FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 4307 A

Product name: PRIMARY MX

Chemical active substance:

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

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: Sharda Cropchem España

Submission date: February 2020

Update date: 07.2021

MS Finalisation date: 07.2022 ; 12.2022; 03.2023

Version history

When	What
July 2021	Applicant update dossier according to dose of 90 g as/ha for mesotrione
July 2022	zRMS first evaluation
December 2022	ZRMs corrected dRR according to comments reviewed.
March 2023	The final Registration Report

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Changes made during commenting period are marked by yellow.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)
					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		
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	-	To be confirmed by cMS. In DE only use against TTTMS and TTTDS can be accepted.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG (PRIMARY MX; Product code: 4307 A)** containing the active substances rimsulfuron, nicosulfuron and mesotrione, which were included into Annex I of Council Directive 91/414/ EEC and 1107/2009, after re-evaluation.

The SANCO reports for rimsulfuron (SANCO/10528/2005-rev. 2), nicosulfuron (SANCO/3780/ 07-rev. 1) and mesotrione (SANCO/1416/2001-final) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directives for rimsulfuron (**2006/39/EC**), nicosulfuron (**2008/40/EC**) and mesotrione (**2003/68/EC**) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on the active substances rimsulfuron, nicosulfuron and mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27/Jan/2006, 22/Jan/2008 and 11/Apr/2003 shall be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of rimsulfuron, nicosulfuron and mesotrione relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	**KCP 6.0/001 Biological Assessment Dossier Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, Central**

Description of the plant protection product

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. Please refer to Table 3.1-1 to see the GAP covered by this document.

To support the registration of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in the GAP claimed crop, trials have been set up in maize field crops. In all maize trials, except two English efficacy trials as well as eight selectivity trials conducted in England (2), France (4) and Spain (2), the rimsulfuron + nicosulfuron + mesotrione WG formulation prepared by Sharda Cropchem España – Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG – was compared against a reference rimsulfuron + nicosulfuron + mesotrione co-formulation currently on the market in Central and South Europe (Arigo / Arigo 51 / Arigo 51 WG / Colombus 51 WG; 30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione WG). In the two English efficacy trials as well as the eight selectivity trials, a nicosulfuron + mesotrione co-formulation was used as reference product (Elumis; nicosulfuron 30 g/l + mesotrione 75 g/L OD). In most trials (except six Polish trials), a rimsulfuron standard product was used as additional reference (rimsulfuron 250 g/kg WG), for comparison. The trials were conducted in 2016, 2017 and 2019 in a range of European countries in the Maritime (i.e. Germany, N-France, Czech Republic and the UK), the North-east (i.e. Poland), the South-east (i.e. Hungary) and the Mediterranean (i.e. S-France, Spain and Italy) EPPO zones.

According to the GAP, the proposed application rate of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is 0.25 kilograms per hectare (kg/ha), with a maximum of one application per season, for the early post-emergence control of grasses and broadleaved weeds in maize. This will deliver 7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG for the control of grasses and broadleaved weeds in maize.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Maize	Grasses and broadleaved weeds	CEU	0.25 kg/ha	Early post-emergence application

Further details are in the table "All intended uses" in Part B - Section 0.

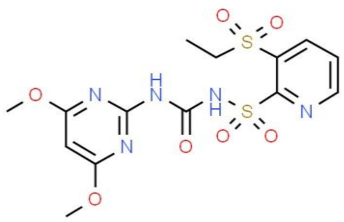
Description of active substance rimsulfuron

Rimsulfuron is a selective post-emergence herbicide used in maize and other crops for broad-spectrum control of important grasses and broadleaved weeds across all climatic zones of Europe. The herbicidal properties of rimsulfuron were first described in 1991. It belongs to the chemical group of Sulfonylureas.

Rimsulfuron is applied as a foliar spray and absorbed through the plants leaves and translocated to the growing point of the plant. After it is taken up, the active ingredient is immediately distributed in the weed plants that immediately stop growing. The best efficacy is achieved during conditions of rapid growth.

Today, rimsulfuron is registered and commercialised in several formulations around the world.

Table 3.2-2: Identity of rimsulfuron

Common name	Rimsulfuron
IUPAC name	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
CA name	*N*-(((4,6-dimethoxy-2-pyrimidinyl)amino)carbonyl)-3-(ethylsulfonyl)-2-pyridinesulfonamide
CIPAC No	716
CAS Registry No.	122931-48-0
EEC No	N.a.
Minimum purity	960 g/kg
Structural formula[1]	
Empirical formula	$C_{14}H_{17}N_5O_7S_2$
Molecular mass	431.44 g/mol

[1] Source: Royal Society of Chemistry (RSC). Internet, Friday December 6th, 2019. URL: http://www.chemspider.com/Chemical-Structure.82876.html

Mode of action

Rimsulfuron acts by inhibiting the action of acetolactate synthase (ALS), also known as acetohydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, rimsulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.

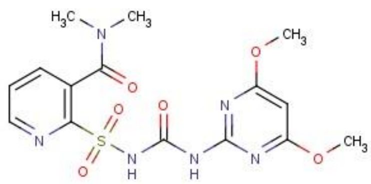
Description of active substance nicosulfuron

Nicosulfuron is a selective herbicide for post emergence applications against weeds in maize across all climatic zones of Europe. The herbicidal properties of nicosulfuron were first described in 1990. It belongs to the chemical group of Sulfonylureas.

The main route of uptake for nicosulfuron is via leaves, but to a lesser extend it is also taken up via the roots of the weeds. After it is taken up, the active ingredient is immediately distributed in the weed plants that immediately stop growing. The best efficacy is achieved during conditions of rapid growth.

Today, nicosulfuron is registered and commercialised in several formulations around the world.

Table 3.2-3: Identity of nicosulfuron

Common name	Nicosulfuron
IUPAC name	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylnicotinamide
CA name	2-(((((4,6-dimethoxy-2-pyrimidinyl)amino)carbonyl)amino)sulfonyl)-*N*,*N*-dimethyl-3-pyridinecarboxamide
CIPAC No	709
CAS Registry No.	111991-09-4
EEC No	686-897-5
Minimum purity	930 g/kg
Structural formula[2]	
Empirical formula	$C_{15}H_{18}N_6O_6S$
Molecular mass	410.41 g/mol

Mode of action

Nicosulfuron is a post emergence herbicide controlling grass weeds including couch grass (AGGRE), crap grass (DIGSS), Foxtail millet (SETSS), Barnyard grass (ECHSS) and Johnson grass (SORHA) as well as a range of broad leaf weeds in maize. Nicosulfuron acts by inhibiting the action of acetolactate synthase (ALS), also known as acetohydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, rimsulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.

[2] Source: Chemical Trading Guide. Internet, Friday December 6th, 2019. URL: https://www.guidechem.com/reference/dic-29477.html

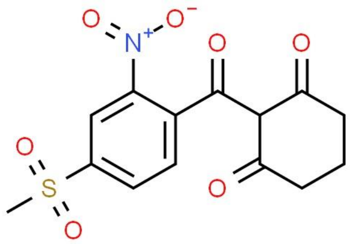
Description of active substance mesotrione

Mesotrione was first introduced in 2001. It belongs to the chemical group of Triketones. Mesotrione is a new callistemone herbicide that inhibits the HPPD enzyme (p-hydroxyphenylpyruvate dioxygenase), a component of the biochemical pathway that converts tyrosine to plastoquinone and α-tocopherol (Lee et al. 1998; Cornes 2005). Following treatment in sensitive plants, carotenoid biosynthesis is disrupted in the chlorophyll pathway, resulting in a bleaching effect (Wichert et al., 1999). Carotenoid pigments protect chlorophyll from decomposing in sunlight. Injured weeds appear white to translucent rather than chlorotic (yellow).

Mesotrione is a member of the benzoylcyclo-hexane-1,3-dione family of herbicides, which are chemically derived from a natural phytotoxin obtained from the *Callistemon citrinus* (Curtis) Skeels plants.

Today, mesotrione is registered and commercialised in several formulations around the world.

Table 3.2-4: Identity of mesotrione

Common name	Mesotrione
IUPAC name	2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione
CA name	2-(4-(methylsulfonyl)-2-nitrobenzoyl)-1,3-cyclohexanedione
CIPAC No	625
CAS Registry No.	104206-82-8
EEC No	609-064-00
Minimum purity	930 g/kg
Structural formula[3]	
Empirical formula	$C_{14}H_{13}NO_7S$
Molecular mass	339.32 g/mol

Mode of action

Mesotrione acts by the inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase which in turn inhibits carotenoid biosynthesis. Due to its primary target site and its chemical family, in the HRAC mode of action classification, it is classified as group F2 herbicide (4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD) inhibition). In the WSSA resistance classification system, the callistemones are classified as group 27.

For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Information on similar formulations and current approvals

Data presented in this dossier is generated using this formulation in comparison with e.g. the DuPont reference product containing rimsulfuron, nicosulfuron and mesotrione. Rimsulfuron, nicosulfuron as well as mesotrione are currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

[3] Source: Royal Society of Chemistry (RSC). Internet, Friday December 6th, 2019. URL: http://www.chemspider.com/Chemical-Structure.153301.html

Table 3.2-5: Current approvals of rimsulfuron, nicosulfuron and/or mesotrione in the EU Central zone as well as connected EPPO zones where trials were conducted. Reference products used in trials are also included

Country	Product	Active ingredient	Approval number
Austria	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	3260-0
	Nicosh	**Nicosulfuron 40 g/L SC**	**3098-0**
Czech Republic	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	4943-0
	Nicosh	**Nicosulfuron 40 g/L SC**	**4798-0**
	RIM 25 WG	**Rimsulfuron 250 g/kg WG**	**5300-0**
France	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	2150994
	Elumis	Nicosulfuron 30 g/L + Mesotrione 75 g/L OD	2100111
	Nicosh	**Nicosulfuron 40 g/L SC**	**2130252**
Germany	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	007526-00
	Nicosh 4% OD	**Nicosulfuron 40 g/L SC**	**008384-00**
Greece	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	007526-00
	Nicosh 4 OD	**Nicosulfuron 40 g/L SC**	**70060**
	RiNiDi	**Rimsulfuron 23 g/kg + Nicosulfuron 92 g/kg + Dicamba 550 g/kg WG**	**70257**
Hungary	Arigo 51 WG	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	04.2/1534-1/2017
	e.g. Nicosh 4 SC	**Nicosulfuron 40 g/L SC**	**04.2/1211-2/2013**
Italy	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	016063
	e.g. Glitter	**Nicosulfuron 40 g/L OD**	**012647**
	e.g. RiNiDi	**Rimsulfuron 23 g/kg + Nicosulfuron 92 g/kg + Dicamba 550 g/kg WG**	**016641**
Netherlands	**Nicosh**	**Nicosulfuron 40 g/L SC**	**13588**
Poland	Columbus 51 WG	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	R-33/2013 zr
	e.g. Nikosh 040 OD	**Nicosulfuron 40 g/L OD**	**R-45/2015**
	Rim 25 WG	**Rimsulfuron 250 g/kg WG**	**R-88/2019**
Spain	Arigo	Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg WG	25864
	Elumis	Nicosulfuron 30 g/L + Mesotrione 75 g/L OD	25423
	Mighty	**Mesotrione 10% SC**	**ES-00842**
	e.g. NIC-4	**Nicosulfuron 40 g/L OD**	**24684**
UK	Elumis	Nicosulfuron 30 g/L + Mesotrione 75 g/L OD	15800
	Nicosh 4 OD	**Nicosulfuron 40 g/L SC**	**19044**

Bold = Sharda formulations registered in the respective countries

Description of the target pests

The damaging economic effects of grass- and broadleaved weeds in maize are well established, and justification for their control well documented. Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG control a number of very important grass weeds and broadleaved weeds found in maize. Among the species that are controlled by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG are grasses, like *Alopecurus myosuroides*, *Apera spica-venti*, *Elymus repens*, *Poa* spp., volunteer cereals, *Digitaria* spp., *Echinochloa* spp., *Panicum* spp., *Setaria* spp., and *Sorghum halepense* and broadleaved weeds, like *Abutilon theophrasti*, *Amaranthus* spp., *Chenopodium album*, *Galium aparine*, *Geranium* spp., *Lamium* spp., *Matricaria* spp., *Myosotis arvensis*, *Polygonum* spp., *Persicaria* spp., *Solanum nigrum*, *Stellaria media*, *Viola arvensis*, a.o.

All the listed weeds are present throughout or in parts of the Central zone and in relevant EPPO zones. These weed species compete with the crops for light, moisture and nutrients, reducing crop yields and may obstruct harvestability.

Table 3.2-6: Glossary of pests mentioned in the report.

EPPO code	Scientific name	Common name
Grass weeds		
AGRRE	*Elymus repens*	Couch grass
ALOMY	*Alopecurus myosuroides*	Blackgrass
APESV	*Apera spica-venti*	Silky Windgrass
CYPRO	*Cyperus rotundus*	Purple nutsedge
DIGSA	*Digitaria sanguinalis*	Hairy crabgrass
ECHCG	*Echinochloa crus-galli*	Common barnyard grass
LOLMU	*Lolium multiflorum*	Italian ryegrass
PANMI	*Panicum miliaceum*	Common millet
POAAN	*Poa annua*	Annual bluegrass
SETPU	*Setaria helvola*	Yellow foxtail
SETVI	*Setaria viridis*	Green foxtail
Broadleaved weeds		
ABUTH	*Abutilon theophrasti*	Velvet leaf
AMARE	*Amaranthus retroflexus*	Common amaranth
ARTVU	*Artemisia vulgaris*	Common mugwort
BRSNX	*Brassica napus*	Oilseed rape (volunteer)
CAPBP	*Capsella bursa-pastoris*	Shepherd’s purse
CHEAL	*Chenopodium album*	Common lambsquarters
CHEPO	*Chenopodium polyspermum*	Many-seeded goosefoot
CIRAR	*Cirsium arvense*	Creeping thistle
DATST	*Datura stramonium*	Common thorn apple
EPHCH	*Euphorbia chamaesyce*	Crenated spurge
EPHHE	*Euphorbia helioscopia*	Sun spurge
FUMOF	*Fumaria officinalis*	Common fumitory
GAETE	*Galeopsis tetrahit*	Common hemp-nettle

EPPO code	Scientific name	Common name
Broadleaved weeds (cont.)		
GALAP	*Galium aparine*	Cleavers
GASPA	*Galinsoga parviflora*	Small-flower galinsoga
GERPU	*Geranium pusillum*	Small-flowered cranesbill
HELAN	*Helianthus annuus*	Sunflower (volunteer)
LAMPU	*Lamium purpureum*	Purple deadnettle
MATIN	*Tripleurospermum inodorum*	Scenless mayweed
MATMA	*Tripleurospermum maritimum*	False mayweed
MERAN	*Mercurialis annua*	Annual mercury
PLAME	*Plantago media*	Hoary plantain
POLAV	*Polygonum aviculare*	Knotgrass
POLCO	*Fallopia convolvulus*	Black bindweed
POLLA	*Persicaria lapathifolia*	Pale smart weed
POLPE	*Persicaria maculosa*	Redshank
POROL	*Portulaca oleracea*	Common purslane
SINAR	*Sinapis arvensis*	Charlock
SONAR	*Sonchus arvensis*	Perennial sow-thistle
SOLNI	*Solanum nigrum*	Black nightshade
SONSS	*Sonchus spp.*	Sow thistles
SPRAR	*Spergula arvensis*	Corn spurry
STEME	*Stellaria media*	Common chickweed
THLAR	*Thlaspi arvense*	Field pennycress
TTTTT	-	All weeds
VERAG	*Veronica agrestis*	Green field speedwell
VERPE	*Veronica persica*	Common field speedwell
VICCR		
VIOAR	*Viola arvensis*	Field violet

Table 3.2-7: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Maize	CEU	-	Mono- and dicotyledon weeds	CEU	-

Compliance with the Uniform Principles

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.

Information on trials submitted (6.2 Efficacy data)

Trials in this report were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this report have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, 33 efficacy trials and 20 selectivity trials were conducted in the Maritime (9 eff. and 9 sel.), the North-east (16 eff. and 6 sel.), the South-east (2 eff.) and the Mediterranean (6 eff. and 5 sel.) EPPO zone.

Table 3.2-8: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s)	Target(s)	Country	Years	Type of trial	Number of trials (number of valid trials)				GEP, non-GEP, official	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Maize	Grasses and broadleaved weeds	Germany	2016	MED + E + S	2 (2)	-	-	-	GEP	
		Czech Rep.	2016	MED + E + S	3 (3)	-	-	-	GEP	
		UK	2016	MED + E + S	2 (2)	-	-	-	GEP	
		France	2016	MED + E + S	2 (2)	2 (2)	-	-	GEP	
		Hungary	2016	MED + E + S	-	-	2 (2)	-	GEP	
		Poland	2016	MED + E + S	-	-	-	8 (8)	GEP	
		Poland	2017	MED + E + S	-	-	-	4 (4)	GEP	
		Poland	2019	MED + E + S	-	-	-	4 (4)	GEP	
		Spain	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Italy	2016	MED + E + S	-	2 (2)	-	-	GEP	
		Total, maize (early post-em)			9 (9)	6 (6)	2 (2)	16 (16)	-	
		Total, all crops			**9 (9)**	**6 (6)**	**2 (2)**	**16 (16)**		

In the 33 trials, the level of control obtained by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was assessed on mono- and dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Climatic zones

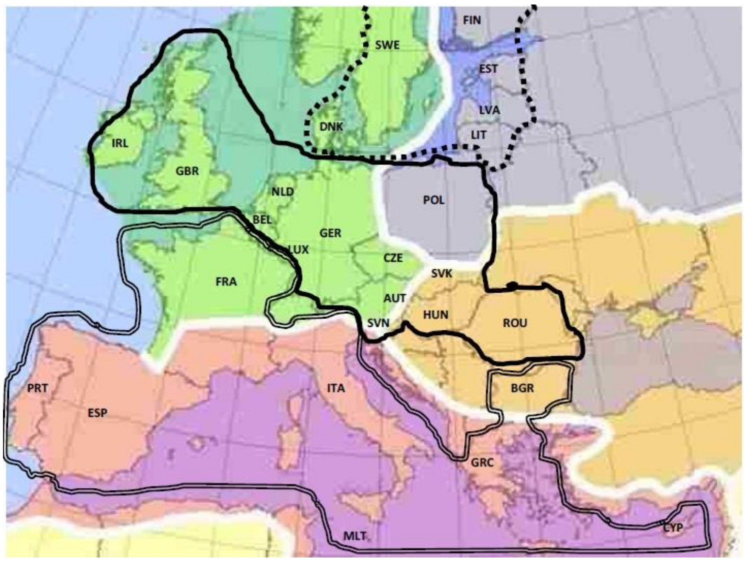
Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country[4].

[4] Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Germany, N-France, Czech Republic and United Kingdom are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; Hungary is located in the South-east EPPO zone; and Spain, Italy and the southern part of France are located in the Mediterranean EPPO zone (Figure 3.2-1).

This Registration Report is prepared to support the submission of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG throughout the Central Registration zone, therefore data from the Maritime, the South-east and the North-east EPPO zones are included. Data from the Mediterranean zone has been included as supporting information. The data from each climatic zone is summarised separately.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions of maize and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between UK, Germany, Czech Republic, France, Hungary, Poland, Spain and Italy. In maize, the same rimsulfuron, nicosulfuron and/or mesotrione containing herbicides are already registered and used in the countries where tested for the same uses, i.e. to control grasses and broadleaved weed species in maize with early post-emergence application.

(i) *Weed physiology*

Grasses, like *Alopecurus myosuroides*, *Apera spica-venti*, *Elymus repens*, *Poa* spp., volunteer cereals, *Digitaria* spp., *Echinochloa* spp., *Panicum* spp., *Setaria* spp., and *Sorghum halepense* and broadleaved weeds, like *Abutilon theophrasti*, *Amaranthus* spp., *Chenopodium album*, *Galium aparine*, *Geranium* spp., *Lamium* spp., *Matricaria* spp., *Myosotis arvensis*, *Polygonum* spp., *Persicaria* spp., *Solanum nigrum*, *Stellaria media*, *Viola arvensis*, a.o., are all controlled by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG and are all key weeds throughout Central Europe. In each country these weeds are very common and can cause large reductions in yield.

According to Heap, 2019, fifteen cases of resistance to nicosulfuron has been reported from Europe on grass weeds (e.g. five cases on *Echinochloa spp.* from Italy, Spain, Greece, Austria and Germany) as well as broadleaved weeds (i.e. one case on *Stellaria media* from Germany in 2011). Heap (2019) also reported that two grass weed species (Echinochloa phyllopogan and Sorghum halepense) and three broadleaved weeds species (*Galinsoga parviflora*, *Kochia scoparia* and *Sonchus asper*) were reported each once as having developed resistance to rimsulfuron in Europe. No resistance to mesotrione has to date yet been reported from within Europe, according to Heap (2019). In the trials conducted, when treating the same weeds at the same application timing, no differences in level of control was be observed between the countries and therefore the efficacy results from one country should be valid in another country.

(ii) *Site selection*

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each weed species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high weed densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted. For each weed species equivalent levels of control were recorded in Germany, Czech Republic, England, France, Hungary, Poland, Spain and Italy.

(iii) *Agronomic practices*

Agronomic practices in maize field crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, the crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG has been tested on a wide range of varieties in both the selectivity- and efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for maize production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

The active ingredients of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG have both contact as well as some residual activity. Therefore, in each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

On the basis that the above factors do not influence the overall performance of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, it is the applicant’s contention that data from the United Kingdom, Germany, the Czech Republic, Hungary and Poland is equally valid in demonstrating the products performance throughout the Central EU zone and the data from Spain, Italy and France is valid as supporting data.

In all maize trials, except two efficacy and eight selectivity trials, the Rimsulfuron + Nicosulfuron + Mesotrione WG ~~pendimethalin + flufenacet SC~~ formulation prepared by Sharda Cropchem España – Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG – was compared against a commercial standard rimsulfuron + nicosulfuron + mesotrione co-formulation currently on the market in Central and South Europe (Arigo / Columbus 51 WG; 30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione WG). In the remaining ten trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was compared against a national standard reference product containing nicosulfuron and mesotrione (Elumis; nicosulfuron 30 g/L + mesotrione 75 g/L OD). Furthermore, in the 15 efficacy trials included in the preliminary range-finding section, a rimsulfuron 250 g/kg WG standard product was used as additional reference (Rim 25 WG, registered by Sharda in e.g. Poland and Czech Republic), for comparison, as well as Elumis (nicosulfuron 30 g/L + mesotrione 75 g/L OD) was also included, for comparison. The trials were carried out on maize.

The reference products used in the efficacy trials are listed in Table 3.2-9.

Table 3.2-9: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Rimsulfuron + nicosulfuron + mesotrione co-formulations					
Arigo	WG	30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione	0.25 0.33	CZ DE ES FR HU IT PL	3 2 2 4 2 2 4
Columbus 51 WG	WG	30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione	0.25 0.33	PL	12
Nicosulfuron + mesotrione reference product					
Elumis	OD	30 g/L nicosulfuron 75 g/L mesotrione	1.2 1.5	CZ DE ES FR HU IT PL UK	3 2 2 4 2 2 12 2
Rimsulfuron reference product					
Rim 25 WG	WG	250 g/kg rimsulfuron	0.4 0.6	CZ DE ES FR HU IT PL UK	3 2 2 4 2 2 12 2

Comments of zRMS:	This document summarizes the information related to the efficacy of the plant protection product Primary MX (product code: SHA 4307 A). The formulation of this product is a water-soluble granule (WG), and it is containing three active substances: rimsulfuron (30 g/kg) + nicosulfuron (120 g/kg) + mesotrione (360 g/kg). For now, these active compounds are on the list of approved active substances. Products based on those three compounds are known for years and are described in some publications. Appendix 1 of this document contains the list of references which are included in this document for support of the evaluation. Poland is a ZRMs.

3.2.1 Preliminary tests (KCP 6.1)

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.).

