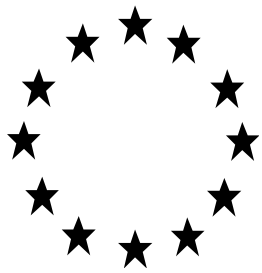
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



LO-CHLOR POOL ALGAECIDE

Product-type 02

Copper sulphate pentahydrate

Case Number in R4BP: BC-UW018517-01

Evaluating Competent Authority: Spain

Date: November 2019

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1 CONCLUSION

The assessment presented in this report has shown that, Lo-Chlor Pool Algaecide, with the active substance copper sulphate pentahydrate, at a level of 12.5% w/w, may be authorised for use as an algaecide (product-type 02) for the control of algal growth by professional and non-professional users. Please, note that this Assessment Report includes the uses requested by the applicant, as information for the concerned member states.

Lo-Chlor Pool Algaecide formulation was found to be a dark blue soluble concentrate, characteristic amine odour liquid. The density was 1.1367 g/cm^3, the pH was 8.15 (20^{o}C).

This product is stable at low-temperature storage (0ºC for 7 days), at high-temperature accelerate storage conditions (54ºC for 2 weeks) and at 24 months of storage at room temperature, thus a self-life storage stability of at least 24 months is expected.

Available information on flammability, explosivity and oxidising potential indicate that copper sulphate pentahydrate is unclassified with regard to these properties and does not represent an unacceptable risk to either professional and non-professional users or the environment, either as a substance as such or as a constituent of a formulated product. Hence, there are not any hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are Substances of Concern in the biocidal product since these substances are classified as dangerous (Directive 67/548/EEC) or hazardous (Regulation No 1272/2008). However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) Nº 1272/2008 and the biocidal product is not classified with regard to the physico chemical properties.

A validated analytical method has been submitted for determining the concentration of copper sulphate pentahydrate in the biocidal product by the applicant. Validated analytical methods are also available for the determination of copper sulphate pentahydrate in soil, water and air matrices. Other analytical methods are not required.

The product was shown to be efficacious against the intended target organisms (algae) in the proposed area for use (bathing and other waters, indoors/outdoors). Please find more information on the efficacy of the product in the correspondent chapter 2.2.5.

Lo-Chlor Pool Algaecide is a liquid product available in the form of soluble concentrate whose approval is sought for the control of algae growth in swimming pools, spas and fountains. The assessment presented here focuses on the use as swimming pool algaecide which is believed to be the worst case for exposure and risk assessment purposes in terms of amount of product used and population exposed considering primary and secondary routes of exposure to the product.

The risk is acceptable for trained professional users when gloves and eye protection are worn during the handling of the product.

The use of the product by professional and non-professional users (general public) presents a low potential of exposure and a frequency of use less than once a week. In addition, packaging intended for non-professional users must have child resistant closure. Therefore, with the RMMs included, the risk is acceptable without wearing PPEs.

For trained professionals and non-professionals users the risk is acceptable from the point of view of secondary exposure. No PPEs are needed for this step.

Environment

The biocidal product LO-CHLOR POOL ALGAECIDE contains no substances of concern for the environment and there are no formulation additives contained in the product or properties of the formulation that are considered to affect the fate and the distribution of the a.s. in the environment. Consequently, the environmental effects assessment for the biocidal product is based on the available data for the a.s. copper sulphate pentahydrate (see Competent Authority Report; RMS France; Applicant: Manica S.p.A.).

However, this biocidal product differs from the biocidal product which was assessed in the CAR of the a.s.. Hence, the environmental exposure assessment described in the CAR could not be translated into the risk assessment for the LO-CHLOR POOL ALGAECIDE. In the CAR, the environmental exposure assessment referred to a ready to use product intended to be used as a laundry disinfectant. The product LO-CHLOR POOL ALGAECIDE is intended to be used as algaecide in swimming pools, spas, hot tubs, padding pools and fountains by trained professionals, professionals and non-professionals (general public). Therefore, the environmental exposure assessment has been adapted accordingly.

The assessment presented in this report has shown that the product can be used as algaecide for private swimming pools (indoor/outdoor), spas (indoor), hot tubs (indoor) and fountains (indoor/outdoor) when the emission pathway is via STP. However the product LO-CHLOR POOL ALGAECIDE can not be used for paddling pools or outdoor foutains due to the risk on surface water and sediment when the emission pathway is the direct soil.

Besides that, the product can also applied in public pools (indoor/outdoor) applying the following RMM "After the last treatment with this product, it must pass at least 21 days with the purification system connected to empty completely the pool", *except if there are national measures that prevent unacceptable risks in environmental compartment when the swimming-pool is emptied*, in order to reduce the unacceptable risk in sediment identified in acute situation.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
LO-CHLOR POOL ALGAECIDE	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	A.Q.A. CHEMICALS, S.L.
	Address	P.I. Riera de Caldes, C/ Camí Reial nº 40, nave 4 08184 – PALAU-SOLITÀ I PLEGAMANS (Barcelona) SPAIN
Authorisation number	ES/APP(NA)-2019-02-00667	
Date of the authorisation	05/11/2019	
Expiry date of the authorisation	05/11/2029	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	A.Q.A. CHEMICALS, S.L.
Address of manufacturer	P.I. Riera de Caldes, C/ Camí Reial nº 40, nave 4 08184 – PALAU-SOLITÀ I PLEGAMANS (Barcelona) SPAIN
Location of manufacturing sites	P.I. Riera de Caldes, C/ Camí Reial nº 40, nave 4 08184 – PALAU-SOLITÀ I PLEGAMANS (Barcelona) SPAIN

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Copper sulphate pentahydrate
Name of manufacturer	MANICA S.P.A.
Address of manufacturer	Via all' Adige,4 I-38068 ROVERETO (Trento) - Italy
Location of manufacturing sites	Via all' Adige,4 I-38068 ROVERETO (Trento) - Italy

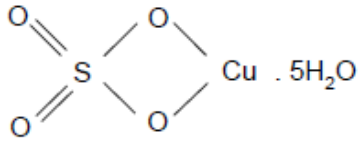
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	No common name, not required by ISO
IUPAC or EC name	Copper sulphate pentahydrate
EC number	231-847-6
CAS number	7758-99-8
Index number in Annex VI of CLP	029-004-00-0
Minimum purity / content	≥99.9 %
Structural formula	

2.1.2.2 Candidate(s) for substitution

There is no indication that copper sulfate pentahydrate would fulfill the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Copper sulphate pentahydrate	Copper sulphate pentahydrate	Active substance	7758-99-8	231-847-6	12.5

Details of the product composition and **information on the co-formulants are confidential** and are presented in the confidential annex.

When "copper sulfate pentahydrate" or "copper sulfate" is written in the dossier, it refers to "copper II sulfate pentahydrate". The active element is cupric ion Cu^{2+} , released from copper sulphate when is in water dissolution, and so all data are refered to copper (Cu) too.

Copper sulfate dissolved in water dissociates into ions and Cu^{2+} ion is the one that actually exerts the biocidal effect. This ion Cu^{2+} may be combined with other anions present in water and coagulate, precipitating with the aid of flocculants, so a greater amount of

copper sulfate would be required to maintain an effective level of free Cu^{2+} ion in water. That is why the formula also contains an equivalent amount of triethanolamine, which has the quelating property of positive ions such as Cu^{2+}, masking the copper and thus prevents its precipitation with flocculants.

Furthermore, Triethanolamine is not classified as hazardous to health or the environment under CLP, so it does not imply greater danger to the mixture

2.1.2.4 Information on technical equivalence

The manufacturing sites for the production of copper sulfate pentahydrate are the same as those evaluated during application for approval for the active substance as biocide (further details in the confidential Annex). Therefore no check for equivalence is necessary.

2.1.2.5 Information on the substance(s) of concern

There are none.

2.1.2.6 Type of formulation

SL - Soluble concentrate

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H318: Causes serious eye damage. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	
Signal words	Danger
Hazard statements	H318: Causes serious eye damage. H410: Very toxic to aquatic life with long lasting effects.

Precautionary statements	P102: Keep out of reach of children P103: Read label before use. Consumer products P273: Avoid release to the environment P391: Collect spillage. Trained professional: P280: Wear protective gloves and eye protection. P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations. Professional/non professional (General public): P501: Remove the content and /or its container as hazardous waste according to the regulations in force.
Note	-

ES has national rules for categories of users. According to this, up to three categories of users could be authorised (trained professional user, professional user and non-professional user). For the Spanish CA, professional users are considered similar to non-professional users. Therefore, exposure assessment and risk characterisation are calculated in the same way for both users, while for trained professional it is different.

2.1.4 Authorised use(s)

2.1.4.1 Authorised use 1

2.1.4.1.1 Use description

Table 1. Use # 1 – Algaecide - Public swimming pools – Trained professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of public swimming pools. The product kills algae and inhibits algae growth.
Target organism (including development stage)	Marine and fresh water algae typical of bathing waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor/Outdoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the pool vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120m^3 of water.
Category(ies) of users	Trained professional user
Pack sizes and packaging material	HDPE Jerry can of 2, 5, 10, 20 L. HDPE Bottle of 0.25, 0.5, 0.75 and 1 L.

2.1.4.1.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.1.3 Use-specific risk mitigation measures

Wear protective gloves and eye protection. After the last treatment with this product, it must pass at least 21 days with purification system connected to empty completely the pool. See section 2.1.5.2.

2.1.4.1.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.1.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.1.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.2 Authorised use 2

2.1.4.2.1 Use description

Table 2. Use # 2 – Algaecide - Private swimming pools – Trained professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of private swimming pools. The product kills algae and inhibits algae growth.
Target organism (including development stage)	Marine and fresh water algae typical of bathing waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor/Outdoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the pool vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation:

	2 L/120 m^3 of water.
Category(ies) of users	Trained professional user
Pack sizes and packaging material	HDPE Jerry can of 2, 5, 10, 20 L. HDPE Bottle of 0.25, 0.5, 0.75 and 1 L.

2.1.4.2.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.2.3 Use-specific risk mitigation measures

Wear protective gloves and eye protection. See section 2.1.5.2.

2.1.4.2.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.2.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.2.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.3 Authorised use 3

2.1.4.3.1 Use description

Table 3. Use # 3 – Algaecide - Private swimming pools –non professional (general public) and Professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of private swimming pools. The product kills algae and inhibits algae growth.
Target organism (including development stage)	Marine and fresh water algae typical of bathing waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor/Outdoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual

	pouring in the pool vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120 m^3 of water.
Category(ies) of users	Non professional (general Public) and Professional user
Pack sizes and packaging material	HDPE Bottle of 0.25, 0.5, 0.75 and 1 L. HDPE Jerry can of 2 and 5 L.

2.1.4.3.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.3.3 Use-specific risk mitigation measures

Packaging with child-resistant fastenings. See section 2.1.5.2.

2.1.4.3.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.3.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.3.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.4 Authorised use 4

2.1.4.4.1 Use description

Table 4. Use # 4 – Algaecide - Spas and hot tubs –Trained professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of spas and hot tubs. The product kills algae and inhibits algae growth
Target organism (including development stage)	Marine and fresh water algae typical of bathing waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor

Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the spa/hot tub vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120 m^3 of water.
Category(ies) of users	Trained professional user
Pack sizes and packaging material	HDPE Jerry can of 2, 5, 10, 20 L. HDPE Bottle of 0.25, 0.5, 0.75 and 1 L.

2.1.4.4.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.4.3 Use-specific risk mitigation measures

Wear protective gloves and eye protection. See section 2.1.5.2.

2.1.4.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.5 Authorised use 5

2.1.4.5.1 Use description

Table 5. Use # 5 – Algaecide - Spas and hot tubs – Non professional (General Public) and Professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of spas and hot tubs.

Target organism (including development stage)	Marine and fresh water algae typical of bathing waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the spa/hot tub vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120 m^3 of water.
Category(ies) of users	Non professional (General Public) and Professional user
Pack sizes and packaging material	HDPE Bottle of 0.25, 0.5, 0.75 and 1 L. HDPE Jerry can of 2 and 5 L.

2.1.4.5.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.5.3 Use-specific risk mitigation measures

Packaging with child-resistant fastenings. See section 2.1.5.2.

2.1.4.5.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.5.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.5.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.6 Authorised use 6

2.1.4.6.1 Use description

Table 6. Use # 6 – Algaecide- Indoor and outdoor Fountains – Trained professional user.

Product Type	PT02 Disinfectants and algaecides not intended for direct

	application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of fountains The product kills algae and inhibits algae growth.
Target organism (including development stage)	Marine and fresh water algae typical of ornamental waters (e.g. green algae (chlorophytes), brown algae (diatoms)
Field of use	Indoor/Outdoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the fountain vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120 m^3 of water.
Category(ies) of users	Trained professional user
Pack sizes and packaging material	HDPE Jerry can of 2, 5, 10, 20 L. HDPE Bottle of 0.25, 0.5, 0.75 and 1 L.

2.1.4.6.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.6.3 Use-specific risk mitigation measures

ONLY for fountains connected to STP (Sewage Treatment Plant) Wear protective gloves and eye protection. See section 2.1.5.2.

2.1.4.6.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.6.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.6.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.4.7 Authorised use 7

2.1.4.7.1 Use description

Table 7. Use # 7 – Algaecide- Indoor Fountains –non professional (General Public) and Professional user

Product Type	PT02 Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of marine or fresh water (diatom and green algae) of fountains The product kills algae and inhibits algae growth.
Target organism (including development stage)	Marine and fresh water algae typical of ornamental waters (e.g. green algae (chlorophytes), brown algae (diatoms).
Field of use	Indoor
Application method(s)	-First: the algaecide is diluted with water in a bucket. -Second: manual or automatic pouring with the pump running, when water treatment circuit is present. Alternatively, manual pouring in the fountain vessel.
Application rate(s) and frequency	- Normal (preventive) dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. - Shock (remedial) dose rate in case of severe infestation: 2 L/120 m^3 of water.
Category(ies) of users	Non professional (General Public) and Professional user
Pack sizes and packaging material	HDPE Bottle of 0.25, 0.5, 0.75 and 1 L. HDPE Jerry can of 2 and 5 L.

2.1.4.7.2 Use-specific instructions for use

See section 2.1.5.1.

2.1.4.7.3 Use-specific risk mitigation measures

Packaging with child-resistant fastenings. See section 2.1.5.2.

2.1.4.7.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 2.1.5.3.

2.1.4.7.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 2.1.5.4.

2.1.4.7.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Please read the instructions before use.

Not to be used in the presence of bathers.

LO-CHLOR POOL ALGAECIDE is a liquid algaecide to control marine and fresh water algae (e.g. green algae, diatoms) in swimming pools, spas and ornamental fountains.

LO-CHLOR POOL ALGAECIDE kills algae and prevents algae growth. The clearance of water in case of visible algae blooms will take up to 2 weeks. The effect of LO-CHLOR POOL ALGAECIDE lasts 3 months.
Severe algae infestations (i.e. visible algae blooms) may be noticed as greenish water, enhanced turbidity, etc. Conditions leading to algae blooms include strong wind and/or storms with high loading of organic material (dust, leaves, pollen, etc.), low disinfectant level, poor maintenance of the water, etc.

LO-CHLOR POOL ALGAECIDE should be used in conjunction with a suitable pool disinfectant for adequate water maintenance. It is not a disinfectant to control microorganisms other than algae (e.g. bacteria, virus, fungi).

DOSES

TREATMENT	USE
Shock dose (remedial) 2 L algaecide/120 m^3 water	- Initial treatment (pool start-up) with greenish water - During the off-season (pool winterization), when maintenance stops - After visible algae blooms (greenish water, turbidity) due to poor maintenance, low disinfectant level, after storms, etc.
Normal dose (preventive) 1 L algaecide/120 m^3 water	- Initial treatment (pool start-up) with clean water - For maintenance, use once every 3 months

INSTRUCTIONS FOR USE

1. Clean the pool/fountain vessel thoroughly and vacuum the walls and floor.
2. Select the treatment type (shock or normal) depending on the use.
3. Calculate the pool/fountain volume as follows:

Volume (m^3) = Length (m) x Breadth (m) x Depth (m)*

*Depth (average) is calculated: shallow end + deep end, divided by 2

Convert the volume in cubic meters (m^3) to litres (L) multiplying by 1,000.

4. Select the dose according to the following table:

Pool Volume (litres of water)	Normal dose (mililitres of algaecide)	Shock dose (mililitres of algaecide)
30,000 L	250 mL	500 mL
60,000 L	500 mL	1,000 mL
90,000 L	750 mL	1,500 mL
120,000 L	1,000 mL	2,000 mL

5. Add the algaecide dose to a bucket with 8-10 L of water to dilute the algaecide.

6. Pour the bucket content into the pool/fountain vessel slowly, preferably through the skimmers[1] and turn on the filter system for 4-5 hours to mix the algaecide properly. In case a filter system is not present, add the bucket water with algaecide evenly around the pool surface.

7. Do not add any other chemicals for at least 24 hours before and after adding LO-CHLOR POOL ALGAECIDE.

8. Keep the water pH from 7.2 to 7.6 and use a suitable water sanitizer.

9. Bathers can use the pool again after complete recirculation of pool water to ensure the total distribution of the product, normally after 4-5 hours.

2.1.5.2 Risk mitigation measures

Do not get in eyes, on skin, or on clothing.

Wash hands thoroughly after use.

Do not eat, drink or smoke when using this product.

Releases of treated water to surface water is not permitted.

Discharge the treated water into the public sewer.Do not use the product over or in the immediate vicinity of surface water

Do not apply near bodies of surface water or in the area of water protection zones.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Likely direct or indirect adverse effects:

- Eye, skin, mucous membrane, respiratory and gastrointestinal tract irritation.
- Nausea, vomiting, metallic taste, epigastric pain, hematemesis and melena.
- Reactions of hypersensitivity and greenish discoloration of hair, teeth, skin and cornea.
- Hypertension, Polyuria, Sialorrhea, Mydriasis, hepatorenal alterations and CNS disturbances.
- Metahaemoglobinemia, haemolysis, circulatory collapse and Shock.

[1] A skimmer is an outlet bin situated at the surface of the swimming pool where floating particles on the water will easily be removed; via the skimmer, the pool water circulates to the pump and filter systems.

