FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SHA 4300 A

Product name: MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

MS Finalisation date: 04/06/2024

Version history

When	What
February 2020	Dossier sent for evaluation
June 2020	Applicant update
June 2020	zRMS finalised evaluation
November 2023	Updated by Applicant
April 2024	Final version prepared by zRMS after Commenting period
June 2024	Final version prepared by zRMS after the second commenting period

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zRMS 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**
					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			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU	**Maize**	F	Broadleaved- and grass weeds	Foliar Spray	BBCH 10-14	a) 1 b) 1	n.r.	a) 1.5 b) 1.5	a) 0.150 b) 0.150	200-600	NA	(*) Weeds at early stages	
1	PL	**Maize**	F	Broadleaved and grass weeds	Foliar Spray	BBCH 10-14 (*)	a) 1 b) 1	N.A	a) 1.0* b) 1.0*	a) 100 b) 100	200-600	-	(*) Weeds at early stages	

* Use covered by dose 1.5 L/ha

Explanation for column 15 “Conclusion”

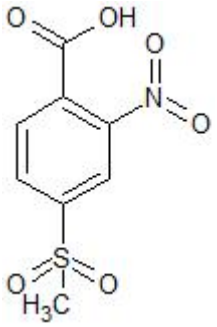
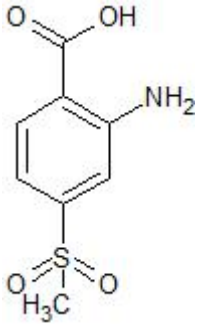
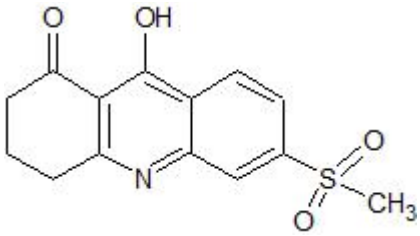
A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during approval of Mesotrione 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	NEU SEU CEU	Maize	F	Annual broadleaved weeds and some annual grasses such as *Echinochloa crusgalli*	Foliar spray	BBCH 12-18	application) 1 b) 1	-	-	a) 150 b) 150	200-400	n/a	-

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
MNBA	245	 4-(methylsulfonyl)-2-nitrobenzoic acid O=S(C)(=O)c1cc(c(cc1)C(=O)O)N(=O)=O	Soil: 57.2% Water/Sediment: 7.9%	PEC_{gw} / PEC_{soil} / $PEC_{sw/sed}$
AMBA	215	 2-amino-4-(methylsulfonyl)benzoic acid O=S(C)(=O)c1cc(N)c(cc1)C(=O)O	Soil: 9.7% Water/Sediment: 24.6%	PEC_{gw} / PEC_{soil} / $PEC_{sw/sed}$
SYN546974	291	 9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin-1(2H)-one CS(=O)(=O)c1cc2nc3CCCC(=O)c3c(O)c2cc1	Soil: 1 x 10^{-10}% Water/sediment: 33%	$PEC_{sw/sed}$

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)

Table 8.3.1-1: Summary of aerobic degradation rates for Mesotrione - laboratory studies

Mesotrione, Laboratory studies, aerobic conditions									
Soil type	**pH water**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa***	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n Reference**
Sandy loam (ERTC)	6.4	20	19[a]	11.6	38.5	8.2	18	SFO	y/EFSA Journal 2016;14(3):4419
Loam (Toulouse)	7.7	20	25[a]	4.3	14.3	4.0	16.4		
Clay loam (Pickett Piece)	7.1	20	28[a]	5.3	17.7	5.3	6.5		
Clay loam (721)	5.6	25	28[a]	20.2	67.1	32.3	4.1		
Silty clay loam (722)	5.7	25	30[a]	10.3	34.2	16.5	3.9		
Silt loam (723)	5.4	25	26[a]	17.6	58.5	28.2	3.4		
Loamy sand (724)	4.8	25	14[a]	23.8	78.9	31.1	4.3		
Loam (725)	5.8	25	25[a]	6.1	20.3	9.5	7.6		
Clay loam (727)	5.1	25	28[a]	20.8	69.2	32.4	6.4		
Sandy loam (728)	5.9	25	25[a]	7.2	24	9.7	5.6		
Silt loam (729)	5.6	25	26[b]	12.7	42.2	20.3	1.6		
Clay loam (730)	5.3	25	28[a]	17.1	56.9	26.9	8.9		
Silty Clay Loam (731)	6.1	25	30[a]	14.1	46.9	22.6	1.0		
Silty Clay Loam (732)	5.0	25	30[a]	14.0	46.4	22.4	5.3		
Silty Clay Loam (741)	5.7	25	30[a]	28.7	95.3	44.3	4.5		
Silty Clay Loam (742)	7.2	25	34.4[a]	9.7	32.1	15.5	5.5		
Silt Loam (Vispetto & Tovshteyn, 1997)	6.2	25	32.04[b]	13.2	44.0	14.68 Average DT_{50}ref of 15.5 & 13.9 days given identical soil descriptions in these 2 studies).	3.1		
Silt Loam (Subba-Rao, 1996)	6.2	25	32.04[b]	11.8	39.3		4.9		
Silt Loam (Miller, 1997)	6.1	20	32.04[b]	14.2	47.2	11.5	46		
Geometric mean/median						Not relevant as pH dependant			
pH dependent						Yes, dergradation increases with increasing pH DT_{50} y = -9.766 x pH + 77.692 r^2 0.4687 (non log)			

*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

[a]FOCUS default; [b]measured pF2

Table 8.3.1-2: Summary of aerobic degradation rates for MNBA - laboratory studies

MNBA, Laboratory studies, aerobic conditions									
Soil type	**pH water**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa***	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n Reference**
silty clay loamb (722)	5.7	25	30[a]	0.6	1.89	1.0	10	SFO	y/EFSA Journal 2016;14(3):4419
Loam (725)	5.8	25	25[a]	0.5	1.5	0.8	10.8		
sandy loam (728)	5.9	25	25[a]	5.1	16.97	6.9	3.1	Decline from peak	
silt loam (729)	5.6	25	26[b]	1.66	5.52	2.7	3.88	SFO	
clay loam (730)	5.3	25	28[a]	2.81	9.35	4.4	14.17		
silty clay loam (731)	6.1	25	30[a]	15.7	52.3	25.2	1.6		
sandy loam (ERTC)	6.4	20	19[a]	6.2	20.7	4.4	21.89	Decline from peak	
loam (Toulouse)	7.7	20	25[a]	5	16.65	4.6	13.08		
Silt loam Richmond (Subba-Rao, 1996)	6.2	25	32.04[b]	1.1	3.67	1.3	11.2	SFO	
Silt loam Richmond (Miller, 1997)	6.1	20	32.04[b]	6.3	21.03	5.1	20.13	Decline from peak	
Geometric mean (n=10)						3.4			
pH-dependency						No			

*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
[a]FOCUS default; [b]measured pF2

Table 8.3.1-3: Summary of aerobic degradation rates for AMBA - laboratory studies

AMBA, Laboratory studies, aerobic conditions									
Soil type	**pH water**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa***	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n Reference**
Wisborough	4.9	20	-	7.8	-	3.7	5.52	DFOP DT_{90}/3.32	y/EFSA Journal 2016;14(3):4419
Wisconsin	6.4	20	-	33	109	23.5	7.98	DFOP K2	
East Anglia	7.9	20	-	58.7	195	47.4	3.66	DFOP K2	
Spinks	6.7	20	-	10.2	34	9.7	6.94	FOMC	
Richmond	6.2	25	-	13.6	45.2	16.0	14.8	SFO	
Richmond	*6.1*	*20°*	-	*>1000*	*>1000*	*>1000***	*26.6*	*SFO*	

AMBA, Laboratory studies, aerobic conditions									
Soil type	**pH water**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa***	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n Reference**
Geometric mean (n=5)						14.5			
pH-dependency						No			

***) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7**
****Italics - outlier**

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3.2-1 Summary of aerobic degradation rates for AMBA - laboratory studies

Mesotrione, Laboratory studies, dark anaerobic conditions								
Soil type	**pH water**	**t.°C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C***	**St. (X^2)**	**Method of calculation**
Wisconsin silt loam cyclohexane-label	6.2	25°C	-	4 days	14 days	-	r^2=0.98	First order (linear least squares fit of natural log of concentration vs. Sampling interval)
Wisconsin silt loam phenyl-label	6.2	25°C	-	4 days	12 days	-	r^2=0.97	
Geometric mean/Median								

*) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

8.4 Field studies (KCP 9.1.1.2)

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

Table 8.4.1-1: Summary of aerobic degradation rates for Mesotrione - field studies

Mesotrione, Field studies – from original DAR								
Soil type	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**St. (χ^2)**	**Method of calculation**	**Evaluated on EU level y/n Reference**
clay loam (bare soil)	France	6.0	0-10	7	73	-	sqrt 1st order -linear regression	y/EFSA Journal 2016;14(3):4419
clay loam (bare soil)	Italy	6.1	0-10	5	59	-		
sandy loam (bare soil)	Italy	8.0	0-10	4	39	-		
sandy loam (bare soil)	Germany	6.2	0-10	7	78	-		
loam (bare soil)	Germany	5.8	0-10	/	/	-		
loam (bare soil)	Germany	7.0	0-10	3	36	-		
sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-		
Maximum (n=7)				7	78	-	-	-

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

According to the EU Review of Mesotrione, soil accumulation and plateau concentration are not triggered (same as initial PEC_{soil}). Soil accumulation testing is therefore not relevant.

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.

Table 8.5-1: Summary of soil adsorption/desorption for Mesotrione

Mesotrione						
Soil type	**OC (%)**	**pH**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Wisborough Green silty clay loam	2.63	5.1	4.46	171	0.902	y/EFSA Journal 2016;14(3):4419
Wisconsin silt loam	1.58	6.2	0.74	47	0.921	
Toulouse clay	1.79	6.5	1.25	70	0.915	
Garonne loam	1.03	7.8	0.15	14	0.971	
Visalia sandy loam	0.53	8.2	0.13	25	0.959	
Wisconsin silt loam	1.28	6.1	0.61	48	0.947	
ERTC sandy loam	0.58	6.4	0.33	57	0.950	
Pickett Piece clay loam	3.31	7.1	0.97	29	0.932	
Garonne loam	0.87	7.7	0.16	18	0.954	
Champaign (1:2 ratio) silty clay loam	3.0	4.4	6.16	354	0.94	
Arithmetic mean (n=10)				-	0.94	-
Worst case				14	-	-
pH-dependency				Yes, sorption decreases as pH increases. K_{foc} $y= 8583.4e^{-0.785x}$ (log) r^2 0.8977		

Table 8.5-2: Summary of soil adsorption/desorption for MNBA

MNBA						
Soil Type	**OC (%)**	**pH**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Wisborough Green silty clay loam	2.63	5.1	0.16	6.1	0.32	y/EFSA Journal 2016;14(3):4419
Wisconsin silt loam	1.58	6.2	0.05	3.2	0.61	

MNBA						
Soil Type	**OC (%)**	**pH**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
			Worst case	3.2	0.9[b]	-
			pH-dependency	No		

a) FOCUS default

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

AMBA						
Soil Type	**OC (%)**	**pH (-)**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Wisborough Green silty clay loam	2.63	5.1	3.2	122	0.83	y/EFSA Journal 2016;14(3):4419
Wisconsin silt loam	1.58	6.2	0.71	44.9	0.85	
Toulouse clay	1.79	6.5	0.91	51.0	0.85	
Garonne loam	1.03	7.8	0.18	18.1	0.82	
Visalia sandy loam	0.53	8.2	0.12	23.9	0.90	
			Arithmetic mean (if not pH dependent)	pH dependent (51.9)	0.85	-
			Worst case	18.1	-	-
			pH-dependency	Yes, sorption decreases as pH increases. K_{foc} $y = 1865e^{-0.563x}(\log)$ r^2 0.9062		

