FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SHA 6821 A

Product name: PIORITY

Chemical active substances:

Dimethomorph, 150 g/kg
Dithianon, 350 g/kg

Southern Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: April 2019

MS Finalisation date: 12/2021; 01.2024

Version history

When	What
12.2021	Evaluation by expert
01.2024	The final Registration Report

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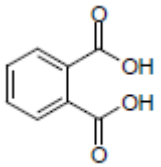
10 Relevance of metabolites in groundwater

10.1 General information

There are not metabolites from Dimethomorph.
No Dithianon's metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L. 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.

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	
Dithianon	Phthalic acid		Max PEC_{gw} Based on:	< 0.001 µg/L All assessed FOCUS PELMO and PEARL scenarios

10.2 Relevance assessment of Phthalic acid

The groundwater metabolite Phthalic acid (Dithianon's metabolite) is not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

10.2.1 STEP 1: Exclusion of degradation products of no concern

Phthalic acid meets the criteria for products of no concern as defined in step 1 of the guidance and therefore doesn't need further assessment.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant, please refer to point 10.1.

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, please refer to point 10.1.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant, please refer to point 10.1.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant, please refer to point 10.1.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant, please refer to point 10.1.

10.2.5 STEP 5: Refined risk assessment

Not relevant, please refer to point 10.1.

Comment

Dimethomorph
Based on EFSA Scientific Report (2006) 82, 1-69, Conclusion on the peer review of dimethomorph it can be concluded that dimethomorph metabolites are not present in plant and animals "Toxicologically relevant compounds (animals and plants) – dimethomorph".
Dimethomorph doesn't produce metabolites in soil therefore the assessment of the relevance of the metabolites according to the EC guidance document SANCO/221/2000 –rev.10 is therefore not required

Dithianon
Based on EFSA Journal 2010;8(11):1904 Peer Review of the pesticide risk assessment of the active substance dithianon
Extensive metabolism leading to the formation of mostly polar products. The metabolic reactions included oxidation of the sulphur atoms, cleavage of the dithiine ring, reduction of the 1,4-naphthoquinone moiety, glucuronidation as well as substitution of the carbonitrile moieties by amino and carboxy groups. The only predominant metabolite in quantitative terms was M216F020, detected mainly in urine (up to 10%) and secondly in kidney and plasma.
Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance is therefore not 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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP	Y/N	Owner

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
			Published/Unpublished		

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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**
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional information

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