FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 4307 A

Product name: PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg

Nicosulfuron, 120 g/kg

Mesotrione, 360 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

Update date: 08.2021

MS Finalisation date: 05.2022; 12.2022; 03.2023

Version history

When	What
August 2021	Applicant update
May 2022	zRMS first evaluation
December 2022	ZRMs corrected dRR according to reviewed comments.
March 2023	Updated assessment after the comment period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of PRIMARY MX, a water dispersible granule containing 30 g/kg of Rimsulfuron, 120 g/kg of Nicosulfuron and 360 g/kg of Mesotrione for use as herbicide on maize in Central Europe.

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.

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	-	-
Central zone	Poland	Germany
Southern zone	Malta	Spain Greece
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Rimsulfuron

Table 0.1-2: Summary of regulatory history of CAS No: 122931-48-0

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 06/39/EC Commission Implementing Regulation (EU) No 2021/566
RMS	Original RMS: Germany RMS: Slovenia Co-RMS: Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.02.2007

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.07.2007
Date of final Commission (re-registration) deadline (Step 2)	31.01.2011
Current expiration of approval	30.04.~~2022~~ 2023
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 non-target plants and groundwater in vulnerable situations. Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Rimsulfuron (SANCO/10528/2005 – rev. 2, 27/01/2006) 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 10 August 2005 (EFSA Scientific Report (2005) 45, 1-61).

Table 0.1-3: Information on minimum purity of Rimsulfuron

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 *, **
960 g/kg	Minimum purity of the technical active substance of 980 ~~985~~ g/kg Equivalence report available: Y RMS: UK (2014)

* 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.

0.1.3.2 Nicosulfuron

Table 0.1-4: Summary of regulatory history of CAS No: 111991-09-4

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 2008/40/EC Commission Implementing Regulation (EU) No 2020/1511
RMS	RMS: Latvia Co-RMS: Netherland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2012
Current expiration of approval	31.12.~~2021~~ 2023

Status	
Low risk substance or Candidate for Substitution?	CfS

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 potential exposure of the aquatic environment to metabolite DUDN when Nicosulfuron is applied in regions with vulnerable soil conditions,
- The protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones,
- The protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone,
- The protection of groundwater and surface water under vulnerable soil and climatic conditions,

The SANCO report for Nicosulfuron (SANCO/3780/07 – rev. 1, 22/01/2008) 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 29 November 2007 (EFSA Scientific Report (2007) 120, 1-91.

Table 0.1-5: Information on minimum purity of Nicosulfuron

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~~ 910 g/kg	Minimum purity of the technical active substance of 930 g/kg Equivalence report available: Y RMS: UK (2009)

* 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.

0.1.3.3 Mesotrione

Table 0.1-6: Summary of regulatory history of CAS No: 104206-82-8

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 03/68EC Commission Implementing Regulation (EU) No 2017/725
RMS	RMS: UK Co-RMS: Belgium
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

Status	
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.

The SANTE 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 7 March 2016 (EFSA Journal 2016;14(3):4419.

Table 0.1-7: 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	Minimum purity of the technical active substance of 985g/kg Equivalence report available: Y RMS: UK (2018)

* 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

Phys-chem section:
The evaluation of the application for PRIMARY MX resulted in the decision to grant the authorization.
Shelf life – 2 years. The formulation is stable.
Recommended packaging: HDPE, COEX (HDPE-EVOH) bottles and PE bags are accepted.
No chemical or physical hazards have been identified.

Analytical Methods section
The data gaps listed in the Analytical Methods section must be completed before authorization.

