

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: M-100 SC-OR2-C

Product name(s): JUZAN EXTRA 100 SC

Chemical active substance:

Mesotrione, 100 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 05/2022

MS Finalisation date: January 2023, May 2023

Version history

When	What
May 2022	First submission for the product authorisation.
January 2023	ZRMS assessment
May 2023	The final version of RR after commenting period

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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.

Noticed data gaps are:

- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: CIECH Sarzyna S.A.
Address: ul. Chemików 1, 37-310 Nowa Sarzyna, Poland

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 Mesotrione

According to COMMISSION IMPLEMENTING REGULATION (EU) 2017/725 of 24 April 2017 renewing the approval of the active substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011:

- mesotrione min. purity is 920 g/kg
- the relevant impurities are as follows:
 - R287431: max. 2 mg/kg
 - R287432: max. 2 g/kg
 - 1,2-dichloroethane: max. 1 g/kg

Details on the purity of mesotrione and impurities are included in Part C.

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

Trade name: JUZAN EXTRA 100 SC

Company code number: M-100 SC-OR2-C

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)
Mesotrione Chemical IUPAC name : 2-(4-mesyl-2-nitrobenzoyl) cyclohexane-1,3-dione	100 g/L	90 – 110 g/L	102.0 g/L	9.76

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers that is 98%

** Based on the density of the formulation = 1.045 g/ml

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
R287431	0.0002 g/L 0,00001791 g/kg
R287432	0.2 g/L 0,0026113 g/kg
1,2-dichloroethane	0.1 g/L 0,0105 g/kg

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

Table 1.4-3: 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: Suspension concentrate

Code: SC

1.6 Function (KCP 1.6)

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 product is homogenous light-beige liquid, with a slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature 530°C. In aqueous solution, it has a pH value 3.52 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate that a shelf life of at least 2 years at ambient temperature has to be expected when stored in *high density polyethylene (HDPE) bottles*. Its technical characteristics are acceptable for a SC formulation. The intended concentration of use is ~~0.1875%~~ 0.375% to 0.75%.

According to available interim report after 2-years of storage the product is stable at ambient temperature when stored in HDPE bottles.

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

Studies	Method	Findings	Classification acc. to Regulation (EC) No. 1272/2008
Explosive properties	EC A.14 and UN Recommendations	Not explosive	None
Oxidising properties	EC A.21 and UN Recommendations	Not oxidizing	None
Flammability	-	Not applicable for SC-formulation	--
Flash point	EC A.9	Has not got the flash point up to the boiling point	None
Auto-flammability	EC A.15	Auto-ignition temperature = 530 °C	None
pH	CIPAC MT 75.3	pH = 4.35 (neat formulation) pH = 3.52 (1% in distilled water)	None
Viscosity	OECD 114	shear rate at 20°C : at 40°C: 2.5 s ⁻¹ 1874 mPa·s 1591 mPa·s 5.0 s ⁻¹ 1092 mPa·s 939 mPa·s 10.0 s ⁻¹ 652 mPa·s 558 mPa·s 25.0 s ⁻¹ 337 mPa·s 288 mPa·s	None
Surface tension	EEC A.5	0,75 % concentration = 45.05 mN/m;	None
Relative density	CIPAC MT 3.2	1.045 g/mL at 20 °C	None

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Risk and safety phrases relevant for this section: none

Compliance with FAO specifications:

The product JUZAN EXTRA 100 SC complies with FAO specifications.

Formulation used for tests

The product used in the tests has the same composition as the one cited in Part C.

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

Annex point	Method used /	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	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	Homogenous light-beige liquid with a slight characteristic odour	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	M-100SC-OR2-C does not have explosive properties	Y	Buczkowski D 2021 Report No BW-04/21	No explosion in thermal sensitivity (Koenen) test nor in the impact sensitivity test (BAM Fallhammer). Accepted.
Oxidizing properties (KCP 2.2.2)	EEC A.21	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	M-100SC-OR2-C has not got the oxidizing properties	Y	Flasińska P., 2021 Report No. BC-05/21	During the test no spontaneous ignition was noted; the pressure did not reach the critical value of 690kPa. Accepted.
Flash point (KCP 2.3.1)	EEC A.9	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	M-100SC-OR2-C has not got the flash point up to the boiling point	Y	Flasińska, P., 2021 Report No. BC-05/21	The test was performed with the Pensky-Martens closed cup apparatus. The formulation is not flammable. Accepted.
Flammability (KCP 2.3.2)			Not required for liquid formulations			

