

# FINAL REGISTRATION REPORT

## Part B

### Section 10

#### **Assessment of the relevance of metabolites in groundwater**

Detailed summary of the risk assessment

Product code: CHR/H/CFF 250 EC

Product name(s): Hapi 250 EC/ Turango 250 EC

Chemical active substance(s):

Clopyralid, 120 g/L

Fluroxypyr-acid, 120 g/L (as fluroxypyr-meptyl, 172.9 g/L)

Florasulam, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: March 2023

MS Finalisation date: November 2023; November 2024

## Version history

When	What
November 2023	Assessment by expert
November 2024	The final Registration Report

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10.2.3.1	STEP 3, Stage 1: screening for biological activity	<b>Błąd! Nie zdefiniowano zakładki.</b>
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## 10 Relevance of metabolites in groundwater

In the following document, data for active substances - Fluroxypyr - was described during its inclusion on Annex 1 process in respectively 2009. Were reference to active substance data in the current risk assessment has been made, it was based on the data which protection for expired 10 years from date of inclusion of active substances on Annex I.

Data matching studies for florasulam have been evaluated by Poland. As a result of the assessment all reports were accepted and considered as equivalent to protected studies. Therefore, to support the authorization of CHR/H/CFF 250 EC INNIGO is allowed to refer to EU approved reports

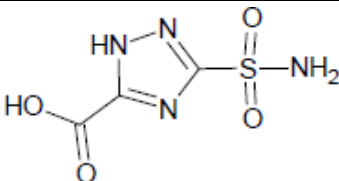
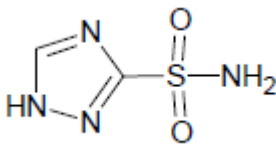
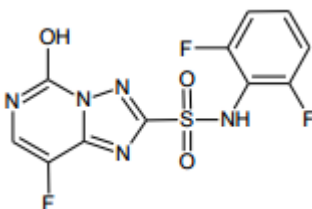
Data matching studies for clopyralid have been evaluated by RMS - Finland. As a result of the assessment all re-ports were accepted and considered as equivalent to protected studies. Therefore, to support the renewal of authorization of CHR/H/CFF 250 EC INNIGO is allowed to refer to EU approved reports

### 10.1 General information

The metabolites 5-ASTCA, TSA and 5-OH Florasulam are predict predicted to occur in groundwater at concentrations above 0.1 µg/L (see PART B Section 8 of CHR/H/CFF 250 EC). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

General information on the metabolites 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 KCP 9.2.4 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	
Florasulam	ASTCA		Max PECgw Based on:	0.285 µg/L  Focus PELMO 6.6.4 Hamburg Winter cereals
	TSA		Max PECgw Based on:	0.2226 µg/L  Focus PEARL 5.5.5 Jokioinen Winter cereals
	5-OH Florasulam		Max PECgw Based on:	0.134 µg/L  Focus PELMO 6.6.4 Hamburg Winter cereals

## 10.2 Relevance assessment of ASTCA

### Summary:

The relevance of the groundwater metabolite ASTCA has already been assessed and the assessment agreed at EU level (RAR Florasulam-2013, Vol3 – B6) , and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the  $PEC_{gw}$  calculated for the GAP and groundwater scenarios considered in this dRR ). ASTCA is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

A summary of the relevance assessment is given in **Błąd! Nie można odnaleźć źródła odwołania.** and the corresponding studies are listed in the corresponding sections.

**Table 10.1-2: Summary of the relevance assessment for ASTCA according to the RAR Florasulam-2013, Vol3 – B6**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contamination	STEP 2		Max PEC <sub>gw</sub>	0.285 µg/L
			Based on	FOCUS PELMO, Hamburg
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic ( T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable <0.75 µg/L
	STEP 5	Refined risk assessment		Not required
		Predicted exposure (% of ADI)		Not required
				ADI based on

\* N/A: not applicable

## 10.3 Relevance assessment of TSA

### Summary:

The relevance of the groundwater metabolite TSA has already been assessed and the assessment agreed at EU level (RAR Florasulam-2013, Vol3 – B6) , and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the  $PEC_{gw}$  calculated for the GAP and groundwater scenarios considered in this dRR ). TSA is not considered relevant according to the

criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

A summary of the relevance assessment is given in **Błąd! Nie można odnaleźć źródła odwołania.** and the corresponding studies are listed in the corresponding sections.

**Table 10.1-3: Summary of the relevance assessment for TSA according to the RAR Florasulam-2013, Vol3 – B6**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contamination	STEP 2		Max PEC <sub>gw</sub>	0.2226 µg/L
			Based on	FOCUS PEARL, Jokioinen,
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic ( T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable <0.75 µg/L
	STEP 5	Refined risk assessment	Not required	
		Predicted exposure (% of ADI)	Not required	
			ADI based on	Not required

\* N/A: not applicable

## 10.4 Relevance assessment of 5-OH-Florasulam

### Summary:

The relevance of the groundwater metabolite 5-OH Florasulam has already been assessed and the assessment agreed at EU level (RAR Florasulam-2013, Vol3 – B6 ) , and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC<sub>gw</sub> calculated for the GAP and groundwater scenarios considered in this dRR ). 5-OH Florasulam is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

A summary of the relevance assessment is given in **Błąd! Nie można odnaleźć źródła odwołania.** and the corresponding studies are listed in the corresponding sections.

**Table 10.1-4: Summary of the relevance assessment for 5-OH Florasulam according to the RAR Florasulam-2013, Vol3 – B6**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contamination	STEP 2		Max PEC <sub>gw</sub>	0.134 µg/L
			Based on	FOCUS PELMO, Hamburg,
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	no
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	Not toxic or very toxic ( T or T+)
			Classification of parent	not currently classified as toxic or very toxic
			Classification of metabolite	not currently classified as toxic or very toxic
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable <0.75 µg/L
	STEP 5	Refined risk assessment		Not required
		Predicted exposure (% of ADI)		Not required
				ADI based on

#### Florasulam:

The relevance of the groundwater metabolite ASTCA and TSA have already been assessed and the assessment agreed at EU level (see EFSA Journal 2015; 13(1):3984)

In the EU review the RMS concluded these metabolites were not toxicologically relevant for groundwater on the basis of the available *in vitro* genotoxicity data, both ASTCA and TSA and for 5-OH Florasulam are not considered relevant.

#### Clopyralid:

Clopyralid is not metabolised (*EFSA Scientific Report* (2005) 50, 1–65,

Conclusion on the peer review of clopyralid). 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. There was no evidence of accumulation.

#### Fluroxypyr:

Fluroxypyr produces soil metabolites and it metabolites Pyridinol and Methoxy pyridine are predicted to occur in groundwater at concentrations below 0.1µg/L therefore not required. (EFSA Journal 2011;9(3):2091): Metabolism in Animals: MHE; rapidly and completely hydrolysed to fluroxypyr sodium salt; unchanged excreted

## 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

### Cross reference to the section B6 of the dRR

### 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**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			-	Y/N	Owner

## **Appendix 2    Additional information**