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| FINAL REGISTRATION REPORT  Part B  Section 10  Assessment of the relevance of metabolites in  groundwater  Detailed summary of the risk assessment |
| Product code: RBN 012 A  Product name: FLENID  Chemical active substance:  Mesotrione, 100 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: Shandong Weifang Rainbow Chemical Co., Ltd.  Submission date: September 2024  MS Finalisation date: 03/2025; 06/2025 |

Version history

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| --- | --- |
| When | What |
| 03/2025 | ZRMS assessment |
| 06/2025 | The final Registration Report |
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# Relevance of metabolites in groundwater

## General information

No Mesotrione metabolites are predicted to occur in groundwater at concentrations above 0.1 µg/L. Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 is therefore not required.

**The PECGW of the mesotrione metabolite AMBA (2-amino-4-(methylsulfonyl) benzoic acid) was** < 0.1 µg/L in the relevant application patterns (please see dRR Part B, Section 8, chapter 8.8.2 and Table 10.1‑1 below). Therefore, no assessment is required for this metabolite.

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 8.1 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 | |
| --- | --- | --- | --- | --- |
| Mesotrione | MNBA | 4-(methylsulfonyl)-2-nitrobenzoic acid  O=S(C)(=O)c1cc(c(cc1)C(=O)O)N(=O)=O | Max PECgw | Not predicted to occur in ground water. |
| AMBA | 2-amino-4-(methylsulfonyl)benzoic acid  O=S(C)(=O)c1cc(N)c(cc1)C(=O)O | Max PECgw | Not predicted to occur in ground water. |

## Relevance assessment of Mesotrione metabolites

The groundwater Mesotrione metabolites are not considered as relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. Studies supporting PECgw data are evaluated in Section 8 (Environmental fate and behaviour). PECsoil calculations . The modelling results PECgw are acceptable to describe predicted environmental concentrations of mesotrione and its metabolites in groundwater. All input parameters considered in the groundwater modelling for mesotrione and its metabolites were EU agreed values (EFSA Scientific Report (2007) 120, 1-91). I

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

Mesotrione metabolites meet the criteria for products of no concern as defined in step 1 of the guidance and therefore they don’t need further assessment.

### STEP 2: Quantification of potential groundwater contamination

Not relevant, please refer to point 10.1.

PECGW calculations after leaching from soil for MNBA and AMBA were performed (see Part B, Section 8, chapter 8.8.2).

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

Not relevant, please refer to point 10.

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

Not relevant, please refer to point 10.1.

**The biological activity of MNBA has been assessed for non-target plants by Shribbs (1997) and for algae (Smyth et al. 1997b) and Lemna (Liedtke 2013b). Full details are provided in the dRR Part B9.**

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

Not relevant, please refer to point 10.1.

All studies were previously reviewed in accordance with Regulation (EC) No 1107/2009; from these studies it can be concluded that MNBA is not genotoxic in vitro or in vivo. Therefore, MNBA is considered to be irrelevant

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

Not relevant, please refer to point 10.1.

MNBA is of low acute oral toxicity. Following dosing by the gavage route for 28 days there was no evidence of any toxicity. In the 90 day study, a NOAEL of 650 ppm (50.6 mg/kg bw/day) was defined in males based on a small but significantly lower bodyweight compared to controls in the 3000 ppm dose group. The NOAEL for females was 3000 ppm (263.7 mg/kg bw/day), the highest dose tested.

In accordance with the latest review of mesotrione, the Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of mesotrione was established. Adopted 14 September 2018; Annex VI CLP table ATP 15 (in force from 1 March 2022 , that mesotrione is classified Repr.2/H361d and STOT RE 2/H373

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

Not relevant, please refer to point 10.1.

MNBA is not considered to exceed the toxicological threshold of concern as defined in EC guidance document SANCO/221/2000 –rev.10.

### STEP 5: Refined risk assessment

Not relevant, please refer to point 10.1.

No unacceptable risk of groundwater contamination is expected for the formulated product according to the intended uses.(See Part B8

**Comment:**

**Mesotrione**

**The relevance of the groundwater metabolite MNBA has already been assessed and the assessment agreed at EU level (see RAR mesotrione), 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 PECgw calculated for the GAP and groundwater scenarios considered in this dRR ). MNBA is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.**

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 |
| --- | --- | --- | --- | --- | --- |
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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 |
| --- | --- | --- | --- | --- | --- |
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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 |
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1. Additional information

Not relevant.