Table 8.5-4: Summary of soil adsorption/desorption for SYN546974

SYN546974						
Soil Type	**OC (%)**	**pH**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Gartenacker Loam	1.8	7.2	30.63	1702	0.82	y/EFSA Journal 2016;14(3):4419
18 Acres Sandy Clay Loam	2.2	5.7	220.07	10003	0.96	
Marysville Clay Loam	1.6	7.6	432.49	27031	0.96	
Sarpy Silt loam	1.7	6.5	376.10	22124	0.88	
Seven Springs Loamy sand	0.6	5.2	19.56	3260	0.84	
			Geometric mean (n=5)	8021	-	-

SYN546974						
Soil Type	**OC (%)**	**pH**	**K_f (mL/g)**	**K_{foc} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Artihmetic mean (n=5)				-	0.89	
pH-dependency				No		

8.5.1 Column leaching (KCP 9.1.2.1)

No data was provided during the EU Review of Mesotrione as considered as not required.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

No data was provided during the EU Review of Mesotrione as considered as not required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No data was provided during the EU Review of Mesotrione as considered as not required.

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

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.

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

Mesotrione Distribution (max. water 98.7% after 0d, max. sediment 4.3% after 1 day)								
Water/sediment system	**pH water**	**pH sed**	**DegT_{50} whole syst. (d)**	**Kinetic, Fit**	**DissT_{50} water (d)**	**Kinetic, Fit**	**Method of calculation**	**Evaluated on EU level y/n Reference**
Basing (Phenyl)	7.86	7.86	2.6	6.8	2.5	6.8	SFO	y/EFSA Journal 2016;14(3):4419
Basing (Cyclohexane)	7.86	7.86	4.2	13.3	4.2	13.3		
Virginia (Phenyl)	7.4	7.4	5.5	12.3	5.3	13.5		
Virginia (Cyclohexane)	7.4	7.4	7.2	14.4	7.0	13.4		
Calwich (Phenyl)	8.4/7.8 (aerobic/anaerobic)	7.6	6.6	4.5	6.7	3.4		
Swiss (Phenyl)	7.4/7.5 (aerobic/anaerobic)	6.1	11.1	3.5	11.0	3.3		
Geometric mean at 20°C[b] (n=6)		-	5.6	-	5.5	-	-	-

a) Normalized using a Q10 of 2.58

Table 8.6-2: Summary of observed metabolites

MNBA Water/sediment system	Max. in water/sediment 7.4 % after 3 d Max. in water 7.4 % after 3 d Max. in sediment <1 %	y/EFSA Journal 2016;14(3):4419

AMBA Water/sediment system	Max. in water/sediment 24.6 % after 46 d Max. in water 15.8 % after 46 d Max. in sediment 8.8 % after 46 d	
SYN546974 Water/sediment system	Max. in water/sediment 33 % after 29 d Max. in water 9.4 % after 29 d Max. in sediment 25.6 % after 102 d	

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

Evaluator's Comments:

Calculations of PEC_S for active substance its metabolites and formulation used for maize accepted.
In case of DT_{50} for metabolites it should be noted, that in EFSA Journal, 2016 there are DT_{50} values for both metabolites MNBA and AMBA: max 15.7 d and 57.8 d, respectively.

The relevant endpoints used for PECs assessment were agreed at the EU level.

The maximum PEC_S values for active substance and its metabolites are presented in following table:

Maize

Compound	PECs ini mg/kg soil
Mesotrione	0.150
MNBA	0.062
AMBA	0.009
Mighty formulation	1.5645

The Applicant has added a new application pattern of 100 g a.s/ha. The former application rate of 150 g a.s./ha covers the added one. No further assessment is required.

These values will be used in further risk assessment.

8.7.1 Justification for new endpoints

By proposing the longest laboratory DT_{50} (43.4 instead of 34.3) the applicant ensures that the resulting PEC values are very conservative. The other used endpoints are the same as the EU agreed endpoints.

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

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 150
Number of applications/interval	1/-
Crop interception (%)	25
Depth of soil layer (cm)	5 cm (worst case)

Table 8.7-2: Input parameter for Mesotrione and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n Reference
Mesotrione	339	-	43.4 d (DFOP, laboratory studies, normalized)	y/EFSA Journal 2016;14(3):4419
MNBA	245	57.2	n/a	
AMBA	215	9.7		

PEC_{soil} values for metabolites were calculated taking into account the molecular weight (MW) and the maximum amount of each metabolite formed aerobically in soil (%). The results of PEC_{soil} calculations are presented below.

8.7.2.1 Mesotrione and its metabolites

Table 8.7-3: PEC_{soil} for Mesotrione on maize

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.150	-
Short term	24h	0.148	0.149
	2d	0.145	0.148
	4d	0.141	0.145
Long term	7d	0.134	0.142
	14d	0.120	0.134
	21d	0.107	0.127
	28d	0.096	0.121
	50d	0.068	0.103
	100d	0.030	0.075
Plateau concentration (20 cm) after year		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

PEC_{soil} of metabolites

Metabolites' PEC_{soil} were assessed based on the parent's PEC_{soil}, 0.15 mg/kg for Mesotrione. PEC_{soil} values for the soil metabolites were calculated taking into account the molecular weight and the maximum amount of each metabolite formed aerobically in soil, thanks to the following equation:

PEC_{soil} = ($MW_{metabolite}$/ MW_{parent}) x (maximum% metabolite formation/100) x $PECsoil_{parent}$

Considering:

$MW_{metabolite}$ = 245 g/mol for NMBA and 215 g/mol for AMBA
MW_{parent} = 339 g/mol
Maximum% metabolite formation = 57.2 % for NMBA and 9.7% for AMBA
$PECsoil_{parent}$ = 0.15 mg/kg

Table 8.7-4: PEC_{soil} for MNBA on maize

PEC_{soil} (mg/kg)	Maize	
	Single application	
	Actual	TWA
Initial	0.062	-

Table 8.7-5: PEC_{soil} for AMBA on maize

PEC_{soil} (mg/kg)	Maize	
	Single application	
	Actual	TWA
Initial	0.009	-

8.7.2.2 PEC_{soil} of MIGHTY

Table 8.7-6: PEC_{soil} for MIGHTYon maize

Preparation	Application rate (g/ha)	PEC_{act} (mg/kg)	Tillage depth (cm)
MIGHTY	1564.5*	1.5645	5

