# FINAL REGISTRATION REPORT

## Part A

## Risk Management

**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**

**NATIONAL ASSESSMENT Poland**

**(authorization)**

**Applicant: Sharda Cropchem España S.L.**

**Submission date: February 2020**

**MS Finalisation date: 12.2020, 07.2021, 01.2022 05.2022**

# Version history

| When | What |
|---|---|
| December 2020 | RMS Assessment |
| July 2021 | Final RMS Assessment |
| January 2022 | ZRMs corrected dRR according to reviewed comments from cMS. |
| May 2022 | ZRMs corrected label according to reviewed comments from MRiRW |

# Table of Contents

# PART A
# RISK MANAGEMENT

## 1 Details of the application

### 1.1 Application background

This application was submitted by SHARDA CROPCHEM ESPAÑA S.L.

This application is for approval of Rimsulfuron 15% + Nicosulfuron 30% WG, a Water dispersible Granules containing 150 g/kg of Rimsulfuron and 300 g/kg of Nicosulfuron, as an herbicide on maize.

zRMS: Poland

### 1.2 Letters of Access

Not applicable. Letter of access not needed.

### 1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation Rimsulfuron 15% + Nicosulfuron 30% WG as required by the EU regulations.

### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

## 2 Details of the authorization decision

### 2.1 Product identity

| | |
|---|---|
| Product code | SHA 0724 A |
| Product name in MS | COREY |
| Authorization number | First authorisation |
| Function | Herbicide |
| Applicant | SHARDA Cropchem España S.L. |
| Active substance(s)<br>(incl. content) | Rimsulfuron, 150 g/kg<br>Nicosulfuron, 300 g/kg |

| | |
|---|---|
| Formulation type | Water dispersible Granules [Code: WG] |
| Packaging | HDPE bottles;<br>100 mL, 200 mL, 500 mL, 750 mL,<br>1L, 2L, 5L<br><br>COEX (HDPE –EVOH )bottles;<br>1L, 5L<br><br>PE bags;<br>50 g, 100 g, 200 g, 250 g, 500 g, 750 g,<br>1 kg, 5 kg, 10 kg, 20 kg, 25 kg<br><br>professional user |
| Coformulants of concern for national authorizations | - |
| Restrictions related to identiy | - |
| Mandatory tank mixtures | - |
| Recommended tank mixtures | - |

## 2.2 Conclusion

**The evaluation of the application for Rimsulfuron 15% + Nicosulfuron 30% WG resulted in the decision to grant the authorization.**

## 2.3 Substances of concern for national monitoring

Not relevant.

## 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

| | |
|---|---|
| Hazard class(es), categories: | Aquatic Acute 1,<br>Aquatic Chronic 1 |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

| | |
|---|---|
| Hazard pictograms: | **GHS09** |
| Signal word: | **Warning** |
| Hazard statement(s): | **H400, H410** |
| Precautionary statement(s): | **P273, P391, P501** |
| Additional labelling phrases: | **To avoid risks to man and the environment, comply with the instructions for use. [EUH401]** |
| | - |

| | |
|---|---|
| | - |

| | |
|---|---|
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: | |
| - | - |
| - | - |

**See Part C for justifications of the classification and labelling proposals.**

### 2.4.2 Standard phrases under Regulation (EU) No 547/2011

| | |
|---|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | *To protect aquatic organism:*<br>• **Maize:** To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies ~~with 50 % drift reduction nozzles.~~<br>**Maize:** To protect non-target plants use 75% drift reducing nozzles OR respect an un-sprayed buffer zone of 5m to non-agricultural land. |

### 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

| | |
|---|---|
| | |

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

| | |
|---|---|
| Operator protection: | |
| - | Without RPE/PPE |
| Worker protection: | |
| - | Work wear (arms, body and legs covered) |
| Integrated pest management (IPM)/sustainable use: | |
| - | - |
| Environmental protection | |
| SPe3 | *To protect aquatic organism:*<br>**Maize:** To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10 m to surface water bodies with ~~50 % drift reduction nozzles~~<br>**Maize:** To protect non-target plants use 75% drift reducing nozzles OR respect an unsprayed buffer zone of 5m to non-agricultural land. |
| Other specific restrictions | |

| | |
|---|---|
| - | - |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

| Integrated pest management (IPM)/sustainable use: | |
|---|---|
| - | - |

### 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
|---|---|---|
| - | - | - |
| Environmental protection: | | Relevant for use no. |
| - | - | - |

## 2.6 Intended uses (only NATIONAL GAP)

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

| | | | |
|---|---|---|---|
| PPP (product name/code): | COREY / SHA 0724 A | Formulation type: | WG (Water disperible granules) [a, b] |
| Active substance 1: | rimsulfuron | Conc. of as 1: | 150 g/kg [c] |
| Active substance 2: | nicosufluron | Conc. of as 2: | 300 g/kg [c] |
| Active substance….: | - | Conc. of as ….: | - [c] |
| Safener: | - | Conc. of safener: | - [c] |
| Synergist: | - | Conc. of synergist: | - [c] |
| 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**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>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<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>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<br>b) 1 | NA | a) 0.1<br>b) 0.1 | a) 0.015 rimsulfuron + 0.03 nicosulfuron<br>b) 0.015 rimsulfuron + 0.03 nicosulfuron | 200-400 | - | |
| 2 | | | | | | | | | | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Use-No.** [e] | **Member state(s)** | **Crop and/ or situation**<br><br>**(crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled**<br><br>(additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**<br><br>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<br><br>a) max. rate per appl. b) max. total rate per crop/season | Water L/ha<br><br>min / max | | |
| **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

# 3 Background of authorization decision and risk management

## 3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is mixture of gray and beige granules of characteristic odour. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of > 400 °C. In aqueous solution, it has a pH value around 5.70 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed.

Active substances content and stability of packaging PP bucket were tested in 2 years at ambient temperature. The active ingredient content and all physical and chemical properties remained stable and acceptable after the tests.
Its technical characteristics are acceptable for a water dispersible granules formulation.

The intended concentration of use is 0.00025% to 0.0005% of PPP.

## 3.2 Efficacy (Part B, Section 3)

Rimsulfuron 15% + Nicosulfuron 30% WG is a Water dispersible granules (WG) formulation containing 150 grams per kilogram (g/kg) rimsulfuron and 300 g/kg nicosulfuron for use in maize.

In compliance with the GAP the following dose rates are applied for registration:

- One application in maize at BBCH 12-18 for control of broadleaved and grass weeds with dose of 0.1 kg/ha

This document serves the registration of Rimsulfuron 15% + Nicosulfuron 30% WG in the Central zone of the EU. The objective of this biological assessment dossier is to prove and support the label claims of the efficacy and crop safety of Rimsulfuron 15% + Nicosulfuron 30% WG in maize.

Comprehensive field trials were conducted in Spain, Italy, France, Germany, Czech Republic, England, Hungary and Poland in 2016, 2017 and 2019. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the control and safety to the crop of Rimsulfuron 15% + Nicosulfuron 30% WG is equivalent to that of the reference products to which it was compared. Furthermore, the efficacy data also demonstrated that Rimsulfuron 15% + Nicosulfuron 30% WG is equivalent, but still as selective to the GAP claimed crops as the different national reference products to which the test product was also compared. The applicant therefore wishes to cite the data on standards now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal evaluators extrapolate from those data.

## 3.3 Efficacy data

**Preliminary tests**

The activity of rimsulfuron and nicosulfuron is well known, as both actives have been marketed since the beginning of the 1990's. Rimsulfuron is registered as straight product (e.g. Titus 25 WG) as well as in mixtures (mainly with nicosulfuron (e.g. Titus Duo and Principal), but also dicamba, mesotrione, ter-

buthylazine, a.o.). Nicosulfuron is also registered as straight product (e.g. Milagro) as well as in mixtures (mainly with mesotrione (e.g. Elumis), but also rimsulfuron, dicamba, sulcotrione, terbuthylazine, a.o.).

To demonstrate the benefits of the mixture and that the co-formulation does not compromise the effectiveness obtained with e.g. rimsulfuron applied alone, a rimsulfuron 250 g/kg WG straight formulation – Rim 25% WG – currently registered by Sharda in e.g. Czech Republic and Poland, has been included to demonstrate the benefit of the mixture. The results obtained on grasses and broadleaved weeds in 15 efficacy trials, treated early post-emergence in maize are presented below, to justify the mixture.

When applied to the grasses and broadleaved weeds present in the trials, Rimsulfuron 15% + Nicosulfuron 30% WG at comparable dose rates gave a more consistent and occasionally a higher level of weed control compared to that of rimsulfuron alone. It is therefore considered demonstrated that the co-formulation of rimsulfuron and nicosulfuron has its justification when controlling grasses and broadleaved weeds in maize.

Combining two actives in Rimsulfuron 15% + Nicosulfuron 30% WG, which are commonly tank-mixed, also has the benefit of reducing the number of products handled by the spray operator as well as an important tool in resistance management.

**Minimum effective dose tests**

Rimsulfuron 15% + Nicosulfuron 30% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Rimsulfuron 15% + Nicosulfuron 30% WG applied at 0.050 kg/ha, 0.075 kg/ha and 0.10 kg/ha was evaluated in 31 maize trials for the control of the mono- and dicotyledonous weeds present in the trials. The dose rates tested reflects 50%, 75% and 100% of the recommended rate of Rimsulfuron 15% + Nicosulfuron 30% WG, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Mediterranean EPPO zone (6, i.e. Spain (2), Italy (2) and S-France (2)), the Maritime EPPO zone (9, i.e. Czech Republic (3), N-France (2), Germany (2) and UK (2)) and the North-east EPPO zone (16, i.e. Poland).

