FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021

MS Finalisation date: 02/2022; 12/2023

When	What
February 2022	ZRMs evaluated dRR submitted by Applicant
December 2023	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate and behaviour for the product Mezot 100 SC containing Mesotrione as active substance which was included into Annex I of Directive 91/414 (current legislation – regulation 540/2011) by Directive 2003/68/EC (July, 11^{th} 2003) and renewed by Regulation (EU) 2017/725 of April, 24^{th} 2017.
A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of Mesotrione. This will be where:

- the protection of operators,
- the protection of groundwater in vulnerable regions,
- the protection of mammals, aquatic and non-target plants.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

Mezot 100 SC as formulation has not been previously evaluated in Poland according to Uniform Principles.

EFSA Journal 2016;14(3):4419 conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Directive 2003/68/EC (July, 11th 2003) and Regulation (EU) 2017/725 of April, 24th 2017 provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the Mesotrione and in particular Appendices thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 March 2017 (SANTE/11654/2016) shall be taken into account.

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, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Maize	F	*Anthemis arvensis, Elymus repens, Amaranthus retroflexus, Capsella bursa-pastoris, Chenopodium album, Echinochloa crus-galli, Falconeria, Fumaria officinalis, Galium aparine, Galium palustre, Lamium purpureum, Tripleurospermum inodorum, Fallopia convolvulus, Sinapis arvensis, Solanum nigrum, Stellaria media, Thlaspi arvense, Viola arvensis.*	Foliar spraying; small drops	BBCH 12-18	1	-	a) 1,5 b) 1,5	Mesotrione - 150	200-300	-	Herbicide for use with field sprayers	A

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

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

Explanation for column 15 “Conclusion”

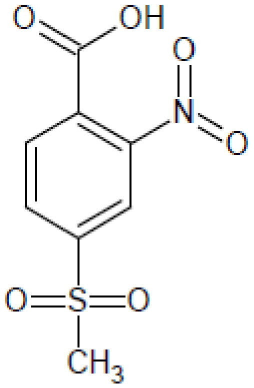
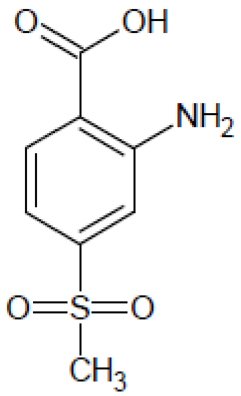
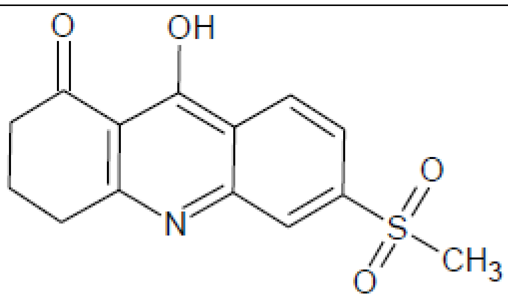
A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

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

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; 4-(methylsulfonyl)-2-nitrobenzoic acid	245		~~57,2 %~~ ~~100 %~~ ~~7,9 %~~ Soil: 57.2 % Water: 7.9% Sediment: <1% Water/sediment: 7.9%	Soil Ground water Surface water
AMBA; 2-amino-4-(methylsulfonyl)benzoic acid	215		~~9,7 %~~ ~~25 %~~ ~~24,6 %~~ Soil: 9.7% Water: 15.8% Sediment: 8.8% Water/sediment: 24.6%	Soil Ground water Surface water
SYN 546974; 9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin-1(2H)-one	291		~~-~~ ~~-~~ ~~33,0 %~~ Soil: <1 x 10^{-10}% Water: 9.4% Sediment: 25.6% Water/sediment: 33%	~~Soil~~ ~~Ground water~~ Surface water

zRMS comments

Information relating to mesotrione metabolites are 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) of Mesotrione and its metabolites.

Table 8.3-1: Summary of aerobic degradation rates for Mesotrione - laboratory studies EFSA Journal 2016;14(3):4419