All three active ingredients are well known. Nicosulfuron is a broad-spectrum herbicide that controls a wide range of post-emergent weeds such as annual and perennial grass weeds, sedges and broad-leaved weeds such as *Sorghum halepense* and *Agropyron repens*. Rimsulfuron has not only effect on annual grasses and broadleaved weeds, but also on some troublesome perennial grasses and broadleaved weeds, such as barnyard grass, quackgrass and crab grass as well as other weeds such as marestail/horseweed, fleabane, filaree, foxtail and dandelion. Mesotrione is a systemic pre-emergence and post-emergence systemic herbicide of broad-leafed weeds as well as some important grass weeds such as *Echinochloa crus-galli*. This mixture can be a useful tool in managing or preventing the establishment of resistant weeds.

Based on the knowledge about the active substances and the experiences in the label claimed crops, the necessary application rates to obtain sufficient control of the weeds are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

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.

3.2.1.1 Justification of the Mixture

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is composed of rimsulfuron, nicosulfuron and mesotrione. These active ingredients have different modes of action, i.e. rimsulfuron and nicosulfuron are sulfonylureas (HRAC B, WSSA 2), whereas mesotrione is a Triketone (HRAC F2, WSSA 27). Using a product which contains three active ingredients, employing two different modes of action, can be an important tool to prevent resistance development. Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG mixture is designed to complement the range of activity of the individual component active substances, to provide a complete product for the control of grasses and broadleaved weeds in maize, with early post-emergence application.

In the summary tables below, the mean control obtained on grasses and broadleaved weeds present in 15 maize trials conducted in the Maritime (9) and the Mediterranean (6) EPPO zones are presented, to demonstrate the benefits of the mixture and that the coformulation does not compromise the effectiveness expected by the single active substances.

Grass weeds

To compare the effectiveness of the mixture and the reference products at comparable dose rates when applied early post-emergence for the control of grass weeds in maize, the assessment results of 13 efficacy trials performed in the Maritime (7) and the Mediterranean (6) EPPO zones in 2016 are reported. In the trials, rimsulfuron straight (250 g/kg WG) was included at 0.04 kg/ha, which equals to 10 g rimsulfuron per hectare. In the same trials, Elumis (nicosulfuron 30 g/l + mesotrione 75 g/l OD) was included at 1.5 l/ha, which equals to 45 g nicosulfuron and 112.5 g mesotrione per hectare. The results obtained with rimsulfuron straight at 10 g ai/ha and nicosulfuron + mesotrione at 45 + 112.5 g ai/ha, respectively, was compared against Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha (7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare). Grass weeds were evaluated in 13 of the 15 efficacy trials included in the Preliminary range section.

The control of frequently occurring monocotyledonous weeds in maize was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out approx. one month after application is presented in the following summary tables. Table 3.2-10 and Table 3.2-11 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-33 days after post-emergence application in the Maritime EPPO zone and the Mediterranean EPPO zone, respectively.

The individual trial results show that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG gave good to excellent control of grass weed species present in the different trials, equivalent to superior to that achieved by the reference formulations. At three of the 12 assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the straight rimsulfuron at comparable dose rate and at two assessments, the rimsulfuron reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining seven assessments, no significant differences were observed between the two tested products. When compared against the nicosulfuron + mesotrione reference product, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the reference product at five of the twelve assessments and at two assessments, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. The similarity between the co-formulated test product and the straight rimsulfuron reference product as well as the nicosulfuron containing reference product was to be expected as the sulfonylureas is the part of the formulation having the best effect on grass weeds.

Table 3.2-10: Maritime zone: Preliminary range-finding results with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, rimsulfuron straight and the nicosulfuron + mesotrione co-formulation applied against frequently occurring grass weeds in maize. Evaluation: Efficacy rating at 14-30 days after post-emergence application; mean values and variation across trials in % control.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Rimsulfuron ref. prod. at 0.04 kg/ha (10 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the rimsulfuron reference product at 10 g ai/ha. = : ± 5% control: >	=	<	Overall
AGRRE	23-30	1	12	93.5	81.3	1			>
ALOMY	09-13	1	6.3	98.8	100		1		=
ECHCG	11-31	5	8-52.5	90.3 (75.0-99.5)	81.7 (45-98.8)	1	4		=
LOLMU	10-22	2	5.5-12	99.4 (98.8-100)	97.4 (94.8-100)	1		1	<
POAAN	09-14	2	6-10	87.5 (75.0-100)	100 (-)		1	1	<
SETPU	11-13	1	11.3	95	95		1		=
Mean, all assessments		12		92.3 (75.0-100)	89.9 (45-100)	3	7	2	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Nicosulfuron + mesotrione ref. prod. at 1.5 L/ha (45 + 112.5 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the nicosulfuron + mesotrione reference product at 157.5 g ai/ha. = : ± 5% control: >	=	<	Overall
AGRRE	23-30	1	12	93.5	87.5	1			>
ALOMY	09-13	1	6.3	98.8	97.3		1		=
ECHCG	11-31	5	8-52.5	90.3 (75.0-99.5)	82.5 (32.5-99.8)	2	2	1	>
LOLMU	10-22	2	5.5-12	99.4 (98.8-100)	99.3 (98.5-100)		1	1	<
POAAN	09-14	2	6-10	87.5 (75.0-100)	83.8 (67.5-100)	1	1		>
SETPU	11-13	1	11.3	95	90	1			>
Mean, all assessments		12		92.3 (75.0-100)	87.8 (32.5-100)	5	5	2	>

The individual trial results show that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG gave good to excellent control of grass weed species present in the different trials, equivalent to superior to that achieved by the reference formulations. At one of the seven assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the straight rimsulfuron at comparable dose rate and at one assessment, the nicosulfuron + mesotrione reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining five assessments, no significant differences were observed between the two tested products. When compared against the nicosulfuron + mesotrione reference product, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the reference product at two of the seven assessments and at one assessment, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. The similarity between the co-formulated test product and the straight rimsulfuron reference product as well as the nicosulfuron containing reference product was to be expected as the sulfonylureas is the part of the formulation having the best effect on grass weeds

Table 3.2-11: Mediterranean zone: Preliminary range-finding results with Rimsulfuron 3% +Nicosulfuron 12% + Mesotrione 36% WG, rimsulfuron straight and the nicosulfuron + mesotrione co-formulation applied against frequently occurring grass weeds in maize. Evaluation: Efficacy rating at 14-33 days after post-emergence application; mean values and variation across trials in % control.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Efficacy obtained with Rimsulfuron ref. prod. at: Mean (min-max) 0.04 kg/ha (10 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the rimsulfuron reference product at 10 g ai/ha. = : ± 5% control: >	=	<	Overall
CYPRO	12	1	8.8	8.8	8.8		1		=
DIGSA	11-13	1	54.5	37.5	30	1			>
ECHCG	11-21	3	5-104.5	94.7 (91.3-99.8)	95.5 (95-96.5)		3		=
SETVI	10-12	2	7.5-20	97.5 (95-100)	93.1 (86.3-100)		1	1	=
Mean, all assessments		7		71.8 (8.8-99.8)	73.1 (8.8-100)	1	5	1	>
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Efficacy obtained with Nicosulfuron + mesotrione ref. prod. at: Mean (min-max) 1.5 L/ha (45 + 112.5 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the nicosulfuron + mesotrione reference product at 157.5 g ai/ha. = : ± 5% control: >	=	<	Overall
CYPRO	12	1	8.8	8.8	10		1		=
DIGSA	11-13	1	54.5	37.5	93.3			1	<
ECHCG	11-21	3	5-104.5	94.7 (91.3-99.8)	96.4 (94.8-98.8)	1	2		=
SETVI	10-12	2	7.5-20	97.5 (95-100)	80.0 (75-85)	1	1		>
Mean, all assessments		7		71.8 (8.8-99.8)	78.9 (10-98.8)	2	4	1	=

Broadleaved weeds

To compare the effectiveness of the mixture and the reference products at comparable dose rates when applied early post-emergence for the control of broadleaved weeds in maize, the assessment results of 15 efficacy trials performed in the Maritime (9) and the Mediterranean (6) EPPO zones in 2016 are reported. In the trials, rimsulfuron straight (250 g/kg WG) was included at 0.04 kg/ha, which equals to 10 g rimsulfuron per hectare. In the same trials, Elumis (nicosulfuron 30 g/l + mesotrione 75 g/l OD) was included at 1.5 l/ha, which equals to 45 g nicosulfuron and 112.5 g mesotrione per hectare. The results obtained with rimsulfuron straight at 10 g ai/ha and nicosulfuron + mesotrione at 45 + 112.5 g ai/ha, respectively, was compared against Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha (7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare). Broadleaved weeds were evaluated in all 15 efficacy trials included in the Preliminary range section.

The control of frequently occurring dicotyledonous weeds in maize was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out approx. one month after application is presented in the following summary tables. Table 3.2-12 and Table 3.2-13 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-58 days after post-emergence application in the Maritime EPPO zone and the Mediterranean EPPO zone, respectively.

The individual trial results show that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG gave good to excellent control of broadleaved weed species present in the different trials, equivalent to superior to that achieved by the rimsulfuron 25% WG reference formulation and equivalent to that achieved by the nicosulfuron + mesotrione reference formulation. At twenty of the 36 assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the straight rimsulfuron at comparable dose rate and at two assessments, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining fourteen assessments, no significant differences were observed between the two tested products. When compared against the nicosulfuron + mesotrione reference product, Elumis performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at five of the 36 assessments (all five from the same French trial). At the remaining 30 assessments, no significant differences were observed between the two tested products. The similarity between the co-formulated test product and the mesotrione containing reference product was to be expected as the Triketone is the part of the formulation having the best effect on broadleaved weeds whereas the strength of the sulfonylureas is primarily on the monocotyledonous weeds

Table 3.2-12: Maritime zone: Preliminary range-finding results with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, rimsulfuron straight and the nicosulfuron + mesotrione co-formulation applied against frequently occurring broadleaved weeds in maize. Evaluation: Efficacy rating at 14-58 days after post-emergence application; mean values and variation across trials in % control.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Efficacy obtained with Rimsulfuron ref. prod. at: Mean (min-max) 0.04 kg/ha (10 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the rimsulfuron reference product at 10 g ai/ha. = : ± 5% control: >	=	<	Overall
BRSNW	14-16	1	13.8	100	100		1		=
CAPBP	34	1	32.5	100	93.8	1			>
CHEAL	10-19	7	6.5-64	94.8 (85.0-100)	61.9 (13.7-91.3)	6		1	>
FUMOF	11-12	1	5.5	100.0	100		1		=
GAETE	12-16	1	5.5	100.0	100		1		=
GALAP	12-14	1	10	92.3	97.5		1		=
HELAN	14-31	1	15	90.0	30	1			>
LAMPU	10-12	1	15.5	100.0	97.5		1		=
MATIN	10-18	3	5-6	93.6 (87.5-99.8)	99.8 (99.5-100)		3		=
POLCO	11-21	5	1-14	91.4 (65.0-100)	73.8 (32.5-96.3)	4	1		>
POLLA	12	1	5	98.5	95		1		=
POLPE	19	1	11	65.0	32.5	1			>
SPRAR	14-19	1	5.3	100.0	90	1			>
STEME	12-16	1	1.3	87.5	87.5	1			>
THLAR	12-35	3	10.8-36	100 (-)	100 (-)		3		=
TTTTT	12-20	2	30-41.2	83.3 (68.8-97.8)	61.5 (33.8-89.3)	2			>
VERPE	09-20	3	7.8-15.8	92.5 (77.5-100)	71.3 (40-100)	2		1	>
VIOAR	10-16	2	3-10.5	98.1 (96.3-100)	92.4 (85-99.8)	1	1		>
Mean, all assessments		36		93.7 (65.0-100)	79.1 (13.7-100)	20	14	2	>
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max)	Efficacy obtained with Nicosulfuron + mesotrione ref. prod. at: Mean (min-max)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the nicosulfuron + mesotrione reference product at 157.5 g ai/ha. = : ± 5% control			Overall

				0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	1.5 L/ha (45 + 112.5 g ai/ha)	>	=	<	
BRSNW	14-16	1	13.8	100	100		1		=
CAPBP	34	1	32.5	100	100		1		=
CHEAL	10-19	7	6.5-64	94.8 (85.0-100)	98.0 (90-100)		6	1	=
FUMOF	11-12	1	5.5	100.0	100		1		=
GAETE	12-16	1	5.5	100.0	100		1		=
GALAP	12-14	1	10	92.3	97.3		1		=
HELAN	14-31	1	15	90.0	94.8		1		=
LAMPU	10-12	1	15.5	100.0	100		1		=
MATIN	10-18	3	5-6	93.6 (87.5-99.8)	94.5 (91.3-98.5)		3		=
POLCO	11-21	5	1-14	91.4 (65.0-100)	97.2 (88.8-100)		4	1	=
POLLA	12	1	5	98.5	99.8		1		=
POLPE	19	1	11	65.0	95.8			1	<
SPRAR	14-19	1	5.3	100.0	100		1		=
STEME	12-16	1	1.3	87.5	90	1			>
THLAR	12-35	3	10.8-36	100 (-)	100 (-)		3		=
TTTTT	12-20	2	30-41.2	83.3 (68.8-97.8)	93.3 (88.8-97.8)		1	1	=
VERPE	09-20	3	7.8-15.8	92.5 (77.5-100)	96.4 (93.8-99.8)		2	1	=
VIOAR	10-16	2	3-10.5	98.1 (96.3-100)	100 (-)		2		=
Mean, all assessments		36		93.7 (65.0-100)		1	30	5	=

Table 3.2-13: **Mediterranean zone: Preliminary range-finding results with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, rimsulfuron straight and the nicosulfuron + mesotrione co-formulation applied against frequently occurring broadleaved weeds in maize. Evaluation: Efficacy rating at 21-48 days after post-emergence application; mean values and variation across trials in % control.**

				Efficacy obtained with		No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the rimsulfuron reference product at 10 g ai/ha. = : ± 5% control			Overall
				Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:	Rimsulfuron ref. prod. at				
				Mean (min-max)					
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	0.04 kg/ha (10 g ai/ha)	>	=	<	
ABUTH	10-11	1	5.8	99.8	92.8	1			>
AMARE	10	1	57.8	95.0	97.5		1		=
CHEAL	10-16	4	7.5-138	96.2 (92.5-100)	67.5 (30-97.5)	3	1		>
DATST	14-20	1	5	98.3	70	1			>
EPHCH	10	1	6.5	87.5	87.5		1		=
GASPA	12-14	1	44.5	93.0	30	1			>
MERAN	12	1	48	83.8	7.5	1			>
POLAV	12	1	6.5	83.8	40	1			>
POLCO	11-25	2	10.4-10.8	70.9 (67.5-74.3)	40 (-)	2			>
POROL	10	1	202.5	73.8	66.3	1			>
SOLNI	10-16	4	6-27.5	95.3 (88.8-100)	65.9 (30-91.3)	3	1		>
SONSS	12	1	17.5	97.5	92.5	1			>
TTTTT	11-25	2	85.8-99.4	82.6 (77.0-88.3)	51.3 (30-72.5)	2			>
Mean, all assessments		21		89.8 (67.5-100)	61.9 (7.5-97.5)	17	4		>
				Efficacy obtained with		No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the nicosulfuron + mesotrione reference product at 157.5 g ai/ha. = : ± 5% control			Overall
				Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:	Nicosulfuron + mesotrione ref. prod. at				
				Mean (min-max)					
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	1.5 L/ha (45 + 112.5 g ai/ha)	>	=	<	
ABUTH	10-11	1	5.8	99.8	93.3		1		=
AMARE	10	1	57.8	95.0	100		1		=
CHEAL	10-16	4	7.5-138	96.2 (92.5-100)	89.0 (78.8-95)	1	3		=
DATST	14-20	1	5	98.3	88.8		1		=
EPHCH	10	1	6.5	87.5	100			1	<
GASPA	12-14	1	44.5	93.0	95		1		=
MERAN	12	1	48	83.8	93.8		1		=
POLAV	12	1	6.5	83.8	93.8		1		=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (7.5 + 30 + 90 g ai/ha)	Efficacy obtained with Rimsulfuron ref. prod. at: Mean (min-max) 0.04 kg/ha (10 g ai/ha)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the rimsulfuron reference product at 10 g ai/ha. = : ± 5% control: >	=	<	Overall
POLCO	11-25	2	10.4-10.8	70.9 (67.5-74.3)	85.6 (81.3-90)		1	1	=
POROL	10	1	202.5	73.8	72.5		1		=
SOLNI	10-16	4	6-27.5	95.3 (88.8-100)	85.9 (48.8-100)	1	3		>
SONSS	12	1	17.5	97.5	70	1			>
TTTTT	11-25	2	85.8-99.4	82.6 (77.0-88.3)	91.3 (-)		2		=
Mean, all assessments		21		92.6 (74.3-100)	88.6 (48.8-100)	7	3	16	=

The individual trial results show that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG gave good to excellent control of broadleaved weed species present in the different trials, superior to that achieved by the rimsulfuron 25% WG reference formulation and equivalent to superior to that achieved by the nicosulfuron + mesotrione reference formulation. At seventeen of the 21 assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the straight rimsulfuron at comparable dose rate. At the remaining four assessments, no significant differences were observed between the two tested products. When compared against the nicosulfuron + mesotrione reference product, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG performed significantly better than the reference product at seven of the 21 assessments and at sixteen assessments, the nicosulfuron + mesotrione reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining 3 assessments, no significant differences were observed between the two tested products. The similarity between the co-formulated test product and the mesotrione containing reference product was to be expected as the Triketone is the part of the formulation having the best effect on broadleaved weeds whereas the strength of the sulfonylureas is primarily on the monocotyledonous weeds.

Conclusion

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.

3.2.1.2 Justification of Ratio of Active Ingredients in the Mixture

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is a WG formulation containing 30 g/kg rimsulfuron, 120 g/kg nicosulfuron and 360 g/kg mesotrione. The co-formulation of rimsulfuron, nicosulfuron as well as mesotrione is not new and has been registered for several years with the same ratio of active substances in markets of Europe.

Comments of zRMS:	The active substances of Primary MX (product code: SHA 4307 A) – mesotrione, nicosulfuron and rimsulfuron are registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing these active compounds. To compare the effectiveness of the mixture and the reference products at compa-

	rable dose rates when applied early post-emergence for the control of grass weeds in maize, the assessment results of 13 efficacy trials performed in the Mediterranean (6) and the Maritime (7) EPPO zones in 2016 were reported by Applicant. ZRMs agree with Applicant: 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 broad-leaved weeds in maize.

3.2.2 Minimum effective dose tests (KCP 6.2.1)

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.15 kg/ha, 0.25 kg/ha and 0.33 kg/ha was evaluated in 31 maize trials for the control of the mono- and dicotyledonous weeds present in the trials. The dose rates tested reflects 60%, 100% and 132% of the recommended rate of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (9, i.e. Czech Republic (3), N-France (2), Germany (2) and UK (2)), the North-east EPPO zone (16, i.e. Poland) and the Mediterranean EPPO zone (6, i.e. Spain (2), Italy (2) and S-France (2)).

Summary and evaluation of Minimum Effective Dose results for 0.25 L/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG target rate against grass weeds in maize, early post-emergence application

To prove and to support the requested dose rate of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG [7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare] applied early post-emergence for the control of grass weeds in maize, the assessment results of 29 efficacy trials performed in the Maritime (7), the North-east (16) and the Mediterranean (6) EPPO zones in 2016, 2017 and 2019 are reported. Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was included in these trials at 0.33 kg/ha dose rate as well as at two lower dose rates (0.15 kg/ha [4.5 g rimsulfuron, 18 g nicosulfuron and 54 g mesotrione per hectare] and/or 0.25 kg/ha [7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare]). Grass weeds were evaluated in 29 of the 31 efficacy trials included in the Minimum Effective Dose section.

The control of frequently occurring monocotyledonous weeds in maize was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out at approximately two to eight weeks after application is presented in the following summary tables. Table 3.2-14, Table 3.2-15 and Table 3.2-16 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-53 days after application in the Maritime EPPO zone, the North-east EPPO zone and the Mediterranean EPPO zone, respectively.

Maritime EPPO zone

In the Maritime EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment carried out 14-33 days after application was 83.9% and 92.3% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.15 kg/ha and 0.25 kg/ha, respectively, compared to 93.7% control achieved by the a higher dose recommended rate, i.e. 0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control.

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.15 kg/ha dose rate at four of the 12 assessments. At two of the four assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha also performed significantly better than the 0.25 kg/ha dose rate. At the remaining eight assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates when applied early post-emergence, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control.

Table 3.2-14: Maritime zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring grass weeds in maize.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.15 kg/ha (~~~45~~ 60%)	0.25 kg/ha (~~~75~~ 100%)	0.33 kg/ha (~~100~~ 132%)
AGRRE	23-30	1	12	85	93.5	92.5
ALOMY	09-13	1	6.3	97.5	98.8	99.8
ECHCG	11-31	5	8-52.5	81.9 (47.5-96)	90.3 (75-99.5)	93.7 (85-99.3)
LOLMU	10-22	2	5.5-12	70.6 (50-91.3)	99.4 (98.8-100)	90.0 (80-100)
POAAN	09-14	2	6-10	91.9 (83.8-100)	87.5 (75-100)	94.4 (90-98.8)
SETPU	11-13	1	11.3	90	90	95
Mean of all assessments		12		83.9 (47.5-100)	92.3 (75-100)	93.7 (80-100)

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment carried out 14-53 days after application was 70.7% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha, compared to 79.0% control achieved by the a higher dose recommended rate, i.e. 0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control..

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.25 kg/ha dose rate at ten of the 19 assessments where the statistical evaluation was reported in the trial reports. At the remaining nine assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates when applied early post-emergence, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control. At four of the 23 assessments included in the summary table, no statistical evaluation was reported in the trial reports, however, also in these, satisfactory levels of control were reported for the recommended dose rate.

Table 3.2-15: North-east zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring grass weeds in maize.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (~~~75~~ 100%)	0.33 kg/ha (~~100~~ 132%)
AGRRE	12-30	4	6-12.5	67.8 (40-81.3)	74.1 (46.3-87.5)
ALOMY	11	1	6	75	83
APESV	12	2	9-11	82.0 (77-87)	87.5 (86-89)
ECHCG	11-24	12	4-120.5	66.6 (19-98)	75.2 (26-99)
POAAN	10	2	6-7	79.5 (73-86)	92.5 (92-93)
SETVI	11-25	2	5-11.8	78.3 (67.5-89)	87.3 (77.5-97)
Mean of all assessments		23		70.7 (19-98)	79.0 (26-99)

Mediterranean EPPO zone

In the Mediterranean EPPO zone, the average control of the assessed monocotyledonous weed species at the assessment carried out 14-33 days after application was 63.9% and 71.8% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.15 kg/ha and 0.25 kg/ha, respectively, compared to 80.4% control achieved by the a higher dose recommended rate, i.e.

0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control..

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.15 kg/ha dose rate at three of the 7 assessments included in the summary table. At two of the three assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at at 0.33 kg/ha also performed significantly better than the 0.25 kg/ha dose rate. At the remaining four assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control.

Table 3.2-16: Mediterranean zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring grass weeds in maize.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max)		
				0.15 kg/ha (~~~45~~ 60%)	0.25 kg/ha (~~~75~~ 100%)	0.33 kg/ha (~~100~~ 132%)
CYPRO	12	1	8.8	7.5	8.8	6.3
DIGSA	11-13	1	54.5	10	37.5	70
ECHCG	11-21	3	5-104.5	88.6 (77.5-100)	94.7 (91.3-99.8)	97.3 (95.3-100)
SETVI	10-12	2	7.5-20	81.9 (71.3-92.5)	86.3 (85-87.5)	97.5 (95-100)
Mean of all assessments		7		63.9 (7.5-100)	71.8 (8.8-99.8)	80.4 (6.3-100)

Conclusion

Based on results achieved on monocotyledonous weeds in 29 of the 31 maize trials, it can be concluded that to consistently control frequently occurring grass weeds in maize, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied early post-emergence at 0.25 kg/ha. However, the data showed that the application of 0.25 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.25 l/ha due to the requirement by the evaluators of other sections.

