REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: MEZI 100 SC

Product name(s): Rumezo Twist 100 SC,

Malton Twist 100 SC

Chemical active substance(s):

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023, October 2024

RMS Assessment: 24/07/2024

Following commenting period: 21/10/2024

Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update

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8 Fate and behaviour in the environment (KCP 9)

Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Calisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Calisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

General comment
For the purpose of this application, Innvigo Sp. z o.o. would like to rely on data for which data protection period has expired and which had been submitted for (re)authorisation of the product CALLISTO 100 SC. The basis of such request is in Art.34(1) of the Regulation 1107/2009. This document provides the results of the assessment for product MEZI 100 SC (Rumezo Twist 100 SC, Malton Twist 100 SC). All comments of the evaluator there are in the "greyboxes".

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	PL	Maize *Zea mays* ZEAMX	F	Mono- and dicotyledonous weeds	Spray, medium sprayer	BBCH 14-15	a) 1 b) 1	n/a	a) 1.0 L/ha b) 1.0 L/ha	a) 100 g as/ha b) 100 g as/ha	200-300	n/a	-	A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														

Minor uses according to Article 51 (zonal uses)														
Minor uses according to Article 51 (interzonal uses)														

* 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

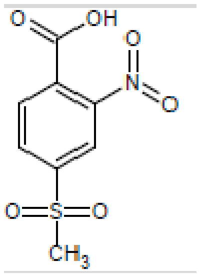
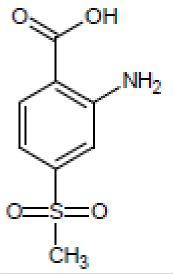
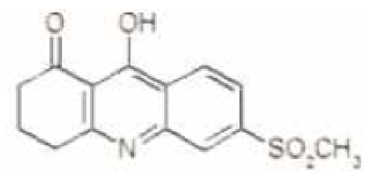
Table 8.1-2: Assessed (critical) uses during approval of Mesotrione concerning the Section Environmental Fate (EFSA Journal 2016;14(3):4419)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Maize	EU N&S	Callisto 100SC (A12739A)	F	annual broadleaved weeds and some annual grasses such as *Echinochloa crus-galli*	SC	100 g/L	Foliar spray application using a hydraulic vehicle-mounted spray equipment	BBCH 12-18	1 application per crop/season	na	30 to 75 g as/hL	200- 400 L/ha	120 to 150 g as/ha	na	-

a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
f) All abbreviations used must be explained
g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
j) Growth stage range from first to 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
k) Indicate the minimum and maximum number of applications possible under practical conditions of use
l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
m) PHI - minimum pre-harvest interval

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		Soil: 57.28% Surface Water: 7.4%* Sediment: 0.6%* (<1%) Total system: 7.4%	PECsoil PECgw: leaching potential to groundwater PEC sw
AMBA	215		Soil: 9.7% Surface Water: 15.8%* Sediment: 8.8%* Total system: 24.6%	PECsoil PEC_{gw}: leaching potential to groundwater PECsw
SYN 546974	291		Surface water: 9.4% Sediment: 253.6% Total system: 33%	PECsw

zRMS comment
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)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Mesotrione -** EFSA Journal 2016;14(3):4419

8.3.1.1 Mesotrione and its metabolites

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

Parent	Dark aerobic conditions - Modelling Endpoints					
Soil type	pH*) water	t. °C/% MWHC	DT_{50} / DT_{90} (days)	DT_{50} (d) 20 °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 (Average DT_{50}ref of	3.1	SFO
silt loam	6.2	25°C /32.04[b]	11.8/ 39.3	15.5 & 13.9	4.9	SFO

Richmond (Subba-Rao, 1996)				days given identical soil descriptions 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; [b]measured pF2

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

MNBA	Dark aerobic conditions - Modelling Endpoints					
Soil type	**pH*) water**	**t. °C / % MWHC**	**DT_{50} / DT_{90} (days)**	**DT_{50} (d) 20 °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; [b]measured pF2

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

AMBA	Dark aerobic conditions - Modelling Endpoints					
Soil type	pH*) water	t. °C/% MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20 °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 italics - outlier

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Mesotrione** - EFSA Journal 2016;14(3):4419

8.3.2.1 Mesotrione and its metabolites

Table 8.3.2.1-1: Summary of anaerobic degradation route for Mesotrione and metabolites- laboratory studies

Parent	Dark anaerobic conditions					
Soil type	pH[a)]	t. °C /% MWHC	DT_{50} / DT_{90} (days)	DT_{50} (d) 20 °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).
Geometric mean (if not pH dependent)						

[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)

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

Annex I inclusion All relevant data are presented in :
-Mesotrione - EFSA Journal 2016;14(3):4419

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

8.4.1-1: Rate of degradation field soil dissipation studies

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 1[st] order - linear regression
clay loam (bare soil)	Italy	6.1	0-10	5	59	-	-	sqrt 1[st] order - linear regression
sandy loam (bare soil)	Italy	8.0	0-10	4	39	-	-	sqrt 1[st] order - linear regression
sandy loam (bare soil)	Germany	6.2	0-10	7	78	-	-	sqrt 1[st] order - linear regression
loam (bare soil)	Germany	5.8	0-10	/	/	-	-	sqrt 1[st] order - linear regression
loam (bare soil)	Germany	7.0	0-10	3	36	-	-	sqrt 1[st] order - linear regression
sandy clay loam (bare soil)	Germany	6.9	0-10	3	38	-	-	sqrt 1[st] 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)

Studies on accumulation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Mesotrione - EFSA Journal 2016;14(3):4419

8.4.2.1 Mesotrione – soil accumulation testing

Soil accumulation and plateau concentration	Not triggered. The same as initial PEC soil.

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.

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Mesotrione -** EFSA Journal 2016;14(3):4419

8.5.1 Mesotrione and its metabolites

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

Parent							
Soil Type	**OC%**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Wisborough Green silty clay loam	2.63	5.1			4.46	171	0.902
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
Geometric mean (if not pH dependent)							
Arithmetic mean (if not pH dependent)							**0.94**
Median							
Worst case						**14**	
pH dependence			Yes, sorption decreases as pH increases. Kfoc y= 8583.4e^{-0785x} (log) r^2 0.8977				

a) Measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-2: Summary of soil adsorption/desorption for MNBA (metabolite of mesotrione)

MNBA							
Soil Type	**OC%**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Wisborough Green silty clay loam	2.63	5.1			0.16	6.1	0.32
Wisconsin silt loam	1.58	6.2			0.05	3.2	0.61
Worst case						3.2	0.9[b]
Geometric mean (if not pH dependent)						-	
Arithmetic mean (if not pH dependent)							-
pH dependence			No				

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) FOCUS default

Table 8.5-3: Summary of soil adsorption/desorption for AMBA (metabolite of mesotrione)

AMBA							
Soil Type	**OC%**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Wisborough Green silty clay loam	2.63	5.1			3.2	122	0.83
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 dependence			Yes, sorption decreases as pH increases. Kfoc y = 1865e$^{-0.563x}$ (log) r^2 0.9062				

a) Measured in [medium to be stated, usually calcium chloride solution or water]

Table 8.5-4: Summary of soil adsorption/desorption for SYN 546974 (metabolite of Mesotrione)

SYN 546974							
Soil Type	**OC%**	**Soil pH[a)]**	**K_d (mL/g)**	**K_{doc} (mL/g)**	**K_F (mL/g)**	**K_{Foc} (mL/g)**	**1/n**
Gartenacker Loam	1.8	7.2			30.63	1702	0.82
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
Arithmetic mean (if not pH dependent)						13000	0.89
Worst case							
pH dependence			No				

8.5.2 Column leaching (KCP 9.1.2.1)

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

EU approved endpoints were evaluated during Annex I inclusion All relevant data are presented in :

- **Mesotrione -** EFSA Journal 2016;14(3):4419

8.5.1.2 Mesotrione

Column leaching	Not required
Aged residue leaching:	Not required.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

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

EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Mesotrione -** EFSA Journal 2016;14(3):4419

Lysimeter / field leaching studies	Not required

8.5.4 Field leaching studies (KCP 9.1.2.3)

See point 8.5.3.

