FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: MEZ-HER 100 SC

Product name(s): MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

MS Finalisation date: April 2024, August 2024

Version history

When	What
October 2023	Applicant submission
April 2024	Initial assessment by the zRMS
August 2024	The final Registration Report after 1st commenting period

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Maize	F	**1 L/ha susceptible** **Pigweed** *Amaranthus retroflexus* AMARE; **Field chamomile** *Anthemis arvensis* ANTAR; **Shepherd's purse** *Capsella bursa-pastoris* CAPBP; **Fat-hen** *Chenopodium album* CHEAL; **Common barnyard grass** *Echinochloa crus-galli* ECHCG; **Cleavers** *Galium aparine* GALAP; **Gallant soldier** *Galinsoga parviflora* GASPA; **Purple deadnettle** *Lamium purpureum* LAMPU; **Wild buckwheat** *Fallopia convolvulus* POLCO; **Common chickweed** *Stellaria media* STEME;	broadcast spraying	BBCH 14-15 Spring, post emergence	1 a) 1 b) 1	N/A	1 L/ha a) 1 L/ha b) 1 L/ha	100g mesotrione a) 100g mesotrione b) 100g mesotrione	200-300 L/ha	not relevant		A

				Fanweed *Thlaspi arvense* THLAR; **Field pansy** *Viola arvensis* VIOAR **<u>1L/ha Moderarely susceptible</u>** **Common fumitory** *Fumaria officinalis* FUMOF										
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

8.2 Metabolites considered in the assessment

Information concerning metabolites relevant for modelling is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC.

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Information concerning aerobic degradation in soil is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Information concerning anaerobic degradation in soil is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.4 Field studies (KCP 9.1.1.2)

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

Information concerning soil dissipation is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Information concerning soil accumulation is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.5 Mobility in soil (KCP 9.1.2)

8.5.1 Column leaching (KCP 9.1.2.1)

Information concerning mobility in soil (column leaching) is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Information concerning mobility in soil (lysimeter studies) is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Information concerning mobility in soil (field leaching studies) is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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

Information concerning degradation in the water/sediment is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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

Information concerning PECs for active substances and relevant metabolites is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

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

~~Not relevant. See point 8.7.~~

Use No.	**1**
Crop	Maize
Application rate (g as/ha)	Mesotrione: 100
Number of applications / interval (d)	1 / -
Application timing	Early post-emergence
Crop interception (%)	25
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage) [a]

[a] Due to DT_{50} of all compounds being <60 days and DT_{90} being <365 days, accumulation in soil is not expected and calculation of $PEC_{soil,accu}$ was not required.

Input parameter for active substances and relevant metabolites for PECs calculation

Substance	**Molar mass [g/mol]**	**Molar ratio**	**Max occurrence**	DT_{50} (days)	**Value in accordance to EU endpoint / Reference**
Mesotrione	339.3	parent	parent	28.7 (max. lab., not normalised)	Yes, EFSA (2016)
MNBA	245	0.722	57.2%	15.7(max. lab., not normalised)	Yes, EFSA (2016)
AMBA	215	0.634	9.7%	58.7 (max. lab., not normalised)	Yes, EFSA (2016)

Results are presented in the table below.

Application pattern	**PECsoil [mg/kg dws]**		
	Mesotrione	**MNBA**	**AMBA**
Maize, 1x100 g a.s./ha	0.100	0.041	0.006

Due to DT_{50} of all compounds being <60 days and DT_{90} being <365 days, accumulation in soil is not expected and calculation of $PEC_{soil,accu}$ was not required.

As for metabolite MNBA higher PEC_{soil} values were calculated with approach indicated by the cMS, the soil risk assessment will be amended accordingly. For AMBA recalculated PEC_{soil} values are lower, so the risk assessment based on higher values derived using ESCAPE does not need to be corrected as it already represents worst case.