Summary and evaluation of Minimum Effective Dose results for 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG target rate against broadleaved weeds in maize, early post-emergence application

In order to prove and to support the requested dose rate of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG [7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare] applied early post-emergence for the control of broadleaved weeds in maize, the assessment results of 31 efficacy trials performed in the Maritime (9), the North-east (16) and the Mediterranean (6) EPPO zones in 2016, 2017 and 2019 are reported. Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was included in these trials at 0.33 kg/ha dose rate as well as at two lower dose rates (0.15 kg/ha [4.5 g rimsulfuron, 18 g nicosulfuron and 54 g mesotrione per hectare] and/or 0.25 kg/ha [7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare]). Broadleaved weeds were evaluated in all 31 efficacy trials included in the Minimum Effective Dose section.

The control of frequently occurring dicotyledonous weeds in maize was assessed at different timings throughout the trial period. However, as the most accurate representation of whole plot product performance, the data obtained from the assessment carried out at approximately two to eight weeks after application is presented in the following summary tables. Table 3.2-17, Table 3.2-18 and Table 3.2-19 therefore contains a summary of the assessment data obtained by visually estimating control obtained by the applied products at 14-58 days after post-emergence application in the Maritime EPPO zone, the North-east EPPO zone and the Mediterranean EPPO zone, respectively.

Maritime EPPO zone

In the Maritime EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment carried out 14-58 days after application was 88.0% and 93.7% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.15 kg/ha and 0.25 kg/ha, respectively, compared to 95.5% control achieved by the a higher dose recommended rate, i.e. 0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control.

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.15 kg/ha dose rate at six of the 36 assessments. At the remaining 30 assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates when applied early post-emergence, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control.

Table 3.2-17: Maritime zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring broad-leaved weeds in maize.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.15 kg/ha (~~~45~~ 60%)	0.25 kg/ha (~~~75~~ 100%)	0.33 kg/ha (~~100~~ 132%)
BRSNW	14-16	1	13.8	100	100	100
CAPBP	34	1	32.5	100	100	100
CHEAL	10-19	7	6.5-64	82.1 (31-100)	94.8 (85-100)	98.3 (91.9-100)
FUMOF	11-12	1	5.5	100	100	100
GAETE	12-16	1	5.5	100	100	100
GALAP	12-14	1	10	86.3	92.3	93.8
HELAN	14-31	1	15	88.8	90	95
LAMPU	10-12	1	15.5	99.5	100	100
MATIN	10-18	3	5-6	88.3 (72.5-99.8)	93.6 (87.5-99.8)	97.2 (94.8-99.3)
POLCO	11-21	5	1-14	89.0 (65-100)	91.4 (65-100)	92.4 (66.3-100)
POLLA	12	1	5	95	98.5	99.8
POLPE	19	1	11	55	65	77.5
SPRAR	14-19	1	5.3	98.8	100	100
STEME	12-16	1	1.3	55	87.5	100
THLAR	12-35	3	10.8-36	100 (-)	100 (-)	100 (-)
TTTTT	12-20	2	30-41.2	79.5 (62.5-96.5)	83.3 (68.8-97.8)	84.4 (70-98.8)
VERPE	09-19	3	7.8-15.8	86.6 (67.5-99.8)	92.5 (77.5-100)	88.8 (77.5-100)
VIOAR	10-16	2	3-10.5	96.8 (96-97.5)	98.1 (96.3-100)	98.6 (97.5-99.8)
Mean of all assessments		36		88.0 (31-100)	93.7 (65-100)	95.5 (66.3-100)

North-east EPPO zone

In the North-east EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment carried out 14-53 days after application was 76.7% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha, compared to 83.9% achieved by the a higher dose recommended rate, i.e. 0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control.

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.25 kg/ha dose rate at 30 of the 68 assessments where the statistical evaluation was reported in the trial reports. At the remaining 38 assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates when applied early post-emergence, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control. At seven of the 75 assessments included in the summary table, no statistical evaluation was reported in the trial reports, however, also in these, satisfactory levels of control were reported for the recommended dose rate.

Table 3.2-18: North-east zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring broad-leaved weeds in maize.

EPPO Code	Weed Growth stage at appli-cation [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha (~ ~~75~~ 100%)	0.33 kg/ha (~~100~~ 132%)
AMARE	11-24	7	1-39.3	84.7 (61.3-100)	87.4 (71.3-100)
ARTVU	14-16	2	4-5	72.5 (66.3-78.8)	81.3 (76.3-86.3)
BRSNW	13-14	1	20	70	73
CAPBP	12-30	7	5-23	85.9 (66-100)	94.0 (79-100)
CHEAL	10-32	11	6-53.8	66.0 (20-94)	75.1 (25-96)
CHEPO	13-20	1	5	94	96
CIRAR	15-31	1	6	57.5	67.5
EPHHE	13-16	1	10.3	78.8	83.8
GALAP	12-15	1	7	95	100
GASPA	14-22	1	12.5	92.5	98.8
GERPU	12-14	2	7-13	89 (-)	93.5 (90-97)
LAMPU	12-16	2	5-9	67.0 (34-100)	72.5 (45-100)
MATIN	12-19	3	3-11	66.3 (14-92.5)	77.1 (35-98.8)
MATMA	13-16	1	4	85	93
PLAME	13-19	2	6-17	58.0 (18-98)	59.5 (20-99)
POLCO	11-51	6	5-12.8	71.5 (50-83)	78.3 (58.8-92.5)
POLPE	12-51	4	11-15.8	63.1 (46.3-81.3)	73.8 (57.5-90)
SINAR	13-30	2	8-9.5	80.0 (73.8-86.3)	89.4 (82.5-96.3)
SOLNI	13-27	2	6-26	97.1 (96.3-98)	98.6 (98.3-99)
SONAR	30-32	1	8	62.5	71.3
STEME	11-25	6	6-11.3	79.3 (63.8-89)	90.8 (86.3-93)
VERAG	10-21	2	4.8-6.3	90.0 (82.5-97.5)	91.9 (87.5-96.3)
VERPE	16	1	6	83	84
VICCR	12-15	1	7.5	91.3	97.5
VIOAR	10-21	7	5-30	79.3 (55-93.8)	87.9 (78.8-100)
Mean of all assessments		75		76.7 (14-100)	83.9 (20-100)

Mediterranean EPPO zone

In the Mediterranean EPPO zone, the average control of the assessed dicotyledonous weed species at the assessment carried out 21-48 days after application was 76.7% and 89.8% following an early post-emergence application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.15 kg/ha and 0.25 kg/ha, respectively, compared to 92.6% control achieved by the a higher dose recommended rate, i.e. 0.33 kg/ha. A satisfactory level of control may be achieved with the higher recommended dose rate when applied early post-emergence, but if weeds have already emerged, or if less susceptible grass weed species are part of the flora in the field, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied at the maximum recommended dose rate (i.e. 0.25 kg/ha) to obtain a enough control.

Statistical evaluation revealed that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the 0.15 kg/ha dose rate at eleven of the 21 assessments. At four of the 11 assessments, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 l/ha also performed significantly better than the 0.25 kg/ha dose rate. At the remaining 10 assessments, no significant differences were observed between the tested Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG dose rates when applied early post-emergence, however, the proposed dose rate of 0.25 kg/ha achieved a sufficiently satisfactory control.

Table 3.2-19: Mediterranean zone: Minimum effective dose of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied against frequently occurring broadleaved weeds in maize.

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max)		
				0.15 kg/ha (~45%)	0.25 kg/ha (~75%)	0.33 kg/ha (100%)
ABUTH	10-11	1	5.8	100	99.8	100
AMARE	10	1	57.8	80	95	100
CHEAL	10-16	4	7.5-138	83.8 (71.3-100)	96.2 (92.5-100)	99.1 (97.5-100)
DATST	14-20	1	5	97.3	98.3	97.5
EPHCH	10	1	6.5	82.5	87.5	100
GASPA	12-14	1	44.5	80	93	99
MERAN	12	1	48	57.5	83.8	81.3
POLAV	12	1	6.5	60	83.8	81.3
POLCO	11-25	2	10.4-17.8	35-55	70.9 (67.5-74.3)	74.6 (74.3-75)
POROL	10	1	202.5	70	73.8	77.5
SOLNI	10-16	4	6-27.5	87.4 (70-100)	95.3 (88.8-100)	98.5 (95-100)
SONSS	12	1	17.5	71.3	97.5	100
TTTTT	11-25	2	85.8-99.4	68.8 (57.5-80)	82.6 (77-88.3)	84.0 (77.5-90.5)
Mean of all assessments		21		76.7 (35-100)	89.8 (67.5-100)	92.6 (74.3-100)

Conclusion

Based on results achieved on dicotyledonous weeds in the 31 maize trials, it can be concluded that to consistently control frequently occurring broadleaved weeds in maize, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be applied early post-emergence at 0.25 kg/ha. However, the data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections.

Summary of all uses claimed on the label

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied early post-emergence at 0.25 kg/ha to control grasses and broadleaved weeds achieved good to excellent control of all target weeds. Reducing the application rate of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG from the proposed dose rate (0.25 kg/ha) to 60% of that rate, resulted in lower levels of efficacy. To ensure that a satisfactory level of control is achieved with the proposed dose rate of 0.25 kg/ha, it is recommended that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is applied under optimal conditions, i.e. early growth stage of the weeds and optimal weather conditions.

As weeds often occur as a complex of several weeds with different susceptibility towards rimsulfuron, nicosulfuron and/or mesotrione, one application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at the recommended rate should be used to efficiently control all weeds claimed on the label.

As will be demonstrated in the following sections, this document clearly demonstrates that the efficacy and crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to that of the standard rimsulfuron – nicosulfuron + mesotrione co-formulated reference products (i.e. Arigo 51 and Columbus 51) to which it was compared. The applicant therefore 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 by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

Comments of zRMS:	Statement accepted. 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 assessment 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.

3.2.3 Efficacy tests (KCP 6.2.2)

Data from 33 efficacy trials conducted in the Maritime (9, i.e. Czech Republic (3), N-France (2), Germany (2) and UK (2)), the North-east EPPO zone (16, i.e. Poland), the South-east EPPO zone (2, i.e. Hungary) and the Mediterranean (6, i.e. Spain (2), Italy (2) and S-France (2)) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

The 33 efficacy trials were conducted in maize where test- and reference products were applied early post-emergence of the crop.

Table 3.2-20: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152(4), PP 1/181(4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/50(3)
Experimental design	Plot design	RCBD (33)
	Plot size	12-33 m²
	Number of replications	4 (33)
Crop	Trials per crop	Maize (33)

	Varieties per crop	Ambition, ES Asteriod, Cedro, Chloelia KWS, RGT Conexxion, Coriolics, DKC 3623, Enigma, RGT Exxclam, Farm Fire, Kobras, Kosmo, LG 30.215, LG 30.220, LG 30.233, MAS 19 H, Messago, Opoka, P1524, PR38A75, Ricardinio, Ronaldinio, KWS Severus, SNH 3616, SY Telias, Unitop, Winxx, Zoom, ES Zorion
	Sowing period	April 3rd to July 15th
Application	Crop stage (BBCH)* at application	BBCH 12-18 (range: BBCH 11-18)
	Timing Pest stage at appl. (1)	Early post-emergence BBCH 09-50 – for details on the growth stage of the specific weed at application, please refer to summary tables in Appendix 5
	Number of appl. Intervals between appl.	1 (33) n.a.
	Spray volumes	200-400 L/ha
Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on weed counts (COUPLA) or weed ground cover (GROUND) in a defined area, as compared to the untreated check. - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was sub-stituted or supplemented by assessments of individual symptoms.
	Assessment dates	6 to 147 DAT
Other rele-vant infor-mation	Soil type	Light to heavy soils
	Natural / artificial innoculation…	Natural
	Field / Greenhouse...	Field

In the 33 trials, the level of control obtained by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was assessed on mono- and dicotyledonous weeds present in the trials. Data on each individual weed species is only included from trials in which a minimum of 5 plants per m² or 1% ground cover were seen at the timing of the assessment.

Use 001: Control of grasses and broadleaved weeds in maize with a single application of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, applied early post-emergence to the crop

The efficacy trials were conducted to prove the following label claims:

Description of Use 001

Crop, stage	Maize, early post-emergence BBCH 12-18
Use rate Use frequency Application timing	0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG 1x Early post-emergence to weeds and crop
Target weeds	Grass weeds, e.g. *Digitaria spp.*, *Echinochloa spp.*, *Panicum spp.*, *Setaria spp.*, *Sorghum halepense*, a.o. Broadleaved weeds, e.g. *Abuthilon theophrasti*, *Amaranthus spp.*, *Polygonum spp.*,

	Solanum nigrum, *Stellaria media*, a.o.

The effectiveness of applying Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG early post-emergence against mono- and dicotyledonous weeds was evaluated in 33 efficacy trials conducted in maize. These trials were carried out in 2016 (25), 2017 (4) and 2019 (4) in the Maritime EPPO zone (9, i.e. Czech Republic (3), N-France (2), Germany (2) and UK (2)), the North-east EPPO zone (16, i.e. Poland), the South-east EPPO zone (2, i.e. Hungary) and the Mediterranean EPPO zone (6, i.e. Spain (2), Italy (2) and S-France (2)). The objective was to confirm the performance of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha (i.e. 7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare) and compare this to national reference products registered for similar uses. In the trials, one application was applied in spring or early summer (April-July).

In 31 of the 33 efficacy trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was tested alongside an EU approved rimsulfuron + nicosulfuron + mesotrione co-formulation, i.e. Arigo/Arigo 51/ Arigo 51 WG (CZ, DE, ES, FR, HU, IT, PL) or Columbus 51 (PL). In two English efficacy trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was compared against a national standard reference product containing nicosulfuron and mesotrione (Elumis; nicosulfuron 30 g/L + mesotrione 75 g/L OD). Furthermore, in all efficacy trials, a rimsulfuron 250 g/kg WG standard product was used as additional reference (Rim 25 WG, registered by Sharda in e.g. Poland and Czech Republic), for comparison. The benefits of applying the co-formulation of rimsulfuron, nicosulfuron and mesotrione compared to rimsulfuron alone was already demonstrated in Section 3.2.1.1 and will therefore not be repeated here in this section.

Maritime zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following early post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented from one assessment carried out approx. four weeks (range: two to eight weeks) after application.

When applied at 0.25 kg/ha early post-emergence in the Maritime zone, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG achieved good to excellent control of annual grasses and broadleaved weeds commonly found in maize. In all species evaluated, the effect achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was similar to the effect obtained with the rimsulfuron + nicosulfuron + mesotrione reference product applied in six of the 8 trials. At the assessments included in the summary table, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at two assessments whereas at the remaining 39 assessments, no significant differences were observed between the two tested products when applied at 0.25 kg/ha.

Table 3.2-21: Maritime zone, maize – Grasses and broadleaved weed control results by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.25 kg/ha early post-emergence and compared against control obtained with the rimsulfuron + nicosulfuron + mesotrione reference product at comparable rate in the efficacy tests 2016. In the same table, the results obtained with the test product at 0.25 kg/ha compared against the nicosulfuron + mesotrione reference product (Elumis) at 1.5 L/ha is also presented (Spring/early summer assessment, 14-58 DAA).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with		No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the reference product at registered dose rate. = : ± 5% control			Overall
				Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:	Reference product at:				
				Mean (min-max)					
				0.25 kg/ha	1N	>	=	<	
Grass weeds, Visual control									
AGRRE	23-30	1	12	93.5	92.3		1		=
ALOMY	09-13	1	6.3	98.8	97.3		1		=

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha	Efficacy obtained with Reference product at: Mean (min-max) 1N	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the reference product at registered dose rate. = : ± 5% control >	=	<	Overall
ECHCG	11-31	5	8-52.5	90.3 (75.0-99.5)	95.3 (87.5-99.8)		4	1	=
LOLMU	10-22	2	5.5-12	99.4 (98.8-100)	100 (-)		1	1	<
POAAN	09-14	2	6-10	87.5 (75.0-100)	83.8 (67.5-100)	1	1		>
SETPU	11-13	1	11.3	95	95		1		=
Mean, all assessments		12		92.3 (75.0-100)	94.0 (67.5-100)	1	9	2	=
Annual broadleaved weeds, Visual control									
BRSNW	14-16	1	13.8	100	100		1		=
CAPBP	34	1	32.5	100	100		1		=
CHEAL	10-19	7	6.5-64	94.8 (85.0-100)	96.8 (90-100)	1	4	2	=
FUMOF	11-12	1	5.5	100.0	100		1		=
GAETE	12-16	1	5.5	100.0	100		1		=
GALAP	12-14	1	10.0	92.3	99			1	<
HELAN	10-12	1	15	90.0	94.8		1		=
LAMPU	14-31	1	15.5	100.0	100		1		=
MATIN	10-18	3	5-6	93.6 (87.5-99.8)	96.0 (93.8-97.3)		2	1	=
POLCO	11-21	5	1-14	91.4 (65.0-100)	97.0 (86.3-100)		4	1	=
POLLA	12	1	5	98.5	97.5		1		=
POLPE	19	1	11	65.0	86.3			1	<
SPRAR	14-19	1	5.3	100.0	100		1		=
STEME	12-16	1	1.3	87.5	100		1		=
THLAR	12-35	3	10.8-36	100 (-)	100 (-)		3		=
TTTTT	12-20	2	30-41.2	83.3 (68.8-97.8)	90.6 (82.5-98.8)		1	1	<
VERPE	09-19	3	7.8-15.8	92.5 (77.5-100)	92.1 (82.5-100))		3		=
VIOAR	10-16	2	3-10.5	98.1 (96.3-100)	98.1 (96.3-100)		2		=
Mean, all assessments		36		93.7 (65.0-100)	96.7 (82.5-100)	1	28	7	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha	Efficacy obtained with Rimsulfuron + nicosulfuron + mesotrione ref. prod. at Mean (min-max) 0.33 kg/ha	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the RIM + NIC + MES reference product at 168.3 g ai/ha. = : ± 5% control >	=	<	Overall
Grass weeds, Visual control									
AGRRE	23-30	1	12	93.5	92.3		1		=
ECHCG	11-31	5	8-52.5	90.3 (75.0-99.5)	95.3 (87.5-99.8)		3	2	=
LOLMU	14-22	1	12	98.8	100		1		=
SETPU	11-13	1	11.3	95	95		1		=
Mean, all assessments		8		92.4 (75-100)	95.4 (87.5-100)		6	2	=
Annual broadleaved weeds, Visual control									
BRSNW	14-16	1	13.8	100	100		1		=
CAPBP	34	1	32.5	100	100		1		=
CHEAL	12-19	6	8.6-64	94.8 (91.9-100)	96.9 (90-100)	1	5		=
FUMOF	11-12	1	5.5	100	100		1		=
GAETE	12-16	1	5.5	100	100		1		=
GALAP	12-14	1	10.0	93.8	99			1	<
HELAN	10-12	1	15	95	94.8		1		=
LAMPU	14-31	1	15.5	100	100		1		=
MATIN	12-18	2	5-6	96.7 (93.5-99.8)	97.1 (97-97.3)		2		=
POLCO	11-21	5	1-14	91.4 (65.0-100)	97.0 (86.3-100)		4	1	=
POLLA	12	1	5	98.5	97.5		1		=
POLPE	19	1	11	65.0	86.3			1	<
SPRAR	14-19	1	5.3	100.0	100		1		=
STEME	12-16	1	1.3	87.5	100			1	<
THLAR	12-35	3	10.8-36	100 (-)	100 (-)		3		=
TTTTT	12-20	2	30-41.2	83.3 (68.8-97.8)	90.6 (82.5-98.8)		1	1	<
VERPE	10-19	2	8.5-15.8	88.8 (77.5-100)	91.3 (82.5-100))		2		=
VIOAR	10-16	2	3-10.5	98.1 (96.3-100)	98.1 (96.3-100)		2		=
Mean, all assessments		33		94.3 (66.3-100)	96.9 (82.5-100)	1	27	5	=
EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max)	Efficacy obtained with Nicosulfuron + mesotrione ref. prod. at Mean (min-max)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 168.3 g ai/ha is >, < or =, compared to the NIC + MES reference product at 1.5 L/ha. = : ± 5% control			Overall

				0.25 kg/ha	1.5 L/ha	>	=	<	
Grass weeds, Visual control									
ALOMY	09-13	1	6.3	98.8	97.3		1		=
LOLMU	10-14	1	5.5	100	100		1		=
POAAN	09-14	2	6-10	87.5 (75.0-100)	83.8 (67.5-100)	1	1		>
Mean, all assessments		4		92.1 (80-99.8)	91.2 (67.5-100)	1	3		=
Annual broadleaved weeds, Visual control									
CHEAL	10-15	1	6.5	85.0	96.3			1	<
MATIN	10-14	1	6	87.5	93.8			1	<
VERPE	09-13	1	7.8	100	93.8	1			>
Mean, all assessments		3		90.8 (85.0-100)	94.6 (93.8-96.3)	1		2	=

In two of the nine trials, conducted in England, a national reference product containing nicosulfuron and mesotrione (Elumis) was included. In all species evaluated, the effect achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was similar to the effect obtained with Elumis in the English trials. At the assessments included in the summary table, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at two assessments whereas at the remaining five assessments, no significant differences were observed between the two tested products when applied at 0.25 kg/ha and 1.5 L/ha, respectively.

In Table 3.2-22, the weed species are classified according to their average sensitivity to 0.33 kg/ha of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in the Maritime EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG early post-emergence to weeds are listed in Table 3.2-29.

Table 3.2-22: Weed control spectrum of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha in the Maritime zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
Alopecurus myosuroides	Blackgrass	ALOMY
Setaria helvola	Yellow foxtail	SETPU
Brassica napus	Volunteer oilseed rape	BRSNW
Capsella bursa-pastoris	Shepherd's purse	CAPBP
Fumaria officinalis	Common fumitory	FUMOF
Galeopsis tetrahit	Common hemp-nettle	GAETE
Lamium purpureum	Purple deadnettle	LAMPU
Persicaria lapathifolia	Pale smart weed	POLLA
Spergula arvensis	Corn spurry	SPRAR
Thlaspi arvense	Field pennycress	THLAR
Viola arvensis	Field violet	VIOAR
Susceptible (85 – 94.9 %)		
Elymus repens	Common couchgrass	AGRRE
Echinochloa crus-galli	Common barnyard grass	ECHCG
Chenopodium album	Common lambsquarters	CHEAL
Lolium multiflorum	Italian Ryegrass	LOLMU
Helianthus annuus	Sunflower (volunteer)	HELAN
Tripleurospermum inodorum	Scentless mayweed	MATIN
Poa annua	Annual bluegrass	POAAN
Stellaria media	Common chickweed	STEME
Galium aparine	Cleavers	GALAP

Scientific name	English common name	EPPO code
Fallopia convolvulus	Black bindweed	POLCO
Veronica persica	Common field speedwell	VERPE
Moderately Susceptible (70 – 84.9 %)		
Persicaria maculosa	Redshank	POLPE
Moderately tolerant (50 – 69.9 %)		
-		
Tolerant (0 – 49.9 %)		
-		

North-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following early post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented from one assessment carried out approx. four weeks (range: two to eight weeks) after application.

When applied at 0.25 kg/ha early post-emergence in the North-east zone, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG achieved good to excellent control of annual grasses and broadleaved weeds commonly found in maize. In all species evaluated, the effect achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was similar to the effect obtained with the rimsulfuron + nicosulfuron + mesotrione reference product applied in the trials. At the assessments included in the summary table, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha performed significantly similar than the rimsulfuron + nicosulfuron + mesotrione reference product at thirty assessments, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining assessments, no significant differences were observed between the two tested products.