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Self-heating Auto-Ignition (KCP 2.3.3)	EEC A.15.	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	M-100SC-OR2-C has got the auto-ignition temperature: 530 °C	Y	Flasińska, P., 2021 Report No. BC-05/21	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	Acidity: 1,46 %	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Accepted.
	CIPAC MT 75.3		pH value (undiluted): 4.35		Kupiec J. 2022 Annex to Report No. BF-59/20	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	pH value (1% aqueous dispersion): 3.52	Y	Enzo Arévalo, 2021 Report No. BF-59/20 Kupiec J. 2022 Annex to Report No. BF-59/20	Accepted.

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments		
Viscosity (KCP 2.5.1)	OECD No. 114	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	Dynamic viscosity	Y	Enzo Arévalo, 2021 Report No. BF-59/20	The Brookfield Test Method was used with a Brookfield DV III viscometer. The formulation is a non-Newtonian liquid. The formulation does not pose an aspiration hazard. Accepted.		
			shear rate				at 20°C	at 40°C
			2.5 s ⁻¹				1874 mPa·s	1591 mPa·s
			5.0 s ⁻¹				1092 mPa·s	939 mPa·s
			10.0 s ⁻¹				652 mPa·s	558 mPa·s
			25.0 s ⁻¹				337 mPa·s	288 mPa·s
Surface tension (KCP 2.5.2)	EEC A.5	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	The determined value of surface tension of solution of M-100SC-OR2-C (0.75% w/w) at 20.0°C is 45.05 mN/m.	Y	Enzo Arévalo, 2021 Report No. BF-59/20	The surface tension of the formulation was tested using ring method. The test was performed for highest recommended conc. The preparation is classified as surface-active. Accepted.		
Relative density (KCP 2.6.1)	CIPAC MT 3.2	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	The average measured absolute density of the initial preparation at 20°C was 1.045g/ml and the calculated relative density at 20°C was 1.045	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Accepted.		
Bulk density (KCP 2.6.2)	Not required for liquid formulations							

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Storage Stability after 14 days at 54°C (KCP 2.7.1)	CIPAC MT 46.3 CropLife International Technical Monograph No 17	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	<p>After storage at 54°C for 14 days the appearance and colour of the product has not changed, no secretion of any solid particles and oily components was observed.</p> <p><u>Content of mesotrione:</u> before storage: 106.18 g/L (10.16%) after storage: 104.72 g/L (10.02%)</p> <p><u>Impurity content:</u> before storage: 1,2-dichloroethane – 0.0105 g/kg (0.011 g/L) IMP 1 (R287431) – 0.00001791 g/kg (0.000019 g/L) IMP 2 (R287432) – 0.0026113 g/kg (0.003 g/L) after storage: 1,2-dichloroethane – 0.0127 g/kg (0.013 g/L) IMP 1 (R287431) – 0.00001443 g/kg (0.000015 g/L) IMP 2 (R287432) – 0.0026386 g/kg (0.003 g/L)</p> <p><u>pH value (undiluted product)</u> before storage: pH = 4.35 after storage: pH = 4.15</p> <p><u>pH value (1%)</u> before storage: pH = 3.52 after storage: pH = 3.54</p> <p><u>Acidity</u> before storage: 1.46 % after storage: 1.45 %</p> <p><u>Dispersion spontaneity</u> before storage: 96.35 % after storage: 91.32 %</p> <p><u>Suspension stability (0.1875 %)</u> before storage: 100.01 % after storage: 100.06 %</p> <p><u>Suspension stability (0.75 %)</u></p>	Y	<p>Enzo Arévalo, 2021 Report No. BF-59/20</p> <p>Kupiec J. 2022 Annex to Report No. BF-59/20</p>	<p>The test item was stored in the original 1 L packages made of HDPE.</p> <p>The test temperature varied between 52.3°C and 54.3°C.</p> <p>The change in a.s. content during storage was 1.4%.</p> <p>The content of the relevant impurities before and after storage was below the limit values.</p> <p>No significant changes of the physical, chemical, and technical properties of the formulation were observed. The packaging remained stable.</p> <p>Accepted.</p>