Rimsulfuron 15% + Nicosulfuron 30% WG applied early post-emergence at 0.10 kg/ha to control grasses and broadleaved weeds achieved good to excellent control of all target weeds. Reducing the application rate of Rimsulfuron 15% + Nicosulfuron 30% WG from the proposed dose rate (0.10 kg/ha) to 50% or 75% of that rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rate of 0.10 kg/ha, it is recommended that Rimsulfuron 15% + Nicosulfuron 30% WG is applied under optimal conditions, i.e. early growth stage of the weeds and optimal weather conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards rimsulfuron and/or nicosulfuron, one application of Rimsulfuron 15% + Nicosulfuron 30% WG at the recommended rate should be used to efficiently control all weeds claimed on the label.

As will be demonstrated in the following sections, this document clearly demonstrates that the efficacy and crop safety of Rimsulfuron 15% + Nicosulfuron 30% WG is equivalent to that of the standard co-formulations containing rimsulfuron and/or nicosulfuron to which it was compared.

**Efficacy tests and conclusions regarding authorization of intended uses**

EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

The applicant was notified that according to PP 1/226 at least 6 trials from each climatic zone are required (in case of reduced number of trials in major pest on major crop). Number of trials for efficacy and selec-

tivity from South-east zone is insufficient, according to EPPO rules. **cMS from S-E should decide if limited number of efficacy and lack of selectivity trials is acceptable.**

Applicant submitted in total 33 efficacy trials carried out in three different growing seasons (2016, 2017 and 2019), which is in line with appropriate EPPO standards:

- Maritime EPPO zone: 9 trials (FR-2, DE-2, CZ-3, UK-2)
- MED EPPO zone: 6 trials (ES-2, IT-2, FR-2)
- S-E: 2 trials (HU)
- N-E EPPO zone: 16 trials (PL)

However, only in N-E EPPO zone three growing seasons was studied, whilst in Maritime, S-E and MED EPPO zone – only one growing season (2016) was studied. cMS from S-E, MED and Maritime should decide if only one growing season is acceptable. In the opinion of ZRMs it should be accepted.

**Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.**

Number of results for particular weed is very limited. Only trials with greater than 5 weeds/$m^2$ or over 2% ground cover should be taken for assessment.

Below we present a list of weed species for each zone separately for which at least two studies have been submitted:

- **MED EPPO zone:**

CYPRO, DIGSA, ABUTH, AMARE, DATST, EPHCH, GASPA, MERAN, POLAV, POROL and SONSS should be excluded, due to not enough trials (only 1 for each weed was presented) in the opinion of Evaluator.

cMS should consider registration the following weed species. For each at least 2 valid trials were presented:

ECHCG – 3 trials, SETVI – 2 trials, CHEAL – 4 trials, POLCO – 2 trials, SOLNI – 4 trials and TTTT – 2 trials.

- **Maritime EPPO zone:**

AGREE, ALOMY, SETPU, BRSNW, CAPBP, FUMOF, GAETE, GALAP, HELAN, LAMPU, POLLA, POLPE, SPRAR and STEME should be excluded, due to not enough trials, due to not enough trials (only 1 for each weed was presented) in the opinion of Evaluator.

cMS should consider registration the following weed species. For each at least 2 valid trials were presented:

ECHCG – 5 trials, CHEAL – 7 trials, POLCO – 5 trials, LOLMU – 2 trials, POAAN – 2 trials, MATIN – 3 trials, THLAR – 3 trials, TTTT- 2 trials, VERPE-3 trials, VIOAR – 2 trials.

- **S-E EPPO zone:**

CHEAL, DATST, MERAN should be excluded due to not enough trials (only 1 for each weed was presented) in the opinion of Evaluator.

cMS should consider registration the following weed species. For each at least 2 valid trials were presented:

ECHCG – 2 trials, PANMI – 2 trials and AMARE – 2 trials.

- **N-E EPPO zone:**

ALOMY, BRSNW, CHEPO, CIRAR, EPHHE, GALAP, GASPA, MATMA, SONAR, VERPE and VICCR should be excluded due to not enough trials (only 1 for each weed species was presented) in the opinion of Evaluator.

cMS should consider registration the following weed species. For each at least 2 valid trials were presented:

AGREE – 4 trials, ECHCG – 12 trials, AMARE – 7 trials, CHEAL – 11 trials, POLCO – 6 trials, POLPE -4 trials, STEME – 6 trials, VIOAR – 7 trials, CAPBP – 7 trials, APESV – 2 trials, POAAN – 2 trials,

SETVI – 2 trials, ARTVU – 2 trials, GERPU – 2 trials, LAMPU – 2 trials, MATIN – 3 trials, PLAME – 2 trials, SINAR – 2 trials, SOLNI – 2 trials and VERAG – 2 trials.

In generally, 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. Therefore, based on knowledge of major/minor status of weeds in each country, weeds with insufficient results should be excluded. Considering comparable results in all zones, it is recommended to take into account results from all zones to get more reliable set of data. The results should be adjusted to known efficacy from long term use of rimsulfuron and nicosulfuron standard products by cMS. Therefore, **the sufficiency of results should be considered on the national level based on importance of weed in their country.**

Applicant presented sensitivity of studied weeds according to SANCO scale. cMS should decide if SANCO is acceptable. If not, cMS should determine the sensitivity of the accepted weed species in accordance with their applicable internal regulations.

The applicant wishes to cite the original registrant's data on rimsulfuron and nicosulfuron now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar rimsulfuron and nicosulfuron products. The spectrum of weeds should be checked with label claims on these reference products.

**SUMMARY:** COREY (product code: SHA 0724 A) is an early post-emergence herbicide in maize (BBCH 12-18) to control weeds. Weeds should be classified on the national level.

Crop: maize
Growth stage of the crop: BBCH 12-18
Product dose rate: 0.1 kg/ha 1x per crop
Water: 200-400 L/ha

**ASSESSMENT FOR POLAND:**

For Poland we can consider also results from neighbouring countries (ex. DE, CZ). Number of trials for maize is acceptable, according to EPPO rules (16 trials carried out in PL during three growing seasons-2016, 2017 and 2019) and 5 trials from neighbouring countries (DE-2, CZ-3) performed in one growing season -2016.

Accepted weed species should be presented to following scale of sensitivity: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations.

The level (>5%) of weed infestation in all studies was sufficient. Only trials with greater than 5 weeds/m2 or over 2% ground cover have been included.

LOLMU (CZ), SETPU (CZ), FUMOF (CZ), GAETE (CZ), HELAN (CZ), POLLA (CZ), SPRAR (CZ), ALOMY (PL), CHEPO (PL), CIRAR (PL), EPHHE (PL), GASPA (PL), MATMA (PL), SONAR (PL) and VICCR (PL) should be excluded from Polish label due to not enough trials (only 1 trial was presented for each weed).

**<u>Following weed species can be accepted in Polish label:</u>**

- AGREE – 5 trials (PL-4, CZ-1) – MT
- ECHCG – 14 trials (PL-12, CZ-3, DE-1) – MS
- CAPBP – 8 trials (PL-7, DE-1) – S
- CHEAL – 16 trials (PL-11, CZ-3, DE-2) – T
- LAMPU – 3 trials (PL-2, CZ-1) – S

- MATIN – 5 trials (PL-3, CZ-2) – S
- POLCO – 10 trials (PL-6, CZ-3, DE-1) – MS
- STEME – 7 trials (PL-6, DE-1) – S
- THLAR – 3 trials (CZ-1) – S
- VERPE – 2 trials (PL-1, CZ-1) – S
- VIOAR – 9 trials (PL-7, DE-1, CZ-1) – MS
- APESV – 2 trials (PL) – S
- POAAN – 2 trials (PL) – S
- SETVI – 2 trials (PL) – MS
- AMARE – 7 trials (PL) – MS
- PLAME – 2 trials (PL) –S
- POLPE – 4 trials (PL) – MT
- VERAG – 2 trials (PL) – T

Also, from Polish label following weed should be excluded:

- BRSNW – 2 trials (DE, PL) – in the opinion of Evaluator this weed should be excluded due to limited number of trials (at least 4 are required). It is a fast-growing weed with great competitive potential.
- GALAP – 2 trials (CZ-1, PL-1) – highly competitive weed – in the opinion of Evaluator this weed should be excluded from label due to limited number of trials, at least 4 are required.
- ARTVU – 2 trials (PL) - competitive due to the height, at least 4 trials are required. It should be excluded from label project due to not enough trials.
- GERPU – 2 trials (PL) - dangerous during the mass occurrence of corn emergence, up to three generations during the vegetation period. In the opinion of evaluator, at least 4 trials are required. It should be excluded from label.
- SINAR – 2 trials (PL) - fast-growing weed, with highly competitive potential. In the opinion of Evaluator, it should be excluded from label due to not enough trials (at least 4 are required).
- SOLNI – 2 trials (PL) - competitive until the end of maize vegetation. In the opinion of Evaluator, it should be excluded from label due to not enough trials (at least 4 are required).

