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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

REVATOP 12%

Product type 2

Hydrogen peroxide as included in the Union list of approved active substances

Asset number: NL-0018705-0000
Evaluating Competent Authority: NETHERLANDS

Date: 1 July 2022

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1 CONCLUSION

APCP
REVATOP 12% is a ready to use liquid containing 11.98 % (w/w) pure hydrogen peroxide as active substance. At ambient temperature the product is clear translucent with a pH 2.8 for the undiluted formulation.
A shelf life of 4 years in the proposed HDPE bottles is considered acceptable, based on data from both accelerated storage and long term storage studies. During storage no changes were observed in appearance, storage containers (HDPE), pH and acidity. The content of active substance in the test substance was determined by HPLC-UV and no significant changes were observed throughout the testing period.
With regard to its physical and chemical hazards the product is classified as oxidizing liquid cat. 2.
The HPLC-UV analytical method used to determine the content of active substance in the product was sufficiently validated in what concerns specificity, linearity, accuracy and precision according to SANCO 3030/99/rev. 4.

Efficacy
REVATOP 12% is claimed to be efficacious against algae in pool water. The intended use and dosage indicated by the applicant is:
- To treat algae spots before bloom starts: 1.5L of REVATOP 12% for 10 m^3 of pool water,
- To treat greenish water in pool: 3L of REVATOP 12% for 10m^3 of pool water.
- To treat very green water in pool: 6L of REVATOP 12% for 10m^3 of pool water.

A semi-field test was provided. This test demonstrates that 1.5L of REVATOP 12% for 10 m^3 of pool water, algae growth is comparable to the control without product. Furthermore, this test demonstrates that REVATOP 12% dosed 3L per 10 m^3 (as well as 6L per 10 m^3) prevents growth of algae for at least 4 days in water. Therefore, the eCA adapted the authorised use to:
REVATOP 12% prevents growth of green algae, for at least 4 days, in water of private pools (permanent or non-permanent pools for private use or collective use, such as in sports complexes, hotels and campings).

Human Health
REVATOP 12% is classified with H318: Causes serious eye damage. Considering the (efficacious) dose, a large volume needs to be added to a swimming pool. This results in an increased risk of being exposed to splashes. For safe use a dosing system should be used to avoid splashing and projection when handling large packaging of 10 or 20 L. Dosing systems can be prescribed for professional use only and thus available volumes to non-professional users are limited to packaging sizes of 1L and 5L only. These packaging can be well handled by an adult, as this volume does not exceed any other water treatment product that can be found on the market. Moreover, for non-professional users, no contact with eyes is expected due to the instructions as application following use instructions reduces the risk of accidental splashing and results in the rapid dilution of the product in the pool, especially in front of the discharges nozzle. Moreover, all packaging contains warnings to inform the user about any possible effects to the eyes as the product is labelled for eye damage. Additionally, the label contains instructions for washing of hands after use to prevent hand-to-eye exposure. Therefore, safe use is concluded for both professional and non-professional use including for application with REVATOP 12% according to the use-instructions.

Environment
When used in accordance with the legal Instructions for Use (SPC), REVATOP 12% complies with the environmental standards and will not cause unacceptable effects to the environment.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
REVATOP 12%	Netherlands

2.1.1.2 Authorisation holder

Name and members of the authorisation holder	**Name**	MAREVA PISCINES ET FILTRATIONS
	Address	ZI du Bois de Leuze, 25, rue Marie Curie, 13310 Saint-Martin de Crau, France
Authorisation number	NL-0018705-0000	
Date of the authorisation	1 July 2022	
Expiry date of the authorisation	1 July 2032	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	MAREVA PISCINES ET FILTRATIONS
Address of manufacturer	ZI du Bois de Leuze, 25, rue Marie Curie, 13310 Saint-Martin de Crau, France
Location of manufacturing sites	ZI du Bois de Leuze, 25, rue Marie Curie, 13310 Saint-Martin de Crau, France

2.1.1.4 Manufacturer of the active substance

Active substance	Hydrogen peroxide
Name of manufacturer	Arkéma
Address of manufacturer	420 rue d'Estienne d'Orves 92705 Colombes Cedex France
Location of manufacturing sites	Arkéma France – RN 85, BP1 – 38560 Jarrie - France

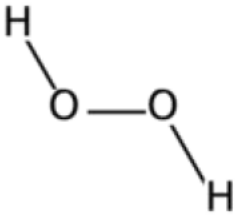
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex (Annex 3.6).

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)	
IUPAC or EC name	Hydrogen peroxide
EC number	231-765-0
CAS number	7722-84-1
Minimum purity / content	The active substance as manufactured is an aqueous solution which contains 35-<70% (by weight) of hydrogen peroxide. On a calculated dry weight basis the minimum purity of hydrogen peroxide is estimated close to 99.5% (by wt).
Structural formula	

2.1.2.2 Candidate(s) for substitution

This active substance is not candidate for substitution.

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

Common name	Function	CAS number	EC number	Content %
Hydrogen peroxide	Active substance	7722-84-1	231-765-0	34.3 (TK) 11.97 (TC) 11.9 (pure)
Phosphoric Acid	Non-active substance	7664-38-2	-	0.0083

The product is intended for the general public. Therefore, the Regulation for explosives precursors Reg (EU) 98/2013 applies. The product complies with the maximum allowed concentration of 12% hydrogen peroxide.
According to the Annex I of the Regulation Reg (EU) 98/2013, Hydrogen Peroxide shall not be made available to members of the general public on their own, or in mixtures or substances including them, except if the concentration is equal to or lower than the limit values of 12%. As the maximum allowed concentration of 12% is set, therefore there is no concern regarding this product in the context of explosives precursors.

eCA remark: According to the production process described in the Confidential annex the applicant suggests that the concentration of H_2O_2 will be kept between 11.3 and 12 %.

2.1.2.4 Information on technical equivalence

MAREVA PISCINES ET FILTRATIONS presents Arkéma as the supplier of active substance. This company is a member of the subgroup "hydrogen peroxide" of CEFIC. The company is included in the list of active substance suppliers who participated in the review program of the active substance (Art. 95 list updated January 19, 2016, available on the ECHA website). The similarity of the active substance is acquired.
Arkéma France – RN85, BP1 - 38560 - Jarrie – France (site of provision) is a reference source.

2.1.2.5 Information on the substance(s) of concern

As for phosphoric acid a community workplace exposure limit (=SCOEL value) is established, it must be considered as Substance of Concern (SoC). Therefore, according to CA-Nov14-Doc.5.11 a risk assessment for the SoC needs to be provided.

2.1.2.6 Information on endocrine disrupting properties

An assessment of the endocrine disruption is presented in section "Assessment of effects" for human health aspect and in section "Effects assessment on the environment" for the environmental aspect. No ED alert was identified.

2.1.2.7 Type of formulation

AL (Any other liquid)

The product is ready to use (applied undiluted).

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	Oxidising liquids cat. 3 Eye dam. 1
Hazard statement	**H272** - May intensify fire; oxidiser **H318** - Causes serious eye damage.
Labelling	
Signal words	Danger
Hazard statements	**H272** - May intensify fire; oxidiser **H318** - Causes serious eye damage.
Precautionary statements	**P101:** If medical advice is needed, have product container or label at hand **P102:** Keep out of reach of children **P103:** Read label before use. **P210**: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P220:** Keep away from clothing and other combustible materials. **P280**: Wear protective gloves/protective clothing/eye protection/face protection. **P305 + P351 + P338 + P310: IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/.... **P501:** Dispose of contents/container in accordance with local/regional/national/international regulation.
Notes	P101, P102, P103 are only required for packaging intended for non-professional users.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Algaecide for pools.

Product Type	PT 2
Target organism (including development stage)	Algae: *Green algae*
Field of use	Indoor, Outdoor REVATOP 12% prevents growth of green algae, for at least 4 days, in water of private pools (permanent or non-permanent pools for private use or collective use, such as in sports complexes, hotels and campings). To be used only in pools with a filtration system

Application method(s)	Manual application by pouring (1L, 5L) or application by professional dosing system (10L, 20L) directly at the water surface in the pool (preferably in front of the outlets stream of the filter = filtration backflow) and in a way that splashes and projection are avoided.
Application rate(s) and frequency	The product is ready to use. **Dosage :** 3L of REVATOP 12% for 10m^3 of pool water equivalent to active substance concentration of 37.51 mg H_2O_2/L considering a product density of 1.042.
Category(ies) of users	Professionals-Non-professionals
Pack sizes and packaging material	HDPE opaque or translucent white or blue. Closure: degassing Screw cap, re-sealable and child-resistant. Bottle volume non-professionals: 1L, 5L. Bottle volume professionals: 10L, 20L.

2.1.4.2 Use-specific instructions for use

Please refer to general directions for use point 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

Please refer to general directions for use point 2.1.5.2

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

Please refer to general directions for use point 2.1.5.3

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

Please refer to general directions for use point 2.1.5.4

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

Please refer to general directions for use point 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Comply with the instructions for use. **Step 1**: In advance of treatment with REVATOP 12%: - Make sure bathers are absent (e.g. apply in the evening)

- Make sure the bathwater has a pH between 6.9-7.7. Adjust the pH if necessary. Filtration to be ran continuously
- Make sure there are no algae deposits present in the pool.

Step 2: Treatment with REVATOP 12%:
1 and 5 L for non-professional users:
Dose 3 L of REVATOP 12% for 10m^3 of pool water.. To avoid splashing, the product need to be poured directly into the water, with the opening of the packaging below the water level. Add product in front of the returns in the pool to allow rapid dilution of the product into the pool. Add the required amount of REVATOP 12% according to your pool volume. Do not pour the product directly into the skimmers. The product is not effective in very green water.

10 and 20 L for professional users:
Dose 3 L of REVATOP 12% for 10m^3 of pool water with a metering pump or other professional dosing systems in place to avoid splashing and projection. Inject the required amount according to your pool volume. When the volume is injected stop the dosing system. Do not pour the product directly into the skimmers. The product is not effective in very green water.

2.1.5.2 Risk mitigation measures

For professional users:
The use of eye protection during handling of the product is mandatory.

For both non-professional and professional users:
Wash hand after use.
Avoid contact with eyes.
Avoid splashes and spills during pouring.
Do not drain pool water directly on soil in the 15 days following treatment.
Do not drain pool water directly to surface water.

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

If medical advice is needed, have product container or label at hand.

- IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance
- IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
- IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

- Do not discharge undiluted product in the surface water or in the sewers.
- In the case of water pollution in lake or sewers, inform authorities in accordance with the local laws.
- Stop / contain the leak if possible.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Never discharge the retrieved product (after a runoff) in containers because of the decomposition risk. - Rinse several times the packaging with water before disposal. The rinsing water must be discharged in the swimming pool. - Never put back the used product bottle in its original packaging.

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

- Do not store near food, drink and feed.- Keep out of reach of children and non-target animals/pets. - Store in a ventilated place with the cap facing upwards. The product must be stored at 5-30°C. - Store away from direct sunlight. - Shelf-life 4 years.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	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
Bottle	1L	White or Blue/ translucent or opaque PEHD	Plug with tamperproof screw sealed with inviolability collar - Degassing seal - Child safety plug	Non-professional for private uses only	Yes
Bottle	5L	White or Blue/ translucent or opaque PEHD	Plug with tamperproof screw sealed with inviolability collar -	Non-professional for private uses only	Yes

			Degassing seal - Child safety plug		
Bottle	10L	White or Blue/ translucent or opaque PEHD	Plug with tamperproof screw sealed with inviolability collar - Degassing seal - Child safety plug - Special handle for easy manipulation - Bottle adapted for the use of metering pump if present	Professional for private uses only	Yes
eCA remark: A packaging of 10L to be handled by a non-professional is considered unsafe from the point of view of handling and application of the biocidal product. The product is classified as eye damaging which restricts the use of a 10L bottle by a non-professional.					
Bottle	20L	White or Blue/ translucent or opaque PEHD	Plug with tamperproof screw sealed with inviolability collar - Degassing seal	Professional for private uses only	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new active substance data was provided. Data on efficacy and physical and chemical properties of the product have been provided by the applicant.

2.1.8.2 Access to documentation

A letter of access is submitted for the active substance full dossier.

2.2 Assessment of the biocidal product (family)

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

Table 2. Intended use # 1 –Preventative treatment against algae in pools.

Product Type	TP2.02
Target organism (including development stage)	Algae: *Green algae*
Field of use	Private. Treatment for all type of private pools and SPA (indoor and outdoor), treated with all type of disinfection products.
Application method(s)	Manual application by dilution directly at the water surface in pools (preferably in the outlets stream). To avoid splashes and projection. Introduce the bottle in the swimming pool with the opening of the bottle at the water level.
Application rate(s) and frequency	The product is directly poured in the pool with respect of the instructions. **Dosage :** To prevent algae bloom start (algae spots on walls, bottom, stairs or shadow areas): 1.5L of REVATOP 12% for 10 m^3 of pool water To treat a green pool: 3L of REVATOP 12% for 10 m^3 of pool water To treat a very green pool: 6L of REVATOP 12% for 10 m^3 of pool water
Category(ies) of users	General public and Pool specialists for private uses.
Pack sizes and packaging material	Please see the relevant section.

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	GIFAP monography N°17, 2nd Edition.	11.98	liquid	[redacted] 2016 [redacted] N°report: 16-33-041-[redacted] (PART 1)
Colour at 20 °C and 101.3 kPa	GIFAP monography N°17, 2nd Edition.	11.98	Colourless translucent	
Odour at 20 °C and 101.3 kPa	GIFAP monography N°17, 2nd Edition.	11.98	As the product is harmful if inhaled (H332) the qualitative determination of odour is not performed according to guideline OPPTS. By users the odor is described as "sour".	
eCA remark Acceptable. For products that pose a potential risk with regard to inhalation, the odour does not need to be reported. However, the product is not classified with regard to inhalation. Hydrogen peroxide is known for its pungent characteristic odour.				
Acidity / alkalinity	CIPAC MT 191 CIPAC MT 75.3	11.98	Free acidity= 0.007 % H_2SO_4 w/w pH = 2.8 $pH_{1\%}$ = 6.3 (20°C)	[redacted] 2016 [redacted] N°report: 16-33-041[redacted] (PART 1)
Relative density / bulk density	OECD 109 (pycnometer)	11.98	D^{20}_4 = 1.042	
Storage stability test – **accelerated storage**	CIPAC MT46 18 weeks at 30°C	11.98	The weight deviation= 0.1% of the initial weight. No deformation or alteration of the packaging (HDPE) was observed. The appearance of the test substance did not change (colourless translucent liquid). pH on neat item before storage = 2.8	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH on neat item after storage = 2.9 pH of a 1% w/v dilution beforeafter storage = 6.3 pH of a 1% w/v dilution after storage = 5.7 Free acidity before storage=0.007 % H_2SO_4 w/w Free acidity after storage=0.007 % H_2SO_4 w/w Hydrogen peroxide before storage: 11.98% Hydrogen peroxide after storage: 11.48% (HPLC-UV)	
eCA remark The HPLC-UV method validation is included in the study report. The method validation is reported in section 2.2.4. The study shows the product is expected to be stable for at least 2 years at ambient conditions in HDPE. As the study was performed at 30°C, the applicant has proposed to limit the recommended storage accordingly.				
Storage stability test – **long term storage at ambient temperature**	GIFAP monography N°17, 2nd Edition	11.98	1L HDPE bottles were stored at 17-23 °C, protected from sunlight for a period of 48 months. The weight deviation after 4years was -0.65% of the initial weight. No deformation or alteration of the packaging (HDPE) was observed after 4 years. The appearance of the test substance did not change after 4 years (colourless translucent liquid).	[redacted] 2016 [redacted] N°report: 16-33-041-[redacted](PART 1) [redacted] 2018 [redacted] N°report: 16-33-041[redacted] (PART 2) [redacted] 2020 [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH of neat item before storage = 2.8 pH of neat item after storage = 2.89 pH 1% w/v dilution before storage = 6.3 pH 1% w/v dilution after storage = 5.0 Free acidity before storage = 0.007 % H_2SO_4 w/w Free acidity after storage = 0.008 % H_2SO_4 w/w Hydrogen peroxide before storage: 11.98% Hydrogen peroxide after storage: 12.05% (+0.58%) (HPLC-UV)	N°report: 16-33-041-[redacted] (PART 3) will be available in December 2020 (48-month storage period)
eCA remark The study shows the product is stable for at least 4 years at ambient conditions in HDPE.				
Storage stability test – **low temperature stability test for liquids**			Waiving: The label gives clear instruction that the product must not be stored under conditions of temperature ≤ 0°C.	
eCA remark The applicant has proposed to store the product between 5 and 30°C. Considering the nature of the product and the proposed conditions, the eCA considers it acceptable that no study is performed.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			No significant change in active substance content after sunlight exposure was recorded. Assessment Report (p36): adsorption spectrum of hydrogen peroxide shows no	[redacted], 2016 [redacted] N°report: 16-33-041-[redacted] (PART 1)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			propensity of the molecule to be decomposed by UV/VIS light.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			No significant change in active substance content after temperature exposure was recorded. Waiving for Humidity: the product is aqueous.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			No reactivity towards container material was observed during storage stability studies.	
Wettability			Waiving: Not relevant for AL formulation	
Suspensibility, spontaneity and dispersion stability			Waiving: Not relevant for AL formulation	
Wet sieve analysis and dry sieve test			Waiving: Not relevant for AL formulation	
Emulsifiability, re-emulsifiability and emulsion stability			Waiving: Not relevant for AL formulation	
Disintegration time			Waiving: Not relevant for AL formulation	
Particle size distribution, content of dust/fines, attrition, friability			Waiving: Not relevant for AL formulation	
Persistent foaming			Waiving: because of no surfactant properties. Surfactants are usually organic compounds that are amphiphilic (hydrophobic groups and hydrophilic groups). It is a chemical compound with characteristics of a highly polar liquid. When the H_2O_2 is in solution with water it	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			is miscible and no foaming reaction occurs.	
Flowability/Pourability/Dustability			Waiving: Not relevant for AL formulation	
Burning rate — smoke generators			Waiving: Not relevant for AL formulation and the product is not intended to produce smoke	
Burning completeness — smoke generators			Waiving: Not relevant for AL formulation and the product is not intended to produce smoke	
Composition of smoke — smoke generators			Waiving: Not relevant for AL formulation and the product is not intended to produce smoke	
Spraying pattern — aerosols			Waiving: Not relevant for AL formulation	
Physical compatibility			Waiving: the product is not intended for use in combination with other substances	
Chemical compatibility			Waiving: the product is not intended for direct use in combination with other substances	
Degree of dissolution and dilution stability			Waiving: Not relevant, not hydrosoluble formulation	
eCA remark The product is not diluted for use and it is an aqueous liquid. Therefore, technical properties are not relevant. The waivers above are acceptable to the eCA.				
Surface tension			Waiving: Distilled water has a surface tension of 72.75 mN/m at 20°C; substances showing a surface tension lower than 60 mN/m under the conditions of this method should be regarded as being surface-active materials (see method A.5 Surface tension 2008).	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			In Assessment Report for hydrogen peroxide, the surface tension is reported to be 80.4 mN/m at 20°C (Schumb et al., p. 205 and 206, 1955 referring to Phibbes and Giguère, 1951) therefore the 34.9% H_2O_2 solution is not considered to be tensio-active. A stabilised 12% hydrogen peroxide product is therefore expected to have a similar surface tension within the range 72 – 80mN/m at 20°C.	
eCA remark The surface tension justification is acceptable to the eCA. The product is not diluted for use. In addition, based on the composition of the product, the surface tension should be equal to or higher than that of water.				
Viscosity	OECD 114 (Ubbelohde)	11.98	Kinematic viscosity At 20°C=1.00 ± 0.00 mm^2/s Kinematic viscosity At 40°C=0.67 ± 0.00 mm^2/s	[redacted] 2016 [redacted] N°report: 16-33-041-[redacted] (PART 1)
eCA remark The kinematic viscosity was determined using an Ubbelohde. The shear dependence was not investigated, but considering the composition of the product, it is not expected that the viscosity is shear dependent.				

