

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: MEPCY

Product name(s): SHA 126085 A

Chemical active substances:

Chlormequat chloride, 345 g/L

Mepiquat chloride, 115 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Ltd.

Submission date: February 2022, September 2023

MS Finalisation date: May 2023, August 2023, January 2024

Version history

When	What
May 2023	ZRMS assessment of dRR.
August 2023	Final version of RR after commenting period.
September 2023	Updated by the Applicant
January 2024	ZRMS assessment after Applicant's update (content of RI in the formulation, new packaging stability)

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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:

- level of relevant impurities in formulation (the study is on going and the results will be available in August 2023)
- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem Ltd.
Address: 2nd floor, Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email: Shardaint@vsnl.com
XXXXXXXXXXXX

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

1.2.1 Producer(s) of the preparation

Name: Sharda Cropchem Ltd.
Address: 2nd floor, Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email: Shardaint@vsnl.com
XXXXXXXXXXXX

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

Name: Sharda Cropchem Ltd.
Address: 2nd floor, Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India
Phone number: + 91 22 6678 2800
Fax number: + 91 22 6678 2828/ 2808
Email: Shardaint@vsnl.com

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

1.2.3.1 Chlormequat chloride

Chlormequat chloride	min. 636 g/kg (SANCO/175/08 final rev 2 29 May 2015) min. 900 g/kg (Sharda source)
1,2-dichloroethane	max. 0.1 g/kg (SANCO/175/08 final rev 2 29 May 2015)
Vinyl chloride	max. 0.0005 g/kg (SANCO/175/08 final rev 2 29 May 2015) (both on the dry chlormequat chloride content)

1.2.3.2 Mepiquat chloride

Mepiquat chloride	min. 990 g/kg (SANCO/106/08 final rev. 2 20 May 2008) min. 990 g/kg (Sharda source)
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1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: MEPCY

Company code number: SHA 126085 A
Chlormequat 345 g/L + Mepiquat 115 g/L SL

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)
Chlormequat chloride	345 g/L	± 5% (327.75 – 362.25)	383.33 g/L	35.23%
Mepiquat chloride	115 g/L	± 6%	116.16 g/L	10.68%

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)
		(108.1 – 121.9)		

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

** Based on the density of the formulation = 1.088 g/mL

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
1,2-dichloroethane	0.03833 g/L (0.0035% w/w 0.0345 g/L; 0.0317 g/kg)
Chloroethene (vinyl chloride)	0.1917 mg/L (0.000018 % w/w 0.000173 g/L; 0.000156 g/kg)

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

Table 1.4-3: Information on Chlormequat chloride

Type	Name/Code Number
ISO common name	Chlormequat chloride
CAS No.	7003-89-6 (chlormequat) 999-81-5 (chlormequat chloride)
EC No.	213-666-4 (chlormequat chloride)
CIPAC No.	143 (chlormequat) 143.302 (chlormequat chloride)

Table 1.4-5: Information on Mepiquat chloride

Type	Name/Code Number
ISO common name	Mepiquat chloride
CAS No.	24307-26-4 (mepiquat chloride) 15302-91-7 (mepiquat)
EC No.	246-147-7 (mepiquat chloride) 604-881-8 (mepiquat)
CIPAC No.	440.302 440.332 440.302 (mepiquat chloride) 440 (mepiquat)

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: Soluble concentrate

[Code: SL]

1.6 Function (KCP 1.6)

The product is intended to be used as growth regulator.

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 green beige slightly oily and opaque liquid with a characteristic odour. It has no explosive and oxidising properties. In an aqueous solution, it has a pH value around 5.37 at 21 °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. Its technical characteristics are acceptable for a *soluble concentrate* formulation. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE/PA* commercial packaging material.

The intended concentration of use is 0.5% to 1%.

