

FINAL REGISTRATION REPORT

Part B

Section 10

**Assessment of the relevance of metabolites in
groundwater**

Detailed summary of the risk assessment

Product code: SHA 1100 D

Product name(s): CANDELA

Chemical active substance(s):

Glyphosate 540 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: February 2018

MS Finalisation date: 18/10/2022

Version history

When	What
10/2018	Dossier sent for evaluation to Merit Mark (PL)
10/2021	zRMS finalised evaluation
10/2022	Final version prepared by zRMS after Commenting period

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Evaluator comments:

The text highlighted in grey was provided by the evaluator.

10 Relevance of metabolites in groundwater

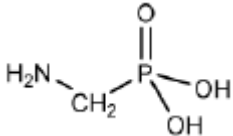
Comments of zRMS:	Based on PEC _{GW} assessment for glyphosate metabolite AMPA the all values are below the trigger value of 0.1 µg/L for all crops include in proposed pattern use. Since none of the metabolites can be found in groundwater in a concentration equal to or higher than 0.1 µg/L, there is no need to perform toxicological assessment.
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10.1 General information

The metabolite AMPA is predicted to occur in groundwater at concentrations below 0.1 µg/L (see Part B8, chapter 8.8 – KCP 9.2.4). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

General information on the metabolite 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	
Glyphosate	AMPA		Max PEC _{gw} Based on:	< 0.001 µg/L PEARL and PELMO (all scenarios)

10.2 Relevance assessment of AMPA

Not relevant.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.2.5 STEP 5: Refined risk assessment

Not relevant.

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information

Not relevant.