

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

Product code: SHA 4307 A

Product name: PRIMARY MX

Chemical active substances:

Rimsulfuron, 30 g/kg

Nicosulfuron, 120 g/kg

Mesotrione, 360 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: February 2020

Update date: 03.2021, 08.2021

MS Finalisation date: 05.2022, 12.2022, 03.2023

Version history

When	What
02.2020	Aplicant Submission
March 2021	Applicant update
August 2021	Applicant update
May 2022	zRMS first evaluation
December 2022	Updatet after commentig period
March 2023	zRMS correction

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: SHARDA Cropchem España S.L
Address: Edificio Atalayas Business Center,
Carril Condomina nº 3, 12th Floor,
30006 Murcia, Spain
Phone: +34868127589
FAX: +34868127588

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Rimsulfuron

Rimsulfuron min. 980 g/kg (Sharda source; equivalence evaluated by UK, 2014)
min. 960 g/kg (Commission Directive 06/39/EC)

1.2.3.2 Nicosulfuron

Nicosulfuron min. 930 910 g/kg (Sharda source; equivalence evaluated by UK, 2009)
min. 930 910 g/kg (Commission Directive 2008/40)

1.2.3.3 Mesotrione

Mesotrione

min. 985 g/kg (Sharda source, Shandong Binnong Technology Co. source; equivalence evaluated by UK, 2018)

min. 920 g/kg (Commission Implementing Regulation (EU) 2017/725)

Relevant impurities (SANTE/11654/2016 23 March 2017, EFSA Journal 2016;14(3):4419):

R287431	max. 2 mg/kg
R287432	max. 2 g/kg
1,2-dichloroethane	max. 1 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: PRIMARY MX

Company code number: SHA 4307 A

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Rimsulfuron	30 g/kg	27-33 g/kg (± 10% of declared content)	30.61 g/kg	3.06
Nicosulfuron	120 g/kg	112.8-127.2 g/kg (± 6% of declared content)	12.9 129.0 g/kg	1.29
Mesotrione	360 g/kg	342-378 g/kg (± 5% of declared content)	365.5 g/kg	36.5

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
R287431	2 mg/kg
R287432	2 g/kg
1,2-dichloroethane	1 g/kg

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-3: Information on Rimsulfuron

Type	Name/Code Number
ISO common name	Rimsulfuron
CAS No.	122931-48-0
EC No.	602-908-8
CIPAC No.	716

Table 1.4-4: Information on Nicosulfuron

Type	Name/Code Number
ISO common name	Nicosulfuron
CAS No.	111991-09-4
EC No.	601-148-4
CIPAC No.	709

Table 1.4-5: Information on Mesotrione

Type	Name/Code Number
ISO common name	Mesotrione
CAS No.	104206-82-8
EC No.	609-064-00
CIPAC No.	625

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water dispersible granules [Code: WG]

1.6 Function (KCP 1.6)

The product PRIMARY MX (Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG) is an herbicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of off-white granules with characteristics and weak odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of < 400 °C. In aqueous solution, it has a pH value around 4.48 at 20 °C.

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

Active substances content and stability of packaging [Al (outside layer)/HDPE (inside layer) bag] were tested in 6 months, 1 year at ambient temperature and 2 years at ambient temperature when stored in Al/PE bags.

The active ingredient content and all physical and chemical properties remained stable and acceptable after the tests.

Its technical characteristics are acceptable for a water dispersible granules formulation.

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

RMS Comments:

The applicant changed the dose of the product to min. 0.25 kg/L with 0.33 kg/L: 0.0625% - 0.125%.

The tests of physicochemical parameters were carried out for the lowest use concentration of 0.0825% v/v. and the highest use concentration of 0.165% v/v.

The maximum use concentrations were taken into account in the physicochemical test (the minimum concentration is similar to the first recommended concentration).

There is no need to submit additional data.

The physicochemical test package which was presented is sufficient for evaluation

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Neither classification or labelling is relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG complies with FAO specifications.

