

# REGISTRATION REPORT

## Part B

### Section 10

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

Detailed summary of the risk assessment

Product code: GLOB2112dH

Product name: Walkover Trio

Chemical active substances:

Thiencarbazone-methyl, 75 g/L

Mesotrione, 375 g/L

Central Zone

Zonal Rapporteur Member State: Poland

#### CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: September 2024

zRMS Assessment : 31/03/2025

Version after commenting: 03/07/2025

List of references update: 10/07/2025

## Version history

When	What
September 2024	Initial dossier submission by applicant for approval of new product.
March 2025	zRMS assessment
July 2025	After commenting round
July 2025	List of references update

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## 10 Relevance of metabolites in groundwater

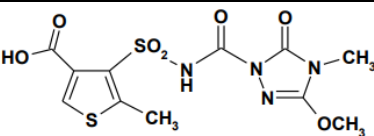
zRMS comment: The relevance of the groundwater metabolite BYH 18636-carboxylic acid has already been assessed at EU level (EU DAR (2012) of thiencarbazone-methyl), and the corresponding EFSA peer review conclusion (EFSA Journal; 11(7): 3270, 2013). BYH 18636-carboxylic acid is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11 (21 October, 2021).

### 10.1 General information

The metabolite BYH 18636-carboxylic acid is predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B, Section 8, chapter 8.8). Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

General information on the metabolite 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	
Thiencarbazone-methyl	BYH 18636-carboxylic acid		Max PEC <sub>gw</sub>	0.660 µg/L
			Based on:	PEARL 5.5.5 Hamburg, 15 g/ha pre-emergence to maize

### 10.2 Relevance assessment of BYH 18636-carboxylic acid

The relevance in groundwater of metabolite BYH 18636-carboxylic acid was evaluated as part of the European review for Annex I inclusion of the active substance thiencarbazone-methyl, the component was considered to be non-relevant. Detailed data and assessment is found in the EU DAR (2012) of thiencarbazone-methyl, and the corresponding EFSA peer review conclusion (EFSA Journal 2013;11(7):3270).

Only a brief tabular summary is therefore provided here, reflecting the stepwise procedure proposed in guidance SANCO/221/2000 –rev.10. Additionally, consumer risk assessment is re-calculated to adapt to the PEC<sub>gw</sub> situation of the present product.

**Table 10.2-1 Summary of the relevance assessment of BYH 18636-carboxylic acid**

	Assessment step	Result of assessment	
	STEP 1	Metabolite of no concern?	No
Groundwater	STEP 2	Max PEC <sub>gw</sub>	0.660 µg/L

		Based on	PEARL 5.5.5 Hamburg, 15 g/ha pre-emergence to maize
<b>Hazard assessment</b>	STEP 3	Stage 1	Biological activity comparable to the parent?
		Stage 2	Genotoxic properties of metabolite
		Stage 3	Toxic properties of metabolite;
			Classification of parent
			Classification of metabolite
<b>Consumer health risk assessment</b>	STEP 4	Estimated consumer exposure via drinking water and other sources; threshold of concern approach	0.022 µg/kg bw/d
	STEP 5	Refined risk assessment	
		Predicted exposure (% of ADI)	0.0096
		ADI based on	NOEL from 90 day rat study

### Consumer health assessment – calculation of ADI usage

BYH 18636-carboxylic acid was shown not relevant with a threshold above 0.75 µg/L. Therefore, a refined risk assessment is needed. The ADI of the parent (0.23 mg/kg bw/d) can be applied.

Metabolite	Max. level in groundwater (µg/L)	Theoretical ingestion		% ADI
		µg/d	µg/kg bw/d	
Adult, 60 kg bw, 2 L/d water consumption				
BYH 18636- carboxylic acid	0.660	1.320	0.022	0.0096

As a conclusion, it was not expected that BYH 18636-carboxylic acid would represent a health hazard to the consumers.

### STEP 1: Exclusion of degradation products of no concern

SANCO/221/2000 –rev.11 allows the exclusion of metabolites from consideration if they satisfy certain criteria that would allow the conclusion to be made that they are of no concern. These criteria are as follows:

- it is CO<sub>2</sub> or an inorganic compound, not containing a heavy metal; or,
- it is an organic compound of aliphatic structure, with a chain length of 4 or less, which consists only of C, H, N or O atoms and which has no "alerting structures" such as epoxide, nitrosamine, nitrile or other functional groups of known toxicological concern.
- it is a substance, which is known to be of no toxicological or ecotoxicological concern, and which is naturally occurring at much higher concentrations in the respective compartment.

BYH 18636-carboxylic acid does not meet the criteria for products of no concern as defined in step 1 of the guidance and therefore needs further assessment.

### STEP 2: Quantification of potential groundwater contamination

PEC<sub>gw</sub> calculations for BYH 18636-carboxylic acid were performed (Part B, Section 8, chapter 8.8.2.2). The uses for which concentrations of BYH 18636-carboxylic acid were considered to exceed 0.1µg/L are listed in Table 10.2-1. Details are given in Part B, Section 8, chapter 8.8.2.3. Further assessment is required.

### **STEP 3: Hazard assessment – identification of relevant metabolites**

As predicted concentration of BYH 18636-carboxylic acid exceeds 0.1 µg/l, a hazard assessment is required to demonstrate that the compound:

- has a lower biological activity than the parent,
- is not genotoxic and
- is not defined as toxic.

### **STEP 3, Stage 1: screening for biological activity**

The available data demonstrates that BYH 18636-carboxylic acid does not have comparable or higher biological activity to the parent.

### **STEP 3, Stage 2: screening for genotoxicity**

The available studies show that there is no evidence for BYH 18636-carboxylic acid being of genotoxic concern (EFSA, 2013).

### **STEP 3, Stage 3: screening for toxicity**

The available toxicity studies show that there is no evidence for BYH 18636-carboxylic being of toxicological concern (EFSA, 2013).

A summary of the results of toxicity studies for BYH 18636-carboxylic is included in dRR Part B6 (Table 6.4-1)

### **STEP 4: Exposure assessment – threshold of concern approach**

Consumer health assessment indicated predicted exposure with drinking water as 0.0096 % of ADI.

The potential exposure to BYH 18636-carboxylic is < 0.75 µg/L. No further assessment is required.

## 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
Please refer to dRR B6.					

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	Author	YYYY	Title	Y/N	Owner

<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>
XX			Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished		