FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 0724 A

Product name: COREY

Chemical active substances:

Rimsulfuron, 150 g/kg

Nicosulfuron, 300 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

MS Finalisation date: 12.2020, 07.2021, 01.2022

Version history

When	What
December 2020	RMS Assessment
July 2021	Final RMS Assessment
January 2022	Final RMS Assessment 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 is submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of COREY, a water dispersible granule containing 150 g/kg of Rimsulfuron and 300 g/kg of Nicosulfuron 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 2019/168
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.
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 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 2019/1589
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	31.12.2022

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 *, **
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.

0.1.4 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 behaviour section: 1
Ecotoxicology section: 1

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

Efficacy section: none
Residues section: none
Environmental fate and behaviour section: none
Ecotoxicology section: 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.

The following text is to be shortened or to be amended as necessary.
Residues section:
Uses/ GAPs are covered by established MRLs

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

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

Efficacy section:
cMS from S-E should decide if limited number of efficacy and lack of selectivity trials is acceptable. The sufficiency of results should be considered on the national level based on importance of weed in their country. Final assessment of the resistance risk should be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States. Detailed information's are presented in dRR B3.

Mammalian toxicology section:
COREY is not classified. Not risk for operator, worker and bystander / resident (child & adult) is acceptable under the conditions of the intended use of COREY

Residues section:
Use is accepted.
Noticed data gaps are:
- none

Fate and behaviour:
In accordance with proposed pattern use, an exposure assessment for the formulation of Corey was accepted.

Ecotoxicology Section:
No unacceptable acute and long-term risks are expected for bird and mammals

Final conclusion on risk assessment for aquatic organism:
Rimsulfuron:

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

For aquatic macrophytes acceptable risk for a.s.- rimsulfuron could be concluded for STEP 3 for all sce-

narios except R3 and R4, and for its metabolites for STEP 1-2.

Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. Taking into account **5 meter vegetative buffer for R2 and R3 scenarios the risk is considered acceptable.**

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 PEC_{sw} values.

Based on RAC of 0.27 microgram/L for Lemna gibba:

- 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 vegetated filter strip was demonstrated in scenarios R1 stream scenario
- Acceptable risk to aquatic macrophytes with consideration of 20 m vegetated filter strip was demonstrated in scenarios R2 stream scenario

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

Based on the results of updated refinement risk assessment for nicosulfuron provided by the applicant 2021 the acceptable PEC/RAC values were obtained for R1, R2, R3 and R4 stream scenarios **with a 5 meter no spray buffer zone including 5 m vegetative buffer strip when VFSMOD is considered.**

COREY

For the endpoints from formulated product COREY, 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 10 m.

Conclusion

Maize – SPe 3: *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies.*

The final risk mitigation measures for aquatic organism should be considered at MSs level.

~~The proposed refined endpoint for nicosulfuron RAC of 0.74 µg/L has not been accepted by zRMS. Therefore, further refinement is required for these scenarios.~~

~~Further refinement is also required for mixture toxicity risk assessment for all streams scenarios at national level.~~

First-tier assessments indicate that no unacceptable risk for bees exposed to COREY is expected according to the proposed intended uses. According to Reg. 284/2009 chronic adult toxicity and chronic larva test should be provided. However, final decision should be made at MSs level based on all available data.

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

The TER values for earthworms and other soil macro- and mesofauna for were above the relevant Annex VI trigger of 5.

Risk mitigation measures for NTP are needed. When there is 75% nozzle reduction OR 5m buffer zone, COREY poses a low risk to non-target plants when applied according to the proposed use rates.

Maize – SPe 3: *To protect non-target plants use 75% drift reducing nozzles OR respect an unsprayed buffer zone of 5m to non-agricultural land.*

Appendix 1 ALL intended uses

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

PPP (product name/code):	Rimsulfuron 15% +Nicosulfuron 30% WG	Formulation type:	WG (Water dispersible granules)
Active substance 1:	rimsulfuron	Conc. of as 1:	150 g/kg
Active substance 2:	nicosulfuron	Conc. of as 2:	300 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		

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) 0.1 b) 0.1	a) 0.015 rimsulfuron + 0.03 nicosulfuron b) 0.015 rimsulfuron + 0.03 nicosulfuron	200-400	-	
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