Parent	**Dark aerobic conditions - Modelling Endpoints**					
Soil type	**pH*) water**	**t. ^{0}C/% MWHC**	**DT_{50} /DT_{90} (days)**	**DT_{50} (d) 20 ^{0}C pF2/ 10 kPa**)**	**St. (χ^2)**	**Method of calculation**
sandy loam (ERTC)	6.4	20°C /19[a]	11.6/ 38.5	8.2	18	SFO
Loam (Toulouse)	7.7	20°C /25[a]	4.3/ 14.3	4.0	16.4	SFO
clay loam (Pickett Piece)	7.1	20°C /28[a]	5.3/ 17.7	5.3	6.5	SFO
clay loam (721)	5.6	25°C /28[a]	20.2 /(67.1)	32.3	4.1	SFO
silty clay loam (722)	5.7	25°C /30[a]	10.3/ (34.2)	16.5	3.9	SFO
silt loam (723)	5.4	25°C /26[a]	17.6/ (58.5)	28.2	3.4	SFO
loamy sand (724)	4.8	25°C /14[a]	23.8/ (78.9)	31.1	4.3	SFO
loam (725)	5.8	25°C /25[a]	6.1/ 20.3	9.5	7.6	SFO
clay loam (727)	5.1	25°C /28[a]	20.8/ (69.2)	32.4	6.4	SFO
sandy loam (728)	5.9	25°C /25[a]	7.2/ 24	9.7	5.6	SFO
silt loam (729)	5.6	25°C /26[b]	12.7/ (42.2)	20.3	1.6	SFO
clay loam (730)	5.3	25°C /28[a]	17.1/ (56.9)	26.9	8.9	SFO
Silty clay loam (731)	6.1	25°C /30[a]	14.1/ (46.9)	22.6	1.0	SFO
Silty clay loam (732)	5.0	25°C /30[a]	14.0/ (46.4)	22.4	5.3	SFO
Silty clay loam (741)	5.7	25°C /30[a]	28.7/ (95.3)	44.3	4.5	SFO
Silty clay loam (742)	7.2	25°C /34.4[a]	9.7/ (32.1)	15.5	5.5	SFO
silt loam Richmond (Vispetto & Tovshteyn, 1997)	6.2	25°C /32.04[b]	13.2/ 44.0	14.68	3.1	SFO
silt loam Richmond (Subba-Rao, 1996)	6.2	25°C /32.04[b]	11.8/ 39.3	(Average DT_{50}ref of 15.5 & 13.9 days given identical soil de-	4.9	SFO

				scriptions in these 2 studies).		
silt loam Richmond (Miller,1997)	6.1	20°C /32.04[b]	14.2/ 47.2	11.5	4.6	SFO
Geometric mean (if not pH dependent)						
pH dependence				Yes – degradation increases with increasing pH. DT50 y = -9.766x pH + 77.692 r^2 0.4687 (non-log)		
*) Measured in [medium to be stated, usually calcium chloride solution or water] **) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 [a] FOCUS default; measured pF2						

Table 8.3-2: Summary of aerobic degradation rates for MNBA - laboratory studies (EFSA EFSA Journal 2016;14(3):4419

MNBA	Dark aerobic conditions - Modelling Endpoints					
Soil type	**pH*) water**	**t. ^{0}C /% MWHC**	**DT_{50} /DT_{90} (days)**	**DT_{50} (d) 20 ^{0}C pF2/ 10kPa**)**	**St. (χ^2)**	**Method of calculation**
silty clay loam (722)	5.7	25°C/30[a]	0.6/1.89	1.0	10	SFO
loam (725)	5.8	25°C/25[a]	0.5/1.5	0.8	10.8	SFO
sandy loam (728)	5.9	25°C/25[a]	5.1/16.97	6.9	3.1	Decline from peak
silt loam (729)	5.6	25°C/26[b]	1.66/5.52	2.7	3.88	SFO
clay loam (730)	5.3	25°C/28[a]	2.81/9.35	4.4	14.17	SFO
Silty clay loam (731)	6.1	25°C/30[a]	15.7/52.3	25.2	1.6	SFO
sandy loam (ERTC)	6.4	20°C/19[a]	6.2/20.7	4.4	21.89	Decline from peak
loam (Toulouse)	7.7	20°C/25[a]	5/16.65	4.6	13.08	Decline from peak
silt loam Richmond (Subba-Rao, 1996)	6.2	25°C/32.04[b]	1.1/3.67	1.3	11.2	SFO
silt loam Richmond (Miller, 1997)	6.1	20°C/32.04[b]	6.3/21.03	5.1	20.13	Decline from peak
Geometric mean (if not pH dependent)				**3.4**		
pH dependence				No		
*) Measured in [medium to be stated, usually calcium chloride solution or water] **) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 [a] FOCUS default; bmeasured pF2						

Table 8.3-3: Summary of aerobic degradation rates for AMBA - laboratory studies EFSA Journal 2016;14(3):4419

AMBA	**Dark aerobic conditions - Modelling Endpoints**					
Soil type	**pH*) water**	**t. ^{0}C**	**DT_{50}/DT_{90} (d)**	**DT_{50} (d) 20 ^{0}C pF2/ 10kPa**)**	**St. (χ^2)**	**Method of calculation**
Wisborough	4.9	20°C	7.8	3.7	5.52	DFOP DT90/3.32
Wisconsin	6.4	20°C	33/109	23.5	7.98	DFOP K2
East Anglia	7.9	20°C	58.7/195	47.4	3.66	DFOP K2
Spinks	6.7	20°C	10.2/34	9.7	6.94	FOMC
Richmond	6.2	25°C	13.6/45.2	16.0	14.8	SFO
Richmond	6.1	20°C	>1000	>1000	26.6	SFO
Geometric mean (if not pH dependent)				**14.5**		
pH dependence				No		
*) Measured in [medium to be stated, usually calcium chloride solution or water] **) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 [a] FOCUS default; b measured pF2						

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3-4: Summary of anaerobic degradation rates for Mesotrione - laboratory studies EFSA Journal 2016;14(3):4419

Parent	**Dark anaerobic conditions**					
Soil type	**pH$^{a)}$**	**t. ^{0}C**	**DT_{50}/ DT_{90} (days)**	**DT_{50} (d) 20 ^{0}C$^{b)}$**	**St. (χ^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	first order (linear least squares fit of natural log of concentration vs.Sampling interval).
a) Measured in [medium to be stated, usually calcium chloride solution or water] b) Normalised using a Q10 of 2.58						

8.4 Field studies (KCP 9.1.1.2)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419) and Draft Assessment Report for Mesotrione.