Note: Some Physical-Chemical and Analytical tests have been performed on REVA-SPA Booster product. This product is exactly the same as all the 12% products named in 2.1.1.2.

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

The product is a ready to use liquid formulation of 11.98 % (w/w) pure hydrogen peroxide. At ambient temperature the product is clear translucent with a pH 2.8 for the undiluted formulation.
During storage for 18 weeks at 30 °C in HDPE no changes were observed in appearance storage containers (HDPE), pH and acidity. The content of active substance in the test substance was determined by HPLC-UV and no significant changes were observed.
A long term stability study at ambient temperature with the biocidal product stored in 1L HDPE bottles was performed for a period of 4 years. No changes in the appearance of the biocidal product and of the packaging was observed. The pH, acidity and content of active substance (determined with HPLC-UV) remained constant throughout the testing period..

Low temperature stability test was waived as the label recommends to store the product at temperatures between 5°C and 30°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Waiving: a substance or mixture with explosive properties, but where the predominant hazard is covered by another class (e.g. organic peroxides, self-reactive substances and mixtures), is not included in the class of explosives. Regarding H_2O_2 the predominant hazard is the oxidising property.	Guidance on the Application of the CLP Criteria: version 4.1 - June 2015
eCA remark Acceptable. Based on the harmonised classification of hydrogen peroxide, the product does not require classification as an explosive.				
Flammable gases			Waiving: Not relevant for liquid formulation	
Flammable aerosols			Waiving: Not relevant for liquid formulation	
Oxidising gases			Waiving: Not relevant for liquid formulation	
Gases under pressure			Waiving: Not relevant for liquid formulation	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable liquids			Waiving: Inorganic oxidising liquids are not flammable and therefore do not have to be subjected to the classification procedures for the hazard classes flammable liquids or pyrophoric liquids.	Guidance on the Application of the CLP Criteria: version 4.1 - June 2015
eCA remark Acceptable. The product does not contain flammable constituents.				
Flammable solids			Waiving: Not relevant for liquid formulation	
Self-reactive substances and mixtures			CLP definitions excludes substances and mixtures classified according to this Part as explosives, organic peroxides or as oxidising	Regulation N° 1272/2008 Version 4.1 June 2015
Pyrophoric liquids			Inorganic oxidising liquids are not flammable and therefore do not have to be subjected to the classification procedures for the hazard classes flammable liquids or pyrophoric liquids	
Pyrophoric solids			Waiving: Not relevant for liquid formulation	
Self-heating substances and mixtures			Not applicable for the product as in general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating.	
Substances and mixtures which in contact with water emit flammable gases			Based on the composition of the product and experience in handling and use it is not expected that the product will emit flammable gases in contact with water.	Regulation N° 1272/2008 Version 4.1 June 2015
Oxidising liquids			According to specific concentration limits of CLP Harmonised Classification of hydrogen peroxide solution the product 34.9% is not classified as oxidising liquid.	

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td colspan="5">eCA remark: Based on known experience from the UN Transport Regulation, products with > 8 % hydrogen peroxide are classified as oxidising liquids. As in this case the transport regulation takes precedence the product is classified as oxidising liquid category 3.</td></tr>
<tr><td>Oxidising solids</td><td></td><td></td><td>Waiving: Not relevant for liquid formulation</td><td></td></tr>
<tr><td>Organic peroxides</td><td></td><td></td><td>Waiving: Based on the composition the product does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.</td><td></td></tr>
<tr><td>Corrosive to metals</td><td>UN test 37.4 C.1</td><td>11.98
Batch no.: 134762</td><td>
<table>
<tr><th>Steel</th><th>Weight at t0 (g)</th><th>Weight after 7 days (g)</th><th>Mass loss (%)</th><th>Localized corrosion (µm)</th></tr>
<tr><td>Fully submerged</td><td>16.112</td><td>16.110</td><td>0.0</td><td>0</td></tr>
<tr><td>Half way submerged</td><td>16.533</td><td>16.533</td><td>0.0</td><td>0</td></tr>
<tr><td>In gas phase</td><td>16.550</td><td>16.549</td><td>0.0</td><td>0</td></tr>
</table>
<table>
<tr><th>Aluminium</th><th>Weight at t0 (g)</th><th>Weight after 7 days (g)</th><th>Mass loss (%)</th><th>Localized corrosion (µm)</th></tr>
<tr><td>Fully submerged</td><td>5.396</td><td>5.397</td><td>0.0</td><td>0</td></tr>
<tr><td>Half way submerged</td><td>5.411</td><td>5.412</td><td>0.0</td><td>0</td></tr>
<tr><td>In gas phase</td><td>5.428</td><td>5.428</td><td>0.0</td><td>0</td></tr>
</table>
No relevant effects on aluminium and on steel were observed. The test item is therefore classified as “not corrosive”.
</td><td>[redacted] n°: 19011801G979</td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td></td><td></td><td>Waiving: Inorganic oxidising liquids are not flammable. The test is not required for liquids not flammable in air.</td><td></td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative self-ignition temperature for solids			Waiving: Not relevant for liquid formulation	
Dust explosion hazard			Waiving: Not relevant for liquid formulation	

Conclusion on the physical hazards and respective characteristics of the product
Due to the nature of the substance many physical hazards have been waived. Due to the concentration of 11.98% of active substance in the product, it is classified as oxidising liquid category 3. A test of corrosiveness to metals has been performed on the test item at 11.98% hydrogen peroxide concentrate and no relevant effects on aluminium and steel were observed. The test item at 11.98% is therefore classified as "not corrosive to metals".

Note: Some physical, chemical and analytical tests have been performed on REVA-SPA Booster product. This product is exactly the same as all the 12% products named in 2.1.1.2.

2.2.4 Methods for detection and identification

Method of analysis of Hydrogen peroxide

Reference:	Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination [redacted] 2016 [redacted] N°report: 16-33-041[redacted] (PART 1)
Guideline(s):	Yes, according to guideline SANCO/3030/99 rev.4 (11/07/2000)
Deviations:	No
GLP:	Yes

Materials and methods.

The purpose of this study was to validate an analytical method using HPLC-UV for the determination of Hydrogen peroxide in a SL formulation. Basic titration of hydrogen peroxide was not considered as accurate and specific enough for purposes of compliance with the SANCO/3030/99 requirements, and further examination of stability over long term storage period (please see Note 2 of the submitted amendment to the report 16-33-041-ES (Part 1)).

Preparation of solutions

Calibration linearity solutions:	Accurately weighed 106.8 mg of analytical grade hydrogen peroxide was diluted to 20 mL in H3PO4 0.1%. The resulting solution was sequentially diluted in H_3PO_4 0.1%. so as to obtain 11 calibration solutions ranging between 0.5 and 261 mg H2O2/L.
Precision solutions	Six distinct stock solutions were prepared using accurately measured 250-260 mg samples of the test item in 25 mL of H_3PO_4 0.1%. The stock solutions were further diluted in 1/10 and 1/100 v/v in H_3PO_4 0.1% so as to obtain two determination series corresponding to approximately 0.1 and 1 g item/L
Accuracy solutions	Accurately measured amounts of the test substance were spiked with analytical grade hydrogen peroxide. The resulting mixtures were submitted to the analysis. The measured spiking amounts were compared to the calculated values, on the basis of 48.9% H_2O_2 in the analytical standard (certified value).

Chromatographic Conditions

HPLC-UV-Conditions:

HPLC	Agilent 1100 System
Column	Synergi Polar RP 250 mm x 4.6 mm x 4 µm
Mobile phase	65.0 %v/v water, with Tetrabutylammonium bromide 5 mM + Phosphate buffer 2 mM pH 7.5 20.0 %v/v Acetonitrile 15.0 %v/v H_3PO_4 0.1% in water
Flow	1.0 mL/min
Temperature	20°C
Injection volume	20 µL
Detection	228 nm

Retention time	2.8 min
Total run time	7 min

Method:
Hydrogen peroxide was assessed by Ion Pair Chromatography using tetra butyl ammonium bromide as ion pairing agent in water.
The mobile phase was delivered by mean of a 4-way pump:
65.0 % v/v Tetrabutylammonium bromide 5 mM + Phopshate buffer 2 mM pH 7.5 in water
20.0 % v/v Acetonitrile
15.0 % v/v H_3PO_4 0.1% in water

Ion pair chromatography (IPC) is an effective reversed-phase liquid chromatographic (RPLC) technique for separation of organic ions and partly ionized organic analytes. The technique utilizes the same types of stationary phases and mobile phases as RPLC; the main characteristic for IPC is that an ion pair reagent is added to the mobile phase. The ion pair reagent is usually an alkylsulfonate, an alkylsulfate or an alkylammonium salt. The high efficiency of RPC columns compared with columns used in ion exchange or ion chromatography also makes IPC a valuable alternative to these techniques.
IPC has been applied in almost all areas of analytical chemistry where chromatography is used. Since many drugs are basic or acidic, the driving force for the development of IPC came from the pharmaceutical industry where today it is used on a routine basis.
(Please see Note 3 of the submitted amendment to the report 16-33-041-[redacted] (Part 1))

Specificity:
Blank determination of the solvent used for the preparation of the working solution (H_3PO_4 0.1%) did not revealed any interfering peak area at the retention time of the hydrogen peroxide. This was also the case for the water used for the preparation of the test substance.

Linearity:
The regression was considered valid over 1.0 – 261.1 mg H_2O_2/L.
Hydrogen peroxide eluted as a single peak area at 2.8mn. A representative chromatogram is presented in appendix 3 of the report 16-33-041-ES (Part 1).
According to the SANCO/3030/99 – General definitions, the linearity is the ability of a detection system, within a defined range, to produce an acceptable linear correlation between the test results and the concentration of analyte in the sample. Allowing for any transformation of the data.
The logarithmic transformation of the data is classically considered as acceptable. The coefficient of determination $r > 0.99$, as required. (Please see Note 4 of the submitted amendment to the report 16-33-041-[redacted] (Part 1)).

Precision:

Two determination series of 6 solutions corresponding to approximately 0.1 and 1 g item/L were performed.
In every case the relative standard deviation complied with the Horwitz's modified value of 1.84 for acceptability of the precision and the two determination series gave confident results. The precision was reported as < 1.0%.

Accuracy (Fortification range):
Two spiking levels were tested. According to the data reported in Table 4 of the report 16-33-041[redacted](Part 1), these spiking levels corresponded to approximately 25 and 50 g/kg for added hydrogen peroxide in the preparation.
The standard addition method was applied because there was no placebo provided for the preparation. (Please see Note 5 of the submitted amendment to the report 16-33-041[redacted](Part 1)). In every case recovery of added hydrogen peroxide was within 98-102% as required.

Robustness:
This was determined in the time course of the analytical development. Tetrabutylammonium (TBAB) in the mobile phase is key for the detection of hydrogen peroxide, otherwise no signal was observed. It was concluded that hydrogen peroxide reacted with TBAB and that signal came from the reaction product. The signal did not depend on the concentration of the TBAB in the mobile phase: the same signal was observed when TBAB was reduced to 0.5 mM instead of 5mM. The detection still remained for a long time even though the HPLC system was purged for several hours with a mobile phase without TBAB.
Day to day determination of the calibration solutions proved that the repeatability of the determination was satisfactory.

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**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Hydrogen peroxide	HPLC-UV	0.075 0.44mg total H_2O_2 / (2 replicates for each level) 2 fortifications ranges were used, corresponding to approx. 25 and 50 g/kg for added hydrogen peroxide in the preparation.	Log(H_2O_2, mg/L)= 0.987(± 0.002)x Log(Area)– 0.329(± 0.003) r^2=0.99998 The regression was considered as valid over 1.0 - 261.1 mg H_2O_2/L	No interfering signal at retention time of the analyte.	101.2 % 98.6 % 101.0 % 98.1 %	99.9% 99.6%	System precision: RSDr = 1.84 RSD At 0.1g/L product in water: 0.35% (n=6) At 1 g/L product in water 0.77% (n=6)	Not relevant.	2016 N°report: 16-33-041-(PART1)

Data gap: The validation report does not contain the required representative chromatograms to insure specificity: blank injections (pure diluent) and placebo (blank formulation).

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		

The same method, as the one used to determine the content of active substance, is relevant for monitoring purpose to analyse hydrogen peroxide in water.

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		
Reference is made to the applicable active substance dossiers.									

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		
Reference is made to the applicable active substance dossiers.									

Analytical methods for water									
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		
Reference is made to the applicable active substance dossiers.									

Analytical methods for animal and human body fluids and tissues									
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		
Reference is made to the applicable active substance dossiers.									

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		
Reference is made to the applicable active substance dossiers.									

Conclusion on the methods for detection and identification of the product
An HPLC-UV method of analysis of active substance in the product has been developed and validated according to the SANCO/ 3030/99 rev 4 in the frame of this dossier. Suitable methods for the analysis of hydrogen peroxide in environmental media are available as addressed in the AR.

Note: Some physical, chemical and analytical tests have been performed on REVA-SPA Booster product. This product is exactly the same as all the 12% products named in 2.1.1.2

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product "REVATOP 12%" falls within Main group 1: Disinfectants.
Product Type 2: Disinfectants and algaecides not intended for direct application to humans or animals.

REVATOP 12% is used as algaecide against green algae in outdoor or indoor pool waters by professional (only for private swimming pools).

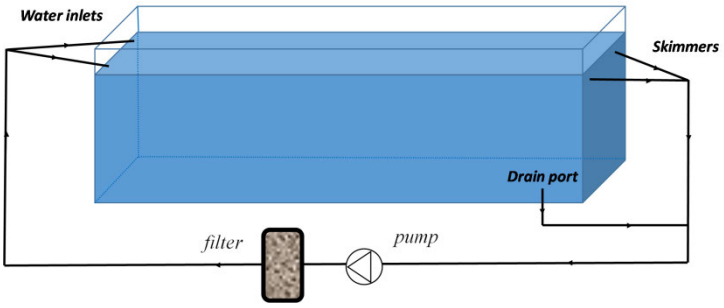
The product is a ready to use liquid formulation (AL) to prevent growth of green algae. The product is used for preventive action to stop algae emergence and to inhibit the growth of algae in water.

Using the Commission P91L AFNOR typology, the areas of uses are:
- Private pools for private use
- Private pools for collective use, type 1, 2 and 3 (sports, hotel complex and camping).

Typology

This product is used for different type of pools: permanent swimming pool, non permanent swimming pool.

2.2.5.2 Figure 1 Scheme of permanent swimming pool with a filtration system.



2.2.5.3 Figure 2 Scheme of non-permanent swimming pool with a filtration system.

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

The aim of
REVATOP 12% is to prevent growth of green algae.

2.2.5.5 Effects on target organisms, including unacceptable suffering

The active substance hydrogen peroxide destroys green algae cells.

2.2.5.6 Mode of action, including time delay

The active substance hydrogen peroxide forms powerful oxidants in water such as hydroxyl and oxygen radicals. These reactive oxygen species cause irreversible damage to cellular components of algae, such as enzymes, membrane constituents and DNA.

The time delay depends on the initial amount of algae, on and interfering substances in the water, temperature and hydraulic parameters as filtration.

2.2.5.7 Efficacy data

eCA comment: Below, the applicant provided an additional explanation of the provided semi-field test. The eCA commented in italics and removed irrelevant information.

There are no standard test methods for algaecide efficacy testing that are currently recommended in the draft guidance on efficacy assessment of biocides PT 1-5.

A tailored protocol for simulated use test (phase 2, step 2 test) has been set up to support the claim of algaecide action in pool waters against green algae. The purpose of the efficacy test is to mimic the practical in-use conditions of application of the algaecide product and to provide objective criteria for the efficacy of the algaecide product.

A European consultation via the Working Group on efficacy has been launched by ANSES in 2016. *The question addressed by ANSES was: is the simulated-use sufficiently robust test and unnecessary field data?* The majority of MS have concluded that the principles of the tests presented are sufficiently robust provided that the volume used is larger than 100L and that the conditions of the test are representative of the field conditions. Therefore a volume of 200L has been used for the simulated-use test and all the conditions – parameters of the test have been justified (see justifications p37-39). Therefore no field trials have been performed.

The protocol has been designed with the collaboration of the members of the Commission PEROX (a Commission of the GIE "H2O BIOCIDE", (prospective authorisation holder of the AMM), CEHTRA (Regulatory consultancy) and IRM (CRO laboratory).

The final protocol is submitted in the efficacy test and data protection is claimed by the applicant GIE H2O BIOCIDE (on the behalf of its members of the Commission PEROX) *See:*

[redacted] *2017. Report N° 1025/0117/A.* A PDF document with high quality pictures is available and submitted conjointly.

The study has been performed at the end of 2016 and in early 2017 by the laboratory [redacted] The study has been done with the product hydrogen peroxide 34.9%. The efficacy data to support the claims were generated in a 3-step process:

STEP 1: In-use cell numeration:

The concept of "green water" is not objective. There is no tool for measuring green colour. The perception of colour depends on the subject who observes, on the colour and configuration of the pool. At an equal concentration of green microalgae, the colouring of a swimming pool water with a 140 cm optical path appears to be more intense than that of an aquarium (optical path 40 cm). Moreover, the notion of green water for the user who treats his swimming pool is very variable: it can range from a few traces of algae on the walls of the pool to a water of which one cannot distinguish the bottom or even the first steps.
This is why it is not possible to think only in terms of "colouring degree of water" when it deals with "Green algae water" to be treated.
Nevertheless the colouring or non-colouring of water is an objective criteria that will be the only available criteria for the end user to assess the efficacy of the biocidal product.
When water is not coloured anymore, it does not mean that there is no more green algae cells in water but that the residual concentration in cells does not entail water coloration. The algaecide treatment controls algal growth and allows the usual pool treatment system to maintain a non-coloured bathing waters. Then, the filtration systems also contribute to the algae cells elimination from the bathing water (the impact of filtration system can be observed in the preliminary efficacy test).
Swimming pools with green water were sampled for subsequent cell numeration to justify the algae inoculum density to be tested in simulated use tests.

The samples were taken directly from the pond at 50 cm under water, in the middle between suction and discharge. The samples were frozen in less than 3 hours after sampling.

Eight samples were taken from eight visually green waters in pools of various regions (photos available in report). The algae cell density was estimated by cell counting with a Malassez counting chamber in triplicate.