**SUMMARY:** COREY (product code: SHA 0724 A) is an early post-emergence herbicide in maize (BBCH 12-18) to control weeds:

Crop: maize
Growth stage of the crop: BBCH 12-18
Product dose rate: 0.1 kg/ha 1x per crop
Water: 200-400 L/ha

**In the opinion of Evaluator, this scale of sensitivity weeds can be accepted in Polish label:**

- **S (susceptible weeds . 85%):**

CAPBP, LAMPU, MATIN, STEME, THLAR, VERPE, APESV, POAAN, PLAME.

- **MS (moderately susceptible weeds 70-85%):**

ECHCG, POLCO, VIOAR, SETVI, AMARE.

- **MT (moderately tolerant weeds 70-60%):**

AGREE, POLPE.

- **T (tolerant weeds < 60%:**

CHEAL, VERAG.

### 3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Resistance is a natural phenomenon embodied in the process of the evolution of biological systems and has been experienced over and over again in the past. According to Heap (2019[1]) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015[2]), the classification of the Herbicide Resistance Action Committee (HRAC)[3] and the international Survey of Herbicide Resistant Weeds (Heap, 2019).

COREY (product code: SHA 0724 A) contains rimsulfuron and nicosulfuron, both sulfonylurea herbicides whose activity is based on the inhibition of the acetolactate synthase enzyme (ALS) (HRAC Group ~~B~~ 2).

COREY is a post-emergence herbicide for the control of weeds in maize with two different active substances and one mode of action.

Due to a ~~medium to~~ high resistance risk, the restriction of COREY (The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.) is required.

The following table shows the current worldwide resistance weeds according to http://www.weedscience.org:

**Reported cases of resistance to rimsulfuron**

| # | Year | Species | Country | MOAs | Actives | Situations |
|---|---|---|---|---|---|---|
| **1** | 2017 | *Poa annua* | Australia (New South Wales ) | ALS inhibitors (B/2) | bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Golf courses |
| **2** | 2017 | *Poa annua* | Australia (New South Wales ) | ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), Microtubule inhibitors (K1/3), Photosystem II inhibitors (C1/5), Unknown (Z/27) | endothall, bispyribac-sodium, rimsulfuron, simazine, glyphosate, propyzamide = pronamide, iodosulfuron-methyl-sodium, foramsulfuron | Golf courses |
| **3** | 2017 | *Poa annua* | Australia (South Australia) | ALS inhibitors (B/2) | bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Golf courses |
| **4** | 2017 | *Poa annua* | Australia (Victoria) | ALS inhibitors (B/2) | bispyribac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Golf courses |
| **5** | 1994 | *Avena fatua* | Canada (Manitoba) | ACCase inhibitors (A/1), ALS inhibitors (B/2), Antimicrotubule mitotic disrupter (Z/25) | fenoxaprop-P-ethyl, imazamethabenz-methyl, rimsulfuron, flamprop-methyl | Spring Barley, Cropland, Wheat, Canola |
| **6** | 2000 | *Solanum ptycanthum* | Canada (Ontario) | ALS inhibitors (B/2) | imazethapyr, prosulfuron, nicosulfuron, rimsulfuron, primisulfuron-methyl, flumetsulam, imazamox | Corn (maize), Soybean |
| **7** | 1996 | *Kochia scoparia* | Czech Republic | ALS inhibitors (B/2), Photosystem II inhibitors (C1/5) | imazapyr, sulfosulfuron, thifensulfuron-methyl, chlorsulfuron, triflusulfuron-methyl, tribenuron-methyl, prosulfuron, metsulfuron-methyl, nicosulfuron, rimsulfuron, atrazine | Railways, Roadsides |
| **8** | 2015 | *Sonchus asper* | France | ALS inhibitors (B/2) | rimsulfuron | Chicory |
| **9** | 2018 | *Galinsoga parviflora* | France | ALS inhibitors (B/2) | rimsulfuron, penoxsulam | Endive |

[1] Heap, I. M., 2018: The International Survey of Herbicide Resistant Weeds. Web site visited January 2018. http://www.weedscience.com
[2] EPPO 2015: Standard PP 1/213 (4): Resistance risk analysis.
[3] HRAC: http://www.HRACglobal.com. Web site visited January 2018.

| # | Year | Species | Country | MOAs | Actives | Situations |
|---|---|---|---|---|---|---|
| **10** | 2009 | *Echinochloa phyllopogon (=E. oryzicola)* | Greece | ALS inhibitors (B/2) | bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penoxsulam | Rice |
| **11** | 2008 | *Amaranthus palmeri* | Israel | ALS inhibitors (B/2) | pyrithiobac-sodium, rimsulfuron, iodosulfuron-methyl-sodium, foramsulfuron, trifloxysulfuron-sodium, mesosulfuron-methyl | Corn (maize), Cotton, Watermelon |
| **12** | 2017 | *Sorghum halepense* | Israel | ALS inhibitors (B/2) | rimsulfuron | Cotton, Watermelon |
| **13** | 2009 | *Sorghum halepense* | Mexico | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron | Corn (maize) |
| **14** | 2014 | *Sorghum halepense* | Serbia | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, imazamox, pyroxsulam, propoxycarbazone-sodium | Corn (maize) |
| **15** | 2004 | *Setaria faberi* | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron | Corn (maize) |
| **16** | 2009 | *Amaranthus tuberculatus (=A. rudis)* | United States (Iowa) | ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5) | thifensulfuron-methyl, rimsulfuron, atrazine, mesotrione, tembotrione, topramezone | Seed corn |
| **17** | 2011 | *Conyza canadensis* | United States (Kansas) | ALS inhibitors (B/2) | thifensulfuron-methyl, chlorsulfuron, tribenuron-methyl, metsulfuron-methyl, rimsulfuron, iodosulfuron-methyl-sodium, thiencarbazone-methyl | Corn (maize), Cotton, Soybean, Wheat |

## Reported cases of resistance to nicosulfuron

| # | Year | Species | Country | MOAs | Actives | Situations |
|---|---|---|---|---|---|---|
| **1** | 2011 | *Echinochloa crus-galli var. crus-galli* | Austria | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **2** | 1993 | *Bidens pilosa* | Brazil | ALS inhibitors (B/2) | imazethapyr, imazaquin, pyrithiobac-sodium, chlorimuron-ethyl, nicosulfuron | Soybean |
| **3** | 1996 | *Bidens subalternans* | Brazil | ALS inhibitors (B/2) | imazethapyr, chlorimuron-ethyl, nicosulfuron | Soybean |
| **4** | 2001 | *Raphanus sativus* | Brazil | ALS inhibitors (B/2) | imazethapyr, chlorimuron-ethyl, metsulfuron-methyl, nicosulfuron, cloransulam-methyl | Wheat |
| **5** | 2004 | *Euphorbia heterophylla* | Brazil | ALS inhibitors (B/2), PPO inhibitors (E/14) | imazethapyr, metsulfuron-methyl, nicosulfuron, diclosulam, flumetsulam, cloransulam-methyl, fomesafen, lactofen, acifluorfen-sodium, flumiclorac-pentyl, saflufenacil | Corn (maize), Soybean |
| **6** | 2000 | *Solanum ptycanthum* | Canada (Ontario) | ALS inhibitors (B/2) | imazethapyr, prosulfuron, nicosulfuron, rimsulfuron, primisulfuron-methyl, flumetsulam, imazamox | Corn (maize), Soybean |
| **7** | 2001 | *Setaria viridis* | Canada (Ontario) | ALS inhibitors (B/2) | imazethapyr, pyrithiobac-sodium, nicosulfuron, flucarbazone-sodium | Corn (maize), Soybean |
| **8** | 2009 | *Sorghum halepense* | Chile | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **9** | 2010 | *Digitaria sanguinalis* | China | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **10** | 2014 | *Alopecurus aequalis* | China | ACCase inhibitors (A/1), ALS inhibitors (B/2) | quizalofop-P-ethyl, fenoxaprop-P-ethyl, nicosulfuron, flucarbazone-sodium, mesosulfuron-methyl, penoxsulam, pinoxaden | Wheat |
| **11** | 2014 | *Alopecurus japonicus* | China | ACCase inhibitors (A/1), ALS inhibitors (B/2) | fenoxaprop-P-ethyl, pyribenzoxim, sulfosulfuron, nicosulfuron, mesosulfuron-methyl, pyroxsulam | Wheat |
| **12** | 1996 | *Kochia scoparia* | Czech Republic | ALS inhibitors (B/2), Photosystem II inhibitors (C1/5) | imazapyr, sulfosulfuron, thifensulfuron-methyl, chlorsulfuron, triflusulfuron-methyl, tribenuron-methyl, prosulfuron, metsulfuron-methyl, nicosulfuron, rimsulfuron, atrazine | Railways, Roadsides |
| **13** | 2011 | *Setaria viridis* | France | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize) |