First aid measures:

- Relocate the individual from the suspected contamination source and remove any contaminated or spattered clothing.
- In case of direct eye contact: flush with plenty of water and occasionally lifting the upper and lower eyelids. Do **NOT** forget to check for and remove any contact lenses. Continue washing eyes for another 10 to 15 minutes.
- In case of skin reaction, wash with soap and plenty of water, without rubbing. Remove the product from skin folds and from under fingernails.
- In case of ingestion: Wash mouth with plenty of water, do **NOT** give fluids or induce vomiting in case of impaired consciousness; place individual in left sideways (recovery) position with the knees bent.
- Inhalation of large quantities: keep at rest in a half-sitting position and maintain body temperature.
- Contact your local poison control center and seek medical advice if signs and symptoms appear, persist or get worse, if necessary take the individual to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE ALONE THE INTOXICATED IN ANY CASE

Advice for medical and healthcare personnel:

- In case of ingestion, digestive decontamination according to the state of consciousness.
- Ipecac syrup is not advised.
- Evaluate the realization of endoscopic procedure.
- In case of severe metahemoglobinemia, administer 1% Methylene Blue.
- Antidote: EDTA, BAL (Dimercaprol) or D-Penicillamine.
- Laboratory tests: copper control in blood and urine, liver function, renal function, and blood count
- Symptomatic and supportive treatment.

WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER ☎ [*INSERT LOCAL NUMBER HERE*].

2.1.5.4 Instructions for safe disposal of the product and its packaging

For non-professional (General public) and professional.

Do not throw on unpaved floors, in watercourses, in the sink or in the drain.

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Eliminate those wastes in accordance with current regulations.

For trained professional.

Empty containers, unused product, washing water, containers and other waste generated during the treatment are considered hazardous waste. Deliver those wastes to a registered establishment or undertaking, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU. Do not release to soil, ground, surface water or any kind of sewer.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Avoid sources of heat, radiation, static electricity and contact with food. Store only in original container, tightly closed, in a cool, dry place, away from reactive products. For additional information see subsection 10.5 of the BP MSDS The product has a self-life storage stability of at least 2 years under normal conditions.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Bottle	0.25L, 0.5L, 0.75L, 1 L	Plastic: HDPE	Plastic: HDPE	non-professional (general public), professional and trained professional	Yes, product is water based therefore unlikely to have a detrimental effect on the plastic containers
Jerry can	2L, 5L,	Plastic: HDPE	Plastic: HDPE	non-professional (general public), professional and trained professional	Yes, product is water based therefore unlikely to have a detrimental effect on the plastic containers
Jerry can	10L,20L	Plastic: HDPE	Plastic: HDPE	Trained professional	Yes, product is water based therefore unlikely to have a detrimental effect on the plastic containers

Description and safety of the packaging:

- For non-professional (general public) and professional user: opaque HDPE that does not let pass ligth, with childresistant fastenings homologated for ADR transport
- Trained Professional user: opaque HDPE that does not let pass ligth, homologated for ADR transport

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.

The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential Annex.

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:

- a letter of access from MANICA SpA (notifier and having on all the data included in the dossier for Copper sulphate pentahydrate presented by MANICA SpA) to all the documents about the active substance associated to the Annex I listing.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 1: Intended use # 1 – Algaecide in Swimming Pools, etc

Product Type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Algaecide treatment of water (marine or fresh water) of swimming pools, spas, hot tubs, padding pools, ornamental fountains, etc.
Target organism (including development stage)	Common algae in marine or fresh water (diatom and green algae) of swimming pools, spas, hot tubs, padding pools, fountains, etc. (growth inhibition and/or death)
Field of use	Public or private, indoor or outdoor swimming pools, spas, hot tubs, padding pools, fountains, etc.
Application method(s)	Manual dilution of BP directly in the pool vessel (in absence of swimmers) or through automatic dosage in water treatment circuit.
Application rate(s) and frequency	Normal dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months. Dose rate in case of severe infestation: 2 L/120m^3 of water.
Category(ies) of user(s)	Professional, General public (non-professional)
Pack sizes and packaging material	Please see the section 2.1.7.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Líquid	See confidential annex
Colour at 20 °C and 101.3 kPa	Visual	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Dark blue, opaque	See confidential annex
Odour at 20 °C and 101.3 kPa	Olfactory	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Characteristic amine odour, very weak	See confidential annex
Acidity / alkalinity	CIPAC MT 191	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Initially: 3.024 % as NaOH After 14 days at 54ºC: 3.055% as NaOH	See confidential annex
Relative density / bulk density	CIPAC MT 3	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Initially: 1.1367 (or 1.1405) g/mL After 14 days at 54ºC: 1.1351 g/mL After 6 months at 25ºC: 1.1404 g/mL After 12 months at 25ºC: 1.1397 g/mL After 18 months at 25ºC: 1.1415 g/mL After 24 months at 25ºC: 1.1393 g/mL	See confidential annex
Storage stability test – **accelerated storage**	CIPAC MT 46	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Stable for 14 days at 54ºC in glass container *(Properties investigated: appearance, AS content, density, alkalinity, pH, etc.)*	See confidential annex
Active Substance content: - as $CuSO_4.5H_2O$ as Copper (Cu)	CIPAC 44/TC/M/3.2 *(Volumetric Thiosulphate Method)*		Initially: **12.84 % w/w** **3.27 % w/w** After 14 days at 54°C: **12.76 % w/w** **3.24 % w/w** Diference: -0.62% -0.92%	
Homogeneity of application			Not available	
Appearance and stability of the package	Visual		Initially: Dark blue opaque liquid with a very weak characteristic odour After 14 days at 54°C: Dark blue opaque liquid with a very weak characteristic odour	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
pH (100%, at 22.6ºC) pH (1%, at 22.8ºC)	CIPAC MT 75.3		Initially: 7.79 After 14 days at 54°C: 7.79 Initially: 8.02 After 14 days at 54°C: 8.03	
Storage stability test – **long term storage at ambient temperature**	GIFAP monograph 17 (Coprofile 2009)	Lote: 391505 Copper sulphate pentahydrate: 12.59% (3.21% as Cu)	Stable for 24 months at 25ºC in HDPE original container (Properties investigated: appearance, AS content, density, stability, compatibility, pH, dilution stability.)	See confidential annex
Active Substance content: as $CuSO_4.5H_2O$ as Copper (Cu)	CIPAC 44/TC/M/3.2 *(Volumetric Thiosulphate Method)*		Initially: **12.62 % w/w** **3.21 % w/w** After 6 months at 25°C: **12.65 % w/w** **3.22 % w/w** Diference: 0.24% 0.31% After 12 months at 25°C: **12.50 % w/w** **3.18 % w/w** Diference: -0.95% -0.93% After 18 months at 25°C: **11.79 % w/w** **3.00 % w/w** Diference: -6.58% -6.54% After 24 months at 25°C: **11.24 % w/w** **2.86 % w/w** Diference: -10.93% -10.90%	
Homogeneity of application			Not available	
Appearance and stability of the package	Visual		No significant changes in the appearance of the product after 24 months at 25ºC. No significant changes in the container material after 24 months at 25ºC.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
pH (100%) pH (1%, at 22.8ºC)	CIPAC MT 75.3		Initially: 8.15 (at 19.5ºC) After 6 months at 25°C: 8.45 (at 22.1ºC) After 12 months at 25°C: 8.26 (at 22.8ºC) After 18 months at 25°C: 8.06 (at 21.6ºC) After 24 months at 25°C: 8.22 (at 21.5ºC) Initially: 7.90 (at 19.0ºC) After 6 months at 25°C: 8.05 (at 20.7ºC) After 12 months at 25°C: 8.01 (at 21.4ºC) After 18 months at 25°C: 7.82 (at 20.6ºC) After 24 months at 25°C: 7.97 (at 20.9ºC)	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Stable for 7 days at 0ºC in glass container *(Properties investigated: appearance)*	See confidential annex
Appearance and stability of the package	Visual		Initially: Dark blue opaque liquid with a very weak characteristic odour After 7 days at 0°C: Dark blue opaque liquid with a very weak characteristic odour. No phase separation or crystallization is observed	
Effects on content of the AS and/or technical characteristics of the biocidal product - **light**	-	-	Store in a dark place.	See confidential annex
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature**	CIPAC MT 46	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	No significant changes in the AS content after 14 days at 54ºC in glass container	See confidential annex
	CIPAC MT 39.3	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	No significant changes in the appearance after 7 days at 0ºC in glass container	See confidential annex
Effects on content of the AS and/or technical characteristics of the biocidal product – **humidity**	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Effects on content of the active substance and technical	GIFAP monograph 17 (Coprofile	Lote: 391505 Copper sulphate pentahydrate: 12.59%	A thin layer of red solid is observed at the bottom of the package after 12, 18	See confidential annex

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
characteristics of the biocidal product - **reactivity towards container material**	2009)	(3.21% as Cu)	and 24 months at 25ºC.	
Wettability	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Wet sieve analysis and dry sieve test	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Disintegration time	-	-	Not relevant	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Persistent foaming	CIPAC MT 47.2	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	Not foaming before and after accelerated storage *(at use dilution of 1L/60m^3 CIPAC C water: 0 mL foam after 10 s)*	See confidential annex
Flowability/Pourability /Dustability	-	-	Not applicable *(the product is an aqueous solution, SL)*	-
Burning rate — smoke generators	-	-	Not applicable	-
Burning completeness — smoke generators	-	-	Not applicable	-
Composition of smoke — smoke generators	-	-	Not applicable	-
Spraying pattern — aerosols	-	-	Not applicable	See confidential annex
Physical compatibility			Not available	
Chemical compatibility			Not available	See confidential annex
Degree of dissolution and dilution stability	CIPAC MT 41.1	-	Completely soluble and Dilution stable before and after accelerated storage *(at use dilution of 1L/60m^3 CIPAC C water: no separation observed)*	See confidential annex
Surface tension	Ring method EEC A5	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	54.6 mN/m	See confidential annex
Viscosity	CIPAC MT 192 OECD 114	Lote: 021508 Copper sulphate pentahydrate: 12.84% (3.27% as Cu)	5.41 mPa.s @ 20ºC (at 100 rpm)	See confidential annex

Conclusion on the physical, chemical and technical properties of the product

The product LO-CHLOR POOL ALGAECIDE is an aqueous soluble liquid (SL) based on copper sulphate pentahydrate (12.5% w/w pure active, equivalent to 3.27% w/w as Cu) for algaecide treatment of water (marine or fresh water) of swimming pools, spas, hot tubs. It is a dark blue liquid with a very weak characteristic odour, not foaming and very estable to high and low temperature. It has a pH of 7.5-8.5. This product is stable at low-temperature storage (0ºC for 7 days) and at high-temperature accelerate storage conditions (54ºC for 2 weeks), thus a self-life storage stability of at least 2 years is expected.

Furthermore, a long-term storage stability study of 2 years and compatibility with the HDPE original container is submitted to confirm the stability provisional data and would be submitted within 2 years, when finish the study. According to the **stability report at 24 months of storage at room temperature**, the physical and chemical determinations show no difference between the values determined before and after storage test at 25 ± 2 °C for 24 months, and no alteration of the product or the packaging is observed, so it is concluded that the test product is storage **stable** at 25 ± 2 ° C for **at least 24 months**.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Theoretical assessment	-	None of the components of the product are explosive. Therefore, it is safe to assume the product itself will not be explosive.	See confidential annex
Flammable gases	Theoretical assessment	-	The product is water based, therefore it is not expected to release flammable gas.	See confidential annex
Flammable aerosols	-	-	Not applicable	-
Oxidising gases	-	-	Not applicable	-
Gases under pressure	-	-	Not applicable	-
Flammable liquids	Theoretical assessment	-	None of the components of the product are classified as flammable. Therefore, it is safe to assume the product itself will not be flammable.	See confidential annex
Flammable solids	-	-	Not applicable	-
Self-reactive substances and mixtures	-	-	Not applicable	-
Pyrophoric liquids	Theoretical assessment		The product is water based, therefore it is not expected to have pyrophoric properties.	See confidential annex
Pyrophoric solids	-	-	Not applicable	-
Self-heating substances and mixtures	-	-	Not applicable	-
Substances and	Theoretical		The product is water based,	See

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
mixtures which in contact with water emit flammable gases	assessment		therefore it is not expected that in contact with water, release flammable gas.	confidential annex
Oxidising liquids	Theoretical assessment		None of the components of the product are oxidising. Therefore, it is safe to assume the product itself will not be oxidising.	See confidential annex
Oxidising solids	-	-	Not applicable	-
Organic peroxides	-	-	Not applicable	-
Corrosive to metals	-	-	Not applicable	-
Auto-ignition temperatures of products (liquids and gases)	Theoretical assessment		None of the components of the product are self-igniting. Therefore, it safe to assume the product itself will not be selfigniting	See confidential annex
Relative self-ignition temperature for solids	-	-	Not applicable	-
Dust explosion hazard	-	-	Not applicable	-

Conclusion on the physical hazards and respective characteristics of the product
It does not need to be classified regarding physical and chemical hazards as it is not flammable, not oxidising or explosive and does not self-ignite.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specifi-city**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active Substance (as Cu)	CIPAC 44/TC/M/3.2 (*volumetric thiosulfate method*)	20-140% (6 measurements)	y= 0.0014 + 0, 4931 x (R^2 = 0.9999)	Not specific for $CuSO_4.5H_2O$	50-150%	100%	2%		See confidential annex

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for water / ground water /wastewater									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active Substance (as Cu)	US EPA method 220.1, (*AAS*)	n.d.	n.d.	Not specific for $CuSO_4.5H_2O$	0.9–29.7% bias between 7.5 and 332 µg/L	n.d	n.d.	LOQ: 0.2 mg/L LOD: 0.02 mg/L	US-EPA 1983,
Active Substance (as Cu)	US EPA method 220.2, (*AAS/ graphite furnace*)	n.d.	n.d.	Not specific for $CuSO_4.5H_2O$	0.9–29.7% bias between 7.5 and 332 µg/L	n.d.	n.d.	LOQ: 5 µg/L LOD: 1 µg/L	US-EPA 1983,
Active Substance (as Cu)	US EPA method 7210, (*AAS*)	n.d.	n.d.	Not specific for $CuSO_4.5H_2O$	0.9–29.7% bias between 7.5 and 332 µg/L	n.d.	n.d	LOQ: 200 µg/L LOD: 20 µg/L	US-EPA 1986
Active	AOAC oficial	n.d.	n.d.	Not specific for	87-113%	100’3	4.35	LOQ: 200 µg/L	AOAC 1995

Substance (as Cu)	method 993.14 (*IPC-AES*)			$CuSO_4.5H_2O$		%	%	LOD: 0,5 µg/L	
Active Substance (as Cu)	US EPA method 220.8 (*IPC-MS*)	n.d.	n.d.	Not specific for $CuSO_4.5H_2O$	n.d.	n.d.	n.d.	LOQ: not determined LOD: 20 µg/L	EMMI 1997
Active Substance (as Cu)	US EPA method 220.13 (*GFAA*)	n.d.	n.d.	Not specific for $CuSO_4.5H_2O$	n.d.	n.d.	n.d.	LOQ: not determined LOD: 20 µg/L	EMMI 1997
Copper	ICP-AES							LOD: 6 µg/L	CAR (2013)

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active Substance (as Cu)	US EPA method 220.1, (AAS)	n.d	n.d	Not specific for $CuSO_4.5H_2O$	0.9–29.7% bias between 7.5 and 332 µg/L			LOQ: 200 µg/L LOD: 20 µg/L	US-EPA 1983,
Active Substance (as Cu)	US EPA method 7210, (AAS)	n.d	n.d	Not specific for $CuSO_4.5H_2O$	0.9–29.7% bias between 7.5 and 332 µg/L			LOQ: 200 µg/L LOD: 20 µg/L	US-EPA 1986
Active Substance (as Cu)	AOAC oficial method 990.8 (IPC-AES)	n.d	n.d		n.d	n.d	n.d	LOQ: not determined LOD: 6 µg/L (estimated)	AOAC 1995

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Copper	AAS							27 ng/m^3	CAR (2013)
	ICP/OES							1 ng/m^3	

Analytical methods for animal and human body fluids and tisues										
Analyte (type of analyte e.g. active substance)		**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
						Range	Mean	RSD		
Copper	Blood	ICP-AES							LOQ: 1 µg Cu/100 g of blood*	CAR (2013)
	Tissue	ICP-AES							LOD: 0.2 µg Cu/g of tissue*	
	Urine	ICP-AES							LOD: 0.1 µg/50 mL of urine*	

* These values are limit of detection

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Conclusion on the methods for detection and identification of the product

Analytical methods for the analysis of the product as such including the active substance, impurities, residues and monitoring purposes

Principle of method and LOQ:
Copper sulfate pentahydrate content is not directly determined but calculated from total copper content. This is possible because other copper forms (i.e. metallic and cuprous) are not expected to be present in the BP (them aren't present in the thecnical active substance).
Total copper content can be determined by various wellknown methods such as volumetric thiosulphate method (CIPAC E Copper 44/TC/M/3.2). Samples are heated with hydrochloric acid and the copper ions reacts with potassium iodide, and the iodine obtained is volumetrically determined with sodium thiosulfate

Analytical methods for water / ground water /wastewater

Principle of method and LOQ:
Filtering and acid digestion with HNO_3 followed by AAS or ICP-AES method.
Methods based on internationally accepted guidelines:

- For water/wastewater: US EPA method 220.1 and US EPA method 7210 (ASS method, with LOD: 20µg/L for both), US EPA method 220.2 (ASS/graphite furnace technique, with LOD: 1 µg/L), and AOAC method 993.14 (ICP-AES method, LOD: 0,5 µg/L)
- For groundwater, surface water and drinking water: US EPA method 220.8 (IPC-MS method, with LOD: 5 µg/L)
- For marine, estuarine, sea and brines water: US EPA method 220.13 (GFAA method, with LOD: 20 µg/L)

Analytical methods for soil

Principle of method and LOQ:
Acid digestion with HNO_3 followed by AAS or ICP-AES method.
Methods based on internationally accepted guidelines:

- US EPA method 220.1,
- US EPA method 7210 (ASS method, with LOD: 20 µg/L for both)
- AOAC official method 990.8 (ICP-AES method, LOD: 6 µg/L, estimated)

Analytical methods for air

Not required. The product is water based, non-volatile, and is used by manual or authomatic dilution in the pool water, therefore emission of Cu in air is not expected

Analytical methods for animal and human body fluids and tisues

Not relevant as Copper sulfate is not classified as toxic or very toxic
However internationally accepted guidelines are available for the determination of elements in body fluids and tissues (NIOSH methods…): acid digestion followed by ICP-AES analysis, LOD: 1 µg/100g blood, 0.2 µg/g tissue and 0.1 µg/50mL urine

Analytical methods for monitoring of active substances and residues in food and feeding stuff

Not applicable/relevant for that biocidal use (PT 02) because the formulated product is not used for direct application to foods or feedingstuffs or to surfaces and areas where foods or feedingstuffs are prepared or stored.

