

FINAL REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: **SNS-F-11**

Product names:

DISFERA 90 EC / LIPOSTAR 90 EC

Chemical active substance:

Difenoconazole, 90.0 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT Poland

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 01/2024

MS Finalisation date: 07/2024; 10/2024; 11/2024

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Version history

When	What
01/ 2024	Initial dRR
07/2024	ZRMs evaluated dRR submitted by Applicant.
10/2024	The Final Registration Report
11/2024	The final RR after the second round of commenting

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10 Relevance of metabolites in groundwater

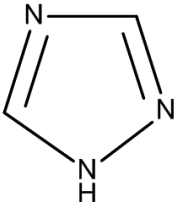
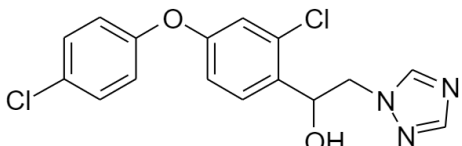
Comment of ZRMS	The metabolites of difenoconazole contained in the product SNS-F-11 are predicted to occur in groundwater at concentrations below 0.1 µg/L. Thus the assessment of the relevance of this metabolite according to the stepwise procedure (acc. to SANCO/221/2000 – rev.10) is not required.
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10.1 General information

The metabolites of difenoconazole (i.e. CGA 71019 and CGA 205375) are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B section 8).

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. General information on the metabolites are provided in Table 10.1-1.

Table 10.1-1: General information on the metabolites

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Difenoconazole	CGA 71019		Max PEC _{gw} Based on:	< 0.1 µg/L each scenario; calculated with PEARL v 5.5.5 PELMO v 6.6.4
Difenoconazole	CGA 205375		Max PEC _{gw} Based on:	< 0.1 µg/L each scenario; calculated with PEARL v 5.5.5 PELMO v 6.6.4

10.2 Relevance assessment of metabolites

Summary:

The groundwater metabolites CGA 71019, CGA 205375, are considered as non-relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10 (*Step 2 – Quantification of potential groundwater contamination*), since their predicted concentration in the groundwater do not exceed

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the concentration of 0.1 µg/L. Studies supporting PEC_{gw} data are evaluated in Section 8 (Environmental fate and behaviour).

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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

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

The following tables are to be completed by MS

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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

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Appendix 2 Additional information

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