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

Neither classification or labelling are 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:

There is no FAO specification for products containing mepiquat chloride. There is FAO specification 143.302/SL for SL products containing chlormequat chloride. The product SHA 126085 A complies with the limits recommended in FAO specification 143.302/SL and “Manual on the development and use of FAO and WHO specifications for chemical pesticides” as regards SL product containing chlormequat chloride and mepiquat chloride ~~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)	Visual	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	Homogeneous slightly oily and opaque liquid, colour: RAL 1000 (green beige) with a characteristic odour	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	Accepted.
Explosive properties (KCP 2.2.1)	CHETAH Software	Chlormequat 345 g/L + Mepiquat 115 g/L SL	The test item has no explosive properties.	N	B. Mena, 2022 Report No. SCE-048/2022	The CHETAH software was used to analyse the molecular structure of the active ingredients and main co-formulants of the test item. It is not expected for PPP Mepcy to exhibit explosive behaviours. Accepted.
Oxidizing properties (KCP 2.2.2)	EC method A.2	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	The test item does not show oxidizing properties.	Y	A. Mazzei, 2018, Innovhub Report 1800928	The mean pressure rise time for the mixture of the tested item with cellulose was higher than for the reference mixture. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CHETAH Software	Chlormequat 345 g/L + Mepiquat 115 g/L SL	The test item has no oxidizing properties.	N	B. Mena, 2022 Report No. SCE-048/2022	The CHETAH software was used to analyse the molecular structure of the active ingredients and main co-formulants of the test item. It is not expected for PPP Mepcy to exhibit oxidizing behaviours. Accepted.
Flash point (KCP 2.3.1)	EEC A.9	Chlormequat 345 g/L + Mepiquat 115 g/L SL (Batch No. SCL-120547)	>110°C	Y	M. Kurka, 2020, Report No. 137/2020	The Pensky-Martens closed cup method was used. At 110°C the boiling of the sample was observed. The product is not flammable. Accepted.
Flammability (KCP 2.3.2)	-	-	Please refer to KCP 2.3.1	-	-	
Self-heating (KCP 2.3.3)	EEC A.15	Chlormequat 345 g/L + Mepiquat 115 g/L SL (Batch No. SCL-120547)	440°C at 99.60 kPa	Y	N. Colombo, 2018 Report No. 299D/18	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3 and CIPAC MT 191	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<u>pH:</u> 2.51 (at 21.0 °C) <u>Acidity (expressed as H₂SO₄)</u> 0.0687% w/w	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	5.37 (at 21.2 °C)	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	Accepted.
Viscosity (KCP 2.5.1)	OECD 114	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<u>Kinematic viscosity:</u> 6.367 mm ² /s (20°C) 3.308 mm ² /s (40°C) <u>Dynamic viscosity:</u> 6.928 mPa s (20°C) 3.599 mPa s (40°C)	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	The kinematic viscosity was determined using a capillary viscometer and dynamic viscosity was calculated from kinematic viscosity. According to Reg. 284/2013, for liquid formulations the viscosity shall be determined at two shear rates and for Mepcy it was not determined. However, as there are no H304-classified components in

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						the formulation and the product does not have to be classified as an aspiration hazard (H304) it can be accepted. Accepted.
Surface tension (KCP 2.5.2)	OECD 115 EC method A.5	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	Undiluted: 32.02 mN/m 1% aqueous solution: 322.45 32.45 mN/m	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	The ring method was used. The surface tension was determined for the highest recommended concentration (1% v/v). The product is surface active. Accepted.
Relative density (KCP 2.6.1)	OECD 109 EC method A.3	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	Density: 1.088 g/mL (at 20°C) Relative density: 1.088	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not relevant for liquid formulation.	-	-	

