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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



[PEROXYDE D’HYDROGENE 34.9 %]

Product type [2]

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

Case Number in R4BP: [BC-SK029576-20]

Evaluating Competent Authority: [FR]

Date: [21/12/2018]

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# CONCLUSION

**Conclusion on physico-chemical properties**

Physico-chemical studies were provided for PEROXYDE D’HYDROGENE 34.9%. The product is stable after 18 weeks at 30°C. A shelf life of 24 months can be granted.

Nevertheless, the long-term (2 years) shelf-life study should be provided within two years.

The product is not classified for physico-chemical aspect. The product should be stored at temperature below 30°C, protect from frost.

Physico chemical hazards have been assessed. It is not explosive, does not possess oxidizing properties and is not autoflammable in the conditions of uses.

Analytical methods for the determination of active substance in the biocidal product are validated according to guidance SANCO3030/99/rev.4.

**Conclusion on efficacy**

The product is intended to be used for curative action to stop algae emergence and to inhibit the growth of existing algae in water when green algae blooms are observed or just starting. Several doses are claimed, depending on the colour of the water.

The time delay for the visible effect (reduction or disappearance of the green colour) according to the initial algal situation has not been demonstrated in the submitted efficacy study since at the beginning of the study, the water was uncoloured and the same level of contamination was used for all application rates. Thus, this claim cannot be validated.

Efficacy data demonstrate that reduction of algae and Chlorophyll A is significant observed within 24-48h at the higher dose 2 L for 10 m3 permitting to maintain the water limpid during this period.

**Conclusion on human health**

The risk for the professional using the product PEROXYDE D’HYDROGENE 34.9 % is acceptable. Chemical goggles, coverall and gloves need to be worn during handling of the product. Moreover, it is recommended to pour the product next to the water surface of the swimming pool to avoid splashes.

The risk for the non-professional using the product PEROXYDE D’HYDROGENE 34.9 % is acceptable. The packaging must be easy to handle and limit splashing (adding a tap, handle, spout). Moreover, it is recommended to pour the product next to the water surface of the swimming pool to avoid splashes.

The risk for swimmer and general public is acceptable.

**Conclusion on indirect exposure via residues in food**

PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected.

**Conclusion on ecotoxicology and environment**

Following the application of the product PEROXYDE D’HYDROGENE 34.9% **in permanent pools (municipal or private pools)** **with releases into the STP compartment:**

- Levels of exposure for non-target species of aquatic and terrestrial compartments are lower than the PNEC of the active substance.

- Concentrations of hydrogen peroxide in groundwater related to the use of product PEROXYDE D’HYDROGENE 34.9% are also lower than the threshold value set by the Directive 98/83/EC.

* For the application of the product PEROXYDE D’HYDROGENE 34.9% **in private "above-ground" small pools not permanently installed** **with direct release into the surface water:**

- levels of exposure for non-target species of the aquatic compartment are higher than the PNEC of the active substance, except for the treatment at 20 mg a.s/L which presents a risk characterization ratio below 1, with the recommendation of the applicant not to drain pool waters directly to surface water in the 40 days following the treatment. At the application rate of 40 mg a.s/L the risk ratio is really closed to 1 (1.01) considering the delay of 40 days.

* In the case of the use of PEROXYDE D’HYDROGENE 34.9% **in private "above-ground" small pools not permanently installed** **with direct release into the soil:**

- levels of exposure for non-target species of soil compartment are higher than the PNEC of the active substance, even with the recommendation of the applicant not to drain pool waters directly to soil in the 40 days following the treatment.

- Concentrations of hydrogen peroxide in groundwater related to the use of product PEROXYDE D’HYDROGENE 34.9% are only lower than the threshold value set by the Directive 98/83/EC with the recommendation of the applicant not to drain pool waters directly to soil in the 40 days following the treatment.

As explained in the infobox 23, the addition of sodium thiosulfate pentahydrate to mitigate the risk related to the drainage of above-ground pools directly to the environment, provided by the applicant, is not fully satisfactory. First, the proposal to use 8.4 kg of sodium thiosulfate pentahydrate as an oxidizer neutralizer able to reduce the totality of hydrogen peroxide in the pool is based on the assumption that there are no other compounds that could be reduced in the pool water. No provided data can confirm this hypothesis. On the other hand, no risk assessment is available for the product of the reaction, the tetrathionate anion (S4O62-). Regarding the lack of information on the degradation products and their concentrations in the pool water, the safe use of the sodium thiosulfate pentahydrate as an oxidizer neutralizer cannot be demonstrated.

Disinfection by-products (DBP) exposure

H2O2 is a highly reactive active substance that will react with organic matter present on the water leading to the formation of Disinfectant By-Product (DBP). The number of DBP formed is very high and neither identification nor quantification is possible.

In the absence of validated methodology, DBPs were not taken into account in the risk assessment.

In conclusion, based on the available information related to the use of the product PEROXYDE D’HYDROGENE 34.9%, the environmental assessment is acceptable when pool waters are released into the STP compartment.

In the context of private "above-ground" small pools not permanently installed, risks following the direct releases to surface water or soil are considered unacceptable. Concerning the use of PEROXYDE D’HYDROGENE 34.9% with the addition of a risk mitigation measure to neutralize H2O2 before direct release to surface water or soil, the safe use of the sodium thiosulfate pentahydrate as an oxidizer neutralizer cannot be demonstrated.

**General conclusion**

**FR CA considers that the product shall be authorised for a reduction of algae and Chlorophyll A during within 24-48h at the higher dose 2 L for 10 m3 permitting to maintain the water limpid during this period, only for the permanent pools (municipal or private pools) with releases into the STP compartment.**

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| PEROXYDE D’HYDROGENE 34.9% | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the prospective authorisation holder** | **Name** | GIE H2O Biocide |
| **Address** | 34 route Nationale  35650 Le Rheu  France |
| **Authorisation number** | **FR-2018-0119** | |
| **Date of the authorisation** | **01/02/2019** | |
| **Expiry date of the authorisation** | **31/01/2029** | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | MAREVA Piscines & Filtrations |
| **Address of manufacturer** | ZI du bois de Leuze  25 Avenue Marie Curie  F-13310 Saint Martin de Crau  FRANCE |
| **Location of manufacturing sites** | ZI du bois de Leuze  25 Avenue Marie Curie  F-13310 Saint Martin de Crau  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | GACHES Chimie Spécialités |
| **Address of manufacturer** | 8 rue Labouche  Z.I. THIBAUD  31084 Toulouse Cedex  FRANCE |
| **Location of manufacturing sites** | 8 rue Labouche  Z.I. THIBAUD  31084 Toulouse Cedex  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | HYDRACHIM, manufacturer for HYDRAPRO |
| **Address of manufacturer** | Z.A. route de St Poix  35370 Le Pertre  FRANCE |
| **Location of manufacturing sites** | Z.A. route de St Poix  35370 Le Pertre  FRANCE |

|  |  |
| --- | --- |
| **Name of manufacturer** | OCEDIS S.A.S.U |
| **Address of manufacturer** | 69 Allée des peupliers  ZI de Fétan  01600 Trevoux  FRANCE |
| **Location of manufacturing sites** | 69 Allée des peupliers  ZI de Fétan  01600 Trevoux  FRANCE |

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

|  |  |
| --- | --- |
| **Active substance** | Hydrogen peroxide |
| **Name of manufacturer** | Peroxychem Spain s.l.u. |
| **Address of manufacturer** | CALLE AFUERAS S/N,  50784 La Zaida (Zaragoza)  Spain |
| **Location of manufacturing sites** | CALLE AFUERAS S/N,  50784 La Zaida (Zaragoza)  Spain |

|  |  |
| --- | --- |
| **Active substance** | Hydrogen peroxide |
| **Name of manufacturer** | Solvay Chemicals International SA |
| **Address of manufacturer** | Rue de Ransbeek, 310  1120, Bruxelles  Belgium |
| **Location of manufacturing sites** | Solvay Interox Limited,  Baronet Road, Solvay House, WA4 6HA Warrington, Cheshire  United Kingdom |
| Solvay Chemicals Finland Oy,  YRJONOJANTIE 2  45910 VOIKKAA  Finland |
| Solvay Chemicals GmbH Germany,  KOETHENSCHE STRASSE 1-3  06406 BERNBURG  Germany |
| Solvay Chimica Italia SpA Italy,  VIA PIAVE, 6  57013 ROSIGNANO SOLVAY LI  Italy |
| Solvay Chemie SA Belgium,  RUE SOLVAY,  39 5190 JEMEPPE-SUR-SAMBRE  Belgium |
| Solvay Interox Produtos Peroxidados SA,  RUA ENG. CLEMENT DUMOULIN  2625-106  POVOA DE SANTA IRIA  Portugal |

|  |  |
| --- | --- |
| **Active substance** | Hydrogen peroxide |
| **Name of manufacturer** | Arkema |
| **Address of manufacturer** | 420 rue d’Estienne d'Orves  92705 Colombes Cedex  France |
| **Location of manufacturing sites** | Arkema France  RN 85  38560 Jarrie  France |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Hydrogen peroxide |
| **IUPAC or EC name** | Hydrogen peroxide |
| **EC number** | 231-765-0 |
| **CAS number** | 7722-84-1 |
| **Index number in Annex VI of CLP** | 008-003-00-9 |
| **Minimum purity / content** | According to Assessment Report on approved  active substance:  The active substance as manufactured is an  aqueous solution which contains 35-<70% (by  weight) of hydrogen peroxide. The upper value (<  70%) is considered to cause no problems  from the toxicological or ecotoxicological point of  view. On a calculated dry weight basis the  minimum purity of hydrogen peroxide is estimated  close to 99.5% (by wt). The sum of  hydrogen peroxide and water is close to 100 %.  For toxicology and ecotoxicology assessments,  concentrations or amounts of hydrogen  peroxide always refers to pure (100%) hydrogen  peroxide unless stated otherwise. The  assessment covers risks from use of biocidal  products containing hydrogen peroxide up to 49.9  %.  Regarding impurities:  There is no significant impurity (impurity at a  concentration > 0.1%) in the substance. The sum  of organic and inorganic impurities in aqueous  solution is below 0.2 % (by wt), and the total  amount of organic impurities in aqueous solutions  is approximately 0.1 % (by wt). Calculated for the  35 % solution of hydrogen peroxide, the  theoretical dry weight total impurity contents is  below 0.5 % (by wt). For the following heavy  metals (Pb, Hg, Cd, As) a maximum level of 1 mg/kg in aqueous solution was set in  specification, for each of the four metals.  Specification includes also organic impurities and  stabilizers such as phosphoric acid <0.03%,  sodium phosphate < 0.05%, sodium stannate <  0.085%, ammonium sulphate < 0.03%, and the  confidential stabilizers. |
| **Structural formula** | Afficher l'image d'origine |

#### Candidate(s) for substitution

Hydrogen peroxide is not candidate for substitution in accordance with Article 10 of BPR.

#### Qualitative and quantitative information on the composition of the biocidal product[[2]](#footnote-2)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Hydrogen peroxide  technique | Hydrogen peroxide | Active substance | 7722-84-1 | 231-765-0 | 35.08 |
| Hydrogen peroxide  pure | Hydrogen peroxide | Active substance | 7722-84-1 | 231-765-0 | 34.9 |

#### Information on technical equivalence

Not relevant.

#### Information on the substance(s) of concern

The product PEROXYDE D’HYDROGENE 34.9% does not contain substance of concern.

#### Assessment of endocrine disruption (ED) properties of the biocidal products

According to our assessment, none of the formulants contained in the product are identified as endocrine disruptors.

Please refer to Confidential Annex.

#### Type of formulation

|  |
| --- |
| AL formulation |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Acute Toxicity, category 4 (oral route)  Acute Toxicity, category 4 (inhalation)  Skin irritation, category 2  Serious eye damage, category 1Specific target organ toxicity – Single exposure cat. 3 – Respiratory tract irritation  Aquatic chronic cat 3 |
| Hazard statement | H302: Harmful if swallowed  H315: Causes skin irritation  H318: Causes serious eye damage  H332: Harmful if inhaled  H335: May cause respiratory irritation  H412: Harmful to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | DANGER |
| Hazard statements | H302: Harmful if swallowed  H315: Causes skin irritation  H318: Causes serious eye damage  H332: Harmful if inhaled  H335: May cause respiratory irritation  H412: Harmful to aquatic life with long-lasting effects |
| Precautionary statements | P102: Keep out of reach of children.  P103: Read label before use.  P261: Avoid vapours.  P264: Wash hands thoroughly after handling.  P270: Do not eat, drink or smoke when using this product.P271: Use only outdoors or in a well ventilated area.  P273: Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection (professionals only).  P301+P312: IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell.  P302+P352: IF ON SKIN: Wash with plenty of water during at least 15 minutes.  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P310: Immediately call a POISON CENTER/doctor.  P312: Call the POISON CENTER or a doctor if you feel unwell.  P321: Specific treatment (see … on this label).  P330: Rinse mouth.  P332+P313: If skin irritation occurs: Get medical advice / attention.  P363: Wash contaminated clothing before reuse.P405: Store locked up.  P501: Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note | - |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Algaecide in pools.

|  |  |
| --- | --- |
| **Product Type** | 2 |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | *Algae: Green algae*  Reduction of algae and Chlorophyll A within 24-48h permitting to maintain the water limpid during this period when 104 algae/mL of water. |
| **Field of use** | • Private pools for private use  • Private pools for collective use, type 1, 2 and 3 (sports, hotel complex and camping).  • Public pool for collective uses  Treatment for all types of the pools (inside and outside) whatever their coating or their filtration systems.  To be used only in pools with a filtration system.  Only for the permanent pools (municipal or private pools) with releases into the STP compartment |
| **Application method(s)** | Liquid to be poured directly at the water surface in pools in front of 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** | One single shock treatment (diminution of algae density).  Application rate 2 L for 10 m3. |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | Professionals:  HDPE opaque white or blue.  Closure: degassing Screw cap, re-sealable and children security.  Volume: 1L (bottles), 5L, 10L, 20L (cans), 60L, 200L (barrels), 1000L (IBC container).  Non–professionals :  HDPE opaque white or blue.  Closure: degassing Screw cap, re-sealable and children security.  Volume: 1L, 5L, 10L.  The packaging must be easy to handle and limit splashes: adding a tap, handle or spout according to the capacity of the containers. |

#### Use-specific instructions for use

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| - |

#### Use-specific risk mitigation measures

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| --- |
| - |

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

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| --- |
| - |

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

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| - |

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

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| - |

### General directions for use

#### Instructions for use

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| --- |
| **FOR NON PROFESSIONAL USES** (cans up to 10 L):  Step 1: before product application  - Stop disinfection treatment of the water before application of the product PEROXYDE D’HYDROGENE 34.9 %.  - Treatment in absence of bathers.  - Treatment to be done preferably in the evening.  - Check pH, if necessary adjust between 6.9 and 7.7.  - Filtration to be ran continuously until visible effects of the product (i.e. end of the treatment).  - Scrub the walls and the bottom thoroughly in order to remove algae deposits.  Step 2: product application  - Pour PEROXYDE D’HYDROGENE 34.9% as a shock dose in one single time. Pour directly very close to the water surface to avoid projections. Pour the can in one single time. Precautions: pour product in the outlets stream to allow rapid diffusion of the product into the pool.  - Do not pour the product directly into the skimmers.  Step 3: after 4 days: After application of the product, wait at least 4 days before a new disinfectant treatment, to avoid incompatibility with other disinfectant product and to ensure the efficacy of the H2O2 treatment.  **FOR PROFESSIONAL USES**:  Step 1: before product application  - Stop disinfection treatment of the water before application of the product PEROXYDE D’HYDROGENE 34.9 %.  - Treatment in absence of bathers.  - Treatment to be done preferably in the evening.  - Check pH, if necessary adjust between 6.9 and 7.7.  - Filtration to be ran continuously until visible effects of the product (i.e. end of the treatment).  - Scrub the walls and the bottom thoroughly in order to remove algae deposits.  Step 2: product application  - Dosage to the appropriate concentration with a metering pump or other professional dosing systems in place. 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.  Step 3: after 4 days: After application of the product, wait at least 4 days before a new disinfectant treatment, to avoid incompatibility with other disinfectant product and to ensure the efficacy of the H2O2 treatment. |

#### Risk mitigation measures

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| --- |
| * Liquid to be poured directly very close to the water surface in pools to avoid projections. * For professionals users, wear chemical goggles, coverall and gloves. * For non-professionals users, the packaging must be easy to handle and limit splashes (adding a tap, handle, spout). |

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

|  |
| --- |
| * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

#### Instructions for safe disposal of the product and its packaging

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| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains. * Dispose of unused product, its packaging and all other waste, in accordance with local regulations. |

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

|  |
| --- |
| * Do not store at temperature above 30°C. * Protect from frost. * Shelf-life: 2 years. |

### Other information

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| --- |
| * The product is not intended for use with other biocidal products. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 1L | HDPE opaque | Degassing Screw cap | Professional and non-professional |  |
| Can | 5L | HDPE opaque | Degassing Screw cap | Professional and non-professional |  |
| Can | 10L | HDPE opaque | Degassing Screw cap | Professional and non-professional |  |
| Can | 20L | HDPE opaque | Degassing Screw cap | Professional |  |
| Barrel | 60L | HDPE opaque | Degassing Screw cap | Professional |  |
| Barrel | 200L | HDPE opaque | Degassing Screw cap | Professional |  |
| IBC container | 1000L | HDPE opaque | One-piece butterfly valve screwed and sealed  Alu (specification provided) | Professional |  |

### Documentation

#### Data submitted in relation to product application

Physico-chemical properties studies and analytical methods on the biocidal product PEROXYDE D’HYDROGENE 34.9% were provided by GIE H2O.

Efficacy data with the product PEROXYDE D’HYDROGENE 34.9% are submitted for the demonstration of the efficacy.

Please refer to the list of references (annex 3.1).

#### Access to documentation

The prospective Authorisation holder GIE H2O Biocide is a consortium of companies (GIE stands for “Groupement d’Interêt Economique”). The denomination of the consortium is: “groupement des formulateurs de biocides pour traitement de l’eau” - H2OBiocide.

GIE H2O has access to data on the active substance hydrogen peroxide with a Letter of Access of PeroxyChem Spain s.l.u., Solvay Chemicals International SA, Arkéma three applicants of the active substance hydrogen peroxide.

## Assessment of the biocidal product

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 35.08% of technical active substance hydrogen peroxide and 34.9% of pure active substance hydrogen peroxide.

The product does not contain PT6 preservative.

The product is not diluted for use.

Formulation type: Any other liquid (AL).

Hydrocarbon and H304 co-formulant content: <10%.

