

REGISTRATION REPORT
Part B
Section 10
Assessment of the relevance of metabolites in
groundwater
Detailed summary of the risk assessment

Product name: ASAHI MAX
Product code: ARY-0469-04
Chemical active substance:
0.9% w/w sodium p-nitrophenolate
0.6% w/w sodium o-nitrophenolate
0.3% w/w sodium 5-nitroguaiacolate

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(authorization)

Applicant: Asahi Chemical Europe s.r.o.
Submission date: June 2022
MS Finalisation date: March 2023 (initial Core Assessment)
June 2023 (final Core Assessment)

Version history

When	What
June 2022	Initial version of dRR for submission to zRMS
March 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
June 2023	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product ARY-0469-04 / ASAHI MAX according art. 33 of 1107/2009.

Document refers data related to the forming of metabolites in the environment (see dRR B8). dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient (see point 10.1) and appropriate for concluding.

10 Relevance of metabolites in groundwater

10.1 General information

There are no metabolites that are considered to be of relevance for groundwater assessment. A data gap for identification and further assessment of the unknown soil metabolite M5 in groundwater was identified during the EU review. This issue has been addressed in a separate confirmatory data submission in accordance with current EU regulatory guidance (SANCO/5634/2009 rev. 6.1) and an assessment has been accordingly performed for PEC_{gw} for metabolite M5 in the present dRR (refer to Point 8.8)

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

Name of active substance	Metabolite name and code	Trigger for relevance assessment	
Na 5-NG Na <i>o</i> -NP Na <i>p</i> -NP	M5	Max PEC _{gw} Based on:	0.092737 µg/L Sugar beet Jokioinen PEARL 5.5.5

10.2 Relevance assessment of M5

Table 10.2-1: Summary of the relevance assessment for M5

Table 102-1: Summary of the Relative Assessment for MZ				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.092737 µg/L
			Based on	Sugar beet Jokioinen PEARL 5.5.5
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	N/A
		Stage 2	Genotoxic properties of metabolite	N/A
		Stage 3	Toxic properties of metabolite;	N/A
			Classification of parent	N/A
			Classification of metabolite	N/A
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	N/A
	STEP 5	Refined risk assessment		N/A
		Predicted exposure (% of ADI)		N/A
				ADI based on

* N/A: not applicable

10.2.1 STEP 1: Exclusion of degradation products of no concern

M5 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for M5 were performed (see Part B, Section 8, chapter 8). All 80th percentiles at 1 m soil depth (µg/L) were estimated to be lower than 0.1 µg/L. Therefore, no further assessment is necessary.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not relevant.

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.2.5 STEP 5: Refined risk assessment

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
Kcp 9.2.4/01	Garitano, M.	2022	ASAHI MAX: Predicted Environmental Concentrations in groundwater (PEC _{gw}) Devreg Consulta SLU, Report No. DR20221021 Non GLP / Non GEP (modelling calculation) Unpublished	N	Asahi Chemical Europe s.r.o.

Appendix 2 Additional information

None.