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) of Mesotrione and its metabolites

Based on the information in the EFSA Review report for the active substance Mesotrione (EFSA Journal 2016;14(3):4419) soil dissipation was investigated in a number of field trials. 7 degradation end points were obtained. Field dissipation studies carried out at four sites in Germany, two in Italy and one in France are available.

Table 8.4.1: Rate of degradation field soil dissipation studies EFSA Journal 2016;14(3):4419

Parent	**Aerobic conditions**							
Soil type (indicate if bare or cropped soil was used).	**Location (country or USA state)**	**pH[a]**	**Depth (cm)**	**DT_{50} (days) actual**	**DT_{90} (days) actual**	**St. (χ^2)**	**DT_{50} (days) Norm[b)]**	**Method of calculation**
clay loam (bare soil)	France	6.0	0-10	7	73	-	-	sqrt 1st order - linear regression
clay loam (bare soil)	Italy	6.1	0-10	5	59	-	-	sqrt 1st order - linear regression
clay loam (bare soil)	Italy	8.0	0-10	4	39	-	-	sqrt 1st order - linear regression
clay loam (bare soil)	Germany	6.2	0-10	7	78	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	5.8	0-10	/	/	-	-	sqrt 1st order - linear regression
loam (bare soil)	Germany	7.0	0-10	3	36	-	-	sqrt 1st order - linear regression
sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-	-	sqrt 1st order - linear regression
Geometric mean (if not pH dependent)							-	
pH dependence				Not reported				
a) Measured in [medium to be stated, usually calcium chloride solution or water]								
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix								

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

According to data contained in Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419) it may be stated that a plateau concentration is the same as initial PECsoil.

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

Table 8.5-1: Summary of soil adsorption for Mesotrione (EFSA Journal 2016;14(3):441)

Test Soil	Organic carbon	pH [$CaCl_2$]	Kf	Kf_{OC}	Kd	Kd_{OC}	1/n
	[%]		[L/kg]	[L/kg]	[L/kg]	[L/kg]	
Silty loam	2.63	5.1	4.48	170	-	-	0.91
Silt loam	1.58	6.2	0.74	47	-	-	0.92
Clay	1.79	6.5	1.25	70	-	-	0.93
Loam	1.03	7.8	0.15	14	-	-	0.94
Sandy loam	0.53	8.2	0.13	25	-	-	0.95
Silt loam	1.28	6.1	0.61	48	-	-	0.95
Sandy loam	0.58	6.4	0.33	58	-	-	0.95
Clay loam	3.31	7.1	0.97	29	-	-	0.93
Loam	0.87	7.7	0.16	19	-	-	0.95
Arithmetic mean			-	53.3	-	-	0.948
Arithmetic mean pH <7			-	78.6	-	-	0.950
Arithmetic mean pH >7			-	21.8	-	-	**0.945**
Worst case			**14**				
pH dependence, Yes or No			Yes, sorption decreases as pH increases. Kfoc $y = 8583.4e^{-0785x}$ (log) r^2 0.8977				

Table 8.5-2.1: Summary of soil adsorption for metabolite of Mesotrione – MNBA (EFSA Journal 2016;14(3):441)

~~Test Soil~~	~~Organic carbon~~	~~pH [CaCl$_2$]~~	~~Kf~~	~~Kfoc~~	~~Kd~~	~~Kdoc~~	~~1/n~~
	~~[%]~~		~~[L/kg]~~	~~[L/kg]~~	~~[L/kg]~~	~~[L/kg]~~	
~~Silty clay loam~~	~~2.63~~	~~5.1~~	~~0.16~~	~~6.1~~	~~-~~	~~-~~	~~0.32<1/n<0.61~~
~~Silt loam~~	~~1.58~~	~~6.2~~	~~0.05~~	~~3.2~~	~~-~~	~~-~~	~~0.32<1/n<0.61~~
~~Clay~~	~~1.79~~	~~6.5~~	~~-~~	~~-~~	~~<0,1~~	~~-~~	~~-~~
~~Loam~~	~~1.03~~	~~7.8~~	~~-~~	~~-~~	~~<0,1~~	~~-~~	~~-~~
~~Sandy loam~~	~~0.53~~	~~8.2~~	~~-~~	~~-~~	~~<0,1~~	~~-~~	~~-~~
~~Loam~~	~~-~~	~~-~~	~~-~~	~~14~~	~~0.42~~	~~-~~	~~-~~
~~Sand~~	~~-~~	~~-~~	~~-~~	~~<8~~	~~<0,1~~	~~-~~	~~-~~
~~Loamy sand~~	~~-~~	~~-~~	~~-~~	~~<12~~	~~<0,1~~	~~-~~	~~-~~
~~Silt loam~~	~~-~~	~~-~~	~~-~~	~~<7~~	~~<0,1~~	~~-~~	~~-~~
		~~Arithmetic mean~~	~~-~~	~~n.r.~~	~~-~~	~~-~~	~~-~~
~~pH dependence, Yes or No~~			~~Yes~~				