Efficacy section:
Only a very limited number of results is available for each zone. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. The results should be adjusted to known efficacy from long term use of rimsulfuron, nicosulfuron and mesotrione standard products. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Toxicology section:
PRIMARY MX is classified:Repr.2/H361d; STOT RE 2/H373 (eye, nervous system) and **Contains formaldehyde. May produce an allergic reaction [EUH208]**
Contains 2-(Aminosulfonyl)-N,N-dimethyl-3-pyridinecarboxamide. May produce an allergic reac-

tion [EUH208] Esti-mates of operator, employee, residents and bystander exposure have shown that the acceptable operator exposure level (AOEL) is acceptable under the conditions of intended use and in accordance with 5 m buffer zone for resident and bystanders

Metabolism and Residues section:
Use is accepted

Fate and behaviour section:
In accordance with proposed pattern use, an exposure assessment for the formulation of PRIMARY MX was accepted zRMS. No unacceptable risks is expected for groundwater.

zRMS to insert overall summary of the assessment focusing on the main conclusions only, including a grouping of safe uses, non-safe uses and uses for which the safety could only be established following additional risk mitigation at a national (non-core) level or the safety is to be confirmed by cMS.

Ecotoxicology section:

Birds and mammals:

No unacceptable acute and long-term risks are expected for birds. According to results, no unac-ceptable acute and long-term risk due to combined exposure are obtained according to the proposed GAP.

After screening and first-tier assessment for mammals for active substance Mesotrione, the TERA value is greater than the Annex VI trigger of 10 whereas TERLT values are lower than the Annex VI trigger of 5 for the use on maize, indicating that PRIMARY MX presents an unacceptable long-term risk to mammals. A refinement of the risk was done by selecting the two focal species European brown hare and wood mouse, using a PT value of 0.62 and 0.139 respectively and other refined parameters (PD and TWA) and indicating an acceptable risk for mammals.

There is no unacceptable risk for drinking water exposures and secondary poisoning.

Aquatic organisms:

Rimsulfuron:

All PEC/RAC values for Rimsulfuron and its metabolite are below the trigger value of 1 at step 3, indicating that Rimsulfuron poses a low risk to aquatic organisms, as well as for IN-70941, IN-70942 and IN-E9260 metabolite.

Nicosulfuron:

For fish, aquatic invertebrates and algae acceptable acute and chronic risk for a.s.- nicosulfuron and its metabolites could be concluded already for Step 1 PECsw values.

For aquatic macrophytes – Lemna sp. two approaches in the risk assessment for the a.s.- nicosulfuron were considered by the Applicant:

- PEC/RAC calculated on the basis of the lowest EyC50 with 1.7 µg a.s./L
- PEC/RAC calculated on the basis on RAC≤ 0.74 µg s.a/L

At the zonal level the standard approach in line with EFSA AGD (2013) is required.

When the risk assessment is based on EyC_{50} value, unacceptable risk is identified for D3, R1 (stream), R (stream), R4 (stream) and R3 (stream) scenarios.

FOCUS Step 4 modelling PECsw value assuming a 5 meter no spray buffer zone for the remaining surface water resulted in an acceptable PEC/RAC values for D3 (ditch) scenario.

In addition, a 10 meter no spray buffer zone including 10 m vegetative buffer strip, resulted in an acceptable PEC/RAC values for the remaining surface water scenario R1 stream.

However, unacceptable PEC/RAC values were obtained for R2, R3 and R4 stream scenarios even with a

20 meter no spray buffer zone including 20 m vegetative buffer strip. However, as consideration of EyC_{50} value is not in line with the recommendations of EFSA (2013), further evaluation was not performed at the zonal level and is deemed necessary in concerned Member States that prefer to use this approach in the aquatic risk assessment.

For this reason PEC/RAC calculations based on ErC_{50} of 2.7 µg s.a/L (RAC-0.27 µg s.a/L) for aquatic macrophytes, agreed at EU level was provided.

It should be noted that zRMS did not accept the risk assessment based on RAC of 0.74 µg s.a./L value proposed by the applicant.

In zRMS's opinion this value is not appropriate to replace the agreed ErC_{50} of 2.7 µg s.a./L value included in the LoEP for nicosulfuron.