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
			before storage: 100.48 % after storage: 99.94 % <u>Wet sieve test</u> before storage: 0.00 % after storage: 0.00 % <u>Pourability</u> before storage: R=3.45 % ; R'=0,17 % after storage: R=3.04 % ; R'=0,17 % The measurements confirm the stability of the formulation. The shape and colour of the 1 liter HDPE package were stable. No visible leaking in the package. Negligible mass change.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	Not required as the formulation was stable at 54°C after 14 days					
Minimum content after heat stability testing (KCP 2.7.3)	Not required as the formulation was stable at 54°C after 14 days. The a.s. content after the heat stability test has not decreased by more than 5% of the initial content (see point IIIA 2.7.1).					Accepted.

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	<p>After storage at 0°C for 7 days the colour of product has not changed, no secretion of any solid particles and oily components was observed.</p> <p><u>Suspension stability (0,1875 %)</u> before storage: 100.01 % after storage: 99.79 %</p> <p><u>Suspension stability (0,75 %)</u> before storage: 100.48 % after storage: 100.46 %</p> <p><u>Wet sieve test</u> before storage: 0.00 % after storage: 0.00 %</p> <p>The measurements confirm the stability of the formulation.</p>	Y	Enzo Arévalo, 2021 Report No. BF-59/20	The recorded temperature of storage was between 0.2°C and 0.7°C. Immediately after low temp. storage, at room temp., and after 24 hours at room temp. - homogenous liquid. Accepted.

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Technical Monograph No. 17 HPLC/DAD/ HPLC/UV-VIS GC/FID UHPLC /MS/MS detection Visual inspection, nasal inhalation CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 160 CIPAC MT 184.1 CPAC MT 185 CIPAC MT	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	The test item in 1 liter HDPE bottles was stored in a acclimatized room at (20±2)°C temperature. Package stability The shape and colour of the 1 litre HDPE package were stable. No visible leaking in the package. Negligible mass change. Active ingredient content 10.04% (104.91 g/l) Impurity content 1,2-dichloroethane: 0.0008% (0.0085 g/kg) IMP 1 (R287431)*: < LOQ (< 0.000014 g/kg) IMP 2 (R287432)*: 0.0003292% (0.003440 g/l); (0.003292 g/kg) Physical state colour and odour: Homogenous light-beige liquid with a slight characteristic odour pH (undiluted product) = 4.17 pH value (1%) = 3.49 Acidity 1.37% Dispersion spontaneity 94.12% Suspension stability (0,1875 %) in CIPAC Water D 99.78% Suspension stability (0,75 %) in CIPAC Water D 99.25% Wet sieve test 0% Pourability	Y	Jarosław Kupiec 2022 2023 Report No. BF- 59/20, Part II	The test item was stored in 1 liter HDPE bottles. The storage temperature varied from 18.1°C to 21.8°C. The change in a.s. content: 1,2%. The content of the relevant impurities after storage was below the limit values. No significant changes in the physical, chemical, or technical properties of the formulation were observed. The packaging remained stable. Accepted.

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Not applicable. The shelf life will be 2 -3 years.					
Wettability (KCP 2.8.1)	Not required for liquid formulations					
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3 and MT 18 (Standard Water D)	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	Foam after 1 and 12 min.: 0.1875% concentration – 24 ml of foam after 1 min and 15 ml after 12 min 0.75% concentration – 0 ml of foam after 1 min and 0 ml after 12 min	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Standard Water D was used. The lower conc. tested was lower than the lowest recommended conc. (0.375%) Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184.1	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	<u>Suspension stability (0,1875 %)</u> Initial preparation: 100.01 % After storage for 14 days at a temperature of + 54°C: 100.06 % <u>Suspension stability (0,75 %)</u> Initial preparation: 100.48 % After storage for 14 days at a temperature of + 54°C: 99.94 %	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Standard Water D was used. The lower conc. tested was lower than the lowest recommended conc. (0.375%) Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	<u>Dispersion spontaneity</u> Initial preparation: 96.35 % After storage for 14 days at a temperature of + 54°C: 91.32 %	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Accepted.
Dispersion stability (KCP 2.8.3.3)			Not required for SC formulations			