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

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

|  |  |
| --- | --- |
| Product Type(s) | 2 |
| Where relevant, an exact description of the authorised use |  |
| Target organism (including development stage) | Algae: *Green algae* |
| Field of use | Algaecide treatment for all type of private pools (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 | Very green water (i.e. bottom is not visible\*) :  The application rate to achieve efficacy in the treated pool is 2 L for 10 m3. The likely active H2O2 substance concentration is 79 mg/L in treated water considering a product density of 1.132.  Greenish water (i.e. bottom is still visible\*):  The application rate to achieve efficacy in the treated pool is 1 L for 10 m3. The likely active H2O2 substance concentration is 39.5 mg/L in treated water considering a product density of 1.132.  Before algal bloom start (i.e. in case of algae spots on walls, bottom, stairs or shadow areas) :  The application rate to achieve efficacy in the treated ,pool is 0.5 L for 10 m3. The likely active H2O2 substance concentration is 19.75 mg/L in treated water considering a product density of 1.132.  In all cases, this is a single shock treatment.  \*The degree of the green colour of a pool water is a subjective and unmeasurable parameter for the end-user. However, this kind of simple criteria is a benchmark for the users of the product, for an adjusted (reasonable) use of the biocidal product |
| Category(ies) of user(s) | Professional and non-professional. |
| Pack sizes and packaging material | Material: PEHD opaque white or blue.  Closure: degassing Screw cap, re-sealable and children security.  Volume: 1L (bottles), 5L, 10L, 20L (cans), 60L, 200L (barrels) and 1000L (IBC container). |

### Physical, chemical and technical properties

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | GIFAP monography N°17, 2nd Edition | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | Liquid colourless translucent | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Colour at 20 °C and 101.3 kPa | GIFAP monography N°17, 2nd Edition | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | Liquid colourless translucent | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Odour at 20 °C and 101.3 kPa | OPPTS 830.6304. Odor | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | As the product is harmful if inhaled (H332) the qualitative determination of odour is not performed according to guideline OPPTS. But from users the odor is described as “acre” | Acceptable | */* |
| Acidity / alkalinity | CIPAC MT 191  CIPAC MT 75.3 | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | pH of neat item: 2.0 at ambient temperature  pH at 1% w/v in water: 6.4 at ambient temperature  Free acidity = 0.0048% w/w H2SO4 at ambient temperature | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Relative density / bulk density | PYCNOMETRIC METHOD, OECD 109 | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | Relative density D204 = 1.132 ± 0.000  Density = 1.131 g/mL | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Storage stability test – **accelerated storage** | CIPAC MT 46 | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | Bottle of 1L HDPE.   |  |  |  | | --- | --- | --- | |  | T0 | 18 weeks at 30°C | | Appearance | Colourless translucent liquid | No change | | AS content | 342 | 332.1 | | Variation of AS content | / | -2.9% | | Weight | 1175.14 g | 1172.99 g | | Variation of weight | / | -0.2 % | | pH on neat at ambient temperature | 2.0 | 2.1 | | pH of 1% w/v dilution | 6.4 | 5.2 | | Free acidity | 0.0048% H2SO4 w/w | 0.0057% H2SO4 w/w | | Acceptable  The mention “Do not store at temperature above 30°C” is added on SPC. | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Storage stability test – **long term storage at ambient temperature** |  |  | On-going | Intermediate or final results of shelf–life study should be provided as soon as possible. |  |
| Storage stability test – **low temperature stability test for liquids** | / | / | No data provided. The mention ”protect from frost” should be added in the SPC. | Acceptable | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | / | / | Test item was exposed to the sunlight during the accelerated storage test, the content of active substance did not change. | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | / | / | Data on temperature have been provided in the accelerated storage stability study. | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | / | / | / | / | / |
| Wettability | / | / | / | Not relevant for an AL formulation | / |
| Suspensibility, spontaneity and dispersion stability | / | / | / | Not relevant for an AL formulation | / |
| Wet sieve analysis and dry sieve test | / | / | / | Not relevant for an AL formulation | / |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | / | Not relevant for an AL formulation | / |
| Disintegration time | / | / | / | Not relevant for an AL formulation | / |
| Particle size distribution, content of dust/fines, attrition, friability | / | / | / | Not relevant for an AL formulation | / |
| Persistent foaming | Statement | / | No foam expected due to composition. | Acceptable | / |
| Flowability/Pourability/Dustability | / | / | / | Not relevant for an AL formulation | / |
| Burning rate — smoke generators | / | / | / | Not relevant for an AL formulation | / |
| Burning completeness — smoke generators | / | / | / | Not relevant for an AL formulation | / |
| Composition of smoke — smoke generators | / | / | / | Not relevant for an AL formulation | / |
| Spraying pattern — aerosols | / | / | / | Not relevant for an AL formulation | / |
| Physical compatibility | / | / | / | Not relevant for an AL formulation | / |
| Chemical compatibility | / | / | / | Not relevant for an AL formulation | / |
| Degree of dissolution and dilution stability | / | / | / | Not relevant for an AL formulation | / |
| Surface tension | / | / | 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). | Acceptable  It is surface-active product. | / |
| Viscosity | OECD 114 | 34.2%  EAU OXYGÉNÉE GIE HYDRACHIM  BATCH NO. 81237 | Kinematic viscosity At 20°C=0.99 ± 0.00 mm² /s Kinematic viscosity At 40°C=0.69 ± 0.00 mm² /s | Acceptable | Servajean E., 2017 Phytosafe s.a.r.l.. N° report: 16-33-032- ES |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product PEROXYDE D’HYDROGENE 34.9% is an any other liquid (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a colourless translucent liquid. There is no effect of temperature on the stability of the formulation, since after 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature when stored in bottle of HDPE packaging material (commercial packaging material). The long term storage stability study is on-going and intermediate results should be provided.  Its technical characteristics are acceptable for an AL formulation.  Protect from frost.  Do not store at temperature above 30°C. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | UN test series 1 to 3 | / | 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 H2O2 the predominant hazard is the oxidising property | Acceptable | Guidance on the Application of the CLP Criteria: version 4.1 - June 2015 |
| Flammable gases | / | / | / | Not relevant as the product is a liquid | / |
| Flammable aerosols | / | / | / | Not relevant as the product is a liquid | / |
| Oxidising gases | / | / | / | Not relevant as the product is a liquid | / |
| Gases under pressure | / | / | / | Not relevant as the product is a liquid | / |
| Flammable liquids | A9 Flash point | / | 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 | Acceptable | Guidance on the Application of the CLP Criteria: version 4.1 - June 2015 |
| Flammable solids | / | / | / | Not relevant as the product is a liquid | / |
| Self-reactive substances and mixtures | UN MTC series A to H | / | CLP definitions excludes substances and mixtures classified according to this Part as explosives, organic peroxides or as oxidising | Acceptable | Regulation N° 1272/2008 Version 4.1 June 2015 |
| Pyrophoric liquids | UN test N.3 | / | 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 | Acceptable | / |
| Pyrophoric solids | / | / | / | Not relevant as the product is a liquid | / |
| Self-heating substances and mixtures | UN Test N.5 | / | According to CLP: The classification procedure for this class need not be applied if: (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or (b) experience in production or handling shows that the substance or mixture does not react with water,e.g. the substance is manufactured with water or washed with water; or (c) the substance or mixture is known to be soluble in water to form a stable mixture. | Acceptable | Regulation N° 1272/2008 Version 4.1 June 2015 |
| Substances and mixtures which in contact with water emit flammable gases | / | / | / | Not relevant as the product is a liquid | / |
| Oxidising liquids | UN test O.2 | / | According to specific concentration limits of CLP Harmonised Classification of hydrogen peroxide solution (CLP00  Ox. Liq. 1; H271: C ≥ 70 %  Ox. Liq. 2; H272: 50 % ≤ C < 70 %) the product 34.9% is not classified as oxidising liquid. | Acceptable | / |
| Oxidising solids | / | / | / | Not relevant as the product is a liquid | / |
| Organic peroxides | / | / | The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. | Acceptable | / |
| Corrosive to metals | UN test C.1 | 35.2 | A GLP test following method 37.4 C.1 of the UN Handbook was performed. Corrosion of metals by the test item was determined over a period of seven days. No relevant effects on aluminium and on steel were examined. The test item is therefore classified as “not corrosive” | Acceptable | Krebs F., 2017. C.1 of the UN Handbook, Laüs Report n°: 16081201G979 |
| Auto-ignition temperatures of products (liquids and gases) | / | / | Inorganic oxidising liquids are not flammable. The test is not required for liquids not flammable in air. | Acceptable | / |
| Relative self-ignition temperature for solids | / | / | / | Not relevant as the product is a liquid | / |
| Dust explosion hazard | / | / | / | Not relevant as the product is a liquid | / |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties due to the concentration of 34.9% of active substance in the product. |

### Methods for detection and identification

Report: Servajean, E., 2017, Stability of Eau oxygénée GIE Hydrachim over accelerated storage and shelf life determination

Report no 16-33-032-ES

Test facilities:

PHYTOSAFE s.a.r.l.

2, rue Marx Dormoy

64000 PAU - FRANCE

Principle of the method:

Hydrogen peroxide was assessed by HPLC-UV and external calibration. Detection: 228 nm.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | Chromatograms of the method (blank, reference item and test item) have been provided and there is no interference. | |
| Linearity | Linearity was studied by carrying out 11 concentrations between 0.5-261 mg/L H2O2.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance | 0.5-261 mg/L H2O2 Log (H2O2, mg/L) = 0.987 (± 0.001) x Log(Area) – 0.320 (± 0.002) R2 = 0.9999  n=1 |
| Precision | Repeatability was evaluated by analyzing 6 (n=1) test item solutions at two levels of concentrations. | |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 0.1% at 40 mg/L  RSD= 1.2% at 400 mg/L |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | n | | 0.063 mg | 98.7; 98.7 | 98.7% | 2 | | 0.63 mg | 99.3; 101.2 | 100.25 | 2 | | |

The analytical method is fully validated for the determination of the active substance H2O2 in the product.

Analytical methods for H2O2 residues in soil, air, water (drinking water) and sediment are available in Assessment Report of H2O2 Product-type 2, Feb. 2017. The applicant GIE H2O has a Letter of Access from PeroxyChem Spain s.l.u. for these data.

Analytical methods for H2O2 residues in soil, air, water (including drinking water) and sediment are unnecessary.

As the active substance H2O2 is not classified Toxic or Very Toxic, an analytical method for the determination of hydrogen peroxide residue in human body fluids and tissues is unnecessary.

As the product PEROXYDE D’HYDROGENE 34.9% is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of hydrogen peroxide residue in food/feed of plant and animal origin is unnecessary.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance hydrogen peroxide in the product.  Analytical methods were provided at EU level for the determination of active substance residue in soil, water and air with respectively LOQ =0.14 mg/m3 and 0.01 µg/L.  Hydrogen peroxide is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  No analytical method in soil is required according to the Assessment report of hydrogen peroxide.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of hydrogen peroxide in food/feed of plant and animal origin is not required. |

### Methods for detection and identification for efficacy test in aquarium

Report: Strohl P., 2017, Transposition and validation of a hydrogen peroxide assay method by HPLC

Report no RE-1220/1016/M1

Test facilities:

IRM no more precision have been provided.

Principle of the method:

Hydrogen peroxide was assessed by HPLC-UV and external calibration. Detection: 229 nm.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | Chromatograms of the method (blank, reference item and test item and algal growth medium) have been provided and there is no interference. | |
| Linearity | Linearity was studied by carrying out 5 concentrations between 3.53-94.2 mg/L H2O2 in triplicate.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance | 3.53-94.2 mg/L H2O2 y = 0.04593x – 0.02482  R2 = 0.9999  n=3 |
| Precision | Repeatability was evaluated by analyzing 6 (n=1) test item solutions at two levels of concentrations. | |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 0.3% at 21 mg/L |
| Accuracy | Accuracy was determined by analysis of 3 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | n | | 3.5 mg/L | 100.7; 98.76; 100.07 | 99.8 | 3 | | 23.7 mg/L | 92.06; 92.22; 92.2 | 92.2 | 3 | | 90 mg/L | 84.72; 94.32; 94.17 | 94.4 | 3 | | |
| LOQ | LOQ was evaluated by analyzing 6 (n=1) test item solutions at one level of concentration.  RSD = 1.13% at 3.53 mg/L | |

The analytical method is fully validated for the determination of the active substance H2O2 in water issued from aquarium.

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

PT2: Disinfectants and algaecides not intended for direct application to humans or animals

PEROXYDE D'HYDROGENE 34.9% is used as Product Type 2. It is intended to be used as algaecide against green algae in outdoor or indoor pool waters by professionnal and non professional users.

The product PEROXYDE D'HYDROGENE 34.9% is a liquid formulation (AL) poured directly at the water surface in pools (preferably in the outlets stream).

Using the Commission P91L AFNOR[[3]](#footnote-3) 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),
* Public pool for collective uses.

The product is intended to be used for curative action to stop algae emergence and to inhibit the growth of existing algae in water when green algae blooms are observed or just starting.

According to the applicant, one single shock treatment is implemented as follows :

* In case of very green water (i.e. bottom and walls are not visible): The application rate to achieve efficacy in the treated pool is 2 L for 10 m3.
* In case of greenish water (i.e. bottom is still visible): the application rate to achieve efficacy in the treated pool is 1 L for 10 m3.
* Before algal bloom start (i.e. in case of algae spots on walls, bottom, stairs or shadow areas): the application rate to achieve efficacy in the treated pool is 0.5 L for 10 m3.

Indeed in the case of spots, the algae will enter an exponential growth phase which will lead to an increased cell density in the water column. In absence of algaecide treatment, the water column will become greenish/very greenish within the next days. This change in the colouring of water is a consequence of the increase in cell density (and thus Chlorophyll A). The purpose of the algaecide treatment is to reduce cell density (and thus Chlorophyll A concentration) and to inhibit the algae growth to a level compatible with elimination capacity of the swimming pool system.

Treatment is intended to be used for all types of pools (indoor and outdoor), whatever their coating or their filtration systems and treated with all types of disinfection products. This product is intended for different types of pools: permanent swimming pool, non permanent swimming pool.

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

The target organisms to be controlled are green algae. Green microalgae are Chlorophyta, i.e. more than 7000 existing species.

A mixture of algae is a configuration that is consistent with the reality where several algae strains can compete. Therefore for the efficacy studies, after an e-consultation of the Efficacy WG (June 2016), three species were proposed *Chlorella vulgaris*, *Chlamydomonas reinhardtii* and *Scenedesmus subspicatus*.This requirement was based on the fact that according to the literature, the sensitivity of various genera of algae against active substances can differ.

The applicant decided to retain the two strains *C. vulgaris* and *C. reinhardtii* for the test and to replace *Scenedesmus subspicatus* by *Pseudokirchneriella subcapitata.*

Indeed, the *S. subspicatus* strain (*Desmodesmus subspicatus* = *Scenedesmus subspicatus*) is one of the strains proposed in the OECD 201 test[[4]](#footnote-4) in the same way as *Pseudokirchneriella subcapitata*. The latter being a very well-known strain, model in ecotoxicology and used routinely by the laboratory, 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), therefore it places the test in a worst-case situation. This reasoning has been accepted by the e-CA.

The applicant 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

#### Effects on target organisms, including unacceptable suffering

The active substance hydrogen peroxide both inhibits the growth and kills green algae cells.

#### Mode of action, including time delay

Hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen. The antimicrobial action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and singlet oxygen. These reactive oxygen species cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA.

The applicant claims that the biocidal activity of hydrogen peroxide is immediate and that the time delay for the visible effect (reduction or disappearance of the green colour) will vary according to the initial algal situation:

* For algal spots the time delay to observe the effect is 24h,
* For greenish water where bottom is visible the time delay to observe the effect is 24 to 48h,
* For very greenish water where bottom is not visible the time delay to observe the effect vary from 24 to 72h.

The delay will also vary with interfering substances level in the water, temperature and hydraulic parameters as filtration.

#### Efficacy data

One simulated-use study has been submitted. The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized below.

There is no standard test method for algaecide efficacy testing that is currently recommended in the efficacy guidance for biocides PT 1-5. A tailored protocol for simulated use test has been set up on purpose 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.

The protocol was developed taking into account:

1) existing guidance documents:

- Guideline ENV / JM / MONO (2012) 15. Series on Testing and Assessment No. 170: Guidance for demonstrating efficacy of pool and spa disinfectants in laboratory and field testing;

- OECD Guideline N°201. Freshwater algae and Cyanobacteria, Growth Inhibition Test (July 2011);

2) the experience of the members of the consortium GIE located in different regions of France to determine a realistic worst-case;

3) the technical constraints of the laboratory (m² available in the laboratory, no weekend measurements, experiments on some strains of algae only, outsourcing some analyses, etc.).

A draft protocol has been discussed during an e-consultation of the Efficacy WG (June 2016) and taking into account technical constraints, available time and financial means, a reviewed protocol has been followed by the applicant to assess algaecide effects of the product.

**a) Simulated-use test design:**

The efficacy data to support the claims were generated in 3-steps process:

**STEP 1: In-use algae cells numeration** (GIE data collection, 2016 study)

Swimming pools with visually green water were sampled for subsequent cells numeration to justify the algae inoculum density to be tested in simulated use tests.

Seven samples were retained from eight visually green waters in pool of various regions (photos available in the report). The algae cells density was estimated by cells counting with Malassez counting chamber in triplicates.

7 values of cells concentration were used to determine a representative inoculum rounded at 1.104 cells / mL.

**STEP 2: a preliminary efficacy test** has been performed to assess the robustness of the designed protocol and to refine it when necessary (Boiseillier M et al., IRM, 2017. Report N°1332/1216).

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 analyzes so that it is more practical at the technical level.

**STEP 3: a final efficacy test** - (Boiseillier M et al., IRM, 2017 Final Report N°1025/0117 + doc. Report IRM 1025/0117 pictures).

The main test was realized in 12 tanks indoor (3 control tanks with filter and 9 assay tanks such as 3 assay tanks by claimed concentration). An initial green algal concentration is inoculated in each tank (1/3 of each species of algae mixed) and growth or growth inhibition is quantified as a function of time (daily algal count using a counting chamber and by quantitative assays of Chlorophyll A by spectrophotometer). The concentration of the active substance H2O2 is also measured every 24H and the test is carried out over 95H (4 days) with controlled lighting and temperature.