There are 2 pools in which hydrogen peroxide has been used without success ("PA30 Nîmes" and "EC34 Pomerols"). But the purpose of the sampling was only to measure algal cell concentrations in visually green algae (*) in order to define for our efficacy study an inoculum that is representative of the reality "of the ground ". Two samples were taken in the same pool "LB_13-SMC", only the sample taken before application of hydrogen peroxide was taken into account. Therefore 7 values of cells concentration were used to determine a representative inoculum.
(*) There are cases of green waters whose coloration is not due to the presence of algae.

Note / business experience: the success of any treatment does not only depend on the treatment products but also on the proper functioning of the filtration system and the control of sources of contamination and development of microalgae (stabilizer content for pools treated with organic chlorine, phosphate content etc ...)

In this application for Authorization, hydrogen peroxide is proposed for use as "shock algaecide" in pools whose water is contaminated by algae (at the beginning of development or in full bloom). This "shock" action aims to kill algae or, depending on the conditions, at least to inhibit their growth.
To obtain a clear water, this operation "shock" is generally followed by a mechanical operation of elimination of dead algae, ensured by the fixed or mobile filtration systems (automatic brooms, robots, ...) assisted or not by a chemical treatment (flocculating products).

Note on counting representativity:
The samples used for the enumeration phase were not concentrated before counting, as it was done after in the semi-field test, so the result of the count is associated with the following remark: "for values between 1.103 and 1.104 cells/ml, the count is not very representative. The number of cells counted on the whole grid is between 1 and 10. "For the semi-field trial, the inoculum was counted at 5.10^5 (Chlamydomonas), 1.81 10^6 (Chlorella) and 2.5 10^6 cells/mL (Pseudokirchneriella) then diluted in the aquariums to reach the target inoculum of 1/3 of 10^4 cell/mL for each strain. In the course of the test, the samples taken to measure the concentration of algae were concentrated by filtration before counting. Therefore it has never been counted below 104 algae on Malassez cell.

Values of algae cell density ranged from 1E+03 to 1.67E+05 cells per mL. Since the number of samples remaining is small (n=7), the counts have extreme values (very low or very high) and we have no way of weighting them, the median was used. Indeed, in the case of very different values, the calculation of an average distorts the representativeness of the sampling, especially for the small numbers.
The median value is 9E+03, the value has been rounded to 1E+04 cells per mL. Supported by this study an inoculum of 1E+04 cells per mL is justified for efficacy testing of the product on green or very green water
See: Report GIE/PEROX/201612/01.

Simulated use test

For STEPS 2 and 3 below, the tested inoculum was made of the three representative green algae species: *Pseudokirchneriella subcapitata, Chlorella vulgaris* and *Chlamydomonas reinhardtii.*

Justification of the selection is given below:
The target organisms to be controlled are green algae. Green microalgae are Chlorophyta, and more than 7000 species exists. There is no data on identification of species causing green water in pools, therefore 3 representative species of Chlorophyta have been selected. Three species were proposed after European consultation of members states authorities: C*. vulgaris, C. reinhardtii and S. subspicatus*.

Among the three strains mentioned during the European consultation; the two strains *Chlorella vulgaris* and *Chlamydomonas reinhardtii* were retained for the test. The laboratory has set up these algae cultures specifically for this efficacy study. The *S. subspicatus* strain (*Desmodesmus subspicatus = Scenedesmus subspicatus*) is one of the strains proposed in the OECD 201 test in the same way as Pseudokirchneriella subcapitata.
The latter being a very well-known strain, model in ecotoxicology and used routinely by the laboratory IRM, it was retained for the test. According to Annex 2 of OECD guideline 201, the *P. subcapitata* strain has a growth rate (1.5-1.7 day^{-1}) higher than the *D. subspicatus* strain (1.2-1.5 day^{-1}), it places the test in a worst-case situation.

Moreover, a mixture of algae is a configuration that is consistent with the reality where several algae strains can compete. It was therefore decided to inoculate the aquariums with a mixture of one third of each of the three species.

In summary the three representative species of green algae selected for the efficacy testing are:
- *Pseudokirchneriella subcapitata*, strain AC152

- *Chlorella vulgaris,* strain AC150
- *Chlamydomonas reinhardtii*, strain AC609

STEP 2: a preliminary efficacy test has been performed to assess the robustness of the designed protocol and to refine it when necessary. The preliminary test was conducted in three 240-L tank over 95 hours with:

- One treated aquarium at the intended dose of 1L product containing 34.9 % of H202 / 10m³ water (equivalent of 3L of REVATOP 12% for 10 m3 of pool water) with filter
- One non-treated aquarium with filtration
- One non-treated aquarium without filtration

See : [redacted] 2017. Report N° 1332/1216/A/M1.

The objective of the preliminary study was to test the implementation of the outlined protocol. This preliminary test revealed malfunctions and possible improvements. It results in the following adjustments in the final test:

- Addition of flow measures, addition of water level measures, larger set of physical and chemical parameters followed
- Adjustment of the pH during the test, in order to remain as close as possible to the target pH
- Adjustment of the quantity of interfering substance (BSA)
- Adjustment of the order of the analysis so that it is more practical at the technical level.

STEP 3: a final efficacy test has been performed according to protocol submitted conjointly.
The features for the test were:
- Experimental unit: 240-L tank (fill volume ca. 200 L)
- Three replicates for control tank and each dose rate
- Control tank: a similar tank is operated in the same test conditions, but without application of formulated product
- Three dose rates: application of dose rate (0.5L, 1L and 2L/10m3 of hydrogen peroxide 34.9%) according to use claims
- Observation period: 95 hours
- Three representative green algae species tested at 1/3 each and an overall inoculum of 1E+04 cells/mL

[redacted] *2017. Report N° 1025/0117/A (Final report available)*

Study parameters justification is as follow:

Test duration:
For reasons of [redacted] laboratory technical constraints that performed the test, no measure can be made on the weekends. Therefore, the experiment was conducted on open days from Monday morning to Friday afternoon. The test duration is 95h.

Outside / inside pool:
The test was performed indoors for a better control of test conditions. Developments of green algae are more common in outdoor pools because they are more exposed to pollutants, including micro-organisms. In this semi-field trial, this exposure is simulated by the addition of an inoculum of green algae cells. It should be noted that the massive intake of algae cells is very "worst case" compared to reality. Indeed, in reality, indoor or outdoor

pools do not become green at once. If we refer to the growth rate of *P. subcapitata* from 1.5 to 1.7 day^{-1} reported in the OECD 201 guideline, several days are needed to pass the first signs (small traces at the bottom or on the pool walls) to the green pool as presented in our report "In situ cells numbering in several swimming pool water samples - A DATA COLLECTION DOCUMENT" (19/01/2017).
The protocol, considering its worst-case nature, therefore covers the indoor and outdoor pools.

Cover:
The most common swimming pool coverings are: liner, polyester shell, masonry, concrete (painted or not) and tiling. The coatings do not affect the growth of algae in the water column but rather their ease to attach better or not on the walls.
The glass walls of the aquariums of the test simulate the smooth coatings of the majority of the swimming pools, but this parameter is not restrictive since the instruction of use is to "well scrub the walls in case of visible deposit" before applying hydrogen peroxide.
The type of coating therefore has no impact on the effectiveness of hydrogen peroxide since the brushing allows the resuspension of the algae to be removed.
For better consistency, the label has been amended accordingly.

Justification of Temperature in aquarium: 27.5°C ± 2.5°C
The temperature of 25 to 30°C is in accordance with the recommendations of the guidance No. 170 on disinfection tests in swimming pools. This temperature range of 27.5°C ± 2.5 is representative of a heated indoor pool for example. Alternatively, the water of an outdoor pool in Europe will be colder and subject to further variations and therefore less favourable to the multiplication of microalgae.
Justification of temperature for algae culture: The microalgae cultures were carried out at temperatures in accordance with the recommendations of guideline 201, item 29, namely 21 to 24°C ± 2.

Light intensity:
Green algae photosynthesize using light as a source of energy to convert inorganic elements into organic matter that allows them to grow and divide. In the semi-field test, this light is provided by four fluorescent lamps above each aquarium. An alternating day / night cycle of 16h / 8h is justified to promote the exposure of green algae to the light and therefore their growth in the basins.
The luminous intensity in the test of 8000 to 10.000 lux is greater than the range of recommendations of the OECD 201 standard (point 31: 60-120 µE.m².s-1, which corresponds to 4440-8880 lux). because of a greater depth. The simulation test aims at favourable conditions for the growth of green microalgae.
During the microalgae cultivation phase, the light intensity is that recommended in the OECD 201 guideline: 6000 to 8800 Lux (Fluorescent lamps: Sun Glo) 24 hours a day.
These conditions aim to obtain an exponentially growing algae population.

pH:
The target pH in the semi-field test is the recommended pH in pools disinfected with chlorinated products (source: Anses, March 2012. Évaluation des risques sanitaires liés aux piscines - Partie I : piscines réglementées Avis de l'Afsset, Rapport d'expertise collective, page 46).
The pH is easily measurable and adjustable by the user (measuring kits, products to increase or decrease the pH of swimming pool water).

Filtration:
A swimming pool is defined by the AFNOR commission P91L as: "an artificial pool, waterproof, in which are practiced aquatic activities and whose water is filtered, disinfected and disinfecting, renewed and recycled, as well as all necessary equipment to its operation. " Sand filtration represents the majority of filtration systems in swimming pools, public or private. The sand filtration system is the most penalizing for hydrogen peroxide. Indeed, the contact with the large mineral active surface is likely to accelerate the degradation of hydrogen peroxide and actually decrease its effectiveness. The test therefore took place under realistic worst-case filtration conditions.

eCA comment:
Specifications of the used filter:
Mini bilayer sand filter for domestic use
Bottom sand layer 25g (1.0-2.5mm)
Top sand layer: 130g (0.4-0.8mm)

Interfering substance justification
A dedicated paragraph has been added on page 20 of Final Report No. RE-1025/0117/A to justify the amount of BSA added. The approach was as follows: ensure that the presence of nutrients + the BSA rate reach at least one of the maximum permissible pollution levels in collective swimming pools; namely either an oxidability of 4 mg O2 /L, or an NKT level of 3 mg N / L.

Study parameters followed up during efficacy study:

The study parameters followed are :
- Physico-chemical parameters (pH, dissolved oxygen rate, redox potential, flow rate and temperature)
- Algal Cell number (cells/mL)
- Chlorophyll a concentration (µg/L)
- Hydrogen peroxide concentration (mg/L)

Regarding **initial concentration in H2O2**
As in the field, the homogenization of the concentration of hydrogen peroxide throughout the pool is not instantaneous. From experience it takes 4 hours to 8 hours with activated filtration for homogenization of the product. In the test, the assay carried out 24 hours later indicates homogeneous concentrations of H2O2. The rate of degradation of hydrogen peroxide is variable and explains a certain variability of the concentration of H2O2 from one point to another of the basin.

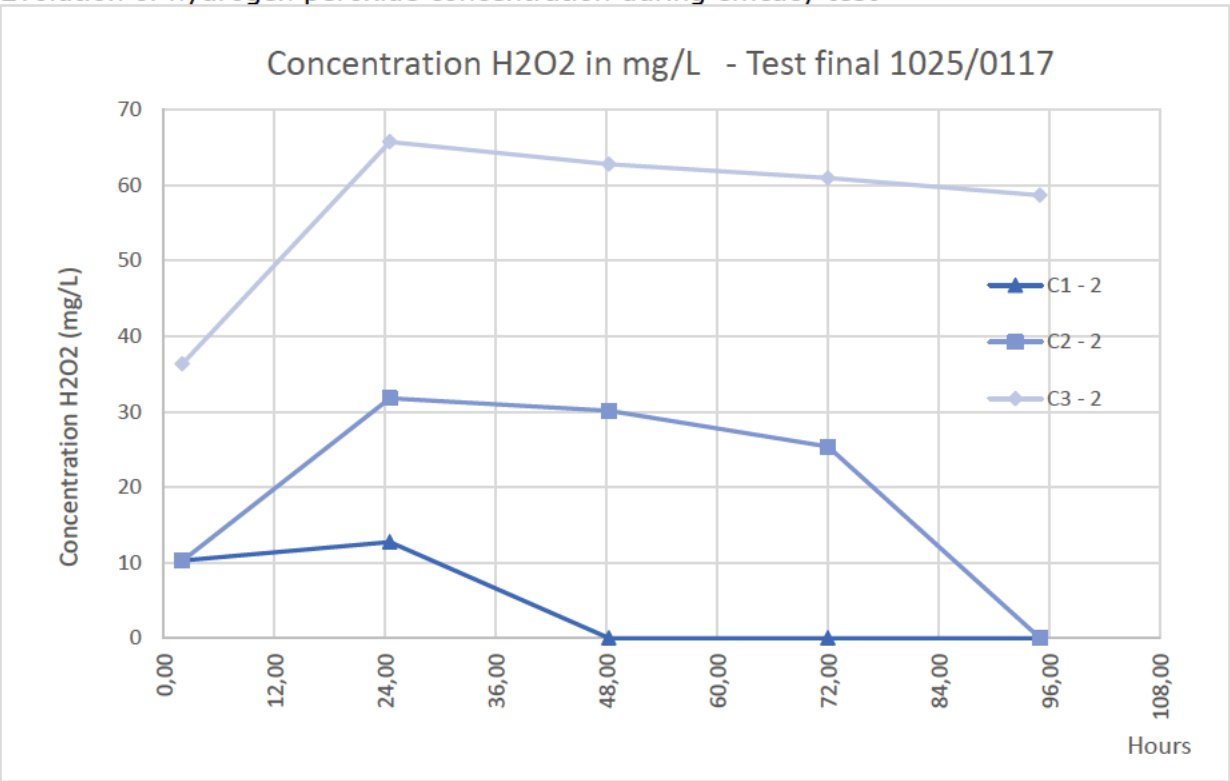
Results on H_2O_2 concentration along the study are as follow:

Table 2. H_2O_2 concentration in mg/L as a function of time

Sampling date and hour		C1 - 1	C1 - 2	C1 -3	C2 - 1	C2 - 2	C2 -3	C3- 1	C3 - 2	C3 -3
09/01/2017 13:00	t0+ 2h	9.63	10.26	13.49	21.24	10.21	10.4	105.18	36.31	44.76
10/01/2017 11:30	t0 +24.5h	11.13	12.72	12.46	31.39	31.76	33.08	69.59	65.71	64.92
11/01/2017 11:15	t0+48.25h		<LOD			30.13			62.75	
12/01/2017 11:00	t0 +72h		<LOD			25.38			60.93	
13/01/2017 10:00	t0 +95h	<LOD	<LOD	<LOD	<LOD	<LOD	LOD	63.57	58.63	58.85

LOD <1.18 mg/L
LOQ = 3.53 mg/L

Evolution of hydrogen peroxide concentration during efficacy test



Data on hydrogen peroxide concentration indicate that:

- Regarding C1 the active substance H_2O_2 is consumed within the first 48h, after 48h the concentration is below the limit of detection (LOD).
- Regarding C2 the active substance H_2O_2 concentration remains at level up to 30 mg/L until 48h, then decreases slowly until 72h and is found below the LOD at 95h.

Regarding C3 the active substance H_2O_2 is maintained to level higher than 60 mg/L until 72h

Efficacy criteria

The efficacy claim is compliant with the definition of algaecide given in the ECHA guidance Volume II V2 which defines the following:
Algaecide: A product or active substance used to control (inhibit the growth) or kill algae
Algaecidal activity: The capability of a product or active substance to produce a reduction in the number of viable algae cells under defined conditions

Efficacy test results 24 h after application of the product are conclusive on growth inhibition effect and therefore on reduction or even disappearance of the green colour.

Comment eCA: *Growth inhibition was demonstrated in provided tests, however, disappearance of green colour nor reduction of green colour was determined.*

Note on the non-relevance of criteria applied for bacteria:

Unlike bacteria, the mathematical magnitudes of the biological variables are not high enough to reason in increase or log reduction, for example in the controls the cells concentration goes from a value in 10^4 to a value in 10^5. In fact, the log reduction is not appropriate for measuring algaecide efficacy.
Moreover time scale for observation of effects on algal cells differs significantly from effects on bacteria due to the volume treated and its inherent inertia.

Algae density reduction and growth rate inhibition

The densities of green algae are presented in the Table below according to water treatment and according to observation period. The % reduction at an observed time is calculated as following: 100 * (Nc – Nt) / Nc
Where: Nc stands for the mean algae cell density in the control and Nt stands for the mean algae cell density in the treatment.

In the simulated use test, the reduction is significant in a short delay once the product is applied. At 24 h, the algae cell densities measured in the aquarium treated with BP are reduced by at least 75%.
At 48, 72 and 95 h the reduction is more pronounced for concentration C2 and C3 and the algae cell densities measured in the aquarium treated with BP are reduced by at least 91%.
At 48, 72 and 95 h the reduction is less pronounced for concentration C1 and this observation is explained by a concentration of active substance that declined at a level below the limit of detection (< 1.18 mg/L) under the conditions of the test.

