REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: IN002B1760

Product name(s): Cymofil

Chemical active substance:

Cymoxanil, 450 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: August 2022

MS Finalisation date: May 2023 (initial Core Assessment)

September 2023, updated April 2024 (final Core Assessment)

Version history

When	What
August 2022	Original version from applicant Indofil Industries (Netherlands) B.V. for submission to z-RMS, Poland, in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No. 1107/2009
May 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
September 2023	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.
April 2024	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in blue. Not agreed or not relevant information are struck through and shaded for transparency.

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Reviewer summary:

This part of dossier has been submitted to support registration of the plant protection product IN002B1760 is a WG formulation containing 450 g/kg cymoxanil) according art. 33 of 1107/2009. Document refers data related to the forming of metabolites in the environment (see dRR B8).
dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient and appropriate for concluding.

zRMS comment (April 2024):
It must be noted that PECgw for IN-W3595 metabolite on potato when accounting for pH-dependence threshold value for groundwater 0.1 µg/L has been exceeded only for scenario Jokioinen, model PELMO 6.6.4; 80th Percentile PECgw at 1 m soil depth (µg/L) basic Koc. For other scenarios and models the threshold value has not been exceeded (for details refer RR B8 table 8.8-4).
In accordance with: *Working Document Of The Central Zone In The Authorisation Of Plant Protection Products SECTION 8 ENVIRONMENTAL FATE AND BEHAVIOUR* Version 1 rev. 1 – June 2018
Groundwater simulations are to be performed for at least the following FOCUS scenarios:
- Châteaudun
- Hamburg
- Kremsmünster
- Okehampton
- Piacenza
- Porto

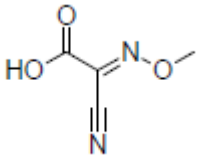
Therefore PECgw values reached considering scenario Jokioinen are not valid for CEU and for that reason further assessment for IN-W3595 metabolite is not required.

10 Relevance of metabolites in groundwater

10.1 General information

The metabolite IN-W3595 is predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is not required.
General information on the metabolite is provided in Table 10.1-1.

Table 10.1-1: General information on the metabolite

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Cymoxanil	IN-W3595 Cyano(methoxyimino)acetic acid		Max PEC_{gw}: Based on:	0.465 µg/L PELMO 6.6.4, Jokioinen scenario, potato late applications

10.2 Relevance assessment of IN-W3595

According to EFSA 2008, no information is available on the toxicological relevance of metabolite IN-W3595, because it is not needed. No groundwater relevance assessment was demanded. Only parent compound and IN-KQ960 were identified as toxicologically relevant compounds. IN-W3595 is not a toxicologically relevant compound, so 0.75 µg/L could be considered the threshold value for groundwater. Furthermore, only a few results are > 0.1 µg/L. Among these, it has to be considered that Jokioinen scenario is not relevant for the application in Southern Zone Member States. The slight exceedance found in Hamburg scenario under alkaline conditions is only theoretical and it is not expected to be found in practice, as the pH conditions associated with Hamburg scenario are acidic (pH 5.7, according to FOCUS 2002).

Appendix 1 Lists of data considered in support of the evaluation

No data submitted.