Table 8.7-1: PECS for mesotrione on maize

PECS (mg/kg)		**Maize, 1 x 100 g a.s./ha**	
		Actual	**TWA**
Initial		0.100	-
Short term	24h	0.098	0.099
	2d	0.095	0.098
	4d	0.091	0.095
Long term	7d	0.084	0.092
	14d	0.071	0.085
	21d	0.060	0.078
	28d	0.051	0.073
	42d	0.036	0.063
	50d	0.030	0.058
	100d	0.009	0.038
$PEC_{S,plateau}$		not relevant	-
$PEC_{S,accumulation}$ (= PEC_{act} +$PEC_{S\ plateau}$)		not relevant	-

PECS of metabolites

Following input parameters were considered:

Substance	**Molar mass [g/mol]**	**Molar ratio**	**Max occurrence**
Mesotrione	339.3	parent	parent
MNBA	245	0.722	57.2%
AMBA	215	0.634	9.7%

Metabolite PEC_{soil} = Parent PEC_{soil} x molar ratio x max occurrence

Results are presented in the table below.

Application pattern	**PECsoil [mg/kg dws]**		
	Mesotrione	**MNBA**	**AMBA**
Maize, 1x100 g a.s./ha	0.100	0.041	0.006

Due to DT_{50} of all compounds being <60 days and DT_{90} being <365 days, accumulation in soil is not expected and calculation of $PEC_{soil,accu}$ was not required.

8.7.1.1 PEC_{soil} of formulation

Not relevant. See point 8.7.

PEC_S of A12739A

Table 8.7-2: PEC_S for A12739A on maize

Use pattern	Preparation	Application rate (g/ha)	Crop interception (%)	$PEC_{S,ini}$ (mg/kg) [b]
Maize (1 x 100 g a.s/ha, early post-emergence)	A12739A	1 x 1090 [a]	25	1.09

[a] Based on an application rate of 1.5 / 1.0 / 0.75 L/ha for Use 1 / 2 / 3 and a product density of 1.09 g/cm³.

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

8.8.1 Justification for new endpoints

Not relevant.

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

In respect to the harmonization guidance for Poland, posted on the website of the Ministry of Agriculture and Rural Development, calculations for Predicted Environmental Concentrations in groundwater (PECgw) with the latest versions of the FOCUS-PELMO v6.6.4, FOCUS - PEARL v5.5.5 and MACRO v5.5.4. Modeling using the EU agreed input parameters, application dates as suggested by App Date 3.06 and relevant crop interception according FOCUS groundwater guidance (2014) was conducted.

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

Use No.	1
Crop	Maize
Application rate (g as/ha)	100
Number of applications/interval (d)	1/-
Relative application date*	14 d after emegrance
Crop interception (%)	25%
Frequency of application	annual
Models used for calculation	FOCUS PEARL, v 5.5.5; FOCUS PELMO v6.6.4, MACRO v5.5.4

*for MACRO calculation, 16.05 (136 respective Julian day) was used

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

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	339.3	245	215	EFSA (2016)

Compound	Mesotrione	MNBA	AMBA	Value in accordance with EU endpoint y/n/ Reference*
Water solubility (mg/L):	160 at 20°C	32400 at 20°C	23000 at 20°C	EFSA (2016)
Saturated vapour pressure (Pa):	0 at 20°C	0 at 20°C	0 at 20°C	Worst case assumption
DT_{50} in soil (d)	pH dependence of degradation, therefore different values simulated: 1) 4 (shortest normalised laboratory DT50) 2) 27.88 (acid value for pH 5.1) 3) 0.54 (alkali value for pH 7.9) 4) 14.2 (intermediate pH 6.5)	3.4 (SFO, normalised, geometric mean DT_{50} lab)	14.5 (SFO, normalised, geometric mean DT_{50} lab)	EFSA (2016)
K_{foc} (mL/g)/K_{fom}	K_{fOC}: pH dependence of sorption, therefore different values simulated: 1) 14/8.12 (worst case) 2) 156.6/90.84 (acid value for pH 5.1) 3) 17.39/10.12 (alkali value for pH 7.9) 4) 52.2/30.28 (intermediate pH 6.5)	3.2 / 1.86 (worst case)	1) 18.1/10.5 (worst case) 2) 105.61/61.26 (acid value for pH 5.1) 3) 21.8/ 12.65 (alkali value for pH 7.9) 4) 48.02/27.85 (intermediate pH 6.5)	EFSA (2016)
1/n	1) 0.97 2) 0.94 3) 0.94 4) 0.94	0.90 (default)	1) 0.82 2) 0.85 3) 0.85 4) 0.85	EFSA (2016)
Plant uptake factor	0	0	0	EFSA (2016)
Formation fraction	-	1 from parent	0.25 from MNBA	EFSA (2016)
Conversion factor for MACRO	-	0.722 referring to mesotrione	0.158 referring to mesotrione	calculated
Formation rate	Transformation rate to MNBA (PELMO): 1) shortest DT50 0.173 2) pH 5.1 linear 0.0249 3) pH 7.9 linear 1.2836 4) pH 6.5 linear 0.0488	0.0510 to AMBA, 0.1529 to CO2	0.0478 to CO2	calculated