***MIGHTY is applied as 1.5 L/ha, and specific density of MIGHTYis 1.043 g/ml (please refer to the Part C).**

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

Evaluator's Comments:	The submitted PECgw assessment for maize was accepted The recommended FOCUS PELMO, and FOCUS PEARL models and all parameters agreed at the EU level were used. The application date was accepted. The PECgw assessment were performed for: mesotrione DT_{50}'s in acid, neutral and alkline soils were used: 27.88 d, 14.2 d and 5.4 d, respectively and for the worst case. In case of pH dependence of sorption for active substance – the log fit values were taken for assessment, as they represent a worse case (lower K_{foc} values). For metabolite AMBA the K_{foc} values for linear and log fit do not differ significantly and use of log fit values does not affect final conclusion. In of PEC_{GW} calculations the factor PUF = 0 for active substance and its relevant metabolite were taken into consideration. The Applicant has added a new application pattern of 100 g a.s/ha. The former application rate of 150 g a.s./ha covers the added one. No further assessment is required. The maximum PEC_{GW} values for active substance were below the trigger value of 0.1

	µg/L.

8.8.1 Justification for new endpoints

Same endpoints as the EU agreed endpoints (EFSA Journal 2016;14(3):4419) were used.

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

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 150
Number of applications/interval (d)	1/-
Relative application date	1 day after emergence*
Crop interception (%)	25
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4 / FOCUS PELMO 5.5.3

***According to AppDate v2.01 (06/09/2016)**

Due to the pH dependency of Mesotrione, PEC calculations were performed with different pH to cover the whole potential cases. Calculations were performed using DT_{50} and K_{foc} values at pH 5.1, 6.5 and 7.9 and for worst case also.

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

Compound	**Mesotrione**	**MNBA**	**AMBA**	**Value in accordance with EU endpoint y/n/ Reference**
Molecular weight (g/mol)	339	245	215	y/EFSA Journal 2016;14(3):4419
Water solubility (mg/mol):	160 at 20°C	160 at 20°C	160 at 20°C	
Saturated vapour pressure (Pa):	0 at 20°C	0 at 20°C	0 at 20°C	
DT_{50} in soil (d)	4 (Worst case) 27.88 (linear fit, pH 5.1 value) 14.2 (linear fit, pH 6.5 value) 0.54 (linear fit, pH 7.9 value) (normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	3.4 (geomean of normailized at 20ºC and pF2, Q_{10} 2.58, lab studies, n=10)	14.5 (geomean of normailized at 20ºC and pF2, Q_{10} 2.58, lab studies, n=5)	
Transformation rate	0.173 (worst case) 0.0249 (pH 5.1 linear) 0.0488 (pH 6.5 linear) 1.2836 (pH 7.9 linear)	~~0.0478~~ 0.0510 to AMBA ~~0.1444~~ 0.1529 to CO_2	0.0478 to CO_2	
K_{foc} (mL/g)/K_{fom}	14 / 8.12 (Worst case) 156.7 / 90.9 (log fit,	3.2 / 1.86 (worst case)	18.1 / 10.5 (Worst case)	

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference
	pH 5.1 value) 52.2 / 30.3 (log fit, pH 6.5 value) 17.4 / 10.1 (log fit, pH 7.9 value)		105.61 / 61.3 (log fit, pH 5.1) 48.02 / 27.9 (log fit, pH 6.5) 21.8 / 12.7 (log fit, pH 7.9)	
1/n	0.97 (worst case) 0.94	1 (default, worst case)	0.82 (Worst case) 0.85	
Plant uptake factor	0	0	0	
Formation fraction	-	1.0 from Parent	0.25 from MNBA	

Table 8.8-3: PEC_{gw} for Mesotrione and metabolites on maize using worst case (Mesotrione DT_{50} of 4 days, Kfoc value for Mesotrione 14 l/kg, Kfoc value for AMBA 18.1 l/kg, with the corresponding 1/n values 0.97 and 0.82) with FOCUS PEARL 4.4.4/PELMO 5.5.3

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		FOCUS PEARL 4.4.4			FOCUS PELMO 5.5.3		
		Mesotrione	MNBA	AMBA	Mesotrione	MNBA	AMBA
Maize	Châteaudun	<0.001	<0.001	0.007	<0.001	<0.001	0.002
	Hamburg	0.001	0.010	0.027	<0.001	0.001	0.011
	Kremsmünster	<0.001	0.004	0.052	0.001	0.003	0.038
	Okehampton	0.001	0.010	0.074	0.003	0.020	0.074
	Piacenza	<0.001	<0.001	0.006	<0.001	0.002	0.009
	Porto	<0.001	<0.001	<0.001	<0.001	0.001	0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.8-4: PEC_{gw} for Mesotrione and metabolites on maize at pH 5.1 (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		FOCUS PEARL 4.4.4			FOCUS PELMO 5.5.3		
		Mesotrione	MNBA	AMBA	Mesotrione	MNBA	AMBA
Maize	Châteaudun	0.001	0.014	0.001	<0.001	0.009	0.001
	Hamburg	0.006	**0.170**	0.037	0.006	**0.167**	0.021
	Kremsmünster	0.003	0.035	0.005	0.003	0.044	0.005
	Okehampton	0.008	0.077	0.011	0.007	**0.100**	0.010
	Piacenza	0.005	0.020	0.004	0.008	0.031	0.006
	Porto	0.001	0.020	0.005	0.002	0.037	0.001

	Sevilla	<0.001	0.002	<0.001	<0.001	0.004	<0.001
	Thiva	<0.001	0.003	<0.001	<0.001	0.006	<0.001

