

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ADM.09050.H.1.A

Product name(s): **STEMPER**

Chemical active substances:

Trinexapac-ethyl, 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **ADAMA**

Submission date: May 2022

Evaluation date: March 2023

Version history

When	What
January 2021	dRR version 1 submitted by applicant
March 2023	Version evaluated by zRMS PL

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

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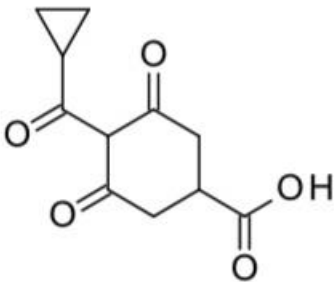
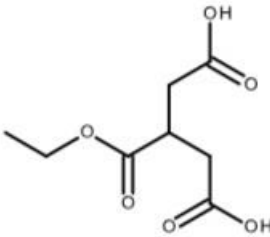
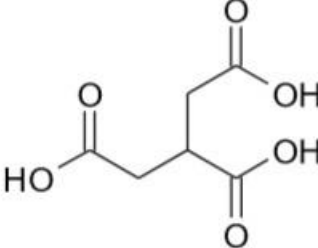
10 Relevance of metabolites in groundwater

10.1 General information

The metabolites CGA179500, CGA300405 and CGA275537 are predicted to occur in groundwater at concentrations **below** 0.1 µg/L (see 8.8.2 of the dRR Part B, Section 8). 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 are provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

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	
Trinexapac-ethyl	CGA179500		Max PEC _{gw} Based on:	<0.001 All scenarios, all models, all cGAPs
Trinexapac-ethyl	CGA300405		Max PEC _{gw} Based on:	<0.001 All scenarios, all models, all cGAPs
Trinexapac-ethyl	CGA275537		Max PEC _{gw} Based on:	<0.001 All scenarios, all models, all cGAPs

10.2 Relevance assessment of CGA179500

Summary:

The groundwater metabolite CGA179500 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment for CGA179500 is given in Table 10.2-1. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

Table 10.2-1: Summary of the relevance assessment for CGA179500

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	<0.001 µg/L
			Based on	All models, all scenarios, all cGAPs
	Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?
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

CGA179500 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 CGA179500 were performed (see Part B, Section 8, chapter 8.8). There were no uses for which concentrations of CGA179500 were considered to exceed 0.1 µg/L therefore no further assessment is required.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

This step is not required, see step 2, point 10.2.2 of this document.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

This step is not required, see step 2, point 10.2.2 of this document.

10.2.5 STEP 5: Refined risk assessment

This step is not required, see step 2, point 10.2.2 of this document.

zRMS:

The assessment of relevance of metabolite CGA179500 provided by the applicant is acceptable. This metabolite is not considered as relevant.

10.3 Relevance assessment of CGA300405

Summary:

The groundwater metabolite CGA300405 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment for CGA300405 is given in Table 10.2-1. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

Table 10.3-1: Summary of the relevance assessment for CGA300405

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	<0.001 µg/L
			Based on	All models, all scenarios, all cGAPs
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

10.3.1 STEP 1: Exclusion of degradation products of no concern

CGA300405 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.3.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for CGA300405 were performed (see Part B, Section 8, chapter 8.8). There were no uses for which concentrations of CGA300405 were considered to exceed 0.1 µg/L therefore no further assessment is required.

10.3.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.3.3.1 STEP 3, Stage 1: screening for biological activity

This step is not required, see step 2, point 10.2.2 of this document.

10.3.3.2 STEP 3, Stage 2: screening for genotoxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.3.3.3 STEP 3, Stage 3: screening for toxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach

This step is not required, see step 2, point 10.2.2 of this document.

10.3.5 STEP 5: Refined risk assessment

This step is not required, see step 2, point 10.2.2 of this document.

zRMS:

The assessment of relevance of metabolite CGA300405 provided by the applicant is acceptable. This metabolite is not considered as relevant.

10.4 Relevance assessment of CGA275537

Summary:

The groundwater metabolite CGA275537 is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment for CGA275537 is given in Table 10.2-1. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

Table 10.4-1: Summary of the relevance assessment for CGA275537

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	<0.001 µg/L
			Based on	All models, all scenarios, all cGAPs
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

10.4.1 STEP 1: Exclusion of degradation products of no concern

CGA275537 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

10.4.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for CGA275537 were performed (see Part B, Section 8, chapter 8.8). There were no uses for which concentrations of CGA275537 were considered to exceed 0.1 µg/L therefore no further assessment is required.

10.4.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.4.3.1 STEP 3, Stage 1: screening for biological activity

This step is not required, see step 2, point 10.2.2 of this document.

10.4.3.2 STEP 3, Stage 2: screening for genotoxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.4.3.3 STEP 3, Stage 3: screening for toxicity

This step is not required, see step 2, point 10.2.2 of this document.

10.4.4 STEP 4: Exposure assessment – threshold of concern approach

This step is not required, see step 2, point 10.2.2 of this document.

10.4.5 STEP 5: Refined risk assessment

This step is not required, see step 2, point 10.2.2 of this document.

zRMS:

The assessment of relevance of metabolite CGA275537 provided by the applicant is acceptable. This metabolite is not considered as relevant.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

None

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

None

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

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