

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: July 2024

MS Finalisation date: March 2025 (initial Core Assessment)

June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by applicant
March 2025	Initial assessment by the zRMS 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.
June 2025	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

Reviewer comments:

This part of dossier has been submitted to support registration of the plant protection product ADM.01851.H.1.A according art. 33 of 1107/2009.

Document refers data related to the forming of metabolites in the environment (for details see dRR B8).

Ethofumesate:

The performed calculations were independently validated by the zRMS in additional modelling using PELMO 6.6.4 and PEARL 5.5.5 and MACRO 5.5.4 models and input parameters indicated in Table 8.8-3 and application dates as suggested by AppDate 3.06.

Since Poland is the only cMS indicated in the GAP table, only scenarios required in Poland were considered (Châteaudun, Hamburg and Kremsmünster). Obtained results were in good agreement with these derived by the Applicant for ethofumesate. **No unacceptable leaching of ethofumesate in scenarios relevant in Poland is expected following application of ADM.01851.H.1.A to sugar beet at the biennial application rate of 3x335 g/ha at BBCH 10-19.** Since the performed modelling at the triennial application was not necessary, thus presented results in Tables 8.8-10 to 8.8-12 were struck through as not relevant.

In case of mutual recognition process additional simulations may be requested by Member States considering other scenarios as representative or not accepting FOCUS modelling at all.

Clopyralid:

The performed calculations were independently validated by the zRMS in additional modelling using PELMO 6.6.4 and PEARL 5.5.5 and MACRO 5.5.4 models and input parameters indicated in Table 8.8-22 and application dates as suggested by AppDate 3.06.

Since Poland is the only cMS indicated in the GAP table, only scenarios required in Poland were considered (Châteaudun, Hamburg and Kremsmünster). Obtained results were in good agreement with these derived by the Applicant for clopyralid. **No unacceptable leaching of clopyralid in scenarios relevant in Poland is expected following application of ADM.01851.H.1.A to sugar beet at the biennial application rate of 3x50.25 g/ha at BBCH 10-19.** In case of mutual recognition process additional simulations may be requested by Member States considering other scenarios as representative or not accepting FOCUS modelling at all.

dRR Part B10 has been reviewed for the purposes of ongoing registration and also checked its compliance with the current guidelines. Information has been considered as sufficient (see point 10.1) and appropriate for concluding.

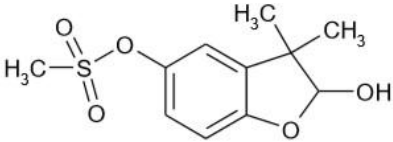
10.1 General information

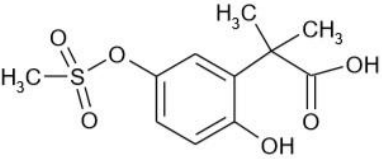
There are two active substances in the product ADM.01851.H.1.A, ethofumesate and clopyralid. Ethofumesate has two major soil metabolites requiring groundwater modelling, NC8493 and NC20645. Clopyralid does not have any major soil metabolites.

The metabolites NC8493 and NC20645 are not predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B8, section 8.8.2.1). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore not required.

General information on the metabolites are provided in Table 10.1-1. The impact of the relevance assessment on whether a particular GAP use leads to acceptable risk or not is presented in the summary of the cGAP evaluation in chapter 8.1 of the dRR Part B, Section 8 (Environmental fate and behaviour).

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	
Ethofumesate	NC 8493		Max PEC _{gw} Based on:	<0.001 µg/L All models, all scenarios

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Ethofumesate	NC 20645		Max PEC _{gw} Based on:	<0.001 µg/L All models, all scenarios

Appendix 1 Lists of data considered in support of the evaluation

No data required.

Appendix 2 Additional information

No additional information required.