

FINAL REGISTRATION REPORT

Part B

Section 10

**Assessment of the relevance of metabolites in
groundwater**

Detailed summary of the risk assessment

Product code: SHA 4300 A

Product name: MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

MS Finalisation date: 04/06/2024

Version history

When	What
February 2020	Dossier sent for evaluation
June 2020	Applicant update
June 2020	zRMS finalised evaluation
April 2024	Final version prepared by zRMS after Commenting period
June 2024	Final version prepared by zRMS after the second commenting period

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

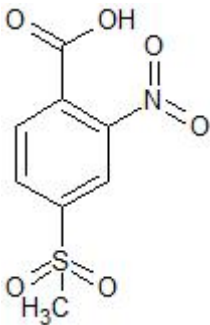
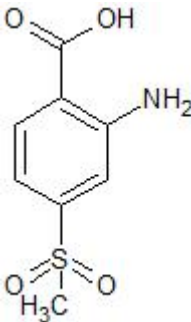
10 Relevance of metabolites in groundwater

Evaluator's Comments:	The submitted justification was accepted. Based on PEC _{gw} assessment for metabolites concentration in groundwater were below the trigger value of 0.1 µg/L. According to the dRR Part B8 ground water conclusion no further risk assessment is needed.
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10.1 General information

No Mesotrione metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Mesotrione ZA1296	MNBA	 <p>4-(methylsulfonyl)-2-nitrobenzoic acid</p> <chem>O=S(C)(=O)c1cc(c(cc1)C(=O)O)N(=O)=O</chem>	Max PEC _{gw}	0.170 µg/L at wrong pH (5.1)*, the value at right pH (6.5) is 0.093 µg/L.
	AMBA	 <p>2-amino-4-(methylsulfonyl)benzoic acid</p> <chem>O=S(C)(=O)c1cc(N)c(cc1)C(=O)O</chem>	Max PEC _{gw}	0.074 µg/L

*According to the dRR Part B8 ground water conclusion:

FOCUS PEARL:

0.170 µg/L in Hamburg at pH 5.1.

It should be taken into account that the Hamburg scenario pH value is 6.4 (Table 8.8-7); therefore, the endpoints used are not realistic for this pH. Hence, the actual PEC_{gw} value for MNBA must be considered at pH 6.5, being the value 0.093 µg/L for Hamburg.

FOCUS PELMO:

0.167 µg/L in Hamburg at pH 5.1.

0.100 µg/L in Okehampton at pH 5.1.

It should be taken into account that the Hamburg and Okehampton scenario pH values are 6.4 and 5.8 respectively (Table 8.8-7); therefore, the endpoints used are not realistic for these pH's. Hence, the actual PEC_{gw} values for MNBA must be considered at pH 6.5, being the PEC_{gw} value 0.065 µg/L for Hamburg.

As refinement for MNBA metabolite in Okehampton, the Mesotrione DT₅₀ (21.05 d) and K_{foc} (90.43 L/kg) had been recalculated at pH 5.8 using the equations given in Tables 8.3.1-1 and 8.5-1 respectively and run FOCUS PELMO being the PEC gw value 0.092 µg/L.

Accordingly to the above mentioned rationales and refinements, the assessment of the relevance of metabolites in groundwater is not necessary.

10.2 Relevance assessment of Mesotrione metabolites

The groundwater Mesotrione metabolites are not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

10.2.1 STEP 1: Exclusion of degradation products of no concern

Mesotrione metabolites meet the criteria for products of no concern as defined in step 1 of the guidance and therefore they don't need further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant, please refer to point 10.1.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant, please refer to point 10.1.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant, please refer to point 10.1.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant, please refer to point 10.1.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant, please refer to point 10.1.

10.2.5 STEP 5: Refined risk assessment

Not relevant, please refer to point 10.1.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information

Not relevant.