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.
EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Mesotrione -** EFSA Journal 2016;14(3):4419

8.6.1 Mesotrione and its metabolites

Table 8.6.1-1: Summary of degradation in water/sediment of Mesotrione

Parent	**Distribution (max in water 98.7% after 0 d. Max. sed 4.3% after 1d)**									
Water / sediment system (radiolabel)	**pH water phase**	**pH sed a)**	**t. °C**	**DT_{50} / DT_{90} whole sys.[c)]**	**St. (χ^2)**	**DT_{50} / DT_{90} water**	**St. (χ^2)**	**DT_{50} / DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
Basing (Phenyl)	7.86		20	2.6	6.8	2.5	6.2	n/a	n/a	SFO
Basing (Cyclohexane)			20	4.2	13.3	4.2	13.3	n/a	n/a	SFO
Virginia (Phenyl)	7.40		20	5.5	12.3	5.3	13.5	n/a	n/a	SFO
Virginia (Cyclohexane)			20	7.2	14.4	7.0	13.4	n/a	n/a	SFO
Calwich (Phenyl)	8.4/7.8 (aerobic/anaerobic)	7.6	20	6.6	4.5	6.7	3.4	n/a	n/a	SFO
Swiss (Phenyl)	7.4/7.5 (aerobic/anaerobic)	6.1	20	11.1	3.5	11.0	3.3	n/a	n/a	SFO
Geometric mean at 20°C[b)]				5.6		5.5		n/a		

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58

Table 8.6.1-2: Summary of degradation in water/sediment of MNBA

Metabolite **MNBA**	Distribution (max in water 7.4%* after 3 days. Max. sed <1%*). Max in total system 7.4% after 3 days. *Detected in Cary., 1999. Not detected in Graham R, 2013 kinetic formation fraction (k_f/k_{dp}): Not available									
Water / sediment system	**pH water phase**	**pH sed a)**	**t.° C**	**DT_{50} / DT_{90} whole sys.**	**St. (χ^2)**	**DT_{50} / DT_{90} water**	**St. (χ^2)**	**DT_{50} / DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b)**]				n/a		n/a		n/a		n/a

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58
** 1000 day default value used in risk assessment

Table 8.6.1-3: Summary of degradation in water/sediment AMBA

Metabolite **AMBA**	Distribution (max in water 15.8% after 46 d. Max. sed 8.8 % after 46 d). Max in total system 24.6% after 46 days, kinetic formation fraction (kf/kdp): Not available										
Water / sediment system	**pH water phase**	**pH sed a)**	**t. oC**	**DT50 /DT90 whole sys.**	**St. (χ^2)**	**DT50 /DT90 water**	**St. (χ^2)**	**DT50 /DT90 sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b)]*				n/a		n/a		n/a		n/a

* 1000 days default value used in risk assessment

Table 8.6.1-4: Summary of degradation in water/sediment SYN 546974

Metabolite **SYN546974**	Distribution (max in water 9.4% after 29 d. Max. sed 25.6% after 102 d). Max in total system 33% after 29 days. kinetic formation fraction (k_f/k_{dp}): Not available									
Water / sediment system	**pH water phase**	**pH sed a)**	**t. °C**	**DT_{50} /DT_{90} whole sys.**	**St. (χ^2)**	**DT_{50} /DT_{90} water**	**St. (χ^2)**	**DT_{50} /DT_{90} sed**	**St. (χ^2)**	**Method of calculation**
n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Geometric mean at 20°C[b)]				n/a		n/a		n/a		n/a

* 1000d default value used in risk assessment

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 comment
Information on degradation mesotrione and its metabolites: MNBA, AMBA, SYN 546974 in water/sediment systems are in accordance 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

All endpoints used for PEC soil calculations are EU approved and were evaluated on EU level and presented in:

- **Mesotrione -** EFSA Journal 2016;14(3):4419

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

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 100 g a.s/ha
Number of applications/interval	1/-
Crop interception (%)	0%
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm – no 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 (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Mesotrione	339.3	-	DT50 (d): 34.3 d Kinetics: DFOP Field or Lab: representative worst case from laboratory studies before normalisation.	EFSA Journal 2016;14(3):4419
MNBA	245	57.2%	DT50 (d): n/a (<100d) ~~25.2 d~~ ~~Kinetics: SFO~~ ~~Field or Lab: representative worst case from laboratory studies~~	EFSA Journal 2016;14(3):4419 (p.68/69)
AMBA	215	9.7%	DT50: n/a (<100d) ~~1000d~~ ~~Kinetics: SFO~~ ~~Field or Lab: representative~~	EFSA Journal 2016;14(3):4419 (p.68/69)

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
			worst case from laboratory studies	

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		0.1333	-
Short term	24h	0.1307	0.1320
	2d	0.1281	0.1307
	4d	0.1230	0.1281
Long term	7d	0.1157	0.1243
	14d	0.1005	0.1161
	21d	0.0872	0.1087
	28d	0.0757	0.1018
	42d	0.0571	0.0899
	50d	0.0485	0.0839
	100d	0.0177	0.0572
Plateau concentration (5 cm) after 10 years		0.0001	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		0.1334	

PEC$_{soil}$ of metabolites

Table 8.7-4: PEC$_{soil}$ for MNBA on Maize

PEC$_{soil}$ (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.0550 0.0175	-
Short term	24h	0.0175	0.0175
	2d	0.0175	0.0175
	4d	0.0174	0.0175

~~Long term~~	~~7d~~	~~0.0173~~	~~0.0174~~
	~~14d~~	~~0.0167~~	~~0.0174~~
	~~21d~~	~~0.0160~~	~~0.0173~~
	~~28d~~	~~0.0150~~	~~0.0172~~
	~~42d~~	~~0.0130~~	~~0.0168~~
	~~50d~~	~~0.0118~~	~~0.0165~~
	~~100d~~	~~0.0057~~	~~0.0143~~
Plateau concentration (5 cm) after 10 years		Not relevant for this metabolite	
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not relevant for this metabolite	

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

PEC_{soil} (mg/kg)		Maize	
		Single application	
		Actual	TWA
Initial		0.0081 ~~0.0073~~	-
~~Short term~~	~~24h~~	~~0.0073~~	~~0.0073~~
	~~2d~~	~~0.0073~~	~~0.0073~~
	~~4d~~	~~0.0073~~	~~0.0073~~
~~Long term~~	~~7d~~	~~0.0073~~	~~0.0073~~
	~~14d~~	~~0.0073~~	~~0.0073~~
	~~21d~~	~~0.0073~~	~~0.0073~~
	~~28d~~	~~0.0072~~	~~0.0073~~
	~~42d~~	~~0.0072~~	~~0.0073~~
	~~50d~~	~~0.0072~~	~~0.0073~~
	~~100d~~	~~0.0070~~	~~0.0072~~
Plateau concentration (5 cm) 10 after years		Not relevant for this metabolite	
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not relevant for this metabolite	

