

# FINAL REGISTRATION REPORT

## Part B

### Section 10

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

Detailed summary of the risk assessment

Product code: GLOB289H / SAP63H

Product name(s): SAP63H

Chemical active substance(s):

Iodosulfuron-methyl-sodium, 6 g/kg

Mesosulfuron-methyl, 30 g/kg

Safener: Mefenpyr-diethyl, 90 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Globachem N.V. / Ascenza Agro S.A.

Submission date: December 2019

MS Finalisation date: 08/2021; 01/2022

## Version history

When	What
December 2019	V0 - Original version from applicant for submission to zRMS POLAND in the frame of new PPP registration
08/2021	Assessment by expert
01/ 2022	RR Final Version

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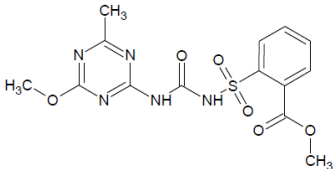
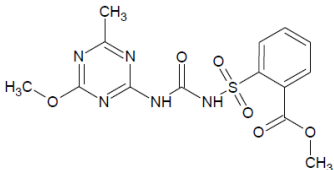
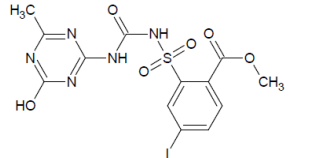
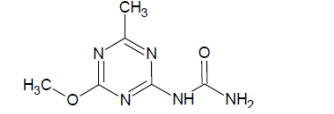
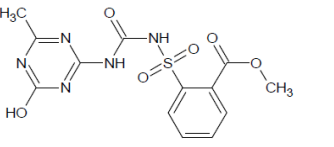
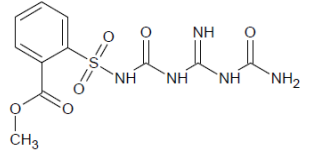
## 10 Relevance of metabolites in groundwater

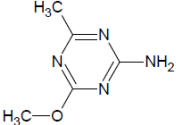
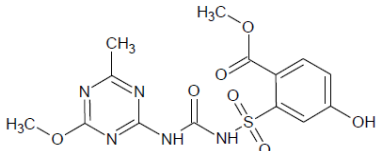
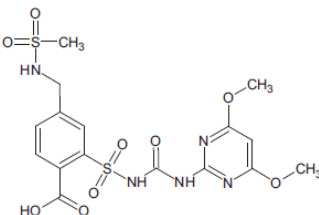
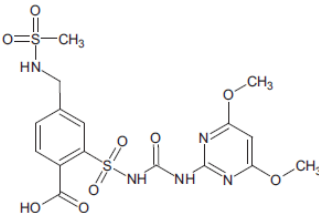
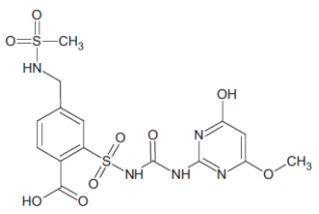
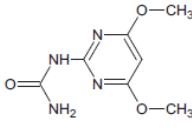
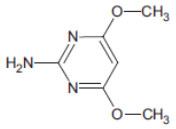
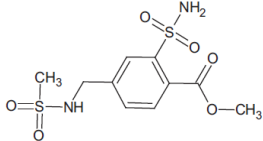
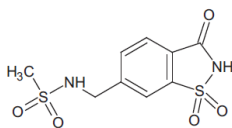
### 10.1 General information

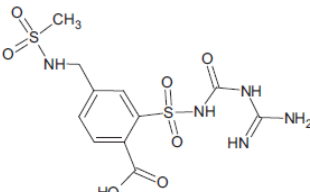
Metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required.

General information on the metabolites 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 9.2 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	
Iodosulfuron-methyl-sodium  AE F115008	Metsulfuron-methyl AE F075736		Max PEC <sub>gw</sub>	0.06 µg/L
			Based on:	Pearl 4.4.4 – Joikoinen scenario Pelmo 5.5.3 – Okehampton scenario
	AE F145740		Max PEC <sub>gw</sub>	0.004 µg/L
			Based on:	Pelmo 5.5.3, Hamburg & Okehampton scenario
	AE F145741		Max PEC <sub>gw</sub>	0.002 µg/L
			Based on:	Pearl 4.4.4 – Joikoinen scenario Pelmo 5.5.3 – Porto scenario
	AE 0000119		Max PEC <sub>gw</sub>	0.002 µg/L
			Based on:	Pearl 4.4.4 – Hamburg scenario
	AE F161778		Max PEC <sub>gw</sub>	0.018 µg/L
			Based on:	Pelmo 5.5.3, Okehampton scenario
	BCS-CW81253		Max PEC <sub>gw</sub>	0.016 µg/L
			Based on:	Pelmo 5.5.3, Okehampton + Kremsmunster scenario

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
	AE F059411		Max PEC <sub>gw</sub>	0.028 µg/L
	AE 0002166		Max PEC <sub>gw</sub>	0.007 µg/L
Mesosulfuron-methyl	Mesosulfuron AE F154851		Max PEC <sub>gw</sub>	0.048 µg/L
	AE F160459		Max PEC <sub>gw</sub>	<b>0.305 µg/L</b>
	AE F160460		Max PEC <sub>gw</sub>	<b>0.260 µg/L</b>
	AE F099095		Max PEC <sub>gw</sub>	< 0.001 µg/L
	AE F092944		Max PEC <sub>gw</sub>	< 0.001 µg/L
	AE F140584		Max PEC <sub>gw</sub>	0.025 µg/L
	AE F147447		Max PEC <sub>gw</sub>	<b>0.328 µg/L</b>
			Based on:	Pelmo 5.5.3, Hamburg scenario
			Based on:	Pelmo 5.5.3, Porto scenario
			Based on:	Pelmo 5.5.3, Okehampton scenario
			Based on:	Pearl 4.4.4, Jokioinen scenario
			Based on:	Pelmo 5.5.3, Hamburg scenario