Formulation used for tests

The product used to determine the physical, chemical and technical properties is the one cited in Part C.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302, OPPTS 830.6303, OPPTS 830.6304	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	Off white granules with characteristics and weak odor	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	The test item does not have explosive properties.	Y	Pawel Sliwa, 2018 Report no. BW-08/18	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.17	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	The maximum burning rate of the tested mixture: 1.31 mm/s The maximum burning rate of the reference mixture: 1.40 mm/s The test sample has no oxidizing properties	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Flash point (KCP 2.3.1)			Please refer to KCP 2.3.2			Statement accepted
Flammability (KCP 2.3.2)	EEC A.10	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	The strip does not burn to the end, after removal of external ignition source the strip is extinguished. The test sample is not considered as flammable.	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Self-heating (KCP 2.3.3)	EEC A.16	Rimsulfuron 3% + Nicosulfuron	The test sample has self-heating properties, but temperature of 400°C has not been reached as a result of the sample self-heating.	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments										
		12% +Mesotrione 36% WG														
Acidity or alkalinity and pH (KCP 2.4.1)			Please refer to KCP 2.4.2			Statement accepted										
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	pH = 4.48	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted										
Viscosity (KCP 2.5.1)			Not relevant for a WG formulation.			Statement accepted										
Surface tension (KCP 2.5.2)			Not relevant for a WG formulation.			Statement accepted										
Relative density (KCP 2.6.1)			Not relevant for a WG formulation.			Statement accepted										
Bulk density (KCP 2.6.2)	CIPAC MT 186	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	Pour density = 0.556 g/mL Tap density = 0.577 g/mL	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted										
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	<table border="1"> <thead> <tr> <th>Test</th> <th>Results after 14 d at 54°C</th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td>Light brown granules with characteristics and weak odor</td> </tr> <tr> <td>pH value (1% w/v aq. sol.)</td> <td>4.81</td> </tr> <tr> <td>Suspensibility (0.0825% w/v aq. sol.)</td> <td>62%</td> </tr> <tr> <td>Suspensibility (0.135% w/v aq. sol.)</td> <td>61%</td> </tr> </tbody> </table>	Test	Results after 14 d at 54°C	Appearance	Light brown granules with characteristics and weak odor	pH value (1% w/v aq. sol.)	4.81	Suspensibility (0.0825% w/v aq. sol.)	62%	Suspensibility (0.135% w/v aq. sol.)	61%	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted Presented results are accepted. Active substances content and stability of packaging [AI (outside
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
Stability after storage for other periods and/or temperatures (KCP 2.7.2)			Not relevant			Statement accepted												
Minimum content after heat stability testing (KCP 2.7.3)	ICSO Procedure No. BA-AB/SPO-3 HPLC method CIPAC MT 46.3	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Batch No.: SCL-78944	<table border="1"> <thead> <tr> <th>Active substance</th> <th>0 days</th> <th>14 d at 54°C</th> </tr> </thead> <tbody> <tr> <td>Rimsulfuron</td> <td>3.27% (w/w) 32.67 g/kg</td> <td>3.18% (w/w) 31.81 g/kg</td> </tr> <tr> <td>Nicosulfuron</td> <td>12.46% (w/w) 124.58 g/kg</td> <td>12.45 (w/w) 124.49 g/kg</td> </tr> <tr> <td>Mesotrione</td> <td>36.25 (w/w) 362.48 g/kg</td> <td>35.18% (w/w) 351.82 g/kg</td> </tr> </tbody> </table>	Active substance	0 days	14 d at 54°C	Rimsulfuron	3.27% (w/w) 32.67 g/kg	3.18% (w/w) 31.81 g/kg	Nicosulfuron	12.46% (w/w) 124.58 g/kg	12.45 (w/w) 124.49 g/kg	Mesotrione	36.25 (w/w) 362.48 g/kg	35.18% (w/w) 351.82 g/kg	Y	Michalec-Minch, 2018 Report no. 7/2018 Nowakowska-Bogdan E., 2020 Report No.: 163/2020	Accepted The content of active substances were not significantly decreased after accelerate storage stability test. The analytical method used (HPLC - UV) is acceptable and validated according to SANCO/3030/99 Rev. 4 (see Section B5). The study to determine the concentration of the relevant impurities R287431, R287432 and 1,2-dichloroethane in Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG have been accepted.
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1,2-dichloroethane	Not detected (<LOQ)	Not detected (<LOQ)																
Effect of low temperatures on			Not required.			Statement accepted												

Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments																																					
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Ambient temperature shelf life (KCP 2.7.5)		Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG	<table border="1"> <thead> <tr> <th>Test</th> <th>Results after 6 months</th> <th>Results after 12 months</th> <th>Results after 24 months</th> </tr> </thead> <tbody> <tr> <td>Rimsulfuron content</td> <td>3.20% (w/w) 31.99 g/kg</td> <td>3.16% (w/w) 31.58 g/kg</td> <td>3.16% (w/w) 31.63 g/kg</td> </tr> <tr> <td>Nicosulfuron content</td> <td>12.27% (w/w) 122.68 g/kg</td> <td>12.09% (w/w) 120.91 g/kg</td> <td>12.01% (w/w) 120.12 g/kg</td> </tr> <tr> <td>Mesotrione content</td> <td>36.31% (w/w) 361.15 g/kg</td> <td>35.47% (w/w) 354.68 g/kg</td> <td>35.74% (w/w) 357.43 g/kg</td> </tr> <tr> <td>Appearance</td> <td>Off white granules with characteristics and weak odor</td> <td>Off white granules with characteristics and weak odor</td> <td>Off white granules with characteristics and weak odor</td> </tr> <tr> <td>pH value (1% w/v aqueous dilution)</td> <td>4.40</td> <td>4.41</td> <td>4.47</td> </tr> <tr> <td>Suspensibility (0.0825% w/v aq. sol.)</td> <td>69%</td> <td>72%</td> <td>63%</td> </tr> <tr> <td>Suspensibility (0.165% w/v aq. sol.)</td> <td>69%</td> <td>74%</td> <td>66%</td> </tr> <tr> <td>Degree of dispersion</td> <td>96%</td> <td>95%</td> <td>94%</td> </tr> <tr> <td>Wettability</td> <td>Without swirling – 2 second) With swirling – 2 second</td> <td>Without swirling – 2 second) With swirling – 1 second</td> <td>Without swirling – 2 second) With swirling – 2 second</td> </tr> </tbody> </table>	Test	Results after 6 months	Results after 12 months	Results after 24 months	Rimsulfuron content	3.20% (w/w) 31.99 g/kg	3.16% (w/w) 31.58 g/kg	3.16% (w/w) 31.63 g/kg	Nicosulfuron content	12.27% (w/w) 122.68 g/kg	12.09% (w/w) 120.91 g/kg	12.01% (w/w) 120.12 g/kg	Mesotrione content	36.31% (w/w) 361.15 g/kg	35.47% (w/w) 354.68 g/kg	35.74% (w/w) 357.43 g/kg	Appearance	Off white granules with characteristics and weak odor	Off white granules with characteristics and weak odor	Off white granules with characteristics and weak odor	pH value (1% w/v aqueous dilution)	4.40	4.41	4.47	Suspensibility (0.0825% w/v aq. sol.)	69%	72%	63%	Suspensibility (0.165% w/v aq. sol.)	69%	74%	66%	Degree of dispersion	96%	95%	94%	Wettability	Without swirling – 2 second) With swirling – 2 second	Without swirling – 2 second) With swirling – 1 second	Without swirling – 2 second) With swirling – 2 second	Y	Michalec-Minch, 2018 Report no. 8/2018	Accepted Active substances content and stability of packaging [Al (outside layer)/HDPE (inside layer) bag] were tested. All physical and chemical properties remained stable after the tests and accepted. Based on 2-years storage stability study: shelf life – 2 years.
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Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
			Particle size distribution	100% less than 60µm Mean: 7.110 µm Mediam: 4.626 µm Mode: 5.878 µm	100% less than 57µm Mean: 9.494 µm Mediam: 5.746µm Mode: 7.084 µm	100% less than 57µm Mean: 9.069 µm Mediam: 5.647µm Mode: 7.084 µm			
			Wet sieve test	0.005% of residue on a 75µm mesh sieve	0.008% of residue on a 75µm mesh sieve	0.011% of residue on a 75µm mesh sieve			
			Attrition characteristics	99.84%	99.34%	99.39%			
			Persistent foaming (0.0825% w/v aq. sol.)	Maximum 54 mL after 1 minute	Maximum 22 mL after 1 minute	Maximum 24 mL after 1 minute			
			Persistent foaming (0.165% w/v aq. sol.)	Maximum 60 mL after 1 minute	Maximum 60 mL after 1 minute	Maximum 50 mL after 1 minute			
			Dry sieve test	0.09% between 2000-3350 µm 84.41% between 1000-2000 µm 14.46% between 500-1000 0.20% between 250-500 µm 0.29%	0.08% between 2000-3350 µm 81.85% between 1000-2000 µm 16.29% between 500-1000 0.28% between 250-500 µm 0.45%	0.62% between 2000-3350 µm 90.76% between 1000-2000 µm 7.76% between 500-1000 µm 0.02% between 250-500 µm 0.04%			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments	
				between 125-500 µm 0.19% between 75-125 µm	between 125-500 µm 0.33% between 75-125 µm	between 125-500 µm 0.08% between 75-125 µm			
