REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: 19202

Product name(s): **KINVARA**

Chemical active substance(s):

MPCA, 233 g/L
Fluroxypyr (acid), 50g/L

Clopyralid, 28 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(formulation renewal)

Applicant: XXXX

Submission date: 31/01/2024

Evaluation date: October 2024

MS Finalisation date: March 2025

Version history

When	What
January 2024	Article 43 of Regulation (EC) No. 1107/2009
October 2024	Conclusions of zRMS

Table of Contents

10 Relevance of metabolites in groundwater

zRMS Comments:	The submitted PECgw values for metabolites of active substances were accepted. **MCPA**. Based on PECgw assessment, metabolites concentration in groundwater were below the trigger value of 0.1 µg/L. **Fluroxypyr.** Based on PECgw assessment, metabolites concentration in groundwater were below the trigger value of 0.1 µg/L. **Clopyralid.** No metabolite was identified.

10.1 General information

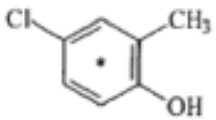
All metabolites covered in this assessment are considered toxicologically relevant because no regulatory assessments were submitted or accepted as part of active substance approval, and no new data are submitted here. All metabolites are predicted to occur in groundwater at concentrations **below 0.1 µg/L** (see sections 8.8.2 and 8.8.3 of the dRR Part B, Section 8).

10.2 Relevance assessment of MCPA metabolites

PCOC, the metabolite of MCPA, was not considered in the active substance approval of MCPA, which predates the current EFSA system, as well as FOCUS modelling. Many member states request its inclusion in risk assessments because it occurs at major (>10%) concentrations in soils. However, the EU decision not to consider its relevance to groundwater means there is a lack of data on the substance resulting in its inclusion as a toxicologically relevant substance.

General information on the metabolites are provided in Table 10.2-1. 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 8.8 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.2-1: General information on the metabolite of MCPA

Name of active substance	Metabolite name and code	Structural/ molecular formula	Trigger for relevance assessment		
MCPA	PCOC		Max $PEC_{gw:}$ Based on:	0.014 µg/L Grassland applications in September (PELMO, Piacenza)	Trigger not met

10.2.1 STEP 1: Exclusion of degradation products of no concern

In the assessment of the leaching of MCPA described in Part B Section 8, there were no metabolites predicted to leach at concentrations greater than 0.1 µg L^{-1}. Therefore, an assessment of relevance of the MCPA metabolite PCOC is not required.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not required.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not required.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not required.

10.2.5 STEP 5: Refined risk assessment

Not required.

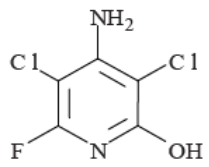
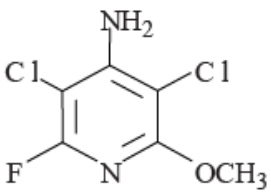
zRMS:
Since PECgw of metabolite PCOC is below 0.1 µg/L, assessment of relevance and risk is not required.

10.3 Relevance assessment of fluroxypyr metabolites

The major metabolites of fluroxypyr, methoxypyridine and pyridinol, were partially screened for toxicologic relevance at EU level. A data gap was identified during the renewal which was never filled, such that the full relevance status remains inconclusive resulting in consideration of the substances as toxicologically relevant.

General information on the metabolites are provided in Table 10.3-1 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 8.8 of the dRR Part B, Section 8 (Environmental fate and behaviour).

Table 10.3-1: General information on the metabolites of fluroxypyr

Name of active substance	Metabolite name and code	Structural/ molecular formula	Trigger for relevance assessment		
Fluroxypyr (MHE)	Pyridinol		Max $PEC_{gw:}$ Based on:	0.001 µg/L Grassland applications in September (PELMO, Piacenza)	Tigger not met
Fluroxypyr (MHE)	Methoxypyridine		Max $PEC_{gw:}$ Based on:	0.005 µg/L Grassland applications in September (PELMO, Piacenza)	Trigger not met

10.3.1 STEP 1: Exclusion of degradation products of no concern

In the assessment of the leaching of fluroxypyr described in Part B Section 8, there were no metabolites predicted to leach at concentrations greater than 0.1 µg L^{-1}. Therefore, an assessment of relevance of the fluroxypyr metabolites pyridinol and methoxypyridine is not required.

10.3.2 STEP 2: Quantification of potential groundwater contamination

Not required.

10.3.3 STEP 3: Hazard assessment – identification of relevant metabolites

Not required.

10.3.4 STEP 4: Exposure assessment – threshold of concern approach

Not required.

10.3.5 STEP 5: Refined risk assessment

Not required.

zRMS:
Since PECgw of metabolites Pyridinol and Methoxypyridine is below 0.1 µg/L, assessment of relevance and risk is not required.

Appendix 1 Lists of data considered in support of the evaluation

The following lists should include all product data considered in support of the evaluation, even if they have been evaluated previously, e.g. in the EU peer review of the active substance(s), and thus are not summarised in this document in detail. New data evaluated for the active substance(s) should be included as well.

Please sort by data points and within one data point by names of authors.

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS

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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	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
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional information

If necessary, additional appendices may be added to include further information.