

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: GLOB1911F

Product name(s): **CURRANDO/ SUBIGON/ COLLECTOR**

Chemical active substance(s):

Difenoconazole, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: August 2020

MS Finalisation date: May 2021

Version history

When	What
August 2020	Version submitted by the applicant
May 2021	Version evaluated by zRMS

Table of Contents

10	Relevance of metabolites in groundwater.....	4
10.1	General information	4
10.2	Relevance assessment of metabolites CGA205375 and CGA71019.....	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.....	6
10.2.3.1	STEP 3, Stage 1: screening for biological activity	6
10.2.3.2	STEP 3, Stage 2: screening for genotoxicity	6
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

10 Relevance of metabolites in groundwater

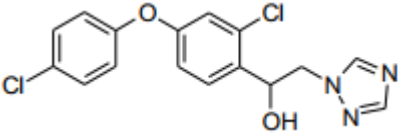

Evaluator's Comments:	Based on PEC _{gw} assessment in Section 8, only the highest concentration will be considered (metabolite relevance for lower concentration will be covered by). The maximum PEC _{gw} value of 0.089 µg/L was assessed for winter OSR, Kremsmünster, 2 applications in autumn: crop interception 40/40, but this value is below the trigger of 0.1 µg/L.
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10.1 General information

The metabolites CGA205375 and CGA71019 (1,2,4-triazole) are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B, Section 8, chapter 8.8). 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 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 8.8 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	
Difenoconazole	CGA205375		Max PEC _{gw}	0.000
			Based on:	(FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3)
Difenoconazole	CGA71019 (1,2,4-triazole)		Max PEC _{gw}	0.079853
			Based on:	(FOCUS PEARL v4.4.4, Winter Oilseed rape, Hamburg, crop interception 40/80)
			Max PEC _{gw}	0.085618
			Based on:	(FOCUS PEARL v4.4.4, Winter Oilseed rape, Kremsmünster, 2 applications in autumn: crop interception 40/40)*
			Max PEC _{gw}	0.087

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
			Based on:	<div data-bbox="1201 313 1449 510" style="background-color: #cccccc;">(FOCUS PELMO v5.5.3, Winter Oilseed rape, Okehampton, crop interception 40/80)</div> <div data-bbox="1201 515 1449 622">Max PEC_{gw} 0.089</div> <div data-bbox="1201 627 1449 878">Based on (FOCUS PELMO v5.5.3, Winter Oilseed rape, Kremsmünster, 2 applications in autumn: crop interception 40/40)*</div>

*This use (winter oilseed rape with 2 applications in autumn) is only intended for the Concerned Member State the Netherlands. However, it is included in the core dossier in order to have it evaluated at Zonal level by the zRMS Poland.

10.2 Relevance assessment of metabolites CGA205375 and CGA71019

10.2.1 STEP 1: Exclusion of degradation products of no concern

Sanco/221/2000 –rev.10- final allows the exclusion of metabolites from consideration if they satisfy certain criteria that would allow the conclusion to be made that they are of no concern. These criteria are as follows:

- it is CO₂ or an inorganic compound, not containing a heavy metal; or,
- it is 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.
- it is 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.

CGA205375 and CGA71019 do 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

FOCUS groundwater modelling for the metabolites CGA71019 and CGA205375 is performed in dRR Part B, Section 8, chapter 8.8.

Calculation of the Predicted Environmental Concentration in groundwater for CGA71019 and CGA205375 after the use of Difenconazole according to the proposed GAP using the FOCUS groundwater models PELMO 5.5.3 and PEARL 4.4.4, shows that the PEC_{gw} of CGA71019 and CGA205375 does not exceed the limit of 0.1 µg/L. Therefore further assessment is not required.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not required

10.2.3.1 STEP 3, Stage 1: screening for biological activity

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

10.2.3.3 STEP 3, Stage 3: screening for toxicity

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not required.

10.2.5 STEP 5: Refined risk assessment

Not required.

zRMS:

There is no health risk arising from use or drinking of ground water after application of the product in line with GAP. No further assessment needed

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	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

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