

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 5500 A

Product name(s): ASSET (ZUXION)

Chemical active substance:

Acetamiprid, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2020; 2021

MS Finalisation date: 10/2020; 07/ 2021

Version history

When	What
July 2020	Assessment by expert
May 2021	The product name was corrected (ASSET instead of Zuxion)
July 2021	Assessment after corrected

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10 Relevance of metabolites in groundwater

10.1 General information

Only metabolite IM-1-5 was predicted to occur in groundwater at concentrations above 0.1 µg/L. it was considered as toxicologically relevant in the EFSA Journal 2016;14(11): 4610. However, considerations must be taken since IM-1-5 metabolite only appears in calcareous soils with pH (water) > 8 and none of the FOCUS scenarios has pH greater than 8, only Châteaudun has pH = 8. Therefore, the FOCUS models are not suitable to assess the ground water concentration of this metabolite. Furthermore, the metabolite IM-1-5 was found only in the top 10 cm in the field studies and not detected in the leaching studies. Therefore no assessment according to the stepwise procedure of the EC guidance document SAN-CO/221/2000 –rev.10 was done.

10.1.1 STEP 1: Exclusion of degradation products of no concern

Not relevant

10.1.2 STEP 2: Quantification of potential groundwater contamination

Not relevant

10.1.3 STEP 3: Hazard assessment – identification of relevant metabolites

According to the SANCO/1392/2001 – Final 16 June 2004:

Toxicologically significant compounds:

Parent compound, IC-0, IM-2-1, IM-1-4 (no compound was considered relevant)

Metabolite IM-1-5, stable in calcareous soils, is considered relevant.

Metabolism in animals:

Approximately > 90% metabolised. Mainly to the nicotinic acid derivative IC-O and demethylated compound IM-2-1 (approx. 50%) and IM-2-1, IS-1-1 and IS-2-1 (approx. 70%) in case of ring labeled and CN labeled, respectively (rats). Metabolite IM-1-5 (4.5%) is detected in rat metabolism only by HPLC analysis

10.1.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant

10.1.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant

According to the SANCO/1392/2001 – Final 16 June 2004:

“No evidence of genotoxicity in the Ames bacterial reverse mutation assay for IM-0, IM-1-2, IM-1-3, IM-2-1, IM-2-3, IS-1-1, IS-2-1, IC-0, IM-1-4, IM-1-5, IB-1-1 metabolites.”

10.1.3.3 STEP 3, Stage 3: screening for toxicity

Considered as toxicologically relevant in EFSA Journal 2016;14(11): 4610.

Regarding to the EU review SANCO/1392/2001-Final. 16 June 2004 the following informations of toxic effects of metabolites on mammals are known:

The metabolites IM-0, IM-1-3, IM-2-3 and IM-1-4 are considered harmful after single oral administration. The metabolite IM-1-5 is considered toxic after single oral administration. No evidence of genotoxicity in the Ames bacterial reverse mutation assay for IM-0, IM-1-2, IM-1-3, IM-2-1, IM-2-3, IS-1-1, IS-2-1, IC-0, IM-1-4, IM-1-5, IB-1-1 metabolites

10.1.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant

10.1.5 STEP 5: Refined risk assessment

Not relevant.

Comment:

On the basis of the assessment contained in the DAR (According to the DAR for Acetamiprid from March 2001 (RMS: GR) Volume 3; Annex B-6: Toxicology and metabolism) and the EU review report for acetamiprid (SANCO/1392/2001 – Final 16 June 2004), is concluded that the metabolites metabolite are not critical toxicological.

According to the EFSA Journal 2016;14(11):4610 Metabolite IM-1-5 is considered a toxicologically relevant groundwater metabolite

Clastogenic and aneugenic potential of metabolite IM-1-5 has not been tested

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

No new or additional data were submitted.

Appendix 2 Additional information

Not relevant