8.7.2.2 PEC_{soil} of formulation MEZI 100 SC

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

Crop interception of 0% was used in PEC_{soil} calculations for formulation MEZI 100 SC

Active substance/ preparation	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)
MEZI 100 SC	1098	1.464	-	-	-	1.464

Application rate of the product:

A=V x ρ

A- Application rate of MEZI 100 SC formulation – [g/ha]
V- volume of product– 1.0 [L/ha]
ρ- density of product- 1098 [g/L]

$$PEC_{soil\ initial} = \frac{A}{d\ x\ a\ x\ 100}$$

A-application rate of product – 1098 [g/ha]
d- depth of the soil- 5 [cm]
a- density of the soil- 1.5 [g]

Evaluation by zRMS PL	PECsoil (KCP 9.1.3)
Modelling	The assumptions of calculations are acceptable. The predicted environmental concentrations in soil (PECsoil) of mesotrione and its metabolites: MNBA and AMBA were calculated according to recommendations of the FOCUS workgroup on degradation kinetics using: - the maximum application rate: 0.1kg for MEZI 100 SC /ha/per season i.e. 100 g mesotrione/ha, considering 0% interception (as the worst case) for maize. It was assumed that the active substance were distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL. The calculated PECs values are presented in Tables from 8.7-3 to 8.7-5. zRMS recalculated the PECsoil initial values for metabolites MNBA and AMBA. Since the DT_{50} and DT_{90} values of these metabolites are < 100 days and < 365 days respectively, modelling of potential accumulation was not required. It is in accordance with the EFSA conclusions on Scientific EFSA Journal 2016;14 (3):4419. In this case, it is sufficient to calculate only the PECsoil initial values for mesotrione metabolites. The applicant correctly calculated the PECsoil for the formulation MEZI 100 SC. The results are shown in the Table 8.7-5. The calculated PECsoil values for MEZI 100 SC, mesotrione as well as its metabolites: MNBA and AMBA are appropriate to be used for the subsequent risk assessment for soil organisms.
Agreed Endpoints	**Mesotrione:** Initial PEC_{soil}: 0.1333mg/kg PECaccumulation = 0.1334mg/kg

	Metabolite of mesotrione: **MNBA** Initial PEC_{soil}: 0.055 mg/kg **AMBA** Initial PEC_{soil}: 0.0081 mg/kg **Formulation: MEZI 100 SC** PECact = 1.464 mg/kg

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

PEC ground water calculations for Mesotrione and his metabolites: MNBA, AMBA have been made for BBCH= 12 and crop interception= 0%, because this is worse case than BBCH=14 and crop interception= 25%.

8.8.1 Justification for new endpoints

All endpoints used for PEC ground water calculations are EU approved and were evaluated on EU level and presented in:

- **Mesotrione -** EFSA Journal 2016;14(3):4419

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

Table 8.8.2-1: Input parameters related to application for PEC_{gw} calculations

Use No.	1
Crop	Maize
Application rate (g as/ha)	Mesotrione: 100 g a.s/ha
Number of applications/interval (d)	1/-
Relative application date	3 days after sowing
Crop interception (%)	0%
Frequency of application	annual
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4

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

Crop	Scenario	Application dates (absolute)
Maize	Châteaudun	9th May
	Hamburg	12th May
	Kremsmünster	12th May
	Okehampton	29th May
	Piacenza	21th May
	Porto	9th May
	Sevilla	15th March
	Thiva	25th April

8.8.2.1 Mesotrione and its metabolites

Table 8.8-3: Input parameters related to active substance Mesotrione and metabolite(s) for PEC_{gw} calculations

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	339.32	245	215	EFSA Journal 2016;14(3):4419
Water solubility (g/mol):	160	160	160	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa):	0	0	0	EFSA Journal 2016;14(3):4419
DT50 in soil (d)	4 d (shortest normalised laboratory DT50) acid value for pH 5.1 (10th percentile maize crop area) - DT50 = 27.88 d (linear), alkali value for pH 7.9 (90th percentile maize crop area) - DT50 = 5.4[#] d (linear), intermediate pH 6.5 14.2 d (linear)	DT50:3.4 days (SFO, normalised, geometric mean DT50lab)	DT50: 14.5 days (SFO normalised, geometric mean DT50lab)	EFSA Journal 2016;14(3):4419
Transformation rate	pH 5.1 linear 0.0249 pH 6.5 linear 0.0488 pH 7.9 linear ~~0.~~1.2836~~1~~ shortest DT50 0.173 A.S to MNBA	0.0510 to AMBA, 0.1529 to CO2	0.0478 to CO2	EFSA Journal 2016;14(3):4419
Kfoc (mL/g)/Kfom	(i) worst case Koc 14 l/kg for that soil (ii) acid value for pH 5.1 (10th percentile	worst case (of n = 2): Kfoc 3.2 l/kg, Kfom 1.86 l/kg	-worst case Koc 18.1 l/kg with 1/n 0.82 for that soil - acid value for pH 5.1	EFSA Journal 2016;14(3):4419

	maize crop area) - Kfoc 156.6 l/kg (log) (iii) alkali value for pH 7.9 (90th percentile maize crop area) - 17.39 l/kg (log), Kfom 10.12 l/kg, median (iv) intermediate pH 6.5 - 52.2 l/kg (log)		(10th percentile maize crop area) - Kfoc 105.61 l/kg (log), arithmetic mean 1/n = 0.85 - alkali value for pH 7.9 (90th percentile maize crop area) - Kfoc 21.8 L/kg (log), arithmetic mean 1/n = 0.85 - intermediate pH 6.5 –48.02 l/kg (log)	
1/n	worst case 1/n 0.97 acid value for pH 5.1 1/n = 0.94 alkali value for pH 7.9 1/n = 0.94	0.9	0.82 (worst case) 0.85 (pH 5.1) 0.85 (pH 7.9)	EFSA Journal 2016;14(3):4419
Plant uptake factor	0	0	0	EFSA Journal 2016;14(3):4419
Formation fraction	-	Formation fraction: 1.0 from parent	Formation fraction: 0.25 from MNBA	EFSA Journal 2016;14(3):4419

The EFSA conclusion (EFSA, 2016) states DT50 incorrectly as 5.4 days, which is not consistent with value used in PEC_{SW} modelling or with linear regression equation (p. 56 of EFSA 2016). The value of 0.54 days should have been used in calculations.