			Stability of packaging	No significant effect of the formulation on the package. After storage procedure weight loss was 0.00% (w/w)	No significant effect of the formulation on the package and vice versa was observed; after storage procedure no changes in appearance of sample and packaging was observed; no significant effect on the weight of the package with sample was observed; After storage procedure weight increase was 0.11% (w/w).	No significant effect of the formulation on the package and vice versa was observed; after storage procedure no changes in appearance of sample and packaging was observed; no significant effect on the weight of the package with sample was observed; After storage procedure weight increase was 0.09% (w/w).			
Shelf life in months (if less than 2 years) (KCP 2.7.6)			On-going			Y	Michalec-Minch, 2018 Report no. 8/2018	Statement accepted	
Wettability	CIPAC MT 53.3	Rimsulfuron	Without swirling – 2 second			Y	Michalec-Minch,	Accepted	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.1)		3% + Nicosulfuron 12% +Mesotrione 36% WG	With swirling – 1 second		2018 Report no. 7/2018	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2 (Standard Water C)	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	0.0825% w/v aqueous solution: Maximum 54 mL after 1 minute 0.165% w/v aqueous solution: Maximum 60 mL after 1 minute	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted RMS Comments: Min application rate: Maximum 54 mL after 1 minute Maximum 53 mL after 3 minute Maximum 51 mL after 12 minute Max application rate: Maximum 60 mL after 1 minute Maximum 57 mL after 3 minute Maximum 55 mL after 12 minute
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 (Standard Water D)	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	0.0825% w/v aquaous solution: 64% 0.165% w/v aquoues solution: 63%	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Spontaneity of dispersion			Not relevant for a WG formulation.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.2)						
Dispersion stability (KCP 2.8.3.3)			Not relevant for a WG formulation.			Statement accepted
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 174	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	93%	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	100% less than 53 µm Mean: 7.860 µm Mediam: 4.644 µm Mode: 6.453 µm	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	0.013% of residue on a 75 µm mesh sieve	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Dry sieve test	CIPAC MT 170	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	0.07% of particles have size between 2000-3350 µm 84.66% of particles have siez between 1000-2000 µm 13.91% of particles have size between 500-1000 µm 0.43% of particles have size between 250-500 µm 0.22% of particles have size between 125-250 µm 0.17% of particles have size between 75-125 µm	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Dust content (KCP 2.8.5.2.1)			Not relevant for a WG formulation. See KCP 2.8.5.1.1 point			Statement accepted
Particle size of dust (KCP 2.8.5.2.2)			Not relevant for a WG formulation.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	99.83%	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Hardness and integrity (KCP 2.8.5.4)			Not relevant for a WG formulation.			Statement accepted
Emulsifiability (KCP 2.8.6.1)			Not relevant for a WG formulation.			Statement accepted
Emulsion stability (KCP 2.8.6.2)			Not relevant for a WG formulation.			Statement accepted
Re-emulsifiability (KCP 2.8.6.3)			Not relevant for a WG formulation.			Statement accepted
Flowability (KCP 2.8.7.1)	CIPAC MT 172 (54°C, 14 days, pressure on the sample 25 g/cm ²)	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	Sample drops through the sieve (4.75 mm) spontaneously	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted
Pourability (KCP 2.8.7.2)			Not relevant for a WG formulation.			Statement accepted
Dustability following accelerated storage (KCP 2.8.7.3)			Not relevant for a WG formulation.			Statement accepted
Physical compatibility of tank mixes (KCP 2.9.1)			Not relevant.			Statement accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)			Not relevant.			Statement accepted
Adhesion to seeds (KCP 2.10.1)			Not relevant, not used for seed treatment.			Statement accepted
Distribution to seed (KCP 2.10.2)			Not relevant, not used for seed treatment.			Statement accepted
Other/special studies (KCP 2.11)	Technical monograph CropLife	Rimsulfuron 3% + Nicosulfuron 12% +Mesotrione 36% WG	<u>Stability of packaging and packaging/preparation interactions:</u> No significant effect of the formulation on the package and vice versa was observed	Y	Michalec-Minch, 2018 Report no. 7/2018	Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

