FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: M-100SC-OR2-C

Product name(s): Juzan Extra 100 SC

Chemical active substance:

mesotrione, 100 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Poland

Applicant: CIECH Sarzyna S.A.

Submission date: 05.2022

MS Finalisation date: 12.2022; 05.2023

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Version history

When	What
May 2022	First submission of product authorization to Poland.
December 2022	Draft assessment performred by zRMS
May 2023	The final version of RR

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

zRMS comments: All comments and conclusions of the zRMS are presented in grey. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.

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. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop desti-nation / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [(f)]	**Conclusion** Groundwater
					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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize (ZEAMX)	F	Monotyledonous weeds (TTDMS); Dicotyledonous weeds (TTDSS)	spraying	BBCH 12 - 18	a) 1 b) 1	n.a.	a) 1,5 L/ha b) 1,5 L/ha	a) 150 g as/ha b) 150 g as/ha	200 / 400	n.a.	Dose range: 0,75 -1,5 l/ha	A
Minor uses according to Article 51 (zonal uses)														
2	PL	sugar maize (ZEAMS); Popcorn (ZEAME);	F	Monotyledonous weeds (TTDMS); Dicotyledonous weeds (TTDSS)	spraying	BBCH 12 - 18	a) 1 b) 1	n.a.	a) 1,5 L/ha b) 1,5 L/ha	a) 150 g as/ha b) 150 g as/ha	200 / 400	n.a.	Dose range: 0,75 -1,5 l/ha	A

*n.a – not applicable

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

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

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

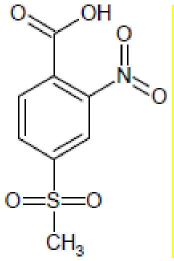
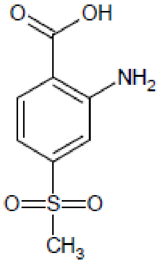
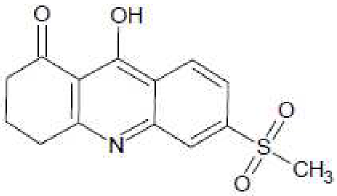
Table 8.1-2: Assessed (critical) uses during approval of mesotrione concerning the Section Environmental Fate

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		
	EU	Maize	F	annual broadleaved weeds and some annual grasses such as Echinochloa crus-galli	Foliar spray application using a hydraulic vehicle-mounted spray equipment	BBCH 12-18	1	N/A	1.2 – 1.5 L/ha	120 g as/ha – 150 g as/ha	200-400	Not applicable	

* 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

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
NOA437130 (MNBA) 4-(methylsulfonyl)-2-nitrobenzoic acid	245		Soil: > 10 % of a.s (aerobic laboratory degradation and soil photolysis studies) Water: > 5 % of a.s. in 1 measurement Sediment: < 5 % of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
NOA422848 (AMBA) 2-amino-4-(methylsulfonyl) benzoic acid	215		Soil: > 5% of a.s. in 2 sequential measurements (aerobic laboratory degradation studies and soil photolysis studies) Water: > 10 % of a.s. Sediment: > 5 % of a.s. in 2 sequential measurements	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
SYN546974 9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin-1(2H)-one	291		Soil: - Water: > 5 % of a.s. in 2 sequential measurements Sediment: > 10 % of a.s.	$PEC_{SW/SED}$: not covered by EU assessment

zRMS comment:

Information regarding mesotrione metabolites is in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419 and have been considered in the exposure assessment presented in this report.

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)

Studies on the aerobic degradation rates of mesotrione and its metabolites MNBA, AMBA are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of mesotrione (EFSA Journal, 2016).

8.3.1.1 Mesotrione and its metabolites

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

Mesotrione, Laboratory studies, aerobic conditions										
Soil name	**Soil type [a]**	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C, pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
ERTC	sandy loam	6.4	20	19[b]	11.6	38.5	8.2	18	SFO	Yes, EFSA (2016)
Toulouse	loam	7.7	20	25[b]	4.3	14.3	4.0	16.4	SFO	Yes, EFSA (2016)
Pickett Piece	clay loam	7.1	20	28[b]	5.3	17.7	5.3	6.5	SFO	Yes, EFSA (2016)
721	clay loam	5.6	25	28[b]	20.2	67.1	32.3	4.1	SFO	Yes, EFSA (2016)
722	silty clay loam	5.7	25	30[b]	10.3	34.2	16.5	3.9	SFO	Yes, EFSA (2016)
723	silt loam	5.4	25	26[b]	17.6	58.5	28.2	3.4	SFO	Yes, EFSA (2016)
724	loamy sand	4.8	25	14[b]	23.8	78.9	31.1	4.3	SFO	Yes, EFSA (2016)
725	loam	5.8	25	25[b]	6.1	20.3	9.5	7.6	SFO	Yes, EFSA (2016)
727	clay loam	5.1	25	28[b]	20.8	69.2	32.4	6.4	SFO	Yes, EFSA (2016)
728	sandy loam	5.9	25	25[b]	7.2	24	9.7	5.6	SFO	Yes, EFSA (2016)
729	silt loam	5.6	25	26[c]	12.7	42.2	20.3	1.6	SFO	Yes, EFSA (2016)
730	clay loam	5.3	25	28[b]	17.1	56.9	26.9	8.9	SFO	Yes, EFSA (2016)
731	silty clay loam	6.1	25	30[b]	14.1	46.9	22.6	1.0	SFO	Yes, EFSA (2016)
732	silty clay loam	5.0	25	30[b]	14.0	46.4	22.4	5.3	SFO	Yes, EFSA (2016)
741	silty clay loam	5.7	25	30[b]	28.7	95.3	44.3	4.5	SFO	Yes, EFSA (2016)
742	silty clay loam	7.2	25	34.4[c]	9.7	32.1	15.5	5.5	SFO	Yes, EFSA (2016)
Richmond (Vispetto & Tovshteyn, 1997)	silt loam	6.2	25	32.04[c]	13.2	44.0	14.68 (average DT_{50} of 15.5 & 13.9 d given identical soil descriptions in 2 studies)	3.1	SFO	Yes, EFSA (2016)
Richmond (Subba-Rao, 1996)	silt loam	6.2	25	32.04[c]	11.8	39.3		4.9	SFO	Yes, EFSA (2016)
Richmond (Miller, 1997)	silt loam	6.1	20	32.04[c]	14.2	47.2	11.5	4.6	SFO	Yes, EFSA (2016)
Geometric mean/Median (n=18)							---			
pH-dependency:							Yes - degradation increases with increasing pH. DT_{50} = -9.766 * pH + 77.692 r^2 = 0.4687 (non-log)			