At the end of the test, the growth rate and the concentration of Chlorophyll A are calculated for each tank and compared to controls.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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% | All type of 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 technic Malassez counting chamber.  3 replicates per sample  Mean value calculated for each sample. | Results of cells counting are :  6,00.103 cells/ml, 1,17.105 cells/ml, 9,0.103 cells/ml, 7,77.104 cells/ml,  2,3. 103 cells/ml, <1,0.103 cells/ml, 1,67.105 cells/ml.  The median value has been used as inoculum in the efficacy test  **=> 9.103 rounded to 104 cells/ml** | GIE data collection,  2016  RI=2 |
| Algaecide | PT2  Outdoor and indoor pools. | PEROXYDE D’HYDROGENE 34.9% | A mixture of 3 representative green algae species:  *P. subcapitata*, strain AC152  *C. vulgaris*, strain AC150  *C. reinhardtii*, strain AC609  1/3 each at t0 and an overall inoculum of 104 cells/mL | **STEP 2: a preliminary efficacy test**  Application of product in tanks inoculated with a mixture of green algae species.  Efficacy has been assessed by:  1. chlorophyll A measurements  2. algal numeration with Malassez counting chamber and calculation of algal growth | Conducted in three 240L (fill volume ca. 200 L) tanks over 96 hours with:  - One treated aquarium at the intended dose of 1L product / 10m3 water  - One non-treated aquarium with filtration  - One non-treated aquarium without filtration1 blank without filtration.  -Monitoring of H2O2 concentration, dissolved oxygen rate, pH, redox potential. | 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. | Boiseillier M et al., IRM, 2017. Report N° 1332/1216  RI=2 |
| Algaecide | PT2  Outdoor and indoor pools. | PEROXYDE D’HYDROGENE 34.9% | A mixture of 3 representative green algae species:  *P. subcapitata,* strain AC152  *C. vulgaris,* strain AC150  *C. reinhardtii,* strain AC609  1/3 each at t0 and an overall inoculum of 104 cells/mL | **STEP 3: a final efficacy test** Semi-Field test (indoor)  Application of product in tanks with sand filtration inoculated with a mixture of green algae species.  Efficacy has been assessed by:  1. chlorophyll A measurements  2. algal numeration with Malassez counting chamber and calculation of the algal growth rate | - Experimental unit: 240-L tank (fill volume ca. 200 L) wrapped in an opaque stretch film.  - 3 replicates for control tank and each dose rate (12 tanks)  - 3 dose rates: 0.5 L (C1), 1 L (C2) and 2 L/10m3 (C3) of hydrogen peroxide 34.9% (i.e. 19.7, 39.5 and 79 mg/L H2O2 nominal concentration)  - Observation period: 96 hours (at T0, 4, 24, 48, 72 and 96h)  -Monitoring: water level, water temperature, flow rate, H2O2 concentration, dissolved oxygen rate, pH (adjusted if needed), redox potential, cell counts, chlorophyll A concentration.  Test conditions:  - tap water +stock solution ISO 8692  - Interfering substance: 27.5 mg/L BSA (=> measured oxidability: 3.2 mg O2/L)  - pH = 7.4 +/- 0.1  -Water hardness: 250 – 300 mg/L CaCO3  - Light intensity: 8000 – 10000 Lux (16h light / 8h darkness).  Temperature: 27.5°C ± 2.5°C  The water is not green at the beginning of the test. | Growth rate after 95h:  - control : 2.99x10-2  - C1: 1.60x10-2-  - C2: 4.96x10-3  - C3: 5.68x10-3  Evolution of the growth rate during the test  C1 and C2: growth rate is negative for time window 0-24h and increases after 24h;  C3 : growth rate is negative and decreases until 48h, but increases after 48h.  From pictures taken all along the test  - The water of the **controls** becomes unclear after 24 hours and becomes clearly green after 48h.  - Aquariums treated with the **C1** concentration (17.9 mg / L) are unclear in 24 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. | Boiseillier M et al., IRM, 2017  Final Report 1025/0117  + doc. Report IRM 1025/0117 pictures  RI=2 |
| Compatibility H2O2 with chlorinated disinfectants | PT2  Outdoor and indoor pools. | PEROXYDE D’HYDROGENE 34.9% | No test organisms tested |  | Pre-test 1: after 48H, decrease in the H2O2 level whatever the concentration is inconsistent with the observations made during the efficacy test (physicochemical test conditions were probably too detrimental but are those of the efficacy test)  Pre-test 2: quantify the impact of factors significantly impacting the H2O2 level and adjustment (conditions are therefore different from the efficacy test).  Final test:  Demineralized water  pH= 7.2 ± 0.2  Test temperature at 22±2°C  Lighting times at 12h / 12h  Control : H2O2 alone, chlorine alone  3 replicates for 1L/m3  2 replicates for 0.5 L and 2L/10m3  2 chlorinated products (2.5 mg/L active chlorine): sodium hypochlorite and sodium dichloroisocyanurate dihydrate. | Pre-test 1:   |  |  |  |  | | --- | --- | --- | --- | | H2O2 (mg/L) | T0 | T24h | T48h | | 2L/10 m3 | 68.73 | 34.56 | 8.776 | | loss vs. T0 | - | -49.7% | -87.2% | | 1L/10 m3 | 36.93 | 17.32 | 4.954 | | loss vs. T0 | - | -53.1% | -86.6% | | 0.5L/10 m3 | 16.44 | 10.03 | 4.424 | | loss vs. T0 | - | -39.0% | -73.1% |   Final test: the concentration of hydrogen peroxide is slightly reduced and the chlorine disappears | RI = 3 |

**b) Study parameters followed up during the final efficacy study**

**1-Claims of the applicant and Efficacy criteria**

The claims of the applicant are essentially based on the colour of water.

Nevertheless from an efficacy point of view the concept of "green water" is not objective and then difficult to implement in an simulated-use test. 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: as an example, 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.

Moreover, 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 applicant also states that the chlorophyll A concentration varies according to the species of green algae, so no direct correlation can be made between the green colour and the number of algae.

No efficacy criteria have been proposed by the applicant. According to the Vol II Part B/C ECHA guidance, algaecidal activity is defined as the capability of a product or active substance to produce a reduction in the number of viable algae cells under defined conditions. Taking into account the claims of the applicant based on green colour, e-CA proposes to consider efficacy criteria as the recovery of limpid water supported by a significant decrease of algae cells and chlorophyll A.

It has to be noted that 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 104 to a value in 105. 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.

In a first step, swimming pools with visually green water were sampled for subsequent cells numeration to justify the algae inoculum density to be tested in simulated use tests. Therefore this algae inoculum density supports the claim “greenish/very greenish water” where the higher doses are recommended.

**2-Growth of algae in the controls**

At the initial H0 time, the 3 green microalgae strains were added in equivalent amount. According to the counts of algae presented, *C. vulgaris* is very minority after 24h of test but not at the initial time H0.

As explained by the laboratory in the frame of additional information request, the very fast prevalence of a strain is a natural phenomenon, even inevitable. There is competition between the algae. As the growth of algae is specific and exponential, the dominance of an alga entails the rapid decline of others.

Indeed when growing microalgae in the laboratory, growth rates were significantly different:

- *Pseudokirchneriella subcapitata*, very well known, has been easy to grow.

- *Chlorella vulgaris*, is representative and grows very well in the ISO environment but has shown a sharp decline in growth in tap water.

- *Chlamydomonas reinhardtii* showed slower growth with a plateau at 5.105 cells /mL under culture conditions.

During the microalgae culture phase carried out between 04/01/2017 and 09/01/2017, the algae concentration evolved from an inoculum of 104 cells / mL for all strains to:

- 2,44.106 cell / mL for *P. subcapitata*,

- 1,81.106 cell / mL for *C. vulgaris*,

- 5,10.105 cell / mL for *C. reinhardtii*.

Therefore, after 120h and under the same conditions of culture, there is a strong disparity in the growth of the three strains of algae. The different growth of the strains under identical culture conditions as well as the passage in the aquariums explains the rapid variation of the equilibrium between the three different strains.

**3-H2O2 measurement**

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.

Table 1. H2O2 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 |
| t0+ 2h | 9.33 | 9.97 | 13.23 | 21.04 | 9.91 | 10.1 | 105.76 | 36.26 | 44.78 |
| **t0 +24.5h** | **10.84** | **12.45** | **12.19** | **31.29** | **31.67** | **32.99** | **69.84** | **65.93** | **65.13** |
| t0+48.25h |  | <LOD |  |  | 30.13 |  |  | 62.75 |  |
| t0 +72h |  |  | <LOD |  | 25.65 |  |  | 61.40 |  |
| t0 +95h | <LOD | <LOD | <LOD | <LOD | <LOD | LOQ | 64.45 | 59.44 | 59.68 |

LOD <1.18 mg/L

LOQ = 3.53 mg/L

Data on hydrogen peroxide concentration indicate that:

* Regarding C1 (0.5 L/10 m3 i.e. 19.75 mg/L) the active substance H2O2 is consumed within the first 48h, after 48h the concentration is below the limit of detection (LOD).
* Regarding C2 (1 L/10 m3 i.e. 39.5 mg/L) the active substance H2O2 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 (2 L/10 m3 i.e. 79 mg/L) the active substance H2O2 is maintained to level higher than 60 mg/L until 72h

It is to be noted that none of the claimed application rate is reached during the test. Indeed, concentration should have been recorded more frequently during the first 24h. However, concentration at T+24.5h are homogeneous and consumption of H2O2 explains lower concentrations.

**4-Algal counting**

Algal counts are carried out using a counting chamber and by quantitative assays of chlorophyll A by spectrophotometer. At the end of the test, the growth rate and the concentration of Chlorophyll A is calculated for each tank and compared to the controls.

* Algae density reduction and growth rate inhibition (tables 2 and 3):

The % reduction at an observed time is calculated by the applicant as following:

100 \* (Nc – Nt) / Nc

Where: Nc stands for the means algae cell density in the control at time t and Nt stands for the mean algae cell density in the treatment at time t.

FR CA calculated additionally the reduction of algae densities compared to the initial inoculum because conditions (e.g. filtration, composition of the algal population) are not totally comparable between all aquariums over time, and assuming that the control aquariums permit to validate the test method. These calculations allow to refine the activity of the product over time.

Thus for algae density, the % reduction at an observed time should be calculated as following: 100 \* (N0 – Nt) / N0

Where: N0 stands for the mean initial algae cell density (t0) and Nt stands for the mean algae cell density at time t in the treatment.

The growth rate was determined from cell densities by the applicant as follows:

µ = ln (Cj) – ln (Ci) / (Tj – Ti)

where : µ = growth rate (in hour-1),

Cj = algal cell number/mL at j time,

Ci = algal cell number/mL at i time (=104 cells/mL),

Tj = J time (in hours), Ti = Initial time in hours (=0h).

Following time windows has been followed by the applicant to calculate the growth inhibition: 0-24h, 0-48h, 0-72h and 0-95h.

Additionally e-CA decided to take into account following time windows: 0-24h, 24-48h, 48-72h and 72-95h; in order to assess the evolution of the growth rate and thus the duration of the efficacy.

* Chlorophyll A reduction and growth rate inhibition (tables 3 and 4)

The % reduction at an observed time is calculated as following:

100 \* (CAc – CAt) / CAc

where: CAc stands for the mean Chlorophyll A concentration in the control at time t and CAt stands for the mean Chlorophyll A concentration in the treatment at time t.

FR CA calculated additionally the reduction of Chlorophyll A compared to the initial concentration in the control, then the % reduction at an observed time should be calculated as following:

100 \* (CA0 – CAt) / CA0

Where: CA0 stands for the mean initial Chlorophyll A concentration measured at 1.5h after inoculation just before product addition (t0) and CAt stands for the mean Chlorophyll A concentration at time t in the treatment.

The growth rate was determined from cell densities as follows:

µ = ln (CAj) – ln(CAi) / (Tj – Ti), where:

µ = growth (in hour-1),

CAj = algal cell number/mL at j time,

CAi = algal cell number/mL at i time (t0+1h30),

Tj = J time (in hours), Ti = I time (in hours).

Following time windows has been followed by the applicant to calculate the growth inhibition: 0-24h, 0-48h, 0-72h and 0-95h.

Additionally e-CA decided to take into account following time windows: 0-22.5h, 22.5-46.5h, 46.5-70.5h and 70.5-93.5h.

1. **Efficacy results**

Table 2. Algae Cells densities (cells / mL)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Algae Cells densities (cells / mL) / Control** | | | |  | **Algae Cells densities (cells / mL) / H0 = 104** | | | |
| **Water treatment** | **24 h** | **48 h** | **72 h** | **95 h** |  | **24 h** | **48 h** | **72 h** | **95 h** |
| Mean Control | 2.59x104 | 5.72x104 | 7.93x104 | 1.74x105 |  | 2.59x104 | 5.72x104 | 7.93x104 | 1.74x105 |
| Mean C1 (0.5L/10 m3) | 6.27x103 | 2.43x104 | 4.58x104 | 4.72x104 |  | 6.27x103 | 2.43x104 | 4.58x104 | 4.72x104 |
| C1: % reduction (\*) | 76% | 58% | 42% | 73% |  | 37.3% | -143% | -358% | -372% |
| Mean C2 (1 L/10 m3) | 4.27x103 | 5.33x103 | 7.00x103 | 6.27x103 |  | 4.27x103 | 5.33x103 | 7.00x103 | 6.27x103 |
| C2: % reduction | 84% | 91% | 91% | 96% |  | 57.3% | 46.7% | 30% | 37.3% |
| Mean C3 (2 L/10 m3) | 6.40x103 | 4.07x103 | 6.47x103 | 5.87x103 |  | 6.40x103 | 4.07x103 | 6.47x103 | 5.87x103 |
| C3 : % reduction | 75% | 93% | 92% | 97% |  | 36% | 59.3% | 35.3% | 41.3% |

(\*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

|  |  |  |
| --- | --- | --- |
| **Comparison with the control** |  | **Comparison with the initial inoculum** |
| At 24 h, the algae cell densities measured in the aquarium treated with BP are reduced by at least 75%.  At 48, 72 and 95h 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 (58%, 42% and 73%) for concentration C1 and this observation could be 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. |  | For the C1 concentration:  - at 24h, the algae cell densities measured in the aquarium treated is reduced by nearly 37%;  - from 24h to 95h, there is no reduction anymore but an important increase of the algae cell density is noticed.  For the C2 concentration:  - at 24h, the algae cell densities is reduced by nearly 57%;  - algae cell densities increases after 24h.  For the C3 concentration:  - the algae cell densities is reduced by nearly 59% within 48h;  - algae cell densities increases after 48h. |

It has to be noted that for the application rates C2 and C3, the aquarium waters stood uncoloured at the end of the test while for the application rate C1 (0.5 L/10 m3) and the controls waters became green.

Table 3. Growth rate inhibition (calculated from Algae Cells densities)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Growth rate inhibition (per hour)**  **(calculated from Algae Cells densities / control** | | | |  | **Growth rate inhibition (per hour)**  **(calculated from Algae Cells densities / control)** | | | |
| **Water treatment** | **0-24h** | **0-48h** | **0-72h** | **0-95h** |  | **0-24h** | **24-48h** | **48-72h** | **72-95h** |
| Mean Control | 3.93x10-2 | 3.62x10-2 | 2.87x10-2 | 2.99x10-2 |  | 3,93x10-2 | 3,32x10-2 | 1,36x10-2 | 3,38x10-2 |
| Mean C1 (0.5L/10 m3) | -1.96x10-2 | 1.84x10-2 | 2.07x10-2 | 1.60x10-2 |  | -1,96x10-2 | 5,64x10-2 | 2,53x10-2 | 1,35x10-3 |
| C1 : % reduction (\*) | 150% | 49% | 28% | 47% |  | 150% | -70% | -86% | 96% |
| Mean C2 (1 L/10 m3) | -3.58x10-2 | -1.43x10-2 | -5.03x10-3 | -4.96x10-3 |  | -3,58x10-2 | 7,16x10-3 | 1,35x10-2 | -4,72x10-3 |
| C2 : % reduction | 191% | 140% | 118% | 117% |  | 191% | 78% | <1% | 114% |
| Mean C3 (2 L/10 m3) | -1.87x10-2 | -1.93x10-2 | -6.32x10-3 | -5.68x10-3 |  | -1,87x10-2 | -1,99x10-2 | 1,96x10-2 | -3,69x10-3 |
| C3 : % reduction | 148% | 153% | 122% | 119% |  | 148% | 160% | -44% | 111% |

(\*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

|  |  |  |
| --- | --- | --- |
| **Comparison with the control** |  | **Comparison with the growth evolution of control** |
| At 24 h, the growth rate is inhibited by at least 148% whatever the concentration.  For concentration C2 and C3, the growth rate is negative (< 0 h-1) indicating a decline of algae population.  For concentration C1, the growth rate is negative (< 0h-1) for time window 0-24h and increase after 24h; 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. |  | For concentration C1 and C2, the growth rate is negative (< 0h-1) for time window 0-24h and increases after 24h;  For concentration C3, the growth rate is negative (< 0h-1) and decreases until 48h, but increases after 48h. |

Table 4. Chlorophyll A concentration (µg/L)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Chlorophyll A concentration (µg/L) / Control** | | | |  | **Chlorophyll A concentration (µg/L) / H1.5H** | | | | |
| Water treatment | 24 h | 48 h | 72 h | 95 h |  | 1.5h | 24 h | 48 h | 72 h | 95 h |
| Mean Control | 21.13 | 62.59 | 44.29 | 31.91 |  | 6,0 | 21,1 | 62,6 | 44,3 | 31,9 |
| Mean C1 (0.5L/10 m3) | 3.44 | 27.02 | 30.55 | 34.32 |  | 5,96 | 3,4 | 27,0 | 30,5 | 34,3 |
| C1: % reduction (\*) | 84% | 57% | 31% | -8% |  |  | 43% | -353% | -412% | -476% |
| Mean C2 (1 L/10 m3) | 1.53 | 0.50 | 1.73 | 1.71 |  | 4,7 | 1,5 | 0,5 | 1,7 | 1,7 |
| C2: % reduction | 93% | 99% | 96% | 95% |  |  | 68% | 93% | 64% | 64% |
| Mean C3 (2 L/10 m3) | 1.04 | 0.59 | 0.74 | 2.39 |  | 5,6 | 1,0 | 0,6 | 0,7 | 2,4 |
| C3: % reduction | 95% | 99% | 98% | 93% |  |  | 82% | 89% | 88% | 57% |

(\*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

|  |  |  |
| --- | --- | --- |
| **Comparison with the control** |  | **Comparison with the initial concentration** |
| At 24 h, the Chlorophyll A concentrations measured in the aquariums treated 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. |  | For the concentration C1:  - at 24h, the Chlorophyll A concentration measured in the aquarium treated with BP is reduced by nearly 43%;  - from 48h to 95h, there is no reduction anymore but an important increase of the Chlorophyll A concentration is noticed.  For the concentration C2:  - Chlorophyll A concentration is reduced by nearly 93% within 48h;  - Chlorophyll A concentration increases after 48h.  For the concentration C3:  - Chlorophyll A concentration is reduced by nearly 89% within 48h;  - Chlorophyll A concentration increases after 72h. |

Table 5. Growth rate inhibition (calculated from Chlorophyll A concentration)

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Growth rate inhibition**  **(calculated from Chlorophyll A concentration /Control** | | | |  | **Growth rate inhibition**  **(calculated from Chlorophyll A concentration / Control** | | | |
| Water treatment | 0->22h30 | 0->46h30 | 0->70h30 | 0->93h30 |  | **0-22.5h** | **22.5-46.5h** | **46.5-70.5h** | **70.5-93.5h** |
| Mean | 5.67E-02 | 5.03E-02 | 2.61E-02 | 1.75E-02 |  | 5,67E-02 | 4,43E-02 | -2,06E-02 | -8,91E-03 |
| Mean C1 (0.5L/10 m3) | -2.50E-02 | 3.12E-02 | 2.26E-02 | 1.68E-02 |  | -2,50E-02 | 8,38E-02 | 5,90E-03 | -8,21E-04 |
| C1 : % reduction (\*) | -144% | -38% | -14% | -4% |  | 144 % | -89 % | -128% | -91% |
| Mean C2 (1 L/10 m3) | -5.17E-02 | -4.92E-02 | -1.46E-02 | -1.49E-02 |  | -5,17E-02 | -4,70E-02 | 5,26E-02 | -1,59E-02 |
| C2 : % reduction | -191% | -198% | -156% | -185% |  | 191,15% | 206,13% | -355% | 78% |
| Mean C3 (2 L/10 m3) | -7.65E-02 | -4.85E-02 | -2.91E-02 | -9.84E-03 |  | -7,65E-02 | -2,23E-02 | 8,46E-03 | 4,93E-02 |
| C3 : % reduction | -235% | -197% | -211% | -156% |  | 234,94% | 150,42% | -141% | -653% |

(\*) H2O2 concentration was already below LOD (limit of detection) by 48 hours.

|  |  |  |
| --- | --- | --- |
| **Comparison with the control** |  | **Comparison with the growth evolution of the control** |
| The average growth rate as the logarithmic increase in Chlorophyll A concentration during the whole test (95h) was -1.52x10-2 after application of C2 and -1.02x10-2 after application of C3 confirming the growth inhibition of green algae by hydrogen peroxide. In controls the average growth rate was +1.81x10-2. |  | The growth rate of the control is decreasing along the test and becomes negative from 46.5h to the end of the test.  For concentration C1, the growth rate is negative (< 0h-1) for time window 0-22.5h, increase after 22.5h and becomes greater than the control between 70.5 and the end of the test;  For concentration C2, the growth rate is negative (< 0h-1) until 48h, but increases between 0 and 70.5h and becomes greater than the control from 46.5h to 70.5h.  For concentration C3, the growth rate is negative (< 0h-1) until 48h, but increases along the test and becomes greater than the control from 46.5h to the end of the test. |

1. **E-CA assessment**

In the efficacy study the inoculated cell density (104 cells/mL) corresponds to a greenish / very greenish water column in real-life conditions.

Therefore at the beginning of the test, even if the water appears not green (no period of acclimatisation performed), the inoculum injected correspond to green pool in the field. The purpose of the treatment is a curative effect.

**Validation of the control:**

Algae cells densities increases during the whole test and algae growth rate is globally stable (around 3.102).

