

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ADM.00900.I.1.C

Product name: COSAYR

Chemical active substance:
Chlorantraniliprole, 200 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Adama country organisation/representative as
specified in Part A

Submission date: October 2022

MS Finalisation date: June 2023 (initial Core Assessment)

November 2023 (final Core Assessment)

Version history

When	What
October 2022	Part B – Section 10 – Core Assessment – Central Zone, Initial version
June 2023	<p>Initial zRMS assessment</p> <p>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.</p>
November 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.</p>

Table of Contents

10	Relevance of metabolites in groundwater.....	4
10.1	General information.....	4
10.2	Relevance assessment of Chlorantraniliprole metabolites.....	5
10.2.1	STEP 1: Exclusion of degradation products of no concern	5
10.2.2	STEP 2: Quantification of potential groundwater contamination	5
10.2.3	STEP 3: Hazard assessment – identification of relevant metabolites.....	5
10.2.3.1	STEP 3, Stage 1: screening for biological activity	5
10.2.3.2	STEP 3, Stage 2: screening for genotoxicity	5
10.2.3.3	STEP 3, Stage 3: screening for toxicity.....	6
10.2.4	STEP 4: Exposure assessment – threshold of concern approach.....	6
10.2.5	STEP 5: Refined risk assessment	6
Appendix 1	Lists of data considered in support of the evaluation.....	7
Appendix 2	Additional information.....	8

Reviewer summary:

This part of dossier has been submitted to support registration of the plant protection product COSAYR (product code ADM.00900.I.1.C an a SC formulation containing Chlorantraniliprole, 200 g/L) 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 and appropriate for concluding.

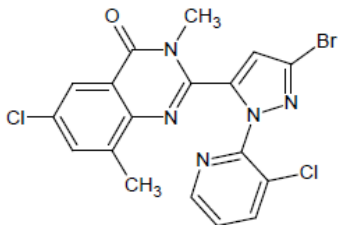
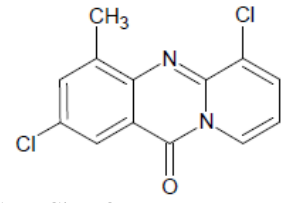
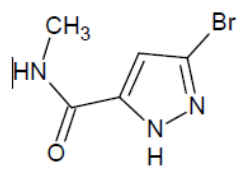
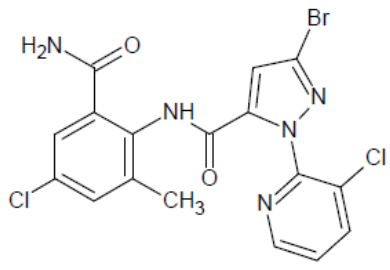
10 Relevance of metabolites in groundwater

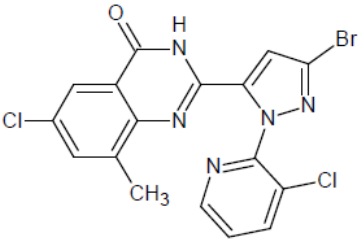
10.1 General information

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

For the uses that are supportable, considering the PEC_{gw} for parent chlorantraniliprole, none of the metabolites exceed 0.1 µg/L as detailed in dRR Part B Section 8 Point 8.8.

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
Chlorantraniliprole	IN-EQW78 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloro-3,8-dimethylquinazolin-4(3H)-one)	 C ₁₈ H ₁₂ BrCl ₂ N ₅ O	Not applicable , (max PEC _{gw} < 0.1 µg/L)
	IN-ECD73 (2,6-dichloro-4-methyl-11H-pyrido[2,1-b]quinazolin-11-one)	 C ₁₃ H ₈ Cl ₂ N ₂ O	Not applicable , (max PEC _{gw} < 0.1 µg/L)
	IN-F6L99 (3-bromo-N-methyl-1H-pyrazole-5-Carboxamide)	 C ₅ H ₆ BrN ₃ O	Not applicable , (max PEC _{gw} < 0.1 µg/L)
	IN-F9N04 (3-bromo-N-(2-carbamoyl-4-chloro-6-methylphenyl)-1-(3-chloropyridin-2-yl)-1H-pyrazole-5-carboxamide)	 C ₁₇ H ₁₂ BrCl ₂ N ₅ O ₂	Not applicable , (max PEC _{gw} < 0.1 µg/L)

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment
	IN-GAZ70 (2-[3-bromo-1-(3-chloropyridin-2-yl)-1Hpyrazol-5-yl]-6-chloro-8-methylquinazolin-4(1H)-one)	 $C_{17}H_{10}BrCl_2N_5O$	Not applicable, (max PEC _{gw} < 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.

10.2 Relevance assessment of Chlorantraniliprole metabolites

Summary:

The metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-F9NO4 and IN-GAZ70 are **not** predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B Section 8 Point 8.8). The metabolites are not likely to pose an unacceptable risk to groundwater if the formulated product ADM.00900.I.1.C is used in compliance with the label recommendations.

10.2.1 STEP 1: Exclusion of degradation products of no concern

The above-mentioned metabolites potentially of concern do not meet the criteria for products of no concern defined in Step 1 of the guideline, since they are not:

- CO₂ or inorganic compound, not containing a heavy metal, or
- Organic compound of aliphatic structure, with a chain length of 4 or less, which consist only of C, H, N or O atoms and which have no “alerting structures” such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern, or
- Substance, which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

For the metabolites IN-EQW78, IN-ECD73, IN-F6L99, IN-F9NO4 and IN-GAZ70 the PEC_{GW} values were all lower than the groundwater threshold 0.1 µg/L (see dRR Part B Section 8 Point 8.8 of the core assessment of the central zone).

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not required. Please refer to Table 10.1-1 above.

10.2.3.1 STEP 3, Stage 1: screening for biological activity

No relevant. Please refer to Table 10.1-1 above.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

No relevant. Please refer to Table 10.1-1 above.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

No relevant. Please refer to Table 10.1-1 above.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

No relevant. Please refer to Table 10.1-1 above.

10.2.5 STEP 5: Refined risk assessment

No relevant. Please refer to Table 10.1-1 above.

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
-	-	-	-	-	-

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
-	-	-	-	-	-

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

Comments of zRMS:	Not applicable.
-------------------	-----------------