FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 4307 A

Product name: PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg
Nicosulfuron, 120 g/kg
Mesotrione, 360 g/kg

Central Zone

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

Update date: 05.2021, 08.2021

MS Finalisation date: 08.2022; 12.2022; 03.2023

Version history

When	What
May 2021	Submission of the 2-years study
August 2021	Applicant update
August 2022	zRMS first evaluation
December 2022	Final zRMS assessment
March 2023	Updated assessment after the comment period

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 3% + Nicosulfuron 12% + Mesotrione 36% WG, a Water dispersible Granules containing 30 g/kg of Rimsulfuron, 120 g/kg of Nicosulfuron and 360 g/kg of Mesotrione, as an herbicide on maize.

zRMS: Poland

1.2 Letters of Access

The letters of access was provided to the studies:
- xxx (2013): Generic field study on small mammals focal species and wood mouse (*Apodemus sylvaticus*) PT in maize fields in Germany, Report P12225
- xxx (2019): Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe, Report R1740045.
-North L (2016). Mesotrione – Foliage Decline Study with A12739A on Maize in Northern France and the United Kingdom in 2015. Report Number S15-02057. Eurofins Agroscience Services Ltd., Slade Lane, Wilson, Melbourne, Derbyshire, DE73 8AG, UK. Syngenta File No. A12739A_11065
- Allen L (2019: Mesotrione – Foliage Decline study on clover in Hungary, Germany, United Kingdom, Northern France and Belgium in 2018, SYN File A12738A_10535.

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 3% + Nicosulfuron 12% + Mesotrione 36% 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	SHA4307A
Product name in MS	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG

Authorization number	First authorisation
Function	Herbicide
Applicant	SHARDA Cropchem España S.L.
Active substance(s) (incl. content)	Rimsulfuron, 30 g/kg Nicosulfuron, 120 g/kg Mesotrione, 360 g/kg
Formulation type	Water dispersible Granules [Code: WG]
Packaging	HDPE bottles; 100 mL, 200 mL, 500 mL, 750 mL COEX (HDPE-EVOH) bottles 1L, 2L, 5L PE- inside layer (multilayers) bags; 50 g, 100 g, 200 g, 250 g, 500 g, 750 g, 1 kg, 5 kg, 10 kg, 20 kg, 25 kg 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 **PRIMARY MX** resulted in the decision to grant the authorization.
The data gaps listed in the Analytical Methods section must be completed before 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, 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:	**GHS08, GHS09**
Signal word:	**Warning**

Hazard statement(s):	**H361d, H373**, H400, **H410**
Precautionary statement(s):	**P260, P280, P308+P313, P314, P391, P501**
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]** **Contains formaldehyde. May produce an allergic reaction EUH208** **Contains 2-(Aminosulfonyl)-N,N-dimethyl-3-pyridinecarboxamide. May produce an allergic reaction [EUH208]**
	-
	-

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 organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies. To protect non-target plants respect 90% drift reducing nozzles OR an unsprayed buffer zone of 3m with 50% drift reducing nozzles OR an unsprayed buffer zone of 10m to non-agricultural land.

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:	
P280	Wear protective gloves, protective clothing.
Worker protection:	
-	Work wear (arms, body and legs covered)

Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe3	Maize – To protect aquatic organisms respect an unsprayed vegetated buffer zone of 5 m to surface water bodies. To protect non-target plants respect 90% drift reducing nozzles OR an unsprayed buffer zone of 3m with 50% drift reducing nozzles OR an unsprayed buffer zone of 10m to non-agricultural land.
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):	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG	Formulation type:	WG (Water dispersible granules)
Active substance 1:	Rimsulfuron	Conc. of as 1:	30 g/kg
Active substance 2:	Nicosulfuron	Conc. of as 2:	120 g/kg
Active substance 3:	Mesotrione	Conc. of as 3:	360 g/kg
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	-	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	**Maize**	F	Broadleaved and grass weeds	Foliar spray	BBCH 12-18	a) 1 b) 1	NA	a) 0.25 b) 0.25	a) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione b) 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione	200-400	-	

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 that of off-white granules with characteristics and weak odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of < 400 °C. In aqueous solution, it has a pH value around 4.48 at 20 °C.

The accelerated storage stability study in 54 degrees showed that the appearance of the product change despite all other properties giving acceptable results.
Because of this result it is recommended to store the product at a temperature not higher than 30 degrees.

Active substances content and stability of packaging [Al (outside layer)/HDPE (inside layer) bag] were tested in 6 months, 1 year and 2 years at ambient temperature.
The active ingredient content and all physical and chemical properties remained stable and acceptable after the tests.
Shelf life – 2 years.
Its technical characteristics are acceptable for a water dispersible granules formulation.

The intended concentration of use is 0.0625% - 0.125%.

RMS comments:
The applicant changed the dose of the product to min. 0.25 kg/L with 0.33 kg/L: 0.0625% - 0.125%.
The tests of physicochemical parameters were carried out for the lowest use concentration of 0.0825% v/v and the highest use concentration of 0.165% v/v.
The maximum use concentrations were taken into account in the physicochemical test (the minimum concentration is similar to the first recommended concentration).

There is no need to submit additional data.
The physicochemical test package which was presented is sufficient for evaluation

3.2 Efficacy (Part B, Section 3)

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is a Water dispersible granules (WG) formulation containing 30 grams per kilogram (g/kg) rimsulfuron, 120 g/kg nicosulfuron and 360 g/kg mesotrione 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 0.25 kg/ha

This document serves the registration of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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 3% + Nicosulfuron 12% + Mesotrione 36% WG in maize.

Comprehensive field trials were conducted in Germany, Czech Republic, England, France, Poland, Hungary, Spain and Italy 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 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to that of the reference products to which it was compared. Furthermore, the efficacy data also demonstrated that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent, but still as selective to the GAP claimed crops as the different nationals reference products to which the test product was also compared.

3.3 Efficacy data

Preliminary tests

The activity of rimsulfuron, nicosulfuron and mesotrione is well known, as all three actives have been marketed since the beginning of the 1990's or the early 2000'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, terbuthylazine, 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.). Finally, mesotrione is also registered as straight products (e.g. Callisto) as well as in mixtures (mainly with terbuthylazine (e.g. Calaris), but also clomazone, nicosulfuron, rimsulfuron, S-metolachlor, 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. Furthermore, in the same trials, an EU approved nicosulfuron 30 g/L + mesotrione 75 g/L OD co-formulation, i.e. Elumis, was also included, to demonstrate the benefit of adding rimsulfuron to 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 3% + Nicosulfuron 12% + Mesotrione 36% WG at comparable dose rates gave a more consistent and occasionally a higher level of weed control compared to that of rimsulfuron alone as well as co-formulation of nicosulfuron and mesotrione. It is therefore considered demonstrated that the co-formulation of rimsulfuron with nicosulfuron and mesotrione has its justification when controlling grasses and broadleaved weeds in maize.

Combining three actives in Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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

To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. During field tests Applicant used different doses of herbicide – Primary MX (product code: SHA 4307 A). So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

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)) and the Maritime EPPO zone (9, i.e., Czech Republic (3), N-France (2), Germany (2) and UK (2)).

Different doses were studied during trials:
- Maritime EPPO zone: 0,15 kg/ha and 0,33 kg/ha
- MED EPPO zone: 0,15 kg/ha, 0,25 kg/ha and 0,33 kg/ha
- N-E EPPO zone: 0,25 kg/ha and 0,33 kg/ha.

To prove and to support the requested dose rate of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied early post-emergence for the control of grass weeds in maize, the assess-

ment results of 29 efficacy trials performed in the Mediterranean (6), the Maritime (7) and the North-east (16) EPPO zones in 2016, 2017 and 2019 are reported.

The applicant has proposed doses of Primary MX (product code: SHA 4307 A) that reflect those of currently authorised rimsulfuron, nicosulfuron and mesotrione products across the EU. Rimsulfuron, nicosulfuron and mesotrione doses vary widely between countries and for specific uses within the same crop depending on the agronomic circumstances and weed challenge.