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Degree of dissolution and dilution stability (KCP 2.8.4)			Not required for SC formulations			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)			Not required for SC formulations. The product is not a solid.			According to SANCO/10473/2003 –rev.5, particle size distribution could be required for SC formulation. However, according to the FAO Manual (2022) the determination of particle size range by laser diffraction is not an ideal criterion to ensure the suitability of liquid formulations. This should be evaluated by wet sieve test (MT 185) and suspensibility (MT 184.1) or dispersion stability (MT 180). As these studies were performed and the results are acceptable it can be accepted.

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	Wet sive test Initial preparation: 0.00% After storage for 14 days at a temperature of + 54°C : 0.00 %	Y	Enzo Arévalo, 2021 Report No. BF-59/20	Accepted.
Dust content (KCP 2.8.5.2.1)			Not required for SC formulations. The product is not a solid.			
Particle size of dust (KCP 2.8.5.2.2)			Not required for SC formulations. The product is not a solid.			
Attrition (KCP 2.8.5.3)			Not required for SC formulations. The product is not a solid.			
Hardness and integrity (KCP 2.8.5.4)			Not required for SC formulations. The product is not a solid.			
Emulsifiability (KCP 2.8.6.1)			Not required for SC formulations. The product is not a emulsion.			
Emulsion stability (KCP 2.8.6.2)			Not required for SC formulations. The product is not a emulsion.			
Re- emulsifiability (KCP 2.8.6.3)			Not required for SC formulations. The product is not a emulsion.			
Flowability (KCP 2.8.7.1)			Not required for SC formulations. The product is not a solid			

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Pourability (KCP 2.8.7.2)	CIPAC MT 148	M-100SC-OR2-C containing 101.1 g/L of mesotrione Batch No.: 1/2020 Production date: 03.06.2020	<u>Pourability</u> Initial preparation: R=3.45 % ; R'=0,17 % After storage for 14 days at a temperature of + 54 °C: R=3.04 %; R'=0,17 %	Y	Enzo Arévalo, 2021 Report No. BF-59/20 Kupiec J. 2022 Annex to Report No. BF-59/20	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)			Not required for SC formulations. The product is not a dustable powder.			
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable. Juzan Extra 100 SC will not be used with other products.			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable. Juzan Extra 100 SC will not be used with other products.			
Adhesion to seeds (KCP 2.10.1)			Not applicable. Juzan Extra 100 SC is not destined for seed treatment.			
Distribution to seed (KCP 2.10.2)			Not applicable. Juzan Extra 100 SC is not destined for seed treatment.			

Annex point	Method used /	Test material	Findings	GLP Y/N	Reference	Acceptability /comments
Other/special studies (KCP 2.11)			No other data provided and required.			

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 Safety intervals and other precautions to protect humans, animals and the environment (KCP 4.1)

The above information is contained in Part B, Section 7.

4.2 Recommended methods and precautions (KCP 4.2)

Comments of zRMS:	Procedures for cleaning an application equipment and protective clothing are considered acceptable.
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Procedures for cleaning application equipment and protective clothing

General statement

All application equipment and contaminated protective clothing should be washed/cleaned with water or a diluted detergent solution and thoroughly rinsed. Care should be taken not to spill the contaminated washings from application equipment into waste water channels. Contaminated cleaning liquids should be disposed of safely according to local regulations.

Application equipment:

Cleaning out of field spraying equipment is an essential part of the recommendations for use of plant protection product.

Procedure:

Empty the spraying equipment completely on the field just sprayed. Remove all filters and nozzles, scrub clean and rinse them with clean water. Put 10 % clean water into tank to cover the agitator. Operate a tank flushing system if fitted. Circulate water through the pump and controls for at least one minute. Drain sprayer, collect washings. Repeat procedure once more. Pump last washing water out through boom feed hoses and pipes. Collect washings. Clean off the outside of the sprayer using minimum water volumes. Collect washings. Replace cleaned nozzles and filters. Collect and put all washings back into the tank and spray out on the field headland, or otherwise safely dispose of them. Ensure the sprayer systems are completely drained before storage. Store Plant Protection Equipment in a properly designated store.

