FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021; 02.2023;

MS Finalisation date: 08.2023; 12/2023

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Version history

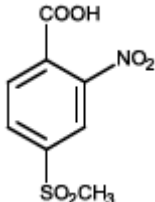| When	What
02.02.2023	Point 10.1 – Correction of data and information.
	Point 10.2 – Correction of data and information.
08.2023	Assessment after correction of data and information.
12.2023	The final Registration Report

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10 Relevance of metabolites in groundwater

10.1 General information

General information on the metabolites are provided in Table 10.1-1.

Table 10.1-1: General information on the metabolite(s)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessmnent	
Mesotrione	4-(methylsulfonyl)-2-nitrobenzoic acid MNBA		Max PEC_{gw} Based on:	PELMO: 0.143 µg/L Model results for the Hamburg scenario.

10.2 Relevance assessment of metabolites

Summary:

Table 10.2-1: PEC_{gw} for Mesotrione (worst case) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

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

Table 10.2-2: PEC_{gw} for Mesotrione (pH_5.1) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Mesotrione	MNBA	AMBA
Maize	Châteaudun	0,001022	0,009301	0,000752

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Hamburg	0,008177	0,116460	0,028499
Kremsmünster	0,003828	0,024723	0,003597
Okehampton	0,006709	0,040705	0,006287
Piacenza	0,005395	0,016068	0,004078
Porto	0,001285	0,016581	0,000458
Sevilla	0,000008	0,001449	0,000068
Thiva	0,000168	0,001918	0,000056

Table 10.2-3:   **PEC$_{gw}$ for Mesotrione (pH_6.5) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)**

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Mesotrione	**MNBA**	**AMBA**
Maize	Châteaudun	0,001004	0,005329	0,006379
	Hamburg	0,006164	0,060582	0,049684
	Kremsmünster	0,002710	0,013271	0,027344
	Okehampton	0,008844	0,027231	0,035145
	Piacenza	0,002966	0,003653	0,009794
	Porto	0,000197	0,001819	0,001249
	Sevilla	0,000003	0,000144	0,000046
	Thiva	0,000085	0,000659	0,000750

Table 10.2-4:   **PEC$_{gw}$ for Mesotrione (pH_7.9) and metabolite(s) on Maize (with FOCUS PEARL 4.4.4)**

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

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Table 10.2-5: **PEC$_{gw}$ for Mesotrione (worst_case) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)**

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

Table 10.2-6: **PEC$_{gw}$ for Mesotrione (pH_5.1) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)**

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

Table 10.2-7: **PEC$_{gw}$ for Mesotrione (pH_6.5) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)**

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

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Sevilla	0,000	0,001	0,000
Thiva	0,000	0,002	0,001

Table 10.2-8: **PEC$_{gw}$ for Mesotrione (pH_7.9) and metabolite(s) on Maize (with FOCUS PELMO 5.5.3)**

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

According to calculation of PECgw made by PELMO and PEARL Focus models, maximum concentration results of the metabolite MNBA show a very slight exceeded of the limit value only in one scenario (Hamburg).

Relevance assessment of metabolite MNBA

Summary:

The relevance of the groundwater metabolite MNBA has already been assessed and the assessment agreed at EU level (see RAR mesotrione), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC$_{gw}$ calculated for the GAP and groundwater scenarios considered in this dRR). MNBA is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in Table 0- and the corresponding studies are listed in the corresponding sections.

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Table 0-9: **Summary of the relevance assessment for MNBA**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC$_{gw}$	0.143 µg/L
			Based on	Model results for the Hamburg scenario with PELMO 5.5.3 and PEARL 4.4.4
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	NO
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Low acute toxicity, no skin irritation, skin sensitising potential, eye irritation, but repeated dose toxicity presents a lower toxicity profile than the parent mesotrione
			Classification of parent	Repr. 2, H361d STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
			Classification of metabolite	Eye Irrit. 2, H319 Skin Sens.1, H317
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable (<0.75 µg/L)
	STEP 5		Refined risk assessment	N/A*
			Predicted exposure (% of ADI)	N/A*
			ADI based on	N/A*

*   N/A: not applicable

STEP 1: Exclusion of degradation products of no concern

MNBA does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

STEP 2: Quantification of potential groundwater contamination

PEC$_{gw}$ calculations after leaching from soil for MNBA were performed (see Part B, Section 8, chapter 8.8). The uses for which concentrations of MNBA were considered to exceed 0.1 µg/L are listed in Table 0-. Details are given in Part B, Section 8, chapter 8.8.

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STEP 3: Hazard assessment – identification of relevant metabolites

STEP 3, Stage 1: screening for biological activity

MNBA is not herbicidally active based on the results from glasshouse preliminary screening trials (Schribbs J, 1997). In these trials, MNBA was applied both pre-and post-emergence at doses up to 4000 g a.s./ha, to a range of monocotyledonous and dicotyledonous weed and crop species. None of the test species exhibited any signs of crop damage throughout the studies. This confirms that at doses far in excess of those likely to enter groundwater, MNBA poses no risk to either crops or other vegetation. A full study summary can be found in B. 9.6.1 of the RAR of mesotrione Volume 3 – B9 (AS).

STEP 3, Stage 2: screening for genotoxicity

MNBA is not considered to be genotoxic based on the following studies:

> *In vitro* genotoxicity:
> - bacterial reverse mutation assay (Callander RD, 1996a)
> - cytogenetic assay in human lymphocytes (Fox V, 2000a)
> *In vivo* genotoxicity
> - Unscheduled DNA synthesis assay (anonymous, 2000)
> - bone marrow micronucleus (anonymous, 2000b)

The summaries of these studies can be found in B 6.8.1.3 of the RAR of mesotrione Volume 3 – B6 (AS).

STEP 3, Stage 3: screening for toxicity

With regard to toxicological relevance of MNBA, studies submitted on this metabolite indicate that it is of comparatively low acute toxicity. MNBA is a potential skin sensitiser. The study summaries of acute toxicity (oral: anonymous, 1996; dermal: anonymous, 1996b), irritation (skin: anonymous, 1996c; eye: anonymous, 1996d) and sensitisation (anonymous, 1996e) can be found in B. 6.8.1.2 of the RAR of mesotrione Volume 3 – B6 (AS).

STEP 4: Exposure assessment – threshold of concern approach

At the levels found in the modelling MNBA is present below the 0.75 µg/L threshold of concern. No further consideration is required.

STEP 5: Refined risk assessment

No refined risk assessment is required as none of the metabolites exceeds the threshold of concern of 0.75 µg/L (see step 4 above).

Accepted

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Appendix 1   Lists of data considered in support of the evaluation

No studies submitted by applicant.

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Appendix 2   Additional information

No additional information submitted by applicant.