Based on results achieved on dicotyledonous weeds in maize trials, it can be concluded that to consistently control frequently occurring broadleaved weeds in maize, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG can be applied early post-emergence at 0.25 kg/ha. Recommended dose was characterized by good efficiency, only slightly lower than 0,33 kg/ha and higher than 0,15 kg/ha. The applicant first requested that a dose of 0.33 kg/ha should be recommended for use. But due to environmental constraints it had to be reduced to a dose of 0.25 kg/ha.a.

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 selectivity from South-east zone is insufficient.

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)

Data from different EPPO climatic zones correctly were presented separately in the core dRR. So, in support of the current application for registration of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, 33 efficacy trials were conducted in the Mediterranean (6 eff.), the Maritime (9 eff.), the South-east (2 eff.) and the North-east (16 eff.) EPPO zone. In the opinion of ZRMs this documentation is acceptable for authorization product in Central zone. Only cMS from S-E should decide if only 2 trials can be acceptable for registration the product.

Also, Concerned Member States will need to consider the relevance of the submit-ted 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 have been included.

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

- MED EPPO zone: ECHCG (3), SETVI (2), CHEAL (4), POLCO (2), SOLNI (4), TTTT (2);
- Maritime EPPO zone: ECHCG (5), LOLMU (2), POAAN (2), CHEAL (7), MATIN (3), POLCO (5), THLAR (3), TTTT (2), VERPE (3), VIOAR (2);
- S-E EPPO zone: ECHCG (2), PANMI (2), AMARE (2);
- N-E EPPO zone: AGREE (4), APESV (2), ECHCG (12), POAAN (2), SETVI (2), AMARE (7), ARTVU (2), CAPBP (7), CHEAL (11), GERPU (2), LAMPU (2), MATIN (3), PLAME (2),

POLCO (6), POLPE (4), SINAR (2), SOLNI (2), STEME (6), VERAG (2), VIOAR (7).

In the opinion of ZRMs weed species which occurred only in 1 trial, should be excluded from label. However, final decision is left to cMS, according to their national rules.

Weed species that should be excluded due to only one trial submitted:

- MED EPPO zone: CYPRO, DIGSA, ABUTH, AMARE, DATST, EPHCG, GASPA, MERAN, POLAV, POROL, SONSS;
- Maritime EPPO zone: AGREE, ALOMY, SETPU, BRSNW, CAPBP, FUMOF, GAETE, GALAP, HELAN, LAMPU, POLLA, POLPE, SPRAR, STEME, LOMLU;
- S-E EPPO zone: CHEAL, DATST, MERAN;
- N-E EPPO zone: ALOMY, BRSNW, CHEPO, CIRAR, EPHEE, GALAP, GASPA, MATMA, SONAR, VERAR, VICCR.

When taking into account results from all four EPPO zones together, the pro-posed label claims of the weed spectrum controlled after application of 0,25 kg/ha could be categorized according to SANCO 10055 as follows:

ANNUAL GRASS WEEDS:

- Highly Susceptible (HS) 95-100%

ALOMY, PANMI, SETPU,

- Susceptible (S) 85-94.9%

APESV, ECHCG, LOLMU, POAAN

- Moderately Susceptible (MS) 70-84.9%

DIGSA, SETVI

PERENNIAL GRASS WEEDS:

- Susceptible (S) 85-94.9%

AGREE

- Tolerant (T) 0-49.9%

CYPRO

BROADLEAVED WEEDS:

- Highly Susceptible (HS) 95-100%

ABUTH, AMARE, BRSNX, CHEPO, DATST, EPHCH, FUMOF, GAETE, GASPA, GERPU, POLLA, SOLNI, SONSS, SPRAR, THLAR, TTTTT, VERAG, VICCR, VIOAR.

- Susceptible (S) 85-94.9%

ARTVU, CAPBP, CHEAL, EPHHE, GALAP, MELAN, MATMA, POLCO, VERPE.

- Moderately Susceptible (MS) 70-84.9%

POLAV, POLPE, POROL, SINAR, STEME.

- Moderately Tolerant (MT) 50-69.9%

CIRAR, LAMPU, MATIN, PLAME, SONAR.

Nevertheless, only a very limited number of results is available in 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, nicosulfuron and mesotrione standard products. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

The Applicant presented no trials for the group of perennial dicotyledonous weeds and only one trial for AGRRE for the group of perennial monocotyledonous weeds for the maritime EPPO zone. Four trials were made for AGRRE for the north-eastern EPPO zone. They show a low effectiveness (67.8% (40.0-81.3)). These results are too insufficient for an evaluation of perennial weeds. More trials for the maritime

zone are required. With the existing data the target group for DE should be limited to annual monocotyledonous and annual dicotyledonous weeds (TTTMS, TTTDS).

The applicant wishes to cite the original registrant's data on rimsulfuron, nicosulfuron and mesotrione 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, nicosulfuron and mesotrione products. The spectrum of weeds should be checked with label claims on these reference products.

SUMMARY: Primary MX (product code: SHA 4307 A) is an early post-emergence herbicide in maize to control broadleaved, annual and perennial weeds. Weeds should be classified on the national level.
Crop: maize
Growth stage of the crop: BBCH 12-18
Product dose rate: 0.25 kg/ha 1x per crop
Water: 200-400 L/ha

ASSESSMENT FOR POLAND:
Applicant submitted in total 21 valid efficacy trials carried out on maize for Poland. 16 trials were performed in N-E (Poland) and 5 trials were carried out in neighbouring countries from Maritime EPPO zone (5: DE-3, CZ-2).

Considering trials with neighbouring countries, below we presented list of studied weed for at least 2 valid trials were presented:

- AGREE – 5 trials (CZ-1, PL-4) – major weed – submitted trials are sufficient. It can be concluded that AGREE is a moderately sensitive weed (1 trial PL–T, 3 trials PL–MS, 1 trial CZ– S). Average efficacy from all trials was: 80,65%.
- ECHCG – 16 trials (DE-1, CZ-3, PL-12) – major weed – submitted trials are sufficient. It can be concluded that ECHCG is a moderately sensitive weed (4 trials PL–S, 4 trials PL–MS, 1 trial PL–MT, 3 trials PL–T, 1 trial DE–3, 3 trials CZ–S). Average efficacy from all trials was: 80,3%.
- BRSNW – 2 trials (DE-1, PL-1) – major weed – due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label.
- CAPBP – 8 trials (DE-1, PL-7) – minor weed – submitted trials are sufficient. It can be concluded that CABPB is a susceptible weed (4 trials PL–S, 2 trials PL–MS, 1 trial Pl–MT, 1 trial DE–S). Average efficacy from all trials was: 92,95%.
- CHEAL – 16 trials (DE-2, CZ-3, PL-11) – major weed – submitted trials are sufficient. It can be concluded that CHEAL is a moderately susceptible weed (3 trials PL–S, 3 trials PL–MS, 2 trials PL–MT, 3 trials PL–T, 2 trials DE–S, 3 trials CZ–S). Average efficacy from all trials was: 85,2%. CHEAL was categorized as moderately susceptible weed, not susceptible, because its average efficacy from Polish trials was only 66,0%.
- GALAP – 2 trials (CZ-1, PL-1) – minor weed. It can be concluded that GALAP is a sensitive weed (1 trial PL–S, 1 trial CZ–S). Average efficacy from all trials was: 94.4%.
- LAMPU – 3 trials (CZ-1, PL-3) – minor weed – submitted trials are sufficient. It can be concluded that LAMPU is a moderately susceptible weed (1 trial PL–S, 1 trial PL–T, 1 trial CZ–S). Average efficacy from all trials was: 83,5%.
- MATIN – 5 trials (CZ-2, PL-3) – minor weed – submitted trials are sufficient. It can be concluded that MATIN is a moderately susceptible weed (2 trials PL–S, 1 trial PL–T, 2 trials CZ–S). Average efficacy from all trials was: 81,5%.
- POLCO – 10 trials (DE-1, CZ-3, PL-6) – major weed – submitted trials are sufficient. It can be concluded that POLCO is a moderately susceptible weed (4 trials PL–MS, 1 trial PL–MT, 1 trial PL–T, 1 trial DE–S, 3 trials CZ–S). Average efficacy from all trials was: 89,6%. POLCO was categorized as

moderately susceptible weed, not susceptible, because its average efficacy from Polish trials was 71,5%.