PRIMARY MX will be supplied in HDPE bottles in volumes of 50 g, 100 g, 200 g, 250 g, 500 g, 750 g, 1 kg and 3 kg with standard bottle neck sizes.

Characteristic	Specifications							
Capacity	50 g	100 g	200 g	250 g	500 g	750 g	1 kg	3 kg
Material	HDPE	HDPE	HDPE	HDPE	HDPE	HDPE	HDPE	HDPE
Type of packaging	100 mL	200 mL	500 mL	500 mL	750 mL	1 L	2 L	5 L
Dimensions	Please refer the Tables presented below (Table 4.1-1 – 4.1-7).							

Table 4.1-1: Packaging information for 0.100 liter bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 56.50 mm diameter x 69.50 mm
Opening:	42 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.200 liter bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 62.0 mm diameter x 141.0 mm
Opening:	39.0 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 0.500 liter bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 73.0 mm diameter x 180.0 mm
Opening:	39.0 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 0.750 liter bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 89.0 mm diameter x 240.0 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 1 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	Round bottle / approx. 89 mm diameter x 240 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 2 liter bottle

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 241.0 mm x 68.0 mm x 159.7 mm
Opening:	33.80 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 5 liter bottle

Type	Description
Material:	COEX (HDPE-EVOH)
Shape/size:	jerrycan / approx. 307 mm x 193 mm x 142 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

The bags used for packaging 50, 100, 200, 250, 500, 750 and 1000 grams are obtained from a coil, and the material of these bags consists in PE* multifilm with the next layers:

Material 1:	PET (Polyethylene terephthalato)	Thickness: 12.0 mc	Outside layer
Material 2:	ALU (Aluminium)	Thickness: 9.0 mc	Middle layer
Material 3:	PEBD TR (Thermoplastic low density polyethylene)	Thickness: 65.0 mc	Inside layer (in contact with the product)

The specifications of size for these bags are in the next tables:

Table 4.1-6: Packaging information for 50 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 105 mm x 70 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 100 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 195 mm x 130 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 200 grams

Type	Description
Material:	PE*

Type	Description
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 250 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 170 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 500 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 210 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information for 750 grams

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information for 1 kg

Type	Description
Material:	PE*
Shape/size:	bag / approx. 190 mm x 260 mm
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-13: Packaging information for 5 kg and 10 kg

Type	Description
Material:	PE
Shape/size:	- Sac / approx. 380 mm (width) x 570 mm (length) x 100 mm (bottom) Layers of sac, the three layers are of paper: 1. Semi-stretchable white (70 g/m ²) (Outside layer) 2. Straight (70 g/m ²) (Middle layer) 3. Straight (70 g/m ²) (Inside layer) - Inner bag (Low density polyethylene): approx. 390 mm (width) x 680 mm (length) [thickness:45 µm] (Layer in contact with the product)
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-14: Packaging information for 20 kg and 25 kg

Type	Description
Material:	PE
Shape/size:	- Sac / approx. 550 mm (width) x 810 mm (length) x 130 mm (bottom) Layers of sac, the three layers are of paper: 1. Semi-stretchable white (70 g/m ²) (Outside layer) 2. Semi-stretchable (70 g/m ²) (Middle layer) 3. Semi-stretchable (70 g/m ²) (Inside layer) - Inner bag (Low density polyethylene): approx. 560 mm (width) x 910 mm (length) [thickness:37 µm] (Layer in contact with the product)
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

RMS Comments:

Recommended packagings have been accepted.

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Experience in use of plant protection products based on Rimsulfuron, Nicosulfuron and Mesotrione has not indicated any particular problems. Low levels of residues of PRIMARY MX (Rimsulfuron 30 g/kg + Nicosulfuron 120 g/kg + Mesotrione 360 g/kg, WG) in the equipment are not expected to present any particular risk to crops to be treated from a tank that has previously been used for the product.

The efficacy of cleaning of the application equipment with regard to impacts on “other” crops can be estimated on the basis of the PSD Efficacy Guideline 302 (December 2001). As worst case, the following prerequisites were considered:

Application rate: 0.33 kg product/ha, (9.9 g rimsulfuron/ha, 39.6 g nicosulfuron/ha and 118.8 g mesotrione/ha)
 Tank volume: 2000 L
 Volume remaining in spray lines and pump after spraying: 20 L
 Spray volume: 200 L/ha (lowest spray volume corresponding to the maximum concentration of PRIMARY MX in diluted spray)

