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 9100 A

Product name: HYCOP

Chemical active substance:

Copper hydroxide, 500 g/kg (as Cu)

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: August 2019

MS Finalisation date: January 2021; 08/2021; 11/2021

Version history

When	What
January 2021	Assessment finalised by RMS
August 2021	The final version of RR after commenting
November 2021	The final version of RR after commenting and update of Part C by applicant

Table of Contents

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

Name:	Sharda Cropchem Ltd.
Address:	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 regn@shardaintl.com

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

~~Name:~~	~~Sharda Cropchem Ltd.~~
~~Address:~~	~~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~~ ~~regn@shardaintl.com~~

Name:	CINKARNA Metallurgical and Chemical Industry Ceije, INC.
Address:	XXX

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

1.2.3.1 Copper hydroxide

Copper hydroxide	min. 930 g/kg as copper hydroxide or ~~600~~ 605 g/kg as copper (Sharda source). min. 880 g/kg as copper hydroxyde or 573 g/kg as copper (Commission Implementing Regulation (EU) 2018/1981 and SANTE/10506/2018 Rev. 5 (27 November 2018))

Relevant impurities:

Lead	max. 0.3 mg/g of copper content in the technical
Cadmiun	max. 0.1 mg/g of copper content in the technical
Arsenic	max. 0.1 mg/g of copper content in the technical
Nickel	max. 1 mg/g of copper content in the technical
Cobalt	max. 3 mg/kg of copper content in the technical
Mercury	max. 5 mg/kg of copper content in the technical
Chromium	max. 100 mg/kg of copper content in the technical
Antimony	max. 7 mg/kg of copper content in the technical

Details of significant impurities are provided in Part C.

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

Trade name:	Please refer to Registration Report Part A for the relevant country (or)
Trade name:	HYCOP
Company code number:	SHA 9100 A Copper hydroxide 50% WP

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)
Copper hydroxide	~~768.0 g/kg~~ 500 g/kg of Cu	~~729.6 – 806.4 g/kg~~ 475 – 525 g/kg (± 5% of the declared content)	~~825.8~~ 825.65 g/kg	~~82.58~~ 82.565 % w/w
~~*Exp. as copper*~~	~~*500.0 g/kg*~~	~~475.0 – 525.0 g/ kg (± 5% of the declared content)~~	~~*537.6 g/kg*~~	~~*53.76 % w/w*~~

* 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)
Lead	max. 0.3 mg/g of copper content in the technical
Cadmiun	max. 0.1 mg/g of copper content in the technical
Arsenic	max. 0.1 mg/g of copper content in the technical
Nickel	max. 1 mg/g of copper content in the technical
Cobalt	max. 3 mg/kg of copper content in the technical
Mercury	max. 5 mg/kg of copper content in the technical
Chromium	max. 100 mg/kg of copper content in the technical
Antimony	max. 7 mg/kg of copper content in the technical

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

Table 1.4-3: Information on Copper hydroxide

Type	Name/Code Number
ISO common name	Copper hydroxide
CAS No.	20427-59-2
EEC No.	243-815-9
CIPAC No.	44.305

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: Wettable powder [Code: WP]

1.6 Function (KCP 1.6)

Copper hydroxide 50% WP is intended to be used as a fungicide.

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 light blue fine crystalline powder, with a slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable and does not have a relative self-ignition temperature. In aqueous solution, it has a pH value around 9.57 at 20°C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 year at ambient temperature when stored in packaging material polypropylene. Its technical characteristics are acceptable for a wettable powder (WP) formulation.
The intended concentration of use is 0.115% w/v to 0.48% w/v.

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

Neither classification nor 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:

The product Copper hydroxide 50% WP 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, Copper hydroxide 50% WP.

