

REGISTRATION REPORT

Part B

Section 10

Assessment of the relevance of metabolites in groundwater

Detailed summary of the risk assessment

Product code: GLOB1817H

Product name: **Eledura**

Chemical active substances:

Prosulfocarb, 667 g/L

Diiflufenican, 14 g/L

Halaxifen-methyl, 1.33 g/L

Cloquintocet-mexyl, 1.33 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: May 2021

MS Finalisation date: January 2022

Version history

When	What
May 2021	Initial submission by the applicant for approval of new product.
January 2022	Version evaluated by zRMS PL

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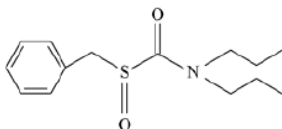
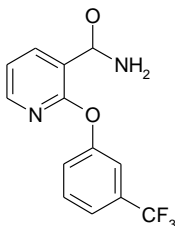
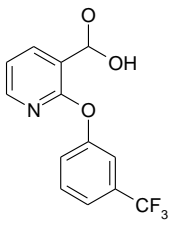
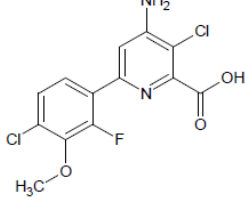
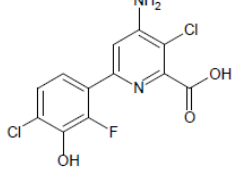
10 Relevance of metabolites in groundwater

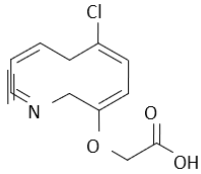
10.1 General information

The metabolites prosulfocarb sulfoxide, AE 0542291, AE B107137, X11393729 (halauxifen), X11449757 and CGA 153433 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B, Section 8, chapter 8.8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

General information on the metabolites is 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 8.8 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	
Prosulfocarb	Prosulfocarb sulfoxide		Max PEC _{gw}	< 0.001 µg/L
			Based on:	FOCUS PELMO 5.5.3
Diflufenican	AE 0542291		Max PEC _{gw}	< 0.001 µg/L
			Based on:	FOCUS PELMO 5.5.3
	AE B107137		Max PEC _{gw}	< 0.001 µg/L
			Based on:	FOCUS PELMO 5.5.3
Halauxifen-methyl	X11393729 (halauxifen)		Max PEC _{gw}	0.001 µg/L
			Based on:	FOCUS PELMO 5.5.3
	X11449757		Max PEC _{gw}	< 0.001 µg/L
			Based on:	FOCUS PELMO 5.5.3

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
Cloquintocet-mexyl	CGA 153433		Max PEC _{gw} Based on:	< 0.001 µg/L FOCUS PELMO 5.5.3

zRMS:

Based on PEC_{gw} assessment submitted in Section 8 the predicted groundwater concentrations of all metabolites of all active substances was below 0.1 µg/L.

The assessment of metabolite relevance and risk is not required in line with the EC guidance document SANCO/221/2000–rev.10.

Appendix 1 Lists of data considered in support of the evaluation

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
None					

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
None					

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