

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

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Version history

When	What
May 2024	zRMS assessment of dRR
August 2024	The final Registration Report after 1 st commenting period

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10 Relevance of metabolites in groundwater

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.
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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.

10.1 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.

10.2 Relevance assessment of metabolite 1

10.2.1 STEP 1: Exclusion of degradation products of no concern

Not relevant.

10.2.2 STEP 2: Quantification of potential groundwater contamination

Not relevant.

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10.2.3 STEP 3: Hazard assessment – identification of relevant metabolites

10.2.3.1 STEP 3, Stage 1: screening for biological activity

Not relevant.

10.2.3.2 STEP 3, Stage 2: screening for genotoxicity

Not relevant.

10.2.3.3 STEP 3, Stage 3: screening for toxicity

Not relevant.

10.2.4 STEP 4: Exposure assessment – threshold of concern approach

Not relevant

10.2.5 STEP 5: Refined risk assessment

Not relevant.

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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
-	-	-	-	-	-

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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

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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Appendix 2 Additional information

Not relevant.