Chlorophyll A concentration increases until 48H and decreases until the end of the test. Furthermore Chlorophyll A growth rate decreases from 24H until the end of the test.

The applicant has provided following explanation to explain this phenomena:

This efficacy study is a multigeneration test where initially inoculated algae cells (mix of three algae cultures) grow and divide. Observation of cell densities and Chlorophyll A concentration were made in the course of the study. Chlorophyll A concentration exhibits variability between replicate at a certain time and over time. Under this study, no distinction is made between Chlorophyll A occurring in intact algae cells and free Chlorophyll A which may have been released from the cells in case of cell lysis. A lower concentration of measured Chlorophyll A concentration may be a result of a lower synthesis of Chlorophyll A by green algae cells as limitation conditions e.g. nutrient levels, light. Despite the aim of mimicking in-use application conditions, it was necessary to bring a certain amount of nutrient solutions at the start of the study; however this amount was not designed to allow unlimited growth of algae during the study. A higher concentration of measured Chlorophyll A concentration may be a result of the presence of both Chlorophyll A released from cells (lysis of originally inoculated cells) and synthesis of Chlorophyll A in new algae cells.

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

**Results with C1 as 0.5 L/10 m3:**

The applicant recommends the application rate of 0.5 L for 10 m3 before algal bloom start (i.e. in case of algae spots on walls, bottom, stairs or shadow areas).

A reduction of algae cell of 76% (84% reduction of Chlorophyll A concentration) is observed by comparison with control at 24 h. But by comparison with the initial inoculum, the reduction in cell density is only of 37% (43% reduction of Chlorophyll A concentration). At the application rate of 0.5 L for 10 m3, the active substance is consumed on the first time window of 24 h (H2O2 concentration below limit of detection at 48 h) and therefore algaecide activity of the application rate 0.5 L for 10 m3 strongly decreases after 24 h.

Aquariums treated with the **C1** concentration (19.75 mg / L) are unclear in 24 to 72 hours and are green at the end of the test.

According to the applicant, as the inoculated cell density (104 cells/mL) corresponds to a greenish / very greenish water column in real-life conditions, it can be reasonably extrapolated that, under real-life conditions, algae spots observed on bottom or walls by the end user correspond to a cell density far below than the inoculated cell density (104 cells/mL) and then the low concentration 0.5 L/10 m3 will be efficient.

Nevertheless, no information has been given by the applicant concerning the level of algal density in that case and this situation has not been tested in the simulated-use test.

e-CA considers that effectiveness of this application rate has not been sufficiently demonstrated.

**Results with C2 as 1 L/10 m3:**

The applicant recommends the application rate of 1L for 10 m3 in case of greenish water.

A reduction of algae cell of 84% (93% reduction of Chlorophyll A concentration) is observed by comparison with control at 24h. But by comparison with the initial inoculum the reduction in cell density is only of 57% (68% reduction of Chlorophyll A concentration). Algaecide activity of the application rate 1 L/10 m3 decreases after 24 h.

Aquariums treated with concentration C2 (39.5 mg / L) do not stain and are clear at the end of the test (95h).

But despite the clear water at the end of the test, taking into account growth inhibition after 24 H with regards of Chlorophyll A concentration and algae cells density, e-CA is of the opinion that the curative effect of this concentration is not guarantee after 24 H in the field. Furthermore, no information has been given by the applicant concerning the level of algal density for this application rate and this situation has not been tested in the simulated-use test. Therefore e-CA is not able to validate the efficacy for this concentration.

**Results with C3 as 2 L/10 m3:**

The applicant recommends the application rate of 2 L for 10 m3 in case of very green water. This condition (algae cells density corresponding to greenish/very green water) has been effectively tested in the simulated-use test.

A reduction of algae cell of 75% (95% reduction of Chlorophyll A concentration) is observed by comparison with control at 24h. But by comparison with the initial inoculum the reduction in cell density is only of 36% (82% reduction of chlorophyll A concentration). Algaecide activity of the application rate 2 L for 10 m3 decreases after 24-48 h.

Aquariums treated with concentration C3 (79.0 mg / L) do not stain and are clear at the end of the test. Therefore e-CA is of the opinion that curative efficacy is then validated for this concentration.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| The product is intended to be used for curative action to stop algae emergence and to inhibit the growth of existing algae in water when green algae blooms are observed or just starting. Several doses are claimed, depending on the colour of the water.  The time delay for the visible effect (reduction or disappearance of the green colour) according to the initial algal situation has not been demonstrated in the submitted efficacy study since at the beginning of the study the water was uncoloured and the same level of contamination was used for all application rates. Thus, this claim cannot be validated.  Efficacy data demonstrate that reduction of algae and Chlorophyll A is significantly observed within 24-48h at the higher dose 2 L for 10 m3 permitting to maintain the water limpid during this period. |

#### Occurrence of resistance and resistance management

According to the assessment report of the active substance: “The lethal effects of oxidative molecular species generated from hydrogen peroxide can be avoided with any damage being repaired in microorganisms such as *Escherichia coli* and *Salmonella* Typhimurium.

When *E.coli* and S.Typhimurium are exposed to low concentrations of H2O2, 3 μM and 60 μM respectively, cells produce enzymes and other proteins which are important for cellular defence and mitigate the toxic effects of the oxidative species. This adaptive response is triggered by nontoxic levels of the oxidative species to protect against and produce resistance to oxidative stress caused when challenged with higher concentrations, 10 mM (Dukan and Touati (1996), Christman et al. (1985)). The resistance to oxidative stress that E.coli develops when exposed to H202, as reported in literature papers, demonstrates an adaptive response only.

Moreover the mode of action of hydrogen peroxide stems from its ability to form powerful oxidants such as the hydroxyl radical and oxygen which cause irreversible damage to cellular components such as enzymes, membrane constituents and DNA. To prevent oxidative cell damage, cells have developed ability to decompose H2O2.

Indeed, 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 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 such protection system to be induced during sunset when algae metabolism is increased. To manage possible capacity of green algae to mitigate the biocidal action of hydrogen peroxide, the applicant recommends application of hydrogen peroxide in evening (reduced solar illumination).

#### 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 soluble or suspended organic matter in swimming-pool waters. This parameter has been taken into account during efficacy trial by adding interfering substance (Serum Bovine Albumin) to simulate pools realistic conditions. In spite of this interfering substance, algae growth inhibition by hydrogen peroxide was effective. Nitrogenous interfering substances (NH4+, EDTA) were brought, in higher quantity than usually found in public pools, by the algae nutrient solutions in simulated use efficacy test.
* High temperature may induce decomposition of hydrogen peroxide and favour dissipation from aquatic phase by evaporation.
* Reaction with 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).

According to the applicant, the experience of professionals indicates that there is no known incompatibility between the shock treatment with hydrogen peroxide and the disinfection products used in swimming pools.

To support this evidence by experience, a protocol has been proposed to verify the compatibility of hydrogen peroxide with disinfectants used in swimming pools. The test consists in following the evolution of the H2O2 concentration (respectively 0.5 L, 1 L et 2 L/10 m3) over 4 days, after addition to a volume of water (~ 1L) initially containing 2 to 2.5 mg/L of chlorinated disinfectant (Please refer to the assessment of the physical and chemical properties of the product).

e-CA Conclusion on the compatibility test:

The reaction between hydrogen peroxide and chlorine has been highlighted by Livingston and Bray, J. Am. Chem. Soc., 1925, 47 (8), pp 2069–2082 :

H2O2 + Cl2 = O2 + 2H+ + 2Cl-

This is a decomposition of the two molecules with a ratio of 1 for 1 to form oxygen.

In the compatibility test, there is a high difference of concentration between the two active substances (30 times more of H2O2 than Cl2). Result show that the concentration of hydrogen peroxide is slightly reduced and the chlorine disappears. If both molecule react one by one, after reaction we can find 29 amount of H2O2 and 0 amount of chlorine. Results from the study are explained.

Hence compatibility between active chlorine and oxygen peroxide is not demonstrated. Disinfection and algicidal treatments must not be performed simultaneously.

Following sentence are included in the instructions of use in the SPC:

* Stop disinfection treatment of the water before application of the product PEROXYDE D’HYDROGENE 34.9 %.
* After application of the product, wait at least 4 days before a new disinfectant treatment, to avoid incompatibility with other disinfectant product and to ensure the efficacy of the H2O2 treatment.

#### Evaluation of the label claims

The product is intented to be used for curative action to stop algae emergence and to inhibit the growth of existing algae in water when green algae blooms are observed or just starting. Several doses are claimed, depending on the colour of the water.

The time delay for the visible effect (reduction or disappearance of the green colour) according to the initial algal situation has not been demonstrated in the submitted efficacy study since at the beginning of the study the water was uncoloured.

Moreover as the same level of contamination was used for all application rates, the claims based on the water colour cannot be validated.

Considering all the results provided, Efficacy data demonstrate that reduction of algae is observed during 24-48h at the higher dose 2 L for 10 m3 permitting to maintain the water limpid during this period.

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

Since impact on effectiveness has not been demonstrated, the product PEROXYDE D’HYDROGENE SOLUTION 34.9% is not intended for use with other biocidal products.

### Risk assessment for human health

#### Assessment of effects on Human Health

In order to avoid unnecessary animal experiment, no study was conducted. Classification is determined by using the calculation method described in the Guidance on the Application of the CLP Criteria Version 5.0 (July 2017), based on the available data on each component.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Corrosive to the skin. |
| Justification for the value/conclusion | As a general rule, mixtures with a pH of ≤ 2 or ≥ 11.5 should be considered as corrosive. The pH of product is eqal to 2.0.  However, according to the Guidance CLP (version 5.0, July 2017): ‘*Where the mixture has an extreme pH value but the only corrosive/irritant ingredient present in the mixture is an acid or base with an assigned SCL (either in CLP Annex VI or set by supplier according to Article 10(1)), then the mixture should be classified according to the SCL. In this instance, pH of the mixture should not be considered a second time since it would have already been taken into account when deriving the SCL for the substance*.’  According to the Specific Concentration Limits:  Skin Corr. 1A; H314: C ≥ 70 %  Skin Corr. 1B; H314: 50 % ≤ C <70 %  Skin Irrit. 2; H315: 35 % ≤ C <50 % |
| Classification of the product according to CLP | Skin Irrit. 2; H315 is required according to Regulation (EC) N°1272/2008. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Eye damage |
| Justification for the value/conclusion | According to the Specific Concentration Limits:  Skin Corr. 1A; H314: C ≥ 70 %  Skin Corr. 1B; H314: 50 % ≤ C <70 %  Eye Dam. 1; H318: 8 % ≤ C <50 %  Eye Irrit. 2; H319: 5 % ≤ C < 8 % |
| Classification of the product according to CLP | H318 ‘Causes serious eye damage’ is required according to Regulation (EC) N°1272/2008. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The classification has been determined using the calculation method.  According to Specific Concentration Limits:  STOT SE 3; H335: C ≥ 35 % |
| Classification of the product according to CLP | STOT SE 3; H335 is required according to Regulation (EC) N°1272/2008. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not sensitising to the skin. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for skin sensitisation. |
| Classification of the product according to CLP | No classification for skin sensitisation is required. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not sensitising to the respiratory system. |
| Justification for the value/conclusion | According to the composition, none of the component is toxicologically relevant for respiratory. |
| Classification of the product according to CLP | No classification for respiratory sensitisation is required. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Acutely toxic via the oral route. |
| Justification for the selected value | The classification has been determined using the calculation method.  According to the CAR, the results of acute oral toxicity studies performed in rats with formulations containing hydrogen peroxide at concentrations from 35 % to 70 % demonstrated acute oral LD50 values in the range of 694-1270 mg/kg bw indicating that hydrogen peroxide, at the tested concentrations, is harmful by the oral route. When corrected to 100% hydrogen peroxide, the LD50 values were around 500 mg/kg bw.  Therefore, ATEmix (oral) is equal to: 100 x 500 / 34.9 = 1433 mg/kg bw |
| Classification of the product according to CLP | Classification Acute Toxicity category 4, H302 is required, according to Regulation (EC) N°1272/2008. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Acutely toxic via inhalation. |
| Justification for the selected value | The classification has been determined using the calculation method.  According to the CAR, the inhalation LC50 value for the test substance containing 49.3% hydrogen peroxide was > 0.17 mg/l/4 h (highest attainable vapour concentration).  The substance was classified acute tox 4 H332, however no clear CL 50 was determined. Calculation was performed considering a generic ATE of 1.5 mg/L.  Therefore, ATEmix (inhalation) is 100 x 1.5/ 34.9 = 4.29 mg/L |
| Classification of the product according to CLP | Classification Acute Toxicity category 4, H332 is required, according to Regulation (EC) N°1272/2008. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route. |
| Justification for the selected value | The classification has been determined using the calculation method. |
| Classification of the product according to CLP | No classification for acute dermal toxicity is required. |

***Information on dermal absorption***

According to the information presented in the CAR of the a.s, no clear systemic effect has been observed for H2O2, then no dermal penetration parameter was needed in order to conclude on human health risks. Only quantitative local risk assessment is performed for H2O2.

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

The product is composed of active substance diluted in water. According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, PEROXYDE D’HYDROGENE 34.9% does not contain any substance of concern.

***Available toxicological data relating to a mixture***

Not applicable.

#### Exposure assessment

PEROXYDE D’HYDROGENE 34.9% is ready-to-use product packaged in cans/bottles (1 L, 5 L, 10 L, and 20 L), in drums (60 L and 200 L) and in IBC container (1000 L) for professionals, and for non-professionals in cans/bottles (1 L, 5 L, and 10 L).

It is intended as algaecide in private and public pools (outdoor or indoor) by professionals and non-professionals. The product is a liquid formulation (AL) poured directly in water.

**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** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | n.a | yes | yes | n.a | yes | yes | no |
| Dermal | n.a | yes | yes | n.a | no | yes | no |
| Oral | n.a | no | no | n.a | no | yes | no |

*n.a.: not applicable*

**Primary exposure:**

This product is used for permanent and non-permanent swimming pool, with the filtration system. It is poured directly at the water surface in pools in front of the outlets streams. Therefore, loading phase of the RTU product is considered for primary exposure for professionals and non-professionals.

**Inhalation exposure**

Due to the high vapour pressure of the active substance (214 Pa at 20°C, 299 Pa at 25°C), professionals and non-professionals will be exposed by inhalation during the short period of the loading directly in water of the can, drum or IBC container.

**Dermal exposure**

To avoid splashes and projections, the bottle is introduced in the swimming pool with the opening of the bottle at the water level. Considering the application poured directly in water, dermal exposure to concentrate product will be limited for professionals and non-professionals.

Nevertheless, due to the local effects, a qualitative risk assessment is performed taking into account the classification of the product and its in use dilutions.

**Oral exposure**

Not relevant.

**Secondary exposure:**

Adults can be exposed to disinfectants contained in swimming pools by swimming by inhalation, dermal and oral routes. Professional swimmers are also taken into account.

For children and infants, swimming results in inhalatory, dermal and oral exposure of disinfectants contained in swimming pools (RIVM Report, 2004[[5]](#footnote-5)).

**Inhalation exposure**

For outdoor swimming pools, inhalation exposure is considered negligible: even if the concentration in water would be very high, the atmospheric concentration above would be negligible (RIVM Report, 2006[[6]](#footnote-6)).

For indoor swimming pools, inhalation exposure is taken into account.

**Dermal exposure**

Adults, children and infants can be exposed through skin by swimming into treated water.

**Oral exposure**

Adults, children and infants can accidentally swallow treated water whilst during swimming, playing or diving in the pool.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Loading | Loading of the RTU product directly applied in the swimming pool considering the high vapour pressure of peroxide hydrogen. | Professionals |
| 2. | Loading | Loading of the RTU product directly applied in the swimming pool considering the high vapour pressure of peroxide hydrogen. | Non- professionals |
| 3. | Swimming | Adults, child and infant swimming and accidentally swallowing treated water | General population |

***Industrial exposure***

PEROXYDE D’HYDROGENE 34.9% is used by professionals and non-professionals only.

***Professional exposure***

*Scenario [1]*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| During application of liquid, dermal exposure could occur via liquid spills around the opening of the bottle and spatters.  Inhalation exposure could also occur due to evaporation from a bottle, considering the high vapour pressure of the active substance (214 Pa at 20°C, 299 Pa at 25°C).  It has to be noted that, since no systemic effect has been identified for Hydrogen Peroxide and that only toxicological reference values for inhalation exposure (mg/m3) are available, quantitative risk assessment for the dermal route is not considered.  A local risk assessment will be performed for the dermal route.  In this context, only the indicative exposure value for inhalation is used.  To calculate the exposure of the user during application of liquid, the ‘evaporation  model’ from a constant surface in ConsExpo is used for inhalation exposure and the following parameters are considered:  *Frequency*  A frequency of 4/day is considered.  *Exposure duration/Emission duration*  Different packaging from 1L to 1000L are claimed. It is considered that manual loading directly in water, as recommended by applicant, could occur only for packaging up to 20L. Therefore for the other packaging, the loading could be performed via a pre-loading in another can.  Since the product has to be loaded directly in water to avoid splashes, the exposure to product available in can is limited. Therefore, exposure duration of 3 min by event is considered.  The same value is considered for emission duration.  *Product amount*  According to Consexpo recommendation, this parameter does not correspond to the product amount but half of the bottle content. Considering a 20L can, an amount of product of 10L with a density of 1.132 (11320 g) is considered in Consexpo.  *Room volume and ventilation rate*  Room volume and ventilation rate is taken into account for indoor pools.  According to RIVM report, ‘Room volume’ is interpreted here as ‘personal volume’: a small area of 1 m3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short use duration in which the treatment takes place, as it enables the evaporation of the active substance from the concentrate to be described.  The ventilation rate of 2hr-1 proposed in Consexpo for the swimming pool is taken as a default value.  *Release area*  It is assumed that evaporation takes place from a can with a not-too-small circular opening with a 5-cm. diameter which gives a release area of 20 cm2. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | *Model settings* | | |
| Frequency (per day) | 4 (daily) | Worst-case |
| Product amount (gram) | 11320 | Corrected by density 1.132 |
| Weight fraction substance (%) | 35.08 | Applicant data (technical) |
| Exposure duration (minutes) | 3 | Expert judgement |
| Room volume (m3) | 1 | Disinfectant Products Fact Sheet, 2006 (section 2.2.1) |
| Ventilation rate (1/hour) | 2 | Disinfectant Products Fact Sheet, 2006 |
| Inhalation rate (m3/hour) | 1.25 | Recommendation no. 14, 2017[[7]](#footnote-7) |
| Vapour pressure (Pa) | 299 | CAR of the active substance |
| Application temperature (°C) | 25 | CAR of the active substance |
| Molecular weight (g/mol) | 34.01 | CAR of the active substance |
| Mass transfer coefficient (m/hour) | 24.3 | Thibodeaux’s method |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| *Release area mode: constant* | | |
| Release area (cm2) | 20 |  |
| Emission duration (min) | 3 |  |

**Calculations for Scenario [1]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** | **Estimated dermal uptake (mg/kg bw/d)** | **Estimated oral uptake (mg/kg bw/d)** | **Estimated total uptake (mg/m3)** |
| Scenario [1] | 1 / no PPE | 1.1 | n.a | n.a | 1.1 |

**Further information and considerations on scenario [1]**

For local effects, please see section 2.2.7.3.

