

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: April 2022

MS Finalisation date: January 2023; June 2023

Version history

When	What
January 2023	ZRMs evaluated dRR submitted by Applicant.
June 2023	Final Registration Report

Table of Contents

10	Relevance of metabolites in groundwater	4
10.1	General information	4
Appendix 1	Lists of data considered in support of the evaluation	5

10 Relevance of metabolites in groundwater

10.1 General information

No metabolite is predicted to occur in groundwater at concentrations $> 0.1 \mu\text{g/L}$, so no further relevance evaluation is required.

No metabolites of prothioconazole are predicted to occur in groundwater at concentrations of $>0.1 \mu\text{g/L}$, therefore, a relevance assessment is not required.

Note:

REGULATIONS COMMISSION IMPLEMENTING REGULATION (EU) 2022/708 of 5 May 2022

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances: prothioconazole

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows

(16) in the sixth column, expiration of approval, of row 168, Prothioconazole, the date is replaced by ‘31 July 2023

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 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

References cited but not submitted:

European Commission (2003): GUIDANCE DOCUMENT ON THE ASSESSMENT OF THE RELEVANCE OF METABOLITES IN GROUNDWATER OF SUBSTANCES REGULATED UNDER COUNCIL DIRECTIVE 91/414/EEC. Sanco/221/2000–rev.10–final (25 February 2003)

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