- STEME – 7 trials (DE-1, PL-6) – minor weed – submitted trials are sufficient. It can be concluded that STEME is a moderately susceptible weed (2 trials PL–S, 3 trials PL–MS, 1 trial PL–MT, 1 trial DE–S). Average efficacy from all trials was: 83,4%
- THLAR – 3 trials (CZ-3) – minor weed – submitted trials are sufficient. It can be concluded that THALR is a susceptible weed (in all trials).
- VERPE – 2 trials (CZ-1, PL-1) – minor weed – submitted trials are sufficient. It can be concluded that VERPE is a moderately susceptible weed (in 1 Polish trial –MS, in 1 trial CZ– S). Average efficacy from all trials was: 91,5%. VERPE was categorized as moderately susceptible weed, not susceptible, because its average efficacy from Polish trials was 83,0%
- VIOAR – 9 trials (DE-1, CZ-1, PL-7) – minor weed – submitted trials are sufficient. It can be concluded that VIOAR is a susceptible weed (3 trials PL–S, 2 trials PL–MS, 1 trial PL–MT, 1 trial PL–T, 1 trial DE–S, 1 trial CZ–S). Average efficacy from all trials was: 91,9%.
- APESV – 2 trials (PL-2) – minor weed – submitted trials are sufficient. It can be concluded that APESV is a moderately susceptible weed (1 trial PL-S, 1 trial PL-MS). Average efficacy from all trials was: 82,0%.
- POAAN – 2 trials (PL-2) – minor weed – submitted trials are sufficient. It can be concluded that POAAN is a moderately susceptible weed (in all trials). Average efficacy from all trials was: 79,5%
- SETVI – 2 trials (PL-2) – major weed – submitted trials are not sufficient (1 trial PL–S, 1 trial PL–MT). Due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label
- AMARE – 7 trials (PL-7) – major weed – submitted trials are sufficient. It can be concluded that AMARE is a moderately susceptible weed (3 trials PL–S, 3 trials PL–MS, 1 trial PL–MT). Average efficacy from all trials was: 84,7%.
- ARTVU – 2 trials (PL-2) – minor weed. It can be concluded that ARTVU is a moderately sensitive weed. Average efficacy from all trials was: 72.5%.
- GERPU – 2 trials (PL-2) - minor weed. It can be concluded that GERPU is a sensitive weed. Average efficacy from all trials was: 89.0%.
- PLAME – 2 trials (PL-2) – minor weed – submitted documentation is sufficient. It can be concluded that PLAME is a tolerant weed (1 trial PL–S, 1 trial PL–T). Average efficacy from all trials was: 58,0%.
- POLPE – 4 trials (PL-4) – major weed – submitted documentation is sufficient. It can be concluded that POLPE is a moderately tolerant weed (2 trials PL–MS, 2 trials PL–MT). Average efficacy from all trials was: 63,1%.
- SINAR – 2 trials (PL-2) – minor weed. It can be concluded that SINAR is a moderately sensitive weed. Average efficacy from all trials was: 80.0%.
- SOLNI – 2 trials (PL-2) – major weed – due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label.
- VERAG – 2 trials (PL-2) – minor weed – submitted documentation is sufficient. It can be concluded that VERAG is a susceptible weed (in all trials). Average efficacy from all trials was: 90,0%.

SUMMARY: Primary MX (product code: SHA 4307 A) is an early post-emergence herbicide in maize to control broadleaved, annual and perennial weeds.

Accepted weed in Polish label:

- *susceptible:* CAPBP, THLAR, VIOAR, VERAG, GALAP, GERPU
- *moderately susceptible:* AGREE, ECHCG, CHEAL, LAMPU, MATIN, POLCO, STEME, VERPE,

APESV, POAAN, AMARE, BRSNW, ARTVU, SINAR

- *moderately tolerant:* POLPE.

Crop: maize

Growth stage of the crop: BBCH 12-18

Product dose rate: 0.25 kg/ha 1x per crop

Water: 200-400 L/ha

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 analyzed 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).

Rimsulfuron: So far, 17 cases of resistance with rimsulfuron in a range of grasses and broadleaved weeds have been reported worldwide. Of these, five have been reported from Europe on different weed species, i.e. two grass species (ECHOR and SORHA) and three broadleaved species (GASPA, KCHSC and SONAS). The active substance is therefore classified as having a high inherent risk.

Nicosulfuron: So far, ~~52~~ 56 cases of resistance with nicosulfuron in a range of grasses and broadleaved weeds have been reported worldwide. Of these, ~~fifteen~~ sixteen has been reported from Europe on different weed species, i.e. five grass species (DIGSA, ECHCG, ECHOR, SETVI and SORHA) and three broadleaved species (AMARE, KCHSC and STEME). The active substance is therefore classified as having a high inherent risk.

Mesotrione: So far, ~~10~~ 14 cases of resistance in two dicotyledonous weed species (both *Amaranthus* spp.) have been reported to have developed resistance to mesotrione. ~~All~~ Most cases have been reported from the United States of America. Two cases reported in Australia against *Raphanus raphanistrum* and one case in Canada against *Amaranthus tuberculatus.* The active substance is therefore classified as having a low inherent risk.

The evaluation of the agronomic risk concludes, that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG bears a low risk of resistance.

The Registration of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is endorsed.

The herbicide Primary MX contains two herbicide modes of action to counteract herbicide resistance evolution. However, the active mesotrione is very limited in its control of grass weeds. So, nicosulfuron and rimsulfuron are the main actives against these weeds. Some of the grass weeds are highly resistance prone and have already evolved resistance to ALS herbicides further enhancing the resistance risk.

The product Primary MX, containing mesotrione, nicosulfuron and rimsulfuron, is a good strategy to prevent the development and spread of resistant biotypes of *Echinochloa cruss-galli*, based on the use of 2 different mode of action. To responsibly manage and maintain the activity of the active substances in Primary MX, it is recommended that resistance management strategies are applied. The commercial

[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.

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**.** It would be helpful to follow resistance evolution progress by data on the variation of sensitivity potential based on herbicide resistance surveys.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

In the evaluation process the fact that the active ingredients – mesotrione, rimsulfuron and nicosulfuron are used in many plant protection products and has been commonly used in crop protection for many years were taken into consideration.

The Applicant submitted in total 20 selectivity studies conducted in different seasons (2016, 2017 and 2019) on herbicide (Primary MX) containing these three active substances.

The selectivity evaluation of the herbicide is to be performed according to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction.

Phytotoxicity assessment was carried out with the use of different cultivars (commercially grown varieties). Dosages higher than recommended was studied in all trials. The applicant first requested that a dose of 0.33 kg/ha should be recommended for use. But due to environmental constraints it had to be reduced to a dose of 0.25 kg/ha. Therefore, higher doses, i.e., 1.32 N (0.33 kg/ha) and 2.64 N were studied during trials. In the opinion, of Evaluator these trials are valid and acceptable for assessment. Experimental details and assessments methods were in accordance with EPPO standards. Detailed information's are presented by Applicant in the tables above.

The trials were conducted in the Maritime zone (9; Germany (2), N-France (3), Czech Republic (2) and United Kingdom (2)); MED zone (5; Spain (2), Italy (2), South France (1)) and N-E zone (6; Poland) to evaluate the crop safeties of Primary MX in maize crops.
In most of the assessments no phytotoxicity symptoms were observed for any tested dosage for all tested maize varieties. In some of the trials the trial phytotoxic symptoms like stunting, lessening, slight chlorosis was visible. The symptoms proved to be short and quickly disappeared. In addition, the crop developed normally and did not involve a loss in yield at harvest. Perhaps at the recommended dose, which was not tested, these adverse effects would not appear. However, because they cannot be excluded, the following warning should be included in the product label: **Phytotoxicity cannot be excluded. Sensitivity of varieties should be consulted with the authorization holder.**

Effects on yield and quality

Twenty selectivity trials were conducted between 2016 and 2019 to evaluate the effect of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG on yield of maize. In selectivity trials conducted in maize, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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 Maritime zone (9), the North-east zone (6) or the Mediterranean zone (5), as defined by EPPO Standard PP1/241(1).