[redacted]

a No details on test method available
b Obtained from the tabulated FOCUS default values (FOCUS 2014)

c measured at pF2

Table 8.3-2: Summary of aerobic degradation rates for MNBA - laboratory studies

MNBA, Laboratory studies, aerobic conditions										
Soil name	**Soil type** [a]	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C, pF2 / 10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
722	silty clay loam	5.7	25	30[c]	0.6	1.89	1.0	10	SFO	Yes, EFSA (2016)
725	loam	5.8	25	25[c]	0.5	1.5	0.8	10.8	SFO	Yes, EFSA (2016)
728	sandy loam	5.9	25	25[c]	5.1	16.97	6.9	3.1	SFO [b]	Yes, EFSA (2016)
729	silt loam	5.6	25	26[d]	1.66	5.52	2.7	3.88	SFO	Yes, EFSA (2016)
730	clay loam	5.3	25	28[c]	2.81	9.35	4.4	14.17	SFO	Yes, EFSA (2016)
731	silty clay loam	6.1	25	30[c]	15.7	52.3	25.2	1.6	SFO	Yes, EFSA (2016)
ERTC	sandy loam	6.4	20	19[c]	6.2	20.7	4.4	21.89	SFO [b]	Yes, EFSA (2016)
Toulouse	loam	7.7	20	25[c]	5	16.65	4.6	13.08	SFO [b]	Yes, EFSA (2016)
Richmond (Subba-Rao, 1996)	silt loam	6.2	25	32.04[d]	1.1	3.67	1.3	11.2	SFO	Yes, EFSA (2016)
Richmond (Miller, 1997)	silt loam	6.1	20	32.04[d]	6.3	21.03	5.1	20.13	SFO [b]	Yes, EFSA (2016)
Geometric mean/Median (n=10)							3.4			
pH-dependency:							No			

a No details on test method available
b Calculated from day of maximum formation (peak-down)
c Obtained from the tabulated FOCUS default values (FOCUS 2014)
d measured at pF2

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

AMBA, Laboratory studies, aerobic conditions										
Soil name	**Soil type** [a]	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C, pF2 / 10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Wisborough	clay	4.9	20	41.26	7.8	-	3.7	5.52	DFOP DT_{90}/3.32	Yes, EFSA (2016)
Wisconsin	silt loam	6.4	20	40.0	33	109	23.5	7.98	DFOP K_2	Yes, EFSA (2016)
East Anglia	sandy loam	7.9	20	34.94	58.7	195	47.4	3.66	DFOP K_2	Yes, EFSA (2016)
Spinks	loamy sand	6.7 [a]	20	-	10.2	34	9.7	6.94	FMOC	Yes, EFSA (2016)
Richmond	silt loam	6.2	25	32.04	13.6	45.2	16.0	14.8	SFO	Yes, EFSA (2016)
Richmond	*silt loam*	*6.1*	*20*	32.04	*> 1000*	*> 1000*	*> 1000*	*26.6*	*SFO*	Yes, EFSA (2016)
Geometric mean/Median (n=5)							14.5			
pH-dependency:							No			

[a] No details on test method available

zRMS comment:

Soil degradation data for mesotrione and its metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The intended product registration mainly foresees application in spring / summer in maize. In these seasons, anaerobic degradation is not considered a relevant breakdown process.

Table 8.3-3: Summary of anaerobic degradation rates for mesotrione - laboratory studies

Mesotrione, Laboratory studies, anaerobic conditions										
Soil name	**Soil type [a]**	**pH [a]**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2**	**Kinetic model**	**Evaluated on EU level / Reference**
Wisconsin cyclohexane-label	silt loam	6.2	25	---	4	14	---	0.98	first order (linear least squares fit of natural log of concentration vs. sampling interval)	Yes, EFSA (2016)
Wisconsin phenyl-label	silt loam	6.2	25	---	4	12	---	0.97	first order (linear least squares fit of natural log of concentration vs. sampling interval)	Yes, EFSA (2016)
Geometric mean/Median (n=2)							n.a.			
pH-dependency:							n.a.			