MNBA							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.63	5.1	0.16	6.1	0.32	EFSA, 2016
Wisconsin	Silt loam	1.58	6.2	0.05	3.2	0.61	EFSA, 2016
				Arithmetic mean (n=2)			
				Worst case	**3.2**	0.9 (FOCUS default)	EFSA, 2016
				pH-dependency	No		

Table 8.5-3.2: Summary of soil adsorption for metabolite of Mesotrione – AMBA EFSA Journal 2016;14(3):4419

~~Test Soil~~	~~Organic carbon~~	~~pH [CaCl$_2$]~~	~~Kf~~	~~Kfoc~~	~~Kd~~	~~Kdoc~~	~~1/n~~
	~~[%]~~		~~[L/kg]~~	~~[L/kg]~~	~~[L/kg]~~	~~[L/kg]~~	
~~Silty clay~~	~~2.63~~	~~5.1~~	~~-~~	~~122.1~~	~~-~~	~~-~~	~~0.9~~
~~Silt loam~~	~~1.58~~	~~6.2~~	~~-~~	~~44.9~~	~~-~~	~~-~~	~~0.9~~
~~Clay~~	~~1.79~~	~~6.5~~	~~-~~	~~51.0~~	~~-~~	~~-~~	~~0.9~~
~~Loam~~	~~1.03~~	~~7.8~~	~~-~~	~~17.7~~	~~-~~	~~-~~	~~0.9~~
~~Sandy loam~~	~~0.53~~	~~8.2~~	~~-~~	~~22.7~~	~~-~~	~~-~~	~~0.9~~
		~~Arithmetic mean:~~		~~51.7~~			
~~pH dependence, Yes or No~~			~~Yes~~				

AMBA							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Wisborough Green	Silty clay loam	2.63	5.1	3.2	122	0.83	EFSA, 2016
Wisconsin	Silt loam	1.58	6.2	0.71	44.9	0.85	EFSA, 2016
Toulouse	Clay	1.79	6.5	0.91	51.0	0.85	EFSA, 2016
Garonne	Loam	1.03	7.8	0.18	18.1	0.82	EFSA, 2016
Visalia	Sandy loam	0.53	8.2	0.12	23.9	0.90	EFSA, 2016
Arithmetic mean (n=5)					pH dependent (51.9)	0.85	EFSA, 2016
Worst case					**18.1**		EFSA, 2016
pH-dependency					Yes, sorption decreases as pH increases. Kfoc $y = 1865e^{-0.563x}$ (log) r^2 0.9062		

Table 8.5-4.3: Summary of soil adsorption for metabolite of SYN 546974 (EFSA Journal 2016;14(3):441)

SYN 546974							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Gartenacker	Loam	1.8	7.2	30.63	1702	0.82	EFSA, 2016
18 Acres	Sandy clay loam	2.2	5.7	220.07	10003	0.96	EFSA, 2016
Marysville	Clay loam	1.6	7.6	432.49	27031	0.96	EFSA, 2016
Sarpy	Silt loam	1.7	6.5	376.10	22124	0.88	EFSA, 2016
Seven Springs	Loamy sand	0.6	5.2	19.56	3260	0.84	EFSA, 2016
Arithmetic mean (n=5)					13000	**0.89**	EFSA, 2016
Geometric mean (n=5)					**8021**		
Worst case					-	-	
pH-dependency					No		

8.5.2 Column leaching (KCP 9.1.2.1)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419) and Draft Assessment Report for Mesotrione.
The submission of data or information on column leaching of these compounds is not required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419) and Draft Assessment Report for Mesotrione.
Studies were not submitted – not required.

zRMS comments:

Soil mobility data for mesotrione and its metabolites are in general in line with EU agreed endpoints.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stance Mesotrione (EFSA Journal 2016;14(3):4419) and Draft Assessment Report for Mesotrione.
The submission of data or information on column leaching of these compounds is 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.

8.6.1 Mesotrione and its metabolites

Table 8.6-1: Summary of degradation in water/sediment of Mesotrione (EFSA Journal 2016;14(3):441)

