

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: IN005B1570

Product name: **INDOFIL** Difenoconazole 250 G/L EC greener

Chemical active substance:

Difenoconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33: Application for authorisation)

Applicant: Indofil Industries (Netherlands) B.V.

Submission date: February 2022

MS Finalisation date: 10.2022, 05.2024

Version history

When	What
February 2022	V0 – 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
October 2022	zRMS first evaluation
May 2024	The final Registration Report

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10 Relevance of metabolites in groundwater

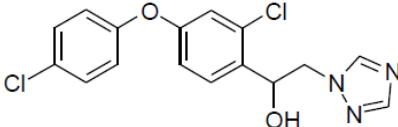
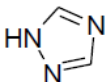
Comment of ZRMS	The metabolites of difenoconazole are predicted to occur in groundwater at concentrations below 0.001 µg/L. Thus, the assessment of the relevance of this metabolite according to the stepwise procedure (acc. to SANCO/221/2000 –rev.10) is not required.
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10.1 General information

Both metabolites CGA-205375 and CGA 71019 predicted to occur in groundwater will occur at concentrations below 0.1 µg/L (see chapter 8.8.2 in dRR Part B, Section 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.

General information on the metabolites is provided in **Błąd! Nieprawidłowy odsyłacz do zakładki: wskazuje na nią samą..**

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	
Difenoconazole	CGA-205375		Max PEC _{gw} Based on:	< 0.001 µg/L FOCUS PEARL v.5.5.5, FOCUS PELMO v.6.6.4, FOCUS MACRO v.5.5.4 in all scenarios
Difenoconazole	CGA 71019		Max PEC _{gw} Based on:	< 0.001 µg/L FOCUS PEARL v.5.5.5, FOCUS PELMO v.6.6.4, FOCUS MACRO v.5.5.4 in all scenarios

Appendix 1 Lists of data considered in support of the evaluation

No data submitted.

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	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		

Appendix 2 Additional information

No data submitted.

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