Name of active substance	Metabolite name and code	Structural/molecular formula	Trigger for relevance assessment	
	BCS-CV14885		Max PEC <sub>gw</sub> Based on:	<b>0.500 µg/L</b>  Pearl 4.4.4, Jokioinen scenario

## 10.2 Relevance assessment of AE F160459

### Summary:

The relevance of the groundwater metabolite AE F160459 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2016; 14(10):4584), 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 ). Metabolite AE F160459 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 Table 10.2-1 and the corresponding studies are listed in the corresponding sections.

**Table 10.2-1: Summary of the relevance assessment for AE F160459**

	Assessment step		Result of assessment	
Quantification of groundwater contaminant	STEP 1		Metabolite of no concern?	Yes
	STEP 2		Max PEC <sub>gw</sub>	0.305 µg/L
			Based on	Pearl 4.4.4, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic based on the structural similarities with mesosulfuron-methyl and AE F160460
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not classified as toxic or very toxic
			Classification of metabolite	Not 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	N/A
			Predicted exposure (% of ADI)	N/A
				ADI based on

\* N/A: not applicable

### 10.3 Relevance assessment of AE F160460

#### Summary:

The relevance of the groundwater metabolite AE F160460 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2016; 14(10):4584), 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 ). Metabolite AE F160460 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 Table 10.3-1 and the corresponding studies are listed in the corresponding sections.

**Table 10.3-1: Summary of the relevance assessment for AE F160460**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contaminant	STEP 2		Max PEC <sub>gw</sub>	0.260 µg/L
			Based on	Pelmo 5.5.3, Hamburg scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Negative Ames test Negative chromosome aberration <i>in vitro</i> Negative gene mutation <i>in vitro</i> in mammalian cells Unlikely to be genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not classified as toxic or very toxic
			Classification of metabolite	Not 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	N/A
			Predicted exposure (% of ADI)	N/A
				ADI based on

\* N/A: not applicable

### 10.4 Relevance assessment of AE F147447

#### Summary:

The relevance of the groundwater metabolite AE F147447 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2016; 14(10):4584), 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 ). Metabolite AE F147447 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 Table 10.3-1 and the corresponding studies are listed in the corresponding sections.

**Table 10.4-1: Summary of the relevance assessment for AE F147447**

	Assessment step		Result of assessment	
Quantification of groundwater contaminant	STEP 1		Metabolite of no concern?	Yes
	STEP 2		Max PEC <sub>gw</sub>	0.328 µg/L
			Based on	Pearl 4.4.4, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Negative Ames test Negative chromosome aberration <i>in vitro</i> Negative gene mutation <i>in vitro</i> in mammalian cells Unlikely to be genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not classified as toxic or very toxic
			Classification of metabolite	Not classified as toxic or very toxic
		Consumer health risk assessment	STEP 4	
STEP 5			Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

\* N/A: not applicable

## 10.5 Relevance assessment of BCS-CV14885

### Summary:

The relevance of the groundwater metabolite BCS-CV14885 has already been assessed and the assessment agreed at EU level (see EFSA Journal 2016; 14(10):4584), 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 ). Metabolite BCS-CV14885 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 Table 10.5-1 and the corre-



sponding studies are listed in the corresponding sections.

**Table 10.5-1: Summary of the relevance assessment for BCS-CV14885**

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	Yes
Quantification of groundwater contamination	STEP 2		Max PEC <sub>gw</sub>	0.500 µg/L
			Based on	Pearl 4.4.4, Jokioinen scenario
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Negative Ames test Negative chromosome aberration <i>in vitro</i> Negative gene mutation <i>in vitro</i> in mammalian cells Unlikely to be genotoxic
		Stage 3	Toxic properties of metabolite;	
			Classification of parent	Not classified as toxic or very toxic
			Classification of metabolite	Not classified as toxic or very toxic
		Consumer health risk assessment	STEP 4	
STEP 5			Refined risk assessment	N/A
			Predicted exposure (% of ADI)	N/A
			ADI based on	N/A

\* N/A: not applicable

### Comments:

As the metabolites of iodosulfuron methylsodium in soil are not expected to occur during loading of groundwater at concentrations above 0.1 µg / L for the intended uses of the product and therefore have no toxicological significance, therefore, their evaluation in accordance with the staged procedure contained in the EC Guideline SANCO / 221 / 2000 –rev.10 is not required

Because metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885 mesosulfuron-methyl are expected to occur during groundwater recharging at concentrations above 0.1 µg / L, therefore the significance of these metabolites has been assessed in accordance with the gradual procedure in the EC guidelines SANCO / 221/2000 - version 10.

**The importance of the AE F160459, AE F160460, AE F147447, BCS-CV14885 groundwater metabolites have already been assessed and accepted at EU level. The metabolite AE F160459, AE F160460, AE F147447, BCS-CV14885 are not considered to be toxicologically relevant according to the criteria in EC Guideline SANCO / 221/2000 - version 10.**

**Since none of the mefenpyr-diethyl metabolites in soil is expected to occur in the recharge of groundwater at concentrations above 0.1 µg / L for the intended uses of the product, there is no justification for substantive assessment of these metabolites according to the gradual procedure contained in the EC 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
-	-	-	-	-	-

### 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

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

**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</b> <b>Y/N</b>	<b>Owner</b>