Spray equipment should be cleaned according to normal good agricultural practices, which are considered adequate:

1. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.
2. Rinse inside of tank with clean water and flush through booms and hoses using at least one-tenth of the spray tank volume. Repeat this operation at least three times. After the last time drain tank completely.

Normal procedures should be followed for the cleaning of protective clothing and equipment. Any contamination on the outside of protective equipment should be removed by washing with clean water.

Protective clothing:

All contaminated clothing should be washed/cleaned through with a dilute detergent solution and thoroughly rinsed with clean water.

- Impermeable overalls, boots and face shields should be washed clean and dried.
- Permeable overalls should be laundered after use.

- Disposable overalls and gloves should be washed and disposed of as contaminated waste.
- Gloves and boots should be washed clean, if necessary on the insides as well.

Protective clothing should be washed using clean water separately from the normal work clothing. Clean clothing should be stored away from contaminated clothing in a well-ventilated area separate from the chemical storage area. Damaged or heavily contaminated clothing should be discarded.

Protective equipment for the face and eyes such as face shield and goggles should be cleaned by wiping with a suitable detergent and a wet cloth and left to air dry. It may be necessary to clean this equipment during the application to maintain clear vision. This should be done with a wet cloth and clean water. Damaged eye protection should be discarded.

Protective gloves should be rinsed with water before they are removed from the hands. At the end of each day's use, gloves and rubber boots should be washed with clean water and detergent and left to air dry. Clean items should be stored in a well-ventilated area separate from the chemical storage area. Damaged gloves or boots should be discarded.

Effectiveness of the cleaning procedures

1. Empty the spraying equipment completely on the field just sprayed
2. Dismantle suction, pressure line and nozzle filters and clean thoroughly in water
3. Fill spraying equipment to 10% of tank capacity and stir thoroughly (a rotating cleaning nozzle is recommended)
4. Apply rinsing liquid on the field just sprayed
5. Repeat steps 3 and 4 for a 2nd rinsing
6. Inspect filters again and clean them if visible deposits are present

4.3 Emergency measures in the case of an accident (KCP 4.3)

(a) containment of spillages;

Prevent the product from getting into sewage system, water reservoir, rivers, underground waters and soil. Juzan Extra 100 SC remains absorb using absorptive materials and collect into tightly closed containers and dispose according to obligatory regulations.

(b) decontamination of areas, vehicles and buildings;

No special procedures.

(c) disposal of damaged packaging, absorbents and other materials;

Damaged packages return to the producer. Other materials dispose according to obligatory regulations. Disposal of wastes into the soil, sewage system and waters is forbidden.

(d) protection of emergency workers and residents, including bystanders;

Standard protection of emergency workers is recommended. Bystanders are recommended to be kept far away from the area.

(e) first aid measures

Skin contact: immediately remove contaminated clothing and footwear. Wash contaminated areas of skin thoroughly with soap and water. Consult a doctor in case of any symptoms of irritation/ allergy.

Contact with the eyes: immediately consult an ophthalmologist. Protect the not-irritated eye, remove contact lenses. Rinse contaminated eyes thoroughly with water for 10-15 minutes. Avoid strong water jet - risk of corneal damage. After rinsing apply sterile dressing.

In case of ingestion: immediately call a doctor, show the packaging or the label. Do not induce vomiting. Rinse mouth thoroughly with water, and then drink plenty of water. Never give anything to eat or drink to an unconscious person.

Respiratory exposure: take the injured person out to fresh air, provide warmth and peace. In case of any worry-

ing symptoms, consult a doctor.

4.4 Packaging and Compatibility with the Preparation (KCP 4.4)

Comments of zRMS:	In the accelerated storage stability study and in the ambient temperature shelf life study, the formulation was stored in commercial packaging (bottles made of HDPE) and the packaging remained stable during the storage, therefore, the proposed commercial packs (HDPE, HDPE/PA COEX, HDPE/EVOH) are considered acceptable.
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Juzan Extra 100 SC will be commercially available in HDPE container with a capacity of 250 and 500 mL and also 1, 3, 5, 10, 20 , 60 , 120, 200 and 1000 L.