Table 3.2-23: North-east zone, maize – Grasses and broadleaved weed control results by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.25 kg/ha early post-emergence and compared against control obtained with the rimsulfuron + nicosulfuron + mesotrione reference product at comparable rate in the efficacy tests 2016, 2017 and 2019 (Spring/early summer assessment, 14-53 DAA).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m^2)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max)	Efficacy obtained with Rimsulfuron + nicosulfuron + mesotrione ref. prod. at: Mean (min-max)	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the RIM + NIC + MES reference product at 168.3 g ai/ha. = : ± 5% control			Overall
				0.25 kg/ha	0.33 kg/ha	>	=	<	
Grass weeds, Visual control									
AGRRE	12-30	4	6-12.5	67.8 (40.0-81.3)	75.9 (56.3-83.8)		2	2	=
ALOMY	11	1	6	75.0	83			1	<
APESV	12	2	9-11	82.0 (77.0-87.0)	89 (-)		1	1	=
ECHCG	11-24	12	4-120.5	66.6 (19.0-98.0)	79.4 (27.5-99)		8	4	=
POAAN	10	2	6-7	79.5 (73.0-86.0)	91 (-)			2	<
SETVI	11-25	2	5-11.8	78.3 (67.0-95.0)	84.0 (83-85)		1	1	=
Mean, all assessments		23		70.7 (19.0-98.0)	81.2 (27.5-99)		12	11	=
Annual broadleaved weeds, Visual control									
AMARE	11-24	7	1-35.8	84.7 (61.3-100)	88.3 (76.3-100)		4	3	=
ARTVU	14-16	2	4-5	72.5 (66.3-78.8)	81.3 (73.8-88.8)			2	<
BRSNW	13-14	1	20	70.0	78			1	<
CAPBP	12-30	7	4-23	85.9 (66.0-100)	94.4 (88-100)		4	3	=
CHEAL	10-32	11	5-53.8	66.0 (20.0-94.0)	80.2 (42.5-95)		4	7	<
CHEPO	13-20	1	5	94.0	93		1		=
CIRAR	15-31	1	6	57.5	68.8			1	<
EPHHE	13-16	1	7	78.8	86.3			1	<
GALAP	12-15	1	7	95.0	100			1	<

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.25 kg/ha	Efficacy obtained with Rimsulfuron + nicosulfuron + mesotrione ref. prod. at Mean (min-max) 0.33 kg/ha	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the RIM + NIC + MES reference product at 168.3 g ai/ha. = : ± 5% control >	=	<	Overall
GASPA	14-22	1	12.5	92.5	98.8			1	<
GERPU	12-14	2	7-13	89.0 (89.0-890)	89.0 (87-91)		2		=
LAMPU	12-16	2	5-9	67.0 (34.0-100)	100 (-)		1	1	=
MATIN	12-19	3	3-16.3	66.3 (14.0-92.5)	96.4 (93.8-98)		2	1	=
MATMA	13-16	1	4	85.0	70	1			>
PLAME	13-19	2	6-15	58.0 (18.0-98.0)	92.5 (86-99)		1	1	=
POLCO	11-51	6	5-25	71.5 (50.0-83.0)	80.2 (70-91.3)		2	4	<
POLPE	12-51	4	10.8-20	63.1 (46.3-81.3)	75.6 (62.5-91.3)			4	<
SINAR	13-30	2	8-15	80.0 (73.8-86.3)	90.6 (85-96.3)			2	<
SOLNI	13-27	2	6-26	97.1 (96.3-98.0)	97.6 (96-99.3)		2		=
SONAR	30-32	1	6.5	62.5	85			1	<
STEME	11-25	6	6-11.3	79.3 (63.8-89.0)	89.5 (88-92.5)		2	4	<
VERAG	10-21	2	4.8-6.3	90.0 (82.5-7.5)	73.8 (52.5-95)	1	1		>
VERPE	16	1	6	83.0	81		1		=
VICCR	12-15	1	7.5	91.3	96.3		1		=
VIOAR	10-21	7	5-30	79.3 (55.0-93.8)	83.9 (50-100)		2	5	<
Mean, all assessments		75		76.7 (14.0-100)	86.2 (42.5-100)	2	30	42	<

In Table 3.2-24, the weed species are classified according to their average sensitivity to 0.25 kg/ha of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in the North-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG early post-emergence to weeds are listed in Table 3.2-29.

Table 3.2-24: Weed control spectrum of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha in the North-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
Galium aparine	Cleavers	GALAP
Solanum nigrum	Black nightshade	SOLNI
Susceptible (85 – 94.9 %)		
Capsella bursa-pastoris	Shepherd's purse	CAPBP
Vicia cracca	Bird vetch	VICCR
Galinsoga parviflora	Small-flower galinsoga	GASPA
Chenopodium polyspermum	Many-seeded goosefoot	CHEPO
Geranium pusillum	Small-flowered cranesbill	GERPU
Tripleurospermum maritimum	False mayweed	MATMA
Veronica agrestis	Green field speedwell	VERAG
Moderately Susceptible (70 – 84.9 %)		
Elymus repens	Common couchgrass	AGRRE
Apera spica-venti	Silky Windgrass	APESV
Setaria viridis	Green foxtail	SETVI
Amaranthus retroflexus	Common amaranth	AMARE
Euphorbia helioscopia	Sun spurge	EPHHE
Sinapis arvensis	Charlock	SINAR
Stellaria media	Common chickweed	STEME
Viola arvensis	Field violet	VIOAR
Alopecurus myosuroides	Blackgrass	ALOMY
Echinochloa crus-galli	Common barnyard grass	ECHCG

Scientific name	English common name	EPPO code
Artemisia vulgaris	Common mugwort	ARTVU
Brassica napus	Volunteer oilseed rape	BRSNW
Fallopia convolvulus	Black bindweed	POLCO
Veronica persica	Common field speedwell	VERPE
Moderately tolerant (50 – 69.9 %)		
Cirsium arvense	Creeping thistle	CIRAR
Tripleurospermum inodorum	Scentless mayweed	MATIN
Plantago media	Hoary plantain	PLAME
Chenopodium album	Common lambsquarters	CHEAL
Persicaria maculosa	Redshank	POLPE
Sonchus arvensis	Perennial sow-thistle	SONAR
Lamium purpureum	Purple deadnettle	LAMPU
Tolerant (0 – 49.9 %)		
-		

South-east zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following early post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented from one assessment carried out approx. four weeks after application.

When applied at 0.33 kg/ha early post-emergence in the South-east zone, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG achieved good to excellent control of annual grasses and broadleaved weeds commonly found in maize. In all species evaluated, the effect achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was similar to the effect obtained with the rimsulfuron + nicosulfuron + mesotrione reference product applied in the trials. At the assessments included in the summary table, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha performed significantly better than the reference product at two assessments whereas at the remaining seven assessments, no significant differences were observed between the two tested products when applied at 0.33 kg/ha.

Table 3.2-25: South-east zone, maize – Annual grasses and broadleaved weed control results by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.33 kg/ha early post-emergence and compared against control obtained with the rimsulfuron + nicosulfuron + mesotrione reference product at comparable rate in the efficacy tests 2016 (Spring/early summer assessment, 28-29 DAA).

EPPO Code	Weed Growth stage at application [BBCH]	No. of trials	Ground cover at assessm. (no/m²)	Efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at: Mean (min-max) 0.33 kg/ha	Efficacy obtained with Rimsulfuron + nicosulfuron + mesotrione ref. prod. at Mean (min-max) 0.33 kg/ha	No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 168.3 g ai/ha is >, < or =, compared to the RIM + NIC + MES reference product at 168.3 g ai/ha. = : ± 5% control: >	=	<	Overall
Grass weeds, Visual control									
ECHCG	11-14	2	8.5-11	99.9 (99.8-100)	98.5 (98-99)		2		=
PANMI	11-13	2	13-22.5	100 (-)	100 (-)		2		=
Mean, all assessments		4					4		=
Annual broadleaved weeds, Visual control									
AMARE	12-14	2	11-13.8	100 (-)	100 (-)		2		=
CHEAL	12-16	1	23.8	100	100		1		=
DATST	10-12	1	8.3	100	100		1		=
MERAN	12-16	1	30	98	98.3		1		=
Mean, all assessments		5		99.6 (98-100)	99.7 (98.3-100)		5		=

In Table 3.2-26, the weed species are classified according to their average sensitivity to 0.33 kg/ha of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in the South-east EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 0.33 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG early post-emergence to weeds are listed in Table 3.2-29.

Table 3.2-26: Weed control spectrum of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.33 kg/ha in the South-east zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
Echinochloa crus-galli	Common barnyard grass	ECHCG
Panicum miliaceum	Common millet	PANMI
Amaranthus retroflexus	Common amaranth	AMARE
Chenopodium album	Common lambsquarters	CHEAL
Datura stramonium	Common thorn apple	DATST
Mercurialis annua	Annual mercury	MERAN
Susceptible (85 – 94.9 %)		
-	-	-
Moderately Susceptible (70 – 84.9 %)		
-	-	-
Moderately tolerant (50 – 69.9 %)		
-	-	-
Tolerant (0 – 49.9 %)		
-	-	-

Mediterranean zone

To demonstrate the effectiveness of the test product at the recommended dose rate against grasses and broadleaved weeds following early post-emergence application in maize as well as compare it to the reference product included in the trials, results are presented from one assessment carried out approx. four weeks (range: two to eight weeks) after application.

When applied at 0.25 kg/ha early post-emergence in the Mediterranean zone, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG achieved good to excellent control of annual grasses and broadleaved weeds commonly found in maize. In all species evaluated, the effect achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was similar to the effect obtained with the rimsulfuron + nicosulfuron + mesotrione reference product applied in the trials. At the assessments included in the summary table, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha performed significantly better than the rimsulfuron + nicosulfuron + mesotrione reference product at seven assessments and at one assessment, the reference product performed significantly better than Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG. At the remaining 20 assessments, no significant differences were observed between the two tested products.

Table 3.2-27: Mediterranean zone, maize – Grasses and broadleaved weed control results by Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.25 kg/ha early post-emergence and compared against control obtained with the rimsulfuron + nicosulfuron + mesotrione reference product at comparable rate in the efficacy tests 2016 (Spring/early summer assessment, 14-48 DAA).

<table>
<tr><th rowspan="3">EPPO Code</th><th rowspan="3">Weed Growth stage at application [BBCH]</th><th rowspan="3">No. of trials</th><th rowspan="3">Ground cover at assessm. (no/m²)</th><th colspan="2">Efficacy obtained with</th><th rowspan="3">No. of trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 127.5 g ai/ha is >, < or =, compared to the RIM + NIC + MES reference product at 168.3 g ai/ha. = : ± 5% control</th><th rowspan="3">Overall</th></tr>
<tr><th>Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:</th><th>Rimsulfuron + nicosulfuron + mesotrione ref. prod. at</th></tr>
<tr><th colspan="2">Mean (min-max)</th></tr>
</table>

				0.25 kg/ha	0.33 kg/ha	>	=	<	
Grass weeds, Visual control									
CYPRO	12	1	8.8	8.8	7.5		1		=
DIGSA	11-13	1	54.5	37.5	82.5			1	<
ECHCG	11-21	3	5-104.5	94.7 (91.3-99.8)	98.6 (97.5-99.5)		3		=
SETVI	10-12	2	7.5-20	97.5 (95-100)	88.8 (77.5-100)	1	1		>
Mean, all assessments		7		71.8 (8.8-99.8)	80.5 (7.5-100)	1	5	1	=
Annual broadleaved weeds, Visual control									
ABUTH	10-11	1	5.8	99.8	100		1		=
AMARE	10	1	57.8	95.0	100		1		=
CHEAL	10-16	4	7.5-138	96.2 (92.5-100)	90.0 (75-100)	1	3		=
DATST	14-20	1	5	98.3	98.5		1		=
EPHCH	10	1	6.5	87.5	100			1	<
GASPA	12-14	1	44.5	93.0	95		1		=
MERAN	12	1	48	83.8	83.8		1		=
POLAV	12	1	6.5	83.8	85		1		=
POLCO	11-25	2	10.4-10.8	70.9 (67.5-74.3)	75.6 (71.3-80)		1	1	=
POROL	10	1	202.5	73.8	80		1		=
SOLNI	10-16	4	6-27.5	95.3 (88.8-100)	88.4 (56.3-100)	1	3		>
SONSS	12	1	17.5	97.5	73.8	1			>
TTTTT	11-25	2	85.8-99.4	82.6 (77.0-88.3)	86.1 (82.5-89.8)		2		=
Mean, all assessments		21		89.8 (67.5-100)	88.3 (56.3-100)	3	16	2	=

In Table 3.2-28, the weed species are classified according to their average sensitivity to 0.25 kg/ha of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in the Mediterranean EPPO zone. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4, based on the mean across the trial results. All weed species have been included in the table below, irrespective of the number of trials where the included weed species were evaluated. However, this does not replace individual MS systems for expressing control on national labels.

Based on the maximum level of control achieved on the individual weed species present in the trials, the combined proposed label claims of the grass- and broadleaved weed spectrum controlled after application of 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG early post-emergence to weeds are listed in Table 3.2-29.

Table 3.2-28: Weed control spectrum of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha in the Mediterranean zone

Scientific name	English common name	EPPO code
Highly Susceptible (≥95 %)		
Setaria viridis	Green foxtail	SETVI
Abutilon theophrasti	Velvet leaf	ABUTH
Amaranthus retroflexus	Common amaranth	AMARE
Chenopodium album	Common lambsquarters	CHEAL
Datura stramonium	Common thorn apple	DATST
Solanum nigrum	Black nightshade	SOLNI
Sonchus spp.	Sow thistles	SONSS
Susceptible (85 – 94.9 %)		
Echinochloa crus-galli	Common barnyard grass	ECHCG
Euphorbia chamaesyce	Crenated spurge	EPHCH
Galinsoga parviflora	Small-flower galinsoga	GASPA
Moderately Susceptible (70 – 84.9 %)		
Mercurialis annua	Annual mercury	MERAN
Polygonum aviculare	Prostrate knotweed	POLAV
Fallopia convolvulus	Black bindweed	POLCO
Portulaca oleracea	Common purslane	POROL
Moderately tolerant (50 – 69.9 %)		
-		
Tolerant (0 – 49.9 %)		
Cyperus rotundus	Purple nutsedge	CYPRO

Scientific name	English common name	EPPO code
Digitaria sanguinalis	Hairy crabgrass	DIGSA

Summary and conclusion

Based on the results of 33 field efficacy trials carried out in 2016, 2017 and 2019, the following can be concluded for the intended use '*Control of grasses and broadleaved weeds*' with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied early post-emergence at the rate of 0.25 kg/ha in maize:

- Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied early post-emergence at the proposed dose rate of 0.25 kg/ha provides a high level of control of a range of grasses and broadleaved weeds commonly found in maize. As weeds often occur as a complex of several weeds with different susceptibility towards rimsulfuron, nicosulfuron and/or mesotrione, one application of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at 0.25 kg/ha in maize should be used to efficiently control all weeds claimed on the label.
- Compared to the rimsulfuron + nicosulfuron + mesotrione co-formulated reference product, the efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is comparable against all weed species.
- Compared to the nicosulfuron + mesotrione co-formulated reference product, the efficacy obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is comparable against the weed species evaluated in the two trials.
- The trial results are considered valid for all intended Central zone countries.

The dose has been reduced to 0.25 l/ha in all uses due to the requirement of the evaluators in the ecotoxicology section. Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied early post-emergence is suitable for the control of grasses and broadleaved weeds in maize.

This report also clearly demonstrates that the efficacy and cropsafetyness of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to the efficacy and cropsafetyness of the standard rimsulfuron + nicosulfuron + mesotrione co-formulated reference products against which Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was compared. The applicant therefore 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 by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

The proposed label claims across uses, based on control achieved with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.25 kg/ha, has been summarized in Table 3.2-29. The classification is made according to Appendix I of regulation SANCO/10055/2013 Rev. 4 (October 3rd, 2013), however this does not replace individual MS systems for expressing control on national labels:

Susceptibility	Abbreviation	Level of control
Highly Susceptible	HS	95-100 %
Susceptible	S	85 – 94.9 %
Moderately Susceptible	MS	70 – 84.9 %
Moderately tolerant	MT	50 – 69.9 %
Tolerant	T	0 – 49.9 %

Table 3.2-29: **Grasses and broadleaved weed spectrum controlled by 0.25 kg/ha Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG after early post-emergence application to weeds, proven by testing results of the applicant in 2016, 2017 and 2019.**

		Application timings
EPPO code	**Scientific name**	**Early post-emergence**
Annual grass weeds		
ALOMY	*Alopecurus myosuroides*	HS
APESV	*Apera spica-venti*	S
DIGSA	*Digitaria sanguinalis*	MS
ECHCG	*Echinochloa crus-galli*	S
LOLMU	*Lolium multiflorum*	S
PANMI	*Panicum miliaceum*	HS
POAAN	*Poa annua*	S
SETPU	*Setaria helvola*	HS
SETVI	*Setaria viridis*	MS
Perennial grass weeds		
AGRRE	*Elymus repens*	S
CYPRO	*Cyperus rotundus*	T
Broadleaved weeds		
ABUTH	*Abutilon theophrasti*	HS
AMARE	*Amaranthus retroflexus*	HS
ARTVU	*Artemisia vulgaris*	S
BRSNX	*Brassica napus*	HS
CAPBP	*Capsella bursa-pastoris*	S
CHEAL	*Chenopodium album*	S
CHEPO	*Chenopodium polyspermum*	HS
CIRAR	*Cirsium arvensis*	MT
DATST	*Datura stramonium*	HS
EPHCH	*Euphorbia chamaesyce*	HS
EPHHE	*Euphorbia helioscopia*	S
FUMOF	*Fumaria officinalis*	HS
GAETE	*Galeopsis tetrahit*	HS
GALAP	*Galium aparine*	S
GASPA	*Galinsoga parviflora*	HS
GERPU	*Geranium pusillum*	HS
HELAN	*Helianthus annuus*	S
LAMPU	*Lamium purpureum*	MT
MATIN	*Matricaria inodorum*	MT
MATMA	*Tripleurospermum maritimum*	S
MERAN	*Mercurialis annua*	HS
PLAME	*Plantago media*	MT
POLAV	*Polygonum aviculare*	MS
POLCO	*Fallopia convolvulus*	S
POLLA	*Persicaria lapathifolia*	HS
Broadleaved weeds (cont.)		
POLPE	*Persicaria maculosa*	MS
POROL	*Portulaca oleracea*	MS
SINAR	*Sinapis arvensis*	MS
SOLNI	*Solanum nigrum*	HS
SONAR	*Sonchus arvensis*	MT
SONSS	*Sonchus spp.*	HS
SPRAR	*Spergula arvensis*	HS
STEME	*Stellaria media*	MS
THLAR	*Thlaspi arvense*	HS
TTTTT	-	HS
VERAG	*Veronica agrestis*	HS
VERPE	*Veronica persica*	S
VICCR	*Vicia cracca*	HS
VIOAR	*Viola arvensis*	HS

Comments of zRMS:	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 submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles. Number of results for particular weed is very limited. Only trials with greater than 5 weeds/m^2 or over 2% ground cover 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 proposed 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 <u>annual</u> monocotyledonous and <u>annual</u> dicotyledonous weeds (TTTMS, TTTDS). The applicant wishes to cite the original registrant’s data on rimsulfuron, nic-

	osulfuron 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~~ minor weed – ~~due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label~~. It can be concluded that BRSNW is a moderately sensitive weed (1 trial PL–MS: 70%, 1 trial DE–S: 100%). BRSNW should be classified as a moderately sensitive weed species because it had a 70% efficacy rate in Poland. • 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) – ~~major~~ minor weed ~~– due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label~~. 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) – ~~major~~ minor weed – submitted trials are sufficient. It can be concluded that MATIN is a moderately susceptible weed (2 tri-

als 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) – ~~minor~~ major weed – submitted trials are not sufficient~~. It can be concluded that SETVI is a moderately susceptible weed~~ (1 trial PL–S, 1 trial PL–MT). ~~Average efficacy from all trials was: 78,3%.~~ 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) – ~~major~~ minor weed – ~~due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label.~~ It can be concluded that ARTVU is a moderately sensitive weed. Average efficacy from all trials was: 72.5%.
- GERPU – 2 trials (PL-2) - ~~major~~ minor weed – ~~due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label .~~ 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) – ~~major~~ minor weed – ~~due to not enough number of trials (at least 4 are required) this weed should be excluded from Polish label.~~ 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, ~~SETVI,~~ AMARE, BRSNW, ARTVU, SINAR - *moderately tolerant:* POLPE. - *tolerant:* PLAME. 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 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

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[5]) resistance is the naturally occurring inheritable ability of some weed biotypes within a population to survive an herbicide treatment that would, under normal conditions of use, effectively control that weed population. Selection of resistant biotypes may eventually result in control failures.

The risk of resistance was analysed following the EPPO-Standard (2015[6]), the classification of the Herbicide Resistance Action Committee (HRAC)[7] 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

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

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 cases of resistance with nicosulfuron in a range of grasses and broadleaved weeds have been reported worldwide. Of these, fifteen 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 cases of resistance in two dicotyledonous weed species (both *Amaranthus* spp.) have been reported to have developed resistance to mesotrione. All cases have been reported from the United States of America. The active substance is therefore classified as having a low inherent risk.

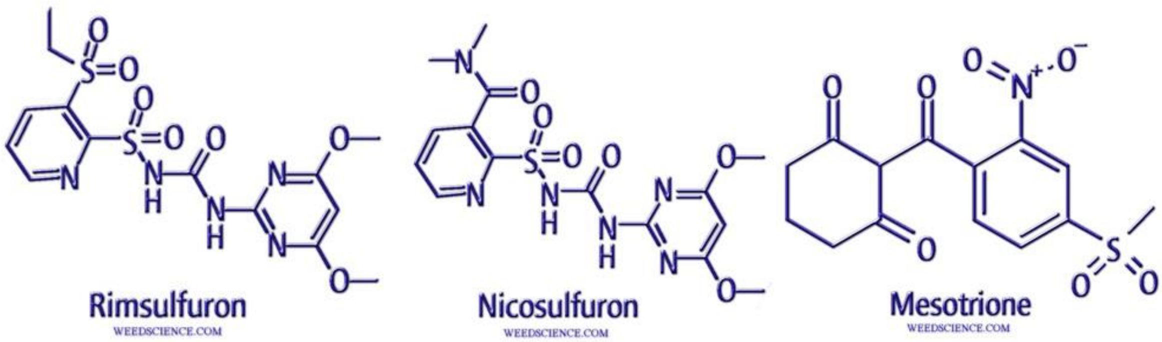
The evaluation of the agronomic risk concludes, that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG bears a low risk of resistance.

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

3.3.2 Mode of Action

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is a mixture of three active ingredients whereof two of them have same mode of action and the third has a different mode of action compared to the two sulfonylureas. In the following, the two sulfonylureas will therefore be treated under one, where possible. The chemical structure of the three active ingredients is shown in Figure 3.3-1.

Figure 3.3-1: Structure of rimsulfuron (left), nicosulfuron (middle) and mesotrione (right) (Source: Heap, I.; The International Survey of Herbicide Resistant Weeds. Online. Internet. Friday, December 13th, 2019. Available at www.weedscience.com)



Mode of action, rimsulfuron

Rimsulfuron, with the chemical name 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea (IUPAC), belongs to the chemical group of Sulfonylureas. Rimsulfuron is a selective post-emergence herbicide used in maize and other crops for broad-spectrum control of important grasses and broadleaved weeds across all climatic zones of Europe.

Rimsulfuron acts by inhibiting the action of acetolactate synthase (ALS), also known as acetohydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, rimsulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.

- Mode of Action: Inhibition of acetolactate synthase (ALS)

- Chemical family: Sulfonylurea

Mode of action, nicosulfuron

Nicosulfuron, with the chemical name 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylnicotinamide (IUPAC), belongs to the chemical group of Sulfonylureas. Nicosulfuron is a selective herbicide for post emergence applications against weeds in maize across all climatic zones of Europe.

Nicosulfuron acts by inhibiting the action of acetolactate synthase (ALS), also known as acetohydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, rimsulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.

- Mode of Action: Inhibition of acetolactate synthase (ALS)
- Chemical family: Sulfonylurea

Mode of action, mesotrione

Mesotrione, with the chemical name 2-(4-mesyl-2-nitrobenzoyl)cyclohexane-1,3-dione (IUPAC), belongs to the chemical group of Triketones. Mesotrione is a selective herbicide for pre- and post emergence applications against weeds in mainly maize across all climatic zones of Europe.