Table 8.8-4: PEC_{gw} for Mesotrione and metabolite(s) on Maize (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione DT50-4 d Koc=14 g/L	**MNBA**	**AMBA Koc=18.1 g/l**
Maize	Châteaudun	< 0.0001	< 0.0001	0.001
	Hamburg	< 0.0001	0.001	0.008
	Kremsmünster	< 0.0001	0.002	0.024
	Okehampton	0.003	0.012	0.058
	Piacenza	< 0.0001	< 0.0001	0.005
	Porto	< 0.0001	< 0.0001	< 0.0001
	Sevilla	< 0.0001	< 0.0001	< 0.0001
	Thiva	< 0.0001	< 0.0001	< 0.0001
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-27.88 (pH5.1) Koc=156.6g/L	**MNBA**	**AMBA Koc=105.61 g/l(pH5.1)**
Maize	Châteaudun	< 0.0001	0.005	< 0.0001
	Hamburg	0.004	0.098	0.011

	Kremsmünster	0.003	0.025	0.002
	Okehampton	0.006	0.060	0.006
	Piacenza	0.006	0.022	0.003
	Porto	0.001	0.023	< 0.0001
	Sevilla	< 0.0001	0.002	< 0.0001
	Thiva	< 0.0001	0.003	< 0.0001
Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-5.4 (pH7.9) Koc=17.39g/L	**MNBA**	**AMBA Koc=21.8 g/l(pH7.9)**
maize	Châteaudun	< 0.0001	< 0.0001	0.002
	Hamburg	0.001	0.002	0.014
	Kremsmünster	0.001	0.003	0.028
	Okehampton	0.007	0.016	0.063
	Piacenza	< 0.0001	0.001	0.008
	Porto	< 0.0001	< 0.0001	0.001
	Sevilla	< 0.0001	< 0.0001	< 0.0001
	Thiva	< 0.0001	< 0.0001	< 0.0001
Crop	**Scenario**	**80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-14.2 (pH6.5) Koc=52.2g/L	**MNBA**	**AMBA Koc=48.02 g/l(pH~~7~~ 6.5)**
maize	Châteaudun	0.008	0.008	0.001
	Hamburg	0.038	0.046	0.011
	Kremsmünster	0.030	0.026	0.006
	Okehampton	0.064	0.055	0.010
	Piacenza	0.017	0.011	0.004
	Porto	0.005	0.005	< 0.0001
	Sevilla	< 0.0001	< 0.0001	< 0.0001
	Thiva	0.002	0.002	< 0.0001

Table 8.8-5: PEC$_{gw}$ for Mesotrione and metabolite(s) on Maize (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (μg/L)		
		Mesotrione DT50-4 d Koc=14 g/L	**MNBA**	**AMBA Koc=18.1 g/l (worst case Koc)**
maize	Châteaudun	0.000019	0.000103	0.001562
	Hamburg	0.000676	0.005142	0.022120
	Kremsmünster	0.000282	0.001706	0.023809
	Okehampton	0.001541	0.006927	0.054190
	Piacenza	0.000005	0.000031	0.003496
	Porto	0.000002	0.000008	0.000157
	Sevilla	< 0.0000001	< 0.0000001	< 0.0000001
	Thiva	< 0.0000001	0.000001	0.000131
Crop	**Scenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (μg/L)**		
		Mesotrione DT50-27.88 (pH5.1) Koc=156.6g/L	**MNBA**	**AMBA Koc=105.61 g/l(pH5.1)**
maize	Châteaudun	0.000417	0.004982	0.000361
	Hamburg	0.04099	0.069323	0.016222
	Kremsmünster	0.002036	0.012882	0.001924
	Okehampton	0.005618	0.035620	0.005396
	Piacenza	0.003032	0.010297	0.002512
	Porto	0.000631	0.009846	0.000253
	Sevilla	0.000003	0.000785	0.000045
	Thiva	0.000080	0.001163	0.000034
Crop	**Scenario**	**80th Percentile PEC$_{GW}$ at 1 m Soil Depth (μg/L)**		
		Mesotrione DT50-5.4 (pH7.9) Koc=17.39g/L	**MNBA**	**AMBA Koc=21.8 g/l(pH7.9)**
maize	Châteaudun	0.000108	0.000294	0.003440
	Hamburg	0.001818	0.008489	0.031411
	Kremsmünster	0.000816	0.002286	0.026791
	Okehampton	0.004682	0.010278	0.064517
	Piacenza	0.000005	0.000030	0.000559
	Porto	0.000008	0.000050	0.001074
	Sevilla	< 0.0000001	< 0.0000001	0.000004
	Thiva	0.000002	0.000005	0.000497

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione DT50-14.2 (pH6.5) Koc=52.2g/L	**MNBA**	**AMBA Koc=48.02 g/l(pH~~7~~ 6.5)**
maize	Châteaudun	0.010729	0.008203	0.001089
	Hamburg	0.042657	0.054560	0.017929
	Kremsmünster	0.029351	0.018181	0.005589
	Okehampton	0.054937	0.046186	0.011625
	Piacenza	0.012032	0.005029	0.002466
	Porto	0.003214	0.003269	0.000107
	Sevilla	0.000190	0.000256	0.000013
	Thiva	0.002791	0.001689	0.000120

Table 8.8-6.: PEC_{gw} for Mesotrione and metabolites on maize (with MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione DT50-27.88 (pH5.1) Koc=156.6g/L	**MNBA**	**AMBA Koc=105.61 g/l(pH5.1)**
maize	Châteaudun	0.000249	0.00258	0.0000014
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-5.4 (pH7.9) Koc=17.39g/L	**MNBA**	**AMBA Koc=21.8 g/l(pH7.9)**
maize	Châteaudun	0.0000449	0.000143	0.000246
Crop	**Scenario**	**80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)**		
		Mesotrione DT50-14.2 (pH6.5) Koc=52.2g/L	**MNBA**	**AMBA Koc=48.02 g/l(pH7)**
maize	Châteaudun	0.00446	0.00344	0.0000066

Conclusions:
According to PECgw modelling with FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5, FOCUS MACRO 5.5.4 a ground water contamination of the active substance Mesotrione at a concentration of ≥ 0.1 µg/L is not expected in use in Maize crop. For the metabolites a groundwater concentration of ≥ 0.1 µg/L can be excluded.
Assessment of relevance of ground water metabolites is performed and presented in section 10 of dRR.

Evaluation by zRMS	**PECgw (KCP 9.2.4)**
Modelling	For the active substance mesotrione and its metabolites MNBA, AMBA the calculations presented here are accepted.

	The applicant has used appropriate models for ground water FOCUS-PEARL 5.5.5, FOCUS-PELMO 6.6.4 and FOCUS MACRO 5.5.4. PEC_{GW} values were calculated for intended use on maize for the growth stage: BBCH 12 and crop interception=0% (the worst case). Input parameters used in FOCUS ground water modelling for active substance and its metabolites are correct. However, it should be noted that the DT50soil value of 0.54 days (pH 7.9) should be used for PECgw calculations instead of the 5.4 d value. The applicant used inappropriate the value of 5.4 d because in the EFSA conclusions (EFSA, 2016) this DT50soil was provided incor-rectly and it is not consistent with linear regression equation (p. 56 of EFSA 2016). The evaluator accepted the use of this incorrect DT50soil value (pH 7.9) for cal-culations of PECgw because this value represents the worst case and it does not affect the risk assessment.
PECgw	Results of modelling with FOCUS PELMO 6.6.4 and PEARL 5.5.5 show that the active substance mesotrione and its metabolites MNBA, AMBA are not ex-pected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the in-tended use for all scenarios. PECgw values for active substance mesotrione and its metabolites MNBA, AM-BA calculated by means the FOCUS MACRO 5.5.4. are below 0.1 µg/L for Châ-teaudun scenario.

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

PEC surface water calculations for Mesotrione and his metabolites: MNBA, AMBA and SYN 546974 have been made for BBCH= 12 because this is worse case than BBCH=14.