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 inspection	Copper Hydroxide 50% WP (N° batch : SCL-20155)	Light blue fine crystalline powder of slight characteristic odour	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I)	Accepted.
Explosive properties (KCP 2.2.1)	EEC A14	Copper Hydroxide 50% WP (N° batch : SCL-20155)	Copper Hydoxide 50% WP does not have explosive properties according to the criteria of EEC A.14 method.	Y	XXX D., 2016 Report No. BW- 08/16	In thermal sensitivity (Koenen) test no explosion occurred. In mechanical sensitivity test (shock and friction) no explosion occurred. Accepted.
Oxidizing properties (KCP 2.2.2)	EEC A.17	Copper Hydroxide 50% WP (N° batch: SCL-150192)	Copper Hydroxide 50% WP does not have the oxidizing properties in accordance with test A.17 criteria.	Y	XXX P., 2016 Report No. BC- 34/16	Accepted.
Flash point (KCP 2.3.1)	-	-	Not required	-	-	
Flammability (KCP 2.3.2)	EEC A.10	Copper Hydroxide 50% WP (N° batch: SCL-150192)	Copper Hydroxide 50% WP is not highly flammable in accordance with test A.10. criteria.	Y	XXX P., 2016 Report No. BC- 34/16	Accepted.
Self-heating (KCP 2.3.3)	EEC A.16	Copper Hydroxide 50% WP (N° batch: SCL-150192)	Copper Hydroxide 50% WP does not have the relative self-ignition temperature in accordance with test A.16. criteria.	Y	XXX P., 2016 Report No. BC- 34/16	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Copper Hydroxide 50% WP (N° batch : SCL-20155)	9.57 (20ºC)	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I)	Accepted.
Viscosity (KCP 2.5.1)	-	-	Not required .	-	-	
Surface tension (KCP 2.5.2)	-	-	Not required.	-	-	
Relative density (KCP 2.6.1)	-	-	Not required.	-	-	
Bulk density (KCP 2.6.2)	CIPAC MT 186	Copper Hydroxide 50% WP (N° batch : SCL-20155)	Pour density – 0.28 g/mL, Tap density – 0.34 g/mL	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I)	Accepted.
Storage Stability after 14 days at 54º C (KCP 2.7.1)	CIPAC MT 46 Visual inspection CIPAC MT 75.3 CIPAC MT 185 CIPAC MT 53.3 CIPAC MT 184 CIPAC MT 187 Potentiometric titration method for active ingredient determination.	Copper Hydroxide 50% WP (N° batch : ~~SCL-20155~~ SCL-150192)	**Appearance:** Before storage: fine crystalline powder After storage: fine crystalline powder **Colour:** Before storage: Light blue After storage: Light blue **Odour:** Before storage: slight characteristic odour After storage: slight characteristic odour **pH of 1% water suspension:** Before storage: 9.57 After storage: 10.10 **Wet sieve test:** Before storage: Residue in 75 µm sieve 0.35% After storage: Residue in 75 µm sieve 0.4% **Wettability:** Before storage: 21s After storage: 26 s **Suspension stability:**	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	During the storage, the temperature ranged from 53.4 to 53.9°C. The tested material was packed in glass. No change in the a.s. content was observed; no change in properties. See KCP 2.8.5.1.2 comment regarding wet sieve test results. Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Before storage: 1.5 kg/1600 l = 79.67% 2.4 kg/500 l = 79.91% After storage: 1.5 kg/1600 l = 73.49% 2.4 kg/500 l = 77.64% **Particle size:** Before storage: d_{10} = 0.94 µm d_{50} = 5.19 µm d_{90} = 12.58 µm *Average $d_{4,3}$ = 6.08 µm SD = 0.016 µm, RSD = 0.263% After storage: d_{10} = 1.27 µm d_{50} = 5.89 µm d_{90} = 13.61 µm *Average $d_{4,3}$ = 6.78 µm SD = 0.016 µm, RSD = 0.236% **Active substance potentiometric titration:** Before storage: Copper 50.333% (503.33 g/kg) After storage: Copper ~~50.648~~ 50.645% (~~506.48~~ 506.45 g/kg) Copper hydroxide 50% WP is stable after accelerated storage at 54 ºC for 14 days.			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not required.	-	-	
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please, refer the KCP 2.7.1.	-	-	
Effect of low temperatures on stability (KCP 2.7.4)	-	-	Not required.	-	-	
Ambient temperature	Visual inspection	Copper	**Appearance:**	Y	Al XXX I., 2016	During the storage, the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
shelf life (KCP 2.7.5)	CIPAC MT 75.3 CIPAC MT 185 CIPAC MT 53.3 CIPAC MT 184 CIPAC MT 187 GIFAP No. 17 Potentiometric titration method for active ingredient determination.	Hydroxide 50% WP (N° batch : SCL-150192)	Before storage: fine crystalline powder After storage: fine crystalline powder **Colour:** Before storage: Light blue After storage: Light blue **Odour:** Before storage: slight characteristic odour After storage: slight characteristic odour **pH of 1% water suspension:** Before storage: 9.57 After storage: 9.36 **Wet sieve test:** Before storage: Residue in 75 µm sieve 0.35% After storage: Residue in 75 µm sieve 1.0% **Wettability:** Before storage: 21s After storage: 31 s **Suspension stability:** Before storage: 1.5 kg/1600 l = 79.67% 2.4 kg/500 l = 79.91% After storage: 1.5 kg/1600 l = 74.89% 2.4 kg/500 l = 77.01% **Particle size:** Before storage: d_{10} = 0.94 µm d_{50} = 5.19 µm d_{90} = 12.58 µm *Average $d_{4,3}$ = 6.08 µm SD = 0.016 µm, RSD = 0.263% After storage: d_{10} = 0.98 µm d_{50} = 5.18 µm d_{90} = 12.59 µm *Average $d_{4,3}$ = 6.10 µm SD = 0.039 µm, RSD = 0.639% **Package:** Before storage: Polypropylene colorless bucket		Report No. BF- 26/16 (Part III)	temperature ranged from 19.0ºC to 21.4ºC. After the storage no change in the a.s. content was observed; no change in properties. No negative effect on the container: no changes to the shape and colour of the 1 L PP packages; the minor mass change was observed (the container in the study was different from commercial packaging). See KCP 2.8.5.1.2 comment regarding wet sieve test results. The contents of the relevant impurities determined before the storage were below the levels of Commission Implementing Regulation (EU) 2018/1981. The content of the relevant impurites after the storage was not determined. However, as the content of the a.s. was stable during the storage and the relevant impurities are derived from the manufacturing