Mesotrione acts by the inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase which in turn inhibits carotenoid biosynthesis. Due to its primary target site and its chemical family, in the HRAC mode of action classification, it is classified as group F2 herbicide (4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD) inhibition). In the WSSA resistance classification system, the callistemones are classified as group 27.

- Mode of Action: Inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase
- Chemical family: Triketone

3.3.3 Mechanism(s) of resistance

Rimsulfuron and nicosulfuron

There are a couple of mechanisms known to cause resistance towards the ALS's. As mentioned earlier crop tolerance is mainly caused by rapid metabolism of the herbicide. There has been reports of the same type of resistance in *Lolium rigidum* (Annual Ryegrass) (Christopher et al., 1991), but most reports concurrent describes changes in the target site as the reason for weed resistance (Hanson et al, 2004, Reed et al., 1989; Saari et al., 1990; Saari et al. 1992, Smith et al, 1988; Thill et al., 1989; Tranel & Wright, 2002). Whether it might be a combination of enhanced metabolism and target site changes (Manley et al., 1999) or an overproduction of ALS (Harms et al. 1992) causing resistance has also been aired.

Target site resistance is caused by alterations in the ALS gene. ALS functions in the plastids but is coded in the nucleus, therefore it follows normal Mendelian inheritance. Mutations in the ALS gene, causing herbicide resistance, can therefore be spread by both pollen and seeds (Smith et al. 1988; Tranel & Wright, 2002). The ALS gene is to a high degree conserved inbetween plant biotypes. So far, at least five conserved amino acids have been identified in the ALS gene and substitution in one of them is known to cause resistance in various plants (Tranel & Wright, 2002). Whether other mutations in the plant can cause resistance is most likely, both regarding enhanced metabolism and especially target site alterations.

Mesotrione

The mechanism for resistance in the two weed species is currently unknown.

3.3.4 Evidence of resistance

Rimsulfuron

To date, twelve different weed species, i.e. five grass weed species and seven broadleaved weed species have been reported in 17 cases to have evolved resistance towards rimsulfuron (Heap, 2019). Of these, five cases 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).

Worldwide, the following cases of rimsulfuron resistance have been reported:

Year	Species	Country	MoA
2008	*Amaranthus palmeri*	Israel	B/2
2009	*Amaranthus tuberculatus*	USA (Iowa)	B/2, F2/27, C1/5
1994	*Avena fatua*	Canada (Manitoba)	A/1, B/2, Z/25
2011	*Conyza canadensis*	USA (Kansas)	B/2
2009	*Echinochloa phyllopogon*	Greece	B/2
2018	*Galinsoga parviflora*	France	B/2
1996	*Kochia scoparia*	Czech Republic	B/2, C1/5
2017	*Poa annua*	Australia (New South Wales)	B/2
2017	*Poa annua*	Australia (South Australia)	B/2
2017	*Poa annua*	Australia (Victoria)	B/2
2017	*Poa annua*	Australia (New South Wales)	B/2, G/9, K1/3, C1/5, Z/27
2004	*Setaria faberi*	USA (Indiana)	B/2
2000	*Solanum ptycanthum*	Canada (Ontario)	B/2
2015	*Sonchus asper*	France	B/2
2009	*Sorghum halepense*	Mexico	B/2
2017	*Sorghum halepense*	Israel	B/2
2014	*Sorghum halepense*	Serbia	B/2

MoA: A=ACCase inhibitors, B=ALS inhibitors; C1=Photosystem II inhibitors, F2=HPPD inhibitors, G=EPSP synthase inhibitors, K1=Microtubule inhibitors, Z=Antimicrotubule mitotic disrupter.

Nicosulfuron

To date, twenty-four different weed species, i.e. ten grass weed species and fourteen broadleaved weed species have been reported in 52 cases to have evolved resistance towards nicosulfuron (Heap, 2019). Of these, fifteen cases have 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).

Worldwide, the following cases of nicosulfuron resistance have been reported:

Year	Species	Country	MoA
2014	*Alopecurus aequalis*	China	A/1, B/2
2014	*Alopecurus japonicus*	China	A/1, B/2
1992	*Amaranthus hybridus*	USA (Kentucky)	B/2
2003	*Amaranthus retroflexus*	Italy	B/2
2012	*Amaranthus retroflexus*	Germany	B/2
2013	*Amaranthus spinosus*	USA (Mississippi)	B/2
2002	*Amaranthus tuberculatus*	USA (Oklahoma)	B/2
1994	*Amaranthus tuberculatus*	USA (Missouri)	B/2
2015	*Ambrosia artemisiifolia*	USA (North Carolina)	B/2, G/9, E/14
1993	*Bidens pilosa*	Brazil	B/2
1996	*Bidens subaltemans*	Brazil	B/2
2010	*Digitaria sanguinalis*	China	B/2
2015	*Digitaria sanguinalis*	France	B/2
2012	*Echinochloa crus-galli*	Germany	B/2

Year	Species	Country	MoA
2011	*Echinochloa crus-galli*	Austria	B/2
2005	*Echinochloa crus-galli*	Italy	B/2
2017	*Echinochloa crus-galli*	Ukraine	B/2
2015	*Echinochloa crus-galli*	Spain	B/2
2009	*Echinochloa phyllopogon*	Greece	B/2
2004	*Euphorbia heterophylla*	Brazil	B/2, E/14
2014	*Ixophorus unisetus*	Mexico	B/2
1996	*Kochia scoparia*	Czech Republic	B/2, C1/5
2001	*Raphanus sativus*	Brazil	B/2
2004	*Rottboellia cochinchinensis*	Venezuela	B/2
2007	*Setaria faberi*	USA (Illinois)	B/2
1996	*Setaria faberi*	USA (Minnesota)	B/2
1999	*Setaria faberi*	USA (Wisconsin)	B/2
2004	*Setaria faberi*	USA (Pennsylvania)	B/2
2006	*Setaria faberi*	USA (Michigan)	B/2
2004	*Setaria faberi*	USA (Indiana)	B/2
2011	*Setaria viridis*	France	B/2
2001	*Setaria viridis*	Canada (Ontario)	B/2
1996	*Setaria viridis var. major*	USA (Minnesota)	B/2
2000	*Solanum ptycanthum*	Canada (Ontario)	B/2
1996	*Sorghum bicolor*	USA (Kansas)	B/2
2001	*Sorghum bicolor*	USA (Pennsylvania)	B/2
2003	*Sorghum bicolor*	USA (Virginia)	B/2
2000	*Sorghum bicolor*	USA (Ohio)	B/2
2000	*Sorghum bicolor*	USA (Illinois)	B/2
2006	*Sorghum bicolor*	USA (Indiana)	B/2
2006	*Sorghum halepense*	USA (Kentucky)	B/2
2000	*Sorghum halepense*	USA (Texas)	B/2
2005	*Sorghum halepense*	USA (Indiana)	B/2
2009	*Sorghum halepense*	Mexico	B/2
2010	*Sorghum halepense*	Venezuela	B/2
2015	*Sorghum halepense*	Hungary	B/2
2009	*Sorghum halepense*	Chile	B/2
2004	*Sorghum halepense*	USA (West Virginia)	B/2
2007	*Sorghum halepense*	Italy	B/2
2014	*Sorghum halepense*	Serbia	B/2
2015	*Sorghum halepense*	Spain	B/2
2011	*Stellaria media*	Germany	B/2

MoA: A=ACCase inhibitors, B=ALS inhibitors; C1=Photosystem II inhibitors, E=PPO inhibitors, G=EPSP synthase inhibitors.

ALS inhibitors

To date, 165 different weed species, mostly dicotyledonous, has been reported as resistant towards one or several HRAC group B herbicides (Heap, December 2019). The first report was from Australia in 1982 where *Lolium ridigum* (Rigid ryegrass) showed multiple resistance towards a range of herbicides with different modes of action, hereunder ALS inhibitors, like chlorosulfuron. Since then, new weeds have been added to the list and there is no reason to believe that this phenomenon will disappear. Many of the weed species has developed resistant independently in different countries and often against several SUs (Heap, 2012). There are many reports from especially US but also Australia and Canada are well represented. However, the below mention examples are from Europe. It is important to emphasise that the examples given below is not necessarily the complete picture of ALS resistance reported in the given countries but merely examples. Further information and updates regarding resistance and weed populations can be seen on www.weedscience.org.

Germany

In 2001, the first official case of resistant *Alopecurus myosuroides* (Blackgrass) was reported in a wheat field in Germany. In 2001, local weed scientist from the Federal Biological Research Centre for Agriculture and Forestry (BBA) suspected that resistant blackgrass occurred at least 6-10 places in Germany and that the area was increasing (Heap, 2012). To date, 33 species have been reported to have developed resistance towards one or several herbicide groups in Germany, hereof 11 species being resistant or cross-resistant to ALS inhibitors. The most common form of resistance is resistance towards Photosystem II inhibitors.

<u>Belgium:</u>
In 1996, ALS resistant *Alopecurus myosuroides* (Blackgrass) were reported in Belgium and weed scientists from the University in Gent estimate that multiple resistant Blackgrass in Belgium infests at least 2-5 sites and that the number of sites are increasing (Heap, 2012). The resistant blackgrass was resistant to five different modes of action. The resistant biotypes were collected from winter wheat and sugar beet field where poor weed control had been observed using Fenoxaprop and/or clodinafop, however, there are no other records of the agricultural production methods. Resistant blackgrass has also been reported in UK, France, Poland, the Netherlands, Germany, Czech Republic, Denmark, Sweden, Turkey and Spain (Heap, 2019). To date, 22 species have been reported to have developed resistance towards one or several herbicide groups in Belgium, hereof four species being resistant or cross-resistant to ALS inhibitors. The most current form of resistance is resistance towards Photosystem II inhibitors.

<u>The Czech Republic:</u>
In 1996, ALS resistant *Kochia scoparia* (Kochia) were reported in the Czech Republic and weed scientists from the Research Institute of Crop Production in Ruzyne estimate that multiple resistant Kochia in the Czech Republic infests at least 11-50 sites and that the number of sites are increasing (Heap, 2012). The kochia from Czech Republic was resistant to herbicides with two different modes of action (HRAC group B and C1). The resistant biotypes were collected from railways and roadsides. To date, 18 species have been reported to have developed resistance towards one or several herbicide groups in the Czech Republic, hereof three species being resistant or cross-resistant to ALS inhibitors. The most current form of resistance is resistance towards Photosystem II inhibitors.

<u>Denmark:</u>
In 1991, *Stellaria media* (Common chickweed) seeds were collected from a field where the plants had survived sulfonylurea herbicide treatments (Kudsk et al. 1995). Whole plant and *in vitro* assays confirmed resistance against various SU's. Spring barley had been grown continuously on the field since 1984 and treated with one application of SU every year. In 1990, the first unsatisfactory control of common chickweed was observed and the same pattern was seen in 1991. Even though half of the area was treated a second time in 1991 with tribenuron, it had no visual effect on common chickweed. A reduced tillage system had been practised on the field since 1984. To date, 13 species have been reported to have developed resistance towards one or several herbicide groups in Denmark, hereof eight species being resistant or cross-resistant to ALS inhibitors.

Resistant common chickweed has also been reported in Belgium, Canada, Finland, France, Germany, Ireland, Latvia, New Zealand, Norway, South Africa, Sweden, the UK and the US (Heap, 2019).

<u>France:</u>
Since 1993, an increasing number of sites with ALS resistant biotypes of *Alopecurus myosuroides* (Blackgrass) has been reported. From the time when the first resistant biotype of blackgrass was observed, an annual survey has been carried out by the French National Institute for Agricultural Research (INRA) (Heap, 2012). To date, 55 species have been reported to have developed resistance towards different herbicide groups in France. The most current form of resistance is resistance towards Photosystem II inhibitors. Cases of *Papaver* sp., and *Matricaria* sp. ALS resistant biotype are reported in several French regions. Of the 55 species reported to be resistant to herbicides in France, 22 species were resistant or cross-resistant to ALS-inhibitors.

<u>Greece:</u>
In 1998, ALS resistant *Papaver rhoeas* (Corn poppy) were reported in Greece and weed scientists from the National Agricultural Research Foundation in Thessaloniki estimate that resistant corn poppy in Greece only infests this site and that the number of sites are increasing (Heap, 2012). The resistant biotypes were collected from winter wheat. ALS-resistant field poppy has also been reported in Belgium, Denmark, France, Germany, Italy, Poland, Spain, Sweden and the UK (Heap, 2019). To date, 17 species have been reported to have developed resistance towards different herbicide groups in Greece, hereof five species being resistant to ALS inhibitors.

<u>Ireland</u>
In 1996, resistant *Stellaria media* (Common chickweed) plants were observed in cereal field in Ireland. Weed scientists form Rothamsted Research and The International Society for Horticultural Science has so far not reported ALS resistant biotypes other places in Ireland (Heap, 2017).

<u>Italy:</u>
In 2003, ALS resistant *Amaranthus retroflexus* (Redroot pigweed) were reported in Italy and weed scientists from the Italian National Research Council in Legnaro estimate that resistant redroot pigweed in Italy only infests this site and that the size of the infested area is 51-100 acres (Heap, 2012). The resistant biotypes were collected from Soybean. ALS-Resistant redroot pigweed has also been reported in Brazil, Canada, China, Germany, Israel, Serbia and the US (Heap, 2019). Multi-resistant *Papaver rhoeas* have also been reported from Italy, being resistant towards ALS-inhibitors and synthetic auxins. To date, 30 species have been reported to have developed resistance towards one or severeal herbicide groups in Italy, hereof 11 species being resistant or cross-resistant to ALS inhibitors.

<u>Poland:</u>
In 2005, ALS resistant *Apera spica-venti* (Wind bentgrass) were reported in Poland and weed scientists from the Institute of Plant Protection in Poznan, among others, estimate that resistant wind bentgrass in Poland infests 51-100 sites (Heap, 2012). The resistant wind bentgrass was resistant to sulfonyl ureas, among others, in the HRAC Group B. The resistant biotypes were collected from winter wheat. ALS-resistant wind bentgrass has also been reported in Austria, Czech Republic, Denmark, France, Germany, Latvia, Lithuania and Sweden (Heap, 2019). To date, 22 species have been reported to have developed resistance towards one or several herbicide groups in Poland, hereof 8 species being resistant or cross-resistant to ALS inhibitors. The same number of weed species was reported to being resistant towards Photosystem II inhibitors in Poland.

<u>Portugal:</u>
In 1995, ALS resistant *Alisma plantago-aquatica* (common waterplantain) were reported in Portugal and weed scientists from the Ministerio da Agricultura Do Desenvolvimento Rural in Oeiras estimate that resistant wind bentgrass in Portugal infests 6-10 sites (Heap, 2012). The resistant common waterplantain was resistant to bensulfuron-methyl. The resistant biotypes were collected from rice. ALS-resistant common water plantain has also been reported in Chile, Italy, Spain and Turkey (Heap, 2019). To date, 5 species have been reported to have developed resistance towards different herbicide groups in Portugal.

<u>Spain:</u>
In 2011, ALS resistant *Sinapis arvensis* (wild mustard) were reported in Spain and weed scientists from the Agricultural technologies and Infrastructures Institute of Navarra estimate that resistant wild mustard in Spain infests only this one site with an area of 1-5 acres (Heap, 2012). The resistant wild mustard was resistant to iodosulfuron and tribenuron. The resistant biotypes were collected from cereals. ALS-resistant wild mustard has also been reported in Australia, Canada, Iran, Italy, Turkey and the US (Heap, 2019). To date, 39 species have been reported to have developed resistance towards one or several herbicide groups in Spain, hereof 9 species being resistant or cross-resistant to ALS inhibitors. The most problematic resistant weed in Spain is multi-resistant *Papaver rhoeas*, which have been reported to be resistant towards ALS-inhibitors and synthetic auxins.

<u>Sweden:</u>

In 1995, resistant *Stellaria media* (Common chickweed) was reported in Sweden, ALS enzyme tests confirmed the suspicion. The field where the biotype was found had been grown with cereals continuous cereals for 10 years and repeatedly treated with sulfonylurea herbicides. To date, 11 species have been reported to have developed resistance towards one or several herbicide groups in Sweden, hereof six species being resistant or cross-resistant to ALS inhibitors.

<u>UK</u>
In 2000, amidosulfuron- and metsulfuron resistant *Stellaria media* (Common chickweed) was found on a cereal field in the UK. According to weed scientists at Rothamsted Research this is the only known site of SU resistant common chickweed in the UK. Metsulfuron resistant *Papaver rhoeas* (Corn Poppy) was located in 2001 by Rothamsted Research, it is estimated that there are at least 2-5 sites with SU resistant corn poppy. In 1994, multiple resistant (including ALS resistance) *Avena fatua* (Wild Oat) was found in the UK in canola, cereal and wheat fields. At least 11 -50 sites are today infested with multiply resistant wild oats and the number is presumably increasing. Chlorsulfuron resistant blackgrass was reported back in 1984. The number of resistant blackgrass sites in the UK is unknown (Heap, 2012). To date, 29 species have been reported to have developed resistance towards one or several herbicide groups in UK, hereof eight species being resistant or cross-resistant to ALS inhibitors.

<u>Hungary</u>
In 2015, foramsulfuron- and nicosulfuron resistant *Sorghum halepense* (Johnsongrass) were found on maize and fallow fields in Hungary. According to weed scientists from Fejér County, the nicosulfuron resistance is an increasingly important problem. ALS-resistant Johnsongrass has also been reported in Chile, Hungary, Israel, Italy, Mexico, Serbia, Spain, the US and Venezuela (Heap, 2019). To date, three species have been reported to have developed resistance towards one or several herbicide groups in Hungary, hereof only *Sorghum halepense* being resistant to ALS inhibitors.

<u>Conclusion</u>
ALS resistant weeds are present worldwide, many cases of resistance occur after several years of mono-cropping and repeatedly use of SU's. On www.weedscience.com, new occurrences of herbicide resistance is monitored, today 165 weed species have been reported as resistant toward one or several ALS's.

<u>Mesotrione / HPPD inhibitors</u>

Currently, there are no reported cases of weed resistance to mesotrione reported from within the EU (Heap, 2019).

From outside Europe, the following weed cases of mesotrione resistance have been reported:

Year	Species	Country	MoA
2009	*Amaranthus tuberculatus*	USA (Iowa)	B/2, F2/27, C1/5
2009	*Amaranthus tuberculatus*	USA (Illinois)	B/2, F2/27, C1/5
2011	*Amaranthus tuberculatus*	USA (Iowa)	B/2, G/9, F2/27, C1/5
2011	*Amaranthus tuberculatus*	USA (Nebraska)	F2/27
2016	*Amaranthus tuberculatus*	USA (Illinois)	B/2, F2/27, C1/5, E/14, O/4
2009	*Amaranthus palmeri*	USA (Kansas)	B/2, F2/27, C1/5
2011	*Amaranthus palmeri*	USA (Nebraska)	F2/27
2014	*Amaranthus palmeri*	USA (Nebraska)	F2/27, C1/5
2015	*Amaranthus palmeri*	USA (Kansas)	B/2, G/9, F2/27, C1/5, O/4
2016	*Amaranthus palmeri*	USA (North Carolina)	F2/27

MoA: F2=HPPD inhibitors; B=ALS inhibitors; C1= Photosystem II inhibitor; G: EPSP synthase inhibitors; E=PPO inhibitors; O=Synthetic Auxins

Further information and updates regarding resistance and weed populations can be found on www.weedscience.org.

3.3.5 Cross-resistance

"When a plant expressing resistance to an herbicide also demonstrates resistance to other herbicides that target the same plant process even though the plant has not been exposed to the other herbicides, the resistance is termed cross-resistance" (Prather et al. 2000).

B herbicides: Since all the ALS's are active towards a single target site, cross resistance is a well-known phenomenon in this group of chemicals. It is therefore important to keep the label recommended limitations concerning the frequency by which the ALS should be used.

As far back as 1987 one of the first signs of cross resistant weeds were evident (Primiani et al. 1990). Seeds from *Kochina scoparia* were collected from a field treated with clorsulfuron for five consecutive years (in total 106g/ha) and greenhouse test showed enhanced resistance towards other ALS's as well, since then numerous reports of cross resistance in between the ALS's has been published (primarily SU's).

Cross-resistance between different SU and other ALS herbicides e.g. Imazethapyr is also well documented (Heap, 2012; Baumgartner et al. 1999; Lovell et al 1996; Rashid et al, 2003). Resistance toward herbicides with different modes of action has also been proven. Studies of *Amaranthus hybridus* showed that resistance towards atrazine (Photosystem II inhibitor) and ALS inhibiting herbicides occurred in the same biotypes but that the reason for resistance was located on different genes (Maertens et al., 2003).

Multiple-resistance between ALS inhibiting herbicides, ACCase inhibitors e.g. clodinafop and Arylaminopropionic acids e.g. Flamprop-M was reported in 1994 in the UK in several wild oats biotypes (Heap, 2012).

There are numerous of other cases, further information and updates on the subject can be seen on www.weedscience.com.

F2 herbicides: Based on the HRAC resistance classification, cross resistance should be expected to be likely between mesotrione and other HRAC group F2 herbicides. Thus, the analysis of the risk for the development of weed resistance to mesotrione is made under the assumption that cross resistance exists between all herbicides classified as HRAC group F2. No cross-resistance was observed between F2 herbicides in the ten cases reported from the US.

The mesotrione resistant Amaranth species (*Amaranthus tuberculatus* and *Amaranthus palmeri*) populations in Iowa, Illinois, Kansas and Nebraska (USA) mentioned in section 3.3.4 were reported to be cross-resistant to ALS inhibitors (HRAC group B/2), Photosystem II inhibitors (HRAC group C1/5), PPO inhibitors (HRAC group E/14), Synthetic Auxins (HRAC group 0/4) and/or EPSP synthase inhibitors (HRAC group G/9).

3.3.6 Sensitivity data

Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. ALS inhibitors and HPPD inhibitors have both been tested and used worldwide for almost 40 years, and it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.

3.3.7 Use pattern

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is composed of rimsulfuron, nicosulfuron and mesotrione which are selective herbicides applied early post-emergence. In the EU Central zone, the formulation is proposed for use against grasses and broadleaved weeds in maize at the beginning of the growing season (BBCH 12-18). The recommended dose rate is 0.25 kg/ha, which will deliver 7.5 g rimsulfuron, 30 g nicosulfuron and 90 g mesotrione per hectare. The maximum number of applications is one application per growing season.

Rimsulfuron, nicosulfuron as well as mesotrione have been used as straight products as well as in mixtures for many years.

3.3.8 Resistance Risk Assessment of unrestricted use patterns

To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. Resistance has often developed where mono-cropping, reduced tillage and subsequent use of ALS inhibitors as well as HPPD inhibitors has been practiced. There is a risk of developing resistance towards rimsulfuron/nicosulfuron and/or mesotrione if the recommended application interval is exceeded as well as if lower than recommended dose rates are applied.

The inherited resistance towards the sulfonylureas rimsulfuron and nicosulfuron should be considered as high due to the mode of action, the short life cycle of many of the target weeds etc. Furthermore, the genes involved in resistance are transmitted both by pollen and seeds and many of the annual grasses and broadleaved weeds produce large amounts of seeds which are dispersed over large areas. By using rimsulfuron and nicosulfuron in mixture with mesotrione as it is the case with the mixture Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, this trait is broken and a built up of resistance is put on hold.

The degradation time of rimsulfuron as well as nicosulfuron is slower in certain soils compared to others, which might have an influence on the inherited risk in these. Mesotrione has residual effect and therefore high soil activity.

3.3.9 Acceptability of the resistance risk

Without any precautions, the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

3.3.10 Management strategy for Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be the followed in the weed management strategy.

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG should be used in alternation with herbicides comprising different modes of action to avoid the build-up of resistant biotypes and cross resistance.

Uses of mixtures with herbicides with different modes of action and weed spectrum is recommended, in order to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max. 1 application per year), growth stage, doses etc.

