

DRAFT REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: MEZOT 250 SC

Product name(s): MezoT 250 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021

MS Finalisation date: 09/2023

Version history

When	What
01/2021	Submission date
09/2023	ZRM's evaluated dRR submitted by Applicant

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

This dossier has been submitted in order to register new product.

0.1.2 Details of zRMS(s) and concerned MS

Not relevant as the product has not yet been authorised in any zone.

Table 0.1-1: Overview of zRMS and cMS

Not relevant as the product has not yet been authorised.

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: 131860-33-8

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No. 540/2011
RMS	UK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	-
Date of final Commission (re-registration) deadline (Step 2)	-
Current expiration of approval	31.05.2032
Low risk substance or Candidate for Substitution?	N/A

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

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

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

An EFSA Scientific Report (EFSA Journal 2016;14(3):4419) was made available on date 7th March 2016. Final Renewal report for the active substance MESOTRIONE, SANTE/11654/2016, was made available on 23 March 2017.

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 *, **
930 920 g/kg	980 g/kg Equivalence report available: Y RMS: UK (2018, updated: 2020, DE)

* 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.

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
Residues section: 1
Environmental fate and behavior section: 1
Ecotoxicology section: 1 for PL

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

Efficacy section: none
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: none for PL

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:

Metabolism and Residues section: none

Metabolism and Residues section:

Use/ GAP is covered by established MRL.

Conclusions:

Efficacy section:

Registration of Mezot 100 SC in Poland should be possible. Accepted dose is 0,75-1,5l/ha. Accepted weed in Polish label: *Dose 1,5 l/ha*: susceptible: weeds CAPBP, CHEAL, ECHCG, GALAP, GALPA, LAMPU, POLCO, SINAR, STEME, THLAR, VIOAR. *Dose 0,75 l/ha*: susceptible weeds: CHEAL, POLCO, VIOAR; moderately susceptible weeds: ECHCG, THLAR.

Mammalian toxicology:

Classification of MEZOT 100 SC: Eye Dam.1/H318; Repr.2/H361d; STOT RE 2/H373.

The operator, worker, bystander and resident (adult & child) exposure estimations carried out is acceptable.

Metabolism and Residues section:

Data gap: none

Ecotoxicology section:

Use is accepted for PL (Part A containing supplementary information with refinement risk assessment for mammals for Mezot 100 SC was accepted by zRMS). The refinement risk assessment for mammals should be considered by MSs level. Refinement chronic risk to mammals from drinking water from puddles is required. Chronic risk to mammals from drinking water from puddles should be considered by MSs level.

Mezot 100 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone: 20 m no-spray buffer zone (the worst case scenario – R1 stream).

To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land.

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Appendix 1 ALL intended uses

GAP rev. 1, date: 2020-01-28

PPP (product name/code): Mezot 100 SC
Active substance 1: Mesotrione
Applicant: Elvita Sp. z o.o.
Zone(s): Central
Verified by MS: No
Field of use: Herbicide

Formulation type: SC – suspension concentrate
Conc. of as 1: 100 g/l
Professional use:
Non professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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	Anthemis arvensis, Elymus repens, Amaranthus retroflexus, Capsella bursa-pastoris, Chenopodium album, Echinochloa crus-galli, Falconeria, Fumaria officinalis, Galium aparine, Galium palustre, Lamium purpureum, Tripleurospermum inodorum, Fallopia convolvulus, Sinapis arvensis, Solanum nigrum, Stellaria media, Thlaspi arvense, Viola arvensis.	Foliar spraying; small drops	BBCH 12-18	1	-	a) 1,5 b) 1,5	Mesotrione - 150	200-300	-	Herbicide for use with field sprayers

Remarks table heading:	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l	(d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (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.
Remarks columns:	1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 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) 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 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. 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.	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 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 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

*Use is accepted for PL (Part A containing supplementary information with refinement risk assessment for mammals for Mezot 100 SC was accepted by zRMS).