FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: M-100SC-OR2-C

Product name(s): Juzan Extra 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT/

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 05/2022

MS Finalisation date: January 2023; May 2023

Katarzyna Czaja Elektronicznie podpisany przez Katarzyna Czaja Data: 2023.05.18 17:29:00 +02'00'

Wojciech Dmuchowski Elektronicznie podpisany przez Wojciech Dmuchowski Data: 2023.05.19 11:27:13 +02'00'

Podpisany elektronicznie przez Justyna Wrzosek-Truszkowska 19.05.2023 13:14:27 +02'00'

Anna Ewa Bojanowicz-Bablok Elektronicznie podpisany przez Anna Ewa Bojanowicz-Bablok Data: 2023.05.19 10:09:54 +02'00'

Bożena Wiadrowska Elektronicznie podpisany przez Bożena Wiadrowska Data: 2023.05.19 10:50:37 +02'00'

Barbara Gworek Elektronicznie podpisany przez Barbara Gworek Data: 2023.05.19 13:36:57 +02'00'

Danuta Teresa Maciaszek Elektronicznie podpisany przez Danuta Teresa Maciaszek Data: 2023.05.19 15:07:12 +02'00'

Version history

When	What
May 2022	First submission for the product authorisation
January 2023	ZRMS evaluated dRR
May 2023	The final version of RR after commenting period

Table of Contents

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application under Article 33 of Regulation 1107/2009 submitted by the applicant in May 2022 is for first authorisation of the product JUZAN EXTRA 100 SC (contains mesotrione, 100 g/l) and follows the data requirements of:

- Regulation (EC) No. 283/2013 for the active substance mesotrione and,
- Regulation (EC) No. 284/2013 for the plant protection product JUZAN EXTRA 100 SC.

Details on the sources of technical active substance are provided in PART C.

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)**
Northern zone	No applicable	-
Central zone	Poland	-
Southern zone	No applicable	-
Inter-zonal	No applicable	-

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 104206-82-8 (mesotrione)

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	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
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	31.05.2018 (renewal)

Status	
deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	N/A
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.
Conditions of use shall include risk mitigation measures, where appropriate.

The SANTE report for mesotrione (SANTE/11654/2016 – 23/03/2017) 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 in March 2016 - see "Conclusion on the peer review of the pesticide risk assessment of the active substance mesotrione", EFSA Journal 2016;14(3):4419.

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 *, **
Min. 920 g/kg	Minimum purity: 980 g/kg 1/ Equivalence report available: Y RMS: PL 2/ Equivalence report available: Y RMS: UK 3/ Equivalence report available: Y RMS: UK For details, please refer to Part C

* 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: 1,2

Residues section: 1,2

Environmental fate and behavior section: 1,2

Ecotoxicology section: 1,2 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:
Residues section:none

Residues section:
All uses/ GAPs are covered by established MRLs.

zRMS' main conclusions:

Physical and chemical properties section:
~~2 years stability study is ongoing.~~ No data gaps.

Analytical methods section:
No data gaps.

Efficacy section:
Juzan Extra 100 SC can be granted in Poland for protect maize crops against weeds. Accepted weed classification is presented in B3 and label project. Sugar maize (ZEAMS) and popcorn (ZEAME) maize can be registered according to Article 51 (without any trial).

Mammalian toxicology:
Classification of JUZAN EXTRA 250 EC Repr.2/H361d, ~~STOT RE 2/H373~~ and Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]. The risk for the operator and worker is acceptable using personal protective equipment: work wear (arms, body and legs covered) Mixing/Loading and Application + gloves, and for resident/ bystander if will be 5 meter buffer strip and the table states that residents and bystanders should not enter the treated area.

Metabolism and residues:
Uses are accepted.

Ecotoxicology section:

~~No safe use was concluded following application of Juzan Extra 100 EC at 1.5 L/ha (corresponding to 150 g a.s./ha) for long term risk assessment for mammals and further refinement is required. The high long term drinking water risk for mammals was identified for dose rate 150 g a.s./ha using the K_{oc} value for pH 7.8 (14 L/kg). Applicant should submit additional refinement option.~~

Uses are accepted for PL. However, it is necessary to reduce the dose in GAP to 0.100 kg s.a./ha. (The National Addendum for Poland containing supplementary information with refinement risk assessment for mammals for Juzan Extra 100 EC was submitted by the Applicant).

Juzan Extra 100 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone: 20 m vegetative buffer zone (the worst case scenario – R1 stream – pH 5.1).

To protect non-target plants respect an unsprayed buffer zone of 10 m or 5 m with 50% drift reduction or 1 m with 90% drift reduction to non-agricultural land.

Appendix 1 ALL intended uses

GAP rev. 1, date: 2022-04-14

PPP (product name/code):	JUZAN EXTRA 100 SC/M-100SC-OR2-C	Formulation type:	SC[a, b]
Active substance 1:	Mesotrione , 100 g/l	Conc. of as 1:	100 g/l [c]
Safener:	Full composition in Part C	Conc. of safener:	N/A [c]
Synergist:	Full composition in Part C	Conc. of synergist:	N/A [c]
Applicant:	CIECH Sarzyna S.A.	Professional use:	X
Zone(s):	Central Zone [d]	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	Herbicide		

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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					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	PL*	Maize (ZEAMX)	F	Monotyledonous weeds (TTDMS); Dicotyledonous weeds (TTDSS)	Medium - drop spraying Field sprayers	BBCH 12 - 18	a) 1 b) 1	n.a.	~~a) 1,5 L/ha~~ a) 1,0 L/ha ~~b) 1,5 L/ha~~ b) 1,0 L/ha	~~a) 150 g as/ha~~ a) 100 g as/ha ~~b) 150 g as/ha~~ b) 100 g as/ha	200 / 400	n.a.	Dose range: 0,75 -~~1,5~~ 1.0 l/ha
-	-	-	-	-	-	-	-	-	-	-	-	-	-

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)													
-	-	-	-	-	-	-	-	-	-	-	-	-	-
Minor uses according to Article 51 (zonal uses)													
2	PL*	sugar maize (ZEAMS); Popcorn (ZEAME);	F	Monotyledonous weeds (TTDMS); Dicotyledonous weeds (TTDSS)	spraying	BBCH 12 - 18	a) 1 b) 1	n.a.	~~a) 1,5 L/ha~~ a) 1,0 L/ha ~~b) 1,5 L/ha~~ b) 1,0 L/ha	~~a) 150 g as/ha~~ a) 100 g as/ha ~~b) 150 g as/ha~~ b) 100 g as/ha	200 / 400	n.a.	Dose range: 0,75 -~~1,5~~ 1.0 l/ha
Minor uses according to Article 51 (interzonal uses)													
-	-	-	-	-	-	-	-	-	-	-	-	-	-

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

* Uses are accepted for PL (The National Addendum for Poland containing supplementary information with refinement risk assessment for mammals for Juzan Extra 100 EC was submitted by the Applicant). However, it is necessary to reduce the dose in GAP to 0.100 kg s.a./ha.