Apply Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG:

- Preferably shortly after emergence of the weeds and not later than the BBCH 14 stage of the weeds.
- Apply the dose rate as recommended

Avoid:

- Late applications – when the weeds are too developed.

- Use of reduced rates particularly where late applications are made.

Do Not:

- Apply to weeds where target site resistance to any of the herbicide classes included in Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG has been confirmed.

Remember herbicide usage should only form part of a strategy to manage herbicide resistance. Where appropriate seed samples should be tested to establish the type and severity of resistance present as this will aid decisions on future herbicide control programmes. Always follow the recommendations of the Weed Resistance Action Group (WRAG) with respect to the integration of chemical and cultural control measures.

Cultural practices:

Since cross resistance between different modes of action cannot be excluded, application limitations and the alternation of herbicides should be supported by additional agricultural measures. To minimize the weed pressure, deep soil cultivation (plough) and late sowing are recommended.

3.3.11 Implementation of the management strategy

The basic recommendations for resistance risk management (maximum 1 application for weed control) will be clearly recommended on the label. Additional recommendations for product alternations and cultural practices will be given on the label.

3.3.12 Monitoring, reporting and reaction to changes in performance

Allegations of weeds control failures in Europe and around the world are monitored.

Sharda will inform the regulatory authorities of any new confirmed occurrence of resistance regarding the use of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG.

Comments of zRMS:

Recently, the HRAC has revised their herbicide mode of action classification. HRAC group F2 is now termed HRAC group 27 and HRAC group B is now termed HRAC group 2. Primary MX contains mesotrione, a potent bleaching herbicide that belongs to the triketone herbicide family (HRAC Group ~~F2~~ 27), and rimsulfuron and nicosulfuron, both sulfonylurea herbicides whose activity is based on the inhibition of the acetolactate synthase enzyme (ALS) (HRAC Group ~~B~~ 2).

Primary MX is a post-emergence herbicide for the control of grass (annual and perennial) and broad-leaved weeds in maize with three different active substances and two different and independent mode of action.

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

The following table shows the current worldwide resistance weeds specifically to the herbicide ~~glyphosate~~ with mesotrione, rimsulfuron and nicosulfuron (according to http://www.weedscience.org):

Reported cases of resistance to mesotrione

#	Year	Species	Country	MOAs	Actives	Situations
1	2009	*Amaranthus tuberculatus (=A. rudis)*	United States (Illinois)	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II	imazethapyr, chlorimuron-ethyl, atrazine, mesotrione, tembotrione, topramezone	Seed corn

					inhibitors (C1/5)		
	2	2016	*Amaranthus tuberculatus (=A. rudis)*	United States (Illinois)	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5), PPO inhibitors (E/14), Synthetic Auxins (O/4)	imazethapyr, chlorimuron-ethyl, atrazine, fomesafen, lactofen, acifluorfen-sodium, 2,4-D, mesotrione, tembotrione, topramezone	Corn (maize), Soybean
	3	2009	*Amaranthus tuberculatus (=A. rudis)*	United States (Iowa)	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	thifensulfuron-methyl, rimsulfuron, atrazine, mesotrione, tembotrione, topramezone	Seed corn
	4	2011	*Amaranthus tuberculatus (=A. rudis)*	United States (Iowa)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	imazamethabenz-methyl, thifensulfuron-methyl, chlorimuron-ethyl, atrazine, isoxaflutole, glyphosate, mesotrione	Corn (maize), Soybean
	5	2009	*Amaranthus palmeri*	United States (Kansas)	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	thifensulfuron-methyl, atrazine, mesotrione, pyrasulfotole, tembotrione, topramezone	Corn (maize), Sorghum
	6	2015	*Amaranthus palmeri*	United States (Kansas)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5), Synthetic Auxins (O/4)	chlorsulfuron, atrazine, glyphosate, 2,4-D, mesotrione	Sorghum
	7	2011	*Amaranthus tuberculatus (=A. rudis)*	United States (Nebraska)	HPPD inhibitors (F2/27)	mesotrione, tembotrione, topramezone	Corn (maize)
	8	2011	*Amaranthus palmeri*	United States (Nebraska)	HPPD inhibitors (F2/27)	mesotrione, tembotrione, topramezone	Corn (maize)
	9	2014	*Amaranthus palmeri*	United States (Nebraska)	HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	atrazine, mesotrione, tembotrione, topramezone	Corn (maize)
	10	2016	*Amaranthus palmeri*	United States (North Carolina)	HPPD inhibitors (F2/27)	mesotrione	Corn (maize)
	11	2020	Raphanus raphanistrum	Australia (Western Australia)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	metsulfuron-methyl, dicamba, 2,4-D, mesotrione, pyrasulfotole, topramezone	Wheat
	12	2021	Amaranthus tuberculatus (=A. rudis)	Canada (Ontario)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, atrazine, metribuzin, lactofen, glyphosate, mesotrione	Corn (maize), Soybean, Dry, bean, edible
	13	2020	Amaranthus tuberculatus (=A. rudis)	United States (North Carolina)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phos-	imazethapyr, atrazine, fomesafen, glyphosate, mesotrione	Soybean

				phate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxy-phenyl Pyruvate Dioxy-genase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)		
14	2015	*Raphanus raphanistrum*	Australia (Western Australia)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolac-tate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxy-phenyl Pyruvate Dioxy-genase HRAC Group 27 (Legacy F2), Phytoene Desaturase inhibitors HRAC Group 12 (Lega-cy F1), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	chlorsulfuron, atrazine, diflufenican, fluridone, isoxaflutole, 2,4-D, mesotri-one, tembotrione	Wheat

Reported cases of resistance to rimsulfuron

#	Year	Species	Country	MOAs	Actives	Situations
1	2017	*Poa annua*	Australia (New South Wales)	ALS inhibitors (B/2)	bispyribac-sodium, rimsul-furon, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
2	2017	*Poa annua*	Australia (New South Wales)	ALS inhibitors (B/2), EPSP synthase inhibi-tors (G/9), Microtubule inhibitors (K1/3), Photosystem II inhibi-tors (C1/5), Unknown (Z/27)	endothall, bispyribac-sodium, rimsulfuron, sima-zine, glyphosate, propyza-mide = pronamide, iodosul-furon-methyl-sodium, foramsulfuron	Golf courses
3	2017	*Poa annua*	Australia (South Australia)	ALS inhibitors (B/2)	bispyribac-sodium, rimsul-furon, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
4	2017	*Poa annua*	Australia (Victoria)	ALS inhibitors (B/2)	bispyribac-sodium, rimsul-furon, iodosulfuron-methyl-sodium, foramsulfuron	Golf courses
5	1994	*Avena fatua*	Canada (Manitoba)	ACCase inhibitors (A/1), ALS inhibitors (B/2), Antimicrotubule mitotic disrupter (Z/25)	fenoxaprop-P-ethyl, imaza-methabenz-methyl, rimsul-furon, flamprop-methyl	Spring Barley, Cropland, Wheat, Canola
6	2000	*Solanum ptycanthum*	Canada (Ontario)	ALS inhibitors (B/2)	imazethapyr, prosulfuron, nicosulfuron, rimsulfuron, primisulfuron-methyl, flumetsulam, imazamox	Corn (maize), Soybean
7	1996	*Kochia sco-paria*	Czech Republic	ALS inhibitors (B/2), Photosystem II inhibi-tors (C1/5)	imazapyr, sulfosulfuron, thifensulfuron-methyl, chlorsulfuron, triflusulfu-ron-methyl, tribenuron-methyl, prosulfuron, metsul-furon-methyl, nicosulfuron, rimsulfuron, atrazine	Railways, Roadsides
8	2015	*Sonchus asper*	France	ALS inhibitors (B/2)	rimsulfuron	Chicory
9	2018	*Galinsoga parviflora*	France	ALS inhibitors (B/2)	rimsulfuron, penoxsulam	Endive
10	2009	*Echinochloa phyllopogon (=E. oryzicola)*	Greece	ALS inhibitors (B/2)	bispyribac-sodium, nicosul-furon, rimsulfuron, imaza-mox, foramsulfuron, penox-sulam	Rice
11	2008	*Amaranthus*	Israel	ALS inhibitors (B/2)	pyrithiobac-sodium, rimsul-	Corn (maize),

		palmeri			furon, iodosulfuron-methyl-sodium, foramsulfuron, trifloxysulfuron-sodium, mesosulfuron-methyl	Cotton, Watermelon
12	2017	Sorghum halepense	Israel	ALS inhibitors (B/2)	rimsulfuron	Cotton, Watermelon
13	2009	Sorghum halepense	Mexico	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
14	2014	Sorghum halepense	Serbia	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, imazamox, pyroxsulam, propoxycarbazone-sodium	Corn (maize)
15	2004	Setaria faberi	United States (Indiana)	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron	Corn (maize)
16	2009	Amaranthus tuberculatus (=A. rudis)	United States (Iowa)	ALS inhibitors (B/2), HPPD inhibitors (F2/27), Photosystem II inhibitors (C1/5)	thifensulfuron-methyl, rimsulfuron, atrazine, mesotrione, tembotrione, topramezone	Seed corn
17	2011	Conyza canadensis	United States (Kansas)	ALS inhibitors (B/2)	thifensulfuron-methyl, chlorsulfuron, tribenuron-methyl, metsulfuron-methyl, rimsulfuron, iodosulfuron-methyl-sodium, thiencarbazone-methyl	Corn (maize), Cotton, Soybean, Wheat

Reported cases of resistance to nicosulfuron

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

					ron-methyl, pyroxsulam	
12	1996	*Kochia scoparia*	Czech Republic	ALS inhibitors (B/2), Photosystem II inhibitors (C1/5)	imazapyr, sulfosulfuron, thifensulfuron-methyl, chlorsulfuron, triflusulfuron-methyl, tribenuron-methyl, prosulfuron, metsulfuron-methyl, nicosulfuron, rimsulfuron, atrazine	Railways, Roadsides
13	2011	*Setaria viridis*	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)
14	2015	*Digitaria sanguinalis*	France	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize)
15	2011	*Stellaria media*	Germany	ALS inhibitors (B/2)	thifensulfuron-methyl, amidosulfuron, triflusulfuron-methyl, tribenuron-methyl, nicosulfuron, imazamox, florasulam, iodosulfuron-methyl-sodium, tritosulfuron, mesosulfuron-methyl, pyroxsulam	Spring Barley, Wheat, Rapeseed
16	2012	*Echinochloa crus-galli var. crus-galli*	Germany	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
17	2012	*Amaranthus retroflexus*	Germany	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
18	2009	*Echinochloa phyllopogon (=E. oryzicola)*	Greece	ALS inhibitors (B/2)	bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penoxsulam	Rice
19	2015	*Sorghum halepense*	Hungary	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Fallow
20	2003	*Amaranthus retroflexus*	Italy	ALS inhibitors (B/2)	imazethapyr, thifensulfuron-methyl, nicosulfuron, oxasulfuron, imazamox	Soybean
21	2005	*Echinochloa crus-galli var. crus-galli*	Italy	ALS inhibitors (B/2)	bispyribac-sodium, azimsulfuron, nicosulfuron, imazamox, penoxsulam	Corn (maize), Rice
22	2007	*Sorghum halepense*	Italy	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
23	2009	*Sorghum halepense*	Mexico	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
24	2014	*Ixophorus unisetus*	Mexico	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
25	2014	*Sorghum halepense*	Serbia	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron, imazamox, pyroxsulam, propoxycarbazone-sodium	Corn (maize)
26	2015	*Echinochloa crus-galli var. crus-galli*	Spain	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
27	2015	*Sorghum halepense*	Spain	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
28	2016	*Amaranthus palmeri*	Spain	ALS inhibitors (B/2)	nicosulfuron	Corn (maize), Roadsides
29	2017	*Echinochloa crus-galli var. crus-galli*	Ukraine	ALS inhibitors (B/2)	imazapyr, nicosulfuron, imazamox, penoxsulam	Rice
30	2000	*Sorghum bicolor*	United States (Illinois)	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
31	2007	*Setaria faberi*	United States (Illinois)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron	Corn (maize), Soybean
32	2004	*Setaria faberi*	United States (Indiana)	ALS inhibitors (B/2)	nicosulfuron, rimsulfuron	Corn (maize)
33	2005	*Sorghum halepense*	United States	ALS inhibitors	nicosulfuron	Corn

				(Indiana)	(B/2)		(maize), Soybean
	34	2006	Sorghum bicolor	United States (Indiana)	ALS inhibitors (B/2)	nicosulfuron, foramsulfuron	Corn (maize), Soybean
	35	1996	Sorghum bicolor	United States (Kansas)	ALS inhibitors (B/2)	nicosulfuron, primisulfuron-methyl	Corn (maize)
	36	1992	Amaranthus hybridus (syn: quitensis)	United States (Kentucky)	ALS inhibitors (B/2)	imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl, flumetsulam	Soybean
	37	2006	Sorghum halepense	United States (Kentucky)	ALS inhibitors (B/2)	nicosulfuron, primisulfuron-methyl, foramsulfuron	Corn (maize)
	38	2006	Setaria faberi	United States (Michigan)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, foramsulfuron	Corn (maize), Soybean
	39	1996	Setaria faberi	United States (Minnesota)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, primisulfuron-methyl	Corn (maize), Soybean
	40	1996	Setaria viridis var. major (=var. robusta-alba, var. robustapurpurea)	United States (Minnesota)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, primisulfuron-methyl	Corn (maize), Soybean
	41	2013	Amaranthus spinosus	United States (Mississippi)	ALS inhibitors (B/2)	imazethapyr, pyrithiobac-sodium, nicosulfuron, trifloxysulfuron-sodium	Cotton, Soybean
	42	1994	Amaranthus tuberculatus (=A. rudis)	United States (Missouri)	ALS inhibitors (B/2)	imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, prosulfuron, nicosulfuron, halosulfuron-methyl, primisulfuron-methyl, flumetsulam, imazamox	Corn (maize), Cotton, Soybean
	43	2015	Ambrosia artemisiifolia	United States (North Carolina)	ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), PPO inhibitors (E/14)	nicosulfuron, cloransulam-methyl, fomesafen, lactofen, acifluorfen-sodium, glyphosate	Corn (maize), Soybean
	44	2000	Sorghum bicolor	United States (Ohio)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, primisulfuron-methyl	Corn (maize)
	45	2002	Amaranthus tuberculatus (=A. rudis)	United States (Oklahoma)	ALS inhibitors (B/2)	imazethapyr, imazaquin, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl	Corn (maize), Soybean
	46	2001	Sorghum bicolor	United States (Pennsylvania)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron, oxasulfuron, primisulfuron-methyl, imazamox	Corn (maize), Soybean
	47	2004	Setaria faberi	United States (Pennsylvania)	ALS inhibitors (B/2)	nicosulfuron, imazamox, foramsulfuron	Corn (maize)
	48	2000	Sorghum halepense	United States (Texas)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron	Corn (maize)
	49	2003	Sorghum bicolor	United States (Virginia)	ALS inhibitors (B/2)	imazethapyr, imazapyr, nicosulfuron	Corn (maize)
	50	2004	Sorghum halepense	United States (West Virginia)	ALS inhibitors (B/2)	nicosulfuron	Corn (maize)
	51	1999	Setaria faberi	United States (Wisconsin)	ALS inhibitors (B/2)	imazethapyr, nicosulfuron	Corn (maize), Soybean
	52	2004	Rottboellia cochinchinensis (=R. exaltata)	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
	53	2010	Sorghum halepense	Venezuela	ALS inhibitors (B/2)	nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron	Corn (maize)
	54	2018	Sorghum halepense	Serbia	Inhibition of	fluazifop-butyl, nicosulfu-	Soybean

				Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A)	ron	
55	2019	*Panicum dichotomiflorum*	United States (Illinois)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B)	nicosulfuron	Sweet corn
56	2022	*Lolium perenne ssp. multiflorum*	United States (North Carolina)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Acetyl CoA Carboxylase HRAC Group 1 (Legacy A), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), PS I Electron Diversion HRAC Group 22 (Legacy D)	clethodim, nicosulfuron, paraquat, glyphosate	Soybean, Winter wheat

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

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broadleaved weeds.

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

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 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.

3.4 Adverse effects on treated crops (KCP 6.4)

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

The twenty selectivity trials were conducted in maize.

Information on trials submitted (6.4 Adverse effects on treated crops)

Trials in this report were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this report have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials EPPO zone				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			MAR	MED	S-E	N-E			
ZEAMX	Germany	Q + Y + S	2	-	-	-	2016	GEP	
	Czech Rep.	Q + Y + S	2	-	-	-	2016	GEP	
	UK	Q + Y + S	2	-	-	-	2016	GEP	
	France	Q + Y + S	3	1	-	-	2016	GEP	
	Poland	Q + Y + S	-	-	-	2	2016	GEP	
	Poland	Q + Y + S	-	-	-	2	2017	GEP	
	Poland	Q + Y + S	-	-	-	2	2019	GEP	
	Spain	Q + Y + S	-	2	-	-	2016	GEP	
	Italy	Q + Y + S	-	2	-	-	2016	GEP	
		Total, Maize (Sel.)	**9**	**5**	**-**	**6**			

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4)
	Specific guidelines	EPPO PP 1/93(3)
Experimental design	Plot design	RCBD (20)
	Plot size	20-45 m²
	Number of replications	4 (20)

Crop	Trials per crop	Maize (20)

	Varieties per crop	Ambition, ES Asteroid, Cadixxio, KWS Carolinio, ES Cubus, DKC 3307, DKC4751, DKC5830, RGT Exxclam, Farmagic, LG 30.215, LG30238, LG31225, Lipexx, PRO725, Reserve, Ricardinio, KWS Severus, Zoom
	Sowing period	April 12th to July 29th
Application	Application period	Maize, post-emergence (20): May 9th to August 11th
	Crop stage (BBCH)* at application	Maize, post-emergence (20): BBCH 11-18
	Number of appl. Intervals between appl.	1 (20) n.a.
	Spray volumes	150-400 L/ha
Assessment	Assessment types	- Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour - Crop yield was assessed in all selectivity trials conducted on ZEAMX. Yield assessments included grain yield [t/ha] as well as different quality parameters (i.e. moisture content, hectolitre weight and/or thousand grain weigh).
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Brown alluvial soil (2), Clay loam (4), Clayed sand (2), Loam (3), Loamy sand (4), Mud (1), Sandy clay loam (2), Sandy loam (2)
	Organic matter content	<1.5%(3), 1.5 to 2.49%(11); 2.5 to 3.5%(1), >3.5%(2); not indicated(3)
	pH	4.88-8.6 (mean = 6.78, n = 18; not indicated (2))
	Natural / artificial innoculation…	Preferably weed-free conditions
	Field / Greenhouse...	Field

Reference products

In 12 of 20 selectivity trials, the performance of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was measured against a commercial standard rimsulfuron + nicosulfuron + mesotrione co-formulation currently on the market in Central and South Europe. In eight selectivity trials, conducted in England (2), France (4) and Spain (2), Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was compared against a national standard reference product containing nicosulfuron and mesotrione (Elumis; nicosulfuron 30 g/L + mesotrione 75 g/L OD). The trials were carried out on maize.

The reference products used in the trials are listed in Table 3.4-3.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Rimsulfuron + nicosulfuron + mesotrione co-formulations					
Arigo	WG	30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione	0.25 0.33 0.66	CZ DE IT PL	2 2 2 2
Columbus 51 WG	WG	30 g/kg rimsulfuron + 120 g/kg nicosulfuron + 360 g/kg mesotrione	0.25 0.33	PL	4

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Rimsulfuron + nicosulfuron + mesotrione co-formulations					
Nicosulfuron + mesotrione reference product					
Elumis	OD	30 g/L nicosulfuron 75 g/L mesotrione	1.2 1.5	ES FR UK	2 4 2

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was assessed in maize in 33 efficacy trials (9 MAR, 16 N-E, 2 S-E and 6 MED) where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied at 0.15 kg/ha, 0.25 kg/ha and 0.33 kg/ha, and in 20 crop safety trials (9 MAR, 6 N-E and 5 MED) where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied at 0.33 kg/ha and 0.66 kg/ha. In the efficacy- and selectivity trials conducted in maize, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied early post-emergence, i.e. when the maize crop was at growth stages ranging between BBCH 11 and BBCH 18.

The trials were conducted in the Maritime zone (18; i.e. Germany (4), N-France (5), the Czech Republic (5) and the United Kingdom (4)), the North-east zone (22, i.e. Poland), the South-east zone (2; i.e. Hungary) and the Mediterranean zone (11, i.e. Spain (4), Italy (4) and S-France (3)) in 2016 (41), 2017 (6) and 2019 (6), to evaluate the crop safetyness of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in maize.

3.4.1.1 Summary and evaluation of maize trials treated post-emergence

Crop phytotoxicity was evaluated in efficacy- and selectivity trials where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied post-emergence, at growth stages ranging from BBCH 11 to BBCH 18, at the rate of 0.15 to 0.66 kg/ha in maize. 0.66 kg/ha corresponds to 260% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals, from application and up to termination of the trial.

Phytotoxicity in maize trials, Maritime EPPO zone

Nine efficacy trials and nine selectivity trials were conducted in the Maritime EPPO zone to assess the crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG when applied as recommended in maize, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in six of the nine efficacy trials as well as no adverse effects were observed in six of the nine selectivity trials conducted in the Maritime EPPO zone.

Thus, adverse effects were observed in three efficacy trials as well as three selectivity trials at the initial assessments but at the following assessments, the symptoms had diminished. At the last assessment, the crop had outgrown the symptoms in all trials.

The maximum phytotoxicity observed in the Maritime efficacy- and selectivity trials is presented in Table 3.4-4. Where the symptoms are significantly more severe compared to untreated, the number is marked with bold.

Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Table 3.4-4: Visual assessment of crop phytotoxicity in maize treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG		Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.		Type of phyto-toxicity
			-	0.25 kg/ha	0.33 kg/ha	0.25 kg/ha	0.33 kg/ha	Symptom
Efficacy trials								
16 1069 5026	Messago	8	0.0	**1.5**	**2.0**	**1.0**	**1.3**	PHYCHL (%)
			UTC			**Nicosulfuron + Mesotrione Ref. Prod.**		
			-	**0.25 kg/ha**	**0.33 kg/ha**	**1.2 L/ha**	**1.5 L/ha**	**Symptom**
SHA840-15-EFF001-001	Ambition	7 7	0.0 0.0	**15.0** 2.0	**15.0** 2.0	0.0 0.0	0.0 0.0	PHYCHL (%) PHYGEN (%)
SHA840-15-EFF001-002	Severus	7 7	0.0 0.0	4.3 4.3	**8.8** **8.8**	0.0 0.0	0.0 0.0	PHYCHL (%) PHYGEN (%)
Trial number	**Variety**	**Ass. date DAA**	**UTC**	**Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG**		**Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.**		**Type of phyto-toxicity**
			-	**0.33 kg/ha**	**0.66 kg/ha**	**0.33 kg/ha**	**0.66 kg/ha**	**Symptom**
Selectivity trials								
16 1047 1258	Ricardinio	7 7	0.0 100.0	0.0 100.0	**8.8** **82.5**	**5.0** **90.0**	**1.0** **80.0**	PHYSTU (%) VIGOR (%)
		153	11.8	101	99	100	100	Yield (% rel.)
			UTC			**Nicosulfuron + Mesotrione Ref. Prod.**		
			-	**0.33 kg/ha**	**0.66 kg/ha**	**1.5 L/ha**	**3.0 L/ha**	**Symptom**
SHA840-15-SEL001-001	Ambition	6 127	0.0 12.0	0.5 91	**2.8** 93	0.0 99	**5.0** 103	YELLOW (%) Yield (% rel.)
SHA840-15-SEL001-002	Severus	7 7	0.0 0.0	**2.0** **2.0**	**3.5** **3.5**	0.0 0.0	0.0 0.0	PHYCHL (%) PHYGEN (%)
		126	5.8	124	149	144	120	Yield (% rel.)

Phytotoxicity in maize trials, North-east EPPO zone

Sixteen efficacy trials and six selectivity trials were conducted in the North-east EPPO zone to assess the crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG when applied as recommended in maize, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in fifteen of the 16 efficacy trials as well as no adverse effects were observed in four of the six selectivity trials conducted in the North-east EPPO zone.