***Non-professional exposure***

*Scenario [2]*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| During application of liquid, dermal exposure could occur via liquid spills around the opening of the bottle and spatters.  Inhalation exposure could also occur due to evaporation from a bottle, considering the high vapour pressure of the active substance (214 Pa at 20°C, 299 Pa at 25°C).  It has to be noted that, since no systemic effect has been identified for Hydrogen Peroxide and that only toxicological reference values for inhalation exposure (mg/m3) are available, quantitative risk assessment for the dermal route is not considered.  A local risk assessment will be performed for the dermal route.  In this context, only the indicative exposure value for inhalation is used.  To calculate the exposure of the user during application of liquid, the ‘evaporation  model’ from a constant surface in ConsExpo is used for inhalation exposure and the following parameters are considered:  *Frequency*  A frequency of 1/day is considered.  *Exposure duration/Emission duration*  Different packaging from 1L to 10L are claimed. Since the product has to be loaded directly in water to avoid splashes, the exposure to product available in can is limited. An exposure duration of 3 min is considered.  The same value is considered for emission duration.  *Product amount*  According to Consexpo recommendation, this parameter does not correspond to the product amount but half of the bottle content. Considering a 10L can, an amount of product of 5 L with a density of 1.132 (5660 g) is considered in Consexpo.  *Room volume and ventilation rate*  Room volume and ventilation rate is taken into account for inside pools.  According to RIVM report, ‘Room volume’ is interpreted here as ‘personal volume’: a small area of 1 m3 around the user. A small area around the user is relevant for the inhalation exposure of the user, for the short use duration in which the treatment takes place, as it enables the evaporation of the active substance from the concentrate to be described.  The ventilation rate of 2hr-1 proposed in Consexpo for the swimming pool is taken as a default value.  *Release area*  It is assumed that evaporation takes place from a can with a not-too-small circular opening with a 5-cm. diameter which gives a release area of 20 cm2. | | | |
|  | Parameters | Value | Reference |
| Tier 1 | *Model settings* | | |
| Frequency (per day) | 1 (daily) | Worst-case |
| Product amount (gram) | 5660 | Corrected by density 1.132 |
| Weight fraction substance (%) | 35.08 | Applicant data (technical) |
| Exposure duration (minutes) | 3 | Disinfectant Products Fact Sheet |
| Room volume (m3) | 1 | Disinfectant Products Fact Sheet, 2006 (section 2.2.1) |
| Ventilation rate (1/hour) | 2 | Disinfectant Products Fact Sheet |
| Inhalation rate (m3/hour) | 1.25 | Recommendation no. 14, 2017[[8]](#footnote-8) |
| Vapour pressure (Pa) | 299 | CAR of the active substance |
| Application temperature (°C) | 25 | CAR of the active substance |
| Molecular weight (g/mol) | 34.01 | CAR of the active substance |
| Mass transfer coefficient (m/hour) | 24.3 | Thibodeaux’s method |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| *Release area mode: constant* | | |
| Release area (cm2) | 20 |  |
| Emission duration (min) | 3 | Disinfectant Products Fact Sheet |

**Calculations for Scenario [2]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [2] | 1 | 1.1 | n.a | n.a | 1.1 |

**Further information and considerations on scenario [2]**

For local effects, please see section 2.2.7.3.

***Exposure of the general public***

*Scenario [3]*

|  |
| --- |
| **Description of Scenario [3]** |
| Three populations are considered in this scenario: infants, children and adults.  Two type of swimming pools are considered:   * Private swimming pool (indoor and outdoor) * Public swimming pool (indoor and outdoor)   Oral and dermal routes are considered for outdoor and indoor swimming pools.  Inhalation exposure is considered negligible for outdoor swimming pools: since the atmospheric concentration above the pool water surface are very low even when their concentration in water are high. For indoor swimming pools, inhalation exposure is taken into account.  Since no systemic effect has been identified for Hydrogen Peroxide and that only toxicological reference values for inhalation exposure (mg/m3) are available, quantitative risk assessments for the dermal and oral routes are not considered.  A local risk assessment will be performed for the dermal route.  In this context, only the indicative exposure value for inhalation is used.  Therefore, to calculate the inhalation exposure of the swimmers after application, the ‘evaporation model’ in ConsExpo is used. Only indoor pools are taken into account. Taking into account RIVM Report on Disinfectant Products Fact Sheet [[9]](#footnote-9) and parameters used at the European level for the previous assessed active substances, the following parameters are considered:  *Exposure duration/Emission duration*   |  |  |  | | --- | --- | --- | | Infants | 1 hour | WG I 2015 and TAB | | Children | 1 hour | WG I 2015 and TAB | | Adults | 6 hours for professional swimmer and 1 hour for others | WG I 2015 and TAB |   *Product amount*  The “amount” of pool water that evaporates is set at   |  |  |  | | --- | --- | --- | |  | Public swimming pool | Private swimming pool | | Infants | 50 m3 (100 m2 release area and 0.5m) = 5\*10^7 grams | 48 m3 (32 m2 release area and 1.5m) = 4.8\*10^7 grams | | Children | 562 m3 (375 m2 release area and 1.5m) = 5.6\*10^8 grams | | Adults | 562 m3 (375 m2 release area and 1.5m) = 5.6\*10^8 grams |   These pools were treated with a maximum dose of 2L of product /10m3 of pool. Therefore, the maximum concentration of H2O2 in pool is 79 mg/L or 0.0079%  Molecular weight matrix: 18g/mol |
| *Release area*   |  |  |  | | --- | --- | --- | |  | Public swimming pool | Private swimming pool | | Infants | 100 m2 | 32 m2 | | Children | 375 m2 | | Adults | 375 m2 |   *Room volume and ventilation rate*  For all swimmers, the inhalation exposure mainly occurs above the pool water surface. A  height of 0.5 meter is taken and with a release area. In this space, the swimmers inhale the chemicals evaporating from the water surface.   |  |  |  | | --- | --- | --- | |  | Public swimming pool | Private swimming pool | | Infants | 50 m3 | 16 m3 | | Children | 187.5m3 | | Adults | 187.5m3 |   The ventilation rate of 2hr-1 proposed in Consexpo for the swimming pool is taken as a default value.  *Temperature*   |  |  |  | | --- | --- | --- | |  | Public swimming pool | Private swimming pool | | Infants | 32°C | 28°C | | Children | 28°C | | Adults | 28°C |   Mass transfer rate: Langmuir’s method  Remark: Since hydrogen peroxide is limited to local effect, the human factors (body weight, inhalator rate) have no impact on the estimated exposure. Therefore, the exposure for private swimming pool will be similar for all populations. |

**Calculations for Scenario [3]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [3] - adult (professional swimmer)  Public swimming pool | 1 | 1.7E-01 | not relevant | not relevant | 1.7E-01 |
| Scenario [3] – adult  Public swimming pool | 1 | 1.7E-01 | not relevant | not relevant | 1.7E-01 |
| Scenario [3] – child  Public swimming pool | 1 | 1.7E-01 | not relevant | not relevant | 1.7E-01 |
| Scenario [3] – infant  Public swimming pool | 1 | 1.7E-01 | not relevant | not relevant | 1.7E-01 |
| Scenario [3] Private swimming pool | 1 | 1.7E-01 | not relevant | not relevant | 1.7E-01 |

**Further information and considerations on scenario [3]**

For local effects, please see section 2.2.7.3.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **mg/m3** |
| 1. | Professional | 1 | 1.1 |
| 2. | Non-professional | 1 | 1.1 |
| 3. adult (professional swimmer)  Public swimming pool | Swimmer | 1 | 1.7E-01 |
| 3. adult  Public swimming pool | Swimmer | 1 | 1.7E-01 |
| 3. child  Public swimming pool | Swimmer | 1 | 1.7E-01 |
| 3. infant  Public swimming pool | Swimmer | 1 | 1.7E-01 |
| 3. Private swimming pool | Swimmer | 1 | 1.7E-01 |

***Dietary exposure***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

*Information of non-biocidal use of the active substance*

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection product | hydrogen peroxide (basic substance – approved on 29/03/2017) | No MRLs required (Reg 396/2005) |
| 2. | Veterinary use | Hydrogen peroxide: all food producing species | No MRL required (Reg 37/2010) |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

*Not relevant*

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

*Not relevant*

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

*Not relevant*

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort-term | NOAEC in 90-day inhalation study (rat) | 7 ppm  (10 mg/m3) | 8 | - | 1.25 mg/m3 |
| AELmedium-term |
| AELlong-term |
| ARfD | Not established  ADI not established, the substance is not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water | | | | |
| ADI |

**Maximum residue limits or equivalent**

Not relevant

***Risk for professional users***

**Systemic effects (inhalation)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated uptake (via inhalation)**  **mg/m3** | **Estimated uptake/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] | 1 | 1.25 | 1.1 | 88 % | Yes |

The exposure to a can of 20 L with an open area surface of 20 cm2 during 3 minutes leads to an acceptable risk.

**Local effects**

According to the guidance on the BPR for human health[[10]](#footnote-10), a qualitative local risk assessment is performed, since PEROXYDE D’HYDROGENE 34.9% is classified H315, H318 and H335:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Very high | Eye Dam 1 – H318 | - | 2 | Professional | M&L of an AL formulation directly in swimming pool | Dermal | Less than few minutes | Sources for contamination being from:  - splashes;  - hand to eye transfer | **RMM Technics:** - Minimisation of manual phases/work tasks,  - Minimisation of splashes and spills; for this it is recommended to pour the product directly next to the water surface;  - Avoidance of contact with contaminated tools and objects;  **RMM Organisation:** - Minimise number of staff exposed  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene  **PPE**  - chemical goggles | Exposure must be limited during application of the product by means of appropriate PPE and RMM.  Considering that these recommendations can be followed during this task, the risk is acceptable according to RMM and PPE. |
| Low | Skin irrit. Cat 2, H315 | - | 2 | Professional | M&L of an AL formulation directly in swimming pool | Dermal | More than few minutes but equal to or less than few hours per day | Sources for contamination being from:  - splashes;  - hand | **RMM Technics**  - Minimisation of manual phases/work tasks,  - Minimisation of splashes and spills;  - Avoidance of contact with contaminated tools and objects;  - Regular cleaning of equipment and work area;  **RMM Organisation**  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene  **PPE**  - Face shield;  - Substance/task appropriate gloves;  - protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure) | Exposure must be limited during application of the product by means of appropriate PPE and RMM.  For PPE, regarding the exposure and the duration, face shield is not required.  Therefore, coverall, chemicals goggles and gloves are required.  Considering that these recommendations can be followed during this task, the risk is acceptable according to RMM and PPE. |
| Low | STOT SE 3, H335 (may cause respiratory irritation) | - | 2 | Professional | M&L of an AL formulation directly in swimming pool | Inhalation | More than few minutes but equal to or less than few hours per day | Sources for contamination being from:  - inhalation | **RMM Technics**  - Minimisation of manual phases/work tasks,  - Minimisation of splashes and spills;  - Avoidance of contact with contaminated tools and objects;  - Regular cleaning of equipment and work area;  **RMM Organisation**  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene  **PPE:**  - Substance/task appropriate respirator | Exposure must be limited during application of the product by means of appropriate PPE and RMM.  For PPE, regarding the exposure and the duration (outdoor, less than few minutes), appropriate respirator is not required.  Considering that these recommendations can be followed during this task, the risk is acceptable according to RMM and PPE. |

**Conclusion**

* The risk for professional users is acceptable with the wearing of coverall, chemicals goggles and gloves during the loading phase. The liquid has to be poured directly very close to the water surface in pools to avoid projections.

***Risk for non-professional users***

**Systemic effects (inhalation)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated uptake (via inhalation)**  **mg/ m3** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [2] | 1 | 1.25 | 1.1 | 88 % | Yes |

The exposure to a can of 10 L with an open area surface of 20 cm2 during 3 minutes leads to an acceptable risk.

**Local effects**

According to the guidance on the BPR for human health[[11]](#footnote-11), a qualitative local risk assessment is performed, since PEROXYDE D’HYDROGENE 34.9% is classified H315, H318 and H335:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM | Conclusion on risk |
| High | Eye Dam 1 – H318 | - | 2 | Non- professional | M&L of an AL formulation directly in swimming pool | Dermal | Less than few minutes per day and equal to or less than once per week | Sources for contamination being from:  - splashes;  - hand to eye transfer | - Minimisation of splashes and spills; for this it is recommended to pour product directly next to the water surface  - Packaging eliminating exposure (addition of tap, handle, spout..) - Labelling, instructions for use  - Child proof closure | Acceptable considering that RMM can be followed |
| Low | Skin irrit. 2, H315 | - | 2 | Non- professional | M&L of an AL formulation directly in swimming pool | Dermal | |  | | --- | | Equal to or  less  than one  hour per  day | | Sources for contamination being from:  - splashes;  - hand | - Labelling, instructions for use  - Child proof closure  - Packaging minimising risk for exposure | Acceptable considering that RMM can be followed |
| Low | STOT SE 3, H335 (may cause respiratory irritation) | - | 2 | Non- professional | M&L of an AL formulation directly in swimming pool | Inhalation | Equal to or  less  than one  hour per  day | Sources for contamination being from:  - inhalation | Labelling, instructions for use that minimise exposure or possible health effects | Acceptable considering that RMM can be followed |

**Conclusion**

* The risk for non-professional users is acceptable with the following RMMs: The liquid has to be poured directly very close to the water surface in pools to avoid projections. The packaging must be easy to handle and limit splashes (adding a tap, handle, spout).

***Risk for the general public***

**Local effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEC**  **mg/m3** | **Estimated uptake**  **(via inhalation)**  **mg/ m3** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [3] - adult (professional swimmer)  Public swimming pool | 1 | 1.25 | 1.7E-01 | 13.6 | Yes |
| Scenario [3] – adult  Public swimming pool | 1 | 1.25 | 1.7E-01 | 13.6 | Yes |
| Scenario [3] – child  Public swimming pool | 1 | 1.25 | 1.7E-01 | 13.6 | Yes |
| Scenario [3] – infant  Public swimming pool | 1 | 1.25 | 1.7E-01 | 13.6 | Yes |
| Scenario [3] Private swimming pool | 1 | 1.25 | 1.7E-01 | 13.6 | Yes |

**Conclusion**

The estimated uptake by inhalation is inferior to the AEC.

The concentration in H2O2 in the swimming pool will be inferior to the concentration limit linked to the classification and the pH of swimming pool is between 6.9 and 7.7. Therefore, no dermal effect is expected. The risk for swimmer is acceptable.

The inhalation exposure of the public will be lower than the inhalation exposure of the swimmers because the concentration of chemicals above the pool water is higher than the concentration in the ambient air.

The exposure detailed above, corresponds to exposure during treatment of indoor pool.

The inhalation exposure in outdoor pools will be negligible. Since toxicological reference value is available only for this path of exposure, no risk is expected.

**Disinfection by-products (DBP) exposure**

H2O2 is a highly reactive active substance that will react with organic matter present on the water leading to the formation of Disinfectant By-Product (DBP).

The number of DBP formed is very high and neither identification nor quantification is possible.

In the absence of European validated methodology, DBPs were not taken into account in the risk assessment.

***Risk for consumers via residues in food***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

### Risk assessment for animal health

*Not applicable.*

### Risk assessment for the environment

|  |
| --- |
| Please notice that the risk assessment for the environment (section 2.2.9) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes**. |

#### 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 substance, 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-6 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 concluded from ecotoxicity and e-fate data from the active substance assessment report.

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **Lowest endpoint** | **AF** | **PNEC value** |
| Aquatic | NOEC (21 d): 0.63 mg/L | 50 | 0.0126 mg/L |
| Sediment | - | - | 0.0103 mg/kg wwt \* |
| STP | EC50 (3h): 466 mg/L | 100 | 4.66 mg/L |
| Soil | - | - | 1.84E-03 mg/kg wwt \* |

\* The PNECsoil and the PNECsediment are derived using the TGD equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, 2017, equations 89 and 91). The Log kow of the active substance being lower than 5.0, no additional assessment factor has been added, leading to a PNECsoil of 1.84E-03 mg/kg wwt and a PNECsediment of 0.0103 mg/kg wwt (equivalent to 0.047 mg/kg dwt).

|  |
| --- |
| Infobox 1 - FR CA position:  The proposed endpoint values for the effect assessment of the active substance hydrogen peroxide are correct.  However, for the PNEC freshwater sediment no value is set in the CAR of hydrogen peroxide (March, 2015). The following explanation is provided: ”*considering the low n-octanol/water partition coefficient of hydrogen peroxide (log Kow –1.57), the expected low adsorption to organic matter (QSAR based log KOC 0.2036) and its generally rapid abiotic and biotic degradation in surface waters […], hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary. Furthermore, any potential risk to sediment dwelling organisms is considered to be adequately covered by using the PNEC for the water phase.*”  Therefore no specific risk assessment for the sediment has to be carried out, and it is considered covered by the risk assessment for surface water. |

Moreover, direct emissions of hydrogen peroxide in surface waters during the drainage of private non-permanent above-ground pools are regarded as intermittent releases, based on the definition provided in the section 2.2.3.4 of the ECHA Guidance BPR Vol IV, Part B, version 2.0 from October 2017. The likelihood of long-term effects arising from such exposure is low, the principal risk being that of short-term toxic effects. Thus, the risk assessment should be based on a no-effect-concentration for intermittent release. In extrapolating to such a PNECwater-intermittent, therefore, generally only short-term studies need to be considered. Regarding the section 3.3.2 of this guidance, a PNECwater-intermittent can be calculated by applying an assessment factor of 100 to the lowest E(L)C50 of at least three short-term tests from three trophic levels. According to the Assessment Report of the substance, LC50 values in the tests with fish range from 16.4 to 37.4 mg/L, the 48-h EC50 for invertebrates is 2.34mg/L and the EbC50 for the marine diatom *Skeletonema costatum* is 2.39 mg/L. Thus, an assessment factor of 100 is applied to the value 2.34 mg/L (48h-EC50, aquatic invertebrates), giving a PNECwater,intermittent of 0.0234 mg/L. The resulting PNECsediment-intermittent is therefore 0.0191 mg/kg wwt, calculated as previously explained, using the TGD equilibrium partitioning method (ECHA Guidance on BPR Vol IV, Part B, v2.0, equations 89).

|  |
| --- |
| Infobox 2 - FR CA position:  As explained by the applicant, the drainages of private non-permanent above-ground pools can be considered as intermittent releases. Thus, the risk assessment should be based on a no-effect-concentration for intermittent release. In accordance with the guidance on BPR: vol IV Parts B+C, to derive a PNECwater,intermittent an assessment factor of 100 is normally applied to the lowest L(E)C50 of at least three short-term tests from three trophic levels. Therefore, the value of PNECwater,intermittent of 0.0234 mg/L is valid.  This PNECwater,intermittent will be used in the assessment scenario 4.1 related to the drainage of private non-permanent above-ground pools directly to surface water. |

These PNEC values will be used for characterising the risk.

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 3 - FR CA position:   |  |  | | --- | --- | | **Classification of the Active Substance Hydrogen peroxide** | | | Value/conclusion | Active substance – Hydrogen peroxide is not classified according to the harmonised classification. Nevertheless, this active substance should be classified H 412 according to the available data of the CAR. | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest chronic ecotoxicity endpoint (21d): NOEC= 0.63 mg/L and the substance is considered as rapidly degradable. |  |  |  | | --- | --- | | **Classification of the Product PEROXYDE D’HYDROGENE 34.9%** | | | Value/conclusion | The product is classified H412. | |

***Further Ecotoxicological studies***

|  |
| --- |
| Infobox 4 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 5 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 6 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 7 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 8 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 9 - FR CA position:  See the fate and distribution in exposed environmental compartments in infobox 27. |

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

|  |
| --- |
| Infobox 10 - FR CA position:  No new data is available. |

***Leaching behaviour (ADS)***

|  |
| --- |
| Infobox 11 - FR CA position:  No new data is available. |

***Testing for distribution and dissipation in soil (ADS)***

|  |
| --- |
| Infobox 12 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 13 - FR CA position:  No new data is available. |

***Testing for distribution and dissipation in air (ADS)***

|  |
| --- |
| Infobox 14 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 15 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 16 - FR CA position:  No new data is available. |

#### 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 here. The biocidal product is intended to be used for the control of green algae in the following areas:

* Private swimming pools with private uses
* Private swimming pools with collective uses (semi-public)
* Public swimming pools

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

The emissions of the active substance hydrogen peroxide to the environment may occur during the following events:

* The backwashing of the filtration system (regular emissions);
* The water replacement rate per swimmer in the case of municipal pools (chronic emissions);
* The discharge of a part of the pool due to the preparation for wintering (acute emissions). This concerns only private pools permanently installed since public pools are usually opened all year round.