~~Water/ sediment system~~	~~pH water phase~~	~~pH sed~~	~~Mineralisation x% after n d. (end of the study).~~	~~Non-extractable residues in sed. max x% after n d~~	~~Non-extractable residues in sed. max x% after n d (end of the study)~~
~~Basing (Phenyl)~~	~~7.86~~		~~5.5~~	~~73.7 (101 DAT)~~	~~73.7 (101 DAT)~~
~~Basing (Cyclo-hexane)~~			~~27.8~~	~~63.8 (101 DAT)~~	~~63.8 (101 DAT)~~
~~Virginia (Phenyl)~~	~~7.40~~		~~15.6~~	~~64.5 (101 DAT)~~	~~64.5 (101 DAT)~~
~~Virginia (Cyclo-hexane)~~			~~26.8~~	~~48.4 (28 DAT)~~	~~44.7 (101 DAT)~~
~~Calwich (Phenyl)~~	~~8.4/7.8 (aerobic / anaerobic)~~	~~7.6~~	~~6.3~~	~~60.7 (102 DAT)~~	~~60.7 (102 DAT)~~
~~Swiss (Phenyl)~~	~~7.4/7.5 (aerobic / anaero-bic)~~	~~6.1~~	~~11.4~~	~~45.0 (102 DAT)~~	~~45.0 (102 DAT)~~

mesotrione Distribution (max. water/sediment 98.7/4.3 % after 0/1 days)								
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**Kinetic, Fit**	**DissT50 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level / Reference**
Basing (Phenyl)	7.86	2.6	SFO, χ^2=6.8	2.5	SFO, χ^2=6.2	n/a	n/a	EFSA, 2016
Basing (Cyclohexane)	7.86	4.2	SFO, χ^2=13.3	4.2	SFO, χ^2=13.3	n/a	n/a	EFSA, 2016
Virginia (phenyl)	7.40	5.5	SFO, χ^2=12.3	5.3	SFO, χ^2=13.5	n/a	n/a	EFSA, 2016
Virginia (Cyclohexane)	7.40	7.2	SFO, χ^2=14.4	7.0	SFO, χ^2=13.4	n/a	n/a	EFSA, 2016
Calwich (Phenyl)	pH water: 8.4/7.8 (aerobic/anaerobic) pH sed: 7.6	6.6	SFO, χ^2=4.5	6.7	SFO, χ^2=3.4	n/a	n/a	EFSA, 2016
Swiss (Phenyl)	pH water: 7.4/7.5 (aerobic/anaerobic) pH sed: 6.1	11.1	SFO, χ^2=3.5	11.0	SFO, χ^2=3.3	n/a	n/a	EFSA, 2016
Geometric mean (n=6)		**5.6**		**5.5**		n/a		

Table 8.6-2: Summary of observed metabolites

~~Max occurrence in water/sediment [%]~~	~~MNBA~~	~~7.4~~	~~As reported in DAR – peaking at 7.4% AR after 3 days~~
	~~AMBA~~	~~19~~	~~LoEP, 11.5% in the water phase~~

MNBA Water/sediment system	Max. in water 7.4% after 3 days. Max. in sediment <1%. Max. in total system 7.4% after 3 days.	Evaluated on EU level / EFSA, 2016
AMBA Water/sediment system	Max. in water 15.8% after 46 days. Max. in sediment 8.8% after 46 days. Max. in total system 24.6% after 46 days.	Evaluated on EU level / EFSA, 2016
SYN546974 Water/sediment system	Max. in water 9.4% after 29 days. Max. in sediment 25.6% after 102 days. Max. in total system 33% after 29 days.	Evaluated on EU level / EFSA, 2016

zRMS comments

Information on degradation mesotrione and its metabolites in water/sediment systems are in line with EU agreed endpoints.

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

8.7.1 Justification for new endpoints

Mezot 100 SC wasn't assessed as representative formulation.
PECsoil was calculated according to endpoints for Mesotrione and submitted for Mezot 100 SC.

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

The PECs of Mesotrione in soil has been assessed assuming that Mesotrione is evenly distributed in the top 5 cm soil horizon with a soil bulk density 1.5 g/cm^3 and with the focus groundwater interception value (60 % interception) and DT50 value established in the EU review which was 43,3 days. Calculation was done for the worst case.

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	150
Number of applications/interval	1/-
Crop interception (%)	25
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm 5/20/x cm (no tillage/tillage)

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	Molecular weight relative to the parent	Dose [g/ha]	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Mesotrione	339,3	-	-	150	43,4 (DFOP, laboratory studies, representative worst case laboratory after normalisation. The RMS .accepted this as conservative and as no impact on initial PECsoil, but notes that the corresponding value before normalisation of 34.3 days should have been used).	Y
MNBA	245	57,2	0,72	46,3	n.a.	Y
AMBA	215	9,7	0,63	6,87	n.a.	Y

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	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
	48d	0.070	0.105
	100d	0.030	0.075
Plateau concentration (5/20 cm) after year x		not required	
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)			-

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for metabolites on Maize.

