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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: MEZ-HER 100 SC  Product names: MECORN 100 SC  Chemical active substance:  mesotrione, 100 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant:  Pestila Spółka z ograniczoną odpowiedzialnością  Submission date: October 2023  MS Finalisation date: May 2024, August 2024 |

Version history

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| When | What |
| May 2024 | zRMS assessment of dRR |
| August 2024 | The final Registration Report after 1st commenting period |
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# Relevance of metabolites in groundwater

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| **Comment of ZRMS** | The metabolites of mesotrione contained in the product MEZ-HER 100 SC are predicted to occur in groundwater at concentrations below 0.1 µg/L. Thus the assessment of the relevance of this metabolite according to the stepwise procedure (acc. to SANCO/221/2000 –rev.10) is not required. |

**Introduction**

This is the application for registration of a plant protection product under working name MEZ-HER 100 SC according to Article 33 and Article 34 of Regulation 1107/2009. MEZ-HER 100 SC is a suspension concentrate, containing 100 g/L of mesotrione to be used as an herbicide to protect maize.

The reference product Callisto 100 SC was registered in Poland in 2004 (authorisation no. R-2/2004 of 02.02.2004). Then in 2009 and 2020 the authorisation was renewed with authorisation no R-25/2009 of 27.02.2009 and decision no. R-990/2020d of 29.12.2020, respectively. In accordance with above, the data for protection for the formulation Callisto 100 SC and active substance mesotrione have expired.

In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant do not provide additional data and apply for using unprotected data of Callisto 100 SC.

The classification of the MEZ-HER 100 SC based on data on hazardous substances calculation method under the guidance of Regulation 1272/2008/EC (CLP) as amended, can be found in the confidential dRR Part C.

## General information

The 80th percentiles of the predicted annual average leachate concentrations of mesotrione and its metabolites were below 0,1 µg/L in all calculated scenarios. No further evaluation is required.

## Relevance assessment of metabolite 1

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

Not relevant.

### STEP 2: Quantification of potential groundwater contamination

Not relevant.

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

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not relevant

### STEP 5: Refined risk assessment

Not relevant.

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 |
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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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The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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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.