

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 123000 A

Product name: AZA

Chemical active substance:

Azadirachtin, 10 g/L

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

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Version history

When	What
July 2021	ZRMs evaluated dRR submitted by Applicant.

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10 Relevance of metabolites in groundwater

10.1 General information

The Azadirachtin A metabolite Azadirachtin H is predicted to occur in groundwater at concentrations below 0.1 µg/L (see Part B8, chapter 8.8). 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.

10.2 Relevance assessment of metabolite Azadirachtin H

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.

Azadirachtin A metabolite Azadirachtin H is predicted to occur in groundwater at concentrations below 0.1 µg/L

And then 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

Appendix 1 Lists of data considered in support of the evaluation

Appendix 2 Additional information

Not relevant.