PEC_{soil} (mg/kg)	Maize	
	Single application	
	Actual	TWA Actual
Initial (MNBA)	0,062	-
Initial (AMBA)	0,009	-
Plateau concentration (5/20 cm) after year x	not calcultaed	

8.7.2.2 PEC_{soil} of Mezot 100 SC

Table 8.7-5: PEC_{soil} for Mezot 100 SC on Maize

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
Mesotrione	100	0,150	0,127	5	-	0,150
Mezot 100 SC	1084	1,63	-	5	-	**1,63**
Density of formulation – Mezot 100 SC = 1,084 g/ml (dRR Secion 1)						

zRMS comments

<u>Mesotrione</u>

PEC_{soil} calculations has been accepted for the active substance mesotrione and its metabolites MNBA and AMBA.
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 for calculation of the soil exposure in EFSA report. However, DT_{50} used by the Applicant was accepted by zRMS because it does not affect the outcome of the PECs. Moreover, due to lack of potential mesotrione for accumulation in soil (DT_{50} <60 days) the soil risk assessment is based on initial PEC_{soil} values.
Below calculation of PECs with DT_{50} = 34.3 days

The acceptable predicted environmental concentrations of mesotrione and its metabolites in soil are appropriate to be used for the subsequent risk assessment
<u>Mesotrione:</u> PECs = 0.150 mg/kg
<u>MNBA</u>: PECs = 0.062 mg/kg
<u>AMBA</u>: PECs = 0.009 mg/kg

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

8.8.1 Justifica tion for new endpoints

Mezot 100 SC was not assessed as representative formulation.
PECgw was calculated according to endpoints for Mesotrione and submitted for Mezot 100 SC.

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

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	~~100~~–150
Number of applications/interval (d)	1/-
Relative application date	15 May - 15 June
Crop interception (%)	Calculated by model
Frequency of application	Annual
Models used for calculation	FOCUS PELMO 5.5.3 FOCUS PEARL 4.4.4

Table 8.8-2: Input parameters related to active substance Mesotrione and metabolite(s) for PEC_{gw} calculations

Compound	Mesotrione	MNBA	AMBA
Molecular weight (g/mol)	339,3	245	215
Water solubility (mg/L):	160	160	160
Saturated vapour pressure (Pa):	0	0	0
DT_{50} in soil (d)	4 * 27,88 (pH 5,1) 14,2 (pH 6,5) 5,4 (pH 7,9)	3,4	14,5
K_{fom} (mL/g) = K_{foc} / 1,724	8,1 * 90,8 (pH 5,1) 30,3 (pH 6,5) 10,1 (pH 7,9)	1,86	10,5 * 61,3 (pH 5,1) 27,9 (pH 6,5) 12,6 (pH 7,9)
K_{foc} (mL/g)	14 * 156,6 (pH 5,1) 52,2 (pH 6,5) 17,39 (pH 7,9)	3,2	18,1 * 105,61 (pH 5,1) 48,02 (pH 6,5) 21,80 (pH 7,9)
1/n	0,97 * 0,94 (pH 5,1) 0,90 (pH 6,5) 0,94 (pH 7,9)	0,90	0,82 * 0,85 (pH 5,1) 0,90 (pH 6,5) 0,85 (pH 7,9)
Plant uptake factor	0	0	0
Foramtion fraction (PEARL)	-	1.0 from Parent	0,25 from MNBA
Transformation rate (PELMO)	Parent → MNBA 0,173 * 0,0249 (pH 5,1)	MNBA → AMBA 0,0510	AMBA → CO_2 0,0478

Compound	Mesotrione	MNBA	AMBA
	0,0488 (pH 6,5) 1,2836 (pH 7,9)	MNBA → CO_2 0,1529	
* - worst case scenario (shortest normalised laboratory DT_{50})			

Table 8.8-3-1: PEC_{gw} for Mesotrione (worst case) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,000032	0,000175	0,004989
	Hamburg	0,001005	0,007618	0,040267
	Kremsmünster	0,000373	0,002388	0,041219
	Okehampton	0,001597	0,006594	0,067533
	Piacenza	0,000010	0,000048	0,005122
	Porto	0,000003	0,000015	0,000402
	Sevilla	0,000000	0,000000	0,000001
	Thiva	0,000000	0,000000	0,000317

Table 8.8-3-2: PEC_{gw} for Mesotrione (pH_5.1) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,001022	0,009301	0,000752
	Hamburg	0,008177	0,116460	0,028499
	Kremsmünster	0,003828	0,024723	0,003597
	Okehampton	0,006709	0,040705	0,006287
	Piacenza	0,005395	0,016068	0,004078
	Porto	0,001285	0,016581	0,000458
	Sevilla	0,000008	0,001449	0,000068
	Thiva	0,000168	0,001918	0,000056

Table 8.8-3-3: PEC_{gw} for Mesotrione (pH_6.5) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Ma	Châteaudun	0,001004	0,005329	0,006379

	Hamburg	0,006164	0,060582	0,049684
	Kremsmünster	0,002710	0,013271	0,027344
	Okehampton	0,008844	0,027231	0,035145
	Piacenza	0,002966	0,003653	0,009794
	Porto	0,000197	0,001819	0,001249
	Sevilla	0,000003	0,000144	0,000046
	Thiva	0,000085	0,000659	0,000750

Table 8.8-3-4: PEC$_{gw}$ for Mesotrione (pH_7.9) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,000214	0,000528	0,008052
	Hamburg	0,003029	0,013884	0,055383
	Kremsmünster	0,001298	0,003536	0,045580
	Okehampton	0,005076	0,010491	0,075773
	Piacenza	0,000070	0,000149	0,007839
	Porto	0,000008	0,000053	0,001123
	Sevilla	0,000000	0,000000	0,000012
	Thiva	0,000004	0,000009	0,001082