Conclusions:

Adequate methodology exists for the determination of the active substance, Copper

sulphate pentahydrate (as Cu) in the biocidal product and in swimming pool water.

The CIPAC 44/TC/M/3.2 volumetric thiosulfate method for the determination of copper in the biocidal product and IPC-AES or AAS methods for Cu in water are validated.

Adequate methodologies exist for the determination of the active substance in soil and body fluids and tissues. Validation data are missing for the analytical methods for the determination of the active substance in air. However due to the very low vapour pressure of copper sulfate pentahydrate (inorganic salt) and the fact that the product is not sprayed, an analytical method for air is not required and no further data will be required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

LO-CHLOR POOL ALGAECIDE is a soluble liquid containing copper sulfate pentahydrate (12.5% w/w, equivalent to a content of copper of 3.18% w/w) as active substance. Copper sulfate pentahydrate releases the active ingredient, cupric ion (Cu^{2+}).

The product is an algaecide providing preventive and remedial treatment in public and private bathing, indoors and outdoors, including swimming pools, spas, hot tubs, paddling pools, ornamental fountains.

The product is intended for use by trained professional, non-professional (general public) and professional users.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

LO-CHLOR POOL ALGAECIDE is intended for the control (growth inhibition) and elimination (kill) of marine and fresh water algae.

LO-CHLOR POOL ALGAECIDE protects the water from greenish and prevents the proliferation of other microorganisms.

2.2.5.3 Effects on target organisms, including unacceptable suffering

LO-CHLOR POOL ALGAECIDE is effective against marine and fresh water algae species typical of bathing such as green algae (chlorophytes) and brown algae (diatoms).

LO-CHLOR POOL ALGAECIDE kills algae and inhibits the algae growth.

2.2.5.4 Mode of action, including time delay

When copper sulphate pentahydrate is dissolved in water, it dissociates into ions releasing free cupric ions (Cu^{2+}). Free cupric ion is the active substance that actually exerts the biocidal effect.

The mode of action of cupric ion (Cu^{2+}) towards algae is by complexing of proteins which disrupts normal cell function and results in the inhibition of photosynthesis and other metabolic processes, thus inhibiting algae growth and eventually causing death of the algae.

The cupric ion (Cu^{2+}) may be combined with other anions present in the water and produce different compounds. These may precipitate, with the help of flocculants

(commonly used in pools), and stop the biocidal effect. Organic molecules also trap cupric ions (chelation), thus decreasing copper bioavailability in the water.

LO-CHLOR POOL ALGAECIDE is formulated as copper sulphate pentahydrate with an equivalent amount of triethanolamine, which acts as a chelating agent for cupric ions and thus prevents copper ions precipitation with other compounds. Triethanolamine is a weak chelating agent that allows a slow release of free Cu^{2+} ions to maintain an effective level of free Cu^{2+} ions in the water. This is the basis of the residual effect of LO-CHLOR POOL ALGAECIDE

2.2.5.5 Efficacy data

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Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Algaecide	Bathing	LO-CHLOR POOL ALGAECIDE: 12.5% Copper sulfate pentahydrate (3.18% Cu)	Green algae (*Pseudokirchneriella subcapitata*)	Laboratory ISO 8692:2012	Algae batch in reconstituted culture medium ($1x10^4$ cell/mL) Doses 0.103, 0.207, 0.405, 1.040 and 2.070 µL de PB/L of solution Exposure: 72 h	ErC-50 (72 h) =0.82 µL PB/L (equiv. 36.3 µg Cu/L)	See confidential annex
			Diatomea algae *(Phaeodactylum tricornutum)*	Laboratory ISO 10253:2014	Algae batch in reconstituted culture medium ($1x10^4$ cell/mL) Doses 0.032, 0.065, 0.129, 0.258 and 0.517 µL de PB/L of solution Exposure: 72 h	ErC-50 (72 h) =0.30 µL PB/L (equiv. 4.9 µg Cu/L)	
			Green algae (*Pseudokirchneriella subcapitata*)	Simulated-use OECD TG 201 - ISO 8692:2012	Under normal conditions (23ºC; 14h:10h (L:D); $1x10^4$ cell/mL Doses: low, normal and shock doses (i.e. 4.15, 8.33, and 16.67 µL of PB/L of solution) Exposure: 28 days	Low and normal doses produced 15% of inhibition after 24h, reaching 95% after 21 d and 14 d respectively. High dose produced 89% inhibition after 24 h and 95% after 48h	
					Under worst-case conditions (28ºC; 16h:8h (L:D); $1x10^6$ cell/mL Doses: low, normal and shock doses (i.e. 4.15, 8.33, and 16.67 µL of PB/L of solution)	Low and normal doses produced 3% of inhibition after 24h, reaching 95% after 7 d and 21 d respectively. High dose	

					Exposure: 28 days	produced 13% inhibition after 24 h, reaching 95% after 14d.	
			Diatomea algae *(Phaeodactylum tricornutum)*	Simulated-use ISO 10253:2006	Under normal conditions (23ºC; 14h:10h (L:D); $1x10^4$ cell/mL Doses: low, normal and shock doses (i.e. 4.15, 8.33, and 16.67 µL of PB/L of solution) Exposure: 28 days	High, normal and low doses produced 90%, 86% and 14% of inhibition after 24h, reaching ca. 95% inhibition after 2d, 4d and 7d respectively.	
					Under worst-case conditions (28ºC; 16h:8h (L:D); $1x10^6$ cell/mL Doses: low, normal and shock doses (i.e. 4.15, 8.33, and 16.67 µL of PB/L of solution) Exposure: 28 days	High, normal and low doses produced 26%, 20% and 9% inhibition after 24h, reaching >95% inhibition after 7d, 7d and 28d respectively.	

Conclusion on the efficacy of the product

In laboratory studies, the inhibition of algae growth was studied in two tests. The first test investigated on the algal growth inhibition of LO-CHLOR POOL ALGAECIDE towards the freshwater green algae *Pseudokirchneriella subcapitata* following the guideline ISO 8692:2012 (with $1x10^4$ cells/mL). The 72h-ErC50 was 0.82 µL/L (equivalent to 36.3 µg Cu/L) based on nominal concentrations. The second study tested the growth inhibition of Lo-Chlor towards the marine diatom *Phaeodactylum tricornutum* following the guideline ISO 10253:2014 ($1x10^4$ cells/mL). The 72h-ErC50 was 0.30 µL/L (equivalent to 4.9 µg Cu/L) based on nominal concentrations.

In addition, simulated-use trials were conducted with the same algae species at two different environmental conditions to simulate the situations when the normal and shock doses of the algaecide are recommended to be used. In the normal situation, typically observed in Valencia (Spain) during the summer season, the following conditions were set: photoperiod of 14:10 h (light:dark), 23±1ºC and low initial algal density of $1x10^4$ cells/mL. Under such conditions algae are not visible (i.e. water is not greenish). The recommended normal dose for maintenance is 250 mL LO-CHLOR / 30 m^3 of pool water (8.3 µL/L, equiv. 300 µg Cu/L). In the worst-case situation, the conditions were: photoperiod of 16:8 h (light:dark), 28±1ºC and high initial algal density of $1x10^6$ cells/mL. These correspond to favourable conditions for the development of an algae bloom in pools (i.e. greenish waters). The recommended shock dose for the curative application is 500 mL LO-CHLOR / 30 m^3 of pool water (16.7 µL/L). The eCA noted that a soiling agent was not included in the trials.

The experiments were carried out in 5 L plastic aquaria in triplicate with 3 different treatments (shock, normal, and low dose; i.e. 16.7, 8.3, 4.1 µL/L) and a negative control. For freshwater algae the Bold's Basal Medium (BBM) was added to tap water as growth medium. For marine algae, the ASTM growth medium was used with the synthetic marine water. The optimal pH range was set, i.e. from 7.4 to 7.6. The concentration of free chlorine was kept constant at 1 ppm. The algae biomass was determined at 2, 4, 12, 24, 48, 96 hours, 7, 14, 21 and 28 days. Growth inhibition was estimated by comparing algae densities in systems treated with LO-CHLOR with densities observed in control systems.

The trials with low algae densities of *P. subcapitata* showed that the low and normal doses of LO-CHLOR produced ca. 15% of growth inhibition after 24h, reaching 95% of inhibition after 21 d and 14 d respectively. The shock dose produced 89% inhibition after 24 h and 95% after 48h.

The trials with high algae densities showed 3% inhibition after 24h of exposure to LO-CHLOR with the low and normal doses and 13% inhibition with the shock dose. Inhibition >95% was achieved after 14, 7 and 21 days with shock, normal and low doses respectively.

The trials with low algae densities of *P. tricornutum* showed that the shock, normal and low doses of LO-CHLOR produced 90%, 86% and 14% of growth inhibition after 24h, reaching ca. 95% of inhibition after 2d, 4d and 7d respectively.

The trials with high algae densities showed 26%, 20% and 9% inhibition after 24h of exposure to LO-CHLOR with the shock, normal and low doses. Inhibition >95% was achieved after 7, 7 and 28 days with shock, normal and low doses, respectively. (more information is included in the confidential PAR)

The results show that the three tested doses were effective for inhibition of algal growth,

being faster when the initial algal density was low. The shock and normal doses were faster than the low dose in achieving the reduction of algal density. In addition, the effects towards the marine species run faster than towards the freshwater species.

According to the results, the greenish of waters (high initial density) can be controlled after 4 days in marine water and after 14 days in freshwater.

Moreover, the concentration of free Cu^{2+} in solution at day 0 and day 28 end of the field trials was determined. At the beginning of the trials, concentrations were 153-749 µg Cu/L in freshwater systems and 78-274 µg Cu/L in marine systems. At the end of trials, concentrations 2-6 µg Cu/L and 2-9 µg Cu/L in freshwater and marine systems, respectively, with high initial algal densities. While final concentrations were 1-16 µg Cu/L and 2-11 µg Cu/L with low densities.

Applicant submitted in 2017 a new report on the stability of the product to demonstrate residual efficacy of 3 months claimed on the label. In order to show the stability the former study was continued up to day 90. Copper concentrations measured after 28 days were compared to those measured after 90 days. According to the results, variation in copper concentrations was not related to algal densities or the biocide dose used. Therefore a specific pattern was not detected. Overall Cu concentrations decreased to a higher extent in freshwater algae systems than in marine algae systems.

The eCA notes that in case of visible freshwater algae blooms (high algal density) normal doses led to a higher reduction of Cu concentrations compared to shock doses. Therefore normal doses should not claim a 3-month residual effect but shock doses are protective for a period of 3 months. However, in case of low algae densities, normal doses can keep a similar Cu level at day 90 compared to day 28. Therefore normal doses can claim a 3-month residual effect when they are used at the start-up of the pool when water is initially clean (not greenish). Shock doses should be used at start-up when water is greenish or in case of favourable conditions for algal growth, with residual effect. For marine species both normal and shock doses with low or high algal densities can claim a 3-month residual effect since Cu concentrations do not show a high decrease.

A field study has not being submitted to demonstrate the efficacy of the product in actual conditions of use. The simulated use studies were run in 5-L containers, which could be considered not as representative as a real pool. The evaluation of efficacy by ES CA has been focused on the most significant factors producing an increase in the algae concentration, according to Applicant’s information. The size of the recipient or vessel is not one of the factors contributing to algae blooms. However it is recognized that the size and shape of the container could affect how the product is dispersed through the container and, therefore, the product efficacy. Nevertheless the instructions for use recommend a proper mix of the algaecide with the pool’s water, preferably by the use of the filter system, after application of the product.

The simulated use trials available were conducted with worst-case conditions, i.e. high sunlight intensity, summer season, high temperature, presence of algal growth medium, and high algal density. These conditions coupled with three exposure doses, use of blanks and use of representative species are sufficient to show the efficacy of this algaecide, which does need to prove disinfection (because it is not a sanitizer) but algicidal or algistatic properties.

Overall, the eCA considers the former information from studies acceptable and concludes it demonstrates sufficient efficacy of LO-CHLOR POOL ALGAECIDE under use conditions recommended by the Applicant.

2.2.5.6 Occurrence of resistance and resistance management

Since copper is an essential element required for life, all organisms possess efficient homeostatic control mechanisms for regulating its uptake and elimination. These mechanisms can however become overwhelmed in the presence of excess copper concentrations, resulting in damage to membranes and cell death. This is the principle upon which copper-based biocidal products work.

The eCA conducted a literature search on the possible resistance of algae and cyanobacteria to copper from copper-based biocidal products. Pesticides releasing copper ions as active substance have been used for the protection of crops for years. More recently copper-based biocides have been extended for use as disinfectants and algaecides due to their antimicrobial/antialgal properties. Numerous studies related to copper resistance exist in the literature.

For instance Cervantes & Gutierrez-Corona (1994)[2] reviewed several studies addressing resistance mechanisms to copper in bacteria and fungi. According to this, the presence of high concentrations of cupric ions in the environment promotes the selection of microorganisms possessing genetic determinants for copper resistance. The mechanisms for several types of bacteria and fungi were already found.

In another review, Elguindi et al. (2011)[3] reported that many bacteria have developed a series of copper-resistance mechanisms to survive the adverse environment with high level copper concentrations. An increased number of highly copper-resistant microorganisms have been isolated which show a remarkable resistance to a wide range of metal ions while surviving in mineral-rich environments.

In a study with the cyanobacteria *Microcystis aeruginosa* it was demonstrated that copper-resistant cells arise by spontaneous mutations that occur randomly. Resistant mutants exhibited a diminished fitness in the absence of copper sulphate, but only these variants were able to grow at Cu^{2+} concentrations. Warnings on the long-term consequences of repetitive algaecide treatments in water supplies were suggested (Garcia-Villada et al. 2004[4]).

Stuart et al. (2009)[5] studied the effects of copper shock in marine *Synechococcus* species indicating that some coastal water *Synechococcus* strains may have developed copper tolerance.

In conclusion, resistance of algae and cyanobacteria to copper algaecides has been reported. This would require higher concentrations of copper to be effective. However a

[2] Cervantes, C., Gutierrez-Corona, F. Copper resistance mechanisms in bacteria and fungi. FEMS Microbiol Rev (1994) 14 (2): 121-137.

[3] J. Elguindi, X. Hao, Y. Lin, H. A. Alwathnani, G. Wei, C. Rensing. Advantages and challenges of increased antimicrobial copper use and copper mining. Applied Microbiology and Biotechnology, 91, (2):237–249.2011

[4] L. García-Villada, M. Rico, M. Altamirano, L. Sánchez-Martín, V. López-Rodas, E. Costas. Occurrence of copper resistant mutants in the toxic cyanobacteria *Microcystis aeruginosa*: characterisation and future implications in the use of copper sulphate as algaecide. Water research, 38(8):2207-2213. 2004.

[5] Stuart RK, Dupont CL, Johnson DA, Paulsen IT, Palenik B. Coastal strains of marine *Synechococcus* species exhibit increased tolerance to copper shock and a distinctive transcriptional response relative to those of open-ocean strains. Appl Environ Microbiol 75:5047–5057; 2009.

particular resistance management plan was not found in the literature or in guidelines for the management of pools. This suggests that, even if possible, resistance to copper is not a major concern.

Therefore the eCA recommends:

- the correct use of the algaecide according to the instructions for use.

- the Applicant should monitor resistance on a continuous basis and if he becomes aware of resistance issues these should be reported to the competent authority.

2.2.5.7 Known limitations

The Applicant included in the product label: 'Not be mixed with other chemicals'

The eCA requested the Applicant to submit any information for justification. It should be considered that pool maintenance require a frequent use of other products (e.g. disinfectants, flocculants, pH reducer or enhancer, etc.). Efficacy studies were conducted with chlorine as disinfectant in the tested water vessels. Apparently there was not any limitation observed with simultaneous use of LO-CHLOR POOL ALGAECIDE.

The Applicant submitted a statement indicating the following:

1) LO-CHLOR POOL ALGAECIDE is compatible with surfactants. In fact the a.s. is used in agriculture intensively in combination with surfactants in order to improve wettability of fungicide formulations.
2) According to the a.s. SDS from their supplier, the a.s. is not compatible with strong acids and bases, therefore the Applicant recommends not to store the algaecide close to strong acids and bases.

Cu^{2+} ions may form complexes with substances dissociating into anions such as anionic surfactants and oxidizing agents. These complexes may decrease the efficacy of copper ions. Informal sources of information related to pool maintenance indicate that algaecides with copper sulphate pentahydrate should not be used with water disinfectants containing polyhexamethylene biguanide (PHMB). These disinfectants are strong bases and positively charged cationic biocides which may also remove copper ions from water.

Hence the eCA accepts the sentence included in the product label as a general precautionary advice for users in order to protect the algaecide function.

In addition the Applicant recommended: 'Not be mixed with other chemicals for at least 24 h before and after adding LO-CHLOR POOL ALGAECIDE'. This is to let the algaecide perform its function during the first 24h with no other addition of soiling agent. However as it was shown in studies, efficacy is achieved after several days. Therefore, in addition to the above sentence, the eCA included information on the time required to see the algaecide effects.

2.2.5.8 Evaluation of the label claims

The following label claims were assessed considering laboratory and simulated use efficacy studies:

- LO-CHLOR POOL ALGAECIDE kills & controls black & green algae in swimming pools.

- Normal and shock doses.

