

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 4300 A

Product name(s): MIGHTY

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: December 2018

MS Finalisation date: 18/10/2024

Version history

When	What
February 2020	Dossier sent for evaluation
June 2020	Applicant update
June 2020	zRMS finalised evaluation
November 2023	Applicant update
April 2024	Version prepared by zRMS after Commenting period
June 2024	Final version prepared by zRMS after the second commenting period
October 2024	clarification of approved packaging

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zRMS comments:

The text highlighted in grey was provided by the evaluator.

Sufficient data on identity, physical and chemical properties and other information are not available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are: none.

- There are no data on analysing relevant impurities of mesotrione in the PPP in the ambient two years storage stability study. Therefore for the procedural reason that study cannot be accepted until adequate data is to submit by the applicant. Nevertheless, the missing data may be evaluated in the post registration at national level.

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 Mesotrione

Mesotrione min. ~~985 g/kg (Sharda source)~~ 980 g/kg

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

The minimum active content of Mesotrione technical is 920 g/kg (SANCO/1416/2001).

Impurities:

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: MIGHTY
MISTER
MAC
MINE
MESOSTAR

Company code number: SHA 4300 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)
Mesotrione	100 g/L	90 g/l – 110 g/l	101.52 g/L	9.28% w/w

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

** Based on the density of the formulation = 1.0936 g/mL

Table 1.4-2: Relevant impurities

~~The study to determine the concentration of the relevant impurities is on going.~~

According to Commission Regulation no 2017/725 following impurities are considered as relevant: R287431, R287432 and 1,2-dichloroethane. Therefore applicant provided additional accelerated storage stability data to cover that requirement (partially covered, no data on two years storage stability study).

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

Table 1.4-2: 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)

MIGHTY is intended to be used as 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 yellow thick liquid, with a characteristic (citrus) odour. It is not explosive, has no oxidising properties. The product is not flammable and has a flash point of 65.5 °C. In aqueous solution, it has a pH value around 2.92. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C, 14 days at 54 °C, and the two-year study at ambient temperature neither the active ingredient content nor the technical properties were changed. ~~The two years storage stability study is being performed.~~ Its technical characteristics are acceptable for a Suspension Concentrate formulation.

~~The intended concentration of use is 9.73% w/w (100 g/l).~~ According to GAP intended tank mix concentration range is from 0.25 to 0.75% w/w.

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

Neither classification nor 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 MIGHTY / MESOTRIONE 10% SC (SHA 4300 A) complies with FAO specifications.

Formulation used for tests

The formulation used for the tests is MESOTRIONE 10% SC (batch: SWEPL-41203).