Table 8.8-5: PEC$_{gw}$ for Mesotrione and metabolites on maize at pH 6.5 (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		FOCUS PEARL 4.4.4			FOCUS PELMO 5.5.3		
		Mesotrione	MNBA	AMBA	Mesotrione	MNBA	AMBA
Maize	Châteaudun	0.006	0.012	0.003	0.003	0.008	0.002
	Hamburg	0.023	0.093	0.036	0.016	0.065	0.019
	Kremsmünster	0.016	0.024	0.016	0.014	0.030	0.013
	Okehampton	0.036	0.058	0.028	0.039	0.062	0.023
	Piacenza	0.007	0.006	0.004	0.013	0.014	0.008
	Porto	0.002	0.004	<0.001	0.002	0.006	0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001	<0.001
	Thiva	0.001	0.002	<0.001	0.001	0.002	<0.001

Table 8.8-6: PEC$_{gw}$ for Mesotrione and metabolites on maize at pH 7.9 (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		FOCUS PEARL 4.4.4			FOCUS PELMO 5.5.3		
		Mesotrione	MNBA	AMBA	Mesotrione	MNBA	AMBA
Maize	Châteaudun	<0.001	<0.001	0.006	<0.001	<0.001	0.002
	Hamburg	<0.001	0.002	0.015	<0.001	<0.001	0.006
	Kremsmünster	<0.001	0.001	0.024	<0.001	0.001	0.023
	Okehampton	<0.001	0.005	0.036	<0.001	0.010	0.037
	Piacenza	<0.001	<0.001	0.006	<0.001	0.001	0.007
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

According to the simulations performed with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models, the maximum predicted concentrations in leachate water at 1m depth were ≤ 0.1 µg/L for Mesotrione and AMBA metabolite.

Table 8.8-7: Soil pH of FOCUS scenarios

FOCUS scenarios	Soil pH
Châteaudun	8
Hamburg	6.4
Jokioinen	6.2
Kremsmünster	7.7
Okehampton	5.8
Piacenza	7

Porto	4.9
Sevilla	7.3
Thiva	7.7

However, the MNBA metabolite exceeded the trigger of 0.1 µg/L in both models.

FOCUS PEARL:

0.170 µg/L in Hamburg at pH 5.1.

It should be taken into account that the Hamburg scenario pH value is 6.4 (Table 8.8-7); therefore, the endpoints used are not realistic for this pH. Hence, the actual PECgw value for MNBA must be considered at pH 6.5, being the value 0.093 µg/L for Hamburg.

FOCUS PELMO:

0.167 µg/L in Hamburg at pH 5.1.
0.100 µg/L in Okehampton at pH 5.1.

It should be taken into account that the Hamburg and Okehampton scenario pH values are 6.4 and 5.8 respectively (Table 8.8-7); therefore, the endpoints used are not realistic for these pH's. Hence, the actual PECgw values for MNBA must be considered at pH 6.5, being the PECgw value 0.065 µg/L for Hamburg.

As refinement for MNBA metabolite in Okehampton, the Mesotrione DT_{50} (21.05 d) and K_{foc} (90.43 L/kg) had been recalculated at pH 5.8 using the equations given in Tables 8.3.1-1 and 8.5-1 respectively and run FOCUS PELMO being the PEC gw value 0.092 µg//L.

Accordingly to the above mentioned rationales and refinements, the assessment of the relevance of metabolites in groundwater is not necessary.

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

Evaluator's Comments:

The submitted PECsw and PECsed calculations were accepted.

The recommended FOCUS models were used: FOCUS Step 1 & 2 and Step 3; mitigation measures were proposed in Step 4. No drift reduction techniques were proposed.
All used endpoints for active substance and its metabolites were agreed at the EU level. The application dates were accepted.

D1 and D2 scenarios are not relevant for Central Zone and were not taken into consideration.

The relevant mitigation measure will be proposed at Member State level.

Mesotrione. The max PECsw and relevant mitigation measure for Central zone and Poland are presented in the table below.

Linear fit

Crop	**Application rate g a.s./ha**	**Central Zone Max PEC_{sw} (µg/l)**		
		acidic	**neutral**	**alkaline**
Maize	1 x 150	20 m vegetative strip and 20 m non-spray buffer strip	20 m vegetative strip and 20 m non-spray buffer strip	10 m vegetative strip and 10 m non-spray buffer strip.

		1.211 R4 stream	1.388 R4 stream	0.432 R3 stream
		Poland Max PEC$_{sw}$ (µg/l)		
		acidic	**neutral**	**alkaline**
		10 m vegetative strip and 10 m non-spray buffer strip	10 m vegetative strip and 10 m non-spray buffer strip	5 m non-spray buffer strip
		1.084 R1 stream	0.837 R1 stream	0.258 D3 ditch

Log fit

Crop	**Application rate g a.s./ha**	**Central Zone Max PEC$_{sw}$ (µg/l)**		
		acidic	**neutral**	**alkaline**
Maize	1 x 150	20 m vegetative strip and 20 m non-spray buffer strip	20 m vegetative strip and 20 m non-spray buffer strip	10 m vegetative strip and 10 m non-spray buffer strip.
		1.289 R4 stream	1.492 R4 stream	0.350 R3 stream
		Poland Max PEC$_{sw}$ (µg/l)		
		acidic	**neutral**	**alkaline**
		10 m vegetative strip and 10 m non-spray buffer strip	10 m vegetative strip and 10 m non-spray buffer strip	5 m non-spray buffer strip
		1.085 R1 stream	0.677 R1 stream	0.258 D3 ditch

Metabolites of mesotrione. The max PECsw and PECsed in Step 1 in alkaline, neutral and acidic soils are presented in the table below:

Maize; log and linear fit.

Compound	**Step 1 Max PEC$_{sw}$ (µg/l)**	**Step 1 Max PEC$_{SED}$ (µg/kg)**
	acidic/neutral/alkaline	**acidic/neutral/alkaline**
MNBA	23.50	0.75
AMBA	9.80/10.44/**10.84**	**10.26**/6.13/2.35
SYN546974	1.60	99.8

For additional non-spray buffer zones, the drift exposure was assessed by evaluator using the Drift Calculator in SWASH model

	<table><tr><th>Crop</th><th>Application rate g prod/a.s./ha</th><th>No spray buffer (m)</th><th>Max PEC$_{sw}$ (µg/l)</th></tr><tr><td rowspan="2">**Maize**</td><td rowspan="2">1564.5</td><td>5</td><td>2.724</td></tr><tr><td>10</td><td>1.445</td></tr></table> The Applicant has added a new application pattern of 100 g a.s/ha. The former application rate of 150 g a.s./ha covers the added one. No further assessment is required. The relevant mitigation measure will be recommended in ecotoxicological section.