In all trials no detrimental effect on the yield was recorded at doses higher than recommended. The applicant first requested that a dose of 0.33 kg/ha should be recommended for use. But due to environmental constraints it had to be reduced to a dose of 0.25 kg/ha. Therefore, higher doses, i.e., 1.32 N (0.33 kg/ha) and 2.64 N (0,66 kg/ha) were studied during trials. In the opinion, of Evaluator these trials are valid and

acceptable for assessment. Application of Primary MX provided a yield like the untreated plots and to those treated with the reference products. No statistical differences were observed between untreated and treated plots and between the tested product and the standard product.

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.

In the label following entry should be applied:

Impact on succeeding crops.

Label recommendation – Succeeding crops

Replacement crop

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 3% + Nicosulfuron 12% + Mesotrione 36% 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 3% + Nicosulfuron 12% + Mesotrione 36% 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 3% + Nicosulfuron 12% + Mesotrione 36% 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 20 meters and nozzles giving a drift reduction of 50% 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 3% + Nicosulfuron 12% +Mesotrione 36% WG in food, feed of plant and animal origin, soil, water and air and in the formulation Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG are available.

zRMS: noticed data gaps are (post registration requirement):

- ILV for Nicosulfuron for drinking water.
- ILV for Rimsulfuron for drinking water

3.4.1 Analytical method for the formulation

The analytical determination of Rimsulfuron, Nicosulfuron and Mesotrione content has been carried out by HPLC-UV. Quantitative analysis of Rimsulfuron, Nicosulfuron and Mesotrione was based on external calibration using standards.
The method for the determination of Rimsulfuron, Nicosulfuron and Mesotrione in Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is acceptable and validated according the requirements SANCO 3030/99 rev. 4.

		Rimsulfuron	**Nicosulfuron**	**Mesotrione**
Author(s), year		Michalec-Minch, 2018		
Principle of method		The active ingredient content of Rimsulfuron, Nicosulfuron and Mesotrione is determined by high performance liquid chromatography and UV detection at 220 nm.		
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)		Linearity range: 23.7 – 35.5 mg/L Calibration equotion y = 0.3058x -0.1627 Correlation coefficient R = 0.998	Linearity range: 95.0 – 142.5 mg/l Calibration equotion y = 0.2978x -1.6402 Correlation coefficient R = 0.999	Linearity range: 276.9 – 415.4 mg/L Calibration equotion y = 0.4974x -0.4525 Correlation coefficient R = 0.998
Precision – Repeatability Mean n = 5 (%RSD)		RSD = 0.17% Horwitz equation RSD = 0.86% RSD_r = 2.27%	RSD = 0.08% Horwitz equation RSD = 1.53% RSD_r = 1.84%	RSD = 0.28% Horwitz equation RSD = 0.90% RSD_r = 1.56%
Accuracy n = 7 (% Recovery)	Analyte conc.80%	Recovery = 97.7%	Recovery = 98.2%	Recovery = 101.6%
	Analyte conc.100%	Recovery = 101.0%	Recovery = 100.9%	Recovery = 101.6%
	Analyte conc.120%	Recovery = 99.7%	Recovery = 98.5%	Recovery = 101.7%
Interference/ Specificity		No interference	No interference	No interference
Comment		Accepted	Accepted	Accepted

Relevant impurities:
The study to determine the concentration of relevant impurities **R287431, R287432** and **1,2-dichloroethane** from mesotrione in Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was provided . Results are acceptable and validated according the requirements SANCO 3030/99 rev. 4.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are (~~post registration requirement~~):

- ILV for Nicosulfuron for drinking water.
- ~~ILV for Rimsulfuron for drinking water~~

Following new methods were provided by the Applicant:
- Methods for high starch content (dry) matrix (primary and ILV);
- Primary and ILV methods for drinking water (Rimsulfuron).

Noticed data gaps are:
Rimsulfuron
The proposed ILV for dry matrices by Rubino, (2019) contains a different extraction step (no addition of water and sodium chloride) and an additional clean-up step (dispersive SPE with C18 material) compared to the proposed primary method by Markowicz (2019). According to table 3 of SANTE/2020/12830 this is considered as an unacceptable alteration of the ILV, resulting in its unacceptability. Therefore, ILV for dry matrices is required.
Nicosulfuron
ILV for drinking water is required

The above-mentioned data gaps should be completed before registration.

Commodity/crop	Supported/ Not supported
Dry commodities / Maize	Supported

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 0.05 mg/kg	HPLC-UV HPLC-UV	LaRochelle, 1989 Amoo, 1996
	ILV	0.05 mg/kg	HPLC-UV	Clayton, 2001
	Confirmatory (if required)	0.01 mg/kg	LC-MS/MS	Fulton, 2001
High acid content	Primary	-	-	-
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
High oil content	Primary	-	-	-
	ILV	-	-	-
	Confirmatory (if required)	-	-	-
High	Primary	0.05 mg/kg	HPLC-UV	LaRochelle, 1989

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**
protein/high starch content (dry)		0.05 mg/kg	HPLC-UV	Amoo, 1996
	ILV	0.05 mg/kg	HPLC-UV	Clayton, 2001
	Confirmatory (if required)	0.01mg/kg	LC-MS/MS	Fulton, 2001
	Primary	0.01 mg/kg	LC-MS/MS	KCP 5.2.1. A. Markowicz, 2019 Report No. 19/FSL/15/1A
	~~ILV~~	~~0.01 mg/kg~~	~~LC-MS~~	~~KCP 5.2.1.1~~ ~~M. Rubino, 2019~~ ~~Report No. 19.500341.0001~~
	Confirmatory (if required)	-	-	The applied LC-MS/MS is highly selective method and 2 transitions were monitored, therefore no other confirmatory method is required.
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 0.05 µg/kg	LC-MS/MS LC-MS/MS	Connolly, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required) Hill and Stry, 2001 (This method is specific, validated on two mass transitions, so confirmatory is not required)
	Confirmatory	-	-	-
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 0.05 µg/L	HPLC-UV LC-MS/MS	Powley and de Bernard, 1996 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
	Primary	0.05 µg/L	LC/MS	KCP 5.2.2

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**
				M. Rubino, 2019 Report No. 19.500341.0007
	ILV	0.05 µg/L	LC-MS/MS	KCP 5.2.2.1 M. Zarębska, 2020 Report No. 30/2020
	Confirmatory	-	-	The applied LC-MS is highly selective method and 2 transitions were monitored, therefore no other confirmatory method is required.
Surface water	Primary	0.1µg/L 0.05 µg/L	HPLC-UV LC-MS/MS	Powley and de Bernard, 1996 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 (This method is specific, validated on two mass transitions, so confirmatory is not required)
	Confirmatory	-	-	-

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 0.01 mg/kg	HPLC-UV HPLC-MS/MS	Huber, 1996a Wolf, 2000
	ILV	0.01 mg/kg	HPLC-MS/MS	Ginzburg, 2000
	Confirmatory (if required)	0.05mg/kg	GC/MS, LC-MS	Mirbach, 1998

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 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 0.01 mg/kg	HPLC-UV HPLC-MS/MS	Huber, 1996a 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	0.02 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	0.02 mg/kg	HPLC-UV	Huber, 1996b
	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 0.05 µg/L	HPLC-UV HPLC-MS/MS	Schulz and Ullrich-Mitzel, 1995a 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.
	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

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**
	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 1.2 µg/m^3 air	HPLC-UV HPLC-UV	Schulz and Ullrich-Mitzel, 1995b Wais, 2000c
	Confirmatory	-	-	-