Annex point	Method used / deviations	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	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896) Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-20220)	Property	Time 0	After 2 weeks at 54°C	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18 K.S. Kishora, 2023, Eurofins Advinus, Report No.: AG-G0028	The formulation was stored in the original commercial packaging (1 L PE/EV plastic bottles). The change of a.s. content was 1.2% for chlormequat chloride and 0.7% for mepiquat chloride. The content of relevant impurities was below the limits set for chlormequat chloride in Regulation No 540/2011. There were no significant changes to the formulation. The packaging remained stable. The additional stability data for commercial packaging made of HDPE (bottles)
			Appearance	Homogeneous slightly oily and opaque liquid	Homogeneous slightly oily and opaque liquid			
			Colour	RAL 1000 Green beige	RAL 1001 Beige			
			Odour	Characteristic	Characteristic			
			Packaging	1 L PEC/EV plastic bottle	1 L PE/EV plastic bottle			
			Weight loss	-	0.02 %			
			Chlormequat chloride content	346.21 g/L 31.82% w/w	341.02 g/L 31.35% w/w			
			Mepiquat chloride	120.62 g/L 11.09% w/w	121.40 g/L 11.16% w/w			
			pH undiluted	2.51 (21.0°C)	1.93 (21.0°C)			
			pH diluted 1% w/w w/v	5.37 (21.2°C)	4.14 (21.1°C)			
			Acidity	0.0687% w/w	0.1079% w/w			
			Dilution stability 1% v/v	Initial				
				Homogeneous	Homogeneous			
After 24 hours								
Homogeneous		Homogeneous						
Content of relevant impurities and Packaging Stability/Corrosion Characteristics:								
Property	Time 0	After 2 weeks at 54°C						
Determination of relevant impurity – 1,2-Dichloroethane	0.00232 % w/w	0.00230 % w/w						
Determination of relevant impurity –	Below LOD (0.00000148 % w/w)	Below LOD (0.00000148 % w/w)						

Annex point	Method used / deviations	Test material	Findings		GLP Y/N	Reference	Acceptability / comments																		
			<table><tr><td>Vinyl chloride</td><td></td><td></td></tr><tr><td>Packaging Stability/Corrosion Characteristics</td><td>No perforation, leakage, discoloration or darkening and no corrosion to the packaging material</td><td>No perforation, leakage, discoloration or darkening and no corrosion to the packaging material</td></tr></table> <p>The test item found to be non-corrosive for commercial packaging (HDPE containers) as there was no significant change in the weights of commercial packaging (HDPE containers bottles) and no perforations, leakage, discolorations, darkening, and no corrosion to packing were found before and after storage at elevated temperature for 14 days.</p>		Vinyl chloride			Packaging Stability/Corrosion Characteristics	No perforation, leakage, discoloration or darkening and no corrosion to the packaging material	No perforation, leakage, discoloration or darkening and no corrosion to the packaging material			were provided. The packaging proved to be stable during storage. Accepted.												
Vinyl chloride																									
Packaging Stability/Corrosion Characteristics	No perforation, leakage, discoloration or darkening and no corrosion to the packaging material	No perforation, leakage, discoloration or darkening and no corrosion to the packaging material																							
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant.		-	-																			
Minimum content after heat stability testing (KCP 2.7.3)	Validated method SANCO/3030/99 rev. 4		After 2 weeks at 54 ± 2°C Chlormequat: 341.02 g/L (31.35% w/w) Mepiquat 121.40 g/L (11.16% w/w)		Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	Accepted.																		
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.2	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<table><tr><th>Property</th><th>After 7 days at 0°C</th></tr><tr><td>Appearance</td><td>Homogeneous slightly oily and opaque liquid</td></tr><tr><td>Colour</td><td>RAL 1000 Green beige</td></tr><tr><td>Odour</td><td>Characteristic</td></tr><tr><td>Separation and precipitation</td><td>Not present</td></tr><tr><td>pH undiluted</td><td>2.59 (21.5°C)</td></tr><tr><td>pH diluted 1% w/w</td><td>4.59 (21.0°C)</td></tr><tr><td>Acidity expressed as H₂SO₄</td><td>0.0588% w/w/</td></tr><tr><td>Dilution stability</td><td>Initial: Homogeneous</td></tr></table>		Property	After 7 days at 0°C	Appearance	Homogeneous slightly oily and opaque liquid	Colour	RAL 1000 Green beige	Odour	Characteristic	Separation and precipitation	Not present	pH undiluted	2.59 (21.5°C)	pH diluted 1% w/w	4.59 (21.0°C)	Acidity expressed as H ₂ SO ₄	0.0588% w/w/	Dilution stability	Initial: Homogeneous	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	There were no significant changes to the formulation. There was no separation or precipitation. Accepted.
Property	After 7 days at 0°C																								
Appearance	Homogeneous slightly oily and opaque liquid																								
Colour	RAL 1000 Green beige																								
Odour	Characteristic																								
Separation and precipitation	Not present																								
pH undiluted	2.59 (21.5°C)																								
pH diluted 1% w/w	4.59 (21.0°C)																								
Acidity expressed as H ₂ SO ₄	0.0588% w/w/																								
Dilution stability	Initial: Homogeneous																								