| # | Year | Species | Country | MOAs | Actives | Situations |
|---|---|---|---|---|---|---|
| **14** | 2015 | *Digitaria sanguinalis* | France | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize) |
| **15** | 2011 | *Stellaria media* | Germany | ALS inhibitors (B/2) | thifensulfuron-methyl, amidosulfuron, triflusulfuron-methyl, tribenuron-methyl, nicosulfuron, imazamox, florasulam, iodosulfuron-methyl-sodium, tritosulfuron, mesosulfuron-methyl, pyroxsulam | Spring Barley, Wheat, Rapeseed |
| **16** | 2012 | *Echinochloa crus-galli var. crus-galli* | Germany | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **17** | 2012 | *Amaranthus retroflexus* | Germany | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **18** | 2009 | *Echinochloa phyllopogon (=E. oryzicola)* | Greece | ALS inhibitors (B/2) | bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penoxsulam | Rice |
| **19** | 2015 | *Sorghum halepense* | Hungary | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize), Fallow |
| **20** | 2003 | *Amaranthus retroflexus* | Italy | ALS inhibitors (B/2) | imazethapyr, thifensulfuron-methyl, nicosulfuron, oxasulfuron, imazamox | Soybean |
| **21** | 2005 | *Echinochloa crus-galli var. crus-galli* | Italy | ALS inhibitors (B/2) | bispyribac-sodium, azimsulfuron, nicosulfuron, imazamox, penoxsulam | Corn (maize), Rice |
| **22** | 2007 | *Sorghum halepense* | Italy | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **23** | 2009 | *Sorghum halepense* | Mexico | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron | Corn (maize) |
| **24** | 2014 | *Ixophorus unisetus* | Mexico | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **25** | 2014 | *Sorghum halepense* | Serbia | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, imazamox, pyroxsulam, propoxycarbazone-sodium | Corn (maize) |
| **26** | 2015 | *Echinochloa crus-galli var. crus-galli* | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **27** | 2015 | *Sorghum halepense* | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **28** | 2016 | *Amaranthus palmeri* | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize), Roadsides |
| **29** | 2017 | *Echinochloa crus-galli var. crus-galli* | Ukraine | ALS inhibitors (B/2) | imazapyr, nicosulfuron, imazamox, penoxsulam | Rice |
| **30** | 2000 | *Sorghum bicolor* | United States (Illinois) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **31** | 2007 | *Setaria faberi* | United States (Illinois) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize), Soybean |
| **32** | 2004 | *Setaria faberi* | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron | Corn (maize) |
| **33** | 2005 | *Sorghum halepense* | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize), Soybean |
| **34** | 2006 | *Sorghum bicolor* | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize), Soybean |
| **35** | 1996 | *Sorghum bicolor* | United States (Kansas) | ALS inhibitors (B/2) | nicosulfuron, primisulfuron-methyl | Corn (maize) |
| **36** | 1992 | *Amaranthus hybridus (syn: quitensis)* | United States (Kentucky) | ALS inhibitors (B/2) | imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl, flumetsulam | Soybean |
| **37** | 2006 | *Sorghum halepense* | United States (Kentucky) | ALS inhibitors (B/2) | nicosulfuron, primisulfuron-methyl, foramsulfuron | Corn (maize) |
| **38** | 2006 | *Setaria faberi* | United States (Michigan) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, foramsulfuron | Corn (maize), Soybean |
| **39** | 1996 | *Setaria faberi* | United States (Minnesota) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean |
| **40** | 1996 | *Setaria viridis var. major (=var. robusta-alba, var. robustapurpurea)* | United States (Minnesota) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean |
| **41** | 2013 | *Amaranthus spinosus* | United States (Mississippi) | ALS inhibitors (B/2) | imazethapyr, pyrithiobac-sodium, nicosulfuron, trifloxysulfuron- | Cotton, Soybean |

| # | Year | Species | Country | MOAs | Actives | Situations |
|---|---|---|---|---|---|---|
| | | | | | sodium | |
| **42** | 1994 | *Amaranthus tuberculatus (=A. rudis)* | United States (Missouri) | ALS inhibitors (B/2) | imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, prosulfuron, nicosulfuron, halosulfuron-methyl, primisulfuron-methyl, flumetsulam, imazamox | Corn (maize), Cotton, Soybean |
| **43** | 2015 | *Ambrosia artemisiifolia* | United States (North Carolina) | ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), PPO inhibitors (E/14) | nicosulfuron, cloransulam-methyl, fomesafen, lactofen, acifluorfen-sodium, glyphosate | Corn (maize), Soybean |
| **44** | 2000 | *Sorghum bicolor* | United States (Ohio) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize) |
| **45** | 2002 | *Amaranthus tuberculatus (=A. rudis)* | United States (Oklahoma) | ALS inhibitors (B/2) | imazethapyr, imazaquin, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean |
| **46** | 2001 | *Sorghum bicolor* | United States (Pennsylvania) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, oxasulfuron, primisulfuron-methyl, imazamox | Corn (maize), Soybean |
| **47** | 2004 | *Setaria faberi* | United States (Pennsylvania) | ALS inhibitors (B/2) | nicosulfuron, imazamox, foramsulfuron | Corn (maize) |
| **48** | 2000 | *Sorghum halepense* | United States (Texas) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize) |
| **49** | 2003 | *Sorghum bicolor* | United States (Virginia) | ALS inhibitors (B/2) | imazethapyr, imazapyr, nicosulfuron | Corn (maize) |
| **50** | 2004 | *Sorghum halepense* | United States (West Virginia) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) |
| **51** | 1999 | *Setaria faberi* | United States (Wisconsin) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize), Soybean |
| **52** | 2004 | *Rottboellia cochinchinensis (=R. exaltata)* | Venezuela | ALS inhibitors (B/2) | nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Corn (maize) |
| **53** | 2010 | *Sorghum halepense* | Venezuela | ALS inhibitors (B/2) | nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Corn (maize) |

Resistance to sulfonylureas is well documented, with the first case recorded in United States in 1987. Since then further cases have been reported including grass and broad-leaved weed resistance in Europe.

In order to responsibly manage and maintain the activity of the active substances in COREY, it is recommended that resistance management strategies are applied. The commercial product, should be used in rotation with herbicides with a different mode of action that are also active against the target weeds, cultural and mechanical practices should be implemented when possible and appropriate, monoculture situations should be avoided, destruction of all seeds produced by the weeds not controlled by the herbicide application is recommended. In addition, a monitoring program to determine any shifts in sensitivity toward the product will be also implemented.

Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant.

**The agronomic resistance risk for COREY due to the possible of ALS herbicides in virtually all crops is considered as high. The overall resistance risk for COREY is high.**

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broad-leaved weeds.
The proposed resistance risk management strategy is acceptable. Final as-sessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

**The Registration Rimsulfuron 15% + Nicosulfuron 30% WG is endorsed.**

### 3.3.2 Adverse effects on treated crops

**Phytotoxicity to host crop**

Data from twenty selectivity trials conducted in the Mediterranean EPPO zone (5, i.e. Spain (2), Italy (2) and S-France (1)), the Maritime EPPO zone (9, i.e. N-France (3), Germany (2), Czech Republic (2) and England (2)) and the North-east EPPO zone (6, i.e. Poland) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

Maize are claimed on the label. The claims of crop safety on maize are supported with a total of 53 trials conducted in Spain, Italy, France, Germany, Czech Republic, England, Hungary and Poland in 2016, 2017 and 2019. In all trials, Rimsulfuron 15% + Nicosulfuron 30% WG proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 0.1 kg/ha in maize. The same was observed in the treatments where Rimsulfuron 15% + Nicosulfuron 30% WG was applied at twice the recommended rate or more, representative of sprayer overlap.

**Effects on yield and quality**

Twenty selectivity trials were conducted between 2016 and 2019 to evaluate the effect of Rimsulfuron 15% + Nicosulfuron 30% WG on yield of maize. In selectivity trials conducted in maize, Rimsulfuron 15% + Nicosulfuron 30% WG was applied early post-emergence, when the crop was at growth stages ranging between BBCH 11 and BBCH 18. All trials conducted on maize presented in this Biological Assessment Dossier were located within the Mediterranean zone (5), the Maritime zone (9) or the South-East zone (6), as defined by EPPO Standard PP1/241(1).

Minor adverse effects were observed in eight selectivity trials in which crop yields were assessed. No significant reductions in crop yield were recorded in any of the plots treated with COREY at dose rates representative of the recommended dose rate or the 2N rate in the trials in which adverse effects were observed.

Rimsulfuron 15% + Nicosulfuron 30% WG applied at the recommended dose rate (0.1 kg/ha) did not affect crop yield significantly in any of the 20 trials conducted on maize. In all trials, Rimsulfuron 15% + Nicosulfuron 30% WG applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

### 3.3.3 Observations on other undesirable or unintended side-effects

**Impact on treated plants or plant products to be used for propagations**
Negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the complete crop safety of the product and the absence of any negative effect on the plants or plant products.

No adverse effect on the yield and quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of nicosulfuron and rimsulfuron in seed crops of maize.
**In the opinion of Evaluator, the product COREY (product code: SHA 0724 A) may be used in seed crops of maize.**

**Label recommendation – Succeeding crops**

**<u>Replacement crop</u>**

If the crop has to be abandoned after application in the spring, forage- and grain maize can be re-seeded immediately after ploughing.

**Rotational crops**

**Autumn**

Winter wheat and winter barley can follow a maize crop treated with Rimsulfuron 15% + Nicosulfuron 30% WG provided the soil has been ploughed to a depth of 15 cm.

**Spring:**

Forage- and grain maize, rye grass, spring wheat and spring barley may be sown in the spring following application of Rimsulfuron 15% + Nicosulfuron 30% WG. Do not sow any other crop at this time.

**Impact on other plants including adjacent crops**

The non-target plant studies show that there is a potential risk to adjacent crops from an application of Rimsulfuron 15% + Nicosulfuron 30% WG, therefore care should be taken to avoid drift onto adjacent crops. However, based on the worst-case risk assessment, the risk for non-target terrestrial plants is considered acceptable if a buffer zone of 5 meters and nozzles giving a drift reduction of 75% is taken into account.

**Effects on beneficial and other non-target organisms**

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy trials conducted.