3.4.2.3 Mesotrione and ist metabolites

Component of residue definition: Mesotrione				
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 0.01 mg/kg 0.01 mg/kg	HPLC-FL GC-MS ChEChERS LC-MS/MS	Alferness, P.L, 1996a, TMR0643B. (DAR 2003) Alferness, P.L., 1999, TMR0882B (Modification of TMR0643B) (RAR 2015) Meyers, T.J, et al, 1997, TMR0689B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	HPLC-FL LC-MS/MS	James, J.W., 1999, RR 99-062B EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	0.02 mg/kg	HPLC-FL	Bolygo, E., 1996, RJ2149B (DAR 2003)
High acid content	Primary	0.01 mg/kg	ChEChERS LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	-	-	-
High oil content	Primary	0.01 mg/kg	ChEChERS LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	-	-	-

Component of residue definition: Mesotrione				
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	0.03mg/kg 0.01 mg/kg 0.01 mg/kg	HPLC-FL GC-MS ChEChERS LC-MS/MS	Alferness, P.L, 1996a, TMR0643B. (DAR 2003) Alferness, P.L., 1999, TMR0882B Meyers, T.J, et al, 1997, TMR0689B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	HPLC-FL LC-MS/MS	James, J.W., 1999, RR 99-062B EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	0.03mg/kg	HPLC-FL	Bolygo, E., 1996, RJ2149B (DAR 2003)
Component of residue definition: Mesotrione				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Milk	Primary	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Meyers *et al*., 1998, TMR0739B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	0.01 mg/kg	GC/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003)
Eggs	Primary	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Meyers *et al*., 1998, TMR0739B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	0.01 mg/kg	GC/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003)
Muscle	Primary	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Meyers *et al*., 1998, TMR0739B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003) EFSA Journal 2016; 14 (3) : 4419

Component of residue definition: Mesotrione				
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	GC/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003)
Fat	Primary	0.01 mg/kg	QuEChERS LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg	QuEChERS LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	-	-	-
Kidney, liver	Primary	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Meyers *et al*., 1998, TMR0739B. (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	ILV	0.01 mg/kg 0.01 mg/kg	GC/MS QuEChERS LC-MS/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003) EFSA Journal 2016; 14 (3) : 4419
	Confirmatory (if required)	0.01 mg/kg	GC/MS	Kahn, B., 1998, RR98-025B (ILV of TMR0739B) (DAR 2003)
Component of residue definition: Mesotrione				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Soil	Primary	0.002 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	0.005 mg/kg	LC-FL	Nagra, B.S. et al., 1997a, RJ2454B
Component of residue definition: MNBA				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Soil	Primary	0.002 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	0.005 mg/kg	LC-FL	Nagra, B.S. et al., 1997a, RJ2454B
Component of residue definition: AMBA				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (*i.e.* GC-MS or HPLC-UV)**	**Author(s), year / missing**
Soil	Primary	0.002 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	0.005 mg/kg	LC-FL	Nagra, B.S. et al., 1997a, RJ2454B

Component of residue definition: Mesotrione				
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	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.05 µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419 According to SANCO/825/00 rev. 8.1, ILV is not required.
	Confirmatory	-	-	-
Surface water	Primary	0.05 µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	-	-	-
Component of residue definition: MNBA				
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	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.05µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419 According to SANCO/825/00 rev. 8.1, ILV is not required.
	Confirmatory	-	-	-
Surface water	Primary	0.05 µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	-	-	-
Component of residue definition: AMBA				
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	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	ILV	0.05µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419 According to SANCO/825/00 rev. 8.1, ILV is not required.
	Confirmatory	-	-	-
Surface water	Primary	0.05 µg/L	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	-	-	-
Component of residue definition: Mesotrione				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or HPLC-UV)**	**Author(s), year / missing**
Air	Primary	0.45 µg/m^3	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	-	-	-

Component of residue definition: Mesotrione				
Matrix type	**Method type**	**Method LOQ**	**Principle of method (i.e. GC-MS or**	**Author(s), year / missing**

			HPLC-UV)	
Body fluids and tissues (if appropriate)	Primary	0.01 mg/kg	LC-MS/MS	EFSA Journal 2016; 14 (3) : 4419
	Confirmatory	-	-	-

3.5 Mammalian toxicology (Part B, Section 6)

The assessment of all acute toxicological properties of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG are derived from the classification of the active compounds and co-formulants.

3.5.1 Acute toxicity

Classification for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% 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.

Repr.2/H361d, STOT RE2 /H373 (eyes, nervous system)
and
Contains formaldehyde. May produce an allergic reaction EUH208
Contains 2-(Aminosulfonyl)-N,N-dimethyl-3-pyridinecarboxamide. May produce an allergic reaction [EUH208]

3.5.2 Operator exposure

Operator exposure to PRIMARY MX was not evaluated as part of the EU review of Rimsulfuron, Nicosulfuron and Mesotrione 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, Nicosulfuron and Mesotrione 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 with the use of working clothing and gloves during mixing/loading and application.

Implication for labelling: Gloves during Mixing/Loading and Application.

zRMS: Acceptable

3.5.3 Worker exposure

Worker exposure to PRIMARY MX was not evaluated as part of the EU review of Rimsulfuron, Nicosulfuron and Mesotrione 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, Nicosulfuron and Mesotrione using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

Conclusion:
Worker activities are not relevant when considering maize on which mechanical procedures are mainly

used. In case of necessity for worker to re-enter maize treated with PRIMARY MX, the risk of exposure is considered to be negligible.

3.5.4 Bystander and resident exposure

Bystander and resident exposure to PRIMARY MX was not evaluated as part of the EU review of Rimsulfuron, Nicosulfuron and Mesotrione 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, Nicosulfuron and Mesotrione using EFSA AOEM Model and default dermal absorption value (10% concentrate and 50% dilution).

Conclusion: According to the EFSA AOEM Model, when a 5 m buffer zone is considered, the risk for residents and bystanders can be considered as acceptable.

Implication for labelling: 5-m buffer zone

zRMS: Acceptable

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

The preparation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is composed of Rimsulfuron, Nicosulfuron and Mesotrione.

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	EFSA Journal 2018;16(5):5258	~~20006~~ 2018	~~Not necessary – not required~~ 1.7	Developmental study in rabbit	100
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		
Mesotrione					
ADI	SANTE/11654/2016	2016	0.01	Mouse multigeneration	200
ARfD		2016	0.02	Mouse multigeneration	100

Unprotected data were sufficient to support all the uses of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG.

An acceptable acute and chronic risk for consumer is expected after the use of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG accordingly to the intended GAP.

3.6.1 Residues

Critical GAP: maize; CEU; 1 application at BBCH 12-18; application rate per treatment: 0.0075 rimsulfuron + 0.03 nicosulfuron + 0.09 mesotrione kg as/ha

Rimsulfuron

Storage stability

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Rimsulfuron is stable in maize forage and grain for 24 months, when stored frozen at approximately –20°C (EFSA 2005, EFSA Journal 2018;16(5):5258)

Metabolism in plants and animals

Metabolism in plants and livestock data was assessed during the EU review of rimsulfuron.

The residue definition for plant commodities both for risk assessment and monitoring is set as rimsulfuron.

Data gap was set to address nature and/or magnitude of residue in rotational crops (EFSA Journal 2018;16(5):5258)

Animal residue definitions: "*not appropriate to propose a residue definition because intake of residues by animals from primary crops is not significant. A residue definition for animals might be needed pending the outcome of studies on nature and/or magnitude of residues in rotational crops* (EFSA Journal 2018;16(5):5258)"

Renewal of rimsulfuron is still pending the inclusion document by the Standing Committee, therefore when the document is published the evaluation of this product will have to be re-viewed.

Magnitude of residues in plants

Proposed GAP is less critical than EU GAP (EU GAP: max. 20 g a.s./ha).

Applicant refers to data available in Draft Assessment Report, Germany 2005. Residue trials complying with the EU GAPs but with an LOQ of 0.05 mg/kg, nevertheless, considering the metabolism studies that showed a no residue situation at exaggerated rates, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg.