Table 8.8-3: PEC_{gw} for mesotrione and its metabolites on maize (with FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		mesotrione	MNBA	AMBA	mesotrione	MNBA	AMBA
		Tier I – worst case			Tier II – acidic soils		
maize BBCH 14	Châteaudun	0.000016	0.000101	0.001436	0.000362	0.004603	0.000343
	Hamburg	0.000748	0.005596	0.026011	0.004008	0.067578	0.015998
	Kremsmünster	0.000261	0.001713	0.018596	0.001833	0.011931	0.001784
	Okehampton	0.000935	0.004374	0.051058	0.004859	0.031919	0.004661
	Piacenza	0.000005	0.000029	0.003647	0.002930	0.010422	0.002481
	Porto	0.000001	0.000005	0.000134	0.000619	0.009803	0.000252
	Sevilla	0.000000	0.000000	0.000000	0.000002	0.000043	0.000778
	Thiva	0.000000	0.000001	0.000197	0.000086	0.001165	0.000037
	-	Tier III – alkaline soils			Tier IV – intermidiete soils		
	Châteaudun	0.000000	0.000012	0.001023	0.003307	0.004973	0.001266
	Hamburg	0.000000	0.000951	0.014570	0.016138	0.047671	0.021403
	Kremsmünster	0.000000	0.000342	0.009543	0.011787	0.012403	0.008355
	Okehampton	0.000000	0.001031	0.030041	0.028523	0.030777	0.014505
	Piacenza	0.000000	0.000003	0.002142	0.006525	0.004294	0.003242
	Porto	0.000000	0.000000	0.000185	0.001116	0.001665	0.000115
	Sevilla	0.000000	0.000000	0.000001	0.000041	0.000156	0.000012
	Thiva	0.000000	0.000000	0.000153	0.000846	0.001041	0.000143

Table 8.8-4: PECgw for mesotrione and its metabolites on maize (with FOCUS PELMO 6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		mesotrione	MNBA	AMBA	mesotrione	MNBA	AMBA
		Tier I – worst case			Tier II – acidic soils		
maize BBCH 14	Châteaudun	0.000	0.000	0.000	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000	0.000	0.001	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.000	0.000	0.002	0.000
	Piacenza	0.000	0.001	0.010	0.004	0.024	0.004
	Porto	0.000	0.000	0.000	0.000	0.004	0.000
	Sevilla	0.000	0.000	0.000	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000	0.000	0.001	0.000

	-	Tier III – alkaline soils			Tier IV – intermidiete soils		
	Châteaudun	0.000	0.000	0.000	0.000	0.000	0.000
	Hamburg	0.000	0.000	0.000	0.000	0.000	0.000
	Kremsmünster	0.000	0.000	0.000	0.000	0.000	0.000
	Okehampton	0.000	0.000	0.001	0.001	0.001	0.000
	Piacenza	0.000	0.000	0.006	0.020	0.009	0.000
	Porto	0.000	0.000	0.000	0.000	0.001	0.000
	Sevilla	0.000	0.000	0.000	0.000	0.000	0.000
	Thiva	0.000	0.000	0.000	0.001	0.000	0.000

Table 8.8-5: PECgw for mesotrione and its metabolites on maize (with MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)											
		Mesotrione				MNBA				AMBA			
		Worst case	pH 5.1	pH 6.5	pH 7.9	Worst case	pH 5.1	pH 6.5	pH 7.9	Worst case	pH 5.1	pH 6.5	pH 7.9
Maize BBCH 14	Châteaudun	<0.001	0.000299	0.00138	0.000	<0.001	0.00358	0.00264	<0.001	<0.001	<0.001	<0.001	<0.001

Conclusions:

The 80th percentiles of the predicted annual average leachate concentrations of mesotrione and its metabolites were below 0,1 µg/L in all calculated scenarios.

zRMS comments:

The calculations was performed for the active substances and their relevant metabolites. The groundwater modelling has been performed in accordance with the Generic guidance for Tier I FOCUS Ground Water Assessments, Version: 2.3, date: June 2021 using FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4 and MARCO 5.5.4.
Input parameters for active substance and metabolites have been taken from EFSA Journal 2016;14(3):4419. Application timing for each crop/scenario was settled with AppDate 3.06 and application date uses was 14 days after emergence.