[a] No details on test method available

zRMS comment:

Anaerobic soil degradation data for mesotrione are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419

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)

8.4.1.1 Mesotrione and its metabolites

Studies on the field dissipation rates of mesotrione are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for the EU review of mesotrione (EFSA Journal, 2016). The data reproduced below are given for information however; the data have not been re-evaluated or considered for the risk assessment.

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for mesotrione - field studies: Triggering endpoints

Mesotrione, Field studies – Triggering endpoints									
Soil type [a]	**Location**	**pH [a]**	**Depth (cm)**	**DissT$_{50}$ (d) Actual**	**DissT$_{90}$ (d) Actual**	**Kinetic parameters**	**r^2**	**Kinetic model**	**Evaluated on EU level / Reference**
Clay loam (bare soil)	France	6.0	0-10	7	73	-	0.97	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Clay loam (bare soil)	Italy	6.1	0-10	5	59	-	0.93	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Sandy loam (bare soil)	Italy	8.0	0-10	4	39	-	0.92	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Sandy loam (bare soil)	Germany	6.2	0-10	7	78	-	0.95	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Loam (bare soil)	Germany	5.8	0-10	/	/	-	/	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Loam (bare soil)	Germany	7.0	0-10	3	36	-	0.96	Timme and Frehse (sqrt 1st order - linear regression)	Yes, EFSA (2016)
Sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-	0.91	Timme and Frehse (sqrt 1st order - linear regression)	Yes, RAR (2015)
Maximum (n=6)				---	---				

[a] *No details on test method available*

zRMS comment:

Field degradation data for mesotrione are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419.

Modelling endpoints

Modelling endpoints are not available for mesotrione or its metabolites.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Mesotrione

Following the proposed uses and given the rapid degradation observed in laboratory and field studies, only very low or negligible residues of mesotrione are expected following harvest or sowing of succeeding crops. Therefore, no soil accumulation testing is required.

zRMS comment:

Accumulation of mesotrione and its metabolites in soil is not expected due to lab DT$_{50}$ values <60 days.

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 Mesotrione and its metabolites

Studies on the mobility of mesotrione and its metabolites MNBA, AMBA and SYN546974 in soil are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of mesotrione, (EFSA Journal, 2016).

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

mesotrione							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H2O)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Wisborough Green	silty clay loam	2.63	5.1	4.46	171	0.902	Yes, EFSA (2016)
Wisconsin	silt loam	1.58	6.2	0.74	47	0.921	Yes, EFSA (2016)
Toulouse	clay	1.79	6.5	1.25	70	0.915	Yes, EFSA (2016)
Garonne	loam	1.03	7.8	0.15	14	0.971	Yes, EFSA (2016)
Visalia	sandy loam	0.53	8.2	0.13	25	0.959	Yes, EFSA (2016)
Wisconsin	silt loam	1.28	6.1	0.61	48	0.947	Yes, EFSA (2016)
ERTC	sandy loam	0.58	6.4	0.33	57	0.950	Yes, EFSA (2016)
Pickett Piece	clay loam	3.31	7.1	0.97	29	0.932	Yes, EFSA (2016)
Garonne	loam	0.87	7.7	0.16	19	0.954	Yes, EFSA (2016)
Champaign (1:2 ratio)	silty clay loam	3.0	4.4	6.16	354	0.94	Yes, EFSA (2016)
				Arithmetic mean (n=10)	-	0.94	
				worst case	14	-	
				pH-dependency	YES; sorption decreases as pH increases. KFOC = 8583.4 e-0.785 * pH r2 = 0.8977 (log)		

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

MNBA							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	silty clay loam	2.63	5.1	0.16	6.1	0.32	Yes, EFSA (2016)
Wisconsin	silt loam	1.58	6.2	0.05	3.2	0.61	Yes, EFSA (2016)
Worst case (n=2)					3.2	0.9 [a]	
pH-dependency					No		

[a] *FOCUS default*

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

AMBA							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	silty clay loam	2.63	5.1	3.2	122	0.83	Yes, EFSA (2016)
Wisconsin	silt loam	1.58	6.2	0.71	44.9	0.85	Yes, EFSA (2016)
Toulouse	clay	1.79	6.5	0.91	51.0	0.85	Yes, EFSA (2016)
Garonne	loam	1.03	7.8	0.18	18.1	0.82	Yes, EFSA (2016)
Visalia	sandy loam	0.53	8.2	0.12	23.9	0.90	Yes, EFSA (2016)
Arithmetic mean (n=5)					52.0	0.85	
Worst case (n=5)					18.1	---	
pH-dependency					Yes, sorption decreases as pH increases. $K_{FOC} = 1865\ e^{-0.563 * pH}$ $r^2 = 0.9062$ (log)		

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

SYN546974							
Soil name	**Soil type [a]**	**OC (%)**	**pH ($CaCl_2$)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	loam	1.8	7.2	30.63	1702	0.82	Yes, EFSA (2016)
18 Acres	sandy clay loam	2.2	5.7	220.07	10003	0.96	Yes, EFSA (2016)
Marysville	clay loam	1.6	7.6	432.49	27031	0.96	Yes, EFSA (2016)
Sarpy	silt loam	1.7	6.5	376.10	22124	0.88	Yes, EFSA (2016)
Seven Springs	loamy sand	0.6	5.2	19.56	3260	0.84	Yes, EFSA (2016)
Arithmetic mean (n=5)					13000	0.89	
pH-dependency					No		

[a] *No details on test method available*

zRMS comment:

Soil mobility data for mesotrione and its metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419.