8.9.1 Justification for new endpoints

All endpoints used for PEC surface water calculations are EU approved and were evaluated on EU level and presented in:

- **Mesotrione -** 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	MEZI 100 SC
Use No.	1
Crop	Maize
Application rate (kg as/ha)	Mesotrione:100 g a.s/ha
Number of applications/interval (d)	1/-

Application window	March-May (relevant for STEP 1 and 2 only)
Application method	Boom sprayer
CAM (Chemical application method)	Appln soil linear
Soil depth (cm)	5
Models used for calculation	FOCUS STEP 1-2, FOCUS SWASH v 5.3, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v4.3.3, SWAN 5

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

Crop	Scenario	Application window used in modelling
Maize	D3	12 May – 11 June
	D4	18 May – 17 June
	D5	15 May – 14 June
	D6	25 April – 25 May
	R1	10 May – 9 June
	R2	9 May – 8 June
	R3	8 May – 7 June
	R4	15 April – 15 May

8.9.2.1 Mesotrione and its metabolites

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

Compound	Mesotrione	MNBA	AMBA	SYN 546974	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	339	245	215	291	EFSA Journal 2016;14(3):4419
Saturated vapour pressure (Pa)	1.0E-10 Pa at 20°C	0	0	0	EFSA Journal 2016;14(3):4419
Water solubility (mg/L)	160	160	160	160	EFSA Journal 2016;14(3):4419
K_{foc} (mL/g)	156.7 (log fit, pH 5.1 value) 52.2 (log fit, pH 6.5 value) 17.4 (log fit, pH 7.9 value)	3.2	- acid value for pH 5.1 (10th percentile maize crop area) - Kfoc 105.61 l/kg (log),	8020.60 (geomean value)	EFSA Journal 2016;14(3):4419

Compound	Mesotrione	MNBA	AMBA	SYN 546974	Value in accordance to EU endpoint y/n/ Reference
			arithmetic mean 1/n = 0.85 - alkali value for pH 7.9 (90th percentile maize crop area) - Kfoc 21.8 L/kg (log), arithmetic mean 1/n = 0.85 - intermediate pH 6.5 –48.02 l/kg (log)		
$DT_{50,soil}$ (d)	27.88 (linear fit, pH 5.1 value) 14.2 d (linear fit, pH 6.5 value) 5.4 d# (linear fit, pH 7.9 value)	3.6 d	14.5 d	0.1 d	EFSA Journal 2016;14(3):4419
$DT_{50,water}$ (d)	5.5 d	1000 d	1000 d	1000 d	EFSA Journal 2016;14(3):4419
$DT_{50,sed}$ (d)	1000 d	1000 d	1000 d	1000 d	
$DT_{50,whole\ system}$ (d)	5.6 d	1000 d	1000 d	1000 d	
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

*Not observed in soil, default values used for FOCUS steps 1 & 2

The EFSA conclusion (EFSA, 2016) states DT_{50} incorrectly as 5.4 days, which is not consistent with value used in PECSW modelling or with linear regression equation (p. 56 of EFSA 2016). The value of 0.54 days should have been used in calculations.

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Mesotrione following single application(s) of MEZI 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)*
Input values for pH 5.1- 100g a.s./ha					
Northern Europe	March-May				
Step 1	---	28.49	runoff/drainage	18.97	43.21

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 2		4.26	runoff/drainage	2.96	6.63
Input values for pH 6.5- 100g a.s./ha					
Northern Europe	March-May				
Step 1	---	32.08	runoff/drainage	21.43	16.27
Step 2		4.39	runoff/drainage	2.97	2.28
Input values for pH 7.9- 100g a.s./ha					
Northern Europe	March-May				
Step 1	---	33.50	runoff/drainage	22.40	5.67
Step 2		3.47	runoff/drainage	2.32	0.60
Step 3 for pH 5.1- 100g a.s./ha					
D3	ditch	0.5247	drainage	0.08460	0.1388
D4	pond	0.04485	drainage	0.04450	0.08687
D4	stream	0.4513	drainage	0.05604	0.07110
D5	pond	0.03121	drainage	0.02985	0.05938
D5	stream	0.4762	drainage	0.02391	0.06536
D6	ditch	0.5278	drainage	0.07580	0.1461
R1	pond	0.08008	runoff	0.06541	0.08850
R1	stream	**1.692**	runoff	0.1576	0.3925
R2	stream	**1.266**	runoff	0.1197	0.3441
R3	stream	**3.249**	runoff	0.2234	0.7096
R4	stream	**3.542**	runoff	0.3926	0.9838
Step 3 for pH 7.9- 100g a.s./ha					
D3	ditch	0.5248	drainage	0.08507	0.05621
D4	pond	0.02119	drainage	0.01664	0.006654
D4	stream	0.4494	drainage	0.001975	0.01475
D5	pond	0.02117	drainage	0.01627	0.006379
D5	stream	0.4689	drainage	0.004285	0.01173
D6	ditch	0.5240	drainage	0.07218	0.05270
R1	pond	0.02840	runoff	0.02309	0.01288
R1	stream	**1.090**	runoff	0.07199	0.07399
R2	stream	**3.174**	runoff	0.2861	0.3329
R3	stream	**3.835**	runoff	0.3622	0.3454
R4	stream	**4.186**	runoff	0.4627	0.4735
Step 3 for pH 6.5- 100g a.s./ha					

Scenario **FOCUS**	**Waterbody**	**Max PEC$_{sw}$ (µg/L)***	**Dominant entry route**	**7 d- PEC$_{sw,twa}$ (µg/L)****	**Max PEC$_{sed}$ (µg/kg)***
D3	ditch	0.5249	drainage	0.08501	0.08595
D4	pond	0.02161	drainage	0.01692	0.01249
D4	stream	0.4506	drainage	0.007030	0.02423
D5	pond	0.02183	drainage	0.01678	0.01632
D5	stream	0.4716	drainage	0.009529	0.02784
D6	ditch	0.5259	drainage	0.07406	0.08526
R1	pond	0.05291	runoff	0.04282	0.03269
R1	stream	**1.130**	runoff	0.1187	0.1580
R2	stream	**2.445**	runoff	0.2232	0.3939
R3	stream	**4.216**	runoff	0.4299	0.5700
R4	stream	**4.259**	runoff	0.4712	0.7232

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

Table 8.9-5: FOCUS Step 1,2 and 3 PEC$_{sw}$ and PEC$_{sed}$ for Mesotrione following single application(s) of MEZI 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)***
Input values for pH 5.1- 50g a.s./ha					
Northern Europe	March-May				
Step 1	---	14.25	runoff/drainage	9.48	21.60
Step 2		**2.13**	runoff/drainage	1.48	3.32
Input values for pH 6.5- 50g a.s./ha					
Northern Europe	March-May				
Step 1	---	16.03	runoff/drainage	10.72	8.13
Step 2		**2.19**	runoff/drainage	1.48	1.14
Input values for pH 7.9- 50g a.s./ha					
Northern Europe	March-May				
Step 1	---	16.75	runoff/drainage	11.20	2.83
Step 2		**1.74**	runoff/drainage	1.16	0.30
Step 3 for pH 5.1- 50g a.s./ha					
D3	ditch	0.2624	drainage	0.04229	0.07069
D4	pond	0.02235	drainage	0.02217	0.04395

Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)***	**Dominant entry route**	**7 d- $PEC_{sw,twa}$ (µg/L)****	**Max PEC_{sed} (µg/kg)***
D4	stream	0.2257	drainage	0.02800	0.03583
D5	pond	0.01546	drainage	0.01479	0.02980
D5	stream	0.2380	drainage	0.01184	0.03166
D6	ditch	0.2637	drainage	0.03766	0.07344
R1	pond	0.04007	runoff	0.03276	0.04568
R1	stream	**0.8474**	runoff	0.07970	0.1996
R2	stream	0.6129	runoff	0.05812	0.1701
R3	stream	**1.594**	runoff	0.1828	0.3546
R4	stream	**1.749**	runoff	0.1939	0.4951
Step 3 for pH 7.9- 50g a.s./ha					
D3	ditch	0.2624	drainage	0.04253	0.02850
D4	pond	0.01059	drainage	0.008316	0.003375
D4	stream	0.2248	drainage	0.002892	0.007462
D5	pond	0.01059	drainage	0.008132	0.003237
D5	stream	0.2346	drainage	0.002144	0.005946
D6	ditch	0.2620	drainage	0.03609	0.02673
R1	pond	0.01442	runoff	0.01172	0.006611
R1	stream	0.5470	runoff	0.03647	0.03762
R2	stream	**1.573**	runoff	0.1419	0.1673
R3	stream	**1.921**	runoff	0.1816	0.1753
R4	stream	**2.089**	runoff	0.2309	0.2396
Step 3 for pH 6.5- 50g a.s./ha					
D3	ditch	0.2626	drainage	0.04272	0.03952
D4	pond	0.01092	drainage	0.008575	0.005863
D4	stream	0.2257	drainage	0.004252	0.01210
D5	pond	0.01094	drainage	0.008428	0.007124
D5	stream	0.2361	drainage	0.005359	0.01275
D6	ditch	0.2629	drainage	0.03699	0.03849
R1	pond	0.02624	runoff	0.02125	0.01424
R1	stream	0.5668	runoff	0.05897	0.07169
R2	stream	**1.246**	runoff	0.1137	0.1871
R3	stream	**2.109**	runoff	0.2148	0.2668
R4	stream	**2.130**	runoff	0.2356	0.3400

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

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

FOCUS Step 4

Table 8.9-6: Global maximum PEC_{sw} values for Mesotrione, following single application(s) of MEZI 100 SC to Maize according to the central EU zone GAP according to surface water Step 4

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 5.1- 100g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	-	-	-
None	D4 pond		-	-
None	D4 stream	-	-	-
None	D5 pond	-	-	-
None	D5 stream	-		
None	D6 ditch	-		
None	R1 pond	-	-	-
None	R1 stream	**1.692**	0.7659	-
None	R2 stream	**1.266**	**0.9189**	0.2892
None	R3 stream	**3.249**	**1.466**	0.7667
None	R4 stream	**3.542**	**1.610**	**0.8437**

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 7.9- 100g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	-	-	-
None	D4 pond	-	-	-
None	D4 stream	-	-	-
None	D5 pond	-	-	-
None	D5 stream	-	-	-
None	D6 ditch	-	-	-
None	R1 pond	-	-	-
None	R1 stream	**1.090**	0.4474	-
None	R2 stream	**3.174**	**1.401**	0.7256
None	R3 stream	**3.835**	**1.731**	**0.9058**

PEC_{SW} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 7.9- 100g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	R4 stream	**4.186**	**1.903**	**0.9972**

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

PEC_{SW} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 6.5- 100g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	**-**	**-**	**-**
None	D4 pond	**-**	**-**	**-**
None	D4 stream	**-**	**-**	**-**
None	D5 pond	**-**	**-**	**-**
None	D5 stream	**-**	**-**	**-**
None	D6 ditch	**-**	**-**	**-**
None	R1 pond		**-**	**-**
None	R1 stream	**1.130**	0.4638	**-**
None	R2 stream	**2.445**	**1.079**	0.5585
None	R3 stream	**4.216**	**1.903**	**0.9957**
None	R4 stream	**4.259**	**1.936**	**1.014**

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

Table 8.9-7: Global maximum PEC_{SW} values for Mesotrione, following single application(s) of MEZI 100 SC to Maize according to the central EU zone GAP according to surface water Step 4

PEC_{SW} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 5.1- 50g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	1	10	20
None	D3 ditch	**-**	**-**	**-**
None	D4 pond	**-**	**-**	**-**

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 5.1- 50g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	None	None
	No spray buffer (m)	1	10	20
None	D4 stream	-	-	-
None	D5 pond	-	-	-
None	D5 stream	-	-	-
None	D6 ditch	-	-	-
None	R1 pond	-	-	-
None	R1 stream	**0.8474**	0.3835	-
None	R2 stream	-	-	-
None	R3 stream	**1.594**	0.7191	-
None	R4 stream	**1.749**	**0.7950**	0.4166

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 7.9- 50g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	10	20
	No spray buffer (m)	1	10	20
None	D3 ditch	-	-	-
None	D4 pond	-	-	-
None	D4 stream	-	-	-
None	D5 pond	-	-	-
None	D5 stream	-	-	-
None	D6 ditch	-	-	-
None	R1 pond	-	-	-
None	R1 stream	-	-	-
None	R2 stream	**1.573**	0.6945	-
None	R3 stream	**1.921**	**0.8670**	0.4537
None	R4 stream	**2.089**	**0.9498**	0.4977
PEC_{sw} (µg/L)	**Scenario**	**STEP 4 Mesotrione pH 6.5- 50g a.s./ha**		
Nozzle reduction	Vegetative strip (m)	None	None	None

	No spray buffer (m)	1	10	20
None	D3 ditch	-	-	-
None	D4 pond	-	-	-
None	D4 stream	-	-	-
None	D5 pond	-	-	-
None	D5 stream	-	-	-
None	D6 ditch	-	-	-
None	R1 pond	-	-	-
None	R1 stream	-	-	-
None	R2 stream	**1.246**	0.5500	-
None	R3 stream	**2.109**	**0.9522**	0.4984
None	R4 stream	**2.130**	**0.9680**	0.5073

According to EFSA Journal 2016;14(3):4419, for Mesotrione Regulatory Acceptable Concentration RAC= 0.77 µg a.s./L and it is set by *Lemma gibba* study on the basis of EbC_{50} = 0.0077 mg a.s./$L_{(nom)}$

Metabolite(s) of Mesotrione

Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for MNBA following single application(s) to Maize (Application rate 100g as/ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Input values for pH 5.1					
Northern Europe	March-May				
Step 1	---	15.67	runoff/drainage	15.63	0.5
Input values for pH 6.5					
Northern Europe	March-May				
Step 1	---	15.67 ~~68~~	runoff/drainage	15.63~~06~~	0.5 ~~4997~~
Input values for pH 7.9					
Northern Europe	March-May				
Step 1	---	15.67	runoff/drainage	15.63	0.50

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

According to EFSA Journal 2016;14(3):4419, for MNBA Regulatory Acceptable Concentration RAC= 4200 µg a.s./L and it is set by Green microalgae *Pseudokirchneriella subcapitata* study on the basis of ErC_{50} = 42 mg a.s./$L_{(nom)}$