To cover these environmental emissions, three scenarios from existing ESDs have been identified and are described in the following sections.

Furthermore, the case of private non-permanent above-ground pools must be taken into account. Indeed, according to the TAB (2016), an assessment for direct releases from above-ground small pools must also be carried out for product authorisation. To cover this situation, a scenario for direct emissions to aquatic systems and another one for direct emissions to soil have been developed at WG-IV-2016 and were included in the TAB (2017).

**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 - Chronic emission to STP due to the water replacement in municipal pools  Scenario 4 - Direct drainage of private "above-ground" small pools not permanently installed |
| ESD(s) used | Scenario 1: PT02 – Private pool scenarios – Permanent installed pools (TAB, 2016).  Scenario 2: PT02 – Private pool scenarios – Permanent installed pools (TAB, 2016).  Scenario 3: Emission Scenario Document on water treatment chemicals, ENV/JM/MONO(2004)9, OECD (2004).  Scenario 4: Emission scenario for the disinfection of above ground small pools (WG-IV-2016, TAB - Version 1.3 from August 2017). |
| Approach | Average consumption |
| Distribution in the environment | Calculated based on ECHA Guidance on BPR Vol IV Part B (2014) |
| Groundwater simulation | Movements of hydrogen peroxide from soil to groundwater is possible. It is calculated according to ECHA Guidance on BPR Vol IV Part B (2014) equations 67 and 68, where the predicted concentration in pore water of agricultural soil is taken as an indication for potential groundwater levels. |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | None |

|  |
| --- |
| Infobox 17 - FR CA position:  We agree with the general information provided for the product PEROXYDE D’HYDROGENE 34.9%. However, it is worth noting that a technical concentration of 35.1% of hydrogen peroxide (instead of the pure concentration taken by the applicant) is further considered in the following revised environmental assessment of the product PEROXYDE D’HYDROGENE 34.9%. Taking into account this change, for the highest concentration (2 L per 10 m3), the quantity of product used for 10 m3 is 2.264 kg (density is 1.132), which corresponds to 79.46 mg H2O2/L, rounded to 80 mg H2O2/L as proposed by the applicant.  For the scenario 3 related to **chronic emissions to STP due to the water replacement in municipal pools**, the proposal of the applicant based on Emission Scenario Document on water treatment chemicals, ENV/JM/MONO(2004)9, OECD (2004) is not relevant as a specific scenario for biocidal products is available. Thus, the assessment of chronic releases is carried out for the use of the product PEROXYDE D’HYDROGENE 34.9% in a scenario 3a based on the Emission scenario document for biocides (RIVM, 2001)[[12]](#footnote-12).  Furthermore, the assessment of **acute emissions from municipal pools** (releases to waste water due to the occasional maintenance emptying) is missing. So, this assessment has been added in a scenario 3b based on the Emission scenario document for biocides (RIVM, 2001) previously used to assess the chronic releases. |

***Emission estimation***

For indirect emissions (via STP), estimates are based on extreme worst-case scenarios, at a local scale. The biocidal product is intended to be used at a rate of 1 L per 10 m3, leading to a concentration in the pool water of about 40 mg/L (as active substance) taking into account the density of the product (Density = 1.132). As a conservative approach for indirect releases, the concentration of active substance (hydrogen peroxide) of 80 mg/L is set for the modelling of environment exposure, corresponding to twice the normal application rate of the product. For direct emissions, estimates are based on realistic scenarios at a local scale, considering the dose recommended by the applicant, that is to say 40 mg H2O2/L.

**Scenario 1**

In order to cover emissions from the backwashing of the filtration system, a scenario was available and has been developed by FR and discussed at the WG-I-2015. This concerns permanent private pools. It is mentioned in the TAB (2016) as a recommended scenario to be used in order to calculate releases from the use of biocides for the treatment of pools.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 | m3 | Default value adopted at WG-I-2015 |
| Number of private pools connected to the same STP | 550 | - | Default value for Tier 1 adopted at WG-I-2015. For Northern European countries, 550 should be replaced by 100 at Tier 2 |
| Fraction of pool volume released to STP everyday | 0.0143 | - | Backwash of the filtration  system corresponding to 10% of pool volume each week (OECD 2004) |
| Application rate of active substance in the pool water | 0.08 | kg.m-3 |  |
| Market share | 0.5 | - | Default value (TAB, 2016) |

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalstp) [kg/d]** | **Remarks** |
| STP | 15.10 kg/day | Emission rate to wastewater |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Infobox 18 - FR CA position:  The input parameters and calculations provided for the scenario 1 “Chronic emission from private permanent pools: releases to wastewater following the cleaning of the filtration system” are relevant.  However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR. The local emission value corresponding to the highest concentration of active substance used (80 mg/L considering the technical concentration of 35.1%) is summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 1** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 3.63E-01 | |

**Scenario 2**

In order to cover emissions to STP because of the discharge of a part of the pool during the preparation for wintering, a scenario was available and has been developed by FR and discussed at the WG-I-2015. This concerns permanent private pools only since municipal pools are intended to stay opened the whole year. It is mentioned in the TAB (2016) as a recommended scenario to be used in order to calculate releases from the use of biocides for the treatment of pools.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 | m3 | Default value adopted at WG-I-2015 |
| Number of private pools per STP with acute releases per day | 10 | d-1 | Default value adopted at WG-I-2015. For Northern European countries, 10 should be replaced by 2 at Tier 2 |
| Fraction acutely released to STP | 0.33 | - | Default value adopted at WG-I-2015 corresponding to 1/3 of the pool volume discharged for the wintering |
| Efficient dose rate of active substance in the pool water | 0.08 | kg/m3 |  |
| Fraction of active substance released to wastewater | 1 | - | Default value adopted for the worst-case situation |
| Market share | 0.5 | - | Default value adopted at WG-I-2015 |

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalstp) [kg/d]** | **Remarks** |
| STP | 6.34 kg/day | Emission rate to wastewater |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Infobox 19 - FR CA position:  The input parameters and calculations provided for the scenario 2 “Acute emission from private permanent pools: releases to waste water due to the preparation for wintering” are relevant. However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP (after a residence time in sewage of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR). The local emission value corresponding to the highest concentration of active substance used (80mg/L) is summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 2** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 1.52E-01 | |

**Scenario 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Chronic emission to STP due to the water replacement in public pools** | | | |
| Volume of public pool | 700 000 | L | Corresponding to the average volume for public pool taken in the pick-list from the OECD scenario |
| Water replacement rate | 0.1 | week-1 | Default value |
| Working concentration of substance | 0.08 | g.L-1 |  |

Calculations for Scenario 3

Calculations for Scenario 3 can be found in Annex 3.2.2.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalstp) [kg/d]** | **Remarks** |
| STP | 0.80 kg/day | Emission rate to wastewater |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 20 - FR CA position:  The scenario 3 proposed above is not relevant to assess the **chronic emissions to STP in municipal pools**.  The revised scenario 3a “Chronic emission to STP due to the water replacement in municipal pools” based on the Emission scenario document for biocides (RIVM, 2001)[[13]](#footnote-13) is used and presented below. According to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP (after a residence time in sewage of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR). The local emission value corresponding to the highest concentration of active substance used (80 mg/L) is summarized in the table below:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Local emission before the release to the STP compartment for scenario 3a** | | | | | | **Variable/parameter (unit)** | **Symbol** | **Default** | **S/D/O/P** | **Source** | | **Input:** | | | | | | Number of visitors per day | Nvisit | 400 | D | RIVM, 2001 | | Concentration in swimming water (kg/m3) | Cproc | 0.08 |  | Maximum concentration of H2O2- Applicant's information. | | Water replaced per visitor (m3) | Vrepl | 0.05 | D | RIVM, 2001 | | Emission period (d) | Ep | 1 | S | RIVM, 2001 | | Fraction of discharged hydrogen peroxide reaching the STP | F | 0.024 | D | CAR (March, 2015) | | **Output:** | | | | | | Emission rate to wastewater (standard STP) (kg/d) | Elocalwater | 3.85E-02 | O |  | | **Elocalwater = [(Nvisit\*Vrepl\*Cproc)/Ep] \* 0.024** | | | | |   To assess the **acute emissions from municipal pools,** a scenario 3b “Acute emissions from municipal pools: releases to waste water due to the occasional maintenance emptying” also based on Emission scenario document for biocides (RIVM, 2001) is applied and detailed below. In this case, as in the previous scenario proposed, only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP. The local emission value corresponding to the highest concentration of active substance used (80 mg/L) is summarized in the table below:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Local emission before the release to the STP compartment for scenario 3b** | | | | | | **Variable/parameter (unit)** | **Symbol** | **Default** | **S/D/O/P** | **Source** | | **Input:** | | | | | | Water surface (m2) | AREAswimw | 440 | D | RIVM, 2001 | | Average depth of water (m) | DEPTHswimw | 1.8 |  | RIVM, 2001 | | Fraction released to STP (/d) | Frel | 1 | D | RIVM, 2001 | | Concentration in swimming water (kg/m3) | Cproc | 0.08 | D | Maximum concentration of H2O2- Applicant's information. | | Emission period (d) | Ep | 3 | S | WGV2016 | | Fraction of the discharged hydrogen peroxide reaching the STP | F | 0.024 | D | CAR (March, 2015) | | **Output:** | | | | | | Emission rate to wastewater (standard STP) (kg/d) | Elocalwater | 0.507 | O |  | | **Elocalwater = [(AREAswimw x DEPTHswimw x Cproc)/Frel] \* 0.024** | | | | | |

**Scenario 4**

Above ground small pools can be described as private temporary (summer only) swimming pools above the ground**.** These pools are expected to be completely emptied at the end of the summer season and stored over the winter months. Therefore, the season of an above ground small pool is one summer, in accordance with ESD for PT 19 this corresponds to 91 days. Draining of the pool water occurs through a valve in the pool wall or a hose over the rim of the pool. Drainage water can be released to the STP, nearby surface water, or adjacent soil. Nevertheless, the emission pathway via STP is covered by the assessment for permanently installed private swimming pools described in the TAB, therefore a separate scenario for above ground small pools is not necessary. Therefore, only direct emissions to nearby surface water and to adjacent soil are taking into consideration.

1. **Scenario 4.1: Direct releases to surface water**

The direct emission of private temporary swimming pools to surface waters is likely to affect water bodies similar to the ‘edge of field’ water bodies described in FOCUS Surface Water[[14]](#footnote-14). Of the three water body types (pond, ditch and stream) defined in FOCUS Surface Water, a ditch is the most likely water body type to occur in the near vicinity of properties having private temporary swimming pools. This water body type occurs in four drainage scenarios of which the hydrological characteristics are given in the following table.

**Hydrological characteristics for ditches in drainage scenarios in FOCUS Surface Water**

|  |  |
| --- | --- |
| **Scenario** | **Discharge [L/s]** |
| D1-ditch | 0.008-3.88 |
| D2-ditch | 0.001-11.5 |
| D3-ditch | 0.08-0.71 |
| D6-ditch | 0.04-12.8 |

The average discharge for a ditch (Flowditch) in FOCUS Surface Water is therefore 3.63 L/s.

* **Tier 1:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Drainage to surface waters of private "above-ground" small pools not permanently installed** | | | |
| Pool volume | 14 | m3 | Default value |
| Concentration in active substance during the drainage | 40 | mg.L-1 | Value used in Tier 1: equivalent to the application rate of the product claimed by the applicant |
| Drainage time | 6 | hours | Default value |
| Average discharge for a ditch | 3.63 | L.s-1 | Calculated (see text above) |

Tier 1 - Calculations for Scenario 4.1 (direct releases to surface water)

Calculations for Scenario 4.1 can be found in Annex 3.2.2. In the tier 1, default values are taken into account for the calculations. The dilution and local concentration of the pool water emitted to surface water are calculated based on equations 48 and 49 of the guidance BPR IV B v2.0 (2017) respectively.

| **Resulting local concentration in surface water** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration (Clocalwater) [mg/L]** | **Remarks** |
| Surface water | 6.06 mg/L | Tier 1 |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 21 - FR CA position:  The input parameters and calculations provided for the scenario 4.1 (Tier1- direct releases to surface water) “Direct drainage of private "above-ground" small pools not permanently installed” are relevant. For all claimed application rates, the local concentration values in surface water are proposed in the table below:   |  |  | | --- | --- | | **Local emission before the release to the aquatic compartment for scenario 4.1-Tier 1** | | | **Treatment** | **Clocalwater [mg/L]** | | Hydrogen peroxide at 80 mg/L | 12.1 | | Hydrogen peroxide at 40 mg/L | 6.06 | | Hydrogen peroxide at 20 mg/L | 3.03 | |

* **Tier 2a:**

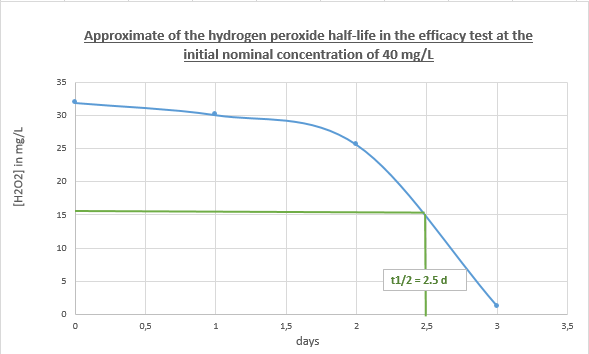
After application of the biocidal product in the pool, the applicant recommends not to drain pool waters directly on surface waters in the 40 days following the treatment. As a consequence, the concentration in active substance during the drainage will be lower than the initial dose of 40 mg a.s/L applied by the user.

In order to predict the decrease of hydrogen peroxide with the time in the pool water, the extreme worst-case half-life of 5 days in freshwater, which was estimated in the EU Assessment Report for hydrogen peroxide, is considered. This is an extreme worst case DT50 value to take account for unfavourable conditions, i.e. oligotrophic cold waters with low microbial density and low transition metal concentrations. It is considered acceptable to extrapolate this conservative half-life in freshwater to swimming pool waters. Indeed, a decreasing concentration was observed during the simulated use efficacy test (in both preliminary and main test). In the study, the concentrations in pool water of hydrogen peroxide has been measured daily, and gave the following values at the initial nominal concentration of hydrogen peroxide of 40 mg/L (*Boiseillier M et al., IRM, 2017. Report N° 1025/0117*).

**Daily average of hydrogen peroxide concentrations during the efficacy test at the initial nominal concentration of 40 mg/L**

|  |  |
| --- | --- |
| **days** | **Hydrogen peroxide concentrations (mg/L)** |
| 0 | 31.983 |
| 1 | 30.13 |
| 2 | 25.65 |
| 3 | 1.18 |

Based on these data, the graph hereafter has been made in order to approximate a half-life (t1/2) for hydrogen peroxide in pool water.



**Approximation of the hydrogen peroxide half-life in the efficacy test at the initial nominal concentration of 40 mg/L**

This result is an approximate, but it provides a supporting evidence of the rapid decreasing of the substance in the pool water. That is why the half-life of the Assessment Report represent a worst-case value.

By considering an initial concentration of 40 mg/L (as hydrogen peroxide) in the pool and a worst case half-life of 5 days, the concentration of hydrogen is decreased to 0.136 mg/L following a delay of 40 days. For the tier 2a of the scenario 4.1, the concentration in active substance during the drainage is therefore set to 0.136 mg/L.

Tier 2a - Calculations for Scenario 4.1 (direct releases to surface water)

Calculations for the Tier 2a of Scenario 4.1 can be found in Annex 3.2.2.

| **Resulting local concentration in surface water** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration (Clocalwater) [mg/L]** | **Remarks** |
| Surface water | 0.0206 mg/L | Tier 2a |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 22 - FR CA position:  The input parameters and calculations provided for the scenario 4.1 (Tier2a- direct releases to surface water) “Direct drainage of private "above-ground" small pools not permanently installed” can be accepted with some modifications.  Based on the DT50 value of 5 days set in the CAR of hydrogen peroxide, it can be estimated the concentration of hydrogen peroxide in swimming pool water the fortieth days following the treatment.  The consideration of hydrogen peroxide decrease is given by the following equation:  Ct = Ct0 \* e –kt   |  |  |  |  | | --- | --- | --- | --- | | **Explanation of symbols** | | | | | **symbol** | **parameter** | **value** | **unit** | | Ct0 | Concentration initial of hydrogen peroxide in swimming pool waters after the treatment | according to the treatment considered | mg/L | | k | Ln(2)/DT50 in water | 0.14 | Days-1 | | t | Number of days considered between the water treatment and the release | 40 | Days |   For all claimed application rates, the local concentration values in surface water are proposed in the table below:   |  |  | | --- | --- | | **Local emission in the freshwater compartment for scenario 4.1- Tier 2a** | | | **Treatment** | **Clocalwater [mg/L]** | | Hydrogen peroxide at 80 mg/L | 4.73E-02 | | Hydrogen peroxide at 40 mg/L | 2.37E-02 | | Hydrogen peroxide at 20 mg/L | 1.18E-02 | |

* **Tier 2b:**

Another measure to mitigate the risk caused by the direct drainage of above-ground pools to surface water is to use sodium thiosulfate (pentahydrate) as an oxidizer neutralizer, in order to neutralize hydrogen peroxide. It is an inorganic compound with the formula Na2S2O3.5H2O. This substance is not considered as a substance of concern.

It is currently used to lower oxidising disinfectants levels in swimming pools of any size. It is also recommended for the neutralisation of chlorine, bromine or ozone in public pools prior to their drainage to rainwater network or to STP[[15]](#footnote-15).

According to the label provided by the applicant, 1.5 kg sodium thiosulfate (pentahydrate)/10 m3 are necessary to neutralize up to 10 mg/L of hydrogen peroxide (as active substance). Therefore, 8.4 kg sodium thiosulfate are necessary in 14 m3 to neutralize 40 mg/L of hydrogen peroxide, corresponding to a dose of 600 mg sodium thiosulfate (pentahydrate)/L. Once the neutralizer applied in the pool, the user must wait at least 24 hours before the drainage of the water.

Reaction

2.S2O32- 🡺 S4O62- + 2.é

H2O2 + 2.H+ + 2.é 🡺 2.H2O .

H2O2 + 2.H+ + 2.S2O32- 🡺 S4O62- + 2.H2O

Based on the principle of chemistry, and taking into account the values of the Reduction potentials (E°) of the electrochemical series in play(\*), it can be assumed that the RedOx reaction is complete and irreversible.

(\*) Electrochemical series[[16]](#footnote-16):

E°(H2O2/H2O) = 1.776 V

E°(S4O62-/S4O62-) = +0.08 V

This is the reason why they are used in several types of quantitative laboratory analysis.

