

FINAL REGISTRATION REPORT

Part B

Section 10

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

Detailed summary of the risk assessment

Product code: K-300 SL-RR

Product name(s): Faworyt 300 SL

Chemical active substance:

Clopyralid, 300 g/L

Central Zone

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT – Art. 43

(Renewal of authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 12/2021

MS Finalisation date: 07/2022; 10/2022

Version history

When	What
December 2021	dRR version 1 submitted by applicant
July 2022	zRMS first assessment
October 2022	Final Registration Report

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10 Relevance of metabolites in groundwater

10.1 General information

During the degradation studies of clopyralid in soil, no significant metabolites were found. Therefore, no predicted environmental concentrations in groundwater for metabolites were calculated. Thereby, the assessment of the relevance of the metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 **is not required**.

General information as above is acceptable

According to the *EFSA Scientific Report (2005) 50, 1–65, Conclusion on the peer review of clopyralid Cis rapidly and nearly completed absorbed, based on urinary excretion data. The excretion is also rapid, >90% within 32 hours mainly in urine (both following oral and intravenous administration). It is widely distributed and the highest concentration was found in the liver. There was no evidence of accumulation. Clopyralid is not metabolised, since clopyralid is the only residue detected.*

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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
-	-	-	-	-	-