## 3.4 Methods of analysis (Part B, Section 5)

Analytical method for Rimsulfuron 15% + Nicosulfuron 30% WG in food, feed of plant and animal origin, soil, water and air and in the formulation Rimsulfuron 15% + Nicosulfuron 30% WG are available.

### 3.4.1 Analytical method for the formulation

The analytical determination of Rimsulfuron and Nicosulfuron was performed by HPLC technique with UV/Vis detector using reversed phase column.

The method for the determination of Rimsulfuron and Nicosulfuron in Rimsulfuron 15% + Nicosulfuron 30% WG is acceptable and validated according the requirements SANCO 3030/99 rev. 4 because of the starting experimental phase on 2017.

### 3.4.2 Analytical methods for residues

#### 3.4.2.1 Rimsulfuron and ist metabolites

| **Component of residue definition: Rimsulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| High water content | Primary | 0.05 mg/kg | HPLC-UV | (Amoo, 1996) EU agreed |
| | ILV | 0.05 mg/kg | HPLC-UV | (Clayton, 2001) EU agreed |

| **Component of residue definition: Rimsulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | (Fultin, 2001) EU agreed |
| High acid content | Primary | - | - | - |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |
| High oil content | Primary | - | - | - |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |
| High protein/high starch content (dry) | Primary | 0.05 mg/kg | HPLC-UV | (LaRochelle et al., 1989 and Amoo, 1996) EU agreed |
| | ILV | 0.05 mg/kg | HPLC-UV | (Clayton, 2001) EU agreed |
| | Confirmatory (if required) | 0.01 mg/kg | LC-MS/MS | (Fultin, 2001) EU agreed |
| **Component of residue definition: Rimsulfuron, IN-70912, IN-70941, IN-J0290 and IN-E9260** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Soil | Primary | 0.2 µg/kg<br><br>0.05 µg/kg | LC-MS/MS<br><br>LC-MS/MS | Connolly, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required)<br><br>Hill and Stry, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | - | - | - |
| | Primary (IN-70942, IN-70941, IN-J0290, IN-E9260 metabolites) | 0.2 µg/kg | LC-MS/MS | Connolly, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory (IN-70942, IN-70941, IN-J0290, | - | - | - |

| **Component of residue definition: Rimsulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| | IN-E9260 metabolites) | | | |
| *IN-70942, IN-70941, IN-J0290, IN-E9260 metabolites are not component of residue definition. | | | | |
| **Component of residue definition: Rimsulfuron** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Drinking water | Primary | 0.1 µg/L<br>0.05 µg/L | HPLC-UV<br>LC-MS/MS | Powley and de Bernard, 1996<br>Devine and Jin, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | ILV | - | - | According to SANCO/825/00 rev. 8.1, ILV is not required. |
| | Confirmatory | 0.1 µg/L | LC-MS/MS | Jin, 2001 |
| Surface water | Primary | 0.1µg/L<br>0.05 µg/L | HPLC-UV<br>LC-MS/MS | Powley and de Bernard, 1996<br>Devine and Jin, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | 0.1 µg/L | LC-MS/MS | Jin, 2001 |
| **Component of residue definition: Rimsulfuron** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Air | Primary | 3 µg/$m^3$ air | LC-MS/MS | Bacher, 2001<br>(This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | - | - | - |

Adequate method exists to monitor Rimsulfuron residues in high protein/high starch content (dry), soil, water and air. The analytical methods presented by the applicant are active substances data, which were reviewed in the Assessment Report for Rimsulfuron and were considered adequate.
Additional methods for the purpose of the evaluation are not required.

### 3.4.2.2 Nicosulfuron and ist metabolites

| **Component of residue definition: Nicosulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| High water content | Primary | 0.01 mg/kg<br>0.01 mg/kg | HPLC-UV<br>HPLC-MS/MS | Huber, 1996a<br>Wolf, 2000 |
| | ILV | 0.01 mg/kg | HPLC-MS/MS | Ginzburg, 2000 |
| | Confirmatory (if required) | 0.025mg/kg | GC/MS, LC-MS | Mirbach, 1998 |
| High acid content | Primary | - | - | - |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |
| High oil content | Primary | - | - | - |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |
| High protein/high starch content (dry) | Primary | 0.02 mg/kg<br>0.01 mg/kg | HPLC-UV<br>HPLC-MS/MS | Huber, 1996a<br>Wolf, 2000 |
| | ILV | 0.01 mg/kg | HPLC-MS/MS | Ginzburg, 2000 |
| | Confirmatory (if required) | 0.025mg/kg | GC/MS, LC-MS | Mirbach, 1998 |
| **Component of residue definition: ADMP** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| High protein/high starch content (dry) | Primary | 0.04 mg/kg | HPLC-UV | Huber, 1996a |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |
| **Component of residue definition: ASDM** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| High protein/high starch content (dry) | Primary | 0.06 mg/kg | HPLC-UV | Huber, 1996a |
| | ILV | - | - | - |
| | Confirmatory (if required) | - | - | - |

| **Component of residue definition: Nicosulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Soil | Primary | 0.005 mg/kg | HPLC-UV | Huber, 1996b |
| | Confirmatory | 0.05 µg/kg | LC-MS/MS | Wais, 2000a |
| **Component of residue definition: ADMP** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Soil | Primary | 0.02 mg/kg | HPLC-UV | Huber, 1996b |
| | Confirmatory | - | - | - |
| Component of residue definition: ASDM | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Soil | Primary | 0.01 mg/kg | LC-MS/MS | Wolf, 2003 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | - | - | - |
| **Component of residue definition: AUSIN and UCSN** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (*i.e.* GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Soil | Primary | 0.01 mg/kg | LC-MS/MS | Wolf, 2003 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | - | - | - |
| **Component of residue definition: Nicosulfuron** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Drinking water | Primary | 0.05 µg/L<br><br>0.05 µg/L | HPLC-UV<br><br>HPLC-MS/MS | Schulz and Ullrich-Mitzel, 1995a<br><br>Wolf, 2007 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | ILV | - | - | According to SANCO/825/00 rev. 8.1, ILV is not required. |

| **Component of residue definition: Nicosulfuron** | | | | |
|---|---|---|---|---|
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing / EU agreed** |
| | Confirmatory | 0.05 µg/L | LC-DAD | Wais, 2000b |
| Surface water | Primary | 0.05 µg/L | HPLC-MS/MS | Wolf, 2007 (This method is specific, validated on two mass transitions, so confirmatory is not required) |
| | Confirmatory | 0.05 µg/L | HPLC-DAD | Wais, 2000b |
| **Component of residue definition: ADMP, ASDM and AUSN** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Drinking water | Primary | 0.05 µg/L | HPLC-UV | Wais and Ullrich-Mitzel, 1997 |
| | ILV | - | - | According to SANCO/825/00 rev. 8.1, ILV is not required. |
| | Confirmatory | - | - | - |
| **Component of residue definition: Nicosulfuron** | | | | |
| **Matrix type** | **Method type** | **Method LOQ** | **Principle of method (i.e. GC-MS or HPLC-UV)** | **Author(s), year / missing** |
| Air | Primary | 1.2 µg/$m^3$ air<br>1.2 µg/$m^3$ air | HPLC-UV<br>HPLC-UV | Schulz and Ullrich-Mitzel, 1995b<br>Wais, 2000c |
| | Confirmatory | - | - | Sufficient confirmatory methods are available for the determination in soil or water therefore confirmatory methods for the determination of residues in air are not required. |

Adequate method exists to monitor Nicosulfuron residues in high protein/high starch content (dry), soil, water and air. The analytical methods presented by the applicant are active substances data, which were reviewed in the Assessment Report for Nicosulfuron and were considered adequate.
Additional methods for the purpose of the evaluation are not required.

## 3.5 Mammalian toxicology (Part B, Section 6)

The assessment of all acute toxicological properties of Rimsulfuron 15% + Nicosulfuron 30% WG are derived from the classification of the active compound and co-formulants.

### 3.5.1 Acute toxicity

Classification for Rimsulfuron 15% + Nicosulfuron 30% WG was calculated based on classification of co-formulants. Based on those calculations for formulation, no classification is required for the oral, dermal and inhalation toxicity, skin irritation, eye irritation and skin sensitizer.

**Classification:** Not classified

### 3.5.2 Operator exposure

Operator exposure to COREY was not evaluated as part of the EU review of Rimsulfuron and Nicosulfuron for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for Rimsulfuron and Nicosulfuron using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

**Conclusions:** According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable without use of personal protective equipment.

**Implication for labelling:** None

### 3.5.3 Worker exposure

Worker exposure to COREY was not evaluated as part of the EU review of Rimsulfuron and Nicosulfuron for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure have been undertaken for Rimsulfuron and Nicosulfuron using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

**Conclusion:** According to the EFSA AOEM Model, it can be concluded there is no unacceptable risk anticipated for the worker re-entering the treated crop even without suitable protective clothing.

### 3.5.4 Bystander and resident exposure

Bystander and resident exposure to COREY was not evaluated as part of the EU review of Rimsulfuron and Nicosulfuron for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures have been undertaken for Rimsulfuron and Nicosulfuron using EFSA AOEM Model and default dermal absorption value (10% concentrate and 50% dilution).

**Conclusion:** According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to COREY.

**Implication for labelling:** None

## 3.6 Residues and consumer exposure (Part B, Section 7)

The preparation Rimsulfuron 15% + Nicosulfuron 30% WG is composed of Rimsulfuron and Nicosulfu-

ron.

