

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 0**

#### **Product Background, Regulatory Context and GAP information**

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 Sp. z o. o.

Submission date: October 2023

MS Finalisation date: May 2024, August 2024

## Version history

When	What
October 2023	Applicant submission
May 2024	Initial assessment of dRR by the zRMS
August 2024	The final Registration Report after 1 <sup>st</sup> commenting period

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## 0 Product background, regulatory context and GAP information

### 0.1 Introduction

#### 0.1.1 Reason for application

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością.

This is the application for registration plant protection product under product code MEZ-HER 100 SC according to Article 33 of Regulation 1107/2009 based on data for which a 10-year protection period has expired (acc. Art. 34 of Reg. 1107/2009). MEZ-HER 100 SC is a suspension concentrate (SC), containing 100 g/L of mesotrione to be used as herbicide to protect maize.

#### 0.1.2 Details of zRMS(s) and concerned MS

**Table 0.1-1: Overview of zRMS and cMS**

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland	Not relevant

#### 0.1.3 Regulatory history of the active(s)

##### 0.1.3.1 Mesotrione

**Table 0.1-2: Summary of regulatory history of CAS No: 104206-82-8**

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.  Commission Implementing Regulation (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance).
RMS	Belgium (BE)
Date of Approval (or most recent renewal) of Active Substance	01.06.2017 (renewal)

(date of Regulation to be applied)	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Not relevant.
Date of final Commission (re-registration) deadline (Step 2)	Not relevant.
Current expiration of approval	31.05.2032
Low risk substance or Candidate for Substitution?	Not relevant.

Issues that need to be considered as part of the EU approval are listed below.

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on mesotrione, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the protection of operators,
- the protection of groundwater in vulnerable regions,
- the protection of mammals, aquatic and non-target plants.

Conditions of use shall include risk mitigation measures, where appropriate.

The EFSA Review Report for mesotrione available to the public.

**Table 0.1-3: Information on minimum purity of mesotrione**

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity of active substance $\geq 920$ g/kg	minimum purity of active substance- confidential information referred in Part C of dRR Equivalence report available: Y RMS: PT

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\* If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Not relevant.	Not relevant.	Not relevant.

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

#### 0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

## 0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Efficacy section: 1  
Mammalian toxicology: 1  
Residues section: 1  
Environmental fate and behavior section: 1  
Ecotoxicology section: 1

Uses to be considered non-safe on the basis of EU methodology:

Efficacy section: none  
Mammalian toxicology: none  
Residues section: none  
Environmental fate and behavior section: none  
Ecotoxicology section: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS: **none**

Residues section: Use/ GAP is covered by established MRL

Conclusions:

**Physical-chemical section:** no data gaps

**Efficacy section:**

Mecorn 100 SC (product code: MEZ-Her 100 SC (can be granted in Poland in line to accepted GAP table and label project).

**Mammalian toxicology:**

Toxicological properties of the formulation MEZ-HER 100 SC have been defined based on the composition of the product and the results of acute toxicity tests performed using representative formulation, i.e. Callisto 100 SC. Following classification and labelling regarding mammalian toxicology is proposed for the product MEZ-HER 100 SC: Eye Irrit. 2, H319, Repr. 2, H361d.

Exposure:

Operator: The product MEZ-HER 100 SC containing mesotrione (100 g/kg) causes acceptable health risk for unprotected operator. However, taking into account the classification of the product (Eye Irrit. 2, H319, Repr. Cat. 2, H361d) eye/face shield during M&L and protective gloves are mandatory.

Worker: The use of MEZ-HER 100 SC containing mesotrione (100 g/kg) causes acceptable health risk for a worker wearing work wear during 2 hour working day (inspection).

Bystander/resident: The use of MEZ-HER 100 SC according to the list of intended uses and buffer zone presented in GAP Table, cause acceptable health risk for bystander/resident (adult and child).

**Ecotoxicology section:**

Mecorn 100 SC (product code: MEZ-Her 100 SC (can be granted in Poland in line to accepted GAP table and label project).

**Metabolism and residues:**

Use is accepted.

## Appendix 1 ALL intended uses

GAP rev.1, date: 2023-10-01

PPP (product name/code): MEZ-HER 100 SC  
Active substance 1: mesotrione  
Safener: n.a.  
Synergist: n.a.  
Applicant: Pestila Sp. z o.o.  
Zone(s): Central Zone <sup>(d)</sup>  
Verified by MS: no

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 100 g/l <sup>(c)</sup>  
Conc. of safener: n.a. <sup>(c)</sup>  
Conc. of synergist: n.a. <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Poland	Maize	F	<b>1 L/ha susceptible</b> <del>Pigweed <i>Amaranthus</i></del> <del><i>retrofractus</i> AMARU</del> <del>Field chamomile</del> <del><i>Anthemis arvensis</i></del> <del>ANTAR</del> <b>Shepherd's purse</b> <i>Capsella bursa-pastoris</i> CAPBP; <del>Fat hen <i>Chenopodium</i></del> <del><i>album</i> CHEAL</del> <del>Common barnyard grass</del> <del><i>Echinochloa crus-galli</i></del> <del>ECHCG</del>	broadcast spraying	BBCH 14-15 Spring, post emergence	1 a) 1 b) 1	N/A	1 L/ha a) 1 L/ha b) 1 L/ha	100g mesotrione a) 100g mesotrione b) 100g mesotrione	200-300 L/ha	not relevant	not relevant  <b>Efficacy section:</b> List of accepted weed species and their sensitivity was changed.



				<p><b>Cleavers</b> <i>Galium aparine</i> GALAP;  <del><i>Gallant soldier</i> <i>Galinsoga</i></del>  <del><i>perviflora</i> GASPA</del>  <b>Purple deadnettle</b>  <del><i>Lamium purpureum</i></del>  <del>LAMPUR</del>  <del><i>Wild buckwheat</i> <i>Fallopia</i></del>  <del><i>convolvulus</i> POLCO</del>  <b>Common chickweed</b>  <i>Stellaria media</i> STEME;  <b>Fanweed</b> <i>Thlaspi arvense</i> THLAR;  <b>Field pansy</b> <i>Viola arvensis</i> VIOAR</p> <p><b>1L/ha Moderately susceptible</b>  <del><i>Common fumitory</i></del>  <del><i>Fumaria officinalis</i></del>  <del>FUMO</del>  <b>Fat-hen</b> <i>Chenopodium album</i> CHEAL;  <b>Common barnyard grass</b>  <i>Echinochloa crus-galli</i> ECHCG;  <b>Volunteer rape seedlings</b>  BRNN <i>Brassica napus</i></p>									
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<b>Remarks table heading:</b>	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
<b>Remarks columns:</b>	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

