

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: HBZ10

Product name: Wizard

Chemical active substances:

Phenmedipham, 125 g/L

Ethofumesate, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation - Art. 33 application)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: October 2021

MS Finalisation date: June 2022 (initial Core Assessment)

March 2023 (final Core Assessment)

Version history

When	What
October 2021	Part B - Section 10 - Core Assessment - Central Zone, version 1
June 2022	<p>Initial assessment by the zRMS</p> <p>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.</p>
March 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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Reviewer summary:

This part of dossier has been submitted to support registration of the plant protection product Wizard/Beetup Pro/Betasana Max (product code HBZ10 an emulsifiable concentrate (EC) containing 125 g/L \pm phenmedipham and 125 g/L ethofumesate) according art. 33 of 1107/2009.

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

10 Relevance of metabolites in groundwater

10.1 General information

The plant protection product HBZ10 consists of two active substances:

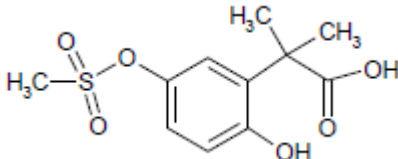
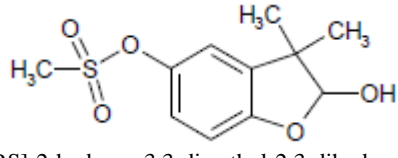
- Ethofumesate: 125 g/L
- Phenmedipham: 125 g/L

Ethofumesate

The PEC_{GW} modelling data for Ethofumesate and its metabolites do not show any findings above the threshold limit of 0.1 µg/L (dRR Part B, Section 8 (Environmental fate and behaviour)).

Since there are no potentially relevant metabolites of Ethofumesate, no further assessment of the relevance of metabolites is required.

Table 10.1-1: General information on the metabolites of Ethofumesate

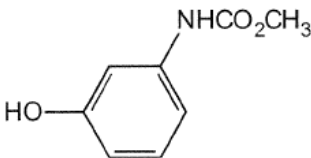
Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Ethofumesate	NC 20645	 <p>2-{2-hydroxy-5-[(methylsulfonyl)methyl]phenyl}-2-methylpropanoic acid</p>	Max PEC _{GW} Based on:	< 0.001 µg/L Modelling data
Ethofumesate	NC 8493	 <p>[RS]-2-hydroxy-3,3-dimethyl-2,3-dihydro-1-benzofuran-5-yl methanesulfonate</p>	Max PEC _{GW} Based on:	< 0.001 µg/L Modelling data

Phenmedipham

The PEC_{GW} modelling data for Phenmedipham and its metabolites do not show any findings above the threshold limit of 0.1 µg/L (dRR Part B, Section 8 (Environmental fate and behaviour)).

Since there are no potentially relevant metabolites, no further assessment of the relevance of metabolites is required.

Table 10.1-2 General information on the metabolites of Phenmedipham

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Phenmedipham	MHPC		Max PEC _{gw} Based on:	<0.001 µg/L Modelling data

10.2 Relevance assessment of metabolites

Refer to 10.1.

10.2.1 STEP 1: Exclusion of degradation products of no concern

Refer to 10.1.

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

10.2.5 STEP 5: Refined risk assessment

Not applicable – no metabolites exceed 0.1 µg/L in groundwater.

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 (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
-	-	-	-	-	-

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
-	-	-	-	-	-

Appendix 2 Additional information

No data submitted.