8.5.2 Column leaching (KCP 9.1.2.1)

Not available, not requested. (EFSA Journal 2016;14(3):4419)

zRMS comment:

Information on column leaching is in line with conclusions derived at the EU level.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Not available, not requested. (EFSA Journal 2016;14(3):4419)

zRMS comment:

Information on lysimeter studies is in line with conclusions derived at the EU level.

8.5.4 Field leaching studies (KCP 9.1.2.3)

See point 8.5.2

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 Mesotrione and its metabolites

Studies on the mobility of mesotrione and its aquatic metabolites MNBA, AMBA and SYN546974 are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of mesotrione, (EFSA Journal, 2016).

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

Mesotrione Distribution (max. water 98.7 % after 0 d, max. sediment 4.3 % after 1 d)									
Water / sediment system (radiolabel)	pH water	pH sed.	$DegT_{50}$ whole syst. (d)	$DegT_{90}$ whole syst. (d) [b]	$DissT_{50}$ water (d)	$DissT_{90}$ water (d) [b]	$DissT_{50}$/ $DissT_{90}$ sed. (d)	Kinetic model	Evaluated on EU level / Reference
Basing (Phenyl)	7.86	7.86	2.6	8.6	2.5	8.3	n.a.	SFO	Yes, EFSA (2016)
Basing (Cyclohexane)	7.86	7.86	4.2	13.8	4.2	13.8	n.a.	SFO	Yes, EFSA (2016)
Virginia (Phenyl)	7.40	7.40	5.5	18.3	5.3	17.5	n.a.	SFO	Yes, EFSA (2016)
Virginia (Cyclohexane)	7.40	7.40	7.2	24.1	7.0	23.2	n.a.	SFO	Yes, EFSA (2016)
Calwich (Phenyl)	8.4/7.8 (aerobic/ anaerobic)	7.6	6.6	21.8	6.7	22.2	n.a.	SFO	Yes, EFSA (2016)
Swiss (Phenyl)	7.4/7.5 (aerobic / anaerobic)	6.1	11.1	36.7	11.0	37.0	n.a.	SFO	Yes, EFSA (2016)
Geometric mean (n=6) at 20 °C [a]			5.6	18.6	5.5	18.4	-		

[a] *normalized using a Q10 of 2.58*

[b] *values presented in the RAR of mesotrione (2015)*

Table 8.6-2: Summary of observed metabolites

MNBA Water/sediment **system**	Max. in water 7.4 % after 3 d (Virginia Water aerobic system, phenyl radiolabel) Max. in sediment < 1 % (Virginia Water aerobic system, phenyl radiolabel) Max. in total system 7.4 % after 3 d (Virginia Water aerobic system, phenyl radiolabel)	Yes, EFSA (2016)
AMBA Water/sediment **system**	Max. in water 15.8 % after 46 d (Calwich Abbey aerobic system, phenyl radiolabel) Max. in sediment 8.8 % after 46 d (Calwich Abbey aerobic system, phenyl radiolabel) Max. in total system 24.6 % after 46 d (Calwich Abbey aerobic system, phenyl radiolabel)	Yes, EFSA (2016)
SYN546974 Water/sediment **system**	Max. in water 9.4 % after 29 d (Swiss Lake aerobic system, phenyl radiolabel) Max. in sediment 25.6 % after 102 d, study end (Swiss Lake aerobic system, phenyl radiolabel) Max. in total system 33 % after 29 d (Swiss Lake aerobic system, phenyl radiolabel)	Yes, EFSA (2016)

zRMS comment:

Information on degradation of mesotrione and its metabolites in water/sediment systems is in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419.

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

8.7.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

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

For determination of the predicted environmental concentrations of the active substance and relevant metabolites in soil the following guideline was used: “Soil persistence models and EU registration” (The final report of the work of the Soil Modelling Work group of FOCUS).

Predicted Environmental Concentrations in soil (PEC_{soil}) for mesotrione and metabolites MNBA & AMBA were calculated using the same approach as used by the zRMS during the EU evaluation (EFSA, 2016), using the ESCAPE 2.0 software.

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

Use No.	1
Crop	Maize
BBCH	BBCH 12 - 18
Application rate (g as/ha)	Mesotrione; 150 g
Number of applications/interval	1/-
Crop interception (%)	25%
Depth of soil layer (relevant for plateauconcentration) (cm)	20 cm (tillage) (*not relevant for mesotrione)*

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Mesotrione	339.3	-	34.3	EFSA Journal 2016;14(3):4419
metabolite MNBA	245	57.2%	15.7 (max. lab., not normalised)	
metabolite AMBA	215	9.7%	58.7 (max. lab., not normalised)	

8.7.2.1 Mesotrione and its metabolites (MNBA & AMBA)

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

PEC_{soil} (mg/kg)		Maize; BBCH 12; CI 25%; application rate 150g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.1500	-	-	-
Short term	24h	0.1470	0.1485	-	-
	2d	0.1441	0.1470	-	-
	4d	0.1384	0.1441	-	-
Long term	7d	0.1302	0.1399	-	-
	14d	0.1130	0.1307	-	-
	21d	0.0981	0.1222	-	-
	28d	0.0852	0.1146	-	-
	42d	0.0642	0.1011	-	-
	50d	0.0546	0.0944	-	-
	100d	0.0199	0.0644	-	-
Plateau concentration		not relevant	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		not relevant	-	-	-

