

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 9700 B

Product name: RULER 10 EC

Chemical active substance:

Fenazaquin, 100 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

When	What
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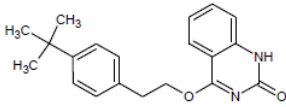
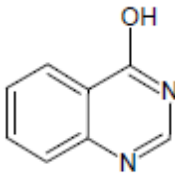
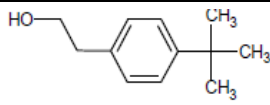
10 Relevance of metabolites in groundwater

10.1 General information

The metabolites 2-oxy-fenazaquin, 4-OHQ and TBPE are predicted to occur in groundwater at concentrations below 0.001 µg/L (see dRR Part B8, Chapter 8.9). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore 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 8.9 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	
Fenazaquin	2-oxy-fenazaquin		Max PEC _{gw} Based on:	< 0.001 µg/L All FOCUS PEARL and PELMO scenarios
Fenazaquin	4-OHQ		Max PEC _{gw} Based on:	< 0.001 µg/L All FOCUS PEARL and PELMO scenarios
Fenazaquin	TBPE		Max PEC _{gw} Based on:	< 0.001 µg/L All FOCUS PEARL and PELMO scenarios

10.2 Relevance assessment of 2-oxy-fenazaquin

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.

10.3 Relevance assessment of 4-OHQ

10.3.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.3.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

10.3.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.3.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.3.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.3.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.3.5 STEP 5: Refined risk assessment

Not relevant.

10.4 Relevance assessment of TBPE

10.4.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.4.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

10.4.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.4.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.4.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.4.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.4.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant.

10.4.5 STEP 5: Refined risk assessment

Not relevant.

According to the Peer review of the pesticide risk assessment of the active substance fenazaquin EFSA Journal 2013;11(4):3166 Studies performed on metabolites or impurities TBPE (28th ATP), 4-OHQ , M34 were toxicologically not relevant compound (animals and plants)

As the metabolites 2-oxy-fenazaquin, 4-OHQ and TBPE are predicted to occur in groundwater at concentrations below 0.001 µg / L, no assessment is required.

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

Appendix 2 Additional information

Comments of zRMS:	Comment on statement; acceptable or not.
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