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			After storage: Polypropylene colorless bucket. The shape and colour of the packages were stable after two year storage. **Active substance potentiometric titration:** Before storage: Copper 50.333% (503.33 g/kg) After storage: Copper 50.742% (507.42 g/kg) **Relevant impurites content** Before storage: Sb – 2.7±0.2 mg/kg (FP-formulated product) Pb – 5.6±0.6 mg/kg (FP) Cr – 2.7±0.3 mg/kg (FP) Co – 0.46±0.04 mg/kg (FP) As – <5 mg/kg (FP) Cd – <5 mg/kg (FP) Ni – 5.3±0.9 mg/kg (FP) Hg – 0.16±0.01 mg/kg (FP) After storage: not determined Copper hydroxide 50% WP is stable after two years storage.			process of the technical active substance and cannot be generated during the manufacturing process of formulation neither during the storage, the results can be accepted without the testing of relevalnt impurities content after storage. During storage, there were no changes to packaging. As, according to "Guidance document for the generation of data on the physical, chemical and technical properties of plant protection products" under Regulation (EC) No. 1107/2009, extrapolation between all container types for flexible containers for powders and granules is possible, the containers are acceptable for packaging of the formulation. Accepted.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not required .	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Wettability (KCP 2.8.1)	CIPAC MT 53.3	Copper Hydroxide 50% WP (N° batch : ~~SCL 20155~~ SCL-150192)	21 s.	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	Wetting time < 1 min. Accepted
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	Copper Hydroxide 50% WP (N° batch : ~~SCL 20155~~ SCL-150192)	0.6% water suspension: 6 ml after 10 s, 4 ml after 1 min, 2 ml after 3 min. and 12 min.	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	The recommended use concentration is from 0.115% w/v to 0.48% w/v. The study was performed with a concentration higher than the maximum recommended concentration and the results are acceptable. Accepted.
Suspensibility (KCP 2.8.3.1)	CIPCAC MT 184	Copper Hydroxide 50% WP (N° batch : ~~SCL 20155~~ SCL-150192)	0.094 % w/v (1.5 kg/1600 l): 79.67% 0.48 % w/v (2.4 kg/500 l): 79.91%	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	CIPAC water D was used. The test was performed at 30°C. According to GAP, the lowest recommended concentration is 0.115% w/v (1.15 kg/1000 L). As the lowest recommended concentration is lower than 0.2%, according to method MT 184 the concentration 0.2% should be used. The results are within limits of FAO specification.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required.	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not required.	-	-	
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required.	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Copper Hydroxide 50% WP (N° batch : ~~SCL 20155~~ SCL-150192)	d_{10} = 0.94 µm d_{50} = 5.19 µm d_{90} = 12.58 µm *Average $d_{4,3}$ = 6.08 µm SD = 0.016 µm, RSD = 0.263%	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	Accepted.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Copper Hydroxide 50% WP (N° batch : ~~SCL 20155~~ SCL-150192)	Residue in 75 µm sieve 0.35%.	Y	Al XXX I., 2016 Report No. BF- 26/16 (Part I) Ammendment No. 1	The procedure of the method used in the study was different from the CIPAC MT 185: - the amount of water used to dilute the material was 20 ml instead of 100 ml - no stirring was applied to the dilution - the amount of water used to rinse the beaker and sieve was 150 ml instead of a jet of tap water (4-5 litres/min.). However, as the procedure used in the study would lead to the higher residue and the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						result is within the limit specified in the FAO specification it is acceptable. Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not required. Please, refer the KCP 2.8.5.1.1.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not required.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not required.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not required.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not required.	-	-	
Flowability (KCP 2.8.7.1)	-	-	Not required.	-	-	
Pourability (KCP 2.8.7.2)	-	-	Not required.	-	-	
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not required.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not required.	-	-	
Other/special studies (KCP 2.11)	-	-	Not 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 Packaging and Compatibility with the Preparation (KCP 4.4)