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
|---|---|---|---|---|---|
| Rimsulfuron | | | | | |
| ADI | SANCO/10528/2005 – rev. 2 –27 January 2006 | 2006 | 0.1 mg/kg bw/day | Rat 2-year oral | 100 |
| ARfD | | 20006 | Not necessary – not required | | |
| Nicosulfuron | | | | | |
| ADI | EFSA Scientific Report 2007; 120, 1-91 | 2007 | 2 mg/kg bw/d | Chronic rat supported by subchronic dog | 100 |
| ARfD | | 2007 | Not necessary – not required | | |

Unprotected data were sufficient to support all the uses of Rimsulfuron 15% + Nicosulfuron 30% WG.

An acceptable acute and chronic risk for consumer is expected after the use of Rimsulfuron 15% + Nicosulfuron 30% WG accordingly to the intended GAP.

### 3.6.1 Residues

**Storage stability**

Storage stability of active substances was investigated in the framework of the EU pesticides peer review. No new data was submitted in the framework of this application. Information provided is sufficient. It is concluded that the residue data are valid with regard to storage stability.

No further data are required to support the proposed uses.

Rimsulfuron

Rimsulfuron residues are stable up to 24 months in maize grain and forage.

Nicosulfuron

Nicosulfuron residues are stable up to 9 months in maize grain and whole plant..

**Metabolism in plants and animals**

The metabolism in plants and livestock for the active substances was reviewed during the Annex I inclusion process. No additional studies are available in the framework of this application.

Rimsulfuron

Due to the rapid and extensive metabolism of rimsulfuron in the tested crops, the residue for enforcement and risk assessment in all plant commodities is defined as rimsulfuron.

Nicosulfuron

Plant residue definition for monitoring and risk assessment: nicosulfuron

**Magnitude of residues in plants**

Maize

Proposed GAP: 1 application; BBCH 12-18, 0.015 rimsulfuron + 0.03 nicosulfuron kg as/ha; PHI: n.a.

Rimsulfuron

The applicant refers to the data available in the draft assessment report, Germany 2005. Field studies are in line with GAP, but method used has LOQ of 0.05 mg / kg, however, considering the metabolism studies that showed no residues at exaggerated rates, it can be concluded that these residues will be below an enforcement LOQ of 0.01 mg / kg.

Moreover, applicant delivers a new study on magnitude of residues to confirm this state (Germany 2017).

GAP on which EU a.s. assessment is based: 1 x 0.0125-0.020 kg as/ha, BBCH 12-17, PHI 13-124, outdoor

Residues: 25 x < 0.05 mg/kg

GAP of the new trial: 1 x 0.015 kg as/ha, BBCH 12, PHI 139d, outdoor

Method of analysis: HPLC/MS/MS; LOQ: 0.001 mg/kg; Storage time: 76 days. Residues; below LOQ.

The data submitted show that no exceedance of the MRL will occur.

Nicosulfuron

The applicant refers to the EU unprotected data (United Kingdom 2007).

GAP on which MRL/EU a.s. assessment is based: 1 x 0.06 kg as/ha, BBCH 12-18, outdoor

Residues: 20x<0.01

The proposed use is considered acceptable.

**Magnitude of residues in livestock**

No additional study was performed or is requested since the intake of nicosulfuron and rimsulfuron by animals is not expected to be significant. Residue levels of both compounds in maize are below LOQ. There is no risk for animal MRL to be exceeded. Additional studies are no required.

**Processing studies**

Additional studies are not required.

**Residues in Representative Succeeding Crops**

Occurrence of rimsulfuron and nicosulfuron residues in rotational crops was already investigated during the peer review of these substances. It was concluded that significant residues in rotational crops are not expected. No additional studies on rotational crops are considered necessary. No restrictions are necessary.

### 3.6.1 Consumer exposure

**Rimsulfuron consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo | 2 % (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant. |
| IESTI (% ARfD) according to EFSA PRIMo | - |
| NTMDI (% ADI) | - |
| NEDI (% ADI) | - |
| NESTI (% ARfD) | - |

The proposed uses of Rimsulfuron in the formulation Rimsulfuron 15% + Nicosulfuron 30% WG do not represent unacceptable chronic risks for the consumer.

**Nicosulfuron consumer risk assessment**

| | |
|---|---|
| TMDI (% ADI) according to EFSA PRIMo | 0.1% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMo | Not relevant. |
| IESTI (% ARfD) according to EFSA PRIMo | - |
| NTMDI (% ADI) | - |
| NEDI (% ADI) | - |
| NESTI (% ARfD) | - |

The proposed uses of Nicosulfuron in the formulation Rimsulfuron 15% + Nicosulfuron 30% WG do not represent unacceptable chronic risks for the consumer.

## 3.7 Environmental fate and behaviour (Part B, Section 8)

Concentration of Rimsulfuron and Nicosulfuron in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentration (PEC values) in soil, surface water, sediment and ground water are provided.

**Intended use pattern of COREY**

| Crop | Application rate (kg a.i./ha) | Application method | Max. number of applications | Min. application interval (days) | Application timing |
|---|---|---|---|---|---|
| **Maize** | Rimsulfuron: 0.015<br>Nicosulfuron: 0.030 | Foliar spray | 1 | NA | BBCH 12-18 |

### 3.7.1 Predicted environmental concentrations in soil ($PEC_{soil}$)

$PEC_{soil}$ calculations have been conducted with Rimsulfuron and its relevant metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290 using the EU agreed endpoints (EFSA Journal 2005; 45, 1-61) and with Nicosulfuron and its relevant metabolites HMUD, ADMP, ASDM, AUSN and UCSN using the EU agreed endpoints (EFSA Scientific report (2007) 120, 1-91).
Maximum $PEC_{soil}$ value for Rimsulfuron was 0.015 mg/kg, 0.007 mg/kg for IN-70941, 0.003 mg/kg for IN-70942, 0.002 mg/kg for IN-E9260 and 0.001 mg/kg for IN-J0290, following the highest application rate of 15 g Rimsulfuron/ha.
Maximum $PEC_{soil}$ value for Nicosulfuron was 0.030 mg/kg, 0.004 mg/kg for HMUD, 0.001 mg/kg for ADMP, 0.011 mg.kg for ASDM, 0.006 mg/kg for AUSN and 0.003 mg/kg for UCSN, following the highest application rate of 30 g of Nicosulfuron.

### 3.7.2 Predicted environmental concentrations in groundwater ($PEC_{gw}$)

$PEC_{gw}$ have been realised for Rimsulfuron and its relevant metabolites IN-70941, IN-70942, IN-E9260 and IN-J0290 and for Nicosulfuron and its relevant metabolites HMUD ADMP, ASDM, AUSN, UCSN and MU-466.
The Rimsulfuron and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941, IN-70942 and IN-E9260 shown PECgw's greater than 0.1 but below 0.75 µg/L.
The Nicosulfuron PECgw was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was 0.226 ug/L. Metabolites HMUD, AUSN, UCSN and ASDM shown PECgw greater than 0.75 but below 10 µg/L, metabolite MU-466 had PECgw greater than 0.1 but below 0.75 µg/L and metabolite ADMP reported PECgw's well below 0.1 µg/L.
Three lysimeter studies were conducted in Germany and Switzerland with pyridine and pyrimidine labelled nicosulfuron. All lysimeters were cropped with maize in the first and second years and with rye in

the third year. Applications were made at 60 and 40 g a.s./ ha. Level of Nicosulfuron in the leachate of lysimeters treated at 40 g a.s./ha were <0.1 µg L (EFSA (2007) 120, 1-91). Lysimeter studies may be accepted as higher tier risk assessment.

The Applicant has submitted its own monitoring study for Nicosulfuron and its metabolites HMUD, AUSN, UCSN and ASDM performed on Italy during almost 3 years (January 2016-November 2018), where all of the monitoring regions are typical for cultivation of maize in Italy. The monitoring regions were Piemonte, Lombardia, Veneto, Emilia-Romagna and Friuli-Venezia Giulia. Within these five selected regions, seven key maize-growing areas of Northern Italy were identified and the 23 wells were distributed throughout these areas. During the study, groundwater sampling was conducted 12 times for 240 samples (20 wells × 12 sampling events) were analyzed for Nicosulfuron and its four metabolites (3 out 23 wells were used as backup samples). According to the study the Nicosulfuron application rate used in the maize crops were 40 g as/ha in all Italian regions. The results of the study shown that the concentration of Nicosulfuron and its four metabolites were all < 0.1 µg/L except for UCSN which showed 4 detections at 1 location up to 0.111 µg/L, AUSN which showed 26 detections at 6 locations up to 0.657 µg/L and also ASDM which showed 4 detections at 1 location up to 0.447 µg/L. The results shown that the Nicosulfuron at its monitored metabolites concentrations are not in agreement with the model predicted values and it can be concluded that the use of Nicosulfuron in maize crops are safe and doesn't pose an unacceptable risk for ground water. Furthermore, the concentration of the monitored non-relevant metabolites was below 0.75 µg/L. The Nicosulfuron $PEC_{gw}$ was below 0.1 µg/L with the exception of Hamburg scenario where the concentration was 0.226 ug/L. Metabolites HMUD, AUSN and ASDM and UCSM shown $PEC_{gw}$ greater than greater than 0.1 µg L. Monitoring study is accepted as supportive for PL.

The assessment relevance of the metabolites in ground water according to SANCO/221/2000 –rev.10 document is reported in the dRR Part B10.

