REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: MEZI 100 SC

Product name(s): Rumezo Twist 100 SC,

Malton Twist 100 SC

Chemical active substance(s):

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo sp. zo.o

Submission date: December 2023, October 2024

zRMS Assessment: 24/07/2024

Following commenting period: 21/10/2024

Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document describes the acceptable use conditions required for authorization of MEZI 100 SC (Rumezo Twist 100 SC, Malton Twist 100 SC) containing in Poland (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part A and C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to MEZI 100 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of MEZI 100 SC have been made using endpoints agreed in the EU review of Mesotrione.

This document describes the specific conditions of use and labelling required for the registration of (Rumezo Twist 100 SC, Malton Twist 100 SC) product code MEZI 100 SC.

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.

In addition to the submission of studies as listed in section(s) B0-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009.

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	PL MEZI 100 SC Rumezo Twist 100 SC, Malton Twist 100 SC.	-

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	Reg. (EU) 2017/626
RMS	BE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/10/2003
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/05/2032
Date of final Commission (re-registration) deadline (Step 2)	31/05/2032
Current expiration of approval	31/05/2032
Low risk substance or Candidate for Substitution?	-

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.

The SANCO report for Mesotrione (SANTE/11654/2016 – 23 March 2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 07 March 2016.

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 *, ** **
920 g/kg	Please refer to Part C- confidential information

* 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 (if relevant)

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:

1

Appendix 1 ALL intended uses

GAP rev. , date: 2023-05-26

PPP (product name/code):	MEZI 100 SC	Formulation type:	SC [a, b]
Active substance 1:	mesotrione	Conc. of as 1:	100 g/L[c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	- [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	No		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
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: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Re-marks:** e.g. g safen-er/synerg ist per ha [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli-cations (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	PL	Maize *Zea mays* ZEAMX	F	Mono- and dicotyle-donous weeds	Spray, medium sprayer	BBCH 14-15	a) 1 b) 1	n/a	a) 1.0 L/ha b) 1.0 L/ha	a) 100 g as/ha b) 100 g as/ha	200-300	n/a	-	
2														
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
4														

Minor uses according to Article 51 (zonal uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

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/m³ 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