Calculations performed for mesotrione and its metabolite MNBA and AMBA was accepted by zRMS.

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

Information concerning PECsw for active substances and relevant metabolites is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

The following data was copied from the report Callisto 100 SC.

Table 8.9-1: Input parameters related to active substance mesotrione and metabolites MNBA, AMBA and SYN546974 for $PEC_{SW/SED}$ calculations STEP 1/2 and 3/4

Compound	Mesotrione	MNBA	AMBA	SYN546974	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	339.3	245	215	291	Yes, EFSA (2016)
Water solubility (mg/L)	160* (20)	32400** (20)	23000** (20)	160*** (---)	* Yes, EFSA (2016) ** Yes, RAR (2015) *** Not available, parent value
Saturated vapour pressure (Pa)	0 (20)	- [a]	- [a]	- [a]	Worst case assumption
Diffusion coefficient in water (m^2/d)	4.3×10^{-5}	- [a]	- [a]	- [a]	FOCUS default
Diffusion coefficient in air (m^2/d)	0.43	- [a]	- [a]	- [a]	FOCUS default
K_{FOC} (mL/g)	acidic soil [b]: 156.7 neutral soil [c]: 52.2 alkaline soil [d]: 17.39 (pH dependent: log fit, n = 10)	3.2 (worst case, n=2, pH independent)	acidic soil [b]: 105.6 neutral soil [c]: 48.0 alkaline soil [d]: 21.8 (pH dependent: log fits, n = 5)	8021 (geometric mean, n=5)	Yes, EFSA (2016)
Freundlich exponent 1/n	0.94 (arithmetic mean, n = 10 to be used for all pH scenarios)	- [a]	- [a]	- [a]	Yes, EFSA (2016)
Plant uptake	0	- [a]	- [a]	- [a]	Yes, EFSA (2016)
Wash-off factor from crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	- [a]	- [a]	- [a]	FOCUS default
$DT_{50,soil}$ (d)	acidic soil [b]: 27.88 neutral soil [c]: 14.2 alkaline soil [d]: 0.54 (pH dependent: linear fit, lab. data, normalisation to pF2, 20 °C, n = 18)	3.4 (geometric mean, n=10, lab. data, pH independent, normalisation to pF2, 20 °C)	14.5 (geometric mean, n=5, lab. data, pH independent, normalisation to pF2, 20 °C)	0.1 (FOCUS default value)	Yes, EFSA (2016)
$DT_{50,water}$ (d)	5.5 (geometric mean, n=6)	1000 (conservative default value)	1000 (conservative default value)	1000 (conservative default value)	Yes, EFSA (2016)
$DT_{50,SED}$ (d)	Step 1-2: 5.6 (whole system value) Step 3-4: 1000 (conservative default value)	1000 (conservative default value)	1000 (conservative default value)	1000 (conservative default value)	Yes, EFSA (2016)
$DT_{50,whole\ system}$ (d)	5.6 (geometric mean, n=6)	1000 (conservative default value)	1000 (conservative default value)	1000 (conservative default value)	Yes, EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 100 Water: 100 Sed.: 4.3 Total sys.: 100	Soil: 57.2 Water: 7.4 Sed.: <1 Total sys.: 7.4	Soil: 9.7 Water: 15.8 Sed.: 8.8 Total sys.: 24.6	Soil: 0 Water: 9.4 Sed.: 25.6 Total sys.: 33	Yes, EFSA (2016)
Formation fraction in soil	-	- [a]	- [a]	- [a]	-

[a] not required for Steps 1 & 2
[b] acid value for pH 5.1
[c] neutral value for pH 6.5
[d] alkaline value for pH 7.9