New overdosed study on the magnitude of residue have been submitted by the applicant in the framework of this application to confirm this state.

GAP of one new trial from NEU: 1 x 0.060 kg as/ha; BBCH 12

Method of analysis: LC/MS/MS, LOQ: 0.001 mg/kg, storage time: 76 days. Trial is accepted. Residues from this trial: 1 x <0.001 mg/kg

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

The uses are considered acceptable.

Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required.

A residue definition for animals is not needed.

Magnitude of residues in processed commodities

As residues of Rimsulfuron are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed com-

modities are therefore not proposed.

Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application and no required.

After the end of the of the renewal process "magnitude of residues in representative succeeding crops" should be re-viewed.

Estimation of exposure through diet and other means

The proposed uses of rimsulfuron in the formulation Primary MX do not represent unacceptable chronic risks for the consumer.

Note:

Renewal of rimsulfuron is still pending the inclusion document by the Standing Committee, therefore when the document is published, the evaluation of this product will have to be re-viewed.

Nicosulfuron

Storage stability

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

The results demonstrate that residues are stable in maize grain and whole plant for 9 months.

Metabolism in plants and animals

Metabolism in plants and livestock data was provided during the EU review of nicosulfuron.

The residue definition for plant commodities both for risk assessment and monitoring is set as nicosulfuron.

Magnitude of residues in plants

Proposed GAP is less critical than EU GAP (EU GAP: max. 60 g a.s./ha).

The number of trials (EU unprotected trials) is sufficient as to support the use of nicosulfuron in maize according to the proposed GAP in Nouthern Zone.

The residues arising from the proposed use will not exceed the MRLs for maize grain set at 0.01 mg/kg (Reg. (EU) No 617/2014).

Use is accepted.

Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required.

Magnitude of residues in processed commodities

As residues of nicosulfuron are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application and no required.

Estimation of exposure through diet and other means

The proposed uses of Primary MX do not represent unacceptable chronic risks for the consumer.

Mesotrione

Storage stability

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Mesotrione is considered to be stable under freezer storage at -18ºC±5ºC for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18ºC±5ºC of MNBA in maize grain and forage was demonstrated for at least 42 months.

Metabolism in plants and animals

Metabolism in plants and livestock data was provided during the EU review of mesotrione.

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) EFSA journal 2016;14(3):4419

Plant residue definition for risk assessment Food commodities: Mesotrione (cereals and pulses/oilseeds only)

Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. EFSA journal 2016;14(3):4419

Magnitude of residues in plants

Proposed GAP is less critical than EU GAP (EU GAP: max. 120 to 150 g as/ha; proposed: 90 g as/ha)

Sufficient unprotected data were submitted and evaluated in DAR and RAR, and considered enough to support the intended use in maize in NEU. Unprotected data are accepted in RAR.

Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required.

Magnitude of residues in processed commodities

As residues of nicosulfuron are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application and no required.

Estimation of exposure through diet and other means

The proposed uses of Primary MX do not represent unacceptable chronic risks for the consumer. EFSA PRIMo rev. 3.1 calculations for rimsulfuron and PRIMo rev.3.0 for nicosulfuron and for mesotrione (provided by the applicant) are accepted. Due to the large margin of safety for the consumer, recalculations using PRIMo rev. 3.1 are not necessary.

3.6.2 Consumer exposure

Rimsulfuron consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant.
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Unprocessed commodities Based on adults Maize/Corn: 0.00% Based on children Maize/Corn: 0.00%

	Processed commodities Based on adults Maize/oil: 0.00% Based on children: Maize/oil: 0.00% Maize/processed (not specified): 0.00%
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

Calculation of acute risk assessment for uses under evaluation using ARfD values from EFSA 2018 was conducted. The proposed uses of rimsulfuron in the formulation Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 12% do not represent unacceptable acute risks for the consumer.

Nicosulfuron consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.0	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)	-

Mesotrione consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev. 3.0	12% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not relevant.
IESTI (% ARfD) according to EFSA PRIMo rev. 3.0	**Unprocessed commodities:** Maize/corn: 0.3% (based on children) Maize/corn: 0.1% (based on adults) **Processed** commodities Maize/oil: 1% (based on children) Maize/oil: 0.6% (based on adults)
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Primary MX do not represent unacceptable chronic risks for the consumer. EFSA PRIMo rev. 3.1 calculations for rimsulfuron and PRIMo rev.3.0 for nicosulfuron and for mesotrione (provided by the applicant) are accepted. Due to the large margin of safety for the consumer, recalculations using PRIMo rev. 3.1 are not necessary.

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

Concentration of Rimsulfuron, Nicosulfuron and Mesotrione 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 Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG

Crop	Application rate (kg a.i./ha)	Application method	Max. number of applications	Min. application interval (days)	Application timing
Maize	Rimsulfuron: 0.0075 Nicosulfuron: 0.03 Mesotrione: 0.09	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), with Nicosulfuron and its relevant metabolites HMUD, ADMP, ASDM, AUSN and UCSN using the EU agreed endpoints (EFSA Scientific report (2007) 120, 1-91) and with Mesotrione and its relevant metabolites MNBA and AMBA using the EU agreed endpoints (EFSA Journal 2016;14(3):4419).

Maximum PEC_{soil} value for Rimsulfuron was 0.008 mg/kg, 0.003 mg/kg for IN-70941, 0.001 mg/kg for IN-70942, 0.001 mg/kg for IN-E9260 and < 0.001 mg/kg for IN-J0290, following the highest application rate of 7.5 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/ha.

Maximum PEC_{soil} value for Mesotrione was 0.090 mg/kg, 0.037 mg/kg for MNBA and 0.006 mg/kg for AMBA, following the highest application rate of 90 g of Mesotrione/ha.

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, for Nicosulfuron and its ~~relevant~~ metabolites HMUD ADMP, ASDM, AUSN, UCSN and MU-466 and for Mesotrione and its ~~relevant~~ metabolites MNBA and AMBA.

The Rimsulfuron, IN-70942 and IN-J0290 PECgw were below 0.1 µg/L. However, the non-relevant metabolites IN-70941 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 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.

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 PECgw of Mesotrione, MNBA and AMBA were below 0.1 µg/L, although the PECgw of toxicological non-relevant metabolite MNBA in Hamburg scenario was 0.102 ug/L for FOCUS PELMO model and pH specific endpoints. However, using the worst case endpoints the PECgw for MNBA in Hamburg was 0.001 µg/L for the same FOCUS model.

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, of Nicosulfuron and its relevant metabolites HMUD, ASDM, AUSN, UCSN, ADMP and DUDN and of Mesotrione and its relevant metabolites MNBA, AMBA and SYN546974 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.

Step 4:
The VFSMOD calculations have been done as refinement for all R1 scenarios and are acceptable.

FOCUS Step 4

Table 3.7-4 bis bis: Global maximum PEC_{sw} values for Rimsulfuron, following single application of COREY PRIMARY to maize according to the southern central EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Rimsulfuron
Nozzle reduction	Vegetative strip (m)	5
	No spray buffer (m)	5
None	**R1 stream**	0.011

Due to requirements on B9 by the ecotox expert VFSMOD calculations have been done as refinement for all R scenarios, with the exception of R1 pond scenario. The results are performed for PL and CZ and given below.

Table 3.7-12 bis: Global maximum PEC_{sw} values for Nicosulfuron, following single application of COREY to maize according to the southern EU zone GAP according to surface water VFSMOD Step 4

PEC_{sw} (µg/L)	Scenario	VFSMOD STEP 4 Nicosulfuron
Nozzle reduction	Vegetative strip (m)	5
	No spray buffer (m)	5
None	**R1 stream**	0.045

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.

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

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

- Birds:

Risk assessment for birds concludes in a low acute and long-term risk as well as for drinking water exposures and secondary poisoning. Therefore, no unacceptable acute and long-term risks are expected for birds. According to results, no unacceptable acute and long-term risk due to combined exposure are obtained in according to the proposed GAP.