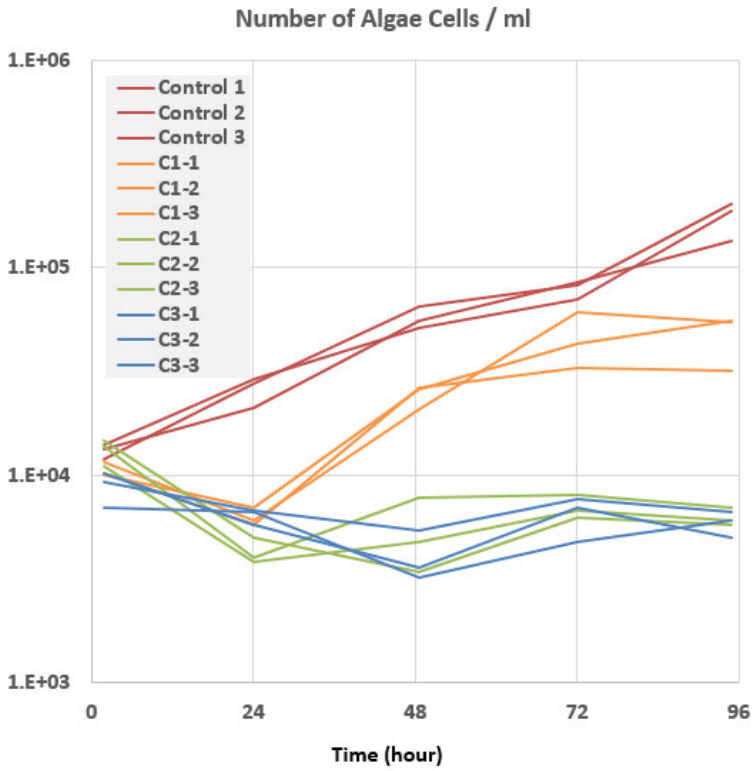
Table 3. Algae Cells densities (cells / mL)

	Algae Cells densities (cells / mL)			
Water treatment	**24 h**	**48 h**	**72 h**	**95 h**
Control 1	2.78E+04	6.50E+04	8.20E+04	2.02E+05
Control 2	2.90E+04	5.13E+04	7.01E+04	1.87E+05
Control 3	2.10E+04	5.53E+04	8.57E+04	1.34E+05
Mean	2.59E+04	5.72E+04	7.93E+04	1.74E+05
Standard deviation	3.52E+03	5.75E+03	6.66E+03	2.92E+04
C1 - 1	5.80E+03	2.63E+04	3.33E+04	3.17E+04
C1 - 2	7.00E+03	2.58E+04	4.30E+04	5.53E+04
C1 - 3	6.00E+03	2.08E+04	6.10E+04	5.47E+04
Mean	6.27E+03	2.43E+04	4.58E+04	4.72E+04
Standard deviation	5.25E+02	2.48E+03	1.15E+04	1.10E+04
C1: % reduction by comparison with control (*)	76%	58%	42%	73%
C2 - 1	4.00E+03	7.80E+03	8.00E+03	7.00E+03
C2 - 2	3.80E+03	4.80E+03	6.80E+03	6.00E+03
C2 -3	5.00E+03	3.40E+03	6.20E+03	5.80E+03
Mean	4.27E+03	5.33E+03	7.00E+03	6.27E+03
Standard deviation	5.25E+02	1.84E+03	7.48E+02	5.25E+02
C2: % reduction by comparison with control	84%	91%	91%	96%
C3- 1	5.80E+03	3.60E+03	7.00E+03	5.00E+03
C3 - 2	6.60E+03	3.20E+03	4.80E+03	6.00E+03
C3 -3	6.80E+03	5.40E+03	7.60E+03	6.60E+03
Mean	6.40E+03	4.07E+03	6.47E+03	5.87E+03
Standard deviation	4.32E+02	9.57E+02	1.20E+03	6.60E+02
C3 : % reduction by comparison with control	75%	93%	92%	97%

C1: 0.5L/10m3, C2: 1L/10m3, C3: 2L/10m3 of hydrogen peroxide 34.9%
(*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

From the efficacy test, a cell density reduction of 3.73E+03 cells/mL is observed 95 hours after single product application at a dose of 1L/10m^3 product (i.e. 39.5 mg H202 /L). A cell density reduction of 4.13E+03 cells/mL is observed 95 hours after single product application at a dose of 2L/10m^3 product (i.e. 79 mg H202/L). The corresponding aquarium waters are uncoloured while in controls the mean cells number per mL increased of 1.64E+05 cells over the time of the test and waters remain green.

Comment of eCA:
Algae cell densities from table 4 we plotted below:



The eCA removed the calculation of growth rate reduction of the applicant, because curative and preventive effect cannot be distinguished when cell densities are plotted against an increasing control. Instead we plotted the cell densities (see plot above). This shows that cell densities increase in the controls. In aquaria with the lowest concentration (C1), no curative and no preventive effect was demonstrated. With the two highest test concentrations (C2 and C3), preventive algicidal effect was demonstrated.

Chlorophyll A reduction and growth rate inhibition

The concentration of Chlorophyll A are presented in the Table below according to water treatment and according to observation period. The % reduction at an observed time is calculated as following: 100 * (CAc – CAt) / Nc
Where: CAc stands for the mean Chlorophyll A concentration in the control and CAt stands for the mean Chlorophyll A concentration in the treatment.

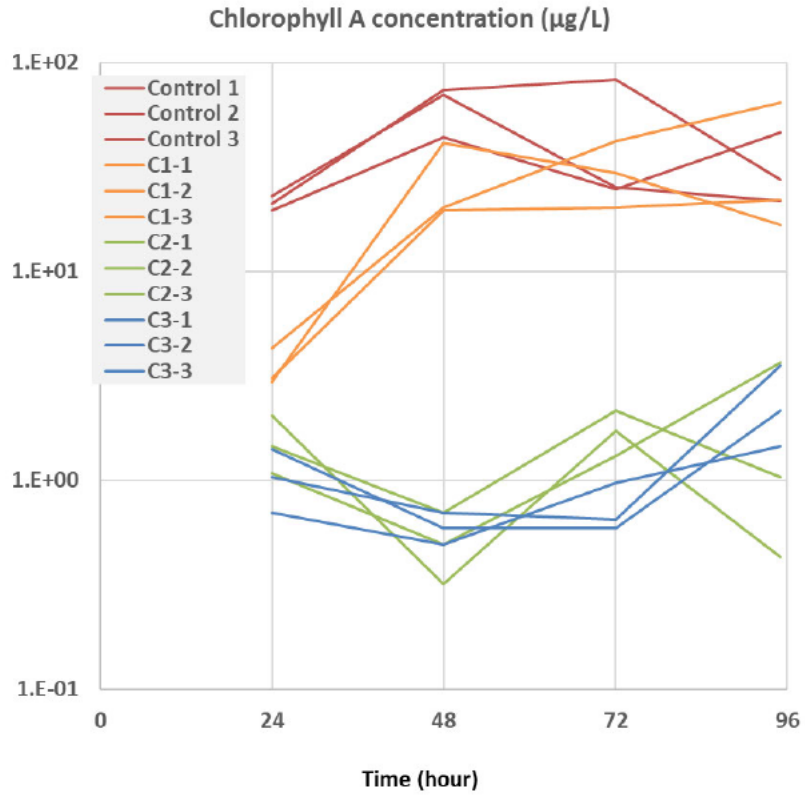
In the simulated use test, the reduction is significant in a short delay once the product is applied. At 24 h, the Chlorophyll A concentrations measured in the aquariums treated with BP are reduced by at least 84%.
At 48, 72 and 95 h the reduction is equal or more pronounced for concentration C2 and C3 and the algae cell densities measured in the aquarium treated with BP are reduced by at least 93%.
At 48, 72 and 95 h the reduction is less pronounced for concentration C1 and this observation is explained by a concentration of active substance that declined at a level below the limit of detection (< 1.18 mg/L) under the conditions of the test.

Table 4. Chlorophyll A concentration (µg/L)

	Chlorophyll A concentration (µg/L)			
Water treatment	24 h	48 h	72 h	95 h
Control 1	22.84	69.77	25.16	21.76
Control 2	19.49	43.96	24.62	46.44
Control 3	21.06	74.03	83.1	27.54
Mean	21.13	62.59	44.29	31.91
Standard deviation	1.37	13.29	27.44	10.54
C1 – 1	2.97	41.31	29.54	16.74
C1 – 2	3.08	19.49	20.09	21.87
C1 -3	4.27	20.25	42.01	64.35
Mean	3.44	27.02	30.55	34.32
Standard deviation	0.59	10.11	8.98	21.34
C1: % reduction by comparison with control (*)	84%	57%	31%	8%
C2 - 1	1.46	0.7	2.16	1.03
C2 - 2	1.08	0.49	1.3	3.67
C2 -3	2.05	0.32	1.73	0.43
Mean	1.53	0.50	1.73	1.71
Standard deviation	0.40	0.16	0.35	1.41
C2: % reduction by comparison with control	93%	99%	96%	95%
C3- 1	0.7	0.49	0.97	1.45
C3 - 2	1.03	0.7	0.65	3.56
C3 -3	1.4	0.59	0.59	2.16
Mean	1.04	0.59	0.74	2.39
Standard deviation	0.29	0.09	0.17	0.88
C3: % reduction by comparison with control	95%	99%	98%	93%

C1: 0.5L/10m3, C2: 1L/10m3, C3: 2L/10m3 of hydrogen peroxide 34.9%
(*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

Initial Chlorophyll A analysis has been performed at t0+1h30 (09/01/2017 12:30) before addition of hydrogen peroxide. Therefore times windows considered to calculate the growth rate are as follow: 0-22h30, 0-46h30, 0-70h30 and 0-93h30.
Comment of eCA:
Chlorophyll A concentrations from table 6 we plotted below:



The eCA removed the calculation of growth rate reduction, because curative and preventive effect cannot be distinguished when Chlorophyll A concentrations are plotted against an increasing control. Instead we plotted the Chlorophyll A concentrations (see plot above). This shows that Chlorophyl A concentrations increase in the controls. In aquaria with the lowest concentration (C1), no curative and no preventive effect was demonstrated. With the two highest test concentrations (C2 and C3), preventive algicidal effect was demonstrated.

End-User criteria for efficacy: The visual effects

The concept of "green water" is not objective. There is no tool for measuring green colour degrees. The perception of colour depends on the subject who observes, on the colour and configuration of the pool.

Nevertheless the colouring or non-colouring of water is an objective criteria that will be the only available criteria for the end user to assess the efficacy of the product

From pictures taken all along the test (document Report [redacted] 1025/0117/A PICTURES)
The water of the **controls** becomes unclear after 24 hours and becomes clearly green after 48h.

Aquariums treated with the **C1** concentration (19.7 mg / L) are unclear in 48 to 72 hours and are green at the end of the test.
Aquariums treated with concentration **C2** (39.5 mg / L) or **C3** (79.0 mg / L) do not stain and are clear at the end of the test.

As indicated above, the effectiveness of the treatment with hydrogen peroxide depends on the administered dose but also on the adjustment of other hydraulic and chemical parameters necessary for the proper functioning of the pool. The filtration system must be efficient.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Algaecide	PT2 Outdoor and indoor pools.	PEROXYDE D'HYDROGENE 34.9%	Natural occurring green algae	**STEP 1: In-use algae cells numeration** Data collection: In situ cells numeration in several swimming pool water samples. The samples were taken directly from the pond at 50 cm under water, in the middle between suction and discharge. The samples were frozen in less than 3 hours after sampling	7 Samples from in situ visually green water pools were taken in various regions of France. Cell counting was performed using laboratory technique Malassez counting chamber. 3 replicates per sample Mean value calculated for each sample.	Results of cells counting are : • $6{,}00.10^3$ cells/ml • $1{,}17.10^5$ cells/ml • $9{,}0.10^3$ cells/ml • $7{,}77.10^4$ cells/ml, • $2{,}3.\ 10^3$ cells/ml • $<1{,}0.10^3$ cells/ml • $1{,}67.10^5$ cells/ml. The median value has been used as inoculum in the efficacy test **=> 9.10^3 rounded to 10^4 cells/ml**	GIE data collection, 2016
Algaecide	*PT2 Outdoor and indoor pools*	*Product Hydrogen peroxide 34 9%* *Storage of product at IRM: 6 months after reception*	*An equal mixture of 3 representative green algal species (total 10^4 cells/mL):* *Pseudokirchneriella subcapitata AC152* *Chlorella vulgaris, strain AC150*	**STEP 2: a preliminary efficacy test** Preliminary test. No guideline available. A tailored protocol has been set up.	**Number of replicates**: 3 tanks: 1 blank without filtration 1 blank with filtration 1 tested dose with single application of 1L/10m3 (200ml tank **Temperature:** 27.5 C	Growth inhibition: a reduction in the growth rate **Algae concentration (cells/mL):** *Treated:* 0h: 10000 4h: 14600 24h: 8360 48h: 8800 72h: 7700 96h: 3960 *Control:* 0h: 10000 4h: 9500	[redacted] *2017 Report N° 1332/1216/A/M1 of 28 April 2018*

			Chlamydomonas reinhardtii, strain AC609		**Incubation times** 4h, 24h, 48h, 72h, 96h. **Concentration :** 20ml of 39.5 mg/L added to 200ml = 3,9 mg/L **Soiling** BSA at 55 mg/L **Other information:** Let chlorine evaporate a few days before the test	24h: 19800 48h: 51700 72h: 72200 96h: 61600 It results in the following adjustments in the final test (STEP 3) : - Addition of flow measures, addition of water level measures, larger set of physical and chemical parameters followed - Adjustment of the pH during the test, in order to remain as close as possible to the target pH - Adjustment of the quantity of interfering substance (BSA) - Adjustment of the order of the analysis so that it is more practical at the technical level.	
Algaecide	*PT2 Outdoor and indoor pools*	*Product Hydrogen peroxide 34 9%* *Storage of product attt IRM: 6 months after reception* *Test from 9 01 2017 to 13 01 2017*	*An equal mixture of 3 representative green algal species (total 10^4 cells/mL): :* Mixed culture *Pseudokirchneriella subcapitata AC152* *Chlorella vulgaris, strain AC150* *Chlamydomonas reinhardtii, strain AC609*	**<u>STEP 3: a final efficacy test</u>** Semi-Field test (indoor) No guideline exist. A tailored protocol has been set up. Efficacy has been assessed by: 1. chlorophyll A measurements 2. algal numeration with Malassez counting chamber and calculation of the algal growth rate	**Number of replicates**: 12 tanks: 3 for each tested product concentration. 200L / tank **H_2O_2 Concentration :** C1: 0.5L/10m³: 19.7mg/L C2: 1L/10m³ : 39.5 mg/L and C3: 2L/10m³ : 79 mg/L Exposure: 95h BSA at 27.5 mg/L (justification on page 20 of the test report) **Temperature:** 27,5 – 30°C	Growth inhibition: C1: +1.60E-02 C2: -4.96E-03 C3: -5.68E-03 Uncoloured water restored with C2 and C3 **Algae concentration (cells/mL):** ***Start culture*:** 1*10^4 cells/mL	[redacted] *20172018 Report 10211025/0117/A of 19 October 2018* Additional PDF document Report IRM 1025/0117/A PICTURES

Incubation times
4.30h,
24h,
48h,
72h,
95h.

Other information:
Let chlorine evaporate a few days before the test

	Algae Cells densities (cells / mL) / Control			
Water treatment	**24 h**	**48 h**	**72 h**	**95 h**
Mean Control	2.59×10^4	5.72×10^4	7.93×10^4	1.74×10^5
Mean C1 (0.5L/10 m^3)	6.27×10^3	2.43×10^4	4.58×10^4	4.72×10^4
Mean C2 (1 L/10 m^3)	4.27×10^3	5.33×10^3	7.00×10^3	6.27×10^3
Mean C3 (2 L/10 m^3)	6.40×10^3	4.07×10^3	6.47×10^3	5.87×10^3

	Chlorophyll A concentration (µg/L) / Control			
Water treatment	**24 h**	**48 h**	**72 h**	**95 h**
Mean Control	21.13	62.59	44.29	31.91
Mean C1 (0.5L/10 m^3)	3.44	27.02	30.55	34.32
Mean C2 (1 L/10 m^3)	1.53	0.50	1.73	1.71
Mean C3 (2 L/10 m^3)	1.04	0.59	0.74	2.39

(*) H_2O_2 concentration was already below LOD (limit of detection) by 48 hours.

Conclusion on the efficacy of the product
eCA: The provided semi-field test demonstrates that a product containing 39.5 mg/L H_2O_2 dosed 1L per 10m^3 pool water prevents growth of green algae, for at least 4 days, in systems with filter, when used according to directions for use. This sufficiently substantiates efficacy of REVATOP 12% dosed 3L per 10 m^3 preventing growth of algae for at least 4 days in water of private pools with a filtration system (permanent or non-permanent pools for private use or collective use).

2.2.5.8 Occurrence of resistance and resistance management

The mode of action of the active substances is that of non-specific general oxidisers. Oxidisers will react with essential macromolecules that make up microbial life, including the oxidation of various proteins, carbohydrates, lipids and nuclear acids. This is such a general reaction to so many different molecules that it is very unlikely that an organism will develop a simple resistance mechanism for that.
Therefore no resistance management strategy is necessary.

To prevent oxidative cell damage, cells have developed ability to decompose H2O2. Reactive oxygen species (ROS), also called oxyradicals, are produced in biological systems as unwanted toxic by-products of normal metabolism. ROS are detoxified by the action of antioxidant protection systems, e.g. antioxidant enzymes or low molecular weight scavengers. The antioxidant enzyme system consists of several enzymes. The most important of them are SOD (superoxide dismutase), CAT (catalase) and GPX (glutathione peroxidase). SOD converts O2 - to H2O2. CAT and GPX converts H2O2 to water. Examples of low molecular weight scavengers are vitamins C and E, carotenoids and glutathione.
It can be concluded that organisms are able to deal with some amount of excess H2O2. The antioxidant enzyme activity varies, however, between cells, tissues and species and also seasonally within same species and in relation to such factors as age.

It can reasonably be expected that such protection systems are induced during sunset when algae metabolism is increased. To circumvent the possible capacity of green algae to mitigate the biocide action of hydrogen peroxide.

2.2.5.9 Known limitations

The Applicant summarises below the factors that can reduce the efficacy through the decomposition of the active substance hydrogen peroxide:

- Interfering substances like organic matter suspended in swimming-pool waters. This parameter has been taken into account during efficacy trial by adding interference substance (Bovine Serum Albumine) to simulate realistic pool conditions. In spite of this interference substance, algae growth inhibition by hydrogen peroxide was effective. Nitrogenous interfering substances (NH4+, EDTA) were present by the algae nutrient solutions in the simulated use efficacy test.
- High temperature (> 40°c) may induce decomposition of hydrogen peroxide and favour dissipation from aquatic phase by evaporation.

- Reaction with UV sunlight. But this reaction has no measurable impact on the product efficacy for the following reasons:
    - the decomposed part of the product vs the applied concentration is negligible
    - The decrease of the hydrogen peroxide concentration in water with sunlight is a long lasting phenomenon
    - As a piece of information, some swimming pools are treated with systems based on UV light reactor combined with hydrogen peroxide. The hydrogen peroxide consumption in these pools is quite low with regards to the actual UV radiation applied (far higher than the UV sunlight).
- Reaction with transition metals that may occur in aquatic phase. Some metals were present at low level in the efficacy test as a part of algae nutrients : Fe, Zn, Co, Cu, Mo, Mn) in concentrations higher than found in swimming pool. However, the efficacy results were satisfying.

In fact, the above initial observations are known general limitations for the hydrogen peroxide but the conditions in swimming pool application are not met for apply them.

2.2.5.10 Evaluation of the label claims

Please refer to the conclusion on the efficacy of the product.

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

In the efficacy study, the product has shown algaecide efficacy when used alone. When used as recommended, no association with other product is deemed necessary.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

No animal or human data are available.

According to the opinion of the BPC, Opinion on the application for approval of the active substance: Hydrogen peroxide, Product type: 2, ECHA/BPC/40/2015, 2 February 2015, hydrogen peroxide only has an impact on the skin corrosion and irritation classification when its content in the product is superior or equal to 35%, which is not the case.

According to the Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 4.1, June 2015: the 'relevant ingredients' of a mixture are those which are present in concentrations of 1% (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for skin irritation/corrosion. As there is no classified substances at a sufficient level for skin irritation/corrosion in the mixture, therefore the product is non classified for this endpoint.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non irritant
Justification for the value/conclusion	The only classified substance for skin irritation/corrosion in the mixture is hydrogen peroxide and is not present at a sufficient content to classify the product, Therefore the product is not classified for this endpoint.
Classification of the product according to CLP	Non classified

Data waiving	
Information requirement	Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	The only classified substance for skin irritation/corrosion in the mixture is hydrogen peroxide and is not present at a sufficient content to classify the product, Therefore the product is not classified for this endpoint.