Table 8.9-1: FOCUS Step 1-2 and 3 PEC_{SW} and PEC_{SED} for mesotrione following application of A12739A (Step 3 maxima of calculations with pH dependent parameter sets

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d-$PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Maize, 1 x 100 g a.s./ha, early post-emergence					
Step 1	---	33.5	-	11.9	43.2
Step 2					
Northern Europe	Mar – May	4.38	-	1.54	6.38
Southern Europe	Mar – May	8.22	-	2.89	12.2
Step 3					
D3	ditch	0.525	Spray drift	0.028	0.137
D4	pond	0.056	Drainage	0.052	0.106
D4	stream	0.451	Spray drift	0.045	0.085
D5	pond	0.031	Drainage	0.025	0.062
D5	stream	0.459	Spray drift	0.018	0.067
D6	ditch	0.527	Spray drift	0.030	0.152
R1	pond	0.076	Runoff	0.048	0.084
R1	stream	1.60	Runoff	0.066	0.372
R2	stream	2.16	Runoff	0.066	0.349
R3	stream	3.94	Runoff	0.140	0.684
R4	stream	4.16	Runoff	0.177	0.994

FOCUS Step 4

Table 8.9-2 contains the maximum PEC_{SW} and PEC_{SED} over all three parameter sets at Step 4. Detailed results for acidic, neutral and alkaline soils are presented in the report Callisto.

Table 8.9-2: Global maximum PEC_{SW} values for mesotrione, following application of A12739A according to surface water Step 4 – maxima of calculations with all pH dependent parameter sets

Mitigation options									
Vegetative filter strip (m) [a]		-		-		10 (L & M)		20 (L & M)	
No spray buffer (m)		-		5		10		20	
Nozzle reduction (%)		50		-		-		-	
Maize 100 g a.s/ha early post-emergence	D3 ditch	0.263	Spray drift	0.172	Spray drift	0.091	Spray drift	0.048	Spray drift
	D4 pond	0.056	Drainage	0.056	Drainage	0.056	Drainage	0.056	Drainage
	D4 stream	0.227	Spray drift	0.191	Spray drift	0.102	Spray drift	0.090	Drainage
	D5 pond	0.031	Drainage	0.031	Drainage	0.031	Drainage	0.031	Drainage
	D5 stream	0.235	Spray drift	0.199	Spray drift	0.111	Spray drift	0.063	Spray drift
	D6 ditch	0.265	Spray drift	0.175	Spray drift	0.094	Spray drift	0.050	Spray drift
	R1 pond	0.071	Runoff	0.075	Runoff	0.033	Runoff	0.018	Runoff
	R1 stream	1.60	Runoff	1.60	Runoff	0.724	Runoff	0.379	Runoff
	R2 stream	2.16	Runoff	2.16	Runoff	0.952	Runoff	0.493	Runoff
	R3 stream	3.94	Runoff	3.94	Runoff	1.78	Runoff	0.931	Runoff
	R4 stream	4.16	Runoff	4.16	Runoff	1.89	Runoff	0.992	Runoff

[a] L & M = mitigation according to FOCUS Landscape and Mitigation V1 (2007); reduction for 10 / 20 m buffer is 60 / 80 % in runoff flux and volume and 85 / 95 % in sediment flux and mass

Table 8.9-3: FOCUS Step 4: TWA PEC_{SW} for mesotrione following application of A12739A according to surface water Step 4– maxima of calculations with all pH dependent parameter sets

Mitigation options								
Vegetative strip (m) [a]		-		-		10 (L & M)		20 (L & M)	
No spray buffer (m)		-		5		10		20	
Nozzle reduction (%)		50		-		-		-	
Use pattern	**Scenario**	**Time weighted average PEC_{SW} (µg/L)**							
		7-d	**21-d**	**7-d**	**21-d**	**7-d**	**21-d**	**7-d**	**21-d**
Maize 1 x 100 g a.s/ha Early post-emergence	D3 ditch	0.042	0.014	0.027	0.009	0.015	0.005	0.008	0.003
	D4 pond	0.055	0.052	0.055	0.052	0.055	0.052	0.055	0.052
	D4 stream	0.070	0.045	0.070	0.045	0.070	0.045	0.070	0.045
	D5 pond	0.030	0.025	0.030	0.025	0.030	0.025	0.030	0.025
	D5 stream	0.023	0.018	0.023	0.018	0.023	0.018	0.023	0.018
	D6 ditch	0.043	0.016	0.029	0.012	0.017	0.008	0.011	0.006
	R1 pond	0.058	0.045	0.061	0.047	0.027	0.021	0.014	0.011
	R1 stream	0.150	0.066	0.150	0.066	0.067	0.029	0.035	0.015
	R2 stream	0.193	0.065	0.192	0.065	0.085	0.028	0.044	0.015
	R3 stream	0.398	0.137	0.398	0.136	0.178	0.061	0.093	0.032
	R4 stream	0.461	0.176	0.461	0.175	0.210	0.080	0.110	0.042