PEC_{soil} of metabolites

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

PEC_{soil} (mg/kg)		Maize; BBCH 12; CI 25%; application rate 150g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0620	-	-	-
Short term	24h	0.0593	0.0606	-	-

	2d	0.0567	0.0593	-	-
	4d	0.0519	0.0568	-	-
Long term	7d	0.0455	0.0533	-	-
	14d	0.0334	0.0462	-	-
	21d	0.0245	0.0404	-	-
	28d	0.0180	0.0356	-	-
	42d	0.0097	0.0282	-	-
	50d	0.0068	0.0250	-	-
	100d	0.0007	0.0139	-	-
Plateau concentration		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

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

PEC_{soil} (mg/kg)		Maize; BBCH 12; CI 25%; application rate 150g			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0092	-	-	-
Short term	24h	0.0091	0.0092	-	-
	2d	0.0090	0.0091	-	-
	4d	0.0088	0.0090	-	-
Long term	7d	0.0085	0.0088	-	-
	14d	0.0078	0.0085	-	-
	21d	0.0072	0.0082	-	-
	28d	0.0066	0.0079	-	-
	42d	0.0056	0.0073	-	-
	50d	0.0051	0.0070	-	-
	100d	0.0028	0.0054	-	-
Plateau concentration		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

8.7.2.2 PEC_{soil} of JUZAN EXTRA 100 SC

Table 8.7-6: PEC_{soil} for JUZAN EXTRA 100 SC on maize

Active substance/ reparation	Crop	Max. application rate (L/ha)	Application rate (g/ha)	Crop interception (%)	PEC_{act} (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
JUZAN EXTRA 100 SC	Maize	1.5	1567.5*	25	**1.57**	n/a	Not required	

* Based on the density of the formulation = 1.045 g/mL

zRMS comments:

The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific EFSA Journal 2016;14 (3):4419. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
It is noted that for mesotrione the maximum non-normalised laboratory DT_{50} of 34.3 days was recommended by the EFSA 2016;14 (3):4419 for calculation of the soil exposure. However, the maximum non-normalised laboratory DT_{50} **of 28.7 days** is reported in the LoEP.
The RMS accepted this DT_{50} 34.3 days due to no impact on initial PECsoil.

zRMS calculation of PECs for mesotrione with DT50 = 28.7d

Days after appl'n	PECsoil (mg/kg)	Time weighted average (mg/kg)
0	0,150	0,150
1	0,146	0,148
4	0,136	0,143
7	0,127	0,138
14	0,107	0,127
28	0,076	0,109
50	0,045	0,087
100	0,013	0,057
365	0,000	0,017

Due to lack of potential for accumulation in soil (DT_{50} <60 days for all considered compounds) the soil risk assessment is based on initial PEC_{soil} values. In addition to that, the evaluation of the risk of secondary poisoning based on 21 TWA PEC_{soil} was not triggered due to log Pow of all compounds being <3. Taking this into account, DT_{50} used in soil exposure has no impact on the risk assessment

The PEC_{soil} initial following values for active substance mesotrione and its metabolites and formulated product are accepted by the zRMS and may be used in the risk assessment for soil organisms:

<u>Mesotrione:</u> PECs = 0.1500 mg/kg
<u>MNBA</u>: PECs = 0.0620 mg/kg
<u>AMBA</u>: PECs = 0.009 mg/kg
<u>Formulation:</u> PECs = 1.57 mg/kg

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

8.8.1 Justification for new endpoints

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

The calculation of the predicted environmental concentrations in ground waters (PEC_{GW}) of mesotrione and relevant metabolites have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL and FOCUS PELMO. Calculation were performed for all FOCUS scenarios (if available).

Application scenarios which were considered for the simulations are summarised in below Tables.
The application dates for the individual crop were selected using the tool "AppDate 3.05" (current system version).

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

Use No.	1	2
Crop	Maize	Sugar maize
Modelling crop	Maize	
BBCH	BBCH 12 - 18	
Crop interception (%)	25%	
Application rate (g as/ha)	Mesotrione; 150 g	
Number of applications/interval (d)	1/-	
Frequency of application	annual	
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v 6.6.4 FOCUS MACRO v5.5.4	

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

Crop	Scenario	Application dates (absolute*)
Maize/ Sugar maize	Châteaudun	emergence +14 days (recommended by EFSA (2016))
	Hamburg	
	Kremsmünster	
	Okehampton	
	Piacenza	
	Porto	
	Sevilla	
	Thiva	

*The application dates for the individual crop
were selected using the tool "AppDate 3.05" (current system version).Mesotrione and its metabolites

Table 8.8-3: Input parameters related to active substance mesotrione and metabolites (MNBA & AMBA) for PEC_{gw} calculations