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	Mesotrione 10% SC SWEPL-41203	Appearance : Thick liquid Colour : 2.5 Y 8/10 (Munsell scale) Odour : Characteristic (citrus)	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Mesotrione 10% SC SWEPL-41203	The product not present danger of explosion to thermal or mechanical stimuli.	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.21	Mesotrione 10% SC SWEPL-41203	The product is not to be considered as an oxidiser.	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Flash point (KCP 2.3.1)	EEC A.9	Mesotrione 10% SC SWEPL-41203	65.5 °C	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Flammability (KCP 2.3.2)	-	-	Mesotrione 10% SC is not flammable. Please refer to point 2.3.1.	-	-	
Self-heating (KCP 2.3.3)	-	-	Not relevant for a SC formulation.	-	-	
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 31 CIPAC 75.3	Mesotrione 10% SC SWEPL-41203	2.34 % NaOH (w/w). Straight pH: 2.17	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Mesotrione 10% SC SWEPL-41203	2.92	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Viscosity (KCP 2.5.1)	OECD 114	Mesotrione 10% SC SWEPL-41203	At 20 °C: - 2387.4 mPa.s at 12 rpm - 1503.5 mPa.s at 30 rpm At 40 °C: - 1787.5 mPa.s at 12 rpm - 946.6 mPa.s at 30 rpm	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Surface tension (KCP 2.5.2)	EEC A.5	Mesotrione 10% SC SWEPL-41203	36.8 mN/m (20 °C). Surface-active material. (26.25 mg/l dilution)	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted. The lab took water solubility (90%) into account. So these results meet EEC A5 requirements
Relative density (KCP 2.6.1)	EEC A.3 OECD 109	Mesotrione 10% SC SWEPL-41203	1.0935 g/cm ³ (20 °C) Relative Density D ²⁰ ₄ : 1.0936 g/cm ³	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Bulk density (KCP 2.6.2)	-	-	Not relevant for SC formulation.	-	-	
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3 OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 31 CIPAC 75.3 OECD 114 CIPAC MT 148 CIPAC MT 161 CIPAC MT 184 CIPAC MT 160 CIPAC 185 CIPAC 59.3	Mesotrione 10% SC SWEPL-41203	<u>Appearance:</u> Before storage: Thick liquid After storage: Thick liquid <u>Colour:</u> Before storage: 2.5 Y 8/10 (Munsell scale) After storage: 2.5 Y 8/10 (Munsell scale) <u>Odour:</u> Before storage: Characteristic (citrus) After storage: Characteristic (citrus) <u>A.i. content:</u> Before storage: 9.00 % w/w After storage: 8.93% w/w <u>Acidity or alkalinity:</u>	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted. The first study contained no data on impurities. So applicant provided additional study covering the missing information.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Before storage: 2.34 % NaOH (w/w) After storage: 2.97 % NaOH (w/w)</p> <p><u>Straight pH:</u> Before storage: 2.17 After storage: 2.15</p> <p><u>pH (1% w/v in water):</u> Before storage: 2.92 After storage: 2.95</p> <p><u>Viscosity:</u> Before storage: At 20 °C: <ul style="list-style-type: none"> - 2387.4 mPa.s at 12 rpm - 1503.5 mPa.s at 30 rpm At 40 °C: <ul style="list-style-type: none"> - 1787.5 mPa.s at 12 rpm - 946.6 mPa.s at 30 rpm After storage: At 20 °C: <ul style="list-style-type: none"> - 2167.3 mPa.s at 12 rpm - 1150.3 mPa.s at 30 rpm At 40 °C: <ul style="list-style-type: none"> - 1428.3 mPa.s at 12 rpm - 946.6 mPa.s at 30 rpm </p> <p><u>Spontaneity of dispersion:</u> Before storage: 79% After storage: 84%</p> <p><u>Wet sieve test (residue at 75µm):</u> Before storage: 0% After storage: 0.02%</p> <p><u>Pourability - residues:</u> Before storage: 9.61% After storage: 12.83%</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	SANCO/3030/99	Mesotrione 10% SC SCL-45912	<p><u>Pourability - rinsed residues:</u> Before storage: 3.09% After storage: 5.31%</p> <p><u>Suspensibility – 0.75% v/v in Std Water D:</u> Before storage: 86% After storage: 76%</p> <p><u>Suspensibility - 0.25% v/v in Std Water D:</u> Before storage: 94% After storage: 89%</p> <p>Mesotrione content Before storage: 9.93 % w/w</p> <p>1,2 dichloroethane content: Before and after storage <LOQ (10 mg of 1,2 dichloroethane /kg of formulation)</p> <p>R-287432 content Before and after storage <LOQ (20 mg of R-287432 /kg of formulation)</p> <p>R-287431 content Before and after storage <LOQ (0.13 mg of R-287431/kg of formulation)</p>	Y	Micaela Banos Gonzalez, 2020 Report 18-4150-28	
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required. Please refer to point 2.7.1.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not relevant.	-	-	
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3 CIPAC MT 39.3 CIPAC MT 185	Mesotrione 10% SC SWEPL-41203 Mesotrione 10% SC SCL - 34891	After being stored 7 days inside the refrigerator at 0 ± 2 °C, the sample remains unchanged, does not generate solid or oily material after storage. <u>Suspensibility – 0.75% v/v in Std Water D:</u> Before storage: 86% After storage: 81% <u>Suspensibility - 0.25% v/v in Std Water D:</u> Before storage: 94% After storage: 93% <u>Wet sieve test (residue at 75µm):</u> After storage: 0.00%	Y Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004 Idris Al Amin, 2018 BF-15/18	Accepted. The latter study covers missing wet sieve information.
Ambient temperature shelf life (KCP 2.7.5)	- CIPAC MT 75.3 CIPAC MT 31 CIPAC 75.3 EPA712-C-96-020 EPA712-C-96-019 EPA712-C-96-021 EEC Method A3 CIPAC MT 148 OECD 114 CIPAC MT 185 CIPAC MT 187	- Mesotrione 10% SC SWEPL-41203	On-going <u>Appearance:</u> Before storage: Thick liquid After storage: Thick liquid <u>Colour:</u> Before storage: 2.5 Y 8/10 (Munsell scale) After storage: 2.5 Y 8/10 (Munsell scale) <u>Odour:</u> Before storage: Characteristic (citrus) After storage: Citric	Y	M ^a DEL MAR DEL VALLE GARCÍA, 2020 EC-15/0019	Accepted Data Gap The study may be partially considered as acceptable. There is no info on relevant impurities levels in the PPP (before and after storage). So, each member state has to