### 3.7.3 Predicted environmental concentrations in surface water ($PEC_{sw}$)

The $PE_{sw/sed}$ of Rimsulfuron and its relevant metabolites IN-70941, IN 70942, IN-E9260, IN-J290 and IN-JF999 and of Nicosulfuron and its relevant metabolites HMUD, ASDM, AUSN, UCSN, ADMP and DUDN have been assessed with the models FOCUS STEP 1, 2, 3 and 4 (when necessary). Please refer to dRR Part B, Section 8, Chapter 8.9 for more details about the results obtained.

### 3.7.4 Predicted environmental concentrations in air ($PEC_{air}$)

The vapour pressure at 20 °C of the active substance Rimsulfuron is < $10^{-5}$ Pa. Hence the active substance Rimsulfuron is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Rimsulfuron due to volatilization with subsequent deposition should not be considered.
The vapour pressure at 20 °C of the active substance Nicosulfuron is < $10^{-5}$ Pa. Hence the active substance Nicosulfuron is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Nicosulfuron due to volatilization with subsequent deposition should not be considered.

## 3.8 Ecotoxicology (Part B, Section 9)

### 3.8.1 Effects on terrestrial vertebrates

- Birds:

All the $TER_a$ and $TER_{lt}$ values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to birds according to the intended uses, as well as for drinking water exposure and secondary poisoning.

- Mammals:

All the $TER_a$ and $TER_{lt}$ values are greater than the Annex VI trigger of 10 and 5, respectively, indicating that COREY presents no unacceptable acute and long-term risk to mammals according to the intended uses, as well as for drinking water exposure and secondary poisoning.

### 3.8.2 Effects on aquatic species

**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 scenarios relevant for Poland.

**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.

- Acceptable risk to aquatic macrophytes with no need for risk mitigation measures based on Step 3 calculations was demonstrated in scenarios relevant for Poland D3,D4, R1 (pond)
- Acceptable risk to aquatic macrophytes with consideration of 5 m vegetated filter strip was demonstrated in scenarios R1 stream scenario

Based on the combined risk assessment provided in the Core assessment for COREY included in dRR PART B the additional calculation for R1 stream scenario for Lemna gibba is required for Poland.
Therefore, zRMS-PL provided the calculations using the PECsw STEP 4 value with 10 meter vegetated buffer zone (0.137 microgram/L) for a.s. nicosulfuron and $PEC_{sw}$ FOCUS STEP 3 value for a.s. rimsulfuron (0.174 microgram/L) using calculator recommend to use during harmonisation meeting in Brno, 2019.

**Mixture toxicity assessment for aaquatic plants– *Lemna* endpoint $ErC_{50}$= 2.7 microgram/L with STEP4 $PEC_{sw}$ calculations.**

| **Macrophytes- Lemna sp.**<br><br>**7 d $E_rC_{50}$=0.0027 mg a.s./L** | |
|---|---|
| **ETRmix-PPP** | |
| **R1 stream scenario** | |
| **PECmix** | 0.00031 |
| **ETRmix** | 0.099 |
| **Trigger value** | 0.1 |

Based on the calculations above the risk form combined toxicity is acceptable when *an unsprayed vegetated buffer zone of 10* ***m to surface water bodies is applied.***
The final following risk mitigation measures should be applied to surface water bodies:

- ***SPe 3:*** *To protect aquatic organisms respect an unsprayed vegetated buffer zone of 10* ***m to surface water bodies*** ~~***with 50 % drift reduction nozzles.***~~

### 3.8.3 Effects on bees

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 ~~to the end of 2021~~ when the new EFSA GD for Bees will be applied at EU level.

### 3.8.4 Effects on other arthropod species other than bees

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

### 3.8.5 Effects on soil organisms

The acute and chronic TER values for earthworms and other soil macro- and mesofauna for COREY were

above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance Rimsulfuron and Nicosulfuron do not pose acute and chronic risk to earthworms and other soil macro- and mesofauna.
Risk assessments conducted with relevant $PEC_{soil}$ for the active substances Rimsulfuron and Nicosulfuron indicate a low risk to soil microorganisms when applied according to the proposed use rates. The use of COREY at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

### 3.8.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Rimsulfuron and Nicosulfuron shows that the Annex VI trigger value of 5 is not reached. Therefore, mitigation measures 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.*

### 3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Rimsulfuron:
Data from a test with activated sludge are available and indicate that the risk to biological methods of sewage treatment plants is low.

Nicosulfuron:
Effects on biological methods for sewage treatment

| **Test type/organism** | **Endpoint** |
|---|---|
| Activated sludge | -- |
| *Pseudomonas putida* | Nicosulfuron $EC_{50}$ > 250 mg as/L (no reported effects)<br>ASDM, AUSN, UCSN, MU-466, HMUD > 100 mg metabolite/L (no significant inhibition) |

## 3.9 Relevance of metabolites (Part B, Section 10)

The metabolites IN-J290 and ADMP, are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B, Section 8, Chapter 8.8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

The non-relevant metabolites IN-70941, IN-70942, IN-E9260, HMUD, AUSN, UCSN, ASDM and MU-466 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see dRR Part B, Section 8, Chapter 8.8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

# 4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance Nicosulfuron is Candidate for Substitution.

Product name contains nicosulfuron which is approved as a candidate for substitution because two of PBT.

For the management of included in GAP crops and weeds some cultural methods are available and can be helpful. They are in most cases used by breeders steps to disrupt the weed cycle: cultivation or ploughing to control emerged plants, hang weeding, diverse crop rotation. However, they seems to be ineffective in

the great area farms in Poland. Thus, cultural and mechanical methods even if necessary, cannot be considered as excluding applicable alternatives to chemical control of weeds present on fields in Poland.

The guidance document SANCO/11507/2013 rev. 12 states the following:
*Article 50 and Annex IV of the Regulation describe the conditions for substitution, such as significantly lower risk to health or the environment, whilst ensuring similar effect of alternative(s) on target organism, sufficient methods or chemical diversity to minimize the occurrence of resistance, and lack of significant economic and practical disadvantages etc.*

Regarding the use of chemical control a detailed research has been carried out for chemical alternatives to the plant protection product COREY. Taking the prescription of the leading regulation Article 50 and Annex IV of the Regulation 1107/2009, we can assume that:

- Many assessed alternative plant protection products presents higher risk for human or animal health (GHS08) than COREY;
- According to public information, within a year many of alternative plant protection products will not be available on the marked and commercially, for the farmers. Exclusion many of potential alternatives causes significant deficiencies in protection of crops listed on the COREY's label. Despite no economical evaluation has been carried out because of lack of reliable data, but COREY will be marketed with competitive price to many alternatives.

**As conclusion of this comparative assessment, the plant protection product COREY is not suitable for substitution.**

# 5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

# Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

# Appendix 2 Copy of the product label

Załącznik do zezwolenia MRiRW nr R - …../…… z dnia ……2020

**Posiadacz zezwolenia:**
Sharda Cropchem España S.L., Edifico Atalayas Business Center
Carril Condomina n°3, 12th Floor, 30006 Murcia, Hiszpania tel. +34868127589, e-mail: eu.sales@shardaintl.com

**Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:**
Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail: eu.sales@shardaintl.com.

# COREY

**Środek przeznaczony do stosowania przez użytkowników profesjonalnych**

Zawartość substancji czynnej:
**Nikosulfuron** (substancja z grupy pochodnych sulfonylomocznika) - **300 g/kg** (30.0 %)
**Rimsulfuron** (substancja z grupy pochodnych sulfonylomocznika) - **150 g/kg** (15.0 %)

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.

| UWAGA | |
|---|---|
| H410 | Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki. |
| EUH401 | W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia. |
| P273<br>P391<br>P501 | Nie wypuszczać do środowiska. (Unikać uwalniania do środowiska)<br>Zebrać wyciek.<br>Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi |

## OPIS DZIAŁANIA

COREY jest selektywnym herbicydem o działaniu systemicznym, w formie granul do sporządzania zawiesiny wodnej. Przeznaczony jest do zwalczania chwastów liściastych i trawiastych w uprawie kukurydzy. COREY zawiera dwie substancje aktywne: nikosulfuron

i rimsulfuron. Środek pobierany jest głównie przez liście chwastów i szybko przemieszczany w roślinie, hamując jej wzrost i rozwój.

**DZIAŁANIE NA CHWASTY**

**Chwasty wrażliwe**: jasnota purpurowa, maruna bezwonna, babka średnia, miotła zbożowa, wiechlina roczna, ~~rzepak samosiewny,~~ tasznik pospolity, ~~komosa wielonasienna, przytulina czepna, żółtlica drobnokwiatowa,~~ gwiazdnica pospolita, przetacznik perski, ~~wyka ptasia~~, tobołek polny
**Chwasty średnio wrażliwe**: ~~wyczyniec polny,~~ chwastnica jednostronna, włośnica zielona, szarłat szorstki, ~~bylica pospolita, wilczomlecz obrotny, bodziszek drobny, maruna nadmorska,~~ rdestówka powojowata, ~~gorczyca polna, psianka czarna,~~ fiołek polny,
**Chwasty średnio odporne**: perz właściwy, ~~komosa biała, ostrożeń polny,~~ rdest plamisty, ~~mlecz polny, przetacznik rolny~~
**Chwasty odporne:** komosa biała, przetacznik rolny

**STOSOWANIE ŚRODKA**

## Kukurydza

Chwasty liściaste i trawiaste

**Maksymalna dawka dla jednorazowego zastosowania:** 0,1 kg/ha

**Zalecana dawka dla jednorazowego zastosowania:** 0,1 kg/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować od fazy rozwoju drugiego do fazy rozwoju ósmego liścia (BBCH 12-18)

Zalecana ilość wody: **200-400 l/ha**.

