

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: Acetamipryd 200 SL

Product name(s): -

Chemical active substance(s):

acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

Submission date: March 2024

MS Finalisation date: 03.2025; 08.2025; 02.2026

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Version history

When	What
03.2025	ZRM's evaluated dRR submitted by Applicant
08.2025	The final Registration Report after the reporting period.
January 2026	Update on Ministry request
February 2026	ZRMS update

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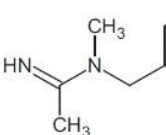
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10 Relevance of metabolites in groundwater

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} Tier I	0. 122248 µg/L (PEARL, Thiva)

10.2 Relevance assessment of IM-1-5

Comments of ZRMs:	<ul style="list-style-type: none"> The results of studies indicate that metabolite IM-1-5 has to be classified regarding acute oral toxicity: Acute Tox. 3, H302 (rat: LD50: 141 mg/kg and 132 mg/kg bw in males and females, respectively). The results of <i>in vitro</i> studies (Ames and mouse lymphoma assay) showed that IM-1-5 is not mutagenic. The parent substance (acetamiprid) is classified regarding reproductive toxicity (Repr. 2, H361d). According to Sanco/221/2000 – rev.11, 21 October 2021, for parent active substances that are classified for reproductive toxicity (any category), it must be shown by an appropriate test or convincing other evidence that the metabolite does not qualify for the same classification. <p>Conclusions:</p> <p>Considering the data presented above, IM-1-5 is a toxicologically relevant groundwater metabolite of acetamiprid. The maximum PEC_{gw} of IM-1-5 exceeds permissible concentration and amounts to 0. 122248 µg/L µg/L. Product field uses that result in an IM-1-5 concentration in the groundwater exceeding 0.1 µg/L cannot be accepted due to unacceptable risk for consumers.</p> <p>zRMS comments: February 2026</p> <p>New PEC gw were provided by the Applicant based on corrected doses. Acc. the ZRMS conclusions in the DRR, sec. B8, estimated values of PEC_{gw} for metabolite IM-1-5 are below the concentration threshold of 0.1 µg/L for all scenarios and crops, except scenario Thiva. This scenario is not relevant for Poland.</p>
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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 groundwater contamination	STEP 2		Max PEC _{gw}	0.122248 µg/L Châteaudun <0.1 µg/L Hamburg <0.1 µg/L Jokioinen<0.1 µg/L Kremsmünster <0.1 µg/L Okehampton <0.1 µg/L Piacenza <0.1 µg/L Porto <0.1 µg/L Sevilla <0.1 µg/L Thiva 0.122247 µg/L
			Based on Tier I	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

* N/A: not applicable

At the request of the Polish Ministry of Agriculture and Rural Development and the evaluator, the PEC_{gw} calculations for uses for which IM-1-5 PEC_{gw} value was above 0.1 µg/L (orchards BBCH 51 - apple, pear, Chinese pear, plum, peach, nectarine, apricot, sour cherry, sweet cherry, walnut, hazelnut, common osier and purple willow) was performed again (details in dRR/RR Part B Section 8).

PEC_{gw} values for IM-1-5 are below the trigger value of 0.1 µg/L indicating there is no unacceptable risk of groundwater contamination in case of every year application except of scenario Thiva for which further

PEC_{gw} modelling or other risk mitigations at national level is needed.

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, acetamipryd, 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.

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.

10.2.5 STEP 5: Refined risk assessment

Not relevant.

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	Verte- brate 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	Verte- brate study Y/N	Owner
-	-	-	-	-	-

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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

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Appendix 2 Additional information

Not relevant.