Thus, adverse effects were observed in one efficacy trial as well as two selectivity trials at the initial assessment but at the following assessments, the crop had outgrown the symptoms in both trials.

The maximum phytotoxicity observed in the North-east efficacy- and selectivity trials is presented in Table 3.4-5. Where the symptoms are significantly more severe compared to untreated, the number is marked with bold. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Table 3.4-5: Visual assessment of crop phytotoxicity in maize treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG		Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.		Type of phyto-toxicity
			-	0.25 kg/ha	0.33 kg/ha	0.25 kg/ha	0.33 kg/ha	Symptom
Efficacy trials								
SH16KU109B	LG 30220	14	-	**10.0**	**12.5**	3.8	**8.8**	PHYGEN (%)
Trial number	**Variety**	**Ass. date DAA**	**UTC**	**Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG**		**Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.**		**Type of phyto-toxicity**
			-	**0.33 kg/ha**	**0.66 kg/ha**	**0.33 kg/ha**	**0.66 kg/ha**	**Symptom**
Selectivity trials								
NUZ 32+33+34/17, Report I	Asteroid	12	0.0	0.0	**11.0**	0.0	**11.0**	PHYGEN (%)
		131	12.1	104	98	100	100	Yield (% rel.)
NUZ 32+33+34/17, Report II	Cubus	12	0.0	0.0	**10.0**	0.0	**10.0**	PHYGEN (%)
		131	12.0	107	99	103	104	Yield (% rel.)

Phytotoxicity in maize trials, South-east EPPO zone

Two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG when applied as recommended in maize, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in either of the two Hungarian efficacy trials. The Hungarian efficacy trials were not harvested.

Phytotoxicity in maize trials, Mediterranean EPPO zone

Six efficacy trials and five selectivity trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG when applied as recommended in maize, i.e. early post-emergence. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in four of the six efficacy trials as well as no adverse effects were observed in two of the five selectivity trials conducted in the Mediterranean EPPO zone.

Thus, adverse effects were observed in two efficacy trials as well as three selectivity trials at the initial assessments but at the following assessments, the symptoms had diminished. At the last assessment, the crop had outgrown the symptoms in all trials.

The maximum phytotoxicity observed in the Mediterranean efficacy- and selectivity trials is presented in Table 3.4-6. Where the symptoms are significantly more severe compared to untreated, the number is marked with bold. Furthermore, the applied treatments did not have any detrimental effects on the yield or grain quality, as will be demonstrated in the following sections.

Table 3.4-6: Visual assessment of crop phytotoxicity in maize treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG and reference products in efficacy- and selectivity trials (maximum crop phytotoxicity observed) as well as relationship to yield (t/ha in untreated and % relative to untreated in treated columns (Untreated = 100%).

Trial number	Variety	Ass. date DAA	UTC	Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG		Max. phytotoxicity [%] Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.		Type of phyto-toxicity
			-	**0.25 kg/ha**	**0.33 kg/ha**	**0.25 kg/ha**	**0.33 kg/ha**	**Symptom**
Efficacy trials								
63.H.SAG16/e	SNH 3616	7	0.0	**15.0**	**15.0**	**10.0**	**10.0**	PHYCHL (%)
		7	100.0	90.0	90.0	90.0	90.0	VIGOR (%)
FR163004XA301	P1524	7	0.0	7.5	17.5	11.3	15.0	PHYCOL (%)
Trial number	**Variety**	**Ass. date DAA**	**UTC**	**Max. phytotoxicity [%] Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG**		**Max. phytotoxicity [%] Rimsulfuron + Nicosulfuron + Mesotrione Ref. Prod.**		**Type of phyto-toxicity**
			-	**0.33 kg/ha**	**0.66 kg/ha**	**0.33 kg/ha**	**0.66 kg/ha**	**Symptom**
Selectivity trials								
64.S.SAG16/e	Reserve	7	0.0	0.3	**2.5**	**2.3**	**3.0**	PHYSTU (%)
		7	0.0	**4.0**	**6.5**	**5.5**	**8.5**	YELLOW (%)
		144	12.1	95	84	95	81	Yield (% rel.)
65.S.SAG16/e	DKC5830	6	0.0	2.0	5.0	2.0	5.0	YELLOW (%)
		132	14.6	103	102	101	99	Yield (% rel.)
			UTC			**Nicosulfuron + Mesotrione Ref. Prod.**		
			-	**0.33 kg/ha**	**0.66 kg/ha**	**1.5 L/ha**	**3.0 L/ha**	**Symptom**
021E16S	Zoom	15	0.0	0.0	**3.0**	0.0	**5.0**	PHYGEN (%)
		133	10.4	128	119	117	116	Yield (% rel.)

3.4.1.2 Overall conclusion

Maize are claimed on the label. The claims of crop safety on maize are supported with a total of 53 trials conducted in Germany, Czech Republic, England, France, Hungary, Poland, Spain and Italy in 2016, 2017 and 2019. In all trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG proved to be crop safe and in the vast majority of the trials did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range, at the maximum proposed label recommended rates of 0.25 kg/ha in maize. The same was observed in the treatments where Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied at twice the recommended rate or more, representative of sprayer overlap.

Early post-emergence application in maize are claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in maize where post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to the standard rimsulfuron + nicosulfuron + mesotrione co-formulation to which it was compared in 43 of the 53 trials. The applicant therefore wishes to cite the original registrant's data on rimsulfuron, nicosulfuron and mesotrione now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Table 3.4-7: Phytotoxicity of product

Number of trials with…		Selectivity trials (20 trials)				Efficacy trials (33 trials)	
		Test product		Standard		Test product	Standard
		0.33 kg/ha	0.66 kg/ha	1N	2N	0.33 kg/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	20	16	19	16	28	30
	>5% to 10%	0	3	1	3	1	2
	>10% to 15%	0	1	0	1	3	1
	>15 %	0	0	0	0	1	0
Level of symptoms at the last assessments	0% to 5%	20	20	20	20	33	33
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Comments of zRMS:	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.**

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

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).

Comments of zRMS:	Submitted trials are sufficient. Influence of Primary MX on quantity and quality of yield was evaluated during selectivity research. Summary of the data on yield can be found at Table 3.4 8. The Applicant submitted in 20 reports the results of yield, carried out in different growing seasons (2016; 2017 and 2019) in maize. The evaluation was carried out in accordance with EPPO guidelines.

3.4.2.1 Summary and evaluation of crop yield from maize field trials treated post-emergence

A summary of the mean yield assessments expressed as %-relative of the untreated, from maize trials treated with post-emergence applications in the Maritime, the North-east and the Mediterranean EPPO zone, are presented in Table 3.4-8.

Maize (ZEAMX)

Twenty selectivity trials conducted in maize were harvested. The trials were conducted in Germany (2), Czech Republic (2), United Kingdom (2), N-France (3), Poland (6), Spain (2), Italy (2) and S-France (1) in 2016, 2017 and 2019. In these trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG was applied early post-emergence at 0.33 kg/ha (i.e. 9.9 g rimsulfuron, 39.6 g nicosulfuron and 118 g mesotrione per hectare) and 0.66 kg/ha (i.e. 19.8 g rimsulfuron, 79.2 g nicosulfuron and 236 g mesotrione per hectare). The trials were sprayed when the majority of the crop was at growth stages ranging between BBCH 11 and BBCH 18.

Table 3.4-8: Maritime, North-east and Mediterranean zone – Crop yield (t/ha) of maize treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, single application early post-emergence, as % of untreated (Untreated = 100%).

Crop, trial type	No. of trials	Untreated	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:		National Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.33 kg/ha [9.9+39.6+118 g ai/ha]	0.66 kg/ha [19.8+79.2+236 g ai/ha]	1N	2N
Maize, grain yield						
Maritime EPPO zone	9	10.0 (3.7-19.7)	105 (91-124)	107 (93-149)	110 (99-144)	105 (96-120)
North-east EPPO zone	6	11.6 (9.2-12.7)	104 (101-107)	102 (98-106)	105 (100-111)	106 (100-112)
Mediterranean EPPO zone	5	11.4 (8.2-14.6)	110 (95-128)	102 (84-119)	109 (95-119)	105 (81-128)
Crop, trial type	No. of trials	Untreated	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:		Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.33 kg/ha [9.9+39.6+118 g ai/ha]	0.66 kg/ha [19.8+79.2+236 g ai/ha]	0.33 kg/ha [9.9+39.6+118 g ai/ha]	0.66 kg/ha [19.8+79.2+236 g ai/ha]
Maize, grain yield						
Maritime EPPO zone	4	11.5 (3.7-19.7)	105 (98-120)	102 (99-108)	105 (100-118)	101 (96-104)
North-east EPPO zone	6	11.6 (9.2-12.7)	104 (101-107)	102 (98-106)	105 (100-111)	106 (100-112)
Mediterranean EPPO zone	2	13.4 (12.1-14.6)	99 (95-103)	93 (84-102)	98 (95-101)	90 (81-99)

Crop, trial type	No. of trials	Untreated	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:		Nicosulfuron 30 g/L + Mesotrione 75 g/L OD Ref. prod. at:	
			% relative, compared to untreated (min-max)			
		Mean (min-max)	0.33 kg/ha [9.9+39.6+118 g ai/ha]	0.66 kg/ha [19.8+79.2+236 g ai/ha]	1.5 L/ha [45+112.5 g ai/ha]	3.0 L/ha [90+225 g ai/ha]
Maize, grain yield						
Maritime EPPO zone	5	8.9 (5.3-13.3)	105 (91-124)	111 (93-149)	113 (99-144)	108 (98-120)
Mediterranean EPPO zone	3	10.0 (8.2-11.4)	118 (108-128)	109 (102-119)	116 (111-119)	115 (102-128)

The harvest results obtained in the twenty trials demonstrate that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG did not significantly affected the yield of maize (Table 3.4-8) when applied at the recommended dose rate (0.33 kg/ha) or the overlapping dose rate (0.66 kg/ha), in any of the twenty trials. The results obtained in these trials supports the label claim that Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is safe to be applied early post emergence at the recommended dose rate in maize, at the recommended application interval.

3.4.2.2 Conclusion

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at 0.33 kg/ha did not affect crop yield significantly in any of the 20 trials conducted on maize. In all trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the crop yield.

Post-emergence application in maize is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in maize where post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to the standard rimsulfuron + nicosulfuron + mesotrione co-formulation to which it was compared in 12 of the 20 selectivity trials harvested. The applicant therefore wishes to cite the original registrant’s data on rimsulfuron, nicosulfuron and mesotrione now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant’s data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	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.

3.4.2.3 Relationship between phytotoxicity and yield

Minor adverse effects were observed in eight selectivity trials in which crop yields were assessed.

In the tables presented in section 3.4.1.1, the maximum level of phytotoxic symptoms, recorded as reduced crop vigour, stunting (PHYSTU), yellowing (YELLOW) or other symptoms of colour change of leaves (PHYCOL) and/or reduction in general crop health (PHYGEN), are presented as well as the grain yield achieved from untreated and treated plots in the affected trials.

No significant reductions in crop yield were recorded in any of the plots treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at dose rates representative of the recommended dose rate or the 2N rate in the trials in which adverse effects were observed.

Comments of zRMS:	Minor adverse effects were observed in eight selectivity trials in which crop yields were assessed. No significant reductions in crop yield were recorded in any of the plots treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at dose rates higher than recommended dose rate in the trials in which adverse effects were observed. Perhaps at the recommended dose, which was not tested, these adverse effects would not appear. However, they cannot be excluded without trial. 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.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Twenty selectivity trials treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG were harvested and yields recorded. Besides recording yield, assessments were also carried out on the potential impact of treatment on a range of quality parameters including moisture content, oil content, protein content, starch content, hectolitre weight and thousand grain weight.

The materials and methods of these trials are described in Section 3.4.

Maize (ZEAMX)

The results obtained from assessments on the quality of the harvested maize kernels are presented in Table 3.4-9.

Table 3.4-9: Maritime, North-east and Mediterranean zone – Quality of harvested maize kernels – crop treated with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG, single application early post-emergence, as % of untreated (Untreated = 100%).

<table>
<tr><th rowspan="3">Crop, trial type</th><th rowspan="3">No. of trials</th><th rowspan="2">Untreated</th><th colspan="2">Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG at:</th><th colspan="2">National reference prod. at:</th></tr>
<tr><th colspan="4">% relative, compared to untreated (min-max)</th></tr>
<tr><th>Mean (min-max)</th><th>0.33 kg/ha [9.9+39.6+118 g ai/ha]</th><th>0.66 kg/ha [19.8+79.2+236 g ai/ha]</th><th>1N</th><th>2N</th></tr>
<tr><td colspan="7">Selectivity trials – Maritime zone</td></tr>
<tr><td>Moisture content (%)</td><td>6</td><td>33.5 (26.2-49.8)</td><td>98 (94-101)</td><td>99 (98-100)</td><td>99 (96-102)</td><td>98 (92-103)</td></tr>
<tr><td>HectoLitre Weight (kg/hL)</td><td>1</td><td>63.1</td><td>100</td><td>100</td><td>101</td><td>101</td></tr>
<tr><td>Thousand Grain Weight (g)</td><td>1</td><td>366.7</td><td>99</td><td>100</td><td>100</td><td>101</td></tr>
<tr><td colspan="7">Selectivity trials – North-east zone</td></tr>
<tr><td>Moisture content (%)</td><td>2</td><td>20.2 (15.0-25.5)</td><td>111 (96-126)</td><td>110 (97-124)</td><td>105 (95-116)</td><td>100 (98-103)</td></tr>
<tr><td>HectoLitre Weight (kg/hL)</td><td>4</td><td>72.7 (66.1-76.1)</td><td>99 (98-101)</td><td>100 (98-102)</td><td>98 (94-102)</td><td>98 (94-101)</td></tr>
<tr><td>Oil content (%)</td><td>1</td><td>3.6</td><td>100</td><td>100</td><td>101</td><td>103</td></tr>
<tr><td>Protein content (%)</td><td>3</td><td>9.4 (8.4-10.0)</td><td>103 (100-105)</td><td>102 (101-103)</td><td>102 (102-103)</td><td>102 (100-104)</td></tr>
<tr><td>Starch content (%)</td><td>1</td><td>70.7</td><td>99</td><td>100</td><td>99</td><td>99</td></tr>
<tr><td>Thousand Grain Weight (g)</td><td>6</td><td>348.9 (312-405)</td><td>102 (90-115)</td><td>102 (93-115)</td><td>101 (90-115)</td><td>102 (96-113)</td></tr>
<tr><td colspan="7">Selectivity trials – Mediterranean zone</td></tr>
<tr><td>Moisture content (%)</td><td>3</td><td>19.1 (17.7-20.5)</td><td>101 (98-106)</td><td>98 (91-104)</td><td>100 (98-102)</td><td>98 (92-105)</td></tr>
<tr><td>HectoLitre Weight (kg/hL)</td><td>2</td><td>62.7 (59.0-66.4)</td><td>100 (99-101)</td><td>103 (100-106)</td><td>101 (100-101)</td><td>102 (101-104)</td></tr>
<tr><td>Thousand Grain Weight (g)</td><td>2</td><td>361.3 (339-384)</td><td>101 (98-105)</td><td>104 (103-105)</td><td>101 (98-103)</td><td>99 (97-101)</td></tr>
</table>

In all trials evaluated, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG had no detrimental effect on the quality parameters assessed on the harvested maize kernels. When comparing the results obtained with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG against the results obtained with the reference products, hereunder the rimsulfuron + nicosulfuron + mesotrione co-formulation as included in the majority of the trials, or the nicosulfuron + mesotrione reference product included in eight of the 20 selectivity trials, all three products performed statistically similar on all quality parameters assessed.

3.4.3.1 Conclusion

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at the recommended dose rate (0.25 kg/ha) did not affect the quality of the harvested grains significantly in any of the 20 trials taken to harvest. In all trials, Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG applied at dose rates higher than the recommended rate – representative for sprayer overlap – did not significantly affect the quality of the harvested crop either.

Post-emergence application in maize is claimed on the label. For crops and recommendation claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in maize where post-emergence applications were tested. This BAD also clearly demonstrates that the efficacy and crop safety of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is equivalent to the standard rimsulfuron + nicosulfuron + mesotrione co-formulation to which it was compared in 12 of the 20 selectivity trials harvested. The applicant therefore wishes to cite the original registrant's data on rimsulfuron, nicosulfuron and mesotrione now out of protection in additional support of any recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal evaluator extrapolate from those data.

Comments of zRMS:	Statement accepted. Parameters such as moisture content (MED, MAR, N-E EPPO zone), hectolitre weight (MED, MAR, N-E EPPO zone), thousand grain weight (MED, MAR, N-E EPPO zone), oil content (N-E EPPO zone), protein content (N-E EPPO zone), starch content (N-E EPPO zone) was assessed during 20 trials. Detailed results were presented by Applicant in table above. Quality of yield of maize in dose higher than recommended dose of tested product – Primary MX were like objects, which used standard reference product. 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.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is composed of rimsulfuron, nicosulfuron and mesotrione, which all have been widely used for several years on maize without identifying any quality problems on the treated crops.

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is applied early in the season (up to BBCH 18), before inflorescence emergence and heading, and it is not expected that the active ingredient is transferred to the grains. For further information on residues, please refer to Part B, Section 4: Metabolism and residues.

Rimsulfuron

To give additional support to these arguments, the applicant wishes to refer to the DAR (Volume 3, Annex B, B.7 (2005)) where results obtained with a number of residue trials are presented. According to the

DAR, in maize, the parent rimsulfuron and its metabolites declined rapidly within 15 days after application. The total radioactive residues in the grain, silage and fodder were below the quantification limit of 0.02 mg/kg in the plants at harvest. Rimsulfuron, IN-70941, and IN-70942 were identified from both labels in immature whole plant extracts. IN-J0290 (also known as IN-J290) and IN-E9260 were observed in the pyrimidine and pyridine treated plants, respectively.

As no quantifiable rimsulfuron residues (<LOQ of 0.05 mg/kg) were found in any maize samples at the time of harvest. Therefore, no processing study is required.

Nicosulfuron

To give additional support to these arguments, the applicant wishes to refer to the DAR (Volume 3, Annex B, B.7 (2006)) where results obtained with a number of residue trials are presented. According to the DAR on nicosulfuron, there were a total of 20 Northern Europe residues trials conducted in accordance with the representative GAP, the majority of which had analysis of both grain and whole plant (silage). No residues were quantified in grain above the LOQ of 0.01 mg/kg. For Southern Europe, there were a total of 14 trials conducted in accordance with the representative GAP, again the majority of which had analysis of both grain and whole plant (silage). No residues were quantified in grain above the LOQ of 0.01 mg/kg. One positive residue was detected in whole plant at 0.013 mg/kg. Given the results of the other trials this positive residue is likely to be as a result of contamination however as there is no decline data it was taken into consideration in the risk assessment.

No data on processing data are required as residues are below the LOQ.

Mesotrione

In the Peer Review report on mesotrione (EFSA Journal 2016;14(3):4419), it was resumed that plant metabolism was studied in maize, among other plants, with mesotrione labelled on cyclohexane-2-14C and phenyl-U-14C. The metabolic pattern of mesotrione was found to be quantitatively different in conventional crops (maize, peanut) compared to genetically modified soya bean. In maize and peanuts, parent mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder; 15% TRR in peanut meat). Further metabolites' identification was not conducted in maize grain due to the very low recovered total residues (0.014 mg/kg). The unextracted radioactivity was further characterized as polar compounds (soya bean), lipids (peanut meat) and carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of mesotrione in maize, peanuts and soya bean proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in conventional maize and peanuts only. The metabolism of mesotrione in rotational crops was found to be similar to the primary crops. Sufficient GAP-compliant residue trials supported by acceptable storage stability data are available to derive a MRL for mesotrione on maize grain. Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered.

No data on processing data are required as mesotrione residues do not exceed 0.01 mg/kg.

Comments of zRMS:	Considering that product is applied at early stage of the crop and maize is not a typical crop used for subsequent processing, it could be agreed that no negative impact on processing is expected. Adverse effects on plant parts (seed) used for propagation purposes did not occur. The latest time of application for Primary MX is crop growth stage BBCH 18. Since applications of Primary MX are made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. The germination of maize seeds will be not negatively affected by the application of Primary MX, in the opinion of Evaluator.

	The evaluators from cMS should consider either to accept this approach or to implement restrictions on the label. Any restrictions/warnings on standard mesotrione, nicosulfuron and rimsulfuron products should also be taken into account

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is composed of rimsulfuron, nicosulfuron and mesotrione, which all have been widely used for several years on maize, without identifying any issues in regard to ability of grains of treated plants to germinate.

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is applied early in the season (early post-emergence), before inflorescence emergence and heading, and it is not expected that the active ingredient is transferred to seeds and grains. Thus, no influence on the ability of plant parts from treated crops to germinate is expected (EPPO guideline PP 1/135 (4) "Phytotoxicity assessment", Table 2).

The product complies with the Uniform Principles.

Comments of zRMS:	The active substances: mesotrione, nicosulfuron and rimsulfuron, are commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported. No adverse effect on the yield and quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of mesotrione, nicosulfuron and rimsulfuron in seed crops of maize. In the opinion of Evaluator, the product Primary MX (product code: SHA 4307 A) may be used in seed crops of maize.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is recommended applied early post-emergence to maize.

Rimsulfuron

As per the Peer review report on rimsulfuron (EFSA Journal 2018;16(5):5258), average DT_{50} is 24.3 days (range: 3.2-26 days, n=9) for the parent compound. Thus, the persistence of rimsulfuron can be considered as low to moderate and therefore no studies are needed according to guidelines. The persistence of the key metabolites (IN-70941 (range: 34.3-552.5 days, n=9), IN-70942 (87.9-383.2 days, n=4) and IN-E9260 (246.7-2162.2 days, n=4)) is considered to be moderate to very high, medium to very high and high to very high persistence, respectively.

Data from soil dissipation studies conducted in Europe (FR, IT, DE (2 sites), DK, ES, BG) revealed that actual DT_{50} of the parent compound following application was ranging between 3.5 and 13.8 days, which gives an average normalised DT_{50} of 6.7 days (n=7). This confirms that the DT_{50} of the parent compound is less than 100 days. In the same field dissipation studies where rimsulfuron was the applied test substance, single first order DT_{90} values for metabolites IN-70941, IN-70942 and IN-E9260 were up to 2130, 1400 and 843 days. These data indicate that in the field, the metabolites IN-70941, IN-70942 and IN-E9620 have the potential to accumulate in soil.

In the risk assessment for calculating the PEC_{soil}, the worst-case value from the field dissipation study is used, i.e. 13.8 days.

Nicosulfuron

As per the Peer review report on nicosulfuron (EFSA Scientific Report (2007) 120, 1-91), average normalised DT_{50} is 16.4 days (range: 5.7-40.4 days, n=11/7) for the parent compound. Thus, the persistence of nicosulfuron can be considered as low to moderate and therefore no studies are needed according to guidelines. The persistence of the key metabolites (HMUD (mean = 23.8 days; range: 22.4-25.2 days, n = 1 soil, from two parent labels), AUSN (mean = 105.8 days; 60.0-192.3 days, n=3), ASDM (mean = 128 days; range: 73.8-236.6 days, n=3) and UCSN (mean = 137 days; range: 102.6-271.0 days, n=3)) is considered to be low to moderate, medium to high, medium to high and high persistence, respectively.

Data from soil dissipation studies conducted in Europe (FR (2 sites), DE (2 sites))) revealed that average actual DT_{50} of the parent compound following application was 19.3 days (range: 8.9-63.3 days, n=4). This confirms that the DT_{50} of the parent compound is less than 100 days. In the review report, the following was concluded in regard to the magnitude of residues for succeeding and rotational crops: *The [worst-case] DT_{50} [of the parent compound] in soil from field studies is 63.3 days, therefore at 100 days there will be greater than 10 % of substance remaining in the soil. However, the main concern was that metabolites ADMP and ASDM have a similar toxicity to nicosulfuron, and that at least ASDM is medium to high persistent in soil. Nevertheless, lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg). Moreover, the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period. So were after a plant back interval of 27 to 30 days marked phytotoxic effects observed in following crops while residues of nicosulfuron, ADMP and ASDM in the soil were found to be below the LOQ (0.01 mg/kg). Thus, other crops than cereals could not be grown until the following spring at which time residues in soil of nicosulfuron and relevant metabolites have decreased to <0.001 mg/kg. It can be concluded that at this level in soil no significant residues will occur in rotational crops. The meeting agreed that no further data would be necessary.*

In the risk assessment for calculating the PEC_{soil}, the worst-case value from the field dissipation study is recommended used, i.e. 63 days.