Compound	Mesotrione	metabolite MNBA	metabolite AMBA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	339.3	245	215	Yes, EFSA (2016)
Water solubility (g/mol): 20⁰C	160*	32400**	23000**	* Yes, EFSA (2016) ** Yes, RAR (2015)
Saturated vapour pressure (Pa): 20⁰C	0	0	0	Worst case assumption
DT_{50} in soil (d)	acidic soil a: 27.88 neutral soil b: 14.2 alkaline soil c: 5.4 0.54 (pH dependent: linear fit, lab. data, normalisation to pF2, 20 °C, n = 18)	3.4 (geomean, normalisation to pF2, 20°C, n = 10)	14.5 (geomean, normalization to pF2, 20°C, n = 5)	Yes, EFSA (2016)
K_{foc} (mL/g)/K_{fom}	acidic soil [a]: 156.7/90.89 neutral soil [b]: 52.2/30.28 alkaline soil [c]: 17.39/10.09 (pH dependent: log fit, n =10)	3.2/1.9 (pH independent, worst case, n=2)	acidic soil [a]: 105.6/61.3 neutral soil [b]: 48.02/27.9 alkaline soil [c]: 21.8/12.6 (pH dependent: log fit, n= 5)	Yes, EFSA (2016) KFOM calculated as KFOC/1.724
1/n	0.94 (arithmetic mean, n = 10 to be used for all pH scenarios)	0.9 FOCUS default	0.85 (arithmetic mean, n = 5 to be used for all pH scenarios)	Yes, EFSA (2016)
Plant uptake factor	0	0	0	Yes, EFSA (2016)
Formation fraction	-	1 from parent	0.25 from MNBA	Yes, EFSA (2016)

a Acid value for pH 5.1 (10th percentile of EU maize growing area)
b Neutral value for pH 6.5 (50th percentile of EU maize growing area)
c Alkaline value for pH 7.9 (90th percentile of EU maize growing area)

Table 8.8-4: PEC_{gw} for mesotrione and metabolites MNBA and AMBA on maize with FOCUS PELMO 6.6.4

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)								
		Mesotrione			MNBA			AMBA		
		pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Maize; 1x150 g a.s./ha; CI 25%; relative app.date; n.a. interval; BBCH 12										
Maize & Sugar maize, 1 x 150 g a.s/ha early postemergence	Châteaudun	0.000	0.003	0.000	0.006	0.007	0.000	0.000	0.001	0.003
	Hamburg	0.007	0.021	0.001	**0.131**	0.056	0.003	0.016	0.018	0.024
	Kremsmünster	0.003	0.017	0.002	0.032	0.027	0.004	0.003	0.012	0.038
	Okehampton	0.007	0.049	0.008	0.082	0.061	0.019	0.008	0.023	0.081
	Piacenza	0.009	0.015	0.000	0.029	0.014	0.001	0.005	0.009	0.014
	Porto	0.002	0.003	0.000	0.031	0.005	0.000	0.001	0.000	0.001

	Sevilla	0.000	0.000	0.000	0.002	0.000	0.000	0.000	0.000	0.000
	Thiva	0.000	0.001	0.000	0.004	0.002	0.000	0.000	0.000	0.000

Table 8.8-5: PEC$_{gw}$ for mesotrione and metabolites MNBA and AMBA on maize with FOCUS PEARL 5.5.5

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)								
		Mesotrione			MNBA			AMBA		
		pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Maize; 1x150 g a.s./ha; CI 25%; relative app.date; n.a. interval; BBCH 12										
Maize & Sugar maize, 1 x 150 g a.s/ha early postemergence	Châteaudun	0.000671	0.005680	0.000187	0.007397	0.008055	0.006489	0.000604	0.002294	0.000511
	Hamburg	0.006975	0.027193	0.003177	**0.106426**	0.074213	0.014311	0.025780	0.035583	0.058372
	Kremsmünster	0.003240	0.019680	0.001174	0.018915	0.020288	0.003480	0.003144	0.014467	0.039685
	Okehampton	0.008441	0.046739	0.006379	0.050192	0.048487	0.012505	0.007794	0.025152	0.090939
	Piacenza	0.005080	0.010516	0.000067	0.016432	0.006715	0.000161	0.004084	0.005534	0.009807
	Porto	0.001106	0.001886	0.000009	0.015390	0.002654	0.000035	0.000426	0.000209	0.000896
	Sevilla	0.000004	0.000070	0.000000	0.001243	0.000251	0.000000	0.000071	0.000021	0.000010
	Thiva	0.000159	0.001468	0.000006	0.001893	0.001702	0.000013	0.000065	0.000260	0.001369

Modelling was performed using PEARL 5.5.5 and PELMO 6.6.4. models. For mesotrione and metabolite AMBA calculated PECgw values were all below the threshold concentration of 0.1 µg/L for both crops (*Maize & Sugar maize*) at application rate of 150 a.s./ha.

For metabolite MNBA unacceptable leaching was observed for maize & sugar maize crops in scenario Hamburg using PEARL (0.106 µg/L) and PELMO (0.131 µg/L) models. The exceedance of the threshold concentration was also observed in acidic soils. Assessment of relevance of ground water metabolite is performed and presented in section 10 of dRR. No unacceptable leaching was observed in neutral and alkaline soils.