8.9.1 Justification for new endpoints

All EU agreed endpoints have been maintained (EFSA Journal 2016;14(3):4419).

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

Plant protection product	MIGHTY
Use No.	1
Crop	Maize
Application rate (kg as/ha)	Mesotrione: 0.15
Number of applications/interval (d)	1/-
Application window	March-May (relevant for STEP 1 and 2 only)
Application method	Ground spray
CAM (Chemical application method)	CAM 1 (appln soil linear)
Soil depth (cm)	4
Models used for calculation	FOCUS STEP 1&2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC$_{sw/sed}$ calculations for the application of MIGHTY

Crop	Scenario	Application window used in modelling*
Maize	D3	06 May – 05 Jun
	D4	11 May – 10 Jun
	D5	11 May – 10 Jun
	D6	21 April – 21 May
	R1	04 May – 03 Jun
	R2	02 May – 01 Jun
	R3	02 May – 01 Jun
	R4	11 Apr – 11 May

***One day after emergence, according to AppDate v2.01 (06/09/2016)**

8.9.2.1 Mesotrione and its metabolites

Table 8.9-3: Input parameters related to active substance Mesotrione and metabolites for $PEC_{sw/sed}$ calculations STEP 1/2 and 3/4

Compound	Mesotrione	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint y/n Reference
Molecular weight (g/mol)	339	245	215	291	y/EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	$1x10^{-10}$ (20°C)	$1x10^{-10}$ (20°C)	$1x10^{-10}$ (20°C)	$1x10^{-10}$ (20°C)	
Water solubility (mg/L)	160 (pH 7, 20°C)	160 (pH 7, 20°C)	160 (pH 7, 20°C)	160 (pH 7, 20°C)	
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	-	-	-	Default
Diffusion coefficient in air (m^2/d)	0.43	-	-	-	Default
K_{foc} (mL/g)	156.7 (Log fit, pH5.1 value) 52.2 (Log fit, pH 6.5 value) 17.4 (Log fit, pH7.9 value) 190.92 (Linear fit, pH 5.1 value) 87.01 (Linear fit, pH 6.5 value) 0 (Linear fit , pH 7.9 value)	3.2 (worst case)	105.6 (Log fit, pH5.1 value) 48.0 (Log fit, pH 6.5 value) 21.8 (Log fit, pH 7.9 value) 101.5 (Linear fit, pH 5.1 value) 59.7 (Linear fit, pH 6.5 value) 18.0 (Linear fit, pH 7.9 value)	8021 (geomean, n=5)	y/EFSA Journal 2016;14(3):4419
Freundlich Exponent 1/n	0.94	-	-	-	y/EFSA Journal 2016;14(3):4419
Plant Uptake	0	-	-	-	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	-	-	-	Default
$DT_{50,soil}$ (d)	27.88 (Linear fit, pH 5.1 value) 14.2 (Linear fit, pH 6.5 value) 0.54 (Linear fit, pH 7.9 value) (normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58)	3.4 (geomean of normailized at 20ºC and pF2, Q_{10} 2.58, lab studies, n=10)	14.5 (geomean of normailized at 20ºC and pF2, Q_{10} 2.58, lab studies, n=5)	0.1 (not observed in soil, default values used for Step 1/2)	y/EFSA Journal 2016;14(3):4419
$DT_{50,water}$ (d)	5.5 (Step 1+2) 5.6 (Step 3+4)	1000	1000	1000	

Compound	Mesotrione	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint y/n Reference
$DT_{50,sed}$ (d)	5.6 (Step 1+2) 1000 (Step 3+4)	1000	1000	1000	
$DT_{50,whole\ system}$ (d)	5.6	1000	1000	1000	
Maximum occurrence observed (% molar basis with respect to the parent)	Sediment: 4.3 (used for PEC_{sed} product calculation)	Soil: 57.2 Water: 7.9 Sediment: 7.9 Total system: 7.9	Soil: 9.7 Water: 24.6 Sediment: 24.6 Total system: 24.6	Soil: $1x10^{-10}$ (not observed in soil, default values used) Water: 33 Sediment: 33 Total system: 33	
Formation fraction in soil:	-	1.0 from parent	0.25 from MNBA	-	

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC_{sw} for Mesotrione following single application of MIGHTY to maize

Scenario FOCUS		Period (Step 2) Waterbody (Step 3)	Max PEC_{sw} (µg/L)*						Dominant entry route
Step 1		---	pH 5.1		pH 6.5		pH 7.9		-
			Log	Linear	Log	Linear	Log	Linear	
			42.74	41.23	48.13	46.18	50.25	51.38	Runoff + drainage
Step 2	Southern Europe	Oct - Feb	11.97	11.54	12.33	11.83	1.38		Runoff + drainage
		March - May							
		June - Sept	9.16	8.83	9.45	9.07			
	Northern Europe	Oct - Feb	14.77	14.24	15.22	14.59			
		March - May	6.35	6.13	6.56	6.30			
		June - Sept							
Step 3	D3	Ditch	**0.787**	**0.787**	**0.787**	**0.787**	**0.787**	**0.787**	Drainage
	D4	Pond	0.084	0.083	0.032	0.032	0.032	0.032	Drainage
	D4	Stream	0.678	0.676	0.676	0.675	0.674	0.674	Drainage
	D5	Pond	0.047	0.044	0.034	0.033	0.032	0.032	Drainage
	D5	Stream	0.689	0.684	0.679	0.678	0.672	0.672	Drainage
	D6	Ditch	**0.792**	**0.789**	**0.789**	**0.790**	**0.787**	**0.787**	Drainage
	R1	Pond	0.114	0.113	0.072	0.092	0.032	0.032	Runoff and erosion
	R1	Stream	**2.397**	**2.396**	**1.650**	**1.850**	0.541	0.535	Runoff and erosion
	R2	Stream	**1.813**	**1.551**	**3.277**	**2.479**	0.730	0.730	Runoff and erosion