[a] L & M = mitigation according to FOCUS Landscape and Mitigation V1 (2007): reduction for 10 / 20 m buffer is 60 / 80 % in runoff flux and volume and 85 / 95 % in sediment flux and mass

Metabolites of mesotrione

The following three tables present the maxima over all pH dependent parameter sets for each metabolite (see Table 8.9-4 for MNBA, Table 8.**9-5** for AMBA and

Table 8.**9-6** for SYN546974. Details for each parameter set are then given in to **Błąd! Nie można odnaleźć źródła odwołania.**.

Table 8.9-4: FOCUS Step 1-2 PEC_{SW} and PEC_{SED} for MNBA- maxima of calculations with all pH dependent parameter sets

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Maize, 1 x 100 g a.s./ha, early post-emergence					
Step 1	---	15.5	-	15.4	0.497
Step 2					
Northern Europe	Mar – May	1.20	-	1.19	0.038
Southern Europe	Mar – May	2.35	-	2.33	0.075
Step 3	not required				

Table 8.9-5: FOCUS Step 1-2 PEC_{SW} and PEC_{SED} for AMBA - maxima of calculations with all pH dependent parameter sets

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Maize, 1 x 100 g a.s./ha, early post-emergence					
Step 1	---	7.18	-	7.13	6.83
Step 2					
Northern Europe	Mar – May	0.978	-	0.969	1.02
Southern Europe	Mar – May	1.82	-	1.80	1.91
Step 3	not required				

Table 8.9-6: FOCUS Step 1-2 PEC_{SW} and PEC_{SED} for SYN546974 - maxima of calculations with all pH dependent parameter sets

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Maize, 1 x 100 g a.s./ha, early post-emergence					
Step 1	---	1.07	-	0.829	66.4
Step 2					
Northern Europe	Mar – May	0.260	-	0.125	10.6
Southern Europe	Mar – May	0.260	-	0.216	19.3
Step 3	not required				

zRMS comments:

The PECsw/sed performed for Callisto 100 SC are suitable for the use of Mecorn 100 SC proposed in GAP.

The input parameters considered by the Applicant for surface water modelling were agreed by the zRMS.

In order to mitigate the risk, Step 4 simulations were performed with assumption of 5, 10 and 20 m spray drift buffer and 10 m and 20 m vegetative filter strips (for run-off scenarios) or 50% nozzle reduction. The run-off reduction was assumed in line with FOCUS Landscape and Mitigation recommendations (FOCUS, 2007).

The PEC_{SW}/PEC_{SED} values presented in Tables 8.9-4 to 8.9-9 for mesotrione and in Tables from 8.9-10 to 8.9-21 for metabolites may be used in the aquatic risk assessment.

8.9.1 Justification for new endpoints

Not relevant. See point 8.9.

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

Not relevant. See point 8.9.

8.9.2.1 $PEC_{sw/sed}$ of formulation

Not relevant. See point 8.9.

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

Information concerning fate and behaviour in air is included in RR for the reference product Callisto 100 SC. Please refer to Renewal RR prepared for Callisto 100 SC. No further data are required.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 9.2/01	Hara-Skrzypiec A.	2023	MEZ-HER 100 SC- calculation of Predicted Environmental Concentrations of mesotrione and its metabolites in ground water using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models. Company Report No: EST/18/2023 Source: ESTICON Sp. z o.o., Poland GEP: No Published: No	N	Pestila*

*Pestila Spółka z ograniczoną odpowiedzialnością

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
-	-	-	-	-	-

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 relevant. No new studies submitted.

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

Not relevant. No new data submitted.