Table 8.8-6: PEC$_{gw}$ for mesotrione and metabolites MNBA and AMBA on maize with FOCUS MACRO 5.5.4

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)								
		Mesotrione			MNBA			AMBA		
		pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9	pH 5.1	pH 6.5	pH 7.9
Maize; 1x150 g a.s./ha; CI 25%; relative app.date; n.a. interval; BBCH 12										
Maize & Sugar maize, 1 x 150 g a.s/ha early postemergence	Châteaudun *(Julian day-135)*	0.000507	0.00211	< 0.001	0.00549	0.00401	0.000208	< 0.001	0.000152	0.000549

Results of MACRO modelling show that for mesotrione and metabolites MNBA & AMBA are not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses.

zRMS comment:

The modelling results PECgw are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in groundwater. All input parameters considered in the groundwater modelling for mesotrione and its metabolites were EU agreed values (EFSA Scientific Report (2007) 120, 1-91). In simulations PUF value of 0 was assumed for all compounds is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

PECgw for mesotrione and its metabolites AMBA and MNBA are below 0.1 µg/L for all modelled scenarios and for all application rate except PECgw for MNBA in Hamburg scenario.

As regards MNBA metabolite exceeds the threshold 0.1 µg/L in cases written above. Overall, on the basis of the available data it could be concluded that metabolite MNBA is not toxicologically relevant.

Therefore, no unacceptable risk of groundwater contamination is expected for the formulated product according to the intended uses.

The assessment relevance of the all metabolites in ground water according to SANCO/221/2000 –rev.10 document was reported in the dRR Part B10.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models

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

8.9.1 Justification for new endpoints

There are no deviations from the EU agreed endpoints.

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

The calculation of the predicted environmental concentrations in surface waters and water sediments (PEC_{SW} and PEC_{SED}) of mesotrione and the formulation have been assessed with a tiered approach (Steps 1 – 4) using FOCUS models. Reference to study – KCP 9.2.5.

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

Plant protection product	**Juzan Extra 100 SC**
Use No.	1-2
Crop	Maize
Application rate (kg as/ha)	Mesotrione: 150 g as/ha
Number of applications/interval (d)	1 /-
Application window	March - May (relevant for STEP 1 and 2 only)
Models used for calculation	Step 1 and 2: STEPS 1-2 in FOCUS v.3.2 Step 3: FOCUS SWASH v.5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOX-SWA v5.5.3 Step 4: SWAN v.5.0.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of Juzan Extra 100 SC

Crop	Scenario	Application window used in modelling
Maize 150 g as/ha	D3	12-May – 11-June
	D4	18-May – 17 June
	D5	15-May – 14 June
	R1	10 May – 9 June

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)	339.3	245	215	291	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	0 E-10 (at 20 °C)	Not required for step 1 + 2			EFSA Journal 2016;14(3):4419
Water solubility (mg/L)	160 at pH 7 and 20°C	160	160	160	EFSA Journal 2016;14(3):4419
Diffusion coefficient in water (m²/d)	4.3 x 10-5	Not required for step 1 + 2			default
Diffusion coefficient in air (m²/d)	0.43	Not required for step 1 + 2			default
K_{foc} (mL/g)	(pH dependent: log fit, n = 10) 156.7 – pH 5.1 52.2 – pH 6.5 17.4 – pH 7.9	3.2	18.0	27031	EFSA Journal 2016;14(3):4419
Freundlich Exponent 1/n	0.94 (arithmetic mean n = 10)	Not required for step 1 + 2			EFSA Journal 2016;14(3):4419
Plant Uptake	0	Not required for step 1 + 2			EFSA Journal 2016;14(3):4419
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	Not required for step 1 + 2			EFSA Journal 2016;14(3):4419
$DT_{50,soil}$ (d)	(pH dependent: linear fit, lab. data, normalisation to pF2, 20 °C, n = 18) 27.88 – pH 5.1 14.2 – pH 6.5 5.4 – pH 7.9	3.6	14.5	0.1	EFSA Journal 2016;14(3):4419
$DT_{50,water}$ (d)	5.5	1000	1000	1000	EFSA Journal

Compound	Mesotrione	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint y/n/ Reference
					2016;14(3):4419
$DT_{50,sed}$ (d)	Step 1-2: 5.6 (whole system value) **Step 3-4:** **1000** **(conservative default value)**	1000	1000	1000	EFSA Journal 2016;14(3):4419
$DT_{50,whole\ system}$ (d)	5.6	1000	1000	1000	EFSA Journal 2016;14(3):4419
Maximum occurrence observed (% molar basis with respect to the parent)	-	Total Water and Sediment: 7.9 Soil: 57.2	Total Water and Sediment: 24.6 Soil: 9.7	Total Water and Sediment: 33.0 Soil: 1.0E-10*	EFSA Journal 2016;14(3):4419
Formation fraction in soil:	-	-			

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for mesotrione following single application(s) of Juzan Extra 100 SC to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1-2					
Input values for pH 5.1					
Step 1	---	42.738	runoff/drainage	28.452	64.809
Step 2		6.349	runoff/drainage	4.202	9.568
Northern Europe	March-May				
Input values for pH 7.9					
Step 1	---	50.246	runoff/drainage	33.599	8.503
Step 2		1.380	runoff/drainage	0.922	0.138
Northern Europe	March-May				
Input values for pH 6.5					
Step 1	---	48.1259	runoff/drainage	17.1117	24.4016
Step 2		6.5648	runoff/drainage	2.3039	3.2889
Northern Europe	March-May				
Step 3					