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for AMBA following single application(s) to Maize (Application rate 100g as/ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Input values for pH 5.1					
Northern Europe	March-May				
Step 1	---	6.50	runoff/drainage	6.47	6.84
Input values for pH 6.5					
Northern Europe	March-May				
Step 1	---	6.96 ~~584~~	runoff/drainage	6.93 ~~161~~	3.34 ~~2725~~
Input values for pH 7.9					
Northern Europe	March-May				
Step 1	---	7.19	runoff/drainage	7.17	1.57

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

According to EFSA Journal 2016;14(3):4419, for AMBA Regulatory Acceptable Concentration RAC= 1400 µg a.s./L and it is set by Green microalgae *Pseudokirchneriella subcapitata* study on the basis of ErC_{50} = 14 mg a.s./$L_{(nom)}$

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for SYN 546974 following single application(s) to Maize (Application rate 100g as/ha)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Input values for pH 5.1					
Northern Europe	March-May				
Step 1	---	1.07	runoff/drainage	~~0.78~~ 0.84	~~64.92~~ 66.50
Input values for pH 6.5					
Northern Europe	March-May				
Step 1	---	1.07	runoff/drainage	~~0.8257~~ 0.84	~~65.50~~ 66.50
Input values for pH 7.9					
Northern Europe	March-May				

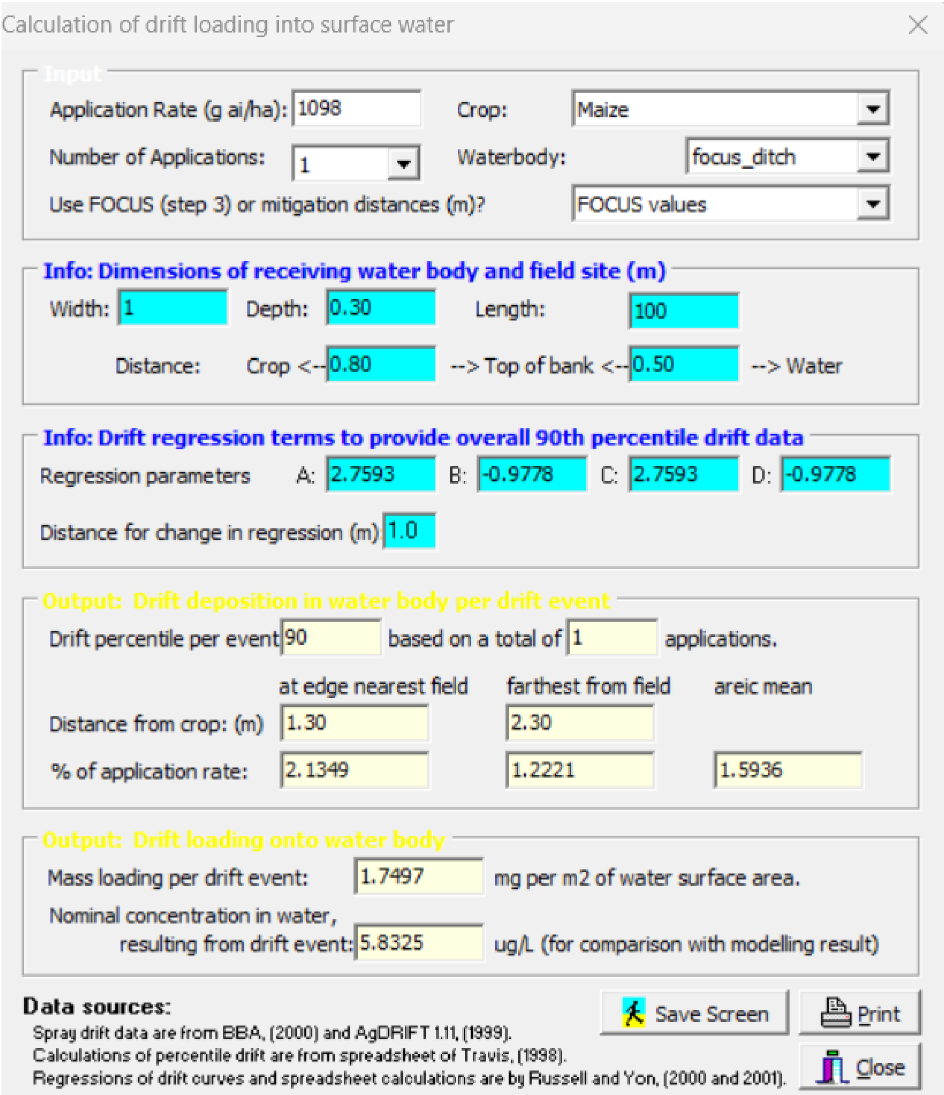
Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.07	runoff/drainage	0.84	66.50

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

According to EFSA Journal 2016;14(3):4419, for SYN546974 Regulatory Acceptable Concentration RAC= 9500 µg a.s./L and it is set by Gibbous duckweed (*Lemna gibba)* study on the basis of ErC_{50} > 95 mg a.s./$L_{(mm)}$

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

Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate in maize	1 x 1098 g [prod]/ha equivalent to 1 x 100 g a.s/ha
Resulting PECsw in maize	5.8325 µg[prod]/L(FOCUS ditch, for FOCUS values: 1.3m buffer zone) 7.0543 µg[prod]/L (FOCUS ditch and FOCUS stream, for 1m buffer zone)



Intended use	maize
Formulation	CHR/H/MEZ
Application rate (g[prod]/ha)	1 X 1098

Entry into surface water via spraydrift (Drift calculator from SWASH)

Waterbody	Buffer zone (m)	**PECsw [µg prod/L]**
FOCUS ditch	FOCUS values	5.8325
FOCUS stream		4.5429
FOCUS pond		0.2330
FOCUS ditch	**1**	~~5.8325~~ 7.0543
FOCUS stream		7.0543
FOCUS pond		0.3604
FOCUS ditch	**5**	1.9121
FOCUS stream		1.9121
FOCUS pond		0.2081
FOCUS ditch	**10**	1.0141
FOCUS stream		1.0141
FOCUS pond		0.1496
FOCUS ditch	**20**	0.5269
FOCUS stream		0.5269
FOCUS pond		0.0999

Conclusions:
In order to protect surface waters after applying MEZI 100 SC, the following restrictions should be applied:

- For Poland, Belgium, Czech Republic, Romania, Slovakia, Slovenia are necessary to maintain the 10 meters of vegetative buffer zone and 10 meters of no-spray zone.
- For Austria, Hungary and Republic of Ireland, are necessary to reduce application rate from 100 g as/ha to 50 g as/ha, because PECsw/sed values in R3, R4 scenarios relevant scenarios for these countries and are necessary to maintain: 20 meters no-spray zone for uses in pH=5.1 and pH=6.5 and 20 meters vegetative buffer zone and 20 meters no-spray zone for uses in pH=7.9.