Scenario FOCUS		Period (Step 2) Waterbody (Step 3)	Max PEC_{sw} (µg/L)*						Dominant entry route
	R3	Stream	**4.741**	**4.304**	**5.929**	**5.426**	**0.776**	**0.956**	Runoff and erosion
	R4	Stream	**5.411**	**5.083**	**6.261**	**5.827**	0.546	0.544	Runoff and erosion

***Scenarios where the trigger of TER are not met at step 3 are marked in bold and thus will be included in step 4**

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sed} for Mesotrione following single application of MIGHTY to maize

Scenario FOCUS		Period (Step 2) Waterbody (Step 3)	Max PEC_{sw} (µg/L)*						Dominant entry route
Step 1		---	pH 5.1		pH 6.5		pH 7.9		-
			Log	Linear	Log	Linear	Log	Linear	
			64.81	76.09	24.40	38.98	8.50	0.00	Runoff + drainage
Step 2	Southern Europe	Oct - Feb	18.37	21.58	6.30	10.07	0.14	0.00	Runoff + drainage
		March - May							
		June - Sept	13.97	16.41	4.79	7.67			
	Northern Europe	Oct - Feb	22.77	26.74	7.81	12.48			
		March - May	9.57	11.24	3.29	5.26			
		June - Sept							
Step 3	D3	Ditch	0.204	0.223	0.127	0.157	0.083	0.048	Drainage
	D4	Pond	0.159	0.169	0.021	0.021	0.010	0.005	Drainage
	D4	Stream	0.127	0.134	0.036	0.038	0.022	0.013	Drainage
	D5	Pond	0.094	0.094	0.029	0.033	0.010	0.005	Drainage
	D5	Stream	0.102	0.085	0.040	0.042	0.014	0.009	Drainage
	D6	Ditch	0.227	0.235	0.134	0.167	0.083	0.048	Drainage
	R1	Pond	0.125	0.145	0.045	0.072	0.012	0.006	Runoff and erosion
	R1	Stream	0.552	0.595	0.212	0.345	0.039	0.021	Runoff and erosion
	R2	Stream	0.487	0.460	0.524	0.502	0.025	0.017	Runoff and erosion
	R3	Stream	1.026	1.017	0.796	0.909	0.079	0.055	Runoff and erosion
	R4	Stream	1.486	1.529	1.053	1.224	0.056	0.035	Runoff and erosion

FOCUS Step 4

The scenarios chosen for step 4 calculations are the scenarios that doesn't pass the aquatic RAC value and have bold numbers in tables above.

As the substance has pH dependence it is very important to take in consideration the actual pH value for every FOCUS scenario, in the next table are reported the actual pH's ~~according to the worst case linear or logarithm Kfoc equation used and their respective pH's~~ (Table 8.9-6 (Generic guidance for FOCUS surface water scenarios v1.4 May 2015)).

Table 8.9-6: SWASH pH scenarios

Crop	Scenario	pH
Maize	D3	5.3
	D4	6.9
	D5	6.5
	D6	7.5
	R1	7.3
	R2	4.5
	R3	7.9
	R4	8.4

Table 8.9-7: Global maximum PEC_{sw} values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction	**Vegetative strip (m)**	**None**	**None**	**10**	**20**
	No spray buffer (m)	**None**	**5**	**10**	**20**
None	D3 ditch (pH 5.1) Linear	0.787	0.258	-	-
	D6 ditch (pH 7.9) Log	0.787	0.258	-	-
	D6 ditch (pH 7.9) Linear	0.787	0.258	-	-
	R1 stream (pH 6.5) Linear*	1.850	-	0.837	0.438
	R2 stream (pH 5.1) Log	1.813	-	0.800	0.414
	R3 stream (pH 7.9) Linear	0.956	-	0.432	-

***For R1 scenario PECsw at pH 6.5 instead of 7.9 has been chosen as worst case.**

The table above reports the worst cases according to the FOCUS scenarios actual pH's and realistic conditions, but the Polish Authorities have required to calculate at all pH for linear and log values that are not realistic field conditions, as example the Step 4 values at pH 5.1 and 6.5 in R3 don't make sense since the actual pH for R3 scenario is 7.9. The results are given in the next tables. Furthermore, the SWAN version used for this new step 4 calculations is v5.0.0 instead of 4.0.0.

Table 8.9-8: Global maximum PEC_{sw} values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 5.1 linear conditions

PEC_{sw} (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	**Vegetative strip (m)**	**None**	**None**	**10**	**20**
	No spray buffer (m)	**None**	**5**	**10**	**20**
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.792	0.260	-	-
	R1 stream	2.397	-	1.084	0.567
	R2 stream	1.813	-	0.685	-
	R3 stream	4.741	-	1.941	~~1.016~~

PECsw (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
					1.015
	R4 stream	5.411	-	~~2.130~~ 2.310	1.211

*Nozzles have not been used since doesn't work

Table 8.9-9: Global maximum PECsw values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 5.1 log conditions

PECsw (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.789	0.263	-	-
	R1 stream	2.396	-	1.085	0.567
	R2 stream	1.551	-	0.800	0.412
	R3 stream	4.304	-	2.139	1.119
	R4 stream	5.083	-	2.460	1.289

*Nozzles have not been used since doesn't work

Table 8.9-10: Global maximum PECsw values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 6.5 linear conditions

PECsw (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.789	0.261	-	-
	R1 stream	1.650	-	0.837	0.438
	R2 stream	3.277	-	1.094	0.567
	R3 stream	5.929	-	2.449	1.281
	R4 stream	6.261	-	2.648	1.388

*Nozzles have not been used since doesn't work

Table 8.9-11: Global maximum PEC_{sw} values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 6.5 log conditions