- Mammals:

According to the screening assessment for maize, the TER_a and TER_{lt} values for the active substances Rimsulfuron and Nicosulfuron are greater than the Annex VI trigger of 10 and 5, respectively. After screening and first-tier assessment for active substance Mesotrione, the TER_a value is greater than the Annex VI trigger of 10 whereas TER_{lt} values are lower than the Annex VI trigger of 5 for the use on maize, indicating that PRIMARY MX presents an unacceptable long-term risk to mammals. A refinement of the risk was done by selecting the two focal species European brown hare and wood mouse, using a PT value of 0.139 for wood mouse and 0.62 for hare, refined TWA for maize for 90 g mesotrione/ha;. Therefore, there is no unacceptable acute and long-term risk for mammals as well as for drinking water expo-

sures and secondary poisoning. According to results, no unacceptable acute and long-term risk due to combined exposure are obtained according to the proposed GAP.

3.8.2 Effects on aquatic species

Rimsulfuron

All PEC/RAC values for Rimsulfuron and its metabolite are below the trigger value of 1 at step 3,4, indicating that Rimsulfuron poses a low risk to aquatic organisms, as well as for IN-70941, IN-70942 and IN-E9260 metabolite.

Table 3.8-5(3): Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Rimsulfuron based on VFSMOD Step 4 calculations and toxicity data for higher plant with mitigation of spray drift and run-off for the use of PRIMARY MX in maize

Intended use		**Maize**
Active substance		Rimsulfuron
Application rate (g/ha)		1 x 9.9
Nozzle reduction	**Vegetated filter strip (m)**	5
	No-spray buffer (m)	5
None	R1 stream	0.011
RAC (µg/L) 0.46		**PEC/RAC ratio**
None	R1 stream	0.024

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

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

- PEC/RAC calculated on the basis of the lowest E_yC_{50} with 1.7 µg a.s./L
- PEC/RAC calculated on the basis on RAC≤ 0.74 µg s.a/L

It should be noted that zRMS did not accept the risk assessment based on RAC of 0.74 µg s.a./L value proposed by the applicant.
In zRMS's opinion this value is not appropriate to replace the agreed E_rC_{50} of 2.7 µg s.a./L value included in the LoEP for nicosulfuron.
For this reason PEC/RAC calculations based on E_rC_{50} of 2.7 µg s.a/L (RAC-0.27 µg s.a/L) for aquatic macrophytes, agreed at EU level was accepted.
On the basis of the standard risk assessment performed in line with EFSA aquatic guidance (2013) and RAC=0.27 µg s.a./L following conclusions could be derived:

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

The applicant provided also further refinement of the risk assessment using PEC_{sw} VFsmod calculations. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies followed using VFS_{MOD} Global maximum PECsw values.
Hence, based on the results of the risk assessment using VFSmod calculations for R scenarios, the 5 m no-spray buffer zone and a 5 m vegetative buffer strip is still required for R1 scenario.

Finally, for Poland 5 m no-spray buffer zone and a 5 m vegetative buffer strip should be applied to surface water bodies

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

Mesotrione

For the intended uses on maize, calculated PEC/RAC ratios ~~did not~~ indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for higher plant as characterised by an EC_{50} for *Lemna gibba* of 7.7 in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios relevant for Poland. For MNBA, AMBA and SYN546974 metabolites, all PEC/RAC values are below the trigger value of 1 at step 1-2. Therefore, no further assessment is necessary.

3.8.3 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to PRIMARY MX is expected according to the proposed intended uses. according to Reg 284/2009 the chronic tests for adult bees and larvae should be submitted by the applicant when EU GD for Bees, 2013 will be applied to 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 PRIMARY MX.

3.8.5 Effects on soil organisms

The TER values for earthworms and other soil macro- and mesofauna for PRIMARY MX were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that active substance Rimsulfuron, Nicosulfuron and Mesotrione do not pose acute and chronic risk to earth-worms and other soil macro- and mesofauna. In addition, tisk assessments conducted with relevant PECsoil for the active substance Rimsulfuron, Nicosulfuron and Mesotrione indicate a low risk to soil macro- and microorganisms when applied according to the proposed use rates.

3.8.6 Effects on non-target terrestrial plants

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for Rimsulfuron, Nicosulfuron and Mesotrione shows that the Annex VI trigger value of 5 is exceeded. Therefore, mitigation measures are needed. When there is 90% nozzle reduction OR 3m buffer zone with 50% nozzle reduction OR 10 m buffer zone, PRIMARY MX poses a low risk to non-target plants when applied according to the proposed use rates.

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

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	**End point**
Activated sludge	--
Pseudomonas putida	Nicosulfuron EC_{50} > 250 mg as/L (no reported effects) ASDM, AUSN, UCSN, MU-466, HMUD > 100 mg metabolite/L (no significant inhibition)

Mesotrione:
Effects on biological methods for sewage treatment

Test type/organism	**End point**
Activated sludge	$EC_{50} \geq 160$ mg as/L
Pseudomonas sp.	NOEC = 100 mg as/L

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites IN-70942, IN-J290, ADMP and AMBA 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-E9260, HMUD, AUSN, UCSN, ASDM, MU-466 and MNBA 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 PRIMARY MX. 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 PRIMARY MX;
- 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 PRIMARY MX's label. Despite no economical evaluation has been carried out because of lack of reliable data, but PRIMARY MX will be marketed with competitive price to many alternatives.

As conclusion of this comparative assessment, the plant protection product PRIMARY MX 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

Sekcja skuteczności:
Wprowadzono do etykiety informacje nt. następstwa roślin oraz strategii przeciwdziałania rozwojowi odporności. Zaktualizowano listę zaakceptowanych gatunków chwastów zgodną z oceną. Wprowadzono informację, iż nie można wykluczyć fitotoksycznego efektu na kukurydzę.

Sekcja toksykologii:
Dodać H361d, H373, P260, P280, P308+P313, P314

Sekcja pozostałości: brak uwag

Sekcja los i zachowanie w środowisku: brak uwag

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.

PRIMARY MX (SHA 4307 A)

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
Mezotrion (substancja z grupy trójketonów) - 360 **g/kg** (36,0 %)
Nikosulfuron (substancja z grupy pochodnych sulfonylomocznika) - 120 **g/kg** (12,0 %)
Rimsulfuron (substancja z grupy pochodnych sulfonylomocznika) - 30 **g/kg** (3,0 %)

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

UWAGA

H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki
H373	Może powodować uszkodzenie narządów (oczy, system nerwowy) poprzez długotrwałe lub powtarzane narażenie
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.
EUH208	Zawiera formaldehyd. Może powodować wystąpienie reakcji alergicznej
EUH208	Zawiera 2-(Aminosulfonyl)-N,N-dimethyl-3-pyridinecarboxamide. Może powodować wystąpienie reakcji alergicznej
P260	Nie wdychać rozpylonej cieczy.
~~P273~~	~~Nie wypuszczać do środowiska.~~
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P308+P313	W przypadku narażenia lub styczności: Zasięgnąć porady/ zgłosić się pod opiekę lekarza.
P314	W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

OPIS DZIAŁANIA

PRIMARY MX jest selektywnym herbicydem o działaniu systemicznym, w formie granul do sporządzania zawiesiny wodnej. Przeznaczony jest do zwalczania jednorocznych chwastów jednoliściennych oraz chwastów dwuliściennych w kukurydzy. PRIMARY MX zawiera trzy substancje czynne: mezotrion, nikosulfuron oraz rimsulfuron. Środek pobierany jest głównie przez liście chwastów. Pierwsze objawy działania środka są widoczne wkrótce po użyciu, po czym następuje stopniowe przebarwianie się roślin. Najskuteczniej zwalcza chwasty we wczesnych fazach rozwojowych.
Środek PRIMARY MX przeznaczony jest do stosowania przy użyciu opryskiwaczy polowych.