Eye irritation

Two in vitro eye irritation studies are submitted:
Isolated Chicken Eye Test (OECD 438) - [redacted] 2017
Reconstructed human Cornea-like Epithelium (RhCE) test (OECD 492) - [redacted] 2019

Summary applicant:
Due to the composition and the high dilution of the substance in water, it has been chosen to test the mixture.
Thanks to existing validated ECVAM tests to assess eye irritation and eye corrosion and in regards with the "Guidance on the BPR: Volume III. Part A Version 1.2 May 2018" that states:
"If after the analysis in steps 1 and 2 (relative to active substances) above further testing is needed to assess the potential for eye irritation, the following test methods should be used. In addition to the test methods mentioned below, new OECD validated tests for eye irritation should be taken into account once available in deciding the test strategy. The OECD Test Guideline programme as well as non-animal test methods that undergo validation available by ECVAM should be regularly consulted for any updates. The tests will provide information on the degree and nature of eye and associated mucous membrane irritation, especially with regard to the reversibility of responses.
1.Testing for eye irritation (in vitro assays)
If after the analysis in steps 1 and 2 above further testing is needed to assess the potential for eye irritation, one of the following assays should be used. Test methods for eye irritation:
•OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants.
•EC method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010).
•OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants.
•EC method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants (Annex of Regulation (EC) No 1152/2010).
Specific limitations that may be described within the Test Guideline protocol should be taken into account before performing a test or during the interpretation of the test results acquired. The test methods mentioned above are suitable for the identification of ocular corrosives and severe irritants. Where negative results are obtained, the assessment of eye irritation using an in vitro test method suitable also for the identification of non-irritants should follow, if a validated method has become available. If such a method is not available proceed to testing for eye irritation (in vivo assays).
Therefore according to the guidance, an OECD 438 studies has been performed.

The aim of the study was to evaluate the possible ocular corrosive or severe irritating effects of the test item after administration on enucleated chicken eyes.
The test item REVATOP-12% was applied, as supplied, at the dose of 30 µL, to 3 enucleated chicken eyes, during 10 seconds. Then the eyes were rinsed twice with 10 mL of physiological saline. Three eyes were treated in the same manner with a positive control and one eye with a negative control.
Damages by the test item were assessed by determination of corneal swelling, opacity, and fluorescein retention at 30, 75, 120, 180 and 240 minutes post-dose. The experimental protocol was established in accordance with O.E.C.D. Test Guideline No. 438 adopted 26 July 2013 and test method B.48 – Commission Regulation (EU) No. 1152/2010 dated 08 December 2010 (EU Journal L324) – ATP Council Regulation No. 440/2008 of 30 May 2008 (E.U. Journal L142).

The ocular reactions observed in eyes treated with the test item were:
- maximal mean score of corneal opacity: 2.7, corresponding to ICE class IV;
- mean score of fluorescein retention: 1.7, corresponding to ICE class III;

- maximal mean corneal swelling: 20%, corresponding to ICE class III.
The combination of the three endpoints for the test REVATOP-12% was 1 x IV, 2 x III.
The combination of the three endpoints for the positive control, 5% Benzalkonium chloride, was
3 x IV. Therefore, the positive control is classified as "Corrosive/Severe Irritant", as expected.
The combination of the three endpoints for the negative control, physiological saline, was 3 x I.
Therefore, the negative control is classified as "No Category", as expected.
In accordance with Regulation (EC) No. 1272/2008, the results obtained under these experimental conditions lead to category "no prediction can be made", as defined by OECD guideline No.438.

Endpoint measured	Eye No.	Time (min) 0	30	75	120	180	240
Corneal opacity	10	0	0.5	1	2	3	3
	11	0	0.5	1	2	2	2
	12	0	0.5	0.5	2	3	3
Mean		0.0	0.5	0.8	2.0	2.7	2.7
ICE class					IV		
Fluorescein retention	10	0.5	2	-	-	-	-
	11	0.5	1	-	-	-	-
	12	0.5	2	-	-	-	-
Mean		0.5	1.7	-	-	-	-
ICE class			III	-	-	-	-
Corneal thickness	10	0.58	0.62	0.62	0.64	0.70	0.71
	11	0.61	0.63	0.66	0.69	0.71	0.73
	12	0.58	0.60	0.63	0.64	0.69	0.69
Corneal swelling (%)	10	-	7	7	10	21	22
	11	-	3	8	13	16	20
	12	-	3	9	10	19	19
Mean		-	5	8	11	19	20
ICE class					III		
Combination of the 3 Endpoints		1 x IV, 2 x III					
CLASSIFICATION		No prediction can be made					

The conclusions of this test gave was "No prediction can be made. **Therefore, test item REVATOP-12% is not predicted as causing serious eye damage (Category 1) or as not classified for eye irritation/serious eye damage (No category) with the Isolated Chicken Eye test method.** Additional testing (in vitro and/or in vivo) are required to establish a definitive classification."

Due to the existing and validated (by ECVAM) studies to determine if a substance is not classified for eye irritation, and due to animal welfare, it has been chosen to continue the *in vitro* strategy.
Moreover, the recent ECHA guidance on "How to use new or revise in vitro test methods to address Serious eye damage/Eye irritation (February 2018) clearly states (page 1) that:
"An in vivo eye irritation study shall only be considered at Annex VIII level (section 8.2) in case the in vitro serious eye damage/eye irritation test(s) are not applicable for the substance or the results obtained are not adequate for classification and risk assessment" but there is tests to assess the serious eye damage/irritation tests so there is no need of *in vivo* data and as there is the possibility to continue the *in vitro* strategy, there is no concern on the possibility to conclude on classification.

The recent ECHA guidance on "How to use new or revise in vitro test methods to address Serious eye damage/Eye irritation (February 2018) also states that the in vivo must only be performed **in last resort**. As the same guidance validates the Test Method TG 492, – Reconstructed human Cornea-like Epithelium Test Method (RhCE), It means that in vivo is not the last resort in our case.
In order to determine the classification of the product for its effects on the eyes, it was decided to perform an O.E.C.D. 492. Test method OECD TG 492 –Reconstructed human Cornea-like Epithelium Test Method (RhCE)is an in vitro assay that may be used to identify chemicals not requiring classification and labelling for eye irritation or serious eye damage. The in vitro test methods currently covered by this Test Guideline are the EpiOcular™ Eye Irritation Test (EIT)and SkinEthic™ Human Corneal Epithelium (HCE) Eye Irritation Test (EIT). The methods are applicable to substances and mixtures, and to solids, liquids, semi-solids and waxes. The liquids may be aqueous or non-aqueous; solids may be soluble or insoluble in water.
The aim of the study was to evaluate the eye hazard potential of test item REVATOP 12% (Hydrogen peroxide solution 12%) after topical administration on in vitro reconstructed human cornea-like epithelium tissues (EpiOcularTM tissue model).
Test item REVATOP 12% (Hydrogen peroxide solution 12%) was applied, as supplied, at the dose of 50 µL, to 2 living DPBS pre-treated RhCE (EpiOcularTM tissue model) during 30 minutes at 37°C, 5% CO2, 95% humidity (standard culture conditions). The exposure period was followed by extensive rinsing with DPBS at room temperature, a 12 minutes post-exposure immersion period at room temperature and a 2 hours post-exposure incubation at standard culture conditions. The tissue viability was measured by performing an MTT assay. The experimental protocol was established in accordance with O.E.C.D. Test Guideline No. 492 adopted 25 June 2018.
The mean percent tissue viability of the RhCE replicates treated with test item REVATOP 12% (Hydrogen peroxide solution 12%) was 1.97% versus 27.85% in the positive control (Methyl acetate).
In accordance with Regulation EC No. 1272/2008, test item REVATOP 12% (Hydrogen peroxide solution 12%) lead to the category "no prediction can be made", as defined by the OECD guideline No.492. The test item has to be identified as potentially requiring classification and labelling according to UN GHS Category 2 or Category 1.

	Well ID	OD	Mean OD / disc (#)	Mean OD / product	Viability %	Mean viability %	Difference of viability %	Conclusion
Negative control	SPL 1	1.041 0.771 0.932	0.915	0.991	92.33	100.00	15.34	
	SPL 2	1.116 1.078 1.006	1.067		107.67			
Positive control	SPL 3	0.301 0.286 0.268	0.285	0.276	28.76	27.85	1.82	UN GHS Category 2 or 1
	SPL 4	0.266 0.278 0.258	0.267		26.94			
Test item PH-19/0027	SPL 7	0.026 0.023 0.024	0.024	0.020	2.42	1.97	0.91	UN GHS Category 2 or 1
	SPL 8	0.017 0.015 0.012	0.015		1.51			

Therefore, the two in vitro test provide these conclusions:

OECD 438: **test item REVATOP-12% is not predicted as causing serious eye damage (Category 1) or as not classified for eye irritation/serious eye damage (No category) with the Isolated Chicken Eye test method.**
OECD 492: The test item has to be identified as potentially requiring classification and labelling according to UN GHS Category 2 or Category 1

Conclusion eCA
Both studies are evaluated. For the results we refer to the tables above
The OECD 438 did not provide a conclusion whether the product needs classification or not for eye effects. The product falls in the category "No prediction can be made". Based on a mean viability of 1.97%, the OECD 492 test shows that classification is required for effect on the eyes. However, OECD 492 does not discriminate between category 2 or 1. Based on the calculations rules, the product needs to classified as Eye Dam. 1, H318.
Therefore, the overall conclusion is that the product needs to be classified as Eye Dam. 1, H318.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	Based on the results of the two *in vitro* studies (492 and 438), the product is classified as H318, Eye Dam. 1. This classification is supported by the calculations rules.
Classification of the product according to CLP	H318, Eye Dam. 1.

Respiratory tract irritation

No animal or human data are available.
There are currently no standard tests and no OECD test guidelines available for respiratory irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. It is not a requirement in the Annex III to the BPR. Based on the reactivity of hydrogen peroxide, respiratory tract irritation could occur. However, as 12% hydrogen peroxide is present in the mixture, no classification is considered necessary.
Classification of the product according to CLP	Non-classified.

Data waiving	
Information requirement	It is not a requirement in the Annex III to the BPR.
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Based on the reactivity of hydrogen peroxide, respiratory tract irritation could occur. However, as 12%

	hydrogen peroxide is present in the mixture, no classification is considered necessary.

Skin sensitization

No animal or human data are available.

According to Guidance on the BPR: Volume III. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014: " Testing on the product/mixture does not need to be conducted if:
- there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected;
- the available information indicates that the product should be classified for skin sensitisation or corrosivity; or
- the substance is a strong acid (pH < 2.0) or base (pH > 11.5).

According to the Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 4.1, June 2015 :"Annex I: 3.4.3.3.1. The mixture shall be classified as a respiratory or skin sensitiser when at least one ingredient has been classified as a respiratory or skin sensitiser and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 "

According to the BPC opinion, hydrogen peroxide is not classified as skin sensitizer.
As there is no classified substances for skin sensitization in the mixture, therefore the product is non classified for this endpoint.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not classified
Justification for the value/conclusion	None of the substances in the mixture are classified for skin sensitization, therefore the product is non classified for this endpoint.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected;

Justification	None of the substances in the mixture are classified for skin sensitization, therefore the product is non classified for this endpoint.

Respiratory sensitization (ADS)

No animal or human data are available.

There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.
The product is not classified as skin sensitizer and there is no classified substances in the mixture classified for this endpoint, therefore, it is highly expected that the product is not classified.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not classified as skin sensitizer and there is no classified substances in the mixture classified for this endpoint, therefore, it is highly expected that the product is not classified.
Justification for the value/conclusion	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.
Classification of the product according to CLP and DSD	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.

Data waiving	
Information requirement	Point 8.4 of Annex III to the BPR states that testing on the product/mixture does not need to be conducted if: • there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. However, there are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

No animal or human data are available.
According to the opinion of the BPC, Opinion on the application for approval of the active substance: Hydrogen peroxide, Product type: 2, ECHA/BPC/40/2015, 2 February 2015, the substance is classified as Acute Tox. 4 * H302. Therefore, ATEmix need to be calculated.

As the product only contains 12% in content of hydrogen peroxide, the resulting ATEmix calculation is 3500 mg/kg bw when considering the 100% hydrogen peroxide value of 420 mg/kg bw from the LoEP of the AR of hydrogen peroxide, therefore the product is not classified for this endpoint.

Value used in the Risk Assessment – Acute oral toxicity	
Value	> 2000 mg/kg bw
Justification for the selected value	Considering the 100% hydrogen peroxide value of 420 mg/kg bw from the LoEP of the AR of hydrogen peroxide, the calculations for the 12% hydrogen peroxide containing product results in an ATEmix of 3500 mg/kg bw. As this is > 2000 mg/kg bw, no classification for acute oral toxicity is necessary.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected;
Justification	Considering the 100% hydrogen peroxide value of 420 mg/kg bw from the LoEP of the AR of hydrogen peroxide, the calculations for the 12% hydrogen peroxide containg product results in an ATEmix of 3500 mg/kg bw. As this is > 2000 mg/kg bw, no classification for acute oral toxicity is necessary. This is based on the formula included in section 3.1.3.6.1 of the CLP Regulation

Acute toxicity by inhalation

No animal or human data are available.

According to the opinion of the BPC, Opinion on the application for approval of the active substance: Hydrogen peroxide, Product type: 2, ECHA/BPC/40/2015, 2 February 2015, the substance is classified as Acute Tox. 4 * H332. Therefore, ATEmix need to be calculated.

The applicant indicates that according to the CEFIC calculation described in their document for Hydrogen Peroxide Classification and Labelling: "
There are no reliable acute inhalation toxicity studies available which show that hydrogen peroxide should be classified". However based on Annex VI of the CLP Regulation hydrogen peroxide has a minimum classification in category 4 for acute inhalation toxicity. For this reason it is proposed to use the ATE values mentioned in Table 3.1.2 of the CLP Regulation for the classification of mixtures which contain hydrogen peroxide. For acute toxicity category 4 the ATE value is 11 mg/l for a vapour of hydrogen peroxide, while the ATE is 1,5 mg/l for a dust/mist of hydrogen peroxide. The low value of the Henry's law constant indicates very low volatilisation of hydrogen peroxide from water. Therefore the acute inhalation toxicity should be determined with the calculation rules using dust and mist approach.
However, based on the outcome of the Working Group discussions for a union authorisation based on hydrogen peroxide (WGII 2019) the converted acute toxicity point estimate of 11 mg/L (vapours, according to Table 3.1.2 of CLP) is used for H2O2 to calculate the ATE_{mix} as the study included in the assessment report of hydrogen peroxide is tested in its vapour form.

When applying the ATE method for the classification of mixtures, the acute inhalation toxicity is calculated to be:
ATE_{mix} = 100*11/12 = 91.7 mg/L.
Since the estimated acute ATE_{mix} falls outside the category 10.0 < ATE Category 4≤ 20.0, the product does not need to be classified for acute inhalation toxicity.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATEmix = 12.5 mg/L
Justification for the selected value	Considering the 1.5 mg/L acute toxicity point estimate of 1.5 mg/L, the calculations for the 12% hydrogen peroxide containing product results in an ATEmix of 12.5 mg/L. As this is > 5 mg/L, no classification for acute inhalation toxicity is necessary.
Classification of the product according to CLP	Non-classified

Data waiving

Information requirement	Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.
Justification	Considering the 1.5 mg/L acute toxicity point estimate of 1.5 mg/L, the calculations for the 12% hydrogen peroxide containing product results in an ATEmix of 12.5 mg/L. As this is > 5 mg/L, no classification for acute inhalation toxicity is necessary.

Acute toxicity by dermal route

No animal or human data are available.
According to the Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 4.1, June 2015: "Annex I: 3.1.3.6.1. Data available for all ingredients.
In order to ensure that classification of the mixture is accurate, and that the calculation need only be performed once for all systems, sectors, and categories, the acute toxicity estimate (ATE) of ingredients shall be considered as follows:
(a) include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories shown in Table 3.1.1;
(b) ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);
(c) ignore components if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table 3.1.1) and do not show acute toxicity.
Components that fall within the scope of this section are considered to be components with a known acute toxicity estimate (ATE)."
There is no substance classified as Acute tox dermal present in the mixture. Therefore, the mixture is non classified.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	not classified for acute dermal toxicity.
Justification for the selected value	There is no substance classified as Acute tox dermal present in the mixture.
Classification of the product according to CLP	Not-classified

Data waiving	
Information requirement	Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Justification	There is no substance classified as Acute tox dermal present in the mixture.

Information on dermal absorption

According to the Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015: "A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product." And "Based on the available data, it can be assumed that dermal exposure to hydrogen peroxide mainly causes local effects in the skin, systemic effects being of much less significance."
As shown above, the product is not classified for dermal irritation/corrosion or dermal acute toxicity.
No systemic risk assessment needs to be performed considering the dermal route of exposure.

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

According to Guidance on the BPR: Volume III. Part A, Chapter III: Requirements for Biocidal Products, Version 1.1 November 2014: " Testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected."

The product is composed of active substance diluted in water. However, to stabilize the product, a co-formulant (phosphoric acid) is added. As SCOEL values are derived (1 mg/m3 8-hr, and 2 mg/m3 for short-term exposure), in accordance to CA-Nov14-Doc.5.11, phosphoric acid is considered a substance of concern.
As phosphoric acid is present at a very low concentration no adverse health risks are expected due to exposure to phosphoric acid by REVATOP 12%.For a more detailed evaluation, see the confidential annex.

Available toxicological data relating to a mixture

The product is composed of active substance diluted in water. There is no concern relating to non-active substance. The risk assessment is based on the content of active substance.

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Commission Delegated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

To examine if any of the other co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property.

Subsequently, it was examined if there are any concerns for adverse effect to meet the critaria a) as described above using ECHA REACH database. This examination did not result in alerts, and therefore no further ED assessment was required.

2.2.6.2 Exposure assessment

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							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use (only private uses)**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a	Yes	Yes	n.a	n.a	Yes	No
Dermal	n.a	n.a	n.a	n.a	n.a	n.a	n.a
Oral	n.a	No	No	n.a	n.a	n.a	n.a

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Addition	Addition of the product in the swimming pool by professional for private uses or non-professional	professional for private uses and non-professionals.
2.	Swimming	Secondary exposure Baby swimmers swimming in private swimming pool	General population
3.	Swimming	Secondary exposure Children swimming in private swimming pool	General population
4.	Swimming	Secondary exposure Adults swimmers swimming in private swimming pool	General population

Industrial exposure

Industrials do not use the product. However, they formulated the product but this assessment is already performed at the substance authorisation stage.

Professional exposure

Professionals could use this product as it is destined to for private uses. The only professionals that could use the product are the pool specialists but only in the context of private uses. Their exposure can be considered as covered/the same as for non-professional.

Non-professional exposure

Scenario 1

Description of Scenario 1: Addition in the swimming pool

The product is a ready-to-use and is directly applied in the swimming pool as algaecide.
The bottle of product should be at the level of the water in order to prevent of eventual splashes/projections during the addition.
In the absence of clear systemic adverse effects the risk characterisation of hydrogen peroxide is focused on local effects and no systemic doses are estimated. For the inhalation route the airborne exposure concentration is compared with the AEC for inhalation (1.25 mg/m^3). For dermal exposure a comparison with the skin irritation limit (35%) in the current classification has been considered to account for the potential local effects of hydrogen peroxide.[1]
In the absence of primary systemic adverse effects the risk characterisation is focused on local effects. The systemic effects, e.g. salivation, urinary incontinence and piloerection, changes in serum proteins, and changes in body weight gain, and with higher concentrations even mortalities, are considered to be secondary to the local irritation/corrosion. Although some NOAEL/LOAEL values have been set based on the study results, there is, however, no need to compare these internal values to any external dose descriptors in order to decide on the most critical effects. Hydrogen peroxide is highly reactive and will degrade rapidly at the site of first contact with organic material, and if entering blood, will be rapidly degraded.[2]
A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product.[3] As the product is not classified for dermal exposure, only inhalation exposure should be assessed and compare with toxicological reference value.
The oral exposure is not considered as relevant.