Table 8.8-3-5: PEC$_{gw}$ for Mesotrione (worst_case) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,000	0,000	0,002
	Hamburg	0,000	0,001	0,017
	Kremsmünster	0,000	0,003	0,037
	Okehampton	0,003	0,013	0,068
	Piacenza	0,000	0,001	0,011
	Porto	0,000	0,000	0,002
	Sevilla	0,000	0,000	0,000
	Thiva	0,000	0,000	0,001

Table 8.8-3-6: PEC$_{gw}$ for Mesotrione (pH_5.1) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,000	0,007	0,001
	Hamburg	0,007	0,143	0,018
	Kremsmünster	0,004	0,035	0,004
	Okehampton	0,008	0,071	0,008
	Piacenza	0,009	0,031	0,005
	Porto	0,003	0,038	0,001
	Sevilla	0,000	0,005	0,000
	Thiva	0,000	0,006	0,000

Table 8.8-3-7: PEC$_{gw}$ for Mesotrione (pH_6.5) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,001	0,005	0,003
	Hamburg	0,005	0,051	0,030
	Kremsmünster	0,004	0,021	0,026
	Okehampton	0,013	0,037	0,040
	Piacenza	0,006	0,009	0,016
	Porto	0,001	0,004	0,002
	Sevilla	0,000	0,001	0,000
	Thiva	0,000	0,002	0,001

Table 8.8-3-8: PEC$_{gw}$ for Mesotrione (pH_7.9) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,000	0,000	0,001
	Hamburg	0,000	0,000	0,009
	Kremsmünster	0,000	0,001	0,023
	Okehampton	0,000	0,005	0,039

	Piacenza	0,000	0,001	0,009
	Porto	0,000	0,000	0,001
	Sevilla	0,000	0,000	0,000
	Thiva	0,000	0,000	0,000

zRMS comments

Mesotrione

The modelling results PEC_{gw} 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 2016;14(3):4419. 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.

PEC_{gw} for mesotrione and its metabolites AMBA and MNBA are below 0.1 µg/L for all modelled scenarios 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 non-relevant 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

Mezot 100 SC was not assessed as representative formulation.
PECsw was calculated according to endpoints for Mesotrione and submitted for Mezot 100 SC.

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	Mezot 100 SC
Use No.	1
Crop	Maize
Application rate (kg as/ha)	150
Number of applications/interval (d)	1/-
Application window	BBCH 12-18
Application method	Air blast
CAM (Chemical application method)	2 (foliar)
Soil depth (cm)	4
Models used for calculation	STEPS1-2 ver.3.2 FOCUS SWASH 5.3, SPIN 2.2, FOCUS PRZM 4.3.1, FOCUS MACRO 5.5.4, FOCUS TOXWA 5.5.3, SWAN 5.0

8.9.2.1 Mesotrione and its metabolites

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

Compound	Mesotrione	MNBA	AMBA	SYN 546974
Molecular weight (g/mol)	339,3	245	215	291
Saturated vapour pressure (Pa)	$1,1 * 10^{-10}$	0	0	0
Water solubility (mg/L)	160	160	160	160
Diffusion coefficient in water (m^2/d)	4.3×10^{-5} (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
Diffusion coefficient in air (m^2/d)	0.43 (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
K_{fom} (mL/g)	90.9 (pH 5.1 value) 30.3 (pH 6.5 value) 10.1 (pH 7.9 value)	1,74	58.9 (linear fit, pH 5.1 value) 34.6 (linear fit, pH	7438,5

Compound	Mesotrione	MNBA	AMBA	SYN 546974
			6.5 value) 10.4 (linear fit, pH 7.9 value) 61.3 (log fit, pH 5.1 value) 27.9 (log fit, pH 6.5 value) 12.7 (log fit, pH 7.9 value)	
Freundlich Exponent 1/n	0,94	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
Plant Uptake	0	0	0	0
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM) (default)	Not required in Step1-2	Not required in Step1-2	Not required in Step1-2
$DT_{50,soil}$ (d)	27,88 (pH 5.1 value) 14,2 (pH 6.5 value) 0,54 (pH 7.9 value)	3,6	14,5	0,1
$DT_{50,water}$ (d)	5,5	1000	1000	1000
$DT_{50,sed}$ (d)	5,6	1000	1000	1000
$DT_{50,whole\ system}$ (d)	5,6	1000	1000	1000
Maximum occurrence observed (% molar basis with respect to the parent)	-	Total: 7,9 Soil: 57,2	Total: 24,6 Soil: 9,7	Total: 33,0 Soil: 0

$PEC_{sw/sed}$

Table 8.9-3-1: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Mesotrione (pH 5.1) following application of Mezot 100 SC to Maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	42,74	15,14	64,81
Step 2				
Northern Europe	March-May	6,35	2,22	9,57
Southern Europe	March-May	11,97	4,20	18,37
Step 3				
D3	ditch	0,7863	0,03890	0,1989
D4	pond	0,04633	0,04332	0,09376
D4	stream	0,6514	0,03755	0,07476
R1	pond	0,05399	0,03275	0,07276
R1	stream	2,149	0,08163	0,4240