- Residual efficacy for 3 months

- Instructions for use

The eCA concluded that the former claims are satisfactory justified with submitted data and information provided by the Applicant upon request by the eCA. Hence they are judged acceptable. Please see the sections on use-specific instructions for use, where acceptable information on the label claim was included by the eCA.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

LO-CHLOR POOL ALGAECIDE is not intended to be authorised for use with other biocidal product(s). However pool maintenance require using an appropriate water disinfectant. This is essential for adequate efficacy of an algaecide. Therefore this information should be included on the product label. Please see the sections on use-specific instructions for use, where acceptable information on the label claim was included by the eCA.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

No acute toxicity studies (for acute oral, dermal, inhalation toxicity, as well as skin and eye irritation and skin sensitisation) have been submitted for the biocidal product.

The classification of the product has been carried out according the classification in Annex VI through the COMMISSION REGULATION (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

Refer to the active substance dossier for each endpoint under the terms of the Letter of Access.

Skin corrosion and irritation

Copper II sulphate pentahydrate is considered to be a weak irritant and does not require classification.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant.
Justification for the value/conclusion	Based on the classification of Copper II sulphate pentahydrate.
Classification of the product according to CLP and DSD	The biocidal product is not classified.

Eye irritation

Copper sulphate pentahydrate is considered to be markedly irritating to the eyes of rabbits; classified as H318: "Causes serious eye damage".

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage

Justification for the value/conclusion	Based on the classification of Copper II sulphate pentahydrate.
Classification of the product according to CLP and DSD	H318: "Causes serious eye damage".

Respiratory tract irritation

No data available, however Copper II sulphate pentahydrate is considered to be a weak irritant therefore does not require classification as irritant to respiratory tract.

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritant to respiratory tract.
Justification for the value/conclusion	Based on the classification of Copper II sulphate pentahydrate and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The biocidal product is not classified.

Skin sensitization

The product is not considered as a dermal sensitizer.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not skin sensitisant.
Justification for the value/conclusion	Based on the classification of Copper II sulphate pentahydrate.
Classification of the product according to CLP and DSD	The biocidal product is not classified.

Respiratory sensitization (ADS)

No data available, however Copper II sulphate pentahydrate is not a dermal sensitiser therefore does not require classification as respiratory sensitiser.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitisant to respiratory tract.
Justification for the value/conclusion	Based on the classification of Copper II sulphate pentahydrate.
Classification of the product according to CLP and DSD	The biocidal product is not classified.

Acute toxicity

Acute toxicity by oral route

The biocidal product contains only one substance, Copper sulphate pentahydrate (12.5% w/w), classified as harmful by the oral route (H302: Harmful if swallowed). Copper sulphate pentahydrate was of moderate toxicity by the oral route and was classified as

Category 4: the LD_{50} for male and female rats combined was 482 mg/kg (Assessment Report, 2013).

Following Regulation 1272/2008, the Acute Toxicity Estimation for a mixture (ATE_{mix}) is calculated according to the formula:

$$\frac{100}{ATE_{mix}} = \sum_{i=1}^{i=n} \frac{C_i}{ATE_i}.$$

where:
C_i = concentration of component i (% w/w o % v/v)
i = individual component, varying i from 1 to n (number of components in mixture)
ATE_i = Acute Toxicity Estimation of component i.
ATE_{mix} = Acute Toxicity Estimation of the mixture.
The acute toxicity estimate (ATE) for the classification of this substance in the mixture is derived using the LD_{50} /LC_{50} where available or the appropriate conversion value from Table 3.1.2. in CLP Regulation.
For Copper sulphate pentahydrate the converted acute toxicity point estimate is 500 (corresponding to 300 < Category 4 ≤ 2000 mg/kg bodyweight).
Hence the ATE of the mixture is determined as follows:

$$\frac{100}{ATE_{mix}} = \frac{12.5\%}{500}; \; ATE_{mix} = 4000$$

Therefore the biocidal product is not classified for acute oral toxicity.

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix} = 4000
Justification for the selected value	Based on the classification of Copper II sulphate pentahydrate and the coformulants and their respective content in the final formulation, according to the addition method of CLP Regulation for mixtures.
Classification of the product according to CLP and DSD	The biocidal product is not classified for acute oral toxicity.

Acute toxicity by inhalation

No inhalation hazard have been indicated for copper II sulphate pentahydrate.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No acute inhalation hazard
Justification for the selected value	Based on the classification of Copper II sulphate pentahydrate and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The biocidal product is not classified for acute inhalation toxicity.

Acute toxicity by dermal route

Copper II sulphate pentahydrate is not classified as acutely toxic by dermal route.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No acute dermal hazard
Justification for the selected value	Based on the classification of Copper II sulphate pentahydrate and the coformulants and their respective content in the final formulation.
Classification of the product according to CLP and DSD	The biocidal product is not classified for acute dermal toxicity.

Information on dermal absorption

No data are available for the biocidal product LO-CHLOR POOL ALGAECIDE.

In CAR it has been agreed to set provisional absorption values of 0.14% and 0.34%, based on the products tested. This value would only apply for active substance approval.

Dermal absorption study of copper in formulated product should be provided at the product authorization level.

According CAR, TMIII08 and WG IV-2015 in the absence of product specific studies, the value of 5% will be used.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Copper Sulphate Pentahydrate
Value(s)	5%
Justification for the selected value(s)	Assessment Report Copper Sulphate Pentahydrate, 2013, TMIII08, WG IV-2015

Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)

Not applicable. The product does not contain any substances of concern.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains only the active substance; Copper Sulphate Pentahydrate .

The CAR of this substance indicate: *"Based on the available data in this dossier, no alert on the endocrine disruption was observed. In the ecotoxicity and toxicity tests with mammals there were no effects in test animals which could be related to possible endocrine disruption".*

Also, according to List compilation exclusion or substitution criteria (Version. January 2019), Copper Sulphate Pentahydrate there id no concern for endocrine disruption.

Assessment of the ED properties of non-active substances (co-formulants):

Regarding *CA-March18-Doc.7.3.b-final* document, the co-formulants have not been assessed or identified for endocrine disruption properties.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided in substance CAR, there is no indication of concern regarding the ED properties of the substances used in the biocidal product LO-CHLOR POOL ALGAECID.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Available toxicological data relating to a mixture

Not applicable. The product does not contain any substances of concern.

Other

Copper is a micronutrient. It is **essential** for life and necessary for all living cells. It is used in many enzyme systems, particularly in energy transfer where the property of electron transfer is exploited in photosynthesis and catabolism. It is involved in the reactions and functions of many enzymes (e.g. amine oxidase, ceruloplasmin, cytochrome-c oxidase...) and in addition, copper is involved in angiogenesis, neurohormoneangiogenesis, neuro-hormone release, oxygen transport and regulation of genetic expression. Copper is present in almost all foods, and some products. Most human diets naturally include between 1 and 2 mg/person/day of copper, with some containing up to 4 mg/person/day.

The copper transport mechanisms in the organism form part of the system of **homeostasis**: the body is able to maintain a balance of dietary copper intake and excretion that allows normal physiological processes to take place. The relationship between copper concentration and observed effects show a flattened 'U'-shaped dose-response curve. The left side of the 'U' curve represents deficiency, where intake of copper is less than required. This can lead to lethality, especially in children, where copper is essential for growth. Copper deficiency is associated with growth retardation, anemia, skin lesions, impaired immunity, intestinal atrophy, impaired cardiac function, reproductive disturbance, neurological defects and skeletal lesions. Copper is essential for normal physiological function such as cellular respiration, free radical defence, synthesis of melanin, connective tissue, iron metabolism, regulation of gene expression, and normal function of the heart, brain and immune system. The central near-horizontal part of the 'U' curve represents homeostasis, where intake and excretion are balanced and copper level is in a normal range. The right-hand part of the 'U' represents toxicity or excess copper disease. Chronic copper toxicity is extremely rare, and the upper limit of homeostasis has never been strictly defined.

The active substance released from copper sulphate pentahydrate is the cupric ion, and all the evaluations are refered to Cu.

2.2.6.2 Exposure assessment

LO-CHLOR POOL ALGAECIDE is a liquid product containing 12.5% w/w $CuSO_4.5H_2O$ (as copper quelated with triethanolamine) whose approval is sought for PT02 uses for the algaecide treatment of water (marine or fresh water) of swimming pools, spas, hot tubs, , fountains. The normal dose rate is 1L product/120 m^3 of water, initially and every 3 months, and 2L product/120m^3 of water in case of severe infestation.

1L of LO-CHLOR POOL ALGAECIDE contains 142 g of $CuSO_4.5H_2O$ or 35.5g of Cu^{2+}, (relative density is 1.1367 g/mL). The maximum application rate is then 2.37 mg $CuSO_4.5H_2O$ /L of water (approx. 0.59 mg Cu/L of pool water).

The product is intended for trained professional, professional and non-professional use (the general public).

The assessment presented here focuses on the use as swimming pool disinfectant which is believed to be the worst case for exposure and risk assessment purposes in terms of amount of product used and population exposed considering primary and secondary routes of exposure to the product.

There are not substances of concern.

Relevant exposure routes of LO-CHLOR POOL ALGAECIDE to humans for the control of algal growth in swimming pools are described in the following.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure to $CuSO_4 \cdot 5H_2O$							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Trained professional use	**Professional use**	**Non-professional use*** **(General public)**	**Trained professional use**	**Professional use**	**Non-professional use*** **(General public)**	**Via food**
Inhalation[1]	No	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	Yes	Yes	Yes	No
Oral	No	No	No	Yes	Yes	Yes	No

* *To Spanish CA, professional users are considered similar to non-professional users. Therefore, exposure assessment and risk characterisation are calculated in the same way for both users.*

[1] *The product is an inorganic salt in solution therefore non-volatile. Exposure via inhalation route is not expected in any of these exposure scenario. There could be exposure via inhalation route to the solid product (copper sulphate pentahydrate) for the Industrial use during the manufacture of the biocidal product. However, the exposure during the production of the biocidal product is not assessed by the rapporteur under the requirements of the BPR. The rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations..*

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Mixing and loading	Primary exposure: loading the product into a bucket and dilution with water.	Trained Professional, Non-professional
2.	Application	Primary exposure: addtion of algaecide diluted with water into a skimmer or the pool.	Trained Professional, Non-professional
3.	Post application: maintenance	Primary exposure: maintenance and testing of the pool water.	Trained Professional, Non-professional

4.	Swimming / bathing indirect exposure	Secondary exposure: Contact to treated water during swimming / bathing, including swallowing.	Bystanders [General public]: Baby Child Adult

Trained professional exposure

Scenario [1] Mix and Load: pouring product into a bucket

Description of Scenario [1]
The scenario describes a trained professional user who pours the required amount of concentrate product from a jerry can of 10 L or 20 L to a bucket to dilute it 10 times with water; this previous dilution of the product facilitates its correct dosage. Therefore, it is not advisable to pour the produc directly into the swimming pool, spa, fountain, etc. since it could lead to an inadequate dosage. The instructions for use of LO-CHLOR POOL ALGAECIDE indicates that the normal dose rate is 1L product/120 m^3 of water, initially and every 3 months, and 2L product/120 m^3 (approx.. 0.6 mg Cu/L of pool water) in case of severe infestation. The maximum dose will be used to estimate the exposure. This task is carried out with a frequency of once a day, 5 days a week; that is 240 times/year. Taking into account that the frequency of use of the product set on its label (once every 3 months and when there is severe infestation) it is assumed that 6 BP additions a year are performed in each installation and hence means that the same operator is carrying over 40 pools (this assumption could be unrealistic because of excessive, but it is taken a priori as a worst case). During mixing and loading a liquid, dermal exposure could occur. On one hand, this is due to liquid spills around the opening of the bottle, which depends on the size of the opening and the way a product is used; on the other hand, when mixing and loading an algaecide product into water, there could be spatters of the liquid concentrate on the skin. Dermal exposure during mixing and loading of biocides for indoor use will almost always be restricted to the hands. Only dermal exposure is considered, because copper sulphate pentahydrate is an inorganic salt non-volatile and it is assumed that users are trained and use the products with care following the instructions and cautions indicated on the label, so inhalation and oral contamination are assumed negligibles. According to the HEEG Opinion 3 (agreed in TM II 08) ConsExpo models allows the adaptation of the default values to assess exposure of trained professional users. This is possible when the following premises are considered: trained professionals are likely to use products for longer periods and more frequently than consumers/non-professionals (240 times/year vs 28 times/year), they use higher capacity containers (10L or 20 L vs 5L or less), they can use PPE (non-professionals can not do it) and trained professionals will be more likely to obey label instructions and apply the product more carefully. Therefore ConsExpo Disinfectant Products Fact Sheet (RIVM report 320005003/2006, Swimming pool disinfectants, p 47), is used to assess the exposure of trained professionals during the use of Lo-Chlor Pool Algaecide:

- According to this Fact Sheet the Mix and Load Model 4 (UK POEM) in TNsG 2002 part 2, p 136 describes the pouring of fluid from a container into a receiving vessel. For containers of unspecified design and 10L or 20L of volume exposure is limited to the hands and expressed as 0.5 mL of in-use product per operation as 75th value.
- It is assumed that a private swimming pool measures 8 m x 4 m x 1.5 m, which gives a water surface area of 32 m^2 and a volume of 48 m^3. So the amount of product required to treat the 48 m^3 volume swimming pool is then 0.8L (48m^3 x 2L/120m^3).
- It is assumed that a competitive swimming pool measures 25 m (length) x 15 m (width) x 1.5 m (depth) i.e. a water surface of 375 m^2 and a water volume of 562 m^3. So the amount of product required to treat the 562 m^3 volume swimming pool is then 9.4L (562m^3 x 2L/120m^3).

	Parameters	**Value**
	Content of ($CuSO_4.5H_2O$)in the product	12.5% w/w
	Content of Copper in the ($CuSO_4.5H_2O$)*	25%
	Amount of product required (private pool)[a]	0.8L product
	Amount of product required (competitive pool)	9.4L product
	Dermal contamination[b]	0.5 mL
	Dermal contamination (product)[c]	0.57g
	Area of both hands (palms+backs)[d]	820 cm^2
	Dermal absorption	5%
	Body weight[d]	60 kg
Tier 1	Penetration without PPE (gloves)[e]	100%
Tier 2	Penetration with PPE (gloves)[e]	10%

**This value is given by the ratio between molecular weights (0.25= MW Cu/ MW $CuSO_4.5H_2O$)*
a) Swimming pool siz: see RIVM report 320005003/2006 Desinfectant Products Fact Sheet, p48 and p90
b) Mixing and loading Model 4 TNsG 2002, part 2, p 136; UK POEM (10L-20L container)
c) Density product 1.1367g/mL. Hence: (0.5ml)x(1.1367g/ml) = 0.57g
d) Recommendation no. 14 of BPC Ad hoc WG-HE
e) HEEG Opinion 9, p 4 (agreed in TM I 2010)

Calculations for Scenario [1]

See calculations in Annex 3.2.

Summary table: estimated exposure for non-professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] (Private pool)	Tier 1/ None	-	$1.47x10^{-2}$	-	$1.47x10^{-2}$
	Tier 2/ Gloves	-	$1.47x10^{-3}$	-	$1.47x10^{-3}$
Scenario [1] (Competitive)	Tier 1/ None	-	$1.47x10^{-1}$	-	$1.47x10^{-1}$
	Tier 2/ Gloves	-	$1.47x10^{-2}$	-	$1.47x10^{-2}$

Further information and considerations on scenario [1]

It is considered that approximately 10 times more product is used in a competition pool than in a private pool. Therefore it is assumed that in a competition pool the procedure is repeated 10 times and consequently the estimated exposure is 10 times higher.

Scenario [2] Application: pouring diluted product from bucket into the pool

Description of Scenario [2] (Trained professional)

The product previously diluted as described in scenario 1, is poured by a trained professional from a 10 L bucket into the pool.

The criteria (dose, frequency, model, etc.) considered in scenario 1 are still valid here, with the only exception that in this scenario 2 the product is diluted and therefore the weight fraction of the 1/10 dilution is 1.25%, assuming that density of the diluted solution is 1 g/cm^3.

The distribution of the diluted liquid with a bucket can be more or less compared to emptying a volume container (10 L) of unspecified design during "mixing and loading", which is described in the model UK POEM. The contamination of emptying a 10 L container is 0.5 ml per operation. In this case, the contamination is set at 0.5 g of diluted formulation (density 1 g/cm^3) during emptying the bucket (see ConsExpo Disinfectant Products Fact Sheet, RIVM report 320005003/2006, Swimming pool disinfectants, p 47)

	Parameters	**Value**
	Content of ($CuSO_4.5H_2O$)in the solution	1.25% w/w
	Content of Copper in the ($CuSO_4.5H_2O$)*	25%
	Amount of product required (private pool[a])	0.8L product
	Amount of product required (competitive pool[a])	9.4L product
	Dermal contamination[b]	0.5 mL
	Dermal contamination (solution)[c]	0.5 g
	Area of both hands (palms+backs) and forearms[d]	1948.8 cm^2
	Dermal absorption	5%
	Body weight[d]	60 kg
Tier 1	Penetration without PPE (gloves)[e]	100%
Tier 2	Penetration with PPE (gloves)[e]	10%

**This value is given by the ratio between molecular weights (0.25= MW Cu/ MW $CuSO_4.5H_2O$)*
a) Swimming pool size: see RIVM report 320005003/2006 Desinfectant Products Fact Sheet, p48 and p90
b) Mixing and loading Model 4 TNsG 2002, part 2, p 136; UK POEM (10L-20L container)
c) Density solution 1g/mL. Hence: (0.5ml)x(1g/ml) = 0.5g
d) Recommendation no. 14 of BPC Ad hoc WG-HE and RIVM report 320005003/2006, Swimming pool disinfectants, p 50
e) HEEG Opinion 9, p 4 (agreed in TM I 2010)

Calculations for Scenario [2]

See calculations in Annex 3.2.

Summary table: estimated exposure for trained professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2] (Private pool)	Tier 1/ None	-	$1.3x10^{-3}$	-	$1.3x10^{-3}$
	Tier 2/ Gloves	-	$1.3x10^{-4}$	-	$1.3x10^{-4}$
Scenario [2] (Competitive)	Tier 1/ None	-	$1.3x10^{-2}$	-	$1.3x10^{-2}$
	Tier 2/ Gloves	-	$1.3x10^{-3}$	-	$1.3x10^{-3}$

Further information and considerations on scenario [2]

It is considered that approximately 10 times more product is used in a competition pool than in a private pool. Therefore it is assumed that in a competition pool the procedure is repeated 10 times and consequently the estimated exposure is 10 times higher.