Input values for pH 5.1					
D3	ditch	0.787	drainage	0.127	0.1982
D4	pond	0.085	drainage	0.086	0.118
D4	stream	0.678	drainage	0.107	0.102
R1	pond	0.116	runoff	0.094	0.094
R1	stream	2.428	runoff	0.227	0.543
Input values for pH 6.5					
D3	ditch	0.788	drainage	0.128	0.124
D4	pond	0.033	drainage	0.026	0.014
D4	stream	0.677	drainage	0.017	0.03217
R1	pond	0.073	runoff	0.041	0.035
R1	stream	1.673	runoff	0.168	0.208
Input values for pH 7.9					
D3	ditch	0.787	drainage	0.127	0.081
D4	pond	0.032	drainage	0.025	0.008
D4	stream	0.674	drainage	0.009	0.022
R1	pond	0.032	runoff	0.026	0.009
R1	stream	0.739	runoff	0.039	0.051

* single applications should be marked.
** twa-time as required by ecotox

FOCUS Step 4

Table 8.9-5: Global maximum PEC_{sw} values for mesotrioe, following single application(s) of Juzan Extra 100 SC to <u>maize</u> according to the surface water Step 4

PEC_{sw} (µg/L)	Scenario	STEP 4 mesotrione pH 5.1	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	D3 ditch	0.1368	0.0711
None	D4 pond	0.08542	0.08542
None	D4 stream	0.1545	0.1383
None	R1 pond	0.05021	0.0269
None	R1 stream	1.099	0.5746
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 mesotrione pH 6.5**	
Nozzle reduction	Vegetative strip (m)	10	20

	No spray buffer (m)	10	20
None	D3 ditch	0.1372	0.0714
None	D4 pond	0.0214	0.0153
None	D4 stream	0.1533	0.0810
None	R1 pond	0.0337	0.0186
None	R1 stream	0.6864	0.3462
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 mesotrione pH 7.9**	
Nozzle reduction	Vegetative strip (m)	10	20
	No spray buffer (m)	10	20
None	D3 ditch	0.1368	0.07108
None	D4 pond	0.02041	0.01363
None	D4 stream	0.1505	0.07819
None	R1 pond	0.02040	0.01362
None	R1 stream	0.3032	0.1529

Metabolites of mesotrione

Table 8.9-6: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite MNBA following single application(s) to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominat entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	23.4824	runoff/dranaige	23.4252	0.7489
Step 2		1.8919	runoff/dranaige	1.8872	0.0605
Northern Europe	March-May				

Table 8.9-7: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite AMBA following single application(s) to maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominat entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
Step 1	---	10.8276	runoff/dranaige	10.7967	1.9103
Step 2		2.0850	runoff/dranaige	2.0784	0.3747
Northern Europe	March-May				

Table 8.9-8: FOCUS Step 1, 2 PEC_{sw} and PEC_{sed} for metabolite SYN546974 following single application(s) to maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.7725	runoff/dranaige	0.4188	103.2687
Step 2		0.3904	runoff/dranaige	0.1005	21.5250
Northern Europe	March-May				

8.9.2.2 $PEC_{sw/sed}$ of Juzan Extra 100 SC

The PEC values of Juzan Extra 100 SC in surface water have been assessed with Drift Calculator the FOCUS SWASH model. Takin into account the density of product - 1.045 g/mL the application rate of 1576g formulation/ha was assumed

Inteded use **Application rate**	**maize** **1 x 1576 g product/ha**
Buffer zone (m)	PECsw [µg prod/L]
1	10.1252
5	2.7445
10	1.4556

zRMS comment:

The PECsw calculations for mesotrone have been approved for applications proposed in GAP. PEC_{sw} and PEC_{sed} calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS 1-2 and Step 3. PECsw/sed were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone. The Applicant used the geometric mean value. In opinion of the zRMS this is acceptable, as being in line with current requirements concerning selection of Kfoc to be used for modelling purposes.

PECsw/sed are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in surface water and sediment and are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

MS should identify risk reduction measures at the national level.

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 studies – no data requested
Photochemical oxidative degradation in air	DT50 of 17.635 hours (1.5 days) derived by the Atkinson model. OH (12h) concentration assumed = 1.5 x 106 OH/cm3
Volatilisation	Vapour pressure (Pa): < 5.7 x 10-6 at 20°C (99.7% pure) Henry's Law Constant (Pa.m3/mol): < 5.1 x 10-7 at 20°C

Metabolites	n/a

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 be considered.

zRMS comment:
Provided above information is in line with EU agreed data reported in EFSA Journal 2016;14(3):4419. Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} <2 days, mesotrione and its metabolites are not expected to be subject to volatilisation and the long- or short-range transport.

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 9.2.4.	Ilona Łożuk	2022	Calculation of the predicted environmental concentrations of mesotrione and its metabolites (MNBA & AMBA) in groundwater after application of JUZAN EXTRA 100 SC (FOCUS PEARL, FOCUS PELMO and MACRO) CIECH Sarzyna S.A., Poland RR/02/22 non GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 9.2.5.	Ilona Siwiec	2022	Calculation of the predicted environmental concentrations of mesotrione and its metabolites in surface after application of JUZAN EXTRA 100 SC (STEPS 1-2 and 3-4 in FOCUS, SWASH, SWAN) CIECH Sarzyna S.A., Poland RR/06/22 non GLP Unpublished	N	CIECH Sarzyna S.A.

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

List of data submitted by the applicant and not relied on

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

Appendix 2 Detailed evaluation of the new Annex II studies

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