Evaluation by zRMS	**PECsw (KCP 9.2.5)**
Inputs for Modelling	For the active substance mesotrione and its metabolites MNBA, AMBA and SYN546974 the calculations presented here are accepted. Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) have been calculated for mesotrione and its metabolites after the application of the product MEZI 100 SC on maize:

	- 1x 1l product MEZI 100 SC /ha; considering the pathways spray drift, drainage and runoff. In addition, for the active substance, $PEC_{SW}/_{SED}$ values were calculated for a dose of 50g a.s./ha. Input parameters used in FOCUS surface water/sediment modelling for active substance and its metabolites are correct. However, it should be noted that the $DT50_{soil}$ value of 0.54 days (pH 7.9) should be used for PECsw calculations instead of the 5.4 d value. The applicant used inappropriate the value of 5.4 d because in the EFSA conclusions (EFSA, 2016) this DT50soil was provided incorrectly and it is not consistent with value used in PECSW modelling and with linear regression equation (p. 56 of EFSA 2016). The evaluator accepted the use of this incorrect DT50soil value (pH 7.9) for calculations of PECsw because this value represents the worst case. The PEC_{SW} and PEC_{sed} were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2, 3 and 4). The calculations were carried out at Step 1 to Step 4 for mesotrione for two doses. For the metabolites, the values of the PEC_{SW} and PEC_{sed} were calculated at Step 1 and 2. **MEZI 100 SC** Calculations of PEC_{SW} values for formulation has been provided by Applicant only for focus ditch. zRMS completed the calculation of PEC_{sw} values for formulation. The results was presented in table above. Presented calculations of $PEC_{sw/sed}$ may be used for risk assessment.
Agreed endpoints	Please refer to Tables from 8.9-4 to 8.9-10.
Implication for risk assessment	Please refer to Part B, Section 9 of this dRR.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT50 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/cm3
Volatilisation	from plant surfaces (BBA guideline): <10% after 24 hours from soil surfaces (BBA guideline): <10% after 24 hours
Metabolites	not applicable

The vapour pressure at 20 °C of the active substance Mesotrione is < 5.7×10^{-6} Pa. Furthermore, photochemical oxidative degradation in air was estimated to be 17.6 hours and therefore, significant long-range transport and accumulation in the stratosphere is unlikely. ~~/between 10^{-5} and 10^{-4} Pa/> 10^{-4} Pa. Hence the active substance Mesotrione is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Mesotrione due to volatilization with subsequent deposition should be considered.~~

Evaluation by zRMS	**Fate and behaviour in air (KCP 9.3)**

Comments	The data on the atmospheric degradation and behaviour for the active substance follows the EU assessment and is therefore agreed by the zRMS.
Conclusion for exposure assessment	The vapour pressure at 20 °C of the active substance mesotrione is < 5.7×10^{-6} Pa. Hence the active substance mesotrione is regarded as non-volatile and the environmental concentrations in air and the transport through air are considered 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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1/71	Fish L.	2013	GIS study of the proportion of acid and alkaline soils under maize crop in Europe Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1012B Not GLP, not published Syngenta File No ZA1296_10160	N	Syngenta
KCP 9.1.1/72	Hand L.	2013	Mesotrione - Assessment of the significance of unidentified components from harsh extraction of soil residues in 14Ccyclohexanedione labelled mesotrione soil metabolism studies Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, Not GLP, not published Syngenta File No ZA1296_10185	N	Syngenta
KCP 9.1.1/73	Graham R., Gilbert J.	2013	Mesotrione - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059C Not GLP, not published Syngenta File No ZA1296_10135	N	Syngenta

KCP 9.1.1/74	Bramley YM, Pinheiro S I, Verity A A	2002	Mesotrione Comparison of Adsorption Properties of Mesotrione and Its copper Salt in Four Soils Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel Switzerland, RJ3289B GLP, not published Syngenta File No ZA1296/0831	N	Syngenta
KCP 9.1.1/75	Hurst L.	2013	SYN546974 - Adsorption and Desorption Properties of Phenyl-U- 14C-SYN546974, a Metabolite of Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252095 GLP, not published	N	Syngenta
KCP 9.1.1/76	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999) GLP, not published	N	Syngenta
KCP 9.1.1/77	Miller, M.M.	1997	[Phenyl-U-14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B In DAR (1999) GLP, not published	N	Syngenta

KCP 9.1.1/78	Miller, M.M., Wilson, W.R.	1997	[phenyl-U-14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory Condition. Zeneca Agrochemicals Report No: RR96-099B GLP, not published	N	Syngenta
KCP 9.1.1/79	Subba-Rao, R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-082B GLP, not published	N	Syngenta
KCP 9.1.1/80	Tarr, J.B.	1997	[phenyl-U-14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions. Zeneca Agrochemicals Report No: RR93-092B GLP, not published	N	Syngenta
KCP 9.1.1/81	Vispetto, A.R., Tovshteyn, M.	1996	[cyclohexane-2-14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B GLP, not published	N	Syngenta
KCP 9.1.1/82	Vispetto, A.R., Tovshteyn, M.	1997	Addendum to: [Cyclohexane-2-14C]ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-047B ADD GLP, not published	N	Syngenta

KCP 9.1.1/83	Lay, M.M	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B GLP, not published	N	Syngenta
KCP 9.1.1/84	Graham, D.G. et al	1997a	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B GLP, not published	N	Syngenta
KCP 9.1.1/85	Graham, D.G. et al	1997b	Field Dissipation Study Carried Out in Italy During 1995-1996. Zeneca Agrochemicals Report No: RR97-025B GLP, not published	N	Syngenta
KCP 9.1.1/86	Graham, D.G. et al	1997c	Field Dissipation Study Carried Out in Germany During 1995-1996. Zeneca Agrochemicals Report No: RR97-051B GLP, not published	N	Syngenta
KCP 9.1.1/87	Graham, D.G. et al	1998a	Field Dissipation Study Carried Out in Germany During 1996-1997. Zeneca Agrochemicals Report No: RR97-067B GLP, not published	N	Syngenta

KCP 9.1.1/88	Graham, D.G. et al	1998b	Field Dissipation Study Carried Out in Italy During 1996-1997. Zeneca Agrochemicals Report No: RR97-070B GLP, not published	N	Syngenta
KCP 9.1.1/89	Wiebe, L.A., Yeh, S. M.	1999	ZA 1296: Stability of ZA 1296 and the metabolites MNBA and AMBA in Frozen Soil (WRC-98-158). (WINO 12775). Zeneca Agrochemicals Report No: RR98-065B	N	Syngenta
KCP 9.1.2/67	Carley, S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR96-033B In DAR (1999)	N	Syngenta
KCP 9.1.2/68	Diaz, D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B In DAR (1999)	N	Syngenta
KCP 9.1.2/69	Diaz, D.G.	1996a	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B In DAR (1999)	N	Syngenta

KCP 9.1.2/70	Diaz, D.G.	1996b	[14C]AMBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-009B In DAR (1999)	N	Syngenta
KCP 9.1.2/71	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999)	N	Syngenta
KCP 9.2/82	Oliver R., Edwards P.	2005	Mesotrione (ZA1296): [U-14C]-Phenyl Labelled Sterile Natural Water Photolysis Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott’s Hill International, Bracknell, Berkshire, United Kingdom, RJ3634B 04JH012 GLP, not published	N	Syngenta

KCP 9.2/83	Graham R., Yeomans P.	2013	Mesotrione - Aerobic Mineralisation of 14C-Phenyl Labelled ZA1296 in Surface Water Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252099 GLP, not published	N	Syngenta
KCP 9.2/84	Graham R., Gilbert J.	2013a	Mesotrione - Aerobic and Anaerobic Aquatic Sediment Metabolism of [Phenyl-14C]-Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8236956 GLP, not published	N	Syngenta
KCP 9.2/85	Hardy I.	2013a	Mesotrione - Kinetic Modelling Analysis of Data from Water Sediment Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059A Not GLP, not published	N	Syngenta

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the new Annex II studies

Not required

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

Not required.