DZIAŁANIE NA CHWASTY

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

STOSOWANIE ŚRODKA

Kukurydza

Chwasty liściaste i trawiaste

Maksymalna dawka dla jednorazowego zastosowania: ~~0,33~~ 0,25 kg/ha

Zalecana dawka dla jednorazowego zastosowania: ~~0,33~~ 0,25 kg/ha

Liczba zabiegów: 1

Termin stosowania środka: stosować po wschodach chwastów, od początku fazy 2. liścia do fazy 8. liści kukurydzy.

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.

Fitotoksyczność nie może być wykluczona. Wrażliwość odmian należy skonsultować z posiadaczem zezwolenia.

Aby zminimalizować ryzyko wystąpienia i rozwoju odporności chwastów należy postępować zgodnie z Dobrą Praktyką Rolniczą:

− ograniczyć stosowanie środków zawierających substancje czynne o podobnym mechanizmie działania**,**

− jeśli stwierdzono lub istnieje podejrzenie, że na danym polu występuje gatunek chwastu odporny na substancje czynne zawarte w PRIMARY MX, w celu zapobieżenia dalszej selekcji form odpornych nie należy stosować na tym polu środka chwastobójczego zawierającego substancję czynne o tym samym mechanizmie działania,

− stosować na tym samym polu przemiennie herbicydy o różnym mechanizmie działania,

− ściśle przestrzegać zaleceń umieszczonych na etykiecie stosowania środka, w tym nie stosować dawek niższych od zalecanych do zwalczania tych chwastów.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Odmierzoną ilość środka wlać 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 wlaniu 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.

NASTĘPSTWO ROŚLIN

Uprawa zastępcza W przypadku konieczności zaniechania uprawy po zastosowaniu na wiosnę, kukurydzę pastewną i ziarnową można wysiać ponownie bezpośrednio po orce.

Uprawy rotacyjne

Jesień Pszenica ozima i jęczmień ozimy mogą być stosowane po uprawie kukurydzy traktowanej PRIMARY MX pod warunkiem, że gleba została zaorana na głębokość 15 cm.

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

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.
Zachować strefę buforową 5 m

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 5 m od zbiorników i cieków wodnych.

SPe3
W celu ochrony roślin niebędących obiektem zwalczania konieczne jest zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% od terenów nieużytkowanych rolniczo LUB określenie strefy buforowej w odległości ~~5~~ 3 m od terenów nieużytkowanych rolniczo z jednoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o ~~75~~ 50%.
LUB
określenie strefy buforowej w odległości 10 m od terenów nieużytkowanych rolniczo

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Nie dotyczy

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

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1, KCP 2.2.2, KCP 2.3.1, KCP 2.3.2, KCP 2.3.3, KCP 2.4.1, KCP 2.4.2, KCP 2.6.2, KCP 2.7.1, KCP 2.7.3, KCP 2.8.1, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.4, KCP 2.8.5.1.1, KCP 2.8.5.1.2, KCP 2.8.5.3, KCP 2.8.7.1, KCP 2.11	Michalec-Minch	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Analysis of active substance and physicochemical properties of initial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis „Blachownia'' report no. 7/2018 GLP; unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.7.5, KCP 2.7.6	Michalec-Minch	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Evaluation of stability of the product after storage in accordance with the Technical Monograph No. 17 (6 months, 1 year, 2 years) Institute of Heavy Organic Synthesis „Blachownia'' report no. 8/2018 GLP; unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.2.1	Pawel Sliwa	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36%	N	Y	Data/study report never submitted	SHARDA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			WG: Determination of explosive properties Institute of Industrial Organic Chemistry report no. BW-08/18 GLP, unpublished			before to Poland	Cropchem Limited
KCP 2.7.1	Ewa Nowakowska-Bogdan	2020	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Analysis of relevant impurities content of initial preparation and preparation after accelerated storage procedure Report No.: 163/2020 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.0-001	Hjorth, S.	2019	Biological Assessment Dossier: Nicosulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG (30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione WG) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1	Michalec-Minch	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Analysis of active substance and physicochemical properties of initial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis „Blachownia'' report no. 7/2018 GLP; unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 5.1.1-01	Ewa Nowakowska-Bogdan	2020	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Analysis of relevant impurities content of initial preparation and preparation after accelerated storage procedure Report No.: 163/2020 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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 ChemService Report No CH-059/2018 GLP Unpublished	N	Y	Data/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 CropTrials G,bH Report no. CT17-1-76 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.8-01	Ferrari, F.	2019	Title: Groundwater Monitoring for Nicosulfuron and 4 Metabolites in Maize Growing Regions of Italy. Company Report No 37/2016 Source Sharda Cropchem Ltd. GLP Unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-01	xxx	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Rainbow trout Acute toxicity test xxx report No. W/204/17 GLP, unpublished	Y	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-02	Bak, P.	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG *Raphidocelis subcapitata* (formely *Pseudokirchneriella subapitata*) SAG 61.81 Growth inhibition test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/205/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-03	Bak, P.	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36%	N	Y	Data/study report never submitted	SHARDA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			WG *Daphnia magna*, acute immobilisation test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/206/17 GLP, unpublished			before to Poland	Cropchem Limited
KCP 10.2.1-04	Bak, P.	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG *Lemna gibba* CPCC 310, growth inhibition test Institute of Industrial Organic Chemistry Branch Pszczyna report No. W/207/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-05	Bätscher, R.	2008	"Toxicity of Nicosulfuron technical to the Aquatic Higher Plant *Lemna gibba* in a 7-Day Growth Inhibition Test, Supplemented With Testing for Recovery of Growth" B75341. GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Stalmach, M.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/172/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.2	Stalmach, M.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/173/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2.1	Ansaloni, T.	2018	Rimsulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* Trialcamp S.L.U. TRC16-193BA GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2.2	Ansaloni, T.	2018	Nicosulfuron Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L. Trialcamp S.L.U. TRC16-049BA	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
KCP 10.3.1.2.3	Gimeno, I.	2019	Mesotrione Technical - Chronic Toxicity to the Honey Bee, *Apis mellifera* L. Trialcamp S.L.U. TRC17-006BA GLP, unpublished	N	Y	Data/study report never submitted before to Poland	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 Trialcamp S.L.U. TRC16-162BA GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.3.2	Scheller, K.	2018	Mesotrione Technical - Repeated exposure of honey bee (*Apis mellifera* L.) larvae under laboratory conditions (*in vitro*) BioChem agrar 17 48 BLC 0088 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-01	Kulec-Płoszczyca, E.	2018	An extended laboratory test for evaluating the effects of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/174/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-02	Stalmach, M.	2019	An extended laboratory test for evaluating the effects of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG on the predatory mite, *Typhlodromus pyri* (Sch.) Institute of Industrial Organic Chemistry Branch Pszczyna report No. B/175/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-03	Mohanraj, M.	2020	A laboratory test for evaluating the effects of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG on larvae of the green lacewing *Chrysoperla carnea* (L.) (Neuroptera: Chrysopidae). Bioscience Research Foundation. 7554/2020 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2.1-04	Sonali, G.	2020	An extended laboratory test for evaluating the effects of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG on the rove beetle, *Aleochara bilineata* (Gyllenhal). Bioscience Research Foundation. 7555/2020 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-05	Varela, S.	2021	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions Trialcamp S.L.U. S20-07857 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.1.1	Dec, W.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG Earthworm Reproduction Test (*Eisenia andrei*) Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/265/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Dec, W.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG Collembolan (*Folsomia candida*) Reproduction Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/266/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5-01	Dec, W.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG Soil Microorganisms: Carbon Transformation Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/263/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5-02	Dec, W.	2019	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG Soil Microorganisms: Nitrogen Transformation Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/264/17	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
KCP 10.6.2-01	Wróbel, A.	2020	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG. Terrestrial Plant Test: Vegetative Vigour Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/269/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-02	Wróbel, A.	2020	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WDG. Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Institute of Industrial Organic Chemistry Branch Pszczyna report No. G/268/17 GLP, unpublished	N	Y	Data/study report never submitted before to Poland	SHARDA Cropchem Limited

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 Company Report No. Source (where different from company) GLP or GEP status 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 Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> 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 Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-