REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ASA-01

Product name(s): **VIARES**

Chemical active substance(s):

Acetamiprid, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: XXXX

Submission date: March 2024

Evaluation date: May 2025

MS Finalisation date: July 2025

Version history

When	What
May 2025	Version evaluated by zRMS PL

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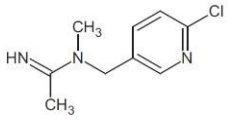
10 Relevance of metabolites in groundwater

zRMS Comments:	The tired approach in PECgw assessment was accepted. Based on Tier 1 assessment (PUF = 0) the PECgw values for metabolite IM-1-5 exceed the trigger in scenarios Châteaudun, Hamburg, Piacenza and Thiva. (max of 0.134 µg/L). Based on PECgw assessment for metabolites concentration in groundwater were below the trigger value of 0.1 µg/L at Tier 2 (PUF = 0.5).

10.1 General information

The metabolite IM-1-5 is predicted to occur in groundwater at concentrations above 0.1 µg/L (see Part B, Section 8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore 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	
acetamiprid	IM-1-5		Max PEC_{gw}	0.133604 µg/L (PEARL, Thiva) < 0.1 µg/L at Tier 2 (PUF = 0.5)

10.2 Relevance assessment of IM-1-5

Summary

The relevance of the groundwater metabolite IM-1-5 has already been assessed and the assessment agreed at EU level, but the relevance assessment is not applicable for the GAP and groundwater scenarios considered in this dRR. Therefore, the assessment and conclusions are presented here. IM-1-5 is 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 10.2-1 and the corresponding studies are listed in the corresponding sections.

Table 10.2-1: Summary of the relevance assessment for IM-1-5

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	yes
Quantification of ground	STEP 2	Max PEC_{gw} (Tier I)	0.133604 µg/L

			Based on	PEARL, Thiva
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;	as parent
			Classification of parent	toxic
			Classification of metabolite	toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	not relevant
	STEP 5		Refined risk assessment	not relevant
			Predicted exposure (% of ADI)	not relevant
			ADI based on	not relevant

* N/A: not applicable

10.2.1 STEP 1: Exclusion of degradation products of no concern

IM-1-5 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 IM-1-5 were performed (see Part B, Section 8). Details on uses for which concentrations of IM-1-5 were considered to exceed 0.1 µg/L are given in Part B, Section 8).

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

The biological activity of IM-1-5 does not have comparable target activity as the parent active compound. IM-1-5 is considered not relevant and is further evaluated in Stage 2.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

IM-1-5 was screened for genotoxic activity by the following data package of *in vitro* and is considered not relevant and is further evaluated in Stage 3.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

The parent, acetamiprid, to IM-1-5 is classified as acutely toxic (or corresponding classification in

accordance with CLP 1272/2008). IM-1-5 has therefore been tested in accordance with the EC guidance document SANCO/221/2000 –rev.10 ~~and is not considered relevant and~~ is further evaluated in Step 4.

zRMS:
According to Peer review of the pesticide risk assessment of the active substance acetamiprid (EFSA Journal 2016;14(11):4610) the metabolite IM-1-5 is a relevant groundwater metabolite based on its acute oral toxicity (triggering the proposal for classification Acute Tox. 3, H301 Toxic if swallowed).

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

~~IM-1-5 was not considered relevant in the hazard assessment of Step 3.~~

The PEC_{gw} for IM-1-5 was < 0.75 µg/L. There is no consumer exposure via other routes. IM-1-5 is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 – rev.10.

zRMS:
The metabolite IM-1-5 is a relevant groundwater metabolite however according to Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater Of Substances Regulated Under Regulation (EC) No 1107/2009 (Sanco/221/2000 – rev.11; 21 October 2021), its concentration in the ground waters does not exceeds the concentration of 0.1 µg/l), thus it is below the maximum permissible concentration (0.1 µg/l) for groundwater and it does not pose health risk to consumers.

10.2.5 STEP 5: Refined risk assessment

~~Not relevant.~~

zRMS: Not 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

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 Additional information

Not relevant.