PEC_{sw} (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.790	0.260	-	-
	R1 stream	1.850	-	0.677	-
	R2 stream	2.479	-	1.446	~~0.748~~ 0.749
	R3 stream	5.426	-	2.677	1.400
	R4 stream	5.827	-	2.846	1.492

***Nozzles have not been used since doesn't work**

Table 8.9-12: Global maximum PEC_{sw} values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 7.9 linear conditions

PEC_{sw} (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.787	0.258	-	-
	R3 stream	0.776	-	0.432	-

***Nozzles have not been used since doesn't work**

Table 8.9-13: Global maximum PEC_{sw} values for Mesotrione, following single application of MIGHTY to maize according to the central EU zone GAP according to surface water Step 4 at pH 7.9 log conditions

PEC_{sw} (µg/L)	Scenario	STEP 3 Mesotrione	STEP 4 Mesotrione		
Nozzle reduction*	Vegetative strip (m)	None	None	10	20
	No spray buffer (m)	None	5	10	20
None	D3 ditch	0.787	0.258	-	-
	D6 ditch	0.787	0.258	-	-
	R3 stream	0.956	-	0.350	-

***Nozzles have not been used since doesn't work**

Metabolites of Mesotrione

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for MNBA following single application to maize

Scenario FOCUS		Season	Max PEC_{sw}(µg/L)						Max PEC_{sed} (µg/kg)					
			pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear	pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear
Step 1			23.50						0.75					
Step 2	SEU	Oct – Feb	3.71		3.64		2.94		0.12		0.12		0.09	
		Mar– May												
		Jun - Sep	2.80		2.75		2.23		0.09		0.09		0.07	
	NEU	Oct – Feb	4.46		4.37		3.50		0.14				0.11	
		Mar– May	1.83		1.79		1.45		0.06				0.05	
		Jun - Sep												

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for AMBA following single application to maize

Scenario FOCUS		Season	Max PEC_{sw} (µg/L)						Max PEC_{sed} (µg/kg)					
			pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear	pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear
Step 1			9.75	9.80	10.44	10.29	10.78	10.84	10.26	9.91	5.00	6.13	2.35	1.95
Step 2	SEU	Oct – Feb	2.72	2.73	2.73	2.69	0.96	0.97	2.86	2.77	1.31	1.60	0.21	0.17
		Mar– May												
		Jun - Sep	2.09	2.10	2.10	2.07	0.78	0.78	2.20	2.12	1.01	1.23	0.17	0.14
	NEU	Oct – Feb	3.35	3.37	3.36	3.32	1.15	1.16	3.53	3.41	1.61	1.97	0.25	0.21
		Mar– May	1.46	1.47	1.47	1.45	0.59	0.59	1.53	1.48	0.70	0.86	0.13	0.11
		Jun - Sep												

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for SYN546974 following single application to maize

Scenario FOCUS		Season	Max PEC_{sw}(µg/L)						Max PEC_{sed} (µg/kg)					
			pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear	pH 5.1 log	pH 5.1 linear	pH 6.5 log	pH 6.5 linear	pH 7.9 log	pH 7.9 linear
Step 1			1.60						99.76					
Step 2	SEU	Oct – Feb	0.39						29.04		26.63		2.84	
		Mar – May												
		Jun - Sep							22.45		20.64		2.80	
	NEU	Oct – Feb	0.39	0.46	0.42		0.39		15.85	35.63	32.62		2.89	
		Mar – May	0.39						15.85		14.65		2.76	
		Jun - Sep												

8.9.2.2 $PEC_{sw/sed}$ of MIGHTY

The PEC_{SW} for MIGHTY was calculated using the following equation:

$$PEC_{SW}\,(\mu g/L) = \frac{\%\,\text{Drift}_{90\text{th}\,\%ile} \times \text{Application rate}\,(g/ha)}{\text{Water depth (cm)} \times 10}$$

The application of MIGHTY is 1.5 L/ha, corresponding to 1564.5 g/ha. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PEC_{SW} value is presented in the table 8.9-11.

Table 8.9-11: PEC_{sw} for MIGHTY following single application to maize

Crop	Distance (m)	Drift (%)	Max PEC_{sw} (µg/l)
Maize	1	2.77	14.45

The PEC_{sed} for MIGHTY was calculated using the following equation:

$$PEC_{sed}\,(\mu g/kg\,dw) = \frac{\%\text{Drift}_{90^{th}\%ile} \times \text{Application rate (g/ha)} \times \%\text{ of Mesotrione in sediment}}{1000 \times \text{Sediment density (g/cm}^3) \times \text{Sediment height (cm)}}$$

The application of MIGHTY is 1.5 L/ha, corresponding to 1564.5 g/ha. The percentage of Mesotrione in the sediment is 4.3 The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm^3. The resulting maximum instantaneous PEC_{sed} value is presented in the table 8.9-12.

Table 8.9-12: PEC_{sed} for MIGHTY following single application to maize

Crop	Distance (m)	Drift (%)	% of Mesotrione in sediment	Max PEC_{sed} (µg/l)
Maize	1	2.77	4.3	2.87

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Mesotrione
Direct photolysis in air	No data requested.
Quantum yield of direct phototransformation **(Source : SANCO/1416/2001-Final)**	1.3×10^{-4} at pH 4 $< 4.6 \times 10^{-6}$ at pH 7 $< 1.6 \times 10^{-5}$ at pH 9
Photochemical oxidative degradation in air	DT_{50} (h): 17.635 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 OH/cm^3
Volatilisation	From plant surfaces (BBA guideline): < 10% after 24 hours From soil surfaces (BBA guideline): < 10% after 24 hours Vapour pressure (Pa): $< 5.7 \times 10^{-6}$ at 20°C Henry's Law Constant (Pa.m^3/mol): $>5.1 \times 10^{-7}$ at 20°C
Metabolites	Not relevant

The vapour pressure at 20 °C of the active substance Mesotrione is $< 10^{-5}$ Pa. Hence the active substance Mesotrione is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial

ecosystems by the active substance Mesotrione due to volatilization with subsequent deposition should not be considered.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Detailed evaluation of the new Annex II studies

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