In a pool, the required time for hydrogen peroxide to be neutralised by sodium thiosulfate will therefore be mainly dependent on the hydraulicity of the pool than the kinetics of the reactions. The pool filtration systems are generally sized so that their equivalent volume is recycled in 4 hours. A continuous filtration time of 24h is sufficient to achieve complete neutralisation of hydrogen peroxide.

|  |
| --- |
| Infobox 23 - FR CA position:  The addition of sodium thiosulfate pentahydrate to mitigate the risk related to the drainage of above-ground pools directly to the environment provided by the applicant is not fully satisfactory.  First, the proposal to use 8.4 kg of sodium thiosulfate pentahydrate as an oxidizer neutralizer able to reduce the totality of hydrogen peroxide in the pool is based on the assumption that there is no other compounds that could be reduced in the pool water. No provided data can confirm this hypothesis.  On the other hand, no risk assessment is available for the product of this reaction, the tetrathionate anion (S4O62-). As well as, it cannot be excluded that other degradation products are generated in the pool water.  Regarding the lack of information on the degradation products and their concentrations in the pool water, the safe use of the sodium thiosulfate pentahydrate as an oxidizer neutralizer cannot be demonstrated. |

1. **Scenario 4.2: Direct releases to soil**

The direct emission of private temporary swimming pools to soil depends on the drainage time and the soils infiltration rate. Depending on the size of the valve or diameter of the hose, the time needed to drain the pool ranges from several hours to a day. For emission estimations, a drainage time (tdrain) of 6 hours as typical is considered (equivalent to 0.25 day). It is assumed that the exposed soils are fairly permeable, corresponding to a maximum infiltration rate (fd) of 1 m.d‑1 (FAO, 1985, Irrigation Water Management: Training manual – Introduction to Irrigation, <http://www.fao.org/docrep/r4082e/r4082e03.htm>). The soil area exposed to the pool’s drainage water is estimated according to the following equation:

where AREAsoil [m2] is the soil area exposed, Vpool [m3] is the pool volume, fd [m.d-1] is the infiltration capacity of the soil, tdrain [d] is the time needed to drain the pool.

AREAsoil = 14 m3 / (1 m.d‑1 \* 0.25 d)

AREAsoil = 56 m2

* **Tier 1:**

For determining the local emission to soil of hydrogen peroxide used in above ground small pools, as a first step for environmental exposure assessment, input parameters of the scenario are shown in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Drainage to adjacent soil of private "above-ground" small pools not permanently installed** | | | |
| Private pool volume | 14 | m3 | Default value |
| Soil area exposed | 56 | m² | Default value (see above) |
| Soil depth | 0.5 | m | Default value |
| Bulk density of soil | 1700 | kg/m³ | Default value |
| Concentration of active substance during the drainage | 40 | mg/L | Value used in Tier 1: equivalent to the application rate of the product claimed by the applicant |
| Number of b.p. applications for one pool in the emission period | 1 | - |  |

Tier 1 - Calculations for Scenario 4.2 (direct releases to soil)

Calculations for Scenario 4.2 can be found in Annex 3.2.2. In the tier 1, default values are taken into account for the calculations.

| **Resulting local concentration in exposed soil** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration (Clocalsoil) [mg/kg]** | **Remarks** |
| Soil | 11.76 mg/kg | Tier 1 |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 24 - FR CA position:  The input parameters and calculations provided for the scenario 4.2 (Tier1- direct releases to soil) “Direct drainage of private "above-ground" small pools not permanently installed” are relevant. For each claimed application rate, the local concentration values in soil are proposed in the table below:   |  |  | | --- | --- | | **Local emission before the release to the soil compartment for scenario 4.2- Tier 1** | | | **Treatment** | **Clocalsoil [mg/kg wwt]** | | Hydrogen peroxide at 80 mg/L | 23.5 | | Hydrogen peroxide at 40 mg/L | 11.8 | | Hydrogen peroxide at 20 mg/L | 5.88 | |

* **Tier 2a:**

After application of the biocidal product in the pool, the applicant recommends not to drain pool waters directly on adjacent soil in the 40 days following the treatment, as for Scenario 4.1 - tier 2a. In the same way, the concentration of a.s. in the pool following a delay of 40 days after the biocidal product application is intended to be 0.136 mg/L, considering the extreme worst-case half-life of 5 days given in the EU Assessment Report. For the tier 2a of Scenario 4.2, the concentration of hydrogen peroxide during the drainage is therefore set to 0.136 mg/L.

Moreover, the PECsoil in the tier 1 is determined at the moment of the drainage. However, However, the PNECsoil was determined (in the EU Assessment Report) by application of the equilibrium partitioning method and thus extrapolated from the PNECwater. This PNECwater (see 2.2.8.1) is determined by application of an assessment factor to the lowest chronic NOEC (aquatic invertebrates) from a 21-days exposure period with flow-through system. Therefore, the risk is characterized by opposing a PECsoil,acute to a PNECsoil,chronic in the tier 1. To face this issue, an option is to determine a PECsoil averaged over 21 days. To do so, an equation has been developed, based on equation 66 from ECHA Guidance on BPR Vol IV Part B, v2.0 (2017), neglecting the aerial deposition flux (Dair).

The table hereunder shows the input parameters for scenario 4.2 – tier 2a.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Drainage to adjacent soil of private "above-ground" small pools not permanently installed** | | | |
| Private pool volume | 14 | m3 | Default value |
| Soil area exposed | 56 | m² | Default value |
| Soil depth | 0.5 | m | Default value |
| Bulk density of soil | 1700 | kg/m³ | Default value |
| Concentration of active substance during the drainage | 0.136 | mg/L | Value used in Tier 2a: concentration of a.s in pool following a delay of 40 days after application |
| Number of b.p. applications for one pool in the emission period | 1 | - |  |
| Half-life of hydrogen peroxide in soils | 0.5 | d | Worst case DT50 estimate based on the literature sources (Assessment Report of hydrogen peroxide, 2015) |
| Averaging time (T) | 21 | d |  |

Tier 2a - Calculations for Scenario 4.2 (direct releases to soil)

Calculations for Scenario 4.2 – tier 2a can be found in Annex 3.2.2.

| **Resulting local concentration in exposed soil** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration (Clocalsoil,21d) [mg/kg]** | **Remarks** |
| Soil | 1.37E-03 mg/kg | Tier 2a |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 25 - FR CA position:  The input parameters and calculations provided for the scenario 4.2 (Tier2a- direct releases to soil) “Direct drainage of private "above-ground" small pools not permanently installed” that consider a degradation of the active substance in the pool water can be accepted with some modifications.  Based on the extreme worst case DT50 value of 5 days set in the CAR of hydrogen peroxide, it can be estimated the concentration of hydrogen peroxide in swimming pool water the fortieth days following the treatment.  The consideration of hydrogen peroxide decrease is given by the following equation:  Ct = Ct0 \* e -kt   |  |  |  |  | | --- | --- | --- | --- | | **Explanation of symbols** | | | | | **symbol** | **parameter** | **value** | **unit** | | Ct0 | Concentration initial of hydrogen peroxide in swimming pool waters after the treatment | according to the treatment considered | mg/L | | k | Ln(2)/DT50 in water | 0.14 | Days-1 | | t | Number of days considered between the water treatment and the release | 40 | Days |   According to the guidance on BPR (vol IV part B+C) section 3.10.2, ‘*If for a substance there is information on the mode of action from which it can be concluded that effects are only expected to be acute (e.g. oxidising substances), the initial concentrations have to be used for the effects assessment and compared with the initial PEC for the risk characterisation. Examples for such substances are hydrogen peroxide or hypochlorite*.‘ Therefore, the PNECsoil for hydrogen peroxide set by EPM is compared with the initial PEC without considering degradation. In this context, for the scenario 4.2-tier 2a, the proposal of PECsoil averaged over 21 days is not valid.  The local concentration value is proposed in the table below:   |  |  | | --- | --- | | **Local emission in the freshwater compartment for scenario 4.2- Tier 2a** | | | **Treatment** | **Clocalsoil [mg/kg wwt]** | | Hydrogen peroxide at 80 mg/L | 9.19E-02 | | Hydrogen peroxide at 40 mg/L | 4.60E-02 | | Hydrogen peroxide at 20 mg/L | 2.30E-02 | |

* **Tier 2b:**

Another measure to mitigate the risk caused by the direct drainage of above-ground pools to adjacent soil is to use sodium thiosulfate (pentahydrate) as an oxidizer neutralizer, in order to neutralize hydrogen peroxide. It is an inorganic compound with the formula Na2S2O3.5H2O. This substance is not considered as a substance of concern.

It is currently used to lower oxidising disinfectants levels in swimming pools of any size. It is also recommended for the neutralisation of chlorine, bromine or ozone in public pools prior to their drainage to rainwater network or to STP[[17]](#footnote-17).

According to the label provided by the applicant, 1.5 kg sodium thiosulfate (pentahydrate)/10 m3 are necessary to neutralize up to 10 mg/L of hydrogen peroxide (as active substance). Therefore, 8.4 kg sodium thiosulfate are necessary in 14 m3 to neutralize 40 mg/L of hydrogen peroxide, corresponding to a dose of 600 mg sodium thiosulfate (pentahydrate)/L. Once the neutralizer applied in the pool, the user must wait at least 24 hours before the drainage of the water.

Reaction

2.S2O32- 🡺 S4O62- + 2.é

H2O2 + 2.H+ + 2.é 🡺 2.H2O .

H2O2 + 2.H+ + 2.S2O32- 🡺 S4O62- + 2.H2O

Based on the principle of chemistry, and taking into account the values of the Reduction potentials (E°) of the electrochemical series in play(\*), it can be assumed that the RedOx reaction is complete and irreversible.

(\*) Electrochemical series[[18]](#footnote-18):

E°(H2O2/H2O) = 1.776 V

E°(S4O62-/S4O62-) = +0.08 V

This is the reason why they are used in several types of quantitative laboratory analysis.

In a pool, the required time for hydrogen peroxide to be neutralised by sodium thiosulfate will therefore be mainly dependent on the hydraulicity of the pool than the kinetics of the reactions. The pool filtration systems are generally sized so that their equivalent volume is recycled in 4 hours. A continuous filtration time of 24h is sufficient to achieve complete neutralisation of hydrogen peroxide.

|  |
| --- |
| Infobox 26 - FR CA position:  As explained in Infobox 23, considering the uncertainties about the safe use of sodium thiosulfate pentahydrate, we conclude that this risk mitigation measure cannot be validated. |

***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 | Groundwater |
| Scenario 1 | Yes | Yes | No | No | Yes | Yes | Yes | Yes |
| Scenario 2 | Yes | Yes | No | No | Yes | Yes | Yes | Yes |
| Scenario 3 | Yes | Yes | No | No | Yes | Yes | Yes | Yes |
| Scenario 4.1 – tier 1 | Yes | Yes | No | No | No | No | No | No |
| Scenario 4.1 – tier 2a | Yes | Yes | No | No | No | No | No | No |
| Scenario 4.1 – tier 2b | No | No | No | No | No | No | No | No |
| Scenario 4.2 – tier 1 | No | No | No | No | No | No | Yes | Yes |
| Scenario 4.2 – tier 2a | No | No | No | No | No | No | Yes | Yes |
| Scenario 4.2 – tier 2b | No | No | No | No | No | No | No | No |

For scenarios 1, 2 and 3, the distribution of hydrogen peroxide in relevant environmental compartments was calculated with EUSES V.2.1. Data from the table “Input parameters for calculating the fate and distribution in the environment” (see section 2.2.8.1) were added in EUSES as well as emissions to wastewater previously calculated that were manually entered at the “*Local emissions to wastewater during episode*” part in EUSES.

Exposure of aquatic systems, air and soils to the active substance hydrogen peroxide was 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;
* Atmosphere may be exposed due to the volatilization of hydrogen peroxide from STPs;
* Soils may be exposed via spreading of sewage sludge.

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 surface waters during the drainage of small above-ground pools in Scenario 4.1 tier 1 and tier 2a, surface waters and freshwater sediments may be exposed to the active substance. In the case of direct releases to adjacent soil during the drainage of small above-ground pools in Scenario 4.2 tier 1 and tier 2a, soils may be exposed to the active substance, as well as the groundwater compartment due to the inherent properties of the active substances as explained above.

However, in the case of direct releases to surface waters in Scenario 4.1 tier 2b or to soils in Scenario 4.2 tier 2b, no emissions of the active substance to the environment are expected, because of its complete neutralisation before drainage of pool water. As a consequence, environmental compartments are not expected to be exposed to the active substance. Therefore, a quantitative risk assessment for these two scenarios is not relevant.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Infobox 27 - FR CA position:  For all scenarios considered in the environmental assessment, the exposure pathways are presented in the following table.   | **Identification of relevant receiving compartments based on the exposure pathways** | | | | | | | | --- | --- | --- | --- | --- | --- | --- | |  | STP | Freshwater | Freshwater sediment | Air | Soil | Groundwater | | Scenario 1: Chronic emission – private permanent pools | ++ | + | + | - | + | + | | Scenario 2: Acute emission - private permanent pools | ++ | + | + | - | + | + | | Scenario3 a: Chronic emission – municipal pools | ++ | + | + | - | + | + | | Scenario3 b: Acute emission – municipal pools | ++ | + | + | - | + | + | | Scenario 4.1: Direct release to surface water –”above-ground” small pools | - | ++ | ++ | - | - | - | | Scenario 4.2 : Direct release to soil –”above-ground” small pools | - | - | - | - | ++ | ++ |   ++ Direct emissions expected  + Indirect emissions expected  - No emission expected |

**Physico-chemical and environmental fate properties for active substance (as reported in assessment report for the active substance Hydrogen Peroxide)**

| **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 | Miscible in water in all proportions | mg/L | Assessment report (2015) |
| Log Octanol/water partition coefficient | -1.57 | Log 10 | Assessment report (2015) |
| Organic carbon/water partition coefficient (Koc) | 1.598 | L/kg | Assessment report (2015) |
| Henry’s Law Constant (at 20°C) | 7.50E-04 | Pa.m3/mol | Assessment report (2015) |
| Biodegradability | Readily biodegradable | | Assessment report (2015) |
| Rate constant for STP | 499 | d-1 | Assessment report (2015). Calculated from the DT50 of 2 min in STP. |
| DT50 for biodegradation in surface water | 5 | d | Assessment report (2015) |
| DT50 for degradation in soil | 0.5 | d | Assessment report (2015). Rapidly decomposed in soil to water and oxygen |
| DT50 for degradation in air | 1 | d | Assessment report (2015) |

**Partitioning in sewage treatment plant**

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| **Compartment** | **Percentage [%]** | **Remarks** |
| **Scenarios 1, 2 and 3** |
| Air | 1.05E-04 | EUSES V2.1 |
| Water | 6.92E-01 | EUSES V2.1 |
| Sludge | 1.44E-02 | EUSES V2.1 |
| Degraded in STP | 99.3 | EUSES V2.1 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 28 - FR CA position:  Input parameters coming from the Hydrogen peroxide CAR presented above are accurate, except for the DT50 values which are measured at 20°C in CAR, and for the provided distribution of the substance in STP. Thus, to assess the fate and distribution of hydrogen peroxide in exposed environmental compartments, the DT50 value of 22.8 hours for degradation in soil at 12°C will be considered and the distribution of the active substance in the STP validated in the CAR of hydrogen peroxide will be used and presented in the following table.   |  |  | | --- | --- | | **Calculated fate and distribution of Hydrogen peroxyde in the STP (EUSES model 2.1)** | | | Compartment | Percentage [%] | | Air | 1E-03 | | Water | 6.85E-01 | | Sludge | 1.6E-02 | | Degraded in STP | 99.3 | |

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | |
| Scenario | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW3** | **PECair** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt] | [μg/L] | [mg/m3] |
| Scenario 1 | 5.23E-02 | 5.23E-03 | 4.27E-03 | 9.68E-051 | 1.11E-01 | 4.39E-09 |
| Scenario 2 | 2.19E-02 | 2.19E-03 | 1.79E-03 | 4.06E-051 | 4.64E-02 | 1.84E-09 |
| Scenario 3 | 2.77E-03 | 2.77E-04 | 2.26E-04 | 5.13E-061 | 5.86E-03 | 2.32E-10 |
| Scenario 4.1 – tier 1 | N/A | 6.06 | 4.95 | N/A | N/A | N/A |
| Scenario 4.1 – tier 2a | N/A | 2.06E-02 | 1.68E-02 | N/A | N/A | N/A |
| Scenario 4.2 – tier 1 | N/A | N/A | N/A | 11.76 | 8.06E+04 | N/A |
| Scenario 4.2 – tier 2a | N/A | N/A | N/A | 1.37E-032 | 9.39 | N/A |
| *1 Averaging time for PECsoil = 30 days.*  *2 Averaging time for PECsoil = 21 days.*  *3 PECGW calculated in mg/L using equations 70 and 71 from ECHA Guidance on BPR Vol IV Part B, v2.0 (2017), and then converted to μg/L.* | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 29 - FR CA position:  The concentrations in the different environmental compartments following releases for the active substance (hydrogen peroxide) are summarized in the following table.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the Hydrogen Peroxide** | | | | | | | |  | Concentration of treatment | PECSTP | PECwater | PECsed | PECsoil (initial) | PECGW | | [mg.L-1l] | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Scenario 1: Chronic emission – private permanent pools | 80 | 1.24E-03 | 1.24E-04 | N.R | 1.08E-04 | 5.44E-03 | | Scenario 2: Acute emission - private permanent pools | 80 | 5.22E-04 | 5.22E-05 | N.R | 4.54E-05 | 2.28E-03 | | Scenario3 a: Chronic emission – municipal pools | 80 | 1.32E-04 | 1.32E-05 | N.R | 1.15E-05 | 5.76E-04 | | Scenario3 b: Acute emission – municipal pools | 80 | 5.22E-03 | 5.22E-04 | N.R | 4.54E-04 | 2.28E-02 | | Scenario 4.1(Tier 1): Direct release to surface water –”above-ground” small pools | 80 | - | 1.21E+01 | N.R | - | - | | 40 | - | 6.06 | N.R | - | - | | 20 | - | 3.03 | N.R | - | - | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | 80 | - | 4.73E-02 | N.R | - | - | | 40 | - | 2.37E-02 | N.R | - | - | | 20 | - | 1.18E-02 | N.R | - | - | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission -No data on degradation products and concentrations | | | | | | 40 | | 20 | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | 80 | - | - | N.R | 2.35E+01 | **1.61E+05** | | 40 | - | - | N.R | 1.18E+01 | **8.07E+04** | | 20 | - | - | N.R | 5.88 | **4.03E+04** | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | 80 | - | - | N.R | 9.19E-02 | **6.30E+02** | | 40 | - | - | N.R | 4.60E-02 | **3.15E+02** | | 20 | - | - | N.R | 2.30E-02 | **1.58E+02** | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission -No data on degradation products and concentrations | | | | | | 40 | | 20 |   N.R: Not relevant |

***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 Kow 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.

|  |
| --- |
| Infobox 30 - FR CA position:  Hydrogen peroxide has a log Kow <3 (with a Log Kow= -1.57) and a BCF <100 (BCF fish=1.4; BCF earthworm = 0.84). Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substance in the food chain is expected. The secondary poisoning assessment is not relevant for this substance. |

#### Risk characterisation

***Atmosphere***

The measured value of Henry's law constant (7.5 × 10-4 Pa.m3/mol) indicates very low volatilisation of hydrogen peroxide from water. Emissions to air from biocidal uses are considered negligible and do not alter existing background concentrations in the troposphere to any relevant degree. Therefore, the risk to the atmosphere is acceptable.

|  |
| --- |
| Infobox 31 - FR CA position:  FRCA agrees with the arguments set out by the applicant.  Conclusion:Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product PEROXYDE D’HYDROGENE 34.9% will not pose a significant risk to the atmospheric compartment. |

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 1.12E-02 |
| Scenario 2 | 4.71E-03 |
| Scenario 3 | 5.94E-04 |

Conclusion: The PECSTP/PNECSTP ratios are < 1 for scenarios 1, 2 and 3. The risk to microorganisms in sewage treatment plant following the uses of the biocidal product is considered acceptable.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 32 - FR CA position:  Risk ratios for the STP are presented in the following table:   |  |  |  | | --- | --- | --- | | **Summary table on calculated STP PEC/PNEC values** | | **Conclusion** | |  | Hydrogen peroxide PEC/PNECSTP |  | | Scenario 1: Chronic emission – private permanent pools | 2.67E-04 | Acceptable | | Scenario 2: Acute emission - private permanent pools | 1.12E-04 | Acceptable | | Scenario3 a: Chronic emission – municipal pools | 2.83E-05 | Acceptable | | Scenario3 b: Acute emission – municipal pools | 1.12E-03 | Acceptable | | Scenario 4.1 (Tier 1): Direct release to surface water –”above-ground” small pools | Not relevant | - | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | Not relevant | - | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | Not relevant | - | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | Not relevant | - | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | Not relevant | - | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | Not relevant | - |   **Conclusion:**  For all the assessed scenarios, risks to the STP compartment are acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9%. |

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 | 4.15E-01 | 4.15E-01 |
| Scenario 2 | 1.74E-01 | 1.74E-01 |
| Scenario 3 | 2.20E-02 | 2.20E-02 |
| Scenario 4.1 – tier 1\* | **259** | **259** |
| Scenario 4.1 – tier 2a\* | 8.80E-01 | 8.80E-01 |

*\* Intermittent releases*

Conclusion: The PECwater/PNECwater and PECsediment/PNECsediment ratios are below 1 for scenarios 1, 2 and 3. Therefore, the uses of the biocidal product associated with these 3 scenarios do not cause unacceptable risk to aquatic organisms and sediment-dwelling organisms.