Scenario [3] Postapplication: exposure via dermal route during maintenance and testing of treated pool water.

Description of Scenario [3] (Trained professional)		
This exposure scenario considers an operator during the maintenance of the water delivery systems within a swimming pool facility (private or public) who dips his hands (or hands and forearms) into the treated water for i.e., checking water pH balance/Cu^{2+} content. In general, exposure is limited to dermal contact of hands/forearms. Hand-to-mouth contact is excluded for trained professional users. Directions for use indicate a maximum application rate of 2 L product /120 m^3 of water, which corresponds to 0.59 mg Cu/L water (i.e. $0.59x10^{-3}$ mg Cu /cm^3 water). Based on the HEEG opinion No. 16 (Biocidal products: model for dipping of hands/forearms in a diluted solution) it is assumed that not the total amount of water in the corresponding reservoir is in contact with the skin but only a layer of 0.01 cm around the exposed skin (hands 820 cm^2 and forearms 1128.8 cm^2).		
	Parameters	**Value**
	Max. concentration of Copper in the pool water	0.59 mg Cu/ L water
	Exposed skin [$A_{(hands\ palms+backs)} + A_{forearms}$]*	1948.8 cm^2
	Thickness of liquid layer on skin*	0.01 cm
	Dermal absorption	5%
	Body weight	60 kg
Tier 1	Penetration without PPE (gloves)	100%
Tier 2	Penetration with PPE (gloves)	10%

** See HEEG Opinion no. 16*

Calculations for Scenario [3]

Systemic dermal exposure = [Exposed skin x layer thickness x concentration as Cu in water x dermal absorption] / body weight

= [(820 + 1128.8) cm^2 x 0.01 cm x 0.59x10^{-3} mg Cu/cm^3 x 5%]/60 kg

= 9.75 x 10^{-6} mg Cu/kg bw/d

Summary table: estimated exposure for trained professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1/ None	-	9.75 x 10^{-6}	-	9.75 x 10^{-6}
	Tier 2 /gloves	-	9.75 x 10^{-7}	-	9.75 x 10^{-7}

Further information and considerations on scenario [3]

None

Combined scenarios

Summary table: combined systemic exposure for trained professional expressed as mg Cu /kg bw [d]				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Private pools				
Scenarios [1+2+3] Tier 1	-	0.016	-	0.016
Scenarios [1+2+3] Tier 2	-	0.0016	-	0.0016
Competitive pools				
Scenarios [1+2+3] Tier 1	-	0.16	-	0.16
Scenarios [1+2+3] Tier 2	-	0.016	-	0.016

Non-professional exposure

Note: To Spanish CA, professional users are considered similar to non-professional users. Therefore, exposure assessment and risk characterisation are calculated in the same way for both users. Likewise, we consider that this type of users will only use the product for the maintenance of private pools.

Scenario [1] Mix and Load: pouring product into a bucket

Description of Scenario [1] (Non-professional)
ConsExpo Disinfectant Products Fact Sheet (RIVM report 320005003/2006, swimming pool disinfectant), is used to assess the exposure of consumers during the use of LO-CHLOR POOL ALGAECIDE. According to this, only dermal exposure is expected. The scenario describes a private user who is sanitizing an outdoor pool of 48 m^3 every 5

days for a period of 4 months (ConsExpo assumes that a private pool measures 8m x 4m x 1.5m, which gives a water surface area of 32 m^2 and a volume of 48 m^3). To prevent algae growth the private user pours the required amount of formulation in a bucket and dilutes it with water (dilution 1/10); subsequently (scenario 2), the user will distribute the dilution evenly around the pool surface during 5 minutes.

The instructions for use of LO-CHLOR POOL ALGAECIDE indicates that the normal dose rate is 1L product/120 m^3 of water, initially and every 3 months, and 2L product/120m^3 of water in case of severe infestation.

The maximum dose is used to estimate the exposure of consumers. The amount of liquid required to treat the 48 m^3 volume swimming pool is then 0.8L (48m^3 x 2L/120m^3). The weight fraction of $CuSO_4.5H_2O$ in the product is 12.5% w/w.

Only dermal exposure is expected, as inorganic salts are not volatile. Dermal exposure during mixing and loading of biocides for indoor use will almost always be restricted to hands/forearms. For dermal exposure of amateurs Mix and Load Model 4 (UK POEM), TNsG part 2, p 136 is used to address exposure following Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure, v3. Although the amount of product needed to treat a private pool is 0.8 L (approximately 1 L), it is considered that the maximum size of container authorized for non-professional users is 5 L. Hence for a container of 5 L and unspecified design the exposure contamination is 0.2 ml, expressed as in-use product per operation as 75th value.

For exposure assessment purposes the exposure frequency of ConsExpo model will be considered here (every 5 days for a period of 4 months, i.e. 28 times per year), hence medium term exposure is assumed.

ConsExpo web model is used for calculations.

Tier 1	**Parameters**	**Value**
	Content of ($CuSO_4.5H_2O$) in the product	12.5% w/w
	Content of Copper in the ($CuSO_4.5H_2O$)*	25%
	Amount of product required[a]	0.8L product
	Dermal contamination[b]	0.2 mL
	Dermal contamination (product)[b]	0.23 g
	Area of hands (palms+backs)[c]	820 cm^2
	Dermal absorption	5%
	Body weight[c]	60 kg

[*] This value is given by the ratio between molecular weights (0.25= MW Cu/ MW $CuSO_4.5H_2O$)
[a] RIVM Report 320005003 Disinfectant Fact Sheet, pp 48 (0.8L product is the amount required to sanitize a 48m^3 pool considering the instructions for use of 2L product/120 m^3 of water)
[b] Mixing and loading Model 4 TNsG part 2, p 136; UK POEM (1L container of unspecified design); density product 1.1367g/mL
[c] Recommendation no. 14

Calculations for Scenario [1]

See calculations in Annex 3.2.

Summary table: estimated exposure for non-professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1/ None	-	6.0×10^{-3}	-	6.0×10^{-3}

Further information and considerations on scenario [1]

None.

***Scenario [2] Application: pouring diluted product from 10 L bucket into the pool*Description of Scenario [2] (Non-professional)**

The product previously diluted as described in scenario 1, is poured by a non-professional user from a 10 L bucket into the pool.

The criteria (dose, frequency, model, etc.) considered in scenario [1] are still valid here, with some exceptions:

- In this scenario [2] the product is diluted and therefore the weight fraction of the 1/10 dilution is 1.25%, assuming that density of the diluted solution is 1 g/cm^3.
- The distribution of the diluted liquid with a bucket can be more or less compared to emptying a volume container (10 L) of unspecified design during "mixing and loading", which is described in the model UK POEM. The contamination of emptying a 10 L container is 0.5 ml per operation. In this case, the contamination is set at 0.5 g of diluted formulation (density 1 g/cm^3) during emptying the bucket (see ConsExpo Disinfectant Products Fact Sheet, RIVM report 320005003/2006, Swimming pool disinfectants, p 47)

Exposure is estimated using ConsExpo web model.

	Parameters	**Value**
	Content of ($CuSO_4.5H_2O$)in the solution	1.25% w/w
	Content of Copper in the ($CuSO_4.5H_2O$)*	25%
	Amount of product required (private pool[a])	0.8L product
	Dermal contamination (solution)[b]	0.5 mL
	Dermal contamination (solution)[c]	0.5 g
	Area of both hands (palms+backs) and forearms[d]	1948.8 cm^2
	Dermal absorption	5%
	Body weight[d]	60 kg
Tier 1	Penetration without PPE[e]	100%

This value is given by the ratio between molecular weights (0.25= MW Cu/ MW $CuSO_4.5H_2O$)
a) Swimming pool size: see RIVM report 320005003/2006 Desinfectant Products Fact Sheet, p48 and p90
b) Mixing and loading Model 4 TNsG 2002, part 2, p 136; UK POEM (10L-20L container)
c) Density solution 1g/mL. Hence: (0.5ml)x(1g/ml) = 0.5g
d) Recommendation no. 14 of BPC Ad hoc WG-HE and RIVM report 320005003/2006, Swimming pool disinfectants, p 50
e) HEEG Opinion 9, p 4 (agreed in TM I 2010)

Calculations for Scenario [2]

See calculations in Annex 3.2.

Summary table: estimated exposure for non-professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1/ None	-	1.3×10^{-3}	-	1.3×10^{-3}

Further information and considerations on scenario [2]

None.

Scenario [3] Postapplication: exposure during maintenance and testing of treated pool water.

Description of Scenario [3] (Non-professional)
This exposure scenario considers an operator during the maintenance of the water delivery systems within a swimming pool facility (private or public) who dips his hands (or hands and forearms) into the treated water for i.e., checking water pH balance/Cu^{2+} content. In general, exposure is limited to dermal contact of hands/forearms. However, in this scenario it cannot be generally excluded that non-professional users has hand-to-mouth contact. It is assumed that an amount comparable to the external dermal load on hands is ingested orally from the finger tips (10 % Transfer coefficient hand-to-mouth, worst case, based on expert judgement). A correction for reduction of the dermal load by oral ingestion was not performed. Note: the biocidal product has no aversive taste.
Directions for use indicate a maximum application rate of 2 L product /120 m^3 of water, which corresponds to 0.59 mg Cu/L water (i.e. 0.59×10^{-3} mg Cu /cm^3 water).
Based on the HEEG opinion No. 16 (Biocidal products: model for dipping of hands/forearms in a diluted solution) it is assumed that not the total amount of water in the corresponding reservoir is in contact with the skin but only a layer of 0.01 cm around the exposed skin (hands 820 cm^2 and forearms 1128.8 cm^2).

Tier 1	**Parameters**	**Value**
	Max. concentration of Copper in the pool water	0.59 mg Cu/ L water
	Exposed skin [$A_{(\text{hands palms+backs})} + A_{\text{forearms}}$]*	1948.8 cm^2
	Thickness of liquid layer on skin*	0.01 cm
	Dermal absorption	5%
	Oral absorption	36%
	Penetration without PPE	100%
	Body weight	60 kg

** See HEEG Opinion 16 and Recommendation no. 14.*

Calculations for Scenario [3]

Systemic dermal exposure = [Exposed skin x layer thickness x concentration as Cu in water x dermal absorption] / body weight

= [(820 + 1128.8) cm^2 x 0.01 cm x $0.59x10^{-3}$ mg Cu/cm^3 x 5%]/60 kg

= 9.75×10^{-6} mg Cu/kg bw/d

Systemic oral exposure = [Hands skin x layer thickness x concentration as Cu in water x transfer coefficient x oral absorption] / body weight

= [820 cm^2 x 0.01 cm x $0.59x10^{-3}$ mg Cu/cm^3 x 10% x 36%]/60 kg

= 2.9×10^{-6} mg Cu/kg bw/d

Total systemic exposure = (9.75×10^{-6} + 2.9×10^{-6}) = 1.24×10^{-5} mg Cu/kg bw/d

Summary table: estimated exposure for non-professionals expressed as mg Cu /kg bw [d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1/ None	-	$9.75x10^{-6}$	$2.9x10^{-6}$	$1.24x10^{-5}$

Further information and considerations on scenario [3]

None

Combined scenarios

Summary table: combined systemic exposure for non-professional, expressed as mg Cu /kg bw [d]				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1+2+3] Tier 1	-	7.3×10^{-3}	$2.9x10^{-6}$	7.3×10^{-3}

Exposure of the general public (Secondary exposure)

Note: In the exposure assessment of all secondary scenarios has been used the maxim dose rate of BP recommended in case of severe algae growth, 2 L/120 m^3 water, as worst case.

Scenario [4] Indirect exposure for the General public by swimming / bathering.

Description of Scenario [4] (General public: infant, child, adult)
Swimming pool users will primarily be exposed to Cu^{2+} while swimming via dermal contact and by incidental swallowing of treated water. The potential for exposure via inhalation, although identified as a potential route, has not been modelled because inorganic products are assumed to be non-volatile due to their salt character. In addition, the amount, which would be systemically available via the inhalation of aerosols is considered small compared to the amount available via the dermal and oral route.

Exposure is assessed for adults, children and infants mainly based on parameters proposed in the Consexpo Disinfectant Products Fact Sheet 2006(RIVM report 320005003 page 54 and 87). It is expected that infants swims for 30 min whereas for children 60 min are expected. For adults a swimming time of 120 min is applied for exposure assessment representing competitive swimmers as a worst case. The amount of water ingested orally is 500 mL/h for infants and children (equivalent to 8300 mg/min) and 50 mL/h for adults (equivalent to 830 mg/min).

In accordance to the document Technical Agreements for Biocides (august 2017, p 58), it is assumed for dermal exposure, that not the total amount of water in the corresponding reservoir is in contact with the skin but only a layer of 0.1 cm around the exposed skin (body surface, e.g. for adults 16600 cm^2).

Exposed area: The exposed area is the body surface area; for adults is 16600 cm^2 and for children (6 to <12 years) is 9200 cm^2, (Recommendation no. 14)

Weight fraction: the weight fraction is the calculated weight fraction of the active substance in the swimming pool water. According to the applicant with a maximum application rate of 2.37g/m^3 of $CuSO_4.5H_2O$, the weight fraction is 0.0002% $CuSO_4.5H_2O$ (expressed as Cu^{2+} is 0.59 mg Cu^{2+}/L water and the corresponding weight fraction is 0.000059%)

Oral absorption for $CuSO_4.5H_2O$ is 36% and Dermal absorption is 5%.

For risk assessment purposes chronic exposure is assumed.

Tier 1	**Parameters**	**Value**
	Application rate of product	0.59 mg Cu^{2+} / L
	Weight fraction product	0.000059% Cu^{2+}
	Frequency[a] (Times a year)	Adult competitive 260 Adult 52 Child 104 Baby 13
	Exposure duration[a]	Adult competitive 120 min Adult 60 min Child 60 min Baby 30 min
	Body weight[b]	Adult 60 kg Child 23.9 kg Baby[a] 6.21 kg
	Body surface area[b]	Adult 16600 cm^2 Child 9200 cm^2 Baby[a] 4100 cm^2
	Thickness of water pool layer on skin	0.1 cm
	Density of pool water (liquid)	1 g/cm^3
	Liquid amount in contact with the skin	Adult 1660 g Children 920 g Baby 410 g
	Ingestion rate[a] (water pool)	Adult 830 mg/min Child and Baby 8300 mg/min
	Oral absorption[c]	36%

	Dermal absorption[c]	5%

*

[a] *RIVM Report 320005003 Disinfectant Fact Sheet, p.54 and 87*
[b] *Recommendation nº 14 (children age 6 to < 12 years)*
[c] *Assessment Report $CuSO_4.5H_2O$, 2013*
Note: all default values for Baby(4.5 months) come from RIVM Report 320005003 Disinfectant Fact Sheet

Calculations for Scenario [4]

Systemic dermal exposure = body surface x layer thickness x density x concentration a.s. as Cu^{2+} in water x dermal absorption / body weight

Systemic oral exposure = ingested rate of water x exposure duration x concentration a.s. as Cu in water x oral absorption / body weight

COMPETITIVE SWIMMER ADULT

S. dermal expure = (16600 cm^2 x 0.1cm x 1 g/cm^3 x 0.000059% x 5%)/ 60 =

$8.16x10^{-7}$ g/kg bw/d = $8.16x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

S. oral exposure = (830 mg/min x 120 min x 0.000059% x 36%)/ 60 =

$3.52x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

Total systemic exposure =$1.17x10^{-3}$ mg/kg bw/d expressed as Cu^{2+}

ADULT

S. dermal expure = (16600 cm^2 x 0.1cm x 1 g/cm^3 x 0.000059% x 5%)/ 60 =

$8.16x10^{-7}$ g/kg bw/d = $8.16x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

S. oral exposure = (830 mg/min x 60 min x 0.000059% x 36%)/ 60 =

$1.76x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

Total systemic exposure =$9.92x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

CHILD

S. dermal expure = (9200 cm^2 x 0.1cm x 1 g/cm^3 x 0.000059% x 5%)/ 60 =

$4x10^{-7}$ g/kg bw/d = $4x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

S. oral exposure = (8300 mg/min x 60 min x 0.000059% x 36%)/ 60 =

$1.76x10^{-3}$ mg/kg bw/d expressed as Cu^{2+}

Total systemic exposure =$2.16x10^{-3}$ mg/kg bw/d expressed as Cu^{2+}

BABY

S. dermal expure = (4100 cm^2 x 0.1cm x 1 g/cm^3 x 0.000059% x 5%)/ 60 =

$2x10^{-7}$ g/kg bw/d = $2x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

S. oral exposure = (8300 mg/min x 30 min x 0.000059% x 36%)/ 60 =

$8.81x10^{-4}$ mg/kg bw/d expressed as Cu^{2+}

Total systemic exposure =$1.08x10^{-3}$ mg/kg bw/d expressed as Cu^{2+}

Summary table: estimated exposure for the general public expressed as mg Cu /kg bw [d]

Exposure scenario (4)	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Competitive Adult	Tier 1/ None	-	8.16E-04	3.52E-04	1.17E-03
Adult	Tier 1/ None	-	8.16E-04	1.76E-04	9.92E-04
Child	Tier 1/ None	-	4E-04	1.76E-03	2.16E-03
Baby	Tier 1/ None	-	2E-04	8.81E-04	1.08E-03

*

Further information and considerations on scenario [4]

Humans are exposed to copper primarily from dietary sources (mainly via food, but also via drinking water) so that the highest uptake rates of copper absorption occurs in the Gl tract and very little percutaneous absorption occurs. The dermal availability of diluted solutions of inorganic Copper is very low (Assessment Report $CuSO_4.5H_2O$, 2013).

Note, some of the parameters of the RIVM report 320005003 are modified according to the values of the current Recommendations, HEEG opinions and TAB criteria.

In this sense, RIVM report 320005003 assumes that only a layer of swim water of 1 cm around the body is in contact with the skin during swimming in treated pools. This parameter is assigned a Q factor =1 which indicates that this value is based on insufficient (or no) data. This value of 1 cm, as given in the ConsExpo Disinfectant Fact Sheet, is considered overly conservative. The thickness of the product layer on the skin is assumed to be 0.1 cm for liquids (Technical Agreement for Biocidal, august 2017, p 58) We also use the parameters established in the RIV for baby swimming because they have no equivalent in any Recommendations or HEEG Opinions.