Table 1.6-1: Packaging information

Type	Description						
	0.25 L bottle	0.5 L bottle	1 L bottle	3 L canister	5 L canister	10 L canister*	20 L canister*
Material:	HDPE	HDPE	HDPE	HDPE	HDPE	HDPE	HDPE
Shape/size:	cylindrical / Ø 62.5 ± 5 mm, 127,5 ± 10.0 mm high	cylindrical / Ø 74.0 ± 5 mm, 183,5 ± 10.0 mm high	cylindrical / Ø 88.5 ± 5 mm, 240 ± 12.0 mm high	rectangular 242 ± 1,5 mm high 161,7 ± 1 mm length 118,5 ± 1 mm width	rectangular 320 ± 16 mm high 186 ± 10 mm length 135 ± 7 mm width	rectangular 376 ± 19 mm high 232 ± 12 mm length 167± 9 mm width	rectangular, 386 ± 20 mm high 290 ± 15 mm length, 248 ± 13 mm width
Opening:	Ø 40 ± 2.0 mm	Ø 40 ± 2.0 mm	Ø 40 ± 2.0 mm	Ø 42 ± 1.0 mm	Ø 57.3 ± 3 mm	Ø 57.3 ± 3 mm	Ø 49 ± 3 mm
Closure:	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type with an element breakable when opening
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/EPE 250/PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR*	Compliant with the current UN and ADR requirements for packaging testing.						
Package stability	HDPE packaging with the product was also tested - it was stored for 14 days at + 54 oC - see test report with code BF-59/20. The shape and colour of the 1 litre HDPE package were stable. The bottle after accelerated storage kept tightly sealed and screwed in the way it was closed during manufacture process. No leakage neither through the bottle surface nor through the seal or cap was observed. Negligible mass change.						

Table 1.6-1: Packaging information continued – for professional user

Type	Description			
	60 L canister*	120 L drum*	200 L drum*	1000 L container

				(IBC)*
Material:	HDPE	HDPE	HDPE	HDPE
Shape/size:	rectangular 641 ± 33 mm high 382 ± 20 mm length 329 ± 17 mm width	cylindrical Ø(d1) 503 mm, Ø(d2) 391 mm, 791 ± 10.0 mm - high	cylindrical Ø(d1) 503 mm, Ø(d2) 391 mm, 791 ± 10.0 mm - high	Cubic 1160 ± 25 mm high 1200 ± 5 mm length 1000 ± 5 mm width
Opening:	Ø max 70 mm	Ø max 70 mm	Ø max 70 mm	Ø max 150 mm
Closure:	screw-on type with an element breakable when opening	screw-on type on the cap is assumed seal	screw-on type on the cap is assumed seal	screw-on type on the cap is assumed seal
Seal:	Seal used but no data on construction	Seal used but no data on construc- tion	Seal used but no data on construction	Seal used but no data on construction
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR*	Compliant with the current UN and ADR requirements for packaging testing.			

The product is contained and handled in suitable packaging material. The material proposed for use is known from experience to be very resistant to the product chemistry and solvents. The content has no negative effect on packaging integrity.

The above packaging material has been tested and was found to be suitable for the product Juzan Extra 100 SC. There were no signs of packaging deformation (see point IIIA 2.7.1).

In accordance with point III 1) a) of the GUIDELINE ON THE RULES FOR APPROVING PACKAGING OF PLANT PROTECTION PRODUCTS, for SC formulation it is possible to apply for extrapolation from HDPE packaging, for which our product was tested before and after storage (Table 4.1-1), to HDPE coextruded packaging, i.e. to HDPE/PA; HDPE/EVOH and HDPE/F packaging.

According to the above, the applicant applies for registration of the following packaging: HDPE/PA - table 4.1-2 ; HDPE/EVOH - table 4.1-3 and HDPE/F - table 4.1-4 as below.