Zalecane opryskiwanie: **średniokropliste**

**Maksymalna liczba zabiegów w sezonie wegetacyjnym**: 1

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

**ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ**

Środka nie stosować:
- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

**NASTĘPSTWO ROŚLIN**

W przypadku konieczności zaniechania uprawy po zastosowaniu środka wiosną, kukurydzę pastewną i ziarnową można wysiać ponownie bezpośrednio po orce.

**Uprawy rotacyjne**

**Jesień**
Po kukurydzy traktowanej środkiem COREY można uprawiać pszenicę ozimą i jęczmień ozimy, pod warunkiem, że gleba została zaorana na głębokość 15 cm.

**Wiosna:**
Kukurydza pastewna i ziarnowa, życica, pszenica jara i jęczmień jary mogą być wysiewane wiosną po zastosowaniu środka COREY. Nie należy w tym czasie wysiewać żadnych innych roślin.

## SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Odmierzoną ilość środka wsypać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wsypaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

## POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:
– po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe lub
– unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.
Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

## WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

**Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)**

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

**Środki ostrożności związane z ochroną środowiska naturalnego:**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

**SPe3**
W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej w odległości 10 m ~~wraz z użyciem końcówek redukujących znoszenie cieczy użytkowej o 50%~~ od zbiorników i cieków wodnych.

SPe3
W celu ochrony roślin niebędących obiektem zwalczania konieczne jest wyznaczenie strefy ochronnej w odległości 5 m od terenów nieużytkowanych rolniczo.
LUB
W celu ochrony roślin niebędących obiektem zwalczania konieczne jest zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%.

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):**
nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**
Nie dotyczy

**Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):**
Nie dotyczy

**Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następczo:**
Nie dotyczy

## WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0$^{o}$C - 30$^{o}$C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

# Appendix 3 Letter of Access

No letter of access is needed.

# Appendix 4 Lists of data considered for national authorization

**List of data submitted by the applicant and relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP 2.1<br>KCP 2.4.1<br>KCP 2.4.2<br>KCP 2.6.2<br>KCP 2.7.1<br>KCP 2.7.3<br>KCP 2.8.1<br>KCP 2.8.2<br>KCP 2.8.3.1<br>KCP 2.8.3.2<br>KCP 2.8.5.1.2<br>KCP 2.8.5.2.1<br>KCP 2.8.5.3<br>KCP 2.8.7.1 | Idris Al Amin | 2017 | Rimsulfuron 15% + Nicosulfuron 30% WG<br>Part I: Evaluation of physicochemical properties of the initial preparation and after accelerated storage<br>Report No: BF-55/16<br>Institute of Industrial Organic Chemistry, Poland<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 2.7.5<br>KCP 2.11 | Idris Al Amin | 2017 | Rimsulfuron 15% + Nicosulfuron 30% WG<br>Part II: Evaluation of physicochemical properties of preparation after the first year of storage<br>Report No: BF-55/16<br>Institute of Industrial Organic Chemistry, Poland<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 2.2.1 | Daniel Buczkowski | 2016 | Rimsulfuron 15% + Nicosulfuron 30% WG<br>Determination of explosive properties<br>Report No: BF-25/16<br>Institute of Industrial Organic Chemistry, Poland<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP 2.2.2<br>KCP 2.3.1<br>KCP 2.3.2<br>KCP 2.3.3 | Paulina Flasińska | 2017 | Rimsulfuron 15% + Nicosulfuron 30% WG<br>Determination of flammability, relative self-ignition temperature and oxidizing properties<br>Report No: BC-04/17<br>Institute of Industrial Organic Chemistry, Poland<br>GLP | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 5.1.1 | Małgorzata Wołoszynowska MSc | 2017 | Rimsulfuron 15% + Nicosulfuron 30% WG: Method development and validation for the determination of active substances content in the formulation<br>Institute of Industrial Organic Chemistry Analytical department, Warsaw, Poland, report no. BA-37/16<br>GLP; unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 6.0-001 | Hjorth, S. | 2020 | Biological Assessment Dossier: Nicosulfuron 15% + Nicosulfuron 30% WG (150 g/kg rimsulfuron + 300 g/kg nicosulfuron WG) – EU Central zone<br>Sharda Cropchem España<br>-, -<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 7.2.3-01 | Pardo Martinez, M. | 2018 | Validation of the Analytical Method for the determination of rimsulfuron residues in maize grains matrix and determination of rimsulfuron residues in maize following one post emergence application with Rimsulfuron 25 WG in Germany in 2017<br>ChemService<br>Report No CH-059/2018<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 7.2.3-01 | Kull S. | 2018 | Residue study (Harvest) in maize following one post emergence application with Rimsulfuron 25% WG in Germany 2017 – field part<br>CropTrials G,bH<br>Report no. CT17-1-76<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP 8.8-01 | Ferrari, F. | 2019 | Title: Groundwater Monitoring for Nicosulfuron and 4 Metabolites in Maize Growing Regions of Italy.<br>Company Report No 37/2016<br>Source Sharda Cropchem Ltd.<br>GLP<br>Unpublished | N | Y | Study report never submitted before to Poland | SHARDA Cropchem Limited |
| KCP 10.1 | J.J. Izquierdo | 2018 | Title: Toxtree v2.6.13 evaluation on the human health hazard of the Rimsulfuron (CAS nº: 122931-48-0) and its metabolite IN-70942.<br>Company Report No: JJI/01/2018<br>Source: Sharda Cropchen Ltd.<br>non GLP<br>Unpublished | N | N | Study report never submitted before to Poland | Sharda Cropchem Ltd. |
| KCP 10.2.1-01 | xxxx | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WG. Rainbow trout, Acute toxicity test<br>xxxxxx report No. W/208/17<br>GLP, unpublished | Y | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.2.1-02 | Bak, P. | 2018 | Rimsulfuron 15% + Nicosulfuron 30% WG. *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) SAG 61.81 Growth inhibition test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/209/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.2.1-03 | Bak, P. | 2018 | Rimsulfuron 15% + Nicosulfuron 30% WG. *Daphnia magna*, acute immobilisation test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/210/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.2.1-04 | Bak, P. | 2018 | Rimsulfuron 15% + Nicosulfuron 30% WG. *Lemna gibba* CPCC 310, Growth inhibition test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/211/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP | Bätscher, R. | 2008 | Toxicity of Nicosulfuron technical to the Aquatic Higher | N | Y | Study report never submitted | SHARDA |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| 10.2.1-05 | | | Plant *Lemna gibba* in a 7-Day Growth Inhibition Test, Supplemented With Testing for Recovery of Growth B75341.<br>GLP, unpublished | | | before to Malta | Cropchem Limited |
| KCP 10.3.1.1.1 | Stalmach, M. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/176/16<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.3.1.1.2 | Stalmach, M. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/177/16<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.3.1.2.1 | Ansaloni, T. | 2018 | Rimsulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera*<br>Trialcamp S.L.U. TRC16-193BA<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.3.1.2.2 | Ansaloni, T. | 2018 | Nicosulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L.<br>Trialcamp S.L.U. TRC16-049BA<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.3.1.3.1 | Aguilar-Alberola, J.A. & Marín Víllora, M. | 2018 | Toxicity of Rimsulfuron Technical on honeybee larvae (*Apis mellifera* L.) after repeated exposure under laboratory conditions<br>Trialcamp S.L.U. TRC16-162BA<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.3.2.1-01 | Stalmach, M. | 2018 | A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/178/16<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP 10.3.2.1-02 | Stalmach, M. | 2019 | A laboratory test for evaluating the effects of Rimsulfuron 15% + Nicosulfuron 30% WDG on the predatory mite, *Typhlodromus pyri* (Sch.)<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/179/16<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.4.1.1 | Pieczka, P. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Earthworm Reproduction Test (*Eisenia andrei*)<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/272/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.4.2.1-01 | Pieczka, P. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Collembolan (*Folsomia candida*) Reproduction Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/273/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.5-01 | Pieczka, P. | 2018 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Soil Microorganisms: Nitrogen Transformation Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/271/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.5-02 | Pieczka, P. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Soil Microorganisms: Carbon Transformation Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/270/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.6.2-01 | Pieczka, P. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/275/17<br>GLP, unpublished | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |
| KCP 10.6.2-02 | Pieczka, P. | 2019 | Rimsulfuron 15% + Nicosulfuron 30% WDG. Terrestrial Plant Test: Vegetative Vigour Test<br>Institute of Industrial Organic Chemistry Branch Pszczyna | N | Y | Study report never submitted before to Malta | SHARDA Cropchem Limited |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| | | | report No. G/276/17<br>GLP, unpublished | | | | |

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP XX | Author | YYYY | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS><br><br>If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization> | Owner |
| | | | | | | | |

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP XX | Author | YYYY | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS><br><br>If previously submitted in **this** MS: Data protection started with: <insert | Owner |

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| | | | | | | authorization number of first au-thorization> | |
| | | | | | | | |

## List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title<br>Company Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Verte-brate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner |
|---|---|---|---|---|---|---|---|
| KCP XX | Author | YYYY | Title<br>Company Report No<br>Source<br>GLP/non GLP/GEP/non GEP<br>Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS><br><br>If previously submitted in **this** MS: Data protection started with: <insert authorization number of first au-thorization> | Owner |
| | | | | | | | |