On the basis of the standard risk assessment performed in line with EFSA aquatic guidance (2013) and RAC=0.27 µg s.a./L following conclusions could be derived:

- Acceptable risk to aquatic macrophytes with no need for risk mitigation measures based on Step 3 calculations was demonstrated in scenarios D3, D4, D5, D6, R1 (pond).
- Acceptable risk to aquatic macrophytes with consideration of 5 m vegetative filter strip was demonstrated in scenarios R1 stream scenario and 20 m vegetative filter strip for R2 scenarios.

An unacceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R3 and R4.

As R3 and R4 scenarios showed an unacceptable risk, an alternative approach was followed using VFSMOD Global maximum PECsw values.

Hence, based on the results of the risk assessment using PECsw VFSmod calculations, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

R1 stream, R2 stream, R3 stream and R4 stream scenarios:

- 5 m no-spray buffer zone and a 5 m vegetative buffer strip are required

The PECsw VFSmod calculations should be decided at MSs level.

For ASDM, AUSN, HMUD, ADMP and UCSN metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

Mesotrione:

For the intended uses on maize, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC50 for Lemna gibba of 7.7 in connection with an assessment factor of 10) in several FOCUS Steps 1 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PECSW considering reduced exposure of surface water bodies. Based on the results of the risk assessment at step 4, the following conclusions regarding buffer zones and vegetative buffer strips may be drawn for maize use:

-R2 stream (pH 5.1) 5m no spray buffer zone and a 5m vegetative buffer strip are required.

For MNBA, AMBA and SYN546974 metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

PRIMARY MX

For the endpoints from formulated product PRIMARY MX, any spray buffer zone with 50% of nozzles reduction OR a 5 m no spray buffer zone are enough for acceptable risk. In addition, for the combined exposure the risk is considered acceptable with an unsprayed vegetated buffer zone of 5 m.

Conclusion for Aquatic organism:

Maize – SPe 3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies.

The final risk mitigation measures to aquatic organism should be decided at MSs level.

Bees

First-tier assessments indicate that no unacceptable risk for adult bees exposed to PRIMARY MX is expected. According to EU Reg 284/2013 the chronic tests for adult and larvae bees formulation ~~should be~~ was provided by the applicant. Further consideration of theses studies should be at MSs level.

NTA

The results of the risk assessment for non-target arthropods showed an acceptable in - field and off-field risk after the application of PRIMARY MX.

Soil organisms

The TER values for earthworms and other soil macro- and mesofauna for PRIMARY MX were above the relevant Annex VI trigger of 5. Therefore, it is concluded that active substance Rimsulfuron, Nicosulfuron and Mesotrione do not pose chronic risk to earthworms and other soil macro- and mesofauna. In addition , for microorganism the risk was considered acceptable.

NTP

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for PRIMARY MX shows that the Annex VI trigger value of 5 is exceeded when following risk mitigation measures are applied:

Maize – SPe3: To protect non-target plants respect 90% drift reducing nozzles OR an unsprayed buffer zone of 3m with 50% drift reducing nozzles OR an unsprayed buffer zone of 10m to non-agricultural land.

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

Insert relevant use number from GAP table in Appendix 1.

Section 3, 7, 8, 9: 1

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

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

Section 3, 7, 8, 9: 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:

Section Ecotoxicology: The risk mitigation measures for aquatic organism and non - target plants should be considered at national level.

~~All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).~~

Use/ GAP is covered by established MRLs

Appendix 1 ALL intended uses

GAP rev. 0, date: 2016-November-28th

PPP (product name/code):	PRIMARY MX / SHA 4307 A	Formulation type:	WG (Water dispersible granules)
Active substance 1:	rimsulfuron	Conc. of as 1:	30 g/kg
Active substance 2:	nicosulfuron	Conc. of as 2:	120 g/kg
Active substance 3:	mesotrione	Conc. of as 3:	360 g/kg
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	SHARDA Cropchem España	Professional use:	☒
Zone(s):	central	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 12-18	a) 1 b) 1	NA	a) 0.25 b) 0.25	a) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione b) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione	200-400	-	**Efficacy section:** In DE only use against TTTMS and TTTDS can be accepted.
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