1984	Runoff	0.168	0.241

* Maximum concentration results from single application

** maximum of single and multiple calculations reported

Metabolites of kresoxim-methyl

Table 8.9-22: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for metabolites of kresoxim-methyl following multiple* applications of 150 g/ha to spring and winter cereals

Scenario FOCUS	Season	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
BF 490-1			
Step 1	---	155.243	35.793
Step 2			
Northern Europe	Oct-Feb	17.593	4.058
	Mar-May	7.948	1.831
	Jun-Sep	7.948	1.831
Southern Europe	Oct-Feb	14.378	3.316
	Mar-May	14.378	3.316
	Jun-Sep	11.163	2.574
BF 490-5			
Step 1	---	4.500	0.149
Step 2			
Northern Europe	Oct-Feb	0.331	0.011
	Mar-May	0.133	0.004
	Jun-Sep	0.133	0.004
Southern Europe	Oct-Feb	0.265	0.009
	Mar-May	0.265	0.009
	Jun-Sep	0.199	0.007

* Maximum of single and multiple calculations reported. All maxima result from multiple application.

8.9.2.3 **PEC_{sw/sed} of BAS 765 00 F**

The application rate in g/ha of the product BAS 765 00 F was calculated by multiplying the application rate of the product of 1.0 L/ha with the product density of 1083 g/L, resulting in an application rate of 1083 g/ha. Maximum initial concentrations in surface water for the formulation were calculated for entry via spray drift after a single application. FOCUS drift rates (water body 'stream') for cereals were chosen for calculating PEC_{sw} at different buffer distances for the surface water body (30 cm depth).

Table 8.9-23: PEC_{sw} (formulation) following single application of BAS 765 00 F

Entry pathway	No spray buffer zone (m)	Drift reduction by drift reducing nozzles (%)	PEC _{sw,ini} (µg/L)
Drift	1	0	6.958
	3		2.946
	5		1.886
	10		1.000

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

Table 8.10-1 Summary of atmospheric degradation and behaviour of mefentrifluconazole

Compound	Mefentrifluconazole
Direct photolysis in air	Not studied
Quantum yield of direct phototransformation	No data available
Photochemical oxidative degradation in air	DT ₅₀ : 19.995 hours (1.97 days) derived by the Atkinson model OH (12h) concentration assumed = $1.5 \times 10^6 \text{ mol cm}^{-3}$
Volatilisation	No data generated Vapour pressure [Pa]: 3.2×10^{-6} at 20°C Henry's Law Constant [$\text{Pa m}^3 \text{ mol}^{-1}$]: 1.6×10^{-3}
Metabolites	n.a.

The vapour pressure at 20 °C of the active substance mefentrifluconazole is $< 10^{-5}$ Pa. Therefore, mefentrifluconazole is regarded as non-volatile.

According to the EFSA Conclusion on mefentrifluconazole, route of exposure via air is not relevant for mefentrifluconazole [EFSA (European Food Safety Authority), 2018. *Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (Mefentrifluconazole)*. EFSA Journal 2018;16(7):5379, 32 pp. doi:10.2903/j.efsa.2018.5379]

Table 8.10-2 Summary of atmospheric degradation and behaviour of kresoxim-methyl

Compound	Kresoxim-methyl
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT ₅₀ (d): 0.28 d (12 h day) derived by the Atkinson model (AOPWIN version 1.88). $K_{OH} = 38.2 \times 10^{-12} \text{ cm}^3 \text{ molecule}^{-1} \text{ s}^{-1}$ OH (12h) concentration assumed = $1.5 \times 10^6 \text{ mol/cm}^3$
Volatilisation	Vapour pressure: 2.3×10^{-6} Pa (20 °C, 99.6%) Henry's Law Constant: $3.6 \times 10^{-4} \text{ Pa m}^3/\text{mol}$
Metabolites	None

The vapour pressure at 20 C of the active substance kresoxim-methyl is $< 10^{-5}$ Pa. Hence the active substance kresoxim-methyl is regarded as non-volatile.

Appendix 1 Lists of data considered in support of the evaluation

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 9.1.3/1	Mendez Gutierrez, A.	2018	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its metabolites in soil, surface water and sediment following application to cereals Europe considering endpoints according to Focus 2018/1099933 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	BASF
KCP 9.1.3/2	Kiener, T.	2020	Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals 2020/2036242 RIFCon GmbH, Hirschberg, Germany Fed.Rep. no Unpublished	No	BASF
KCP 9.2.4.1/1	Szegedi, K.	2017	Predicted environmental concentrations of M750F001 (1.2.4-triazole) in groundwater following application of BAS 750F to cereals using geometric mean Koc for both compounds 2017/1219165 BASF SE, Limburgerhof, Germany Fed.Rep. no 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 9.2.4.1/2	Kiener, T.	2020	Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals 2020/2036242 RIFCon GmbH, Hirschberg, Germany Fed.Rep. no Unpublished	No	BASF
KCP 9.2.5/1	Mendez Gutierrez, A.	2018	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its metabolites in soil, surface water and sediment following application to cereals Europe considering endpoints according to Focus 2018/1099933 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	BASF
KCP 9.2.5/2	Ward Liebig, E.	2019	Predicted environmental concentrations of BAS 750 F – Mefentrifluconazole and its aquatic metabolites in surface water and sediment following application to cereals in Europe 2019/2034636 Dr. Knoell Consult GmbH, Mannheim, Germany Fed.Rep. no Unpublished	No	BASF
KCP 9.2.5/3	Kiener, T.	2020	Predicted environmental concentrations of BAS 490 F – kresoxim-methyl and its metabolites in soil, groundwater, surface water and sediment following application to cereals 2020/2036242 RIFCon GmbH, Hirschberg, Germany Fed.Rep. no 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 studies are available

Appendix 2 Detailed evaluation of the new Annex II studies

No additional Annex II data was generated

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

All model input / output files will be provided to the zRMS