The primary exposure is in relation with the addition of the product in the mixture (application).

According to the ECHA Biocides Human health Exposure Methodology, Version 1, October 2015 : "It is recommended to consult the ConsExpo Disinfectants Factsheet for potential scenarios/pattern of use regarding Swimming Pool Disinfectants as the scenarios available within the Factsheet for non-professional may also be applicable for professional users."

The relevant models (Consexpo, BEAT…)[4] for application only consider dermal exposure and the inhalation is not considered.
According to the HEEG opinion n°1, for repeated addition, the two recommended models are Addition DEGBE model and Riskofderm, however none provides inhalation exposure.

There is no dedicated model to assess this kind of exposure for Consumer and Consexpo only assess the exposure of mixing + loading in dedicated equipment (bottle, sprayer..) and not an addition in open-space.
As noted in the Hydrogen Peroxide CAR: "The application is comparable to the scenario for professionals as a worst case. Exposure estimates for non-professionals do not include mixing and loading, since non-professionals purchase **a ready to use** 7.4/4.9 % solution."

The only relevant model that could be used to assess inhalation exposure is Mixing & addition model 7;TNSG part 2 p.142 (corrected) used in the Hydrogen Peroxide CAR for PT 5 – disinfection of water, professional use). This model provides an indicative value (the potential exposure is estimated using a factor 100) of 0.94 mg/m^3 (maximum value as the range is from 0.09 to 0.94) of exposure by inhalation. According to the HEEG opinion 1 - Mixing loading model 7 alternatives, the Model 7 should be used with care as it was no longer taken up in TNsG 2007, which might indicate little confidence in the model. However, it is a worst case assumption.
As the concentration of the product is in a worst case 12%, therefore the exposure is 0.94 x 12% i.e 0.11 mg/m^3

For the exposure to vapour of hydrogen peroxide, an assessment using ART is carried out. Based on the instruction in 2.1.5.2 "*to avoid splashing, the product need to be poured directly into the water, with the opening of the packaging below the water level*" the submerged loading type is selected. The results of ART modelling are included in Annex 3.2.1.

	Parameters	Value
Tier 1	Concentration hydrogen peroxide	12%
	Inhalation exposure[1]	0.94 mg/m^3
ART	Duration	10 min
	Emission source	Near field exposure
	Activity class	Transfer of liquid products - Falling liquids
	Transfer flow [2]	10-100 l/min
	Level of containment	Handling that reduces contact between product and adjacent air
	Loading type	Submerged loading
	Primary localised controls	No localized controls
	Surface contamination	Process fully enclosed? No Effective housekeeping practices in place? No General housekeeping practices in place? Yes
	Dispersion	Indoors Any size workroom No restriction on general ventilation characteristics

[1] Indicative value for inhalation: Mixing and Loading model 7: manual pouring and pumping liquids

[2] Depending on the use, 1.5 L, 3 L or 6L of REVATOP 12% needs to be added per 10 m3 of pool water, resulting in adding of 7.2L, 14.4L or 28.8L to a representative pool of 48 m^3. As worst case a transfer flow of 10-100 l/min is chosen. A transfer flow of 1-10 L/min which may be more representative for the non-professional will result in lower exposure predictions.

Calculations for Scenario 1

[1] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015

[2] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015

[3] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015

[4] HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale

Summary table: external exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total external exposure**
Scenario 1 (M&L model 7)	1/no PPE	0.11 mg/m^3	0	0	0.11 mg/m^3
Scenario 1 (ART)	1/no PPE	0.57 mg/m^3	0	0	0.57 mg/m^3

Exposure of the general public

The general population will only be secondarily exposed when they swim in treated pools.

Scenario 2

Description of Scenario 2 – baby swimmers swimming in private treated pools
General description of swimming in private treated pools: According to the ECHA Biocides Human health Exposure Methodology, Version 1, October 2015, the relevant person to consider as secondary exposed are the swimmers swimming in the treated pool.
In the absence of clear systemic adverse effects the risk characterisation of hydrogen peroxide is focused on local effects and no systemic doses are estimated. For the inhalation route the airborne exposure concentration is compared with the AEC for inhalation (1.25 mg/m^3). For dermal exposure a comparison with the skin irritation limit (35%) in the current classification has been considered to account for the potential local effects of hydrogen peroxide.[5] In the absence of primary systemic adverse effects the risk characterisation is focused on local effects. The systemic effects, e.g. salivation, urinary incontinence and piloerection, changes in serum proteins, and changes in body weight gain, and with higher concentrations even mortalities, are considered to be secondary to the local irritation/corrosion. Although some NOAEL/LOAEL values have been set based on the study results, there is, however, no need to compare these internal values to any external dose descriptors in order to decide on the most critical effects. Hydrogen peroxide is highly reactive and will degrade rapidly at the site of first contact with organic material, and if entering blood, will be rapidly degraded.[6] A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product.[7] As the product is not classified for dermal exposure and oral exposure, only inhalation exposure should be assessed and compare with toxicological reference value. Oral exposure occurs during the use of the pool and cannot be excluded. However, as written in the Assessment Report, ADI is not established, the substance is not systemically available. Moreover, the product is not classified for acute oral toxicity or skin irritation. As no ADI is needed, as the product is not systemically available and as it is not classified via oral route, there is no need of an assessment regarding oral exposure via swimming and no concern regarding a potential risk in relation with exposure to H2O2 via this way of exposure.

[5] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015
[6] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015
[7] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015

The product is directly poured in the pool with respect of the instructions. The concentration of efficacy to achieve in the treated pool is 38 mg/L for curative treatment and 75 mg/L for curative treatment when the water is very green.
To be in a worst case conditions, a concentration value of 75 mg/L is considered even if it is not recommended to directly swim in the just treated pool. Moreover, the concentration of 75 mg/L is the highest dose (shock dose) and it is not attended that swimmers be exposed at this dose chronically. This concentration will decrease with the time and this situation and associated dose are not the expected conditions to swim (expected condition 38 mg/L).

The relevant model to consider is Consexpo with the swimming pool disinfectants scenario described in the Consexpo Disinfectant Products Fact Sheet[8].

In Consexpo Disinfectant Products Fact Sheet (p48), "The scenario describes a private user who swims in a private outdoor pool of 48 m^3." Moreover, it is stated that :" Product information over private swimming pools gives a volume ranging from 14 to 52 m^3. 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."

The inhalation exposure is generally non-assessed because the swimming pool are the most of the time outside, however, to comply with the claim (i.e. indoor spa/swimming pools) the inhalation exposure will be estimated. To calculate the exposure during swimming in a public indoor pool, the 'evaporation model-exposure to vapour-constant release mode is used for inhalation exposure
The inhalation exposure in outdoor pools will be negligible, as atmospheric concentrations above the pool water surface are very low, even when their concentrations in water are high.

The scenario for baby swimming is in line with the scenario described in Consexpo Disinfectant Products Fact Sheet, adapted to private pool situation; a baby of 4.5 months of age 'swims' for 30 minutes in an indoor private pool of 32^{O}C.

	Parameters	Value
Tier 1	Frequency	Daily
	Weight[1]	6.21 kg
	Water surface area (release area)[2]	32m²
	Pool volume[2]	48 m^3
	Exposure time[2]	30 minutes
	Concentration (weight fraction)	0.0075% (75 mg/L)
	Product amount (i.e. pool amount) [2]	4.8*10^7 grams
	Room volume [2,3]	16 m^3
	Ventilation rate[2]	2/hour
	Application duration[2]	30 minutes
	Application temperature[2]	32^{O}C
	Vapour pressure	299 Pa
	Molecular weight	34 g/mol
	Mass transfer coefficient[4]	10 m/hr
	Inhalation rate[5]	0.314 m^3/hr

1 General Fact Sheet (Bremmer 2002, RIVM- Report no. 61334003/2002): baby of 4.5 months representative for baby 'swimmers' age category of 3-6 months.
2.Disinfectant Products Fact Sheet (Prud'homme de Lodder 2006 - RIVM. Report nr. 320005003/2006).

3 for all swimmers, the inhalation exposure mainly occurs above the pool water surface. A height of 0.5 meter is taken and using the release area of 32 m2, the default 'room' volume is 16m3
4 default included in ConsExpoweb
5 default included in ConsExpoweb, Estimate, using bodyweight and exercise level (6.21 kg and exercise level; light exercise)

Calculations for Scenario 2

Calculation are provided in Annex 3.2.1

Summary table: external exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total external exposure**
Scenario 2	1/no PPE	Mean event concentration: $5.8E^{-05}$ mg/m³ Peak concentration (TWA 15 min): $8.3E^{-05}$ mg/m³	n.a	n.a	Mean event concentration: $5.8E^{-05}$ mg/m³ Peak concentration (TWA 15 min): $8.3E^{-05}$ mg/m³

Scenario 3

[8] RIVM report 320005003/2006, Disinfectant Products Fact Sheet To assess the risks for the consumer, L.C.H. Prud'homme de Lodder, 2006.

Description of Scenario 3 – children swimming in private treated pools		
Considering general description of swimming in private treated pools see text included in scenario 2. The scenario for child swimming is in line with the scenario described in Consexpo Disinfectant Products Fact Sheet, adapted to private pool situation; a child of 6 to < 12 years old swims for 60 minutes in an indoor private pool of 28°C.		
	Parameters	Value
Tier 1	Frequency	Daily
	Weight[1]	15.6 kg
	Water surface area (release area)[2]	32m^2
	Pool volume[2]	48 m^3
	Exposure time[2]	60 minutes
	Concentration (weight fraction)	0.0075% (75 mg/L)
	Product amount (i.e. pool amount) [2]	4.8*10^7 grams
	Room volume[2]	16 m^3
	Ventilation rate[2]	2/hour
	Application duration[2]	60 minutes
	Application temperature[2]	28°C
	Vapour pressure	299 Pa
	Molecular weight	34 g/mol
	Mass transfer coefficient[4]	10 m/hr
	Inhalation rate[1]	1.26 m^3/hr

1 HEAdhoc recommendation no. 14: child of 6 to < 12 years old- irrespective of gender.
2.Disinfectant Products Fact Sheet (Prud'homme de Lodder 2006 - RIVM. Report nr. 320005003/2006).
3 for all swimmers, the inhalation exposure mainly occurs above the pool water surface. A height of 0.5 meter is taken and using the release area of 32 m2, the default 'room' volume is 16m3
4 default included in ConsExpoweb

Calculations for Scenario 3

Calculation are provided in Annex 3.2.1

Summary table: external exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total external exposure**
Scenario 3	1/no PPE	Mean event concentration: $9.1E^{-05}$ mg/m³ Peak concentration (TWA 15 min): $1.3E^{-04}$ mg/m³	n.a	n.a	Mean event concentration: $9.1E^{-05}$ mg/m³ Peak concentration (TWA 15 min): $1.3E^{-04}$ mg/m³

Combined scenarios

No combined exposure is expected regarding this secondary exposure scenario.

Scenario 4

Description of Scenario4– adults swimming in private treated pools		
Considering general description of swimming in private treated pools see text included in scenario 2. The scenario for adult swimming is in line with the scenario described in Consexpo Disinfectant Products Fact Sheet, adapted to private pool situation; An adult swims for 120 minutes in an indoor private pool of 28°C.		
	Parameters	Value
Tier 1	Frequency	Daily
	Weight[1]	60 kg
	Water surface area (release area)[2]	32m²
	Pool volume[2]	48 m³
	Exposure time[2]	120 minutes
	Concentration (weight fraction)	0.0075% (75 mg/L)
	Product amount (i.e. pool amount) [2]	$4.8*10^7$ grams
	Room volume[2]	16 m³
	Ventilation rate[2]	2/hour
	Application duration[2]	120 minutes
	Application temperature[2]	28°C
	Vapour pressure	299 Pa
	Molecular weight	34 g/mol
	Mass transfer coefficient[4]	10 m/hr
	Inhalation rate[1]	1.25 m³/hr

1 HEAdhoc recommendation no. 14: adult - irrespective of gender.
2.Disinfectant Products Fact Sheet (Prud'homme de Lodder 2006 - RIVM. Report nr. 320005003/2006).
3 for all swimmers, the inhalation exposure mainly occurs above the pool water surface. A height of 0.5 meter is taken and using the release area of 32 m2, the default 'room' volume is 16m3
4 default included in ConsExpoweb

Calculations for Scenario 4

Calculation are provided in Annex 3.2.1

Summary table: external exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total external exposure**
Scenario 4	1/no PPE	Mean event concentration: $1.2E^{-04}$ mg/m³ Peak concentration (TWA 15 min): $1.6E^{-04}$ mg/m³	n.a	n.a	Mean event concentration: $1.2E^{-04}$ mg/m³ Peak concentration (TWA 15 min): $1.6E^{-04}$ mg/m³

Combined scenarios

Only one combined exposure scenario is expected: an adult treating the pool (scenario 1) and afterwards swims in the treated pool (scenario 4).

Summary table: combined external exposure from non-professional uses				
Scenarios combined	**Estimated inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total external exposure**
Scenario 1& 4	0.11 mg/m³	n.a	n.a	0.11 mg/m³

Monitoring data

No monitoring data regarding the human exposure were needed and provided with this product assessment.

Dietary exposure

Regarding the use, the exposure via food, via livestock exposure or via transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) is not possible. Moreover, the RMM "Do not store near food, drink and feed" is included on the label.

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

This assessment is covered during the approval stage of the active substance and therefore should not be performed at the product authorisation stages.

Aggregated exposure

No aggregated exposure is necessary to be assessed.
The Assessment report on Hydrogen Peroxide notes that: "In the absence of clear systemic adverse effects the risk characterisation of hydrogen peroxide is focused on local effects and no systemic doses are estimated. For the inhalation route the airborne exposure concentration is compared with the AEC for inhalation (1.25 mg/m³). For dermal exposure a comparison with the skin irritation limit (35%) in the current classification has been considered to account for the potential local effects of hydrogen peroxide.[9]
In the absence of primary systemic adverse effects the risk characterisation is focused on local effects. The systemic effects, e.g. salivation, urinary incontinence and piloerection, changes in serum proteins, and changes in body weight gain, and with higher concentrations even mortalities, are considered to be secondary to the local irritation/corrosion. Although some NOAEL/LOAEL values have been set based on the study results, there is, however, no need to compare these internal values to any external dose descriptors in order to decide on the most critical effects. Hydrogen peroxide is highly reactive and will degrade rapidly at the site of first contact with organic material, and if entering blood, will be rapidly degraded.[10]
A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product.[11]" As the product is not classified for dermal exposure, only inhalation exposure should be assessed and compare with toxicological reference value.
The aggregated exposure is based on the systemic exposure and the possible multiple uses which take parts of the exposure.
The only relevant systemic exposure assessment is based on inhalation route and so the atmospheric exposure within the breathing area of the person exposed. However, to aggregate the exposure to comply with a possible multiple use of the product/active substance, that implies to consider the manipulation of several products in the same time to charge the atmosphere. This assumption is irrelevant. No aggregated exposure needs to be assessed.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AEC $_{inhalation}$ short-term	90-day inhalation rat study	10 mg/m³	8	No	1.25 mg/m³
AEC $_{inhalation}$ medium-term	90-day inhalation rat study	10 mg/m³	8	No	1.25 mg/m³

[9] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015
[10] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015
[11] Assessment report, Hydrogen Peroxide Product-types 1-6, March 2015

AEC $_{inhalation}$ long-term	90-day inhalation rat study	10 mg/m³	8	No	1.25 mg/m³
ARfD	Not established, the substance is not systemically available.				
ADI	Not established, the substance is not systemically available				

Maximum residue limits or equivalent

The setting of MRL is not relevant for this product. No relevant oral exposure and no systemic exposure are expected.

Risk for industrial users

Industrials do not use the product. However, they formulated the product but this assessment is already performed at the substance authorisation stage.

Risk for professional users

External Inhalation exposure

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/kg bw/d	Estimated external exposure mg/m³	Estimated external exposure/ AEC (%)	Acceptable (yes/no)
1.	1	10	1.25	0.11	8.8	Yes

Combined scenarios

Combined exposure is not expected for an professional pool specialist treating private pools. However, if it does occur that a pool specialist treats a pool and swims afterwards in the same pool, the exposure included for the non-professional user covers this exposure.

Local effects

A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product".

As the product is classified for eye damaging effects (H318), a qualitative RC (risk characterisation) for local effects is necessary.

According to Table 26 of the Guidance on the BPR: Volume III Assessment & Evaluation (Parts B+C), Version 4, December 2017, the hazard category for this kind of classification is high. The persons exposed to the product are only the persons (general population) who

will load the product in the swimming pool. The concentration in the swimming pool does not lead to any classification.
The persons (adult, general population) in charge of the loading can be exposed via skin route and could potentially be exposed via eyes if splashes reach open eyes during the loading or during a hand contact with eye.
There is no claimed frequency for application as it is based on visual aspect of the swimming pool. It is highly conservative to consider that one application per working day per week is performed. However, to comply with this quality risk assessment and to comply with risk assessment (Consexpo), a frequency of one a week (maximum and very conservative value) is considered. The duration of loading is very short and will not exceed few minutes.

Regarding the packaging, it should be highlighted that the packaging is well-adapted to a safe use of the product with the presence of:

- Plug with tamperproof screw sealed with inviolability collar
- Degassing seal
- Child safety plug

Moreover, the instruction for the disposal of the product guarantee the elimination of possible exposure when the use of the product is performed: "Rinse several times the packaging with water before disposal. The rinsing water must be discharged in the swimming pool."
Finally the instruction of use clearly highlights that "Liquid to be poured directly very close to the water surface in pools to avoid splashing and projections." In order not to have any projection in the eye. When handling large packaging of 10 or 20 L the instructions for use include that dosing should be done with a metering pump or other professional dosing systems.
Moreover, a potential splash should be the consequence of a loading performed with the bottle at a significant height. That also means the user is at a significant distance from the swimming-pool, leading to the conclusion that there is very low probability to have an eye exposure via splash and if there is an exposure, the splash content will not be 100% of the product but a mix with a high level of the water of the swimming pool.
Regarding the hand contact, the labelling instruction to use, the precautionary sentences, the packaging and the fact that the product should be poured directly to the water surface (i.e. the hand will only hold the bottle in the pool and will not have any other action regarding the loading) leads to the conclusion that practically no exposure is expected. The following risk mitigations are included:

- The use of eye protection during handling of the product is mandatory.
- Wash hands after use
- Avoid contact with eyes
- Avoid splashes and spills during pouring.