Total combined scenarios

The combined exposure for trained professional and non-professional users of Lo-Chlor Pool Algaecide considering the use of the product as swimming pool disinfectant and the indirect exposure resulting from swimming in treated swimming pool is shown below.
As worst case, it is assumed that all these scenarios will take place at once and will repeat regularly. Thus, long-term exposure is expected.
Note (*): we assume that the trained professional who is in charge of the product's application and maintenance of the competition pool, is at the same time a competitor swimmer (this is an unlikely theoretical worst case).
Note (**): we suppose, as a worst case, that of a competitor swimmer who is responsible for the care and maintenance of his own private pool, but who is not trained in biocidal use.

Summary table: combined systemic exposure expressed as mg Cu /kg bw [d] for: Trained professional (*)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 2, 3](tier 1) +[4(competitive swimmer]	-	0.1608	3.52E-04	0.1611

Scenarios [1](tier 2)+ [2, 3](tier 1) + [4(competitive swimmer)]	-	0.0285	3.52E-04	0.0288
Non-professional (**)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 2, 3](tier 1) +[4(competitive swimmer)]	**-**	0.0081	3.54E-04	0.0084

Monitoring data
Not applicable.

Dietary exposure
Dietary exposure as a result of use in PT02 for the treatment of pool waters is not expected.

Residue definitions
Not applicable.

Information of non-biocidal use of the active substance
Major uses of Copper Sulphate are as plant protection product and feed additive. Other uses include animal health, soil steriliser or plant nutrient (the list is necessarily non-exhaustive).

Residue definitions: total Copper for plant protection uses.

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant Protection Product	Fungicide/Bactericide	MRL[1]
2.	Veterinary	Copper deficiency in food-producing animals /foot-bath for the control of foot-rot	No MRL[2]
3.	Food additive	Colour retention agent/ Preservative	Report[3] NMRS 53/TRS 539-JECFA 17/35, 1982
4.	Feed additive	Nutritional supplement	Regulation (EC) No 1831/2003[4]

[1] Reg. (EC) No 149/2008
[2] Council Regulation (EEC) No 2377/90
[3] Joint FAO/WHO Expert Committee on Food Additives (JECFA)
[4] See 'Revision of the currently authorised maximum copper content in complete feed', EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), EFSA Journal 2016;14(8):4563

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Livestock exposure as a result of use in PT02 for the treatment of pool waters is not expected.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Transfer of biocidal product into foods as a result of use in PT02 for the treatment of pool waters is not expected.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Transfer of biocidal product into foods as a result of use in PT02 for the treatment of pool waters is not expected.

Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of biocidal product is not covered by the BPR. It is expected that production and formulation are performed in conformity with European and national worker protection legislation

Aggregated exposure

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information."

In accordance with the FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources or pathways: food, drinking water, and if applicable, residential or other non-occupational exposures.

Copper is a ubiquitous, naturally occurring metal that is essential to human health, found naturally at low levels in a variety of food products as well as in drinking water from copper plumbing pipes. Additionally, copper generally has low to moderate acute toxicity via the oral, dermal, and inhalation routes of exposure. Available literature and studies do not indicate any systemic toxicity associated with copper exposure.

Effects seen in the existing data base are as a result of response mechanisms that protect the body from excessive exposure to copper. Considering all available information on copper and the relatively low toxicity via all exposure routes from all sources, the cupric ion (regardless of the original form/species of copper) when used in pesticide products is unlikely to pose a significant hazard to the general public or any population subgroup. Based on available studies and literature, there are no human health aggregate risks of concern resulting from aggregate dietary and residential exposures.

Aggregate risk refers to the combined risk from dietary (food and drinking water) and residential or other non-occupational exposures. Aggregate risk can result from onetime (acute), short-term or chronic exposures. Because of the lack of systemic toxicity, copper exposures from combined sources do not pose any health risks of concern.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

According the approval AR of Copper Sulpfate pentahydrate for PT02 and the information given for the supplier (see LoA), all AELs (AELacute-term, AELmedium-term and AELlong-term) were derived on the basis of the NOAEL of 1000 ppm, corresponding to 16.3 mg

Cu/kg bw/day obtained in the 90-day oral rat study. An oral absorption rate of 25% was taken into account for calculating the systemic NOAEL as follows:

NOAELsystemic = 16,3 x 0,25 = 4,1 mg Cu/kg bw/d

Reference	**Study**	**NOAEL** (mg Cu/kg bw/d)	**AF**[1]	**Correction for oral absorption**	**Value** (mg Cu/kg bw/d)
AEL $_{short-term}$	(see LoA)	4,1	50	-	0'082
AEL $_{medium-term}$	(see LoA)	4,1	50	-	0'082
AEL $_{long-term}$	(see LoA)	4,1	100	-	0'041
ArfD	Not applicable				
ADI (if residues in food or feed)	Not relevant, an ADI value of 0.5 mg/kg/d is nevertheless available in the literature (WHO, IPCS).				
Drinking water limit (Spanish RD 140/2003)	2 mg/L				

[1] Regarding the assessment factors, after refinement, a value of 50 (including an inter-species factor of 5 and an intra-species factor of 10) was applied for deriving AELshort-term and AELmedium-term. An additional factor of 2 was integrated for taking into account the duration extrapolation from subchronic to chronic exposures. An overall assessment factor of 100 was therefore adopted for deriving AELlong-term. These refined assessment factors were agreed by the technical meeting TM I09. In all scenarios and tasks of BP use, a short or medium-term human exposure to AS occur and AF value of 50 seems to be sufficient, but in the risk assessment an AF of 100 will be used for all users, as worst case.

Maximum residue limits or equivalent

Residue definitions

Not applicable. No MRL in food or feed is foreseen for this use

MRLs or other relevant reference values	**Reference**	**Relevant commodities**	**Value**
-	-	-	-

Specific reference value for groundwater

n.d.

Risk for industrial users

Not applicable.

Risk for trained professional users

Systemic effects

Scenario (private pool)	**Tier**	**Estimated uptake** (mgCu/kg bw/d)	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (yes/no)
1 – Mixing and loading	1 (without PPE)	0.0147	4.1	0.041	35.8	**Yes**
	2 (with gloves)	0.00147	4.1	0.041	3.5	**Yes**

2 – Application	1 (without PPE)	0.0013	4.1	0.041	3.1	**Yes**
	2 (with gloves)	0.00013	4.1	0.041	0.3	**Yes**
3 – Post-application: maintenance	1 (without PPE)	$9.75x10^{-6}$	4.1	0.041	0.02	**Yes**
	2 (with gloves)	$9.75x10^{-7}$	4.1	0.041	0.002	**Yes**
Scenario 1+2+3	1 (without PPE)	0.016	4.1	0.041	39	**Yes**
Scenario (competitive pool)	**Tier**	**Estimated uptake** (mgCu/kg bw/d)	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (yes/no)
1 – Mixing and loading	1 (without PPE)	0.147	4.1	0.041	358	**NO**
	2 (with gloves)	0.0147	4.1	0.041	35.8	**Yes**
2 – Application	1 (without PPE)	0.013	4.1	0.041	31.7	**Yes**
	2 (with gloves)	0.0013	4.1	0.041	3.1	**Yes**
3 – Post-application: maintenance	1 (without PPE)	$9.75x10^{-6}$	4.1	0.041	0.02	**Yes**
	2 (with gloves)	$9.75x10^{-7}$	4.1	0.041	0.002	**Yes**
Scenario 1+2+3	1 (without PPE)	0.16	4.1	0.041	390	**NO**
Scenario 1(with gloves) + [2+3] (without PPE)	T2(1)+T1(2&3)	0.0277	4.1	0.041	67.5	**Yes**

Combined scenarios (primary and secondary exposure) Regarding the systemic effects risk is estimated for the worst theoretical case:we assume that the trained professional who is in charge of the product's application and maintenance of the competition pool, is at the same time a competitive swimmer (this is an unlikely theoretical worst case).

Scenarios combined	**Tier**	**Systemic NOAEL mg/kg bw/d**	**AEL mg/kg bw/d**	**Estimated uptake mg Cu/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenarios [1, 2, 3](tier 1) +[4(competitive swimmer]	No PPE	4.1	0.041	0.1611	392.9	**NO**
Scenarios [1](tier 2)+ [2, 3](tier 1) + [4(competitive swimmer)]	With PPE	4.1	0.041	0.0288	70.2	**Yes**

Local effects

The BP has been classified, according to CLP Regulation, based on its components, as Eye dam cat.1, with the H318 (causes serious eye damage) hazard statement, which is assigned to a very high hazard category, according the section 4.3.2. of Guidance for Human Health Risk Assessment Volume III, Part B.

Conclusion

For trained professionals users who pours the product Lo-Chlor Pool Algaecide from big packages (10-20 l), the risk is acceptable when PPEs (gloves and eye protection) are worn.

Risk for general public and non-trained professional users

Systemic effects

Task/ Scenario	**Tier**	**Estimated uptake** (mgCu/kg bw/d)	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (yes/no)
1 – Mixing and loading	1 (no PPE)	0.006	4.1	0.041	14.6	**Yes**
2 – Application	1 (no PPE)	0.0013	4.1	0.041	3.1	**Yes**
3 – Post-application: maintenance	1 (no PPE)	$1.24x10^{-5}$	4.1	0.041	0.03	**Yes**
Scenario 1+2+3	1 (no PPE)	0.0073	4.1	0.041	17.8	**Yes**

Combined scenarios (primary and secondary exposure)

Regarding the systemic effects risk is estimated for the worst theoretical case:we assume that a competition swimmer who is responsible for the care and maintenance of his own private pool, but who is not trained in biocidal use.

Task/ Scenario	**Tier**	**Estimated uptake** (mgCu/kg bw/d)	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (yes/no)
Scenario 1+2+3+4 (competition swimmer)	1 (no PPE)	0.0084	4.1	0.041	20.4	**Yes**

Local effects

In light of the classification (Eye dam. Cat 1 – H318) for the product which is used by the general public, in accordance with Guidance on BPR: Volume III Parts B+C, version 4 (p. 253), a qualitative risk assessment is required.

The expected frequency of use of the product is equal to or less than once per week and less than few minutes per event for a general public user. The potential of exposure is low due to the nature of the user task (the concentrate from packages with child-resistant closure and less than 5 L is loading/pouring into a bucket water). The labeling and instructions for use contain appropriate RMM. Therefore the risk of exposure is considered to be low.

Conclusion

It can be concluded that the risk of exposure to general public and non-trained professional users is mitigated and as such no PPE is required for these users.

Risk for the general public (secondary exposure)

Systemic effects

Task/ Scenario	**Tier**	**Estimated uptake** (mg Cu/kg bw/d)	**Systemic NOAEL** (mg/kg bw/d)	**AEL** (mg/kg bw/d)	**Estimated uptake/AEL** (%)	**Acceptable** (yes/no)
Post- application exposure for an **ADULT COMPETITION swimmer**	1	0.00117	4,1	0,041	2.8	**yes**
Post- application exposure for an **ADULT swimmer**	1	0.000992	4,1	0,041	2.4	**yes**
Post- application exposure for an **CHILD swimmer**	1	0,00216	4,1	0,041	5.2	**yes**
Post- application exposure for an **BABY swimmer** i	1	0,00108	4,1	0,041	2.6	**yes**

Combined scenarios

The possible combined scenarios would only affect an adult swimmer and have already been considered in previous sections.

Local effects
No local effects are foreseen.

Conclusion
Regarding the systemic and local effects due to secondary exposure, no risk for general public are foreseen.

Risk for consumers via residues in food
Not applicable. No residues in food or feed is foreseen for this use

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not applicable. There not are any other active substance or substance of concern in this BP

2.2.7 Risk assessment for animal health

Not Relevant: copper is a micronutrient, essential for life and necessary for all living cells. Moreover, the concentration of Cu^{2+} added to the water, even at shock doses (0'618 ppm), is much lower than the parametric value limit allowed Cu^{2+} in drinking water (2 ppm) established by the R.D. 140/2003 that establish the health criteria for water quality for human consumption in Spain, and analyzes of Cu conducted during field trials of efficacy show that after 28 days, the concentration of Cu in water is down to ppb levels, and therefore the risk assessment for animal health exposed to water treated with the BP is not considered necessary.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The BP is used as algaecide treatment of marine or fresh water (diatom and green algae) of public and private swimming pools, spas, hot tubs, padding pools, fountains, etc.

The Normal dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months.
Dose rate in case of severe infestation: 2 L/120m^3 of water.

The BP contain only one substance classified as hazardous to the aquatic environment: 12.5% of Copper sulphate pentahydrate, and no synergic effect with the co-formulant are expected.

The product for which approval is being sought is not the same as that which was used to support the application for Annex I listing of copper sulfate pentahydrate in PT02. However, the hazard data previously reviewed are considered to be applicable to the current application, as the environmentally relevant moiety (the cupric ion (Cu^{2+}) derived from copper sulphate Pentahydrate) is identical. The Predicted No Effect Concentrations (PNEC) for environmental compartments relevant to this risk assessment are shown in the next table.

Summary PNECs values for substance active:

Compartment	PNEC	Unit
STP	0.23	mg l^{-1}
Surface water	7.8	µg l^{-1}
Sediment	87 18.9	mg kg_{dwt}^{-1} mg kg_{wwt}^{-1}
Soil	45.6 40.35	mg kg_{dwt}^{-1} mg kg_{wwt}^{-1}

As a result of the unique fate of copper in water, soil, sediment and sludge, many of the data requirements of the Guidance on the Biocidal Product Regulation, Volume IV, Part A, are not applicable for inorganic compounds and metals in particular hydrolysis, photodegradation, sediment degradation and biodegradation.Photo transformation in water is not expected to occur. It is therefore not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation.

Adsorption to organic carbon, manganese and iron oxides increases in soil with increasing pH. An extensive literature on the partitioning of copper in the aquatic and soil compartments was reviewed and the following partition coefficients have been derived for Cu metal and Cu compounds:

- Partition coefficient in suspended matter:
  Kp_{susp} = 30,246 l/kg (log Kp(pm/w) = 4.48) (50^{th} percentile)
- Partition coefficient in sediment:
  Kp_{sed} = 24,409 l/kg (log Kp(sed/w) = 4.39) (50^{th} percentile)
- Partition coefficient in soil:
  Kp_{soi}l = 2 120 l/kg (log Kp(soil/w) = 3.33) (50^{th} percentile)

As is the case for all metals, copper becomes complexed with organic and inorganic matter in water, soil and sediments and this affects copper speciation, bioavailability and toxicity. Because biological organisms possess homeostatic mechanisms for the internal regulation of metals, use of Bioconcentration Factors (BCF) as indicators of bioaccumulation potential is considered to be inappropriate. Evidence of accumulation and secondary poisoning by inorganic forms of metals and biomagnification in food webs is very limited.

Further Ecotoxicological studies

Not data available

Data waiving	
Information requirement	Not necessary
Justification	The product for which approval is sought is not the same that was used to support the application of the SA, however, data on the risks to health and the environment previously reviewed for approval of the SA is considered which are applicable to the present assesment, since the cupric ion (Cu^{2+}) derived from pentahydrate copper sulphate, it is identical.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Not applicable for the foreseen use of this BP

Supervised trials to assess risks to non-target organisms under field conditions

Not applicable for the foreseen use of this BP

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not applicable for the foreseen use of this BP

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant for the foreseen use of this BP

Foreseeable routes of entry into the environment on the basis of the use envisaged

The BP is used as algaecide treatment of marine or fresh water (diatom and green algae) of swimming pools, spas, hot tubs, padding pools, fountains, etc. For such use, it was considered that the relevant environmental exposure pathway is via emission to the STP as wastewater from the pools or direct to soil adjacent to the paddling pools.

The foreseable routes of entry into the copper in the environment on the basis of the use envisaged of this BP are water, soil, sediment and sludge, because the active substance is not-volatile, hydrolytically stable, non-photo or non-biodegradable.

Further studies on fate and behaviour in the environment (ADS)

As an inorganic compound, copper sulphate pentahydrate is not subject to biological degradation in any environmental compartment. The substance is non-volatile, hydrolytically stable and non-biodegradable. Photo transformation in water is not expected to occur. It is therefore not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation.

Leaching behaviour (ADS)

Not relevant for the foreseen use of this BP

Testing for distribution and dissipation in soil (ADS)

As an inorganic compound, copper sulphate pentahydrate is not subject to biological degradation in any environmental compartment. The substance is non-volatile, hydrolytically stable and non-biodegradable. Photo transformation in water is not expected to occur. It is therefore not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation.

Testing for distribution and dissipation in water and sediment (ADS)

As an inorganic compound, copper sulphate pentahydrate is not subject to biological degradation in any environmental compartment. The substance is non-volatile, hydrolytically stable and non-biodegradable. Photo transformation in water is not expected to occur. It is therefore not applicable to discuss copper in terms of degradation half-lives or possible routes of degradation.

Testing for distribution and dissipation in air (ADS)

Not applicable, because the active susbstance is non-volatile

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not applicable for the foreseen use of this BP.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not applicable

2.2.8.2 Exposure assessment

The BP is used as algaecide treatment of marine or fresh water (diatom and green algae) of public and private swimming pools, spas, hot tubs, padding pools, fountains, etc.

The Normal dose rate (summer and winter): 1 L/120 m^3 of water, initially and every 3 months.
Dose rate in case of severe infestation: 2 L/120m^3 of water.

The normal dose of LO-CHLOR POOL ALGAECIDE required to prevent algae growth in outdoors swimming pools (the worts case) at the start of the swimming season is 250 ml/30 m^3, and after that, a maintenance dose similar is needed every 3 months or after rainfall, including during winter (off-season) when maintenance stops and the concentration of active chlorine is below 0.1 mg/L. In case of visible algae (greenish water) a shock treatment of 500 ml of LO-CHLOR POOL ALGAECIDE /30 m^3 should be added.