The bags used for packaging 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:	OPP (Oriented polypropylene)	Thickness: 20.0 mc	Outside layer
Material 2:	PET met (Metallized ethylene polyter-ephthalate)	Thickness: 12.0 mc	Middle layer
Material 3:	~~PEBD~~ LDPE TR (Thermoplastic low density polyethylene)	Thickness: 70.0 mc	Inside layer (in contact with the product)

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

Table 4.1-1: Packaging information for 20 - 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 4.1-2: 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 4.1-3: Packaging information for 200 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 4.1-4: 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 4.1-5: 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 4.1-6: 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 4.1-7: 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 4.1-8: Packaging information for 4 kg, 5 kg and 10 kg

Type	Description
Material:	PE
Shape/size:	- Sac / approx. 380 mm (width) x 570 mm (length) x 100 mm (bottom)

Type	Description
	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 : in contact with the product) - Inner bag (Low density polyethylene): approx. 390 mm (width) x 680 mm (length) [thickness:45 µm]
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: 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: in contact with the product) - Inner bag (Low density polyethylene): approx. 560 mm (width) x 910 mm (length) [thickness:37 µm]
Seal:	Heat seal
Manner of construction	extruded
UN/ADR	compliant

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Tank cleaning

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles three times with clean water until the foam and all traces of product have been removed.

Effectiveness of the cleaning procedures

At the time of compilation of this dossier, no specific study was conducted for the product Copper hydroxide 500 g/kg WP to investigate the effectiveness of the cleaning procedure.

Experience in use of plant protection products based on cupper hydroxide has not indicated any particular problems. Low levels of residues of Copper hydroxide (Copper hydroxide 500 g/kg WP) 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:	2.4 kg product/ha, corresponding to 1.2* kg Copper hydroxide/ha
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	20 L
Spray volume:	500 L/ha (lowest spray volume corresponding to the maximum concentration of Copper hydroxide 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, Copper hydroxide 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* [g as/L]**
Tank filling: Residues after spraying:	2000 20	4.8	2.4
1st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	0.48	0.24
2nd step: 20% of tank volume added: Residues after spraying:	400 20	0.024	0.012
3rd step: 20% of tank volume added: Residues after spraying:	400 20	0.0012	0.0006
Addition of fresh spray solution: Residues in the tank filling:	2000 20	0.000012	6×10^{-6}

PPP = Copper hydroxide 50% WP as = Copper hydroxide

Residues remaining in the last cleaning solution were calculated to be 0.0006* g/L of Copper hydroxide resulting in residue concentration of 6.0* µg/L Copper hydroxide after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 500-1000 L/ha applied to succeeding crops, residues of 0.6 – 1.2* mg assuming a range of spray volumes will be applied per ha.

Compared to the effect levels on non-target plants, these residues are clearly below the lowest ER_{50} found in the studies conducted with 5 different copper-based test item for emergence and vegetative vigour of > 2000 g a.s./ha (EFSA Journal 2018;16(1):5152). Thus, any detrimental effect on plants from tank residues can be excluded.

*Expressed as Cu

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 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.5.1.1 KCP 2.8.5.1.2	Al XXX I.	2016	Copper Hydroxide 50% WP, Part I: Evaluation of physicochemical properties of the initial preparation and after accelerated storage. Institute of industrial organic chemistry, Study code No BF-26/16 (Part I) GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.1 KCP 2.4.2 KCP 2.6.2 KCP 2.7.1 KCP 2.8.1 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.5.1.1 KCP 2.8.5.1.2	XXX J.	2020	Amendment No. 1 to Final Report. Copper Hydroxide 50% WP Part I, II: Evaluation of physicochemical properties Institute of industrial organic chemistry, Study code No BF-26/16 Unpublished	N	Sharda Cropchem Limited
KCP 2.2.1	XXX D.	2016	Copper Hydroxide 50% WP, Determination of explosive properties. Institute of industrial organic chemistry, Study code: BW-08/16 GLP	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
			Unpublished		
KCP 2.2.2 KCP 2.3.2 KCP 2.3.3	XXX P.	2016	Copper Hydroxide 50% WP, Determination of flammability, relative self ignition temperature and oxidizing properties. Institute of industrial organic chemistry, Study code: BC- 34/16 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.5	Al XXX I.	2016	Copper Hydroxide 50% WP, Part II: Evaluation of physicochemical properties after the first year of storage. Institute of industrial organic chemistry, Study code No BF-26/16 (Part III) GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.5	Al XXX I.	2018	Copper Hydroxide 50% WP, Part III: Evaluation of physicochemical properties after the second year of storage. Institute of industrial organic chemistry, Study code No BF-26/16 (Part III) 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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP	Y/N	Owner

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
			Published/Unpublished		

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	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**
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

A 2.1 Copper hydroxide

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