Table 1.6-2: Packaging information for next package type

Type	Description						
	0.25 L bottle	0.5 L bottle	1 L bottle	2 L canister	3 L canister	5 L canister	10 L canister*
Material:	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex	HDPE/PA type Coex
Shape/size	cylindrical Ø 63,5 ± 1 mm, 127 ± 20 mm high	cylindrical Ø 69 ± 5 mm, 144 ± 40 mm high	cylindrical Ø 69 or 84 or 88,5 ± 5 mm, 239 or 248.2 or 293 ± 12 mm high	rectangular, 255 ± 12 mm high 140 ± 8 mm length, 94 ± 6 mm width	rectangular, 241 ± 12 mm high, 193 ± 10 mm length, 142 ± 8 mm width	rectangular, 285 or 310 or 320 or 335 ± 20 mm high, 186 or 192 ± 10 mm length, 136 or 140 ± 8 mm width	rectangular, 376 or 380 ± 19 mm high, 232 or 240 ± 12 mm length, 167 or 180 ± 9 mm width
Opening:	Ø 42 mm ± 3 mm	Ø 42 mm ± 3 mm	Ø 39.5 or 42 mm ± 5mm	Ø 42 mm ± 5 mm	Ø 54 ± 6 mm	Ø 53 or 54.7 or 57.3 or	Ø 54 or 57.3 ± 6 mm

Table 1.6-3: Packaging information for next package type

Table 1.6-4: Packaging information for next package type

[illegible]

Type	Description							
Shape/size:	cylindrical Ø 63,5 ± 1 mm, 127 ± 20 mm high	cylindrical Ø 69 ± 5 mm, 144 ± 40 mm high	cylindrical / Ø 84 or 88.5 ± 14 mm, 234 or 240 ± 40 mm high	rectangular 255 or 260 ± 16 mm high 140 ± 14 mm length 94 ± 30 mm width	rectangular 201 or 242 ± 16 mm high 162 or 193 ± 16 mm length 118 or 125 or 142 ± 40 mm width	rectangular 310 or 320 or 329 ± 20 mm high 186 or 190 ± 16 mm length 135 or 140 ± 41 mm width	rectangular 376 ± 20 mm high 227 or 232 or 242 ± 20 mm length 163 or 167 or 175 or 186 ± 44 mm width	rectangular, 376 or 386 ± 20 mm high 290 or 294 or 297.7 ± 15 mm length, 248 or or 258 or 264 ± 14 mm width
Opening:	Ø 42 mm ± 3 mm	Ø 42 mm ± 3 mm	Ø 40 ± 6 mm	Ø 42 ± 6 mm	Ø 36 or 42 or 54.7 or 57.3 mm ± 8 mm	Ø 54 or 57.3 or 59.3 ± 6 mm	Ø 40 or 51 or 54 57.3 or 59 ± 10 mm	Ø 49 or 51.4 ± 6 mm
Closure:	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type for induction heating process	screw-on type with an element breakable when opening
Seal:	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/Al/PET or PE	PE/EPE 250/PE
Manner of construction	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding	extrusion blow moulding
UN/ADR	Compliant with the current UN and ADR requirements for packaging testing.							

4.5 Procedures for destruction or decontamination of the plant protection product and its packaging (KCP 4.5)

4.5.1. Neutralisation procedures

Do not allow to escape into sewage system or water courses. Do not wash residues into drains or other waterways.

Any chemical treatment at the location of an accidental spillage would be difficult to control in terms of efficiency and safety and is therefore not recommended.

All wastes of the product and its packages should be collected and incinerated.

4.5.2. Controlled incineration

Unwanted amounts of product can be best destroyed by combustion in a licensed incinerator in accordance with the criteria laid down in Directive 94/67/EC of the Council.

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 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2	Enzo Arévalo	2021	M-100SC-OR2-C Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and low temperature. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BF-59/20 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.2.1	Buczkowski D	2021	M-100SC-OR2-C. Determination of explosive properties Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BW-04/21 GLP Unpublished	N	CIECH Sarzyna S.A.

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 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P	2021	M-100SC-OR2-C. Determination of flash point, auto-ignition temperature and oxidizing properties Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BC-05/21 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.7.5	Kupiec J.	2022 2023	M-100SC-OR2-C Part II: Determination of physicochemical properties after the second year of storage Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Study code no. BF- 59/20 GLP Unpublished	N	CIECH Sarzyna S.A.
KCP 2.4.1_1 KCP 2.8.7.2_1	Kupiec J.	2022	Annex No 1 to Report M-100SC-OR2-C Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and low temperature. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BF-59/20 GLP Unpublished	N	CIECH Sarzyna S.A.

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

None.

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 Active substance

No additional data are submitted for the active substance