General information

Assessed PT	PT 2
Assessed scenarios	**Scenario 1**: Public swimming pools (acute and chronic emission)- This scenario covers the use in public pools (Indoor/Outdoor) and indoor spas and hot tubs. **Scenario 2**: Private Pools – permanent installed pools (chronic and peak emission). This scenario covers the use in private pools (Indoor/Outdoor) and indoor spas and hot tubs. **Scenario 3:**Above ground small pools– This scenario covers the use in paddling pools (outdoor), hot tubs (outdoors) and fountaints (outdoor). **Scenario 4:** Fountains (indoor).
ESD(s) used	**Scenario 1:** Emission Scenario Document for Biocides. Emission scenarios for 23 product types of the Biocidal Products Directive (EU Directive 98/9/EC) (Van der Poel and Bakker, 2002/ OECD, 2002). **Scenario 2:** Emission scenario for the permanently installed pools. According to Technical Agreement for Biocides (TAB 2017, ENV 36) **Scenario 3**: Emission scenario for the disinfections of above ground small pools. According to Technical Agreement for Biocides (TAB 2017, ENV 41). **Scenario 4:** Emission scenario for indoor fountain. According to Technical Agreement for Biocides (TAB 2017, ENV 40).
Approach	*[Please indicate per scenario if the approach is tonnage based, average consumption based or, if both are not applicable, describe the approach chosen.]* Average consumption
Distribution in the environment	The current ESD for PT02, which covers the use of biocides for the disinfection of water in swimming pools, has been used to determine the daily emissions to local waste water. The resulting

	emissions have been inputted into the local emissions sheet of EUSES (v.2.1.2) for the determination of the predicted environmental concentrations in the local environment.
Groundwater simulation	*[Please indicate per scenario if any simulation for leaching to groundwater using a higher tier model like e.g. one of the FOCUS models was performed.]*
Confidential Annexes	NO
Life cycle steps assessed	**Scenario n:1 y 2** • Production: No • Formulation No • Use: No • **Service life: Yes**
Remarks	• The production step is not considered here because it has been already assessed by the supplier in the PAR of active substance. • The formulation step is not considered because, as it has been comment in the description of Scenario 14, the wastewater from cleaning of manufacturing and packaging the BP are collected in a container for use in following fabrication, getting residue 0. • The use step is not considered either because it is claimed in the label that the user has to rinse vigorously three times each package you use, pouring water from washing the pool, so it is not foreseen the environmental pollution by contaminated packaging.

Emission estimation

Scenario 1: Public swimming pools

INPUT PARAMETES				
Parameter	**Nomenclature**	**Acute situation**	**Chronic situation**	**Remarks**
Water surface [m2]	AREAswimw	440		D
Average depth of water [m]	DEPTHswimw	1.8		D
Number of visitors per day [-]	Nvisit	400		D
Concentration in swimming water [kg·m3]	Cproc	0.000618		S
Water replaced per r visitor [m3]	Vrepl	0.05		D
Fraction acutely released to STP [d-1]	Fchro_rel	0.33		D
Number of emission days [d]	Temission	2	300	D
OUTPUT PARAMETES				
Emission rate to waste water (standard STP) [kg·d-1]	Elocal(water)	0.16	0.01	O

Scenario 2: Private swimming pools

These scenarios cover only emissions from permanent installed polls with releases to STP and not above ground small pools for which direct releases to soil or surface could be foreseen.

2a) Permanent installed pools

For the purpose of the environmental exposure assessment, the maximum initial treatment concentration of 0.618 mg Cu/L has been used accordingly the information submitted by the applicant.

The current ESD for PT02 covers the use of biocides for the disinfection of water in swimming pools and it has been used as a reasonable worst-case surrogate for swimming/spa pools and hot tubs to determine the daily emissions to local waste water or soil.

INPUT PARAMETES				
Parameter	Nomenclature	Value for Southern countries	Value for Northern countries	Remarks
Private pool volume [m3]	Vpool	48		D
Number of private pools per STP [-]	Npool	550	100	D
Fraction chronically released to STP [d-1]	Fchro_rel	0.0143		D
Application rate of active substance in the pool water [g·L-1]	Qappl	0.000618		S
Market share [-]	Fmarket	0.5		D
OUTPUT PARAMETES				
Number of treated private pools with daily releases [d-1]	Npool_chro_rel	275	50	O
Emission rate to waste water (standard STP) [kg·d-1]	Elocal(water)	0.12	0.02	O

2b) Peak emission: releases to wastewater due to the preparation for wintering

INPUT PARAMETES				
Parameter	Nomenclature	Value for Southern countries	Value for Northern countries	Remarks
Private pool volume [m3]	Vpool	48		D
Number of private pools with releases by day [-]	Npool	10	2	D
Fraction acutely released to STP [d-1]	Fchro_rel	0.33		D
Efficient dose rate of active substance in the pool water [g·L-1]	Qappl	0.000618		
Fraction of active substance released to wastewater	Fwater	1		D
Market share [-]	Fmarket	0.5		D

OUTPUT PARAMETES				
Number of treated private pools with daily releases [d-1]	Npool_chro_rel	5	1	O
Emission rate to waste water (standard STP) [kg·d-1]	Elocal(water)	0.049	0.010	O

D: Default value from scenario; S: Input value for the applicant; O: Output value (calculated)

Scenario 3 Emission scenario for the disinfections of above ground small pools (TAB 2017, ENV 41).

This scenario take into consideration direct release for above ground of small pools as hot tubs (outdoor) and paddling pools. These pools are expected to be completely emptied at the end of the summer season and stored over the winter months.

One application lasts 3 months in normal conditions. Taking into account the frequency to treat the pool with the BP recommended in its label (once every 3 months and when there is severe infestation) is assumed that 1 BP addition a year is performed in each installation in the summer period of 91 days.

STP: The emission pathway via STP is covered by the assessment of Scenario 2.

Surface water: The direct emission of private temporary swimming pools to surface waters is likely water bodies similar to the "edge of field" water bodies described in FOCUS Surface Water. The dilution and local concentration of the pool water emitted to surface water is calculated based on equation 48 and 49 in the guidance BPR IV v 2.0(2017):

Effluent pool = Vpool/tdrain
DILUTION = (Effluentpool + Flowditch)/Effluentpool = 6.6
Clocal water = Aappl/((1 + Kpsusp*SUSPwater*10^{-6}) * DILUTION)

INPUT PARAMETES			
Parameter	**Nomenclature**	**Value**	**Remarks**
Private pool volume [m3]	Vpool	14	D
Drainage time[h]	tdrain	6	D
Ditch discharge [L/s]	Flowditch	3.63	D
Local concentration of a.s. in pool water at the end of the emission period [mg/L]	Aappl	0.618	S
Partition coefficient in suspender matter [L/kg]	Kpsup	30246	CAR (a.s.)
Concentration of suspender matter in the river [mg/L]	SUSPwater	15	D
OUTPUT PARAMETES			
Discharge from pool[L/s]	Effluentpool	0.65	O
Dilution factor	DILUTION	6.56	O
Local concentration of a.s. in	Clocalwater	0.065	O

surface water [mg/L]			

D: Default value from scenario; S: Input value for the applicant; O: Output value (calculated)

Soil: The direct soil emission of private temporary swimming pools ($14m^3$) to soils depends on the drainage time and the soils infiltration rate. Depending on the size of the valve or diameter of the hose, the time needed to drain the pool ranges from several hours to a day. For emission estimations, a drain age time (t_{drain}) of 6 hours as typical is considered. It is assumed that the exposed soils are fairly permeable, corresponding to a maximum infiltration rate (f_d) of 1 $m \cdot d^{-1}$. The scenario is described in the following table:

INPUT PARAMETES (Tier-1)			
Parameter	**Nomenclature**	**Value**	**Remarks**
Private pool volume [m3]	Vpool	14	D
Soil area exposed [m2]	AREA soil	56	D
Soil depth [m]	depthsoil	0.5	D
Bulk density of soil [kg/m3]	RHOsoil	1700	D
Application rate of a.s. in the pool water [mg/L]	Aappl	0.618	S
Number of b.p. applications for one pool in the emission period	Nappl	1	D
OUTPUT PARAMETES			
Quantity of a.s.in pool water [kg]	Qpool	0.009	O
Concentration of a.s.in exposed soil [mg/kg]	Csoil	0.182	O

D: Default value from scenario; S: Input value for the applicant; O: Output value (calculated)

Scenario 4: Emission scenario for indoor fountain (TAB 2017, ENV 40)

The route of exposure to the environment is via de STP, subsequent to routine cleaning by discarding the treated water via sewage system. For emission estimations, a 10L fountain as a common size is considered. Furthermore, it is assumed that 100% of the fountain volume is replaced and discarded on a daily basis cleaning.

INPUT PARAMETES (Tier-1)			
Parameter	**Nomenclature**	**Value**	**Remarks**
Fountain volume [L]	Vfountain	10	D
Number of fountains per STP [-]	Nfountain	600	D
Fraction of water replaced due to product aplication [d-1]	Frep	1	D/S
Concentration of a.s.in fountain [mg/L]	Cfountain	0.618	S
Fraction of a.s.realised to wastewater	Fwater	1	D
Market share	Fmarket	0.5	D
OUTPUT PARAMETES			
Emission rate to waste water (standard STP) [kg·d-1]	Elocal(water)	0.0019	O

Resulting local emission to relevant environmental compartments				
Scenario	**Compartment**		**Local emission ($Elocal_{compartment}$) [kg Cu/d]**	**Remarks**
Scenario 1 – Public pools	Wastewater	Tier -1*	0.16	0
		Tier-2*	0.01	0
Scenario 2a –Private pool scenario-permanent installed pools	Wastewater	Tier -1**	0.12	0
		Tier-2**	0.02	0
Scenario 2b –Private pool scenario-Peak emission: releases to wastewater due to the preparation for wintering	Wastewater	Tier -1**	0.049	0
		Tier-2**	0.010	
Scenario 3 Emission scenario for the disinfections of above ground small pools	Soil		0.182	0
Scenario 4 Emission scenario for indoor fountain	Wastewater		0.0019	0

* Tier- 1 Acute Situation Tier- 2 Chronic Situation
** Tier- 1 Southern countries Tier-2 Northern countries

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 – Public pools	YES	YES	n.r	n.r	YES	NO	YES	YES	-
Scenario 2a –Private pool scenario-permanent installed pools	YES	YES	n.r	n.r	YES	NO	YES	YES	-
Scenario 2b –Private pool scenario-Peak emission: releases to wastewater due to the preparation for wintering	YES	YES	n.r	n.r	YES	NO	YES	YES	-
Scenario 3 Emission scenario for the disinfections of above ground small pools	YES	YES	n.r	n.r	NO	NO	YES	YES	-
Scenario 4 Emission scenario for indoor fountain	YES	YES	n.r	n.r	YES	YES	YES	YES	-

The resulting emissions (kg/d) have been inputted into EUSES (v.2.1.2) for the determination of the predicted environmental concentrations in the local environment using the following endpoints.

Input parameters (only set values) for calculating the fate and distribution in the environment using EUSES 2.1.2			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	249.68	g/mol	
Vapour pressure (at 25°C)	1.00E-06	Pa	CuSO4.5H2O is an inorganic salt and as such has negligible volatility at environmentally relevant temperatures. For the environmental exposure assessment, the vapour pressure is thus set at the minimum value.
Water solubility (at 25°C)	1.00E+5	mg/L	The solubility of CuSO4.5H2O is 220g/L. Nevertheless, in EUSES the solubility is set to maximum value of $1x10^5$ mg/L.
Log Octanol/water partition coefficient	8.50E-07	Log 10	This value is set at a minimum in EUSES due to this parameter is not to be relevant to cooper.
Organic carbon/water partition coefficient (Koc)	1.06E+05	L/kg	Calculated value based on the given kpsoil value according to the CAR
Adsorption-desorption	The distribution of metals between aqueous phase and soil/sediment/suspended matter should preferentially be described on the basis of measured soil/water, sediment/water and suspended matter/water equilibrium distribution coefficient. Partition coefficient in soil : Kpsoil = 2 120 L/kg (log Kp = 3.33) (50th (Sauvé et al. 2000) percentile) Partition coefficient in Suspended matter : Kpsusp = 30 246 L/kg (log Kp (pm/w) = 4.48) (50th percentile) (Heijerick et al.. 2005) Partition coefficient in Sediment and porewater Kpsed = 24 409 L/kg (log Kp(sed/w) = 4.39) (50th percentile) (Heijerick et al.. 2005)		According to the CAR

Calculated fate and distribution in the STP [if STP is a relevant compartment] using EUSES 2.1.2		
Compartment	**Percentage [%]**	**Remarks**
Air	1.24E-05	Calculated by EUSES 2.1.
Water	13.9	
Sludge	86.1	
Degraded in STP	0	

Calculated PEC values

This risk assessment has been carried out on the basis of total copper concentrations in the environment, taking into account background plus added amounts of copper. Consequently, the Predicted Environmental Concentrations (PEC), initially calculated as 'added values', were corrected in order to integrate the background concentrations of copper. Total copper concentrations were calculated by taking into account the natural/pristine or the regional copper background concentrations (as agreed under the Council Regulation (EEC) 793/93 on Existing Substances - EU-RAR).

Compartment	Natural/pristine background concentration	Regional background concentration	Unit
Surface water	0.88	2.9	$\mu g \cdot L^{-1}$
Ground water	0.88	2.9	$\mu g \cdot L^{-1}$
Soil	12 10.6	24.4 21.6	$mg \cdot kg_{dwt}^{-1}$ $mg \cdot kg_{wwt}^{-1}$
Sediment	21 4.56	67.5 14.7	$mg \cdot kg_{dwt}^{-1}$ $mg \cdot kg_{wwt}^{-1}$

Results from studies on copper toxicity in aged contaminated soils showed a decrease in the copper toxicity threshold after 18 months ageing, with increased No Observed Effect Concentrations (NOEC) for plants and soil invertebrates. NOECS also increased for micro-organisms, but this was probably due to an adaptation to copper. In view of these findings, an ageing factor of 2 was applied to the total copper concentrations in soil, in order to take account of the copper ageing phenomenon in soil. This strategy was validated at TMIII08.

The local PECs values from the intended uses are presented in the following table, for completeness, but they are not used in this risk assessment.

Summary table on calculated PEC local values from the intended uses

		PEC stp [µg/L]	PEC sw [µg/L]	PEC sed [mg/kgwwt]	PEC soil [mg/kgwwt]	PEC gw [µg/L]
Scenario 1-Public pool scenario-acute and chronic emission	Tier-1*	11.20	0.77	5.08	2.88	1.54
	Tier-2*	0.86	0.06	0.39	0.22	0.18
Scenario 2a-Private pool scenario-Chronic emission:releases to wastewater following the cleaning of filtration system	Tier-1**	8.34	0.57	3.77	2.14	1.14
	Tier-2**	1.39	0.10	0.63	0.36	0.19

Scenario 2b – Private pool scenario-Peak emission:releases to wastewater due to the preparation for wintering	Tier-1**	3.41	0.23	1.54	0.87	0.47
	Tier-2**	0.70	0.05	0.31	0.18	0.10
Scenario 3 Emission scenario for the disinfections of above ground small pools			65.00	427.00	0.16	0.09
Scenario 4 Emission scenario for indoor fountain		0.13	0.01	0.06	0.03	0.02

* Tier- 1 Acute Situation Tier- 2 Chronic Situation
** Tier- 1 Southern countries Tier-2 Northern countries

The environmental risk assessment will be carried out on the basis of total concentrations of copper in the environment, the local PEC values from the intended uses are further corrected in order to integrate the background concentrations of copper (PEC values from the intended uses are summed up to the background concentration).

Summary table on calculated PEC values including natural and regional background concentration

			PEC stp [µg/L]	PEC sw [µg/L]	PEC sed [mg/kgwwt]	PEC soil [mg/kgwwt]	PEC gw [µg/L]
Total concentrations - Natural/pristine Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier -1*	11.20	1.65	9.64	13.48	2.42
		Tier -2*	0.86	0.94	4.95	10.82	1.06
	Scenario 2a-Private pool scenario-Chronic emission:releases to wastewater following the cleaning of filtration system	Tier -1**	8.34	1.45	8.33	12.74	2.02
		Tier -2**	1.39	0.98	5.19	10.96	1.07
	Scenario 2b – Private pool scenario-Peak emission:releases to wastewater due to the preparation for wintering	Tier -1**	3.41	1.11	6.10	11.47	1.35
		Tier -2**	0.70	0.93	4.87	10.78	0.98

	Scenario 3 Emission scenario for the disinfections of above ground small pools		0.00	65.88	431.56	10.76	0.97
	Scenario 4 Emission scenario for indoor fountain		0.13	0.89	4.62	10.63	0.90
Total concentrations -Regional Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier -1*	11.20	3.67	19.78	24.48	4.44
		Tier -2*	0.86	2.96	15.09	21.82	3.08
	Scenario 2a-Private pool scenario-Chronic emission:releases to wastewater following the cleaning of filtration system	Tier -1**	8.34	3.47	18.47	23.74	4.04
		Tier -2**	1.39	3.00	15.33	21.96	3.09
	Scenario 2b – Private pool scenario-Peak emission:releases to wastewater due to the preparation for wintering	Tier -1**	3.41	3.13	15.01	22.47	3.37
		Tier -2**	0.70	2.95	14.76	21.78	3.00
	Scenario 3 Emission scenario for the disinfections of above ground small pools		0.00	67.90	441.70	21.76	2.99
	Scenario 4 Emission scenario for indoor fountain		0.13	2.91	14.76	21.63	2.92

* Tier- 1 Acute Situation Tier- 2 Chronic Situation
** Tier- 1 Southern countries Tier-2 Northern countries

PEC air, no significant release of cooper sulfhate pentahydrate to air is expected.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

Not relevant

Waiving: Copper is an essential micronutrient. The use of copper sulphate pentahydrate in animal nutrition is extensively documented in the scientific literature. It is recognised as an efficacious source of copper in meeting animal requirements and is safe for all animal species/categories up to the maximum total copper content authorised in feed. No further assessment of primary or secondary exposure via the food chain is therefore considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

Not applicable due to low volatility of the active substance.

