FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 4300 A

Product name(s): MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

Update date: June 2020

MS Finalisation date: 04/06/2024

Version history

When	What
February 2020	Dossier sent for evaluation
June 2020	Updated by Applicant
September 2023	zRMS finalised evaluation
November 2023	Updated by Applicant
April 2024	zRMS updated comments following change in GAP
June 2024	Final version prepared by zRMS after the second commenting period

Table of Contents

zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of MIGHTY a suspension concentrate containing 100 g/L of Mesotrione for use as a herbicide in maize.
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 Regula-tion (EC) No. 284/2013.

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)**
Southern zone	Malta MIGHTY MISTER MAC MINE MESOSTAR	Bulgaria, Croatia, France, Greece, Italy, Portugal, Spain, MIGHTY, MISTER, MAC, MINE, MESOSTAR
Central zone	Poland	Poland
Northern zone	-	-

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 Directive 2003/68/EC
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.

Conditions of use shall include risk mitigation measures, where appropriate.
The applicant shall submit confirmatory information as regards:
1. the genotoxic profile of the metabolite AMBA;
2. the potential endocrine disrupting mode of action of the active substance in particular level 2 and 3 tests, currently indicated in the OECD Conceptual framework (OECD 2012) and analysed in the EFSA Scientific opinion on the hazard assessment of endocrine disruptors;
3. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water.
The applicant shall submit to the Commission, the Member States and the Authority the relevant information requested under point 1 by 1 July 2017 and the relevant information requested under point 2 by 31 December 2017. The applicant shall submit to the Commission, the Member States and the Authority the confirmatory information requested under point 3 within a period of two years after a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater be made public by the Commission.

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.

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	~~985~~ 980 g/kg Equivalence report available: Y RMS: United Kingdom

* 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 endpoints used in the evaluation are in line with EU endpoints.

0.1.4 Regulatory history of the product

Not relevant as the product has not been authorised yet.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
~~The two-years storage stability study cannot be accepted without data on concentrations of mesotrione's relevant impurities in the PPP. It has to be done in the post-registration~~. The two-year study allows to accept the shelf life of two years for this PPP.

Based on physicochemical properties the PPP is not classified.

Section 3. Efficacy
The evaluation of the application of Mighty resulted in the decision to grant authorization for use in maize, according to the GAP table.

Section 5. Analytical methods
The analytical methods used for analysing mesotrione and its relevant impurities in the PPP are accepted.

Section 6. Mammalian Toxicology
The hazard identification of SHA 4300A/MIGHTY has been assessed applying the calculation method in accordance with Regulation (EC) No 1272/2008 and results from the studies.

Classification according to Regulation (EC) No 1272/2008: Repr.2, H361d

Additional labelling phrases:

EUH401: To avoid risks to human health an the environment, comply with the instructions for use.

EUH208 Contains 1,2-benzisothiazolin-3-one. May produce an allergic reaction.

Conclusions regarding operator, worker, bystander and resident exposure:

- Considering classification of product operator should wear the personal protective equipment: protective gloves and protective clothing when handling the concentrate (mixing-loading) and during application.
- With regard to the worker exposure assessment it was concluded that no unacceptable risk is anticipated for the worker (wearing work wear) re-entering the treated crop after inspection
- The reference value acutely toxic active substance (RVAAS) for the mesotrione are not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure. No undue risk to residents was found when SHA 4300 A / Mesotrione 10% SC is applied as intended.

Section 7. Metabolism and Residues
GAP proposed for SHA 4300A: foliar spray, 1 application in BBCH 10-14 on maize, max application rate 0.15 kg as/ha.

GAP already evaluated at EU level (SANTE/11654/2016, 23 March 2017): 1 application per crop/season in BBCH 12-18 on maize, max application rate 0.15 kg as/ha.

The Applicant has not submitted any new studies for the purpose of this application. The use pro-posed in the GAP for SHA 4300A is covered by GAP already evaluated at EU level.

The crops under consideration can be grown in rotation. No waiting periods beyond normal agricultural practice are proposed for succeeding crops to be planted.

The risk assessment performed using PRIMo 3.0 and applicable MRLs indicates that the chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.

No additional data/studies are required.

As far as consumer health protection is concerned, the zRMS (PL) agrees with the authorisation of the intended use on maize.

During the commenting stage, the Applicant proposed lowering the application dose from 0.15 kg a.s./ha to 0.10 kg a.s./ha. It was accepted. The assessment covers a more critical scenario.

Section 8. Environmental Fate
In accordance with proposed pattern use, an exposure assessment for the formulation of MIGHTY was submitted and sufficient.

Section 9. Ecotoxicology
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of Mighty in maize poses ~~un~~acceptable risk ~~to mammals~~ only for application rate of 1.0 L product/ha (100 g a.s./ha). For aquatic organisms for R3 (pH 5.1 and pH 6.5) and R4 scenarios the 20 m of no spray buffer and 20 m vegetated filter strip is not sufficed to confirmed safe use. Further consideration is required for NTA.

The risk for other organisms / scenarios is acceptable if applied according to the recommended use pattern.

Section 10. Assessment of the relevance of metabolites in groundwater

The submitted justification was accepted.
Based on PECgw assessment for metabolites concentration in groundwater were below the trigger value of 0.1 µg/L.

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

The safe use is concluded only for application rate of 1.0 L product/ha (100 g a.s./ha)

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

B9 Use No.1:

1. Mammals: no safe use was concluded following application of MIGHTY at 1.5 L/ha (corresponding to 150 g a.s./ha) and further refinement is required. The high long-term and drinking water risk was identified. The safe use is concluded only for application rate of 1.0 L product/ha (100 g a.s./ha). ~~However, in the proposed use pattern of MIGHTY such a dose rate is not included.~~

2. Aquatic organisms: for R4 stream scenario 20 m of no spray buffer and 20 m vegetated filter strip is not sufficed to confirmed safe use.

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:

B9:

1. Aquatic organisms: for R3 stream scenario: A 20 m of no spray buffer and 20 m vegetated filter strip is not sufficed to confirmed safe use for pH 5.1 and pH 6.5; only for pH 7.9 a 10m no spray buffer zone and a 10m vegetative buffer strip are required.
2. non-target arthropods: off-field assessment need to be confirmed by relevant cMS

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 0, date: 2015-September-30th

PPP (product name/code):	MIGHTY / SHA 4300 A	Formulation type:	Suspension concentrate (SC)(a, b)
Active substance 1:	Mesotrione	Conc. of as 1:	100 g/L (c)
Active substance 2:	-	Conc. of as 2:	- (c)
Safener:	-	Conc. of safener:	- (c)
Synergist:	-	Conc. of synergist:	- (c)
Applicant:	Sharda Cropchem España S.L.	Professional use:	☒
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~~	~~CEU~~	~~**Maize**~~	~~F~~	~~Broadleaved and grass weeds~~	~~Foliar Spray~~	~~BBCH 10-14 (*)~~	~~a) 1 b) 1~~	~~N.A~~	~~a) 1.5 b) 1.5~~	~~a) 150 b) 150~~	~~200-600~~	~~-~~	~~(*)Weeds at early stages~~
1	PL	**Maize**	F	Broadleaved and grass weeds	Foliar Spray	BBCH 10-14 (*)	a) 1 b) 1	N.A	a) 1.0 b) 1.0	a) 100 b) 100	200-600	-	(*) Weeds at early stages

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