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 160 CIPAC MT 184		<p>A.i. content: Before storage: 9.00 % w/w After storage: 8.90% w/w</p> <p>Acidity or alkalinity: Before storage: 2.34 % NaOH (w/w) After storage: 2.09 % NaOH (w/w)</p> <p>Straight pH: Before storage: 2.17 After storage: 2.29</p> <p>pH (1% w/v in water): Before storage: 2.92 After storage: 2.89</p> <p>Relative density Before storage: 1.0936 After storage: 1.0884</p> <p>Viscosity: Before storage: At 20 °C: - 2387.4 mPa.s at 12 rpm - 1503.5 mPa.s at 30 rpm At 40 °C: - 1787.5 mPa.s at 12 rpm - 946.6 mPa.s at 30 rpm After storage: At 20 °C: - 960.20 mPa.s at 20 rpm - 774.47 mPa.s at 50 rpm At 40 °C: - 620.77 mPa.s at 20 rpm - 422.87 mPa.s at 50 rpm</p> <p>Spontaneity of dispersion:</p>			<p>consider admission of eventual provisional shelf life for the PPP. In our opinion adequate data on impurities level in the PPP may be submitted and evaluated in the post-registration at national level.</p> <p>All other physicochemical properties are accepted. This study was done using coex HDPE/EOH packs. the packs remained intact after the storage.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments												
			<p>Before storage: 79%</p> <p>After storage: 92%</p> <p><u>Wet sieve test (residue at 75µm):</u></p> <p>Before storage: 0.00%</p> <p>After storage: 0.00%</p> <p><u>Pourability - residues:</u></p> <p>Before storage: 9.61%</p> <p>After storage: 11.56%</p> <p><u>Pourability - rinsed residues:</u></p> <p>Before storage: 3.09%</p> <p>After storage: 1.88%</p> <p><u>Suspensibility – 0.75% v/v in Std Water D:</u></p> <p>Before storage: 85.5%</p> <p>After storage: 102.3%</p> <p><u>Suspensibility - 0.25% v/v in Std Water D:</u></p> <p>Before storage: 94.1%</p> <p>After storage: 108.6%</p> <p><u>Particle size analysis</u></p> <p>T-6 months</p> <table><tr><td>d(0.1) µm</td><td>5.044 ± 0.160</td></tr><tr><td>d(0.5) µm</td><td>15.240 ±0.235</td></tr><tr><td>d(0.9) µm</td><td>29.602 ±0.337</td></tr></table> <p>T-25 months</p> <table><tr><td>d(0.1) µm</td><td>0.121 ± 0.004</td></tr><tr><td>d(0.5) µm</td><td>6.735 ± 1.566</td></tr><tr><td>d(0.9) µm</td><td>21.249 ± 2.098</td></tr></table> <p>No particles smaller than 0.035 µm or larger than 60.256 µm were detected in any of the samples tested on this analysis.</p>	d(0.1) µm	5.044 ± 0.160	d(0.5) µm	15.240 ±0.235	d(0.9) µm	29.602 ±0.337	d(0.1) µm	0.121 ± 0.004	d(0.5) µm	6.735 ± 1.566	d(0.9) µm	21.249 ± 2.098			
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	SANCO/3030/99	Mesotrione 10% SC SCL-45912	Relevant impurities content: 1,2 dichloroethane content: Before and after storage <LOQ (10 mg of 1,2 di- chloroethane /kg of formulation) R-287432 content Before and after storage <LOQ (20 mg of R- 287432 /kg of formulation) R-287431 content Before and after storage <LOQ (0.13 mg of R- 287431/kg of formulation)		Micaela Banos Gonzalez, 2022 Report 18-4150-29	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.	-	-	
Wettability (KCP 2.8.1)	-	-	Not relevant for SC formulation.	-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Mesotrione 10% SC SWEPL-41203	0.25% v/v: 2 ml of foam at 1 minute. 0.75% v/v: 2 ml of foam at 1 minute.	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Suspensibility (KCP 2.8.3.1)	CIPAC MT 161 CIPAC MT 184	Mesotrione 10% SC SWEPL-41203	0.75 % v/v in std. water D: 86% 0.25% v/v in std. water D: 94%	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Mesotrione 10% SC SWEPL-41203	79%	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Dispersion stability	-	-	Not relevant for a SC formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.3.3)						
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for a SC formulation.	-	-	
Dry sieve test (KCP 2.8.5.1)	-	-	Not relevant for a SC formulation.	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for a SC formulation.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 59.3 CIPAC MT 167 CIPAC MT 182 CIPAC MT 185	Mesotrione 10% SC SWEPL-41203	0% of residue on sieve.	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted
Nominal size range of granules (KCP 2.8.5.2.1)	-	-	Not required for SC formulation.	-	-	
Dust content (KCP 2.8.5.2.2)	-	-	Not required for SC formulation.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for SC formulation.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not required for SC formulation.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for SC formulation.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not required for SC formulation.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not required for SC formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required for SC formulation.	-	-	
Stability of dilute emulsions (CP 2.8.6.4)	-	-	Not required for SC formulation.	-	-	
Stability of emulsions (CP 2.8.6.5)	-	-	Not required for SC formulation.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not required for SC formulation.	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Mesotrione 10% SC SWEPL-41203	Residue: 9.61% Rinse Residue: 3.09%	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted. These results are too high..Yet, please refer to the KCP.2.11. Effectiveness of cleaning procedure study.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for SC formulation.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required. Product not intended to be mixed.	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required. Product not intended to be mixed.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not required. Product is not intended to be applied to seeds.	-	-	
Distribution to seed	-	-	Not required. Product is not intended to be applied	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.10.2)			to seeds.			
Other/special studies: Effectiveness of cleaning procedure (KCP 2.11)	Efficacy Guideline 305 Efficacy Guideline 302	Mesotrione 10% SC SWEPL-41203	0.25% v/v: 100.0% removed 0.75% v/v: 100.0% removed	Y	Mónica Berrios, Labs & Technological Services AGQ, E-15/0004	Accepted. Hence proposed cleaning procedere is enoug to remove residues of the active substance, the pourbility may be accepted as well.

