

**FINAL REGISTRATION REPORT**

**Part B**

**Section 10**

**Assessment of the relevance of metabolites in  
groundwater**

Detailed summary of the risk assessment

Product code: Diflufenikan 500 SC

Product name(s): -

Chemical active substance:

diflufenican, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

(authorization)

Applicant: Pestila Sp. z o.o. / ProAgri International Sp. z o.o.

Submission date: January 2023;

MS Finalisation date: May 2023 January 2024

## Version history

When	What
May 2023	Assessment by expert
January 2024	The final Registration Report

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## **10 Relevance of metabolites in groundwater**

### **10.1 General information**

Metabolites of diflufenikan are predicted to occur in groundwater at concentration below 0.1 µg/L (see dRR Part B8). 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.

### **10.2 Relevance assessment**

#### **10.2.1 STEP 1: Exclusion of degradation products of no concern**

Not relevant.

#### **10.2.2 STEP 2: Quantification of potential groundwater contamination**

Not relevant.

#### **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.

##### **10.2.3.2 STEP 3, Stage 2: screening for genotoxicity**

Not relevant.

##### **10.2.3.3 STEP 3, Stage 3: screening for toxicity**

Not relevant.

#### **10.2.4 STEP 4: Exposure assessment – threshold of concern approach**

Not relevant.

#### **10.2.5 STEP 5: Refined risk assessment**

Not relevant.

**EFSA Scientific Report (2007) 122, 1-84, Conclusion on the peer review of  
Diflufenican**

**“ Extensively metabolised, predominantly by hydroxylation of difluorophenyl ring (with or without conjugation). AE B107137 (M&B 38181): oral LD50 >2000 mg/kg bw (rat), dermal LD50 >1000 mg/kg bw (rat), Ames test: negative, in vitro cytogenetic assay (metaphase analysis in human lymphocytes): equivocal. Overall, no genotoxic potential in vitro.”**

## 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

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
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**List of data relied on not submitted by the applicant but necessary for evaluation**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
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## **Appendix 2 Additional information**

Not relevant.