Mesotrione

Not relevant.

As per the Renewal Assessment Report for mesotrione (RAR, February 2015), average DT_{50} in the laboratory is 16.4 days (range 4.3-28.7 days, n=19) and therefore no studies are needed according to guidelines. The persistence of the key metabolites (MNBA and AMBA) is considered to be low for both, with average DT_{50} in the laboratory of 3.6 days (range: 0.5-15.7 days, n=10) and 16.6 days (range: days, n=5), respectively.

Field dissipation studies are not considered for the risk assessment of mesotrione and its metabolites, however, in the original DAR, results from seven field dissipation studies conducted in Germany (4), Italy (2) and France (1) are presented. In these, the average DT_{50} in the field dissipation studies was 5 days (range: 3-7 days).

Hence, no significant residue levels are to be expected in rotational crops following application of mesotrione according to the proposed GAP.

In the risk assessment for calculating the PEC_{soil}, the worst-case value from laboratory study is recommended used, i.e. 34.3 days.

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.

Comments of zRMS:	The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should present the assessment of the possible effect of Primary MX on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance with the EPPO Standard Efficacy evaluation of plant protection products. Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure. The half-life (DT_{50}) for mesotrione in soil is short – about 16.4 days; for nicosulfuron – about 16.4 days and rimsulfuron – about 24.3 Therefore, the impact on succeeding crops is unlikely to occur. No risk of phytotoxicity for succeeding crops is expected, in the opinion of Evaluator and lack of calculations of TER values submitted by the applicant based on ER_{10} values coming out from" Seedling Emergence and Seedling Growth test" can be accepted. In the opinion of Evaluator, necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim. Usually after deep ploughing can be sown all crops. In the case of sensitive crops, i.e. sugar, legumes, oilseed rape, sunflower and vegetables and early sown winter cereals in unfavourable conditions for decomposition of the possible occurrence of damage, according to the current knowledge about active compounds from tested plant protection product. ZRMs accepted label recommendations proposed by Applicant. So, in the label following entry should be applied: ***"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."*

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials and selectivity trials, no observations about negative or positive effects on other plants or neighbouring crops were reported.

EPPO guidelines PP1/256(1) is intended to examine whether the active substance of a plant protection product can cause negative effects on crop which would be in contact with that product. Based on the actual drift value calculated with the Ganzelmeier model and on the EC_{50} value obtained from herbicidal screening studies presented in the DAR, TER values are obtained.

- If the active substance has no activity against plants at the highest doses tested in the bioassays. Then field trials are unnecessary.
- If the TER values are > 5. Then no further testing is necessary.
- If the TER values are ≤ 5. Damage to the relevant adjacent crop is possible and further field testing is necessary as described in the EPPO guideline.

The maximum proposed rate of Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG is 0.33 kg/ha, which would deliver 9.9 g rimsulfuron, 39.6 g nicosulfuron and 118.8 g mesotrione per hectare.

<u>Rimsulfuron</u>

The following risk assessment is based upon reported Non-Target Plant endpoints from unprotected studies presented by Dupont and the Helm AG/Sapec Agro S.A. task force with their respective test formulations Rimsulfuron 25WG (rimsulfuron 250 g/kg WG) in the RAR, summarized in the Peer review of rimsulfuron (EFSA Journal 2018;16(5):5258).

A summary of the results reported in laboratory dose response tests are presented in the table below.

Table 3.5-1: Results of laboratory dose response tests (EFSA Peer Review (2018))

Test substance	Test type	Group	Species	Endpoint
Rimsulfuron 25 WG	Vegetative vigour	Monocots	*Sorghum bicolor*	21-d ER_{50} = 4.89 g form./ha (nom)
Rimsulfuron 25 WG + IN-KG691 surfactant	Vegetative vigour	Dicots	*Brassica napus*	21-d ER_{50} = 6.32 g form./ha (1.58 g a.s./ha)
			Clycine max	21-d ER_{50} = 22.5 g form./ha
			Beta vulgaris	21-d ER_{50} = 20.2 g form./ha
		Monicots	*Zea mays*	21-d ER_{50} > 50 g form./ha
			Avena sativa	21-d ER_{50} = 22.2 g form./ha
			Allium cepa	21-d ER_{50} = 7.22 g form./ha
Rimsulfuron 25 WG + IN-KG691 surfactant	Vegetative vigour	Dicots	*Brassica napus*	21-d ER_{50} = 3.7 g form./ha (0.948 g a.s./ha)
		Monocots	*Sorghum bicolor*	21-d ER_{50} = 1.09 g form./ha (0.272 g a.s./ha)
Rimsulfuron 25 WG + HAG 530 01 S	Vegetative vigour	Dicots	*Brassica napus*	21-d ER_{50} = 0.23 g a.s./ha
			Clycine max	21-d ER_{50} = 0.78 g a.s./ha
			Lycopersicon esculentum	21-d ER_{50} = 83.3 g a.s./ha
			Cucimis sativa	21-d ER_{50} = 18.3 g a.s./ha
			Pisum sativum	21-d ER_{50} = 0.85 g a.s./ha
		Monocots	*Zea mays*	21-d ER_{50} >30 g a.s./ha
			Triticum aestivum	21-d ER_{50} = 0.12 g a.s./ha
			Allium cepa	21-d ER_{50} = 0.92 g a.s./ha
			Sorghum bicolor	21-d ER_{50} = 0.093 g a.s./ha

IN-70942	All parameters	Dicots	*Brassica napus*	21-d ER_{50} > 137.5 g IN-70942/ha (>183 µg IN-70942/kg dry soil)
		Monocots	*Sorghum bicolor*	21-d ER_{50} > 137.5 g IN-70942/ha (>183 µg IN-70942/kg dry soil)
IN-E9260	All parameters	Dicots	*Brassica napus*	21-d ER_{50} > 137.5 g IN-E9260/ha (>183 µg IN-E9260/kg dry soil)
		Monocots	*Sorghum bicolor*	21-d ER_{50} > 137.5 g IN-E9260/ha (>183 µg IN-E9260/kg dry soil)
Rimsulfuron 25 WG + IN-KG691 surfactant	Seedling emergence	Dicots	*Cucumer sativa*	21-d ER_{50} >27.5 g a.s./ha
			Pisum sativum	21-d ER_{50} >27.5 g a.s./ha
			Clycina max	21-d ER_{50} >27.5 g a.s./ha
			Lycopersicon esculentum	21-d ER_{50} >27.5 g a.s./ha
			Beta vulgaris	21-d ER_{50} = 8.79 g a.s./ha
			Brassica napus	21-d ER_{50} = 1.77 g a.s./ha
		Monocots	*Zea mays*	21-d ER_{50} >27.5 g a.s./ha
			Avena sativa	21-d ER_{50} =22.4 g a.s./ha
			Allium cepa	21-d ER_{50} = 8.14 g a.s./ha
			Sorghum bicolor	21-d ER_{50} = 4.72 g a.s./ha
Rimsulfuron 25 WG + IN-KG691 surfactant	Seedling emergence	Dicots	*Brassica napus*	21-d ER_{50} = 0.325 g a.s./ha
		Monocots	*Sorghum bicolor*	21-d ER_{50} = 1.12 g a.s./ha
Rimsulfuron 25 WG + HAG 530 01 S	Seedling emergence	Dicots	*Brassica napus*	21-d ER_{50} = 1.77 g a.s./ha
			Clycine max	21-d ER_{50} = 34.7 g a.s./ha
			Cucumber sativa	21-d ER_{50} = 16.3 g a.s./ha
			Beta vulgaris	21-d ER_{50} = 3.90 g a.s./ha
			Pisum sativum	21-d ER_{50} = 9.58 g a.s./ha
		Monocots	*Triticum aestivum*	21-d ER_{50} = 5.04 g a.s./ha
			Allium cepa	21-d ER_{50} = 1.58 g a.s./ha
			Sorghum bicolor	21-d ER_{50} = 1.812 g a.s./ha

In the DAR (Volume 3, Annex B, B.9 (2003)), results obtained from two studies where three major metabolites of rimsulfuron (IN-70941, IN-70942 and IN-E9260) were tested for herbicidal activity in pre- and post-emergence studies at different application rates for a number of species. The conclusion was that there were no herbicidal effects of the metabolites on 17 plant species tested. Therefore, any risk to non-target plants posed by rimsulfuron's soil metabolites is considered likely to be covered by that for the active substance and no further risk assessment is required.

Taking into account the endpoints reported in the Peer review of rimsulfuron, the most sensitive monocotyledonous species was *Sorghum bicolor*, with ER_{50} of 0.272 g ai/ha. The most sensitive dicotyledonous species was *Brassica napus* with ER_{50} of 0.325 g ai/ha.

Risk assessment

Terrestrial non-target plants may be exposed to rimsulfuron by spray drift in the vicinity of the treated area. Rimsulfuron is mainly taken up via plant foliage, but also roots and shoots (seedlings). The maximum proposed dose rate of rimsulfuron, when applying Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG as recommended, is 9.9 g ai/ha.

The risk to adjacent crops was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the EPPO trigger of 5.

Results are presented in the table below:

Table 3.5-2: Effects on non-target plants, rimsulfuron

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value[a] (%)	Drift reducing nozzles (%)	Drift rate (g a.s./ha)	Timing	ER_{50} (g a.s./ha)	TER	Trigger
Rimsulfuron	1	1 x 9.9	2.77	0	0.27	Post-emergence	0.272	**0.99**	5
		1 x 9.9	2.77	50	0.14		0.272	**1.98**	5
		1 x 9.9	2.77	75	0.07		0.272	**3.97**	5
		1 x 9.9	2.77	90	0.03		0.272	9.92	5
	5	1 x 9.9	0.57	0	0.06		0.272	**4.82**	5
		1 x 9.9	0.57	50	0.03		0.272	9.64	5
	10	1 x 9.9	0.29	0	0.03		0.272	9.47	5

[a] Drift estimates are based on 90th percentile values for field crops (BBA 2000); EC_{50} values on *Sorghum bicolor*, as the worst case

Without risk mitigation measures, the calculated TER values are below the trigger of 5, indicating a potential risk to non-target plants, if applied for weed control in maize. A TER trigger of above 5 (according to SANCO 10329/2002, rev. 2) is achieved when taking a buffer zone of 10 meter into account; a buffer zone of 5 meter and nozzle of minimum 50% drift reduction into account or a buffer zone of 1 m and nozzle of 90% drift reduction into account.

Nicosulfuron

The following risk assessment is based upon reported Non-Target Plant endpoints from the ISK unprotected study with the test formulation SL-950 4% SC (nicosulfuron 40 g/L SC) in the DAR (Volume 3, Annex B, B.9 (2006)). In a post-emergence study, treated plants were grown in pots in the greenhouse, with three replicate pots per treatment. The percentage "growth inhibition" was assessed 14 days after treatment based on the number of plants showing adverse visible effects (e.g. discoloration, necrosis, complete kill) – 0% indicating no plants with visible symptoms (the NOEL) and 100% indicating all treated plants showing some visible adverse effects. Treatment doses causing no adverse visible effects and adverse visible effect of approximately 50% are summarized in Table 3.5-3.

Table 3.5-3: Results of Vegetative Vigour test in seventeen non-target plant species [SL-950 4% SC] (DAR B.9.9.1)

Crop (listed in order of least sensitivity based on EC50)	NOEL* g a.s. /ha	EC50# (symptoms present) g a.s. /ha
Potato	3.8	60 (40% shrinked leaf) [highest rate tested]
Tomato	0.94	15-30 (45 & 65% discolouration / reddening)
Soybean	3.8	15-30 (5 & 80% shrinked leaf)
Azuki bean	0.47	7.5-15 (40 & 90% discolouration, shrinked leaf, or necrosis)
Cabbage	1.9	7.5 (50% discolouration)
Alfalfa	0.94	3.8-7.5 (40 & 70%, symptoms not recorded)
Lettuce	0.47	3.8-7.5 (20 & 55% discolouration)
Melon	0.94	3.8-7.5 (35 & 60% discolouration)
Spinach	1.9	3.8-7.5 (30 & 60%, symptoms not recorded)
Sugar beet	0.47	3.8 (50% discolouration)
Italian ryegrass	0.23	1.9 (50% symptoms not recorded)
Radish	0.12	1.9 ((50% discolouration, shrinked leaf)
Aubergine (eggplant)	0.12	0.94-1.9 (30 & 65% discolouration)
Timothy	0.12	1.9 -0.94 (40 & 55%, symptoms not recorded)
Chinese cabbage	0.23	0.47-0.94 (20 & 60% discolouration)
Cucumber	0.12	0.47-0.94 (15 & 55% discolouration)
Rice	0.12	0.47 (50% - symptoms not recorded, discolouration at 0.94)

* Based on absence of any recorded effect
# Where no treatment dose produced precisely 50% effect, the two doses on either side of this point are recorded.

Of the treated crops, Chinese cabbage, cucumber and rice were shown to be particularly sensitive to nicosulfuron, with EC_{50} of less than one sixtieth of the maximum proposed dose of 60 g ai/ha (i.e. $EC_{50's}$ of < 1.0 g ai/ha).

In the same DAR, a conventional seedling emergence study, a conventional vegetative vigour study as well as a field study with early post-emergence spray application are summarized. In the seedling emergence study and the vegetative vigour study, six representative species (three dicotyledonous species (carrot (*Daucus carota*), oilseed rape (*Brassica napus*) and pea (*Pisum sativum*)) and three monocotyledonous species (maize (*Zea mays*), oats (*Avena sativa*) and onion (*Allium cepa*)) were tested. The results are presented in Table 3.5-4.

Table 3.5-4: Results of laboratory- (seedling emergence test and vegetative vigour test) and field studies in six non-target plant species [SL-950 4% SC] (DAR B.9.9.1)

Test substance	'SL-950 SC 4% SC'					
Plant species	Effect on emergence		Effects on vegetative vigour			
	[g a.s./ha]					
	EC_{50}	NOEC*	EC_{50}	NOEC*	EC_{50}	NOEC*
Monocots						
Maize	> 20 (w, h)	≥ 20	> 20 (w, h)	≥ 20	> 40	≥ 40 (p, w)
Oat	> 20 (w, h)	≥ 20	> 20 (w, h)	≥ 20	11.5	2.0 (p, w)
Onion	> 20 (w, h)	≥ 20	> 20 (w, h)	≥ 20	16.9	2.0, 10 (p, w)
Dicots						
Carrot	> 20 (w, h)	≥ 20	5.0, 8.9 (w, h)	2.22	> 40	2.0, 20 (p, w)
Oilseed rape	> 20 (w, h)	≥ 20	0.8, 0.7 (w, h)	0.25	6.6	0.4, 2.0 (p, w)
Pea	> 20 (w, h)	≥ 20	14.9, 15.2 (w, h)	6.67	32.5	10, 20 (p, w)
Reference	Porch & Krueger (2000a)		Porch & Krueger (2000b)		Oberwalder & Landvogt (2000a-f)	

Note: The lowest values determined in the studies are given with w = plant weight, h = plant height and p = phytotoxicity.
* Determined by statistically significant difference/s from control (P=0.05)

Finally, also in the DAR, results obtained from two studies with the key metabolites of nicosulfuron are presented and the conclusion was that it is considered that the evidence is sufficient to indicate that nicosulfuron's soil metabolites are likely to be of significantly lower phytotoxicity to non-target plants than the parent active substance. These metabolites will also be present at significantly lower maximum soil concentrations than that of nicosulfuron. Therefore, any risk to non-target plants posed by nicosulfuron's soil metabolites is considered likely to be covered by that for the active substance and no further risk assessment is required.

Taking into account the quantitative parameters, the most sensitive species reported were Chinese cabbage, cucumber and rice, with EC_{50} of 0.47 g a.s./ha.

Risk assessment

Terrestrial non-target plants may be exposed to nicosulfuron by spray drift in the vicinity of the treated area. Nicosulfuron is mainly taken up via plant foliage, but also roots and shoots (seedlings). The maximum proposed dose rate of nicosulfuron, when applying Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG as recommended, is 39.6 g ai/ha.

The risk to adjacent crops was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the EPPO trigger of 5.

Results are presented in the table on the following page.

Without risk mitigation measures, the calculated TER values are below the trigger of 5, indicating a potential risk to non-target plants, if applied for weed control in maize. A TER trigger of above 5 (according to SANCO 10329/2002, rev. 2) is achieved when taking a buffer zone of 5 meter and nozzle of minimum 75% drift reduction into account or a buffer zone of 10 m and nozzle of minimum 50% drift reduction into account.

Table 3.5-5: Effects on non-target plants, nicosulfuron

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value[a] (%)	Drift reducing nozzles (%)	Drift rate (g a.s./ha)	Timing	ER_{50} (g a.s./ha)	TER	Trigger
Nicosulfuron	1	1 x 39.6	2.77	0	1.10	Post-emergence	0.47	**0.43**	5
		1 x 39.6	2.77	50	0.55		0.47	**0.86**	5
		1 x 39.6	2.77	75	0.27		0.47	**1.71**	5
	5	1 x 39.6	0.57	0	0.23		0.47	**2.08**	5
		1 x 39.6	0.57	50	0.11		0.47	**4.16**	5
		1 x 39.6	0.57	75	0.06		0.47	8.33	5
	10	1 x 39.6	0.29	0	0.11		0.47	**4.09**	5
		1 x 39.6	0.29	50	0.06		0.47	8.19	5

[a] Drift estimates are based on 90th percentile values for field crops (BBA 2000); ER_{50} values on *Oryza sativa*, as the worst case

Mesotrione

In the studies summarized in the peer review (EFSA Journal 2016; 14(3): 4419, 103pp), 10 representative species (7 dicotyledonous species (cabbage, turnip, soybean, cucumber, tomato, linseed and lettuce) and three monocotyledonous species (onion, oat and ryegrass)) were tested.

These studies are presented in the table below.

Table 3.5-6: Effects of mesotrione on shoot fresh weight, obtained from vegetative vigour and seedling emergence study (DAR B.9.9.2)

Species	Shoot Fresh Weight ER_{50}			
	Vegetative vigour		Seedling Emergence	
	[L/ha]	[g mesotrione/ha]	[L/ha]	[g mesotrione/ha]
Oats	>5.000	>500	>1.250	>125
Ryegrass	>5.000	>500	>1.250	>125
Onion	**0.089**	**8.93**	**0.332**	**33.2**
Cabbage	0.062	6.18	0.198	19.8
Turnip	0.023	2.27	0.206	20.6
Soybean	0.067	6.70	>1.500	>150
Linseed	2.640	264	>1.250	>125
Cucumber	0.015	1.53	>1.500	>150
Lettuce	**0.0088**	**0.883**	**0.138**	**13.8**
Tomato	0.0015	1.50	0.197	19.7

In both tests (vegetative and seedling), lettuce (*Lactuca sativa*) was the most sensitive species with an ER_{50} value of 0.883 g mesotrione/ha and 13.8 g mesotrione/ha, respectively. The most sensitive endpoint was on vegetative vigour of lettuce with an ER_{50} = 0.883 g mesotrione/ha and the results obtained will be used in the table below to assess the TER and compare it to the trigger value of 5 (SANCO 10329/2002, rev. 2).

Risk assessment

Terrestrial non-target plants may be exposed to mesotrione by spray drift in the vicinity of the treated area. Mesotrione is mainly taken up via plant foliage, roots and shoots (seedlings). The maximum proposed dose rate of mesotrione, when applying Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG as recommended, is 118.8 g ai/ha.

The most sensitive of the species and parameters tested in seedling emergence and vegetative vigour studies was Lettuce biomass (*Lactuca sativa*) with an ER_{50} of 0.883 g mesotrione/ha. The risk was assessed by calculation of the toxicity to exposure ratio (TER), and comparison of this value with the EPPO trigger of 5.

Table 3.5-7: Effects on non-target plants, mesotrione

Test substance	Buffer distance (m)	Application rate (g a.s./ha)	Drift value[a] (%)	Drift reducing nozzles (%)	Drift rate (g a.s./ha)	Timing	ER_{50} (g a.s./ha)	TER	Trigger
Mesotrione	1	1 x 118.8	2.77	0	3.29	Post-emergence	0.883	**0.27**	5
		1 x 118.8	2.77	50	1.65		0.883	**0.54**	5
		1 x 118.8	2.77	75	0.82		0.883	**1.07**	5
	5	1 x 118.8	0.57	0	0.68		0.883	**1.30**	5
		1 x 118.8	0.57	50	0.34		0.883	**2.61**	5
		1 x 118.8	0.57	75	0.17		0.883	5.22	5
	10	1 x 118.8	0.29	0	0.34		0.883	**2.56**	5
		1 x 118.8	0.29	50	0.17		0.883	5.13	5
	20	1 x 118.8	0.15	0	0.18		0.883	**4.96**	5
		1 x 118.8	0.15	50	0.09		0.883	9.91	5

[a] Drift estimates are based on 90^{th} percentile values for field crops (BBA 2000); ER_{50} values on *Lactuca sativa*, as the worst case

Without risk mitigation measures, the calculated TER values are below the trigger of 5, indicating a potential risk to non-target plants, if applied for weed control in maize. A TER trigger of above 5 (according to SANCO 10329/2002, rev. 2) is achieved when taking a buffer zone of 5 meters and nozzle of minimum 75% drift reduction into account, a buffer zone of 10 meter and nozzle of minimum 50% drift reduction into account or a buffer zone of 20 m and nozzle of minimum 50% drift reduction into account.

Conclusion

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 5 meters and nozzles giving drift reduction of 75% or a buffer zone of 10 meters and nozzles giving a drift reduction of 50% is taken into account. Please, for more information, refer to Registration Report, Part B, Section 9.

Comments of zRMS:	Statement accepted by Evaluator. The calculated TER value for the most sensitive crop was above the trigger of 1. Conclusions from Section 9 considering the trigger value 5: An application of Primary MX in respect of the GAP does not present an unacceptable risk for non-target terrestrial plants when risk mitigation measures are considered: 75% drift reduction nozzles OR 5m no-spray buffer zone. Generally, the product is a foliar herbicide effective on broadleaved weeds. Therefore, warnings to avoid spray drift on adjacent crops should appear on the label.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG in 2016, 2017 and 2019, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 9.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Regulation 1107/2009.

Comments of zRMS:	For detailed consideration of risks to beneficial organisms please see the eco-toxicology section B section 9.

3.6 Other/special studies

3.6.1 Tank-cleaning (KCP 6.6.1)

For more information, please refer to Section B124.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

			Year and trial type					
			2016		**2017**		**2019**	
			Efficacy	**Selectivity**	**Efficacy**	**Selectivity**	**Efficacy**	**Selectivity**
Testing facility	**Zone**	**Country**	Post-em.	Post-em.	Post-em.	Post-em.	Post-em.	Post-em.
Maize								
Biochem Agrar	MAR	DE	2	2				
Z.z.s. Kujavy	MAR	CZ	2	1				
Z.s. Trutnov	MAR	CZ	1					
Zemservis	MAR	CZ		1				
SGS Group	MAR	UK	2	2				
Anadiag France	MAR	FR	2	3				
IOR-PIB Poznan	N-E	PL	8	2				
IUNG-PIB Puławy	N-E	PL			4	2		
Sharda Polska	N-E	PL					4	2
Plant-Art Research	S-E	HU	2					
GMW Bioscience	MED	ES	2	2				
SAGEA	MED	IT	2	2				
Anadiag France	MED	FR	2	1				
Total, Maize			**25**	**16**	**4**	**2**	**4**	**2**

Appendix 1 Lists of data considered in support of the evaluation

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	Vertebrate study Y/N	Owner
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	Sharda