Note NL CA:

For the exposure calculations a pool of 48m3, representative of a private pool was taken into account. Based in the intended use depending on the use, 1.5L, 3L or 6L of REVATOP 12% needs to be added per 10 m3 of pool water, resulting in adding of 7.2L, 14.4L or 28.8L to the representative pool. In the instructions it is included that professional users should dose the product with a metering pump or other professional dosing systems when handling large packaging of 10 or 20 L. Therefore there is no concern considering the amount that needs to be added that could increase the risk to be exposed to splashes.

Qualitative risk assessment matrix for local effects
Primary exposure: use of product

Hazard		**Exposure**							**Risk**	
Hazard Category	Classification	PT	Who is exposed	Taks, uses, process	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)

High	Eye dam. Cat1, H318	2	Professional users	Loading product in the pool with a metering pump or other professional dosing systems (handling large packaging of 10 or 20 L)	Skin, Eye (splashes, hand to eye transfer)	one application per working day per week Few minutes per day	Considering the low frequency and low duration and considering the relevant RMM &PPE, the potential exposure to the eye is considered low.	- instructions for use reducing risk for eye exposure due to hand to eye contact: dose the product with a metering pump or other professional dosing systems. RMM: - Wash hands after use - Avoid contact with eyes - Avoid splashes and spills during pouring. PPE: Eye protection	Acceptable: +low frequency, + low duration + Relevant RMMs and PPE that reduces probability for eye exposure.	Frequency of use may be lower or higher than noted in the qualitative RC (no claimed frequency of use) (↑↓)

Conclusion
Based on the quantitative external inhalation exposure to hydrogen peroxide and an qualitative local effects assessment due to H318 classification, it can be concluded that there is no unacceptable risks identified for the professional user (i.e. pool specialist) using the product with the use recommendations, the risk mitigation measures, and in line with labelling due to its classification.

Risk for non-professional users

External Inhalation exposure

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/kg bw/d	Estimated uptake mg/m³	Estimated uptake/ AEC (%)	Acceptable (yes/no)
1. M&L model 7 (aerosols)	1	10	1.25	0.11	8.8	Yes
1. ART	1	10	1.25	0.57	45.6	Yes

Combined scenarios
Combined exposure is expected if the adult in charge of the addition the product swim in the treated pool directly after treatment

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/kg bw/d	Estimated uptake mg/m³	Estimated uptake/ AEC (%)	Acceptable (yes/no)
1 (aerosols) +4	1	10	1.25	0.11	8.8	Yes
1 (ART) +4	1	10	1.25	0.57	45.6	Yes

Local effects
A qualitative risk assessment should be performed for the local dermal effects taking into account the classification of the product".
As the product is classified for eye for eye damaging effects (H318), a qualitative RC (risk characterisation) for local effects is necessary.
According to Table 26 of the Guidance on the BPR: Volume III Assessment & Evaluation (Parts B+C), Version 4, December 2017, the hazard category for this kind of classification is high. The persons exposed to the product are only the persons (general population) who will load the product in the swimming pool. The concentration in the swimming pool does not lead to any classification.
The persons (adult, general population) in charge of the loading can be exposed via skin route and could potentially be exposed via eyes if splashes reach open eyes during the loading or during a hand contact with eye.
There is no claimed frequency for application as it is based on visual aspect of the swimming pool. It is highly conservative to consider that one application per week is performed. However, to comply with this quality risk assessment and to comply with risk assessment (Consexpo), a frequency of one a week (maximum and very conservative value) is considered. The duration of loading is very short and will not exceed few minutes.

Regarding the packaging, it should be highlighted that the packaging is well-adapted to a safe use of the product with the presence of:

- Plug with tamperproof screw sealed with inviolability collar
- Degassing seal
- Child safety plug

Moreover, the instruction for the disposal of the product guarantee the elimination of possible exposure when the use of the product is performed: "Rinse several times the packaging with water before the disposition. The rinsing water must be discharged in the swimming pool."
Finally the instruction of use clearly highlights that "Liquid to be poured directly very close to the water surface in pools to avoid splashing and projections." In order not to have any projection in the eye.
Moreover, a potential splash should be the consequence of a loading performed with the bottle at a significative height. That also means the user is at a significant distance from the swimming-pool, leading to the conclusion that there is very low probability to have an eye exposure via splash and if there is an exposure, the splash content will not be 100% of the product but a mix with a high level of the water of the swimming pool.
Regarding the hand contact, the labelling instruction to use, the precautionary sentences, the packaging and the fact that the product should be poured directly to the water surface (i.e. the hand will only hold the bottle in the pool and will not have any other action regarding the loading) leads to the conclusion that practically no exposure is expected.

The following risk mitigations are included:

- Wash hands after use
- Avoid contact with eyes
- Avoid splashes and spills during pouring.

Note NL CA:
For the exposure calculations a pool of 48m3, representative of a private pool was taken into account. Based in the intended use depending on the use, 1.5 L, 3 L or 6L of REVATOP 12% needs to be added per 10 m3 of pool water, resulting in adding of 7.2L, 14.4L or 28.8L to a representative pool. Considering the package size for non-professional users (1L or 5L bottles), multiple packaging needs to be used to apply the correct dosing. Although multiple packaging needs to be used, there is a very low probability that all bottles will be poured at the same time into the pool. Timed applications (between each loading as the user takes another container) will result in the rapid dilution of the product in the pool especially in front of the discharges nozzle.
When higher volumes need to be added, it is assumed that for this the larger package (max. 5L for non-professional use) will be used. One could argue that this larger package of 5L is considered a little more difficult to handle compared to the 1L bottle, also increasing the risk for eye exposure due to splashes. However, based on information from the applicant, this packaging is easy to handle as a 5 L container is originally equipped with a built-in handle for easier operation and the NL CA agrees with the applicant that a 5L bottle can be well handed by an adult, as this volume does not exceed any other water treatment product that can be found on the market. Moreover, all packaging contains warnings to inform the non-professional user about any possible effects to the eyes as the product is labelled for eye damage (to pour in the contact with water, not in the direction of the eyes). Additionally, the label contains instructions for washing of hands after use to prevent hand-to-eye exposure.
The applicant also indicated that as suppliers of a product containing a higher amount of active substance, REVATOP 34.9%, it was never brought to their attention that any incident involving accidental splashing into the eyes occurred. Pouring the product from

the height of an adult, without following the uses' instructions, will mean that the user's eyes are at a significant distance from the water. It is very unlikely that droplets can have a sufficient power to reach the user's eyes.

Thus taken the above into account, the product is classified as damaging to the eye but considering the amount to be used to apply correct dosing in accordance to the intended use, the potential eye exposure is considered low, and therefore acceptable.

Qualitative risk assessment matrix for local effects
Primary exposure: use of product

Hazard		**Exposure**							**Risk**	
Hazard Category	Classification	PT	Who is exposed	Taks, uses, process	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)

High	Eye dam. Cat1, H318	2	General public: Adults loading product in the pool	Manual loading product in the pool (handling small packaging of 1 or 5 L)	Skin, Eye (splashes, hand to eye transfer)	Once a week max. Few minutes per day	no expected contact with eyes due to the instructions (to pour in the contact with water, not in the direction of the eyes) as application following use instructions reduces the risk of accidental splashing and rapid dilution of the product in the pool. and washing of hands after use (P264) product is added by non-professional dosing equipment in way that splashes and	-labelling for eye damage, -child proof closure -instructions for use reducing risk for eye exposure by splashes:' Liquid to be poured directly very close to the water surface in pools to avoid splashing and projection' RMM: - Wash hands after use - Avoid contact with eyes - Avoid splashes and spills during pouring.	acceptable as the potential eye exposure is considered low.	Frequency of use may be lower or higher than noted in the qualitative RC (no claimed frequency of use) (↑↓)

							projection is avoided. - multiple packaging needs to be used but limiting available volumes to non-professional user to 1L and 5L only. A 5L bottle can be well handed by an adult, as this volume does not exceed any other water treatment product that can be found on the market. - -			

Conclusion
Regarding the qualitative assessment adverse health effects for the non-professional user are not expected when using the product with the use recommendations, the risk mitigation measures, and in line with labelling due to its classification.

Risk for the general public

The general population will only be secondarily exposed when they swim in treated pools.

External Inhalation exposure

Task/ Scenario	Tier	NOAEC mg/m³	AEC mg/kg bw/d	Estimated external exposure mg/m³	Estimated uptake/ AEC (%)	Acceptable (yes/no)
2.	1	10	1.25	Mean event concentration: $5.8E^{-05}$ mg/m³ Peak concentration (TWA 15 min): $8.3E^{-05}$ mg/m³	0.005 0.007	yes
3.	1	10	1.25	Mean event concentration: 9.1E-05 mg/m³ Peak concentration (TWA 15 min): $1.3E^{-04}$ mg/m³	0.007 0.01	yes
4.	1	10	1.25	Mean event concentration: $1.2E^{-04}$ mg/m³ Peak concentration (TWA 15 min): $1.6E^{-04}$ mg/m³	0.01 0.01	yes

Combined scenarios

No combined exposure is expected regarding this secondary exposure scenario.

Local effects
The maximal content in the water (75 mg/l) does not lead to any classification and therefore no concern for local effects.

Conclusion
Regarding the use, the conservative assessment of the exposure (consideration of possible systemic exposure), it can be concluded that there is no undue risk to baby swimmers, children or adults (competitors or not) to swim in a treated pool.

Risk for consumers via residues in food

Regarding the use, this section is not relevant for the product.

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

The product only contains the active substance diluted in water. This section is not relevant for the product.

2.2.7 Risk assessment for animal health

Regarding the use, this section is not relevant for the product.

In accordance with CG-44_e-c P-statements for non-professional uses_Final, the sentence "Keep out of reach of children and non-target animals/pets." is included in section 2.1.5.5.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The biocidal product is an aqueous formulation (type AL) of the active substance (hydrogen peroxide) in water. There is no other active, neither non active substance added by the Applicant in the biocidal product.

The Applicant has a letter of access (LoA) to an Active Substance Dossier that meets the requirement of Annex II from Regulation (EC) 528/2012. That LoA is attached in the IUCLID dataset.

In accordance with the Annex III Column 3 specific rules for adaptation from standard information concerning some of the information requirements that may require recourse to testing, there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture in accordance with rules laid down in Regulation (EC) No 1272/2008 (CLP). Further ecotoxicological studies on the biocidal product itself are not required.

Therefore, the effect assessment of the biocidal product on the environment is deduced from ecotoxicity and e-fate data from the active substance assessment report.

Assessment for endocrine disrupting properties

As discussed in Section 2.1.2.5, the Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for REVATOP 12%. The product contains the active substance hydrogen peroxide and various co-formulants (see confidential annex).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for hydrogen peroxide (March 2015), hydrogen peroxide is not included in the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters- a range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). There is no evidence of any endocrine disruption potential in the human health or ecotoxicological studies presented in the dossier.

For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- The United States EPA
- The United Nations Environment Program (July 2017)

Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

None of the co-formulants triggered an alert for potential endocrine disruption properties. Hence, no further ED assessments are required for REVATOP 12%.

Based on the hydrogen peroxide assessment report, the relevant PNECs for the environmental risk characterisation are reported below.

PNEC values for the active (as reported in assessment report for the active substance Hydrogen Peroxide):

Compartment	Lowest endpoint	Extrapolation method	PNEC value
Aquatic	21d-NOEC = 0.63 mg/L	Assessment factor: 50	0.0126 mg/L
Sediment	-	Equilibrium partitioning	0.047 mg/kg wwt *
STP	3h-EC50 = 466 mg/L	Assessment factor: 100	4.66 mg/L
Soil	-	Equilibrium partitioning	1.84E-03 mg/kg wwt *

*The $PNEC_{soil}$ and the $PNEC_{sediment}$ are derived using the TGD equilibrium partitioning method (Guidance Vol IV, Part B, equations 87 and 89). The Log kow of the active substance being lower than 5.0, no

additional assessment factor has been added, leading to a $PNEC_{soil}$ of 1.84E-03 mg/kg wwt and a $PNEC_{sediment}$ of 0.047 mg/kg wwt.

These PNEC values will be used for characterising the risk.

In addition, the physico-chemical and environmental fate properties of the table below will be used as input parameters for calculating the fate and distribution in the environment.

Input parameters for calculating the fate and distribution in the environment:

Input	Value	Unit	Remarks
Molecular weight	34.01	g/mol	Assessment report (2015)
Melting point	-0.43	°C	Assessment report (2015)
Boiling point (at 101,3 kPa)	150.2°C	°C	Assessment report (2015)
Vapour pressure (at 25°C)	299	Pa	Assessment report (2015)
Water solubility	1000000	mg/L	(Miscible in water in all proportions) Assessment report 2015) [1]
Log Octanol/water partition coefficient	-1.57	Log 10	Assessment report (2015) [1]
Organic carbon/water partition coefficient (Koc)	1.598	L/kg	Estimated by QSAR, Assessment report (2015) [1]
Henry's Law Constant (at 20°C)	7.50E-04	$Pa.m^3/mol$	Assessment report (2015) [1]
Biodegradability	Readily biodegradable		Assessment report (2015) [1]
Rate constant for STP	499	d^{-1}	Calculated with data from AS Assessment Report: DT50 in STP = 2 min (at 20°C)
DT_{50} for biodegradation in surface water (at 12°C)	5	d	Assessment report (2015) [1]
DT_{50} for degradation in soil (at 12°C)	0.5	d	Assessment report (2015) [1] Rapidly decomposed in soil to water and oxygen
DT_{50} for degradation in air	1	d	Assessment report (2015)[1]

[1] Assessment report Hydrogen peroxide product-types 1-6, March 2015

2.2.8.2 Exposure assessment

The uses claimed under this application are different compared to those covered in the assessment report for the active substance hydrogen peroxide. Therefore, a new exposure

and risk assessment for environment is provided in the present document. The biocidal product is intended to be used in private swimming pools (including SPAs) with private uses.

This environmental exposure assessment addresses the uses made by the end-user and does not address other life-cycle steps (e.g. production, formulation). The environmental compartments may be exposed to the active substance consecutively to releases of water from swimming pools.

According to the section 3.1.3 – ENV 44 from the Technical Agreement for Biocides (TAB, 2018), emissions of the active substance hydrogen peroxide to the environment following treatment of private pools permanently installed, may occur during the events hereafter:

- Backwashing of the filtration system (chronic emissions);
- Draining of pool water for overwintering purposes (acute emissions).

To cover these environmental emissions, two scenarios from existing ESDs were identified. They are the two recommended scenarios in order to assess releases from the use of biocides for the treatment of private pools (section 3.1.3 - ENV 49, TAB, 2018). They are described in the next sections of the present report.

Furthermore, the case of private above-ground pools not permanently installed must be taken into account. Being non-permanent, these smaller pools are emptied at least once a year until the next warm season. In addition, they can be emptied in the land of the property since they are generally not connected to the sewers and are generally not covered by local regulations. This complies with the conclusion from WG (TAB, 2018), stating that in addition to the releases to municipal STP, an assessment for direct releases from above ground small pools must be also carried out for product authorisation. However, such a scenario needs to be developed since no scenario is available in the literature to cover this situation.

General information

Assessed PT	PT 2
Assessed scenarios	Scenario 1 - Chronic emission from private permanent pools: releases to wastewater following the cleaning of the filtration system Scenario 2 - Acute emission from private permanent pools: releases to waste water due to the preparation for wintering Scenario 3 - Direct discharges to surface water and the soil compartment from private non-permanent "above-ground" small pools
ESD(s) used	Scenario 1: PT02 – Private pool scenarios – Permanent installed pools (TAB 2018) Scenario 2: PT02 – Private pool scenarios – Permanent installed pools (TAB 2018) Scenario 3: No ESD available

Approach	Average consumption
Distribution in the environment	Calculated based on ECHA Guidance on BPR Vol IV Part B+C (2017) and SimpleTreat version 3
Groundwater simulation	No higher tier groundwater simulation with PEARL 4.4.4. was required
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	None

Emission estimation

Emission estimates are based on realistic worst-case scenarios, at a local scale.

The biocidal product is intended to be used at different concentration levels, as detailed in the section 2.1.4. As a reminder, the concentration of efficacy to achieve in the treated pool is of 37.3 mg a.s/L for curative treatment and of 74.5 mg a.s /L for curative treatment when the water is very green.
For environmental risk assessment, application rates were rounded up as a worst-case approach (40 mg a.s/L for curative treatment and 80 mg/L of hydrogen peroxide for curative treatment when the water is very green).

As a conservative approach, the concentration of active substance (hydrogen peroxide) of 80 mg/L is considered for the modelling of environment exposure.

Furthermore, emissions were calculated by applying the relevant emission scenario documents by using the default parameters unless otherwise noted. Abiotic degradation in the sewer was included by multiplying emission to the sewer (Elocal) by the fraction lost over one hour (0.024).