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)

Table 4.1-1: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX
Shape/size:	Round bottle / approx. 61 mm diameter x 138.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.500 liter bottle

Type	Description
Material:	COEX
Shape/size:	Round bottle / approx. 69 mm diameter x 199.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 liter bottle

Type	Description
Material:	COEX
Shape/size:	Round bottle / approx. 88.5 mm diameter x 239.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-4: Packaging information for 5 liter bottle

Type	Description
Material:	COEX
Shape/size:	jerrycan / approx. 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 10 liter bottle

Type	Description
Material:	COEX
Shape/size:	jerrycan / approx. 174 mm x 226 mm x 368 mm
Opening:	54.7 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 20 liter bottle

Type	Description
Material:	Fluorinated HDPE
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

RMS comment:

All showed packs are accepted in Poland. According to the Polish Guideline, in the case of aqueous formulations such as SC, extrapolation from one type of plastic to any other plastic used as packaging for the plant protection product is allowed.. The packaging used in two-year study was not specified. Furthermore, the packaging made of HDPE/EVOH was used in the study covering the data gas on missing levels of relevant impurities in PPP provided for evaluation in Poland in National Addendum. The COEX packaging is a plastic container with several layers (multilayer), thanks to the use of several extruders, containing one of them a material that has barrier properties such as EVOH or PA (So Mainly polyethylene is used with EVOH or PA). The second type material proposed for packaging was fluorinated HDPE.

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 2.1 KCP 2.2.1 KCP 2.2.2 KCP 2.3.1 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 KCP 2.11	Mónica Berrios	2016	PHYSICAL AND CHEMICAL PROPERTIES AND ACCELERATED STORAGE STABILITY TEST FOR MESOTRIONE 10% SC (SUSPENSION CONCENTRATE, 10.2% W/W MESOTRIONE) - SPAIN 2015- Labs & Technological Services AGQ, S.L., study number E-15-0004 GLP/Unpublished	N	Sharda Cropchem Ltd.
KCP 2.7.1	Micaela Banos Gonzalez	2020	Determination of impurities and mesotrione in mesotrione 10% SC. Laboratorios Munuera Report: 18-4150-28 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 2.7.4	Idris Al Amin	2018	Mesotrione 10% SC. Wet sieve test after low temperature storage. Institute of Industrial Organic Chemistry Report: BF-15/18 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 2.7.5	Mª DEL MAR	2020	Long term storage stability test for mesotrione 10% sc (suspension concentrate, 10.2% w/w mesotrione) -	N	Sharda

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
	DEL VALLE GARCÍA		spain 2015- Labs & Technological Services AGQ, S.L., study number E-15-0019 GLP/Unpublished		Cropchem Ltd.
KCP 2.7.5	Micaela Banos Gonzalez	2022	Determination of impurities in mesotrione 10% SC during storage stability for two years at 25±2°C. Laboratorios Munuera Report: 18-4150-29 GLP Unpublished	N	Sharda Cropchem Ltd.

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

A 2.1 Mesotrione

No additional study submitted.