

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ADM.03502.F.1.A

(alternative codes: MCW-2091)

Product name(s): see part A

Chemical active substance(s):

Fenpropidin 250 g/L

Prothioconazole 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation/representative
as specified in Part A

Submission date: September 2021

MS Finalisation date: December 2022 (initial Core Assessment)

March 2023 (final Core Assessment)

Version history

When	What
2021/09	Version 1 Applicant
December 2022	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.
March 2023	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03502.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03502.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

- from the owner of the data, or
- from a second party that has obtained permission from the owner of the data for this purpose or,
- following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation, unless the period of protection of the proprietary data concerned has expired.

Table of Contents

10	Relevance of metabolites in groundwater.....	5
10.1	General information.....	5
10.2	Relevance assessment of prothioconazole and fenpropidin metabolites	6
10.2.1	STEP 1: Exclusion of degradation products of no concern	6
10.2.2	STEP 2: Quantification of potential groundwater contamination	7
10.2.3	STEP 3: Hazard assessment – identification of relevant metabolites.....	7
10.2.3.1	STEP 3, Stage 1: screening for biological activity	7
10.2.3.2	STEP 3, Stage 2: screening for genotoxicity	7
10.2.3.3	STEP 3, Stage 3: screening for toxicity.....	7
10.2.4	STEP 4: Exposure assessment – threshold of concern approach.....	7
10.2.5	STEP 5: Refined risk assessment	7
Appendix 1	Lists of data considered in support of the evaluation.....	8
Appendix 2	Additional information.....	9

Reviewer summary:

This part of dossier has been submitted to support registration of the plant protection product ADM.03502.F.1.A (an a EC formulation containing fenpropidin 250 g/L and prothioconazole 175 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.

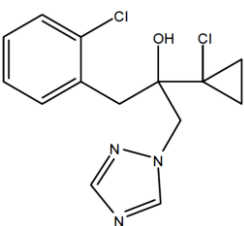
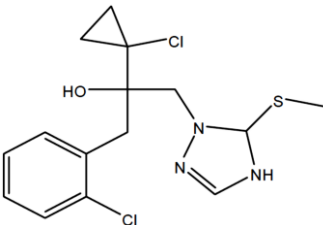
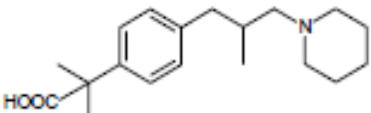
10 Relevance of metabolites in groundwater

10.1 General information

The prothioconazole metabolites prothioconazole-desthio (JAU-Desthio) and prothioconazole-S-methyl (JAU-S-methyl) as well as the fenpropidin metabolite CGA 289267 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR part B 8, chapter 8.8.2 of the core assessment of the central zone). 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.

General information on the metabolites together with their maximum PEC_{gw} values is provided in Table 10.1-1 below. For details on the critical GAP uses of the formulated product ADM.03502.F.1.A (MCW-2091), please refer to Table 8.1-1 of the dRR, part B 8 of the core assessment of the central zone.

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
Prothioconazole	prothioconazole-desthio (M04) (JAU-Desthio)		Max PEC _{gw} : < 0.001 µg/L Based on: FOCUS PEARL 4.4.4*, all intended uses/scenarios
	prothioconazole-S-methyl (M01) (JAU-S-methyl)		Max PEC _{gw} : < 0.001 µg/L Based on: FOCUS PEARL 4.4.4*, all intended uses/scenarios
Fenpropidin	2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid CGA 289267		Max PEC _{gw} : 0.004 µg/L Based on: FOCUS PELMO 5.5.3 (Okehampton), Winter cereals 1 × 250 g a.s.

* In accordance with the working document of the central zone (2018), one model indicated PEC_{gw} values <0.001 µg/L in all relevant scenarios for all investigated prothioconazole metabolites and it is thus not necessary to perform simulation runs with the other model. Therefore, only FOCUS PEARL results are presented in part B 8, chapter 8.8.2 of the core assessment of the central zone.

10.2 Relevance assessment of prothioconazole and fenpropidin metabolites

Summary:

As evaluated in model calculations provided in Part B Section 8, 8.8.2, the prothioconazole metabolites prothioconazole-desthio (JAU-Desthio) and prothioconazole-S-methyl (JAU-S-methyl) as well as the fenpropidin metabolite CGA 289267 did not exceed the groundwater threshold value of 0.1 µg/L in leachate at 1 m soil depth (see Table 10.2-1 to Table 10.2-3).

Thus, a further relevance assessment according to SANCO/221/2000 –ev.10 is not required and the metabolites are not likely to pose an unacceptable risk to groundwater if the formulated product ADM.03502.F.1.A (MCW-2091) is used in compliance with the label recommendations.

Table 10.2-1: Summary of the relevance assessment for prothioconazole-desthio (JAU-Desthio)

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	no (cannot be excluded)
Quantification of groundwater contamination	STEP 2	Max PEC _{gw}	< 0.001 µg/L
		Based on	FOCUS PEARL 4.4.4* (80 th Percentile PEC _{gw} at 1 m soil depth)

* In accordance with the working document of the central zone (2018), one model indicated PEC_{gw} values <0.001 µg/L in all relevant scenarios for all investigated prothioconazole metabolites and it is thus not necessary to perform simulation runs with the other model. Therefore, only FOCUS PEARL results are presented in part B 8, chapter 8.8.2 of the core assessment of the central zone.

Table 10.2-2: Summary of the relevance assessment for prothioconazole-S-methyl (JAU-S-methyl)

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	no (cannot be excluded)
Quantification of groundwater contamination	STEP 2	Max PEC _{gw}	< 0.001 µg/L
		Based on	FOCUS PEARL 4.4.4* (80 th Percentile PEC _{gw} at 1 m soil depth)

* In accordance with the working document of the central zone (2018), one model indicated PEC_{gw} values <0.001 µg/L in all relevant scenarios for all investigated prothioconazole metabolites and it is thus not necessary to perform simulation runs with the other model. Therefore, only FOCUS PEARL results are presented in part B 8, chapter 8.8.2 of the core assessment of the central zone.

Table 10.2-3: Summary of the relevance assessment for fenpropidin metabolite CGA 289267

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	no (cannot be excluded)
Quantification of groundwater contamination	STEP 2	Max PEC _{gw}	0.004 µg/L
		Based on	FOCUS PELMO 5.5.3 (Okehampton), Winter cereals 1× 250 g a.s.

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, nitroso-mine, 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.

In conclusion, the metabolites further need to be assessed in Step 2.

10.2.2 STEP 2: Quantification of potential groundwater contamination

For the prothioconazole metabolites prothioconazole-desthio (JAU-Desthio) and prothioconazole-S-methyl (JAU-S-methyl) as well as the fenpropidin metabolite CGA 289267, PEC_{gw} values were all lower than the groundwater threshold of 0.1 µg/L (see dRR part B 8, chapter 8.8.2 of the core assessment of the central zone).

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not required (see summary of chapter 10.2 above).

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not required (see summary of chapter 10.2 above).

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not required (see summary of chapter 10.2 above).

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not required (see summary of chapter 10.2 above).

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not required (see summary of chapter 10.2 above).

10.2.5 STEP 5: Refined risk assessment

Not required (see summary of chapter 10.2 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

None.