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
			1% v/v		After 24 hours: Homogeneous					
Ambient temperature shelf life (KCP 2.7.5)	-	-	Please refer to KCP 2.7.6					-	-	
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Visual CIPAC MT 75.3 CIPAC MT 191 CIPAC MT 41.1	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	Test	Initial	6 months	12 months	24 months	Y	S. Aversa, 2019 2020 Biotecnologie BT Report No. BT023/18	The formulation was stored in the original commercial packaging (1 L PE/EV plastic bottles). The sample was maintained in a range of 18.0 – 22.0°C. The change of a.s. content was 3.4% for chlormequat chloride and 2.1% for mepiquat chloride. The study of RI content in the formulation is ongoing and the results will be available in August 2023. The content of RI was determined
			Appearance	Green beige slightly oily liquid with characteristic odour	Green beige slightly oily liquid with characteristic odour	Green beige slightly oily liquid with characteristic odour	Green beige slightly oily liquid with characteristic odour			
			Weight loss	-	0%	0.01%	0.01%			
			Chlormequat chloride % w/w	31.82%	32.04%	31.47%	30.73%			
			Mepiquat chloride % w/w	11.09%	10.48%	10.68%	10.86%			
			pH Undiluted	2.51	2.55	2.24	2.71			
			1% dilution	5.37	4.99	5.66	4.53			
			Acidity expressed as H ₂ SO ₄	0.0687% w/w	0.0739% w/w	0.0981% w/w	0.060% w/w			
			Dilution stability (1% v/v)	Initial: homogenous After 24h: Homogenous	Initial: homogenous After 24h: Homogenous	Initial: homogenous After 24h: Homogenous	Initial: homogenous After 24h: Homogenous			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						before and after storage at 54°C (see 2.7.1). There were no significant changes to the formulation. The formulation remained stable (no sedimentation). The packaging remained stable. Accepted.
Wettability (KCP 2.8.1)	-	-	Not relevant for SL formulation.	-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<u>Persistent foaming 0.5% v/v</u> 1 min: 9 mL 12 min: 4 mL <u>Persistent foaming 1.0% v/v</u> 1 min: 9 mL 12 min: 4 mL	Y	S. Aversa, 2018, Biotechnologie BT Report No. BT022/18	CIPAC Standard Water D was used. The test was performed for the highest (1% v/v) and lowest (0.5% v/v) recommended concentrations. Accepted.
Suspensibility (KCP 2.8.3.1)	-	-	Not relevant for SL formulation.	-	-	
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not relevant for SL formulation.	-	-	
Dispersion	-	-	Not relevant for SL formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
stability (KCP 2.8.3.3)						
Degree of dissolution and dilution stability (KCP 2.8.4)	CIPAC MT 41.1	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<u>1.0% v/v:</u> Initial: homogeneous After 24 hours: homogeneous	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT022/18	CIPAC Standard Water D was used. The test was performed for the highest (1% v/v) recommended concentration. No separated material and the formulation was homogeneous. Accepted.
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for SL formulation.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not relevant for SL formulation.	-	-	
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for SL formulation.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for SL formulation.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant for SL formulation.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for SL formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for SL formulation.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for SL formulation.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for SL formulation.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not relevant for SL formulation.	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not relevant for SL formulation.	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for SL formulation.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant for SL formulation.	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant for SL formulation.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not required. The product is not intended to be applied to seeds.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not required. The product is not intended to be applied to seeds.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Other/special studies (KCP 2.11)	Internal method POS BT 337	Chlormequat 345 g/L + Mepiquat 115 g/L SL (batch No. SCL-11896)	<i>Chlormequat chloride</i> (mg/L measures - %rinse efficacy)	Y	S. Aversa, 2018, Biotecnologie BT Report No. BT0214/18 BT024/18	Accepted.
			a.i. in the tank			
			1 st wash (water)			
			2 nd wash(water)			
			3 rd wash (water)			
			4 th wash (3% acetone)			
			<i>Mepiquat chloride</i> (mg/L measured - %rinse efficacy)			
			a.i. in the tank			
			1 st wash (water)			
			2 nd wash(water)			
			3 rd wash (water)			
			4 th wash (3% acetone)			