Table 8.9-3-2: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Mesotrione (pH 6.5) following application of Mezot 100 SC to Maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	48,13	17,11	24,40
Step 2				
Northern Europe	March-May	6,56	2,30	3,29
Southern Europe	March-May	12,33	4,33	6,30
Step 3				
D3	ditch	0,7865	0,03911	0,1234
D4	pond	0,03264	0,02049	0,02087
D4	stream	0,6499	0,004179	0,02463
R1	pond	0,03177	0,02302	0,02527
R1	stream	2,390	0,05765	0,3065

Table 8.9-3-3: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Mesotrione (pH 7.9) following application of Mezot 100 SC to Maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	50,25	17,89	8,50
Step 2				
Northern Europe	March-May	1,38	0,49	0,14
Southern Europe	March-May	1,38	0,51	0,14
Step 3				
D3	ditch	0,7864	0,03900	0,08090
D4	pond	0,03178	0,01994	0,01219
D4	stream	0,6486	0,001816	0,01514
R1	pond	0,03177	0,01852	0,01131
R1	stream	0,5438	0,005107	0,02695

FOCUS Step 4

Table 8.9-4: Global maximum PEC_{sw} values for Mesotrione, following application of Mezot 100 SC to Maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	**Scenario**	**STEP 4**	
Nozzle reduction	Vegetative strip (m)	-	-
	No spray buffer (m)	10	20
0 %	D3 ditch	0,1368	0,0712
0 %	R1 stream	1,013	0,5171
RAC (µg/L) = 0,77		**PEC/RAC ratio**	
0 %	D3 ditch	0,18	0,09
0 %	R1 stream	1,32	0,67

Metabolite(s) of Mesotrione

Table 8.9-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for metabolites of Mesotrione following application to Maize

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
MNBA				
Step 1	---	23,48	23,31	0,75
Step 2				
Northern Europe	March-May	1,89	1,88	0,06
Southern Europe	March-May	3,71	3,68	0,12
SYN 546974				
Step 1	---	0,77	0,40	106,04
Step 2				
Northern Europe	March-May	0,39	0,07	16,85
Southern Europe	March-May	0,39	0,11	30,87
AMBA (Linear; pH 5.1)				
Step 1	---	9,79	9,69	9,90
Step 2				
Northern Europe	March-May	1,46	1,45	1,48
Southern Europe	March-May	2,73	2,70	2,76
AMBA (Linear; pH 6.5)				
Step 1	---	10,28	10,19	6,12
Step 2				
Northern Europe	March-May	1,54	1,52	0,91
Southern Europe	March-May	2,87	2,84	1,71
AMBA (Linear; pH 7.9)				
Step 1	---	10,83	10,74	1,95
Step 2				
Northern Europe	March-May	1,62	1,60	0,29
Southern Europe	March-May	3,02	3,00	0,54
AMBA (Log; pH 5.1)				

Step 1	---	9,74	9,64	10,25
Step 2				
Northern Europe	March-May	1,46	1,44	1,53
Southern Europe	March-May	2,72	2,69	2,86
AMBA (Log; pH 6.5)				
Step 1	---	10,43	10,34	5,00
Step 2				
Northern Europe	March-May	1,56	1,54	0,75
Southern Europe	March-May	2,91	2,89	1,39
AMBA (Log; pH 7.9)				
Step 1	---	10,78	10,69	2,35
Step 2				
Northern Europe	March-May	1,61	1,60	0,35
Southern Europe	March-May	3,01	2,98	0,65

zRMS comments

Mesotrione

The PECsw/sed calculations for mesotrone have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS1-2 and Step 3. $PEC_{sw/sed}$ 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.

Poland

In accordance with national requirements, only D3, D4 and R1 scenarios were taken into consideration. The max PECsw and proposed mitigation measures are presented in the tables above.

8.9.2.2 $PEC_{sw/sed}$ of Mezot 100 SC

Mezot 100 SC is a formulation containing of one active ingredient Mesotrione for which PECsw/sed was submitted in point 8.9.2.

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	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 17.635 hours (1.5 days) derived by the Atkinson model (AOP version 1.8). OH (12h) concentration assumed = 1.5 x 10^6 OH/cm^3
Volatilisation	from plant and soil surfaces (BBA guideline): <10% after 24 hours
Metabolites	None

The vapour pressure at 20 °C of Mesotrione is < 10^{-5} Pa. Hence the active substance is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance due to volatilization with subsequent deposition should not be considered.
PECa is assumed to be negligible.

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 9.2.4.1	Janus, K.	2020	PECgw calculation for Mezot 100 SC. Report No.: 1/2020 non GLP Unpublished	N	Elvita Sp. z o.o.
KCP 9.2.5	Janus, K.	2020	PECsw calculation for Mezot 100 SC. Report No.: 2/2020 non GLP Unpublished	N	Elvita Sp. z o.o.

Appendix 2 Detailed evaluation of the new Annex II studies

No studies submitted.

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

No additional information submitted.