Based on these prerequisites and in consideration of 3 rinses with each 300 – 500 L of water based on good agricultural cleaning procedures, Rimsulfuron, Nicosulfuron and Mesotrione residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues			
		product [g PPP/L water]	active substance 1 [g as/L]	active substance 2 [g as/L]	active substance 3 [g as/L]
Tank filling: Residues after spraying:	2000 20	1.65	0.0495	0.198	0.594
1 st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.165	0.00495	0.0198	0.0594
2 nd step: 20% of tank volume added: Residues after spraying:	400 20	0.00825	2.475×10^{-4}	9.9×10^{-4}	2.97×10^{-3}
3 rd step: 20% of tank volume added: Residues after spraying:	400 20	4.125×10^{-4}	1.2375×10^{-5}	4.95×10^{-5}	1.485×10^{-4}
Addition of fresh spray solution: Residues in the tank filling:	2000	4.125×10^{-6}	1.2375×10^{-7}	4.95×10^{-7}	1.485×10^{-6}

PPP = PRIMARY MX as1 = Rimsulfuron; as2 = Nicosulfuron; as3 = Mesotrione

Residues remaining in the last cleaning solution were calculated to be 1.2375×10^{-5} g/L of Rimsulfuron resulting in residue concentration of 1.2375×10^{-7} g/L Rimsulfuron after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 600 L/ha applied to succeeding crops, residues of 2.475×10^{-5} – 7.425×10^{-5} g Rimsulfuron will be applied per ha.

Residues remaining in the last cleaning solution were calculated to be 4.95×10^{-5} g/L of Nicosulfuron resulting in residue concentration of 4.95×10^{-7} g/L Nicosulfuron after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 600 L/ha applied to succeeding crops, residues of 9.9×10^{-5} – 2.97×10^{-4} g Nicosulfuron will be applied per ha.

Residues remaining in the last cleaning solution were calculated to be 1.485×10^{-4} g/L of Mesotrione resulting in residue concentration of 1.485×10^{-6} g/L Mesotrione after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 600 L/ha applied to succeeding crops, residues of 2.97×10^{-4} – 8.91×10^{-4} g Mesotrione will be applied per ha.

Compared to the effect levels on non-target plants, these residues are clearly below the ED₅₀ (Green House Test; EFSA Scientific Report (2005), 45, 1-61) for Rimsulfuron, below the ER₅₀ (Post-emergence (vegetative vigour), Pre-emergence (emergence); EFSA Scientific Report (2007) 120, 1-91) for

Nicosulfuron and below the ER₅₀ (Vegetative vigour and emergence (lab.), Seedling emergence (lab.), Vegetative vigour; EFSA Journal 2016;14(3):4419) for Mesotrione. Thus, any detrimental effect on plants from tank residues can be excluded.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.1, KCP 2.2.2, KCP 2.3.1, KCP 2.3.2, KCP 2.3.3, KCP 2.4.1, KCP 2.4.2, KCP 2.6.2, KCP 2.7.1, KCP 2.7.3, KCP 2.8.1, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.4, KCP 2.8.5.1.1, KCP 2.8.5.1.2, KCP 2.8.5.3, KCP 2.8.7.1, KCP 2.11	Michalec-Minch	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Analysis of active substance and physicochemical properties of initial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis „Blachownia” report no. 7/2018 GLP; unpublished	N	SHARDA Cropchem Limited

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 2.7.5, KCP 2.7.6	Michalec-Minch	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Evaluation of stability of the product after storage in accordance with the Technical Monograph No. 17 (6 months, 1 year, 2 years) Institute of Heavy Organic Synthesis „Blachownia” report no. 8/2018 GLP; unpublished	N	SHARDA Cropchem Limited
KCP 2.2.1	Pawel Sliwa	2018	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG: Determination of explosive properties Institute of Industrial Organic Chemistry report no. BW-08/18 GLP, unpublished	N	SHARDA Cropchem Limited
KCP 2.7.1	Ewa Nowakowska- Bogdan	2020	Rimsulfuron 3% + Nicosulfuron 12% + Mesotrione 36% WG Analysis of relevant impurities content of initial preparation and preparation after accelerated storage procedure Report No.: 163/2020 GLP Unpublished	N	SHARDA Cropchem Limited

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Rimsulfuron

Not relevant. There is no additional data on the active substance Rimsulfuron.

A 2.2 Nicosulfuron

Not relevant. There is no additional data on the active substance Nicosulfuron.

A 2.3 Mesotrione

Not relevant. There is no additional data on the active substance Mesotrione.