

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: AG-E1-500 SC1

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Agan Ltd.

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: March 2021

MS Finalisation date: January 2022 (initial Core Assessment)

June 2022 (final Core Assessment)

Version history

When	What
March 2021	dRR version 1 submitted by applicant
January 2022	Initial assessment by the zRMS 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.
June 2022	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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

STATEMENT FOR OWNERSHIP

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- 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.

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Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product AG-E1-500 SC1 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.

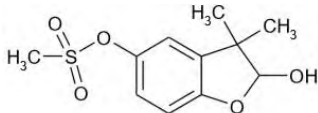
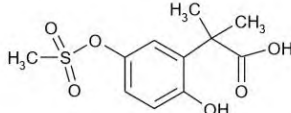
10 Relevance of metabolites in groundwater

10.1 General information

The metabolites NC8493 and NC20645 are predicted to occur in groundwater at concentrations **below 0.1 µg/L** (see 8.8.2.1, 8.8.2.2 and 8.8.2.3 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 NC8493 and NC20645 is 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	
Ethofumesate	NC8493 Ethofumesate-2-hydroxy		Max PEC _{gw} Sugar beet [µg/L] Based on:	Triennial: 0.004/0.005 FOCUS PEARL 4.4.4 Scenario Jokioinen 2 x 500 g/ha/3 x 330 g/ha Application post-emergence BBCH 10-18 (20% interception)
Ethofumesate	NC20645		Max PEC _{gw} Sugar beet [µg/L] Based on:	Triennial: 0.004 FOCUS PELMO 5.5.3 Scenario Jokioinen 2 x 500 g/ha/3 x 330 g/ha Application post-emergence BBCH 10-18 (20% interception)

10.2 Relevance assessment of NC8493

Summary:

The groundwater metabolite NC8493 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 NC8493 is given in Table 10.2-1. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour), the genotoxicity studies are evaluated in Section 6 (Mammalian Toxicology); the data on biological activity are evaluated in Appendix 2 of this Section.

Table 10.2-1: Summary of the relevance assessment for NC8493

Table 10-1: Summary of the relevance assessment for PCBs				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	no
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.004/0.005 µg/L
			Based on	FOCUS PEARL 4.4.4 Scenario Jokioinen
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

10.2.1 STEP 1: Exclusion of degradation products of no concern

NC8493 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

It cannot be excluded as a product of no concern as it is not:

- CO₂ or an inorganic compound, not containing a heavy metal;
- an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern;
- a 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

PEC_{gw} calculations after leaching from soil for NC8493 were performed (see Part B, Section 8, chapter 8.8). There were no uses for which concentrations of NC8493 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.

10.3 Relevance assessment of NC20645

Summary:

The groundwater metabolite NC20645 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 NC20645 is given in Table 10.2-1. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour), the genotoxicity studies are evaluated in Section 6 (Mammalian Toxicology); the data on biological activity are evaluated in **Błąd! Nie można odnaleźć źródła odwołania.** of this Section.

Table 10.3-1: Summary of the relevance assessment for NC20645

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	yes
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	0.004 µg/L
			Based on	FOCUS PELMO 5.5.3 Scenario Jokioinen
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

NC20645 does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

It cannot be excluded as a product of no concern as it is not:

- CO₂ or an inorganic compound, not containing a heavy metal;
- an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern;
- a 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

10.3.2 STEP 2: Quantification of potential groundwater contamination

PEC_{gw} calculations after leaching from soil for NC20645 were performed (see Part B, Section 8, chapter 8.8). There were no uses for which concentrations of NC20645 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 10.3.2 of this document.

10.3.3.2 STEP 3, Stage 2: screening for genotoxicity

This step is not required, see step 2, point 10.3.2 of this document.

10.3.3.3 STEP 3, Stage 3: screening for toxicity

This step is not required, see step 2, point 10.3.2 of this document.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach

This step is not required, see step 2, point 10.3.2 of this document.

10.3.5 STEP 5: Refined risk assessment

This step is not required, see step 2, point 10.3.2 of this document.

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.

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
-	-	-	-	-	-