Aquatic compartment (sediment and sewage treatment plant)

			PEC/PNEC stp [µg/L]	PEC/PNEC sw [µg/L]	PEC/PNEC sed [mg/kgwwt]
Total concentrations - Natural/pristine Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier-1*	0.05	0.21	0.51
		Tier-2*	0.004	0.12	0.26
	Scenario 2a-Private pool scenario-Chronic emission:releases to wastewater following the cleaning of filtration system	Tier-1**	0.04	0.19	0.44
		Tier-2**	0.01	0.13	0.27
	Scenario 2b –Private pool scenario-Peak emission:releases to wastewater due to the preparation for wintering	Tier-1**	0.01	0.14	0.32
		Tier-2**	0.003	0.12	0.26
	Scenario 3 Emission scenario for the disinfections of above ground small pools		-	**8.45**	**22.83**
	Scenario 4 Emission scenario for indoor fountain		0.00	0.11	0.24
Total concentrations -Regional Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier-1*	0.05	0.47	**1.05**
		Tier-2*	0.00	0.38	0.80
	Scenario 2a-Private pool scenario-Chronic emission:releases to wastewater following the cleaning of filtration system	Tier-1**	0.04	0.44	0.98
		Tier-2**	0.01	0.38	0.81

	Scenario 2b –Private pool scenario-Peak emission:releases to wastewater due to the preparation for wintering	Tier-1**	0.01	0.40	0.79
		Tier-2**	0.003	0.38	0.78
	Scenario 3 Emission scenario for the disinfections of above ground small pools			**8.71**	**23.37**
	Scenario 4 Emission scenario for indoor fountain		0.0006	0.37	0.78

* Tier- 1 Acute Situation Tier- 2 Chronic Situation
** Tier- 1 Southern countries Tier-2 Northern countries

Conclusion:

If the product is applied in artificial fountains (indoor) and private pools (indoor/outdoor), a release of treated water to the STP was assumed for the environment exposure assessment. The PEC/PNEC for surface water as well as sediment to this use are below 1 and thus not indicating an unacceptable risk for both compartments. However, when the product is applied in public pools the risk for the sediment compartment were identified, in acute situation. This unacceptable risk is due to scenario 1 considers that the total draining of a swimmingpool happens in 3 consecutive days when the biocidal product concentration is still 1mg Cu/L. Therefore, ES CA considers that the following RMM has to be applied to reduce this risk, regarding the chronic emission rate to waste water and replaced water: "After the last treatment with this product, it must pass at least 21 days with the purification system connected to empty completely the pool", *except if there are national measures that prevent unacceptable risks in environmental compartment when the swimming-pool is emptied.*

Furthermore, for the use in temporarily installed swimming pools (paddling pool, outdoor hot tubs and outdoor fountain), for which a direct release of the entire content of treated water to surface water at the end of the summer was assumed as a worst case, an unacceptable risk for surface water and sediment has been identified. Therefore, this use cannot be authorised.

Terrestrial compartment

			PEC/PNEC soil [mg/cwt.]
Total concentrations - Natural/pristine Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier-1*	0.33
		Tier-2*	0.27
	Scenario 2a-Private pool scenario-Chronic emission: releases to wastewater following the cleaning of filtration system	Tier-1**	0.32
		Tier-2**	0.27
	Scenario 2b –Private pool scenario-Peak emission: releases to wastewater due to the preparation for wintering	Tier-1**	0.28
		Tier-2**	0.27

	Scenario 3 Emission scenario for the disinfections of above ground small pools		0.27
	Scenario 4 Emission scenario for indoor fountain		0.26
Total concentrations - Regional Background	Scenario 1-Public pool scenario-acute and chronic emission	Tier-1*	0.61
		Tier-2*	0.54
	Scenario 2a-Private pool scenario-Chronic emission: releases to wastewater following the cleaning of filtration system	Tier-1**	0.59
		Tier-2**	0.54
	Scenario 2b –Private pool scenario-Peak emission: releases to wastewater due to the preparation for wintering	Tier-1**	0.56
		Tier-2**	0.54
	Scenario 3 Emission scenario for the disinfections of above ground small pools		0.54
	Scenario 4 Emission scenario for indoor fountain		0.54

* Tier- 1 Acute Situation Tier- 2 Chronic Situation
** Tier- 1 Southern countries Tier-2 Northern countries

Conclusion: The PEC/PNEC ratios for all intended uses of LO-CHLOR POOL ALGAECIDE were found to be below 1. Hence, no unacceptable risk for the soil compartment were identified, independent of whether natural or regional background concentrations were considered for the environmental exposure assessment.

Ageing of cooper in soil was identified in the CAR as an important consideration in determining the effect of copper to terrestrial organisms. In order to consider the phenomenon of copper ageing in soil, an ageing factor of 2 was applied on the total copper concentrations in soil. However, this ageing factor was not taken into account in this risk assessment because no risks was identified.

Groundwater

The concentrations that were determined for the groundwater compartment are in a range from 0.90 to 4.44 µg Cu/L and thus below the reference value of 2 mg Cu/L as stated in Directive 98/83/EC.

Primary and secondary poisoning

Primary poisoning

Not relevant

Conclusion:
Copper is an essential micronutrient. The use of copper sulphate pentahydrate in animal nutrition is extensively documented in the scientific literature. It is recognised as an efficacious source of copper in meeting animal requirements and is safe for all animal

species/categories up to the maximum total copper content authorised in feed. No further assessment of primary or secondary exposure via the food chain is therefore considered necessary.

Mixture toxicity

The only relevant substance present in the BP is the active ingredient.

2.2.9 Measures to protect man, animals and the environment

The BP has been classified as: Eye Dam. 1, Aquatic Acute 1 and Aquatic Chronic 1, with the next hazard phrases:
H318: Causes serious eye damage
H410: Very toxic to aquatic life with long lasting effects

The risk is acceptable for trained professional users when gloves and eye protection are worn during the handling of the product.

The use of the product by professional and non-professional users (general public) presents a low potential of exposure and a frequency of use less than once a week. In addition, packaging intended for non-professional users must have child resistant closure. Therefore, with the RMMs included (see section 2.1.5.2), the risk is acceptable without wear PPEs.

For trained professionals, professionals and no-professionals (general public) users the risk is acceptable from the point of view of secondary exposure. No PPEs are needed for this step.

Although the product is classified as very toxic to aquatic life with long lasting effects, it has been shown to have an acceptable risk for the environment at recommended doses for the foreseen use. However, it will be recommended in the label to rinse vigorously three times each package you use, pouring water from washing the pool, and the following phrases:

P273: Avoid release to the environment.
P391: Collect spillage.

Trained professional:

P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

Professional/non professional (General public):

P501: Remove the content and /or its container as hazardous waste according to the regulations in force.

Finally it has been demonstrate that this BP at the dose recommended is safe because presents an acceptable risk to man and the environment

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products

3 ANNEXES

3.1 List of studies for the biocidal product

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
2.1.2	Anonymous	2014	MSDS of LO-CHLOR POOL ALGAECIDE (12.5% copper sulphate pentahydrated and 15-25% trietholamine)	N	PUBLIC
2.1.2	Anonymous	2013	MSDS of COPPER(II) SULPHATE PENTAHYDRATE (≥98%)	N	PUBLIC
2.1.2	Anonymous	2013	TDS of SULFATO DE COBRE PENTAHIDRATO "Snow High Purity Bio Grade" microcristales (≥99.9% Copper Sulphate pentahydrated)	N	PUBLIC
2.1.2	Anonymous	2013	MSDS of coformulant 1	N	PUBLIC
2.1.10/ Lab. Munuera 15-4727-01	See confidential annex	2015	Caracterización físico-química de LO-CHLOR POOL ALGAECIDE – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.
2.1.10/ Lab. Munuera 16-4727-01 (initial report)	See confidential annex	2016	Estudio de estabilidad a 25ºC durante 2 años de LO-CHLOR POOL ALGAECIDE – Validación del método de análisis y determinaciones iniciales – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.
2.1.10/ Lab. Munuera 16-4727-02	See confidential annex	2018	Estudio de estabilidad a 25ºC durante 2 años de LO-CHLOR POOL ALGAECIDE – Validación del método de análisis y determinaciones a t= 0, 6, 12, 18 y 24 meses. – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.
2.1.10/ Lab. Munuera 16-4727-02	See confidential annex	2017	Estudio de estabilidad a 25ºC durante 2 años de LO-CHLOR POOL ALGAECIDE – Validación del método de análisis y determinaciones a t= 0, 6, 12 y 18 meses. – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.

2.2.2/ ATQ expert declaration on LoChlor	See confidential annex	2017	ATQ declaración experto LoChlor	Y	ATQ QUIMYSER, S.L.
2.2.4/ Lab. Munuera 16-4727-01 (initial report)	See confidential annex	2016	Estudio de estabilidad a 25ºC durante 2 años de LO-CHLOR POOL ALGAECIDE – Validación del método de análisis y determinaciones iniciales – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.
2.2.4/ US-EPA 1983,	US – EPA	1983	Methods of chemical analysis of water and wastes. US-EPA. Not GPL, Published	N	PUBLIC
2.2.4/ US-EPA 1983	US –EPA	1983	Methods of chemical analysis of water and wastes. US-EPA	N	PUBLIC
2.2.4/ US-EPA 1986	US-EPA	1986	Test methods for evaluating solid waste1A: Laboratory manual physical/chemical methods. Washington, DC: U.S. Environmental Protection Agency.	N	PUBLIC
2.2.4/ AOAC 1995	AOAC	1995	Association of Official Analytical Chemistry (AOAC). 1995. Official Methods of Analysis of AOAC International, 16th ed. Vol. 1 and 2. AOAC International, Arlington, Virginia.	N	PUBLIC
2.2.4/ EMMI 1997	EMMI	1997	Environmental monitoring methods index. Version 1.1. PC#4082. Rockville, MD: U.S. Environmental Protection Agency, Government Institutes	N	PUBLIC
2.2.5/UV-LEyCA 2016	See confidential annex	2016	Estudio para la evaluación de la ecotoxicidad y eficacia del alguicida comercial LO CHLOR POOL ALGAECIDE – **CONFIDENTIAL REPORT**	Y	A.Q.A. CHEMICALS S.L.
2.2.5/UV-LEyCA 2016	See confidential annex	2016	Title: Stability assessment of LO CHLOR POOL ALGAECIDE 90 days after algaecide application (Estudio para la evaluación de la estabilidad a 90 días del alguicida comercial LO CHLOR POOL ALGAECIDE)	Y	A.Q.A. CHEMICALS S.L.
2.2.6.1/EFSA 2012	EFSA	2012	Guidance on Dermal Absorption1 EFSA Panel on Plant	N	PUBLIC

			Protection Products and their Residues (PPR). EFSA Journal 2012; 10(4): 2665, p. 17		
All sections	EFSA	2012	Scientific Opinion on the safety and efficacy of copper compounds (E4) as feed additives for all animal species: cupric sulphate pentahydrate based on a dossier submitted by Manica S.p.A. EFSA Journal 2012;10(12): 2969	N	PUBLIC
All sections	ECHA	2013	Competent Authority Report and Assessment Repor of Copper Sulphate Pentahydrated	N	PUBLIC
All sections	Official Journal of the European Union	2013	COMMISSION IMPLEMENTING REGULATION (EU) No 1033/2013	N	PUBLIC

3.2 Output tables from exposure assessment tools

3.2.1 Human health exposure

TRAINED PROFESSIONALS

a) Scenario [1] Mix and Load: pouring product into a bucket

ConSexpo Web calculator

Substance Name	CuSO4.5H2O
Molecular weight	250 g/mol
KOW	0.0045 10Log
Product Name	LO-CHLOR POOL ALGAECIDE
Weight fraction substance	12.5 %
Population Name	Trained professional
Body weight	60 kg
Frequency	240 per year
Description	pour undiluted liquid, contamination 0.5 ml hands M&L model 4 UKPOEM

Dermal (No inhalation, no oral)

Exposure model	Direct contact - Instant application
Exposed area	820 cm²
Weight fraction substance	12.5 %
Product amount	0.57 g
Absorption model	Fixed fraction
Absorption fraction	5%

$CuSO4.5H_2O$

Dermal load	8.7×10^{-2} mg/cm²
External event dose	1.2 mg/kg bw
External dose on day of exposure	1.2 mg/kg bw
Internal event dose	5.9×10^{-2} mg/kg bw
Internal dose on day of exposure	5.9×10^{-2} mg/kg bw/day
Internal year average dose	3.9×10^{-2} mg/kg bw/day

Integrated

Internal event dose	5.9×10^{-2} mg/kg bw
Internal dose on day of exposure	5.9×10^{-2} mg/kg bw/day
Internal year average dose	3.9×10^{-2} mg/kg bw/day

Cu x(25/100)

Integrated

Internal event dose	1.47×10^{-2} mg/kg bw
Internal dose on day of exposure	1.47×10^{-2} mg/kg bw/day
Internal year average dose	0.97×10^{-3} mg/kg bw/day

Note: It is considered that approximately 10 times more product is used in a competition pool than in a private pool. Therefore it is assumed that in a competition pool the procedure is repeated 10 times and consequently the estimated exposure is 10 times higher.

b) <u>Scenario [2] Application: pouring diluted product from bucket into the pool</u>

ConSexpo Web calculator (Privated pools)

Substance Name	CuSO4.5H2O
Molecular weight	250 g/mol
KOW	0.0045 10Log
Product Name	LO-CHLOR POOL ALGAECIDE
Weight fraction substance	12.5 %
Population Name	Trained professional
Body weight	60 kg
Frequency	240 per year
Description	Pour diluted product 1/10 from a 10 L bucket, contamination 0.5 ml hands M&L model 4 UKPOEM. We assume that density of diluted solution is 1g/cm^3.

<u>Dermal (No inhalation, no oral)</u>

Exposure model	Direct contact - Instant application
Exposed area	1948.8 cm²
Weight fraction substance	1.25 %
Product amount	0.5 g
Absorption model	Fixed fraction
Absorption fraction	5%

$CuSO4.5H_2O$

Dermal load	3.2×10^{-2} mg/cm²
External event dose	1.0×10^{-1} mg/kg bw
External dose on day of exposure	1.0×10^{-1} mg/kg bw
Internal event dose	5.2×10^{-3} mg/kg bw
Internal dose on day of exposure	5.2×10^{-3} mg/kg bw/day
Internal year average dose	3.4×10^{-3} mg/kg bw/day

Integrated

Internal event dose	5.2×10^{-3} mg/kg bw
Internal dose on day of exposure	5.2×10^{-3} mg/kg bw/day
Internal year average dose	3.4×10^{-3} mg/kg bw/day

Cu x(25/100)

Integrated

Internal event dose	1.3×10^{-3} mg/kg bw
Internal dose on day of exposure	1.3×10^{-3} mg/kg bw/day
Internal year average dose	8.5×10^{-4} mg/kg bw/day

Note: It is considered that approximately 10 times more product is used in a competition pool than in a private pool. Therefore it is assumed that in a competition pool the procedure is repeated 10 times and consequently the estimated exposure is 10 times higher.

NON-PROFESSIONALS

a) Scenario [1] Mix and Load: pouring product into a bucket

ConSexpo Web calculator

Substance Name	CuSO4.5H2O
Molecular weight	250 g/mol
KOW	0.0045 10Log
Product Name	LO-CHLOR POOL ALGAECIDE
Weight fraction substance	12.5 %
Population Name	Non-professional (Consumer)
Body weight	60 kg
Frequency	28 per year
Description	Pour undiluted liquid. It is considered that the maximum size of container authorized for non-professional users is 5 liters: contamination 0.2 ml hands M&L model 4 UKPOEM. Note: density of the product 1.1367 g/ml.

Dermal (No inhalation, no oral)

Exposure model	Direct contact - Instant application
Exposed area	820 cm²
Weight fraction substance	12.5 %
Product amount	0.23 g
Absorption model	Fixed fraction
Absorption fraction	5%

$CuSO4.5H_2O$

Dermal load	3.5×10^{-2} mg/cm²
External event dose	4.8×10^{-1} mg/kg bw
External dose on day of exposure	4.8×10^{-1} mg/kg bw
Internal event dose	2.4×10^{-2} mg/kg bw
Internal dose on day of exposure	2.4×10^{-2} mg/kg bw/day
Internal year average dose	1.8×10^{-3} mg/kg bw/day

Integrated

Internal event dose	2.4×10^{-2} mg/kg bw
Internal dose on day of exposure	2.4×10^{-2} mg/kg bw/day
Internal year average dose	1.8×10^{-3} mg/kg bw/day

Cu x(25/100)

Integrated

Internal event dose	6.0×10^{-3} mg/kg bw
Internal dose on day of exposure	6.0×10^{-3} mg/kg bw/day
Internal year average dose	**3.5×10^{-4} mg/kg bw/day**

b) Scenario [2] Application: pouring diluted product from 10L bucket into the pool

ConSexpo Web calculator (Privated pools)

Substance Name	CuSO4.5H2O
Molecular weight	250 g/mol
KOW	0.0045 10Log
Product Name	LO-CHLOR POOL ALGAECIDE
Weight fraction substance	12.5 %
Population Name	Non-professional (Consumer)
Body weight	60 kg
Frequency	28 per year
Description	Pour diluted product 1/10 from a 10 L bucket, contamination 0.5 ml hands M&L model 4 UKPOEM. We assume that density of diluted solution is 1g/ml.

Dermal (No inhalation, no oral)

Exposure model	Direct contact - Instant application
Exposed area	1948.8 cm²
Weight fraction substance	1.25 %
Product amount	0.5 g
Absorption model	Fixed fraction
Absorption fraction	5%

$CuSO4.5H_2O$

Dermal load	3.2×10^{-3} mg/cm²
External event dose	1.0×10^{-1} mg/kg bw
External dose on day of exposure	1.0×10^{-1} mg/kg bw
Internal event dose	5.2×10^{-3} mg/kg bw
Internal dose on day of exposure	5.2×10^{-3} mg/kg bw/day
Internal year average dose	4.0×10^{-4} mg/kg bw/day

Integrated

Internal event dose	5.2×10^{-3} mg/kg bw
Internal dose on day of exposure	5.2×10^{-3} mg/kg bw/day
Internal year average dose	4.0×10^{-4} mg/kg bw/day

Cu x(25/100)

Integrated

Internal event dose	1.3×10^{-3} mg/kg bw
Internal dose on day of exposure	1.3×10^{-3} mg/kg bw/day
Internal year average dose	1.0×10^{-4} mg/kg bw/day

3.2.2 Environmental exposure

Not applicable

3.3 New information on the active substance

Not applicable..

3.4 Residue behaviour

Not applicable..

3.5 Summaries of the efficacy studies

Summaries of efficacy studies are provided in section 2.2.5.5.

3.6 Confidential annex

See the document PAR confidential Annex.