

REGISTRATION REPORT

Part B

Section 10

Assessment of the Relevance of Metabolites in Groundwater

Detailed summary of the risk assessment

Product code: HCV07

Product names: Vivendi 300 SL, Auksendy 300 SL, Cliophar Super

Chemical active substance:

Clopyralid-olamine, 395 g/l (300 g ae/l)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Renewal of Authorization under Art.43)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 22/12/2021

MS Finalisation date: July 2023 (initial Core Assessment)

March 2024 (final Core Assessment)

Version History

When	What
December 2021	Article 43 submission for reregistration of HCV07 following Clopyralid Renewal of approval (Commission Implementing Regulation (EU) 2021/1191)
July 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.
March 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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10 Relevance of Metabolites in Groundwater

10.1 General Information

There are no metabolites of clopyralid predicted to occur in groundwater (see Part B8) when applied according to the product GAP. Therefore, assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 **is not required**.

10.2 Relevance assessment

Not required.

Appendix 1 Lists of data considered in support of the evaluation

Not required.

Appendix 2 Additional information

Not required.

zRMS comment:

A non-relevance assessment is therefore not required; it is accepted.

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

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.