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)

Comment of zRMS:	<p>In the accelerated stability study and shelf-life study, the formulation has been tested in its original commercial packaging (1 L PE/EV plastic bottles) and the packaging remained stable. In 2023, additional data on stability of commercial packaging made of HDPE (bottles) were provided (see 2.7.1), therefore packaging made of HDPE is also acceptable.</p> <p>Since the formulation is SL formulation, it is possible, according to the guideline of the Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results to another plastic packaging, therefore, also the other proposed commercial packs are considered acceptable.</p>
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Table 4.1-1: Packaging information for 250 ml bottle

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 62.5 mm diameter x 126.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-2: Packaging information for 0,5 litre bottle

Type	Description
Material:	HDPE/PA
Shape/size:	Round bottle / approx. 67.0 mm diameter x 188.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 litre bottle

Type	Description
Material:	HDPE/PA
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

Type	Description
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-4: Packaging information for 5 litre jerrycan

Type	Description
Material:	HDPE/PA
Shape/size:	jerrycan / approx. 136.0 mm x 192.0 mm x 285.0 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-5: Packaging information for 10 litre jerrycan

Type	Description
Material:	HDPE/PA
Shape/size:	jerrycan / approx. 174.0 mm x 226.0 mm x 368.0 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-6: Packaging information for 20 litre jerrycan

Type	Description
Material:	HDPE/PA
Shape/size:	jerrycan / approx. 245.0 mm x 294.0 mm x 400.0 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-7: Packaging information for 250 ml bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 62.5 mm diameter x 126.5 mm
Opening:	41.7 mm inner diameter

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

Table 4.1-8: Packaging information for 0,5 litre bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 67.0 mm diameter x 188.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-9: Packaging information for 1 litre 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	coextrusion
UN/ADR	compliant

Table 4.1-10: Packaging information for 5 litre jerry can

Type	Description
Material:	HDPE
Shape/size:	jerry can / approx. 136.0 mm x 192.0 mm x 285.0 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-11: Packaging information for 10 litre jerry can

Type	Description
Material:	HDPE
Shape/size:	jerry can / approx. 174.0 mm x 226.0 mm x 368.0 mm

Type	Description
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

Table 4.1-12: Packaging information for 20 litre jerry can

Type	Description
Material:	HDPE
Shape/size:	jerry can / approx. 245.0 mm x 294.0 mm x 400.0 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	coextrusion
UN/ADR	compliant

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 2.7.3, KCP 2.7.4, KCP 2.8.2, KCP 2.8.4	Stefano Aversa	2018	Physical-chemical characterization and accelerated storage stability (2 weeks/54±2°C) of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL Biotechnologie BT report No. BT022/18 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.1 KCP 2.2.2/02	B. Mena	2022	Chlormequat chloride 34.5% + Mepiquat chloride 11.5% SL Determination of the oxidizing properties and explosive properties. Sharda Cropchem España S.L. Report No. SCE-048/2022 Non-GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.2/01	Antonella Mazzei	2018	Determination of Oxidizing properties (liquids) n the sample Chlormequat 345 g/L + Mepiquat 115 g/L SL Innovhub – Stazioni Sperimentali per l'Industria report No. 1800928 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 2.3.1 KCP 2.3.3	M. Kurka	2020	Chlormequat 345 g/L + Mepiquat 115 g/L SL Determination of Flash point (A.9) and Flammability (A.15) Institute of Heavy Organic Synthesis "Blachownia" Report No. 137/2020 GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.7.5	Stefano Aversa	2020	Physical-chemical properties of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL after 2 years shelf life (2 years/20±2°C) Biotechnologie BT report No. BT023/18 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.11	Stefano Aversa	2018	Effectiveness of cleaning procedure of test item Chlormequat 345 g/L + Mepiquat 115 g/L SL Biotechnologie BT report No. BT024/18 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 2.7.1	K.S. Kishora	2023	Accelerated storage stability test of Chlormequat 34.5% + Mepiquat 11.5% SL. Report No.: AG-G0028 EUROFINS ADVINUS AGROSCIENCES SERVICES 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 Chlormequat chloride

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

A 2.2 Mepiquat chloride

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