Scenario 1

Scenario 1 was available in order to calculate chronic emissions during the backwashing of the filtration system from private pools permanently installed. It has been developed by FR and then discussed at WG-I-2015. After being endorsed by the Working Group, this scenario is now present in the Technical Agreement for Biocides as a recommended scenario in order to assess releases from the use of biocides for the treatment of private pools (TAB, 2018). Scenario 1 is shown in the table below and details are available in the following link:
https://echa.europa.eu/documents/10162/22002949/pt02_private_pool_scenarios_en.pdf

For the number of private pools connected to the same STP, the value (550) for the southern countries was used. This is worst case compared to the value (100) for the Northern countries. Therefore only chronic emissions resulted from private permanent pools in southern countries were calculated.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Chronic emission from private permanent pools: releases to wastewater following the cleaning of the filtration system			
Private pool volume	48	m^3	Default value
Number of private pools connected to the same STP	550	-	Default value for Tier 1.
Fraction of pool volume released to STP everyday	0.0143	-	Default value
Application rate of active substance in the pool water	0.08	g/L	Applicant data
Market share	0.5	-	Default value

Calculations for Scenario 1

1) Number of treated private pools with chronic releases per day ($Npool_{chro}$):

   $Npool_{chro}$ = Number of private pool connected to the STP (-) * Market share (-)

   $Npool_{chro}$ = 550 * 0.5

$Npool_{chro}$ = 275 d^{-1}

2) Emission rate to wastewater (standard STP):

   Elocal(water) = Pool volume (m^3) * Fraction of the pool volume released to STP everyday (-) * $Npool_{chro}$ (d^{-1}) * Application rate of active substance in the pool water (kg/m^3)

   Elocal(water) = 48 * 0.0143 * 275 * 0.08

   Elocal(water) = 15.10 kg/d

STP = Elocal(water)* fraction lost over one hour
STP = 15.10* 0.024

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	0.36	Emission rate to wastewater

Scenario 2

Scenario 2 was available in order to calculate acute emissions due to the preparation for wintering of private pools permanently installed. As for scenario 1, it has been developed by FR and then discussed at WG-I-2015. After being endorsed by the Working Group, this scenario is now present in the Technical Agreement for Biocides as a recommended scenario

in order to assess releases from the use of biocides for the treatment of private pools (TAB, 2018). Scenario 2 is shown in the table below and details are available in the following link: https://echa.europa.eu/documents/10162/22002949/pt02_private_pool_scenarios_en.pdf

For the number of private pools connected to the same STP, the value (10) for the southern countries was used. This is worst case compared to the value (2) for the Northern countries. Therefore only acute emissions resulted from private permanent pools in southern countries were calculated.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Acute emission from private permanent pools: releases to waste water due to the preparation for wintering			
Private pool volume	48	m^3	Default value
Number of private pools per STP with acute releases per day	10	d^{-1}	Default value for Tier 1.
Fraction of the pool volume acutely released to STP	0.33	-	Default value
Efficient dose rate of active substance in the pool water	0.08	g/L	Applicant data
Fraction of active substance released to wastewater	1	-	Default value for tier 1
Market share	0.5	-	Default value

Calculations for Scenario 2

1) Number of treated private pools with acute releases per day ($Npool_{acute}$):

   $Npool_{acute}$ = Number of private pool per STP with acute releases per day (d^{-1}) * Market share (-)

   $Npool_{acute}$ = 10 * 0.5

$Npool_{acute}$ = 5 d^{-1}

2) Emission rate to wastewater (standard STP):

   Elocal(water) = Pool volume (m^3) * Fraction released to wastewater (-) * $Npool_{acut}$ (d^{-1}) * Efficient dose rate of active substance in the pool water (kg/m^3)

   Elocal(water) = 48 * 0.33 * 5 * 0.08

   Elocal(water) = 6.34 kg/d

STP = Elocal(water)* fraction lost over one hour
STP = **6.34** * 0.024

Resulting local emission to relevant environmental compartments			
Compartment	**Scenario**	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2	0.15	Emission rate to wastewater

Scenario 3

A qualitative assessment is proposed for direct releases of pools in the case of non-permanent above-ground small pools. For releases to the municipal sewer systems the risks has been sufficiently assessed by the previous scenarios. As a result of its biocide function, the active substance hydrogen peroxide is consumed in-use conditions. A decreased concentration is observed during the simulated use efficacy test (in both preliminary and main test). As a conservative approach, the applicant recommends not to drain pool waters directly in surface water and on soil in the 15 days following shock treatment. This period corresponds to three times the extreme worst case half-life of 5 days which was estimated in the EU Assessment Report for hydrogen peroxide. During this period, hydrogen peroxide concentration is anticipated to further decrease in relation to known limitation including reaction with interfering materials and abiotic degradation e.g. by reaction with transition metals, UV sunlight. Note that rapid degradation was observed during the efficacy tests. Removal of hydrogen peroxide was complete within 96 hours for the lower doses and significant for the highest dose (see section 2.2.5.7). It may be therefore expected that the active substance's half-life in pools is remarkably faster than 5 days. Once hydrogen peroxide will reach the soil, it is further (bio)degraded as well. A worst case soil DT50 was estimated to 12 hours in the EU Assessment Report.

Regarding the inherent properties of the active substance hydrogen peroxide combined to the 15 days before release, environmental emissions from that situation are anticipated to be low.
Furthermore, based on the mode of action (oxidising), the effects are expected to be acute and limited in time. However, the PNEC soil was determined (in the EU Assessment Report) by application of the equilibrium partitioning method and thus extrapolated from the PNEC aquatic. This PNEC aquatic (see section 2.2.8.1) is determined by application of an assessment factor to the lowest chronic NOEC (Daphnia) from a 21-days exposure period with flow-through system. In such situation, the PNEC soil does not reflect the soil exposure scenario. However, as hydrogen is acutely toxic for the aquatic environment, direct discharge of the swimming pool's contents is not recommended at all. An additional risk mitigation measure has been added to the SPC.

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**
Scenario 1	Yes	Yes	No	No	Yes	No	Yes	Yes
Scenario 2	Yes	Yes	No	No	Yes	No	Yes	Yes

For scenarios 1 and 2, the distribution of hydrogen peroxide in relevant environmental compartments was calculated with SimpleTreat version 3. Data from the table "Input parameters for calculating the fate and distribution in the environment" (see section 2.2.8.1) were applied in SimpleTreat version 3. Exposures of aquatic systems and soils to the active substance hydrogen peroxide were evaluated since these compartments are likely to be exposed following wastewater treatments in STPs:

- Aquatic systems (including freshwater sediments) may be exposed via STP effluents;
- Soils may be exposed via spreading of sewage sludge.

Emissions to air from the use of REVATOP 12% are negligible and do not alter existing background concentrations in the troposphere to any relevant degree. Therefore, an assessment of PECs in air and rainwater from emissions due to use of biocidal products is not relevant.

As hydrogen peroxide is miscible with water in all proportions and taking into account that the calculated log Koc is low, it is expected that hydrogen peroxide has a low potential for adsorption to soil and for partitioning to suspended matter or sediment. Therefore, the groundwater compartment may also be exposed.

In the case of direct releases to soil in Scenario 3, the environment is not likely to be exposed to the active substance due to specific draining conditions as well as physico-chemical and environmental fate properties, as it was explained previously.

Partitioning in sewage treatment plant

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenarios 1 and 2	
Air	1.05E-04	SimpleTreat version 3.1
Water	6.92E-01	SimpleTreat version 3.1
Sludge	6.08E-4	SimpleTreat version 3.1
Degraded in STP	99.3	SimpleTreat version 3.1

Calculated PEC values

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}[1]**	**PEC_{GW}[2]**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1	1.25E-03	1.25E-04	9.77E-05	4.08E-06	8.18E-04
Scenario 2	5.19E-04	5.19E-05	4.07E-05	1.70E-06	3.41E-04

[1] Concentration in top soils after ten years of successive sludge applications

[2] Concentration in porewater of agricultural soil, averaged over 30 days after the last application

Primary and secondary poisoning

Primary poisoning

The proposed use will not result in direct exposures to birds and mammals. No assessment of primary poisoning is therefore considered necessary.

Secondary poisoning

The estimated log K_{ow} of hydrogen peroxide is –1.57 indicating a negligible potential for bioconcentration in biota. Therefore, accumulation of hydrogen peroxide in the food chain is not expected. As a consequence, the secondary poisoning in aquatic and terrestrial predators is negligible and its assessment is not considered necessary.

2.2.8.3 Risk characterisation

Atmosphere

The measured value of Henry's law constant (7.5 × 10-4 $Pa.m^3/mol$ at 20°C) indicates very low volatilisation of hydrogen peroxide from water. Furthermore, Emissions to air from biocidal uses are considered negligible. Therefore, the risk to the atmosphere is acceptable.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	<0.001
Scenario 2	<0.001

Conclusion: The $PEC_{STP}/PNEC_{STP}$ ratios are < 1 for scenarios 1 and 2. The risk to microorganisms in sewage treatment plants following the uses of the biocidal product is considered acceptable.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
Scenario 1	1.00E-02	2.00E-03
Scenario 2	4.00E-03	< 0.001

Conclusion: The $PEC_{water}/PNEC_{water}$ and $PEC_{sediment}/PNEC_{sediment}$ ratios are below 1 for scenarios 1 and 2. Therefore, the uses of the biocidal product do not cause unacceptable risk to aquatic organisms and sediment-dwelling organisms.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	2.00-03
Scenario 2	< 0.001

Conclusion: The $PEC_{soil}/PNEC_{soil}$ ratios of the scenarios 1 and 2 are below 1, indicating low risks. In the case of direct water releases from non-permanent above-ground pools, the risk to soil is considered acceptable due to negligible exposition of this compartment.

Groundwater

According to BPR Annex VI (point 68), PEC_{GW} values were compared to the standard of 0.1 µg/L for the production of drinking water from groundwater and these were below this threshold value for both scenarios. Therefore, the risk for groundwater can be considered as acceptable.

Primary and secondary poisoning

Primary poisoning

As the proposed use will not result in direct exposures to birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

The estimated log K_{ow} of hydrogen peroxide is –1.57 indicating a negligible potential for bioconcentration in biota. Therefore, accumulation of hydrogen peroxide in the food chain is not expected, and the risk of secondary poisoning in aquatic and terrestrial predators is considered negligible.

Mixture toxicity

The biocidal product contains only one active substance. There are no substances of concern with regard to the environment. An assessment of the mixture toxicity is therefore not necessary.

Aggregated exposure (combined for relevant emmission sources)

According to Article 10(1) of BPD a cumulative risk assessment shall be performed where relevant. For hydrogen peroxide it was agreed at the WG V 2014 that aggregated risk assessment is not regarded relevant due to the high reactivity of the substance.

Overall conclusion on the risk assessment for the environment of the product
When used in accordance with the legal Instructions for Use (SPC), REVATOP 12% complies with the environmental standards and will not cause unacceptable effects to the environment.

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

In efficacy study, the product has shown algaecide efficacy when used alone. When used as recommended, no association with other product is deem necessary to restore uncoloured waters when green algal bloom occurs.

3 ANNEXES

3.1 List of studies for the biocidal product (family)

BPR Annex III Point	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed	
						Yes	No	Yes	No
3.1. 3.1.1. 3.1.2.	[redacted] N°report: 16-33-041-[redacted] (PART1)	[redacted]	*2016*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau FRANCE			yes	
3.1.3.		[redacted]							
3.2. 3.3. 3.4.	[redacted] N°report: 16-33-041-[redacted] (PART1)	[redacted]	*2016*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau FRANCE			yes	
3.4.1. 3.4.1.1. 3.4.1.2.	[redacted] N°report: 16-33-041-[redacted] (PART1) [redacted] N°report: 16-33-041-[redacted] (PART 2)	[redacted] [redacted]	*2016* *2018*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination* *Stability of SPA Booster peroxide 12% over accelerated*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin			Yes Yes	

				storage and shelf life determination Part 2: Physical-chemical properties over 24-month storage at room temperature	de Crau FRANCE				
3.4.1.3.									
3.4.2. 3.4.2.1. 3.4.2.2. 3.4.2.3.	[redacted] N°report: 16-33-041-[redacted] (PART1)	[redacted]	*2016*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France			yes	
3.9.	[redacted] N°report: 16-33-041-[redacted] (PART1)	[redacted]	*2016*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France			yes	
4.16.	[redacted] n°: 19011801G979	[redacted]	*2019*	*Determination of the corrosion of metals by REVATOP 12 % following method 37.4 C.1 of the UN Handbook*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin			yes	

					de Crau France				
5.1	[redacted] N°report: 16-33-041-[redacted] (PART1)	[redacted]	*2016*	*Stability of SPA Booster peroxide 12% over accelerated storage and shelf life determination*	MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France			yes	
6.7.	[redacted] 201612/01	[redacted]	2017	In situ cells numeration in several swimming pool water samples. A data collection document.	[redacted] MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France is owner of the study			yes	
	[redacted] 2016 [redacted] report RE-1220/1016/M1	[redacted]	2016	Transposition and validation of a hydrogen peroxide assay method by HPLC	Study done for GIE H2O BIOCIDE - Commission PEROX			Yes	

					but MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France is owner				
	[redacted] Report N° 1332/1216/A/M1	[redacted]	2017	Essai d'efficacité d'un produit algicide. Essai préliminaire. Produit : PEROXYDE HYDROGENE 34,9%.	Study done for GIE H2O BIOCIDE - Commission PEROX but MAREVA PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France is owner of the study			Yes	
	[redacted] 2018. [redacted] Report N° 1025/0117/A + PDF supporting document with pictures	[redacted]	2018	Algicide efficacy testing. Product: PEROXYDE D'HYDROGENE 34.9%.	Study done for GIE H2O BIOCIDE - Commission PEROX but MAREV			Yes	

					A PISCINES ET FILTRATIONS 25 avenue Marie Curie F-13310 Saint Martin de Crau France is owner of the study				
8.1.2.	[redacted]	[redacted]	2017	Isolated Chicken Eye Test - Method for Identifying Chemicals Inducing Serious Eye Damage and Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage REVATOP-12%.	Study done for MAREVA			yes	
8.1.2	[redacted]	[redacted]	2019	Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage	Study done for MAREVA			yes	

3.2 Output tables from exposure assessment tools

3.2.1 Human Exposure Assessment

Scenario 1: Addition in the swimming pool

ART modelling

pouring
submerged 75 perce

Scenario 2: Baby swimming

ConsExpo Web - Wed Jun 05 2019

Substance		
Name	hydrogen peroxide	
CAS number		
Molecular weight	34	g/mol
K_{ow}	−1.57	10Log
Product		
Name		
Weight fraction substance	0.0075	%
Population		
Name	4.5 month baby	
Body weight	6.21	kg

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	30	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	48000000	g
Weight fraction substance	0.0075	%
Room volume	16	m^3
Ventilation rate	2	per hour
Inhalation rate	0.314	m^3/hr
Application temperature	32	°C
Vapour pressure	299	Pa
Molecular weight	34	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	32	cm^2
Emission duration	30	minute
Absorption model	n.a.	

Results for scenario *baby swimming*

☐ Show dose descriptions

Inhalation

Mean event concentration	5.8×10^{-5}	mg/m^3
Peak concentration (TWA 15 min)	8.3×10^{-5}	mg/m^3
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	1.5×10^{-6}	mg/kg bw
External dose on day of exposure	-	

Scenario 3: Child swimming

ConsExpo Web - Wed Jun 05 2019

Substance		
Name	hydrogen peroxide	
CAS number		
Molecular weight	34	g/mol
Kow	−1.57	10Log
Product		
Name		
Weight fraction substance	0.0075	%
Population		
Name	child (6 to < 12 years old)	
Body weight	15.6	kg

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	60	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	48000000	g
Weight fraction substance	0.0075	%
Room volume	16	m^3
Ventilation rate	2	per hour
Inhalation rate	1.26	m^3/hr
Application temperature	28	°C
Vapour pressure	299	Pa
Molecular weight	34	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	32	cm^2
Emission duration	60	minute
Absorption model	n.a.	

Results for scenario *child swimming*

☐ Show dose descriptions

Inhalation

Mean event concentration	9.1×10^{-5}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-4}	mg/m³
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	7.4×10^{-6}	mg/kg bw
External dose on day of exposure	-	

Scenario 4: Adult swimming

ConsExpo Web - Wed Jun 05 2019

Substance		
Name	hydrogen peroxide	
CAS number		
Molecular weight	34	g/mol
K_{ow}	−1.57	10Log
Product		
Name		
Weight fraction substance	0.0075	%
Population		
Name	adult	
Body weight	60	kg

Inhalation

Exposure model	Exposure to vapour - Evaporation	
Exposure duration	120	minute
Product is substance in pure form	No	
Molecular weight matrix	18	g/mol
The product is used in dilution	No	
Amount of solution used	48000000	g
Weight fraction substance	0.0075	%
Room volume	16	m^3
Ventilation rate	2	per hour
Inhalation rate	1.25	m^3/hr
Application temperature	28	°C
Vapour pressure	299	Pa
Molecular weight	34	g/mol
Mass transfer coefficient	10	m/hr
Release area mode	Constant	
Release area	32	cm^2
Emission duration	120	minute
Absorption model	n.a.	

Results for scenario *adult swimming*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.2×10^{-4}	mg/m^3
Peak concentration (TWA 15 min)	1.6×10^{-4}	mg/m^3
Mean concentration on day of exposure	-	
Year average concentration	-	
External event dose	5.0×10^{-6}	mg/kg bw
External dose on day of exposure	-	

ConsExpo 5.0 report

Report date: 15/11/2016

Compound

Compound name :	Hydrogen Peroxide	
CAS number :		
molecular weight	34	g/mol
vapour pressure	3E2	Pascal

Populations

Baby swimmers

body weight 6,2 kilogram

Products

Liquids

weight fraction compound 0,008 %

Aggregate Exposures

Aggregate exposure for Baby swimmers :

Total chronic potential dose (mg/kg/day):
0,033

Total chronic systemic dose (mg/kg/day):
0,033

Inhalation chronic potential dose (mg/kg/day):
0,033

Inhalation chronic systemic dose (mg/kg/day):
0,029

Dermal chronic potential dose (mg/kg/day):
--

Dermal chronic systemic dose (mg/kg/day):
--

Oral chronic potential dose (mg/kg/day):
--

Oral chronic systemic dose (mg/kg/day):
--

Details for scenario: Baby swimmers, Liquids : Post-application

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,008 %
exposure duration	30 minute
room volume	16 m3
ventilation rate	2 1/hr
applied amount	4,8E7 gram
release area	32 m2
application duration	30 minute
mol weight matrix	18 g/mol
mass transfer rate	6,5E3 m/min

Uptake model: Fraction

uptake fraction	1 fraction
inhalation rate	0,041 m3/min

Populations

Child swimmers

body weight 16 kilogram

Products

Liquids

weight fraction compound 0,008 %

Aggregate Exposures

Aggregate exposure for Child swimmers :

Total chronic potential dose (mg/kg/day):
0,031

Total chronic systemic dose (mg/kg/day):
0,031

Inhalation chronic potential dose (mg/kg/day):
0,031

Inhalation chronic systemic dose (mg/kg/day):
0,031

Dermal chronic potential dose (mg/kg/day):
--

Dermal chronic systemic dose (mg/kg/day):
--

Oral chronic potential dose (mg/kg/day):
--

Oral chronic systemic dose (mg/kg/day):
--

Details for scenario: Child swimmers, Liquids : Post-application

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,008 %
exposure duration	60 minute
room volume	16 m3
ventilation rate	2 1/hr
applied amount	4,8E7 gram
release area	32 m2
application duration	60 minute
mol weight matrix	18 g/mol
mass transfer rate	6,5E3 m/min

Uptake model: Fraction

uptake fraction	1 fraction
inhalation rate	0,048 m3/min

Populations

Adult swimmers

body weight	60	kilogram

Products

Liquids

weight fraction compound	0,008	%

Aggregate Exposures

Aggregate exposure for Adult swimmers :

Total chronic potential dose (mg/kg/day):
0,026

Total chronic systemic dose (mg/kg/day):
0,026

Inhalation chronic potential dose (mg/kg/day):
0,026

Inhalation chronic systemic dose (mg/kg/day):
0,026

Dermal chronic potential dose (mg/kg/day):
--

Dermal chronic systemic dose (mg/kg/day):
--

Oral chronic potential dose (mg/kg/day):
--

Oral chronic systemic dose (mg/kg/day):
--

Details for scenario: Adult swimmers, Liquids : Post-application

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0,008	%
exposure duration	1,2E2	minute
room volume	16	m3
ventilation rate	2	1/hr
applied amount	4,8E7	gram
release area	32	m2
application duration	1,2E2	minute
mol weight matrix	18	g/mol
mass transfer rate	6,5E3	m/min

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	0,078	m3/min

Based on the results provided by Consexpo and the hypothesis set for the assessment it can be

concluded that

Population	**Exposure (mg/kg bw/day)**	Inhaled Volume (m^3)	Weight (kg)	**Exposure (mg/m^3)**
Baby	**0.033**	1.23	6.21	**0.166**
Child	**0.031**	2.88	16.3	**0.173**
Adults	**0.026**	9.36	60	**0.168**

These results are compliant as they lead to the same exposure for the same environment for all the assessed population.

3.2.2 Environmental Exposure Assessment

No additional data submitted.

3.3 New information on the active substance

No additional data submitted.

3.4 Residue behaviour

Not relevant.

3.5 Summaries of the efficacy studies

A IUCLID file is available.

3.6 Confidential annex

Please see separate file.

3.7 Other