For scenario 4.1 - tier 1, PECwater/PNECwater-intermittent and PECsediment/PNECsediment-intermittent ratios are above 1. At the tier 2a, they are below 1. Therefore, with the recommendation of the applicant not to drain pool waters directly to surface water in the 40 days following the treatment, the uses of the biocidal product do not cause unacceptable risk to aquatic organisms and sediment-dwelling organisms.

For scenario 4.1 – tier 2b, the applicant recommends as an alternative to neutralise H2O2 potentially remaining in treated water with sodium thiosulfate. This product is already available in pool treatment programs and currently used by pool owners or professionals. The well-known corresponding reaction being complete and irreversible, and the recommendation to wait for 24h under continuous filtration, allow the neutralisation to be achieved before draining. These conditions allow the biocidal product not to cause unacceptable risk to aquatic and sediment-dwelling organisms.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 33 - FR CA position:  Risk ratios for the surface water compartment are presented in the following table:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated freshwater PEC/PNEC values** | | | **Conclusion** | |  | Concentration of treatment [mg.L-1l] | Hydrogen peroxide PEC/PNECFreshwater |  | | Scenario 1: Chronic emission – private permanent pools | 80 | 9.86E-03 | Acceptable | | Scenario 2: Acute emission - private permanent pools | 80 | 4.14E-03 | Acceptable | | Scenario3 a: Chronic emission – municipal pools | 80 | 1.04E-03 | Acceptable | | Scenario3 b: Acute emission – municipal pools | 80 | 4.14E-02 | Acceptable | | Scenario 4.1(Tier 1): Direct release to surface water –”above-ground” small pools | 80 | 5.18E+02\* | **Unacceptable** | | 40 | 2.59E+02\* | **Unacceptable** | | 20 | 1.29E+02\* | **Unacceptable** | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | 80 | 2.02\* | **Unacceptable** | | 40 | 1.01\* | **Unacceptable** | | 20 | 5.06E-01\* | Acceptable | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission- No data on degradation products and concentrations | **Unacceptable** | | 40 | | 20 | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | 80 | Not relevant | - | | 40 | | 20 |   \* PEC compared to the PNEC sw intermittent  For the sediment, considering that PNEC value for the active substance is derived from the PNECsw using the equilibrium partitioning method, risk ratios for surface water cover the sediment compartment.  **Conclusion:**  For all the scenarios with releases to the STP (scenario 1, 2 and 3), risks to the aquatic compartment are acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9%.  Except for the scenario 4.1-Tier2a with a treatment of 20 mg/L of active substance, risks to the aquatic compartment linked to the use of PEROXYDE D’HYDROGENE 34.9% in private "above-ground" small pools not permanently installed are unacceptable when direct releases to the aquatic compartment are foreseen.  In the case of the scenario 4.1 – Tier2b (direct release to surface water with an addition of neutralizer in the pool water before the pool is drained), the risk to the aquatic compartment is not acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9%, as the lack of information on the degradation products and their concentrations in the pool water does not allowed to conclude on safe use. |

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 | 5.26E-02 |
| Scenario 2 | 2.21E-02 |
| Scenario 3 | 2.79E-03 |
| Scenario 4.2 – tier 1 | **6391** |
| Scenario 4.2 – tier 2a | 7.45E-01 |

Conclusion: The PECsoil/PNECsoil  ratios of the scenarios 1, 2 and 3 are below 1, indicating low risks. Therefore, the uses of the biocidal product associated with these 3 scenarios do not cause unacceptable risk to soils.

For scenario 4.2 – tier 1, the PECsoil/PNECsoil ratio is above 1. However, the ratio is below 1 at the tier 2a. Therefore, with the recommendation of the applicant not to drain the pool water directly on soil in the 40 days following the treatment, the uses of the biocidal product do not cause unacceptable risk to the terrestrial compartment.

For scenario 4.2 – tier 2b, the applicant recommends as an alternative to neutralise H2O2 potentially remaining in treated water with sodium thiosulfate. This product is already available in pool treatment programs and currently used by pool owners or professionals. The well-known corresponding reaction being complete and irreversible, and the recommendation to wait for 24h under continuous filtration, allow the neutralisation to be achieved before draining. These conditions allow the biocidal product not to cause unacceptable risk to the terrestrial compartment.

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| Infobox 34 - FR CA position:  Risk ratios for the soil compartment are presented in the following table:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated soil PEC/PNEC values** | | | **Conclusion** | |  | Concentration of treatment [mg.L-1l] | Hydrogen peroxide PEC/PNECSoil |  | | Scenario 1: Chronic emission – private permanent pools | 80 | 5.87E-02 | Acceptable | | Scenario 2: Acute emission - private permanent pools | 80 | 2.47E-02 | Acceptable | | Scenario3 a: Chronic emission – municipal pools | 80 | 6.22E-03 | Acceptable | | Scenario3 b: Acute emission – municipal pools | 80 | 2.47E-01 | Acceptable | | Scenario 4.1(Tier 1): Direct release to surface water –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | 80 | Not relevant | - | | 40 | | 20 | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | 80 | 1.28E+04 | **Unacceptable** | | 40 | 6.39E+03 | **Unacceptable** | | 20 | 3.20E+03 | **Unacceptable** | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | 80 | 5.00E+01 | **Unacceptable** | | 40 | 2.50E+01 | **Unacceptable** | | 20 | 1.25E+01 | **Unacceptable** | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission- No data on degradation products and concentrations | **Unacceptable** | | 40 | | 20 |   **Conclusion:**  For all the scenarios with releases to the STP (scenario 1, 2 and 3), risks to the soil compartment are acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9%.  Furthermore, risks to the soil compartment linked to the use of PEROXYDE D’HYDROGENE 34.9% in private "above-ground" small pools not permanently installed are unacceptable in case of direct releases to soil whatever the treatment concentrations.  However in the case of the scenario 4.2 – Tier2b (direct release to soil with an addition of neutralizer in the pool water before the pool is drained), risk to the aquatic compartment is not acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9% as the lack of information on the degradation products and their concentrations in the pool water does not allowed to conclude on safe use. |

***Groundwater***

As a worst-case approach, concentrations of Hydrogen peroxide in groundwater were calculated using equations 70 and 71 from ECHA guidance on BPR, *Vol IV Part B, v2.0 (2017)*. According to BPR Annex VI (point 68), PECGW values were compared to 0.1 µg/L.

For Scenarios 2 and 3, PECGW values were below this threshold value. However, it was just slightly above 0.1 µg/L for Scenario 1. Nevertheless, due to the high reactivity of the active substance in the soil, the values are extremely conservative. Therefore, the risk can be considered as acceptable for Scenarios 1, 2 and 3.

A risk assessment for the groundwater compartment was also relevant for Scenario 4.2 tier 1 and tier 2a. With the worst-case approach, PECGW was widely above the threshold limit value of 0.1 µg/L for the tier 1. For the tier 2a, the PECGW was still above 0.1 µg/L with the worst-case approach. Regarding the high reactivity of the substance in the soil and the worst-case half-life of 12 hours, these values are extremely conservative. However, a refinement with a more realistic assessment has been performed for Scenario 4.2 tier 1 and tier 2a.

In order to refine PECgroundwater values, two modelling softwares were used: FOCUS PELMO (v5.5.3) and FOCUS PEARL (4.4.4), following the FOCUS working group recommendations (FOCUS, 2000[[19]](#footnote-19) , 2009[[20]](#footnote-20) and 2011[[21]](#footnote-21)).

An overall vulnerability corresponding to the 90th percentile of predicted concentration in groundwater is defined as a realistic worst-case. This is approximated by combining a 80th percentile value for soil and a 80th percentile value for weather. The softwares and the different scenario properties are described in the FOCUS document (FOCUS, 2000).

Nine scenarios have been defined. Together, they allow to encompass differences in soils and climate through Europe. Location of the scenarios and their main properties are shown in the figure and the table below.



**Location of the 9 groundwater scenarios (excerpt from FOCUS, 2009)**

**Properties of the 9 groundwater scenarios**

| **Location** | **Mean Annual Temp. (°C)** | **Annual Rainfall**  **(mm)** | **Topsoil** | **Org. matter**  **(%)** |
| --- | --- | --- | --- | --- |
| Châteaudun | 11.3 | 648 + I\* | Silty clay loam | 2.4 |
| Hamburg | 9.0 | 786 | Sandy loam | 2.6 |
| Jokioinen | 4.1 | 650 | Loamy sand | 7.0 |
| Kremsmünster | 8.6 | 899 | loam/silt loam | 3.6 |
| Okehampton | 10.2 | 1038 | loam | 3.8 |
| Piacenza | 13.2 | 857 + I\* | Loam | 2.2 |
| Porto | 14.8 | 1150+ I\* | loam | 2.5 |
| Sevilla | 17.9 | 493+ I\* | Silt loam | 1.6 |
| Thiva | 16.2 | 500 + I\* | loam | 1.3 |

\* *I: Irrigation*

To run the assessment, the following input parameters for hydrogen peroxide were entered in both models: molecular weight, vapour pressure, water solubility at 25°C, Koc and the DT50 in soil at 12°C. The related values can be found in the table “Physico-chemical and environmental fate properties for active substance (as reported in assessment report for the active substance Hydrogen Peroxide)” in chapter 2.2.8.1.

Also, application rates of the active substance in kilograms per hectare have been calculated based on the quantity of active substance during the drainage and the soil area exposed. The calculated application rates are as follows:

* Tier 1: Qappl[[22]](#footnote-22)/AREAsoil = 0.56 kg/56 m² = 0.01 kg/m² = 100 kg/ha
* Tier 2a: Qappl/AREAsoil = 0.001904 kg/56 m² = 0.34 kg/ha

Moreover, the number of application per year has been set to 1. Indeed, drainage of pools are intended to occur once a year, for wintering purposes. The chosen date of pool discharge (application to soil) in the model was September 21st, corresponding to the last day of summer season. As a supportive information, simulations have also been done for October 15th. Indeed, it is overall one of the rainiest months of the year and therefore, where the leaching to groundwater is potentially the most important.

Finally, crop interceptions/uptakes were not considered and were therefore set to 0 as a worst-case default value.

The results for both FOCUS models are presented in the two tables below.

**PECgroundwater PELMO 5.5.3. on September 21st // Scenario 4.2 - tier 1**

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** |
| --- | --- | --- |
| **Hydrogen peroxide** |
| Scenario 4.2 - Tier 1 | Châteaudun | <0.001 |
| Hamburg | <0.001 |
| Jokioinen | 0.002 |
| Kremsmünster | <0.001 |
| Okehamtpon | <0.001 |
| Piacenza | 0.013 |
| Porto | 0.031 |
| Sevilla | <0.001 |
| Thiva | <0.001 |

**PECgroundwater PELMO 5.5.3. on October 15th // Scenario 4.2 - tier 1**

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** |
| --- | --- | --- |
| **Hydrogen peroxide** |
| Scenario 4.2 - Tier 1 | Châteaudun | <0.001 |
| Hamburg | <0.001 |
| Jokioinen | 0.069 |
| Kremsmünster | <0.001 |
| Okehamtpon | <0.001 |
| Piacenza | 0.002 |
| Porto | <0.001 |
| Sevilla | <0.001 |
| Thiva | <0.001 |

**PECgroundwater PEARL 4.4.4. on September 21st// Scenario 4.2 - tier 1**

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** |
| --- | --- | --- |
| **Hydrogen peroxide** |
| Scenario 4.2 - Tier 1 | Châteaudun | <0.001 |
| Hamburg | <0.001 |
| Jokioinen | 1.33E-03 |
| Kremsmünster | <0.001 |
| Okehamtpon | <0.001 |
| Piacenza | <0.001 |
| Porto | 1.45E-03 |
| Sevilla | <0.001 |
| Thiva | <0.001 |

**PECgroundwater PEARL 4.4.4. on October 15th // Scenario 4.2 - tier 1**

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** |
| --- | --- | --- |
| **Hydrogen peroxide** |
| Scenario 4.2 - Tier 1 | Châteaudun | <0.001 |
| Hamburg | 1.60E-02 |
| Jokioinen | **2.50** |
| Kremsmünster | <0.001 |
| Okehamtpon | 1.84E-03 |
| Piacenza | 2.85E-03 |
| Porto | <0.001 |
| Sevilla | <0.001 |
| Thiva | <0.001 |

**PECgroundwater PEARL 4.4.4. on October 15th // Scenario 4.2 - tier 2a**

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** |
| --- | --- | --- |
| **Hydrogen peroxide** |
| Scenario 4.2 - Tier 2a | Châteaudun | <0.001 |
| Hamburg | <0.001 |
| Jokioinen | 5.73E-03 |
| Kremsmünster | <0.001 |
| Okehamtpon | <0.001 |
| Piacenza | <0.001 |
| Porto | <0.001 |
| Sevilla | <0.001 |
| Thiva | <0.001 |

Conclusion: For scenario 4.2 – tier 1, the refined PECgroundwater estimated with FOCUS PELMO 5.5.3 were below the threshold value of 0.1 µg/L, at the 2 application dates selected. Therefore, an assessment for the tier 2a of scenario 4.2 was not necessary.

With FOCUS PEARL 4.4.4, the refined PECgroundwater were below the threshold value of 0.1 µg/L at the 2 dates selected, except for Jokioinen scenario on October 15th. Therefore, simulations on October 15th with FOCUS PEARL have been done for Scenario 4.2 – tier 2a, taking into account as input the related H2O2 application rates calculated previously in this chapter. This time, all PECgroundwater of the nine EU locations were below the threshold value of 0.1 µg/L.

To conclude, risk of contamination of groundwater for hydrogen peroxide is considered acceptable regarding the use of the product following the presented conditions of use and the recommendations of the applicant.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 35 - FR CA position:  Concentrations in groundwater are presented in the following tables:   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Acceptable risks for PEC < the limit value of 0.1 µg/L** | | | **Conclusion** | |  | Concentration of treatment [mg.L-1l] | Hydrogen peroxide PECGroundwater |  | | Scenario 1: Chronic emission – private permanent pools | 80 | 5.44E-03 | Acceptable | | Scenario 2: Acute emission - private permanent pools | 80 | 2.28E-03 | Acceptable | | Scenario3 a: Chronic emission – municipal pools | 80 | 5.76E-04 | Acceptable | | Scenario3 b: Acute emission – municipal pools | 80 | 2.28E-02 | Acceptable | | Scenario 4.1(Tier 1): Direct release to surface water –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | 80 | Not relevant | - | | 40 | Not relevant | - | | 20 | Not relevant | - | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | 80 | Not relevant | - | | 40 | | 20 | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | 80 | 1.61E+05 | **Unacceptable** | | 40 | 8.07E+04 | **Unacceptable** | | 20 | 4.03E+04 | **Unacceptable** | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | 80 | 6.30E+02 | Acceptable\* | | 40 | 3.15E+02 | Acceptable\* | | 20 | 1.58E+02 | Acceptable\* | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission - No data on degradation products and concentrations | **Unacceptable** | | 40 | | 20 |   \*When FOCUS refinement is applied  **Conclusion:**  For all the scenarios with releases to the STP (scenario 1, 2 and 3), concentrations of hydrogen peroxide substance are below the threshold value of 0.1 µg/l. Therefore, risks to the groundwater compartment are acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9% when releases to STP are expected.  Furthermore, in case of direct release to the soil, concentrations of hydrogen peroxide are above the threshold value of 0.1 µg/l in groundwater compartment linked to the use claimed in scenario 4.2 (Tier 1 and 2a) whatever the treatment concentrations.  Regarding the refinement proposed by the applicant with FOCUS softwares, we agree with the results obtained for the scenario 4.2 – tier 1. Nevertheless, we disagree with the application rates used to assess the leaching to groundwater for the scenario 4.2 – tier 2a, which underestimate the releases. Nonetheless, if we refine the groundwater assessment with FOCUS PEARL4.4.4, for the scenario 4.2 – tier 2a, the risk is acceptable for each treatment considered.  Considering that the risk for the soil compartment is unacceptable for the scenario 4.2-tier 1 and tier 2a, the results of FOCUS PEARL model for the groundwater compartment are not detailed.  In the case of the scenario 4.2 – tier 2b (direct release to soil with an addition of neutralizer in the pool water before the pool is drained), risk to the groundwater compartment is not acceptable for the use of the product PEROXYDE D’HYDROGENE 34.9%, as the lack of information on the degradation products and their concentrations in the pool water does not allowed to conclude on safe use. |

***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 Kow 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.

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| --- |
| Infobox 36 - FR CA position:  As detailed in the infobox 30 above, Hydrogen peroxide has a log Kow <3 and a BCF <100. Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substance in the food chain is expected. The secondary poisoning assessment is not relevant for this substance. |

***Mixture toxicity***

Not relevant.

|  |
| --- |
| Infobox 37 - FR CA position:  Not relevant |

***Aggregated exposure (combined for relevant emmission sources)***

According to Article 10(1) of BPR 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.

|  |
| --- |
| Infobox 38 - FR CA position:  Not relevant |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| For any given environmental compartment, the PEC/PNEC ratio is less than 1. The risk characterisation is determined for the active substance hydrogen peroxide from the biocidal product. |

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| Infobox 39 - FR CA position:  Overall conclusion on the risk assessment for the environment of the product PEROXYDE D’HYDROGENE 34.9%.   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Summary table for the risk assessment of the product PEROXYDE D’HYDROGENE 34.9%** | | | | | | | | |  | Concentration of treatment [mg.L-1l] | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PECGW (mg/L) | Conclusion | | Scenario 1: Chronic emission – private permanent pools | 80 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario 2: Acute emission - private permanent pools | 80 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario3 a: Chronic emission – municipal pools | 80 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario3 b: Acute emission – municipal pools | 80 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario 4.1(Tier 1): Direct release to surface water –”above-ground” small pools | 80 | Not relevant | **Unacceptable** | **Unacceptable** | Not relevant | Not relevant | **Unacceptable** | | 40 | Not relevant | **Unacceptable** | **Unacceptable** | Not relevant | Not relevant | **Unacceptable** | | 20 | Not relevant | **Unacceptable** | **Unacceptable** | Not relevant | Not relevant | **Unacceptable** | | Scenario 4.1 (Tier 2a): Direct release to surface water, after 40 days of degradation –”above-ground” small pools | 80 | Not relevant | **Unacceptable** | **Unacceptable** | Not relevant | Not relevant | **Unacceptable** | | 40 | Not relevant | **Unacceptable\*** | **Unacceptable\*** | Not relevant | Not relevant | **Unacceptable\*** | | 20 | Not relevant | Acceptable | Acceptable | Not relevant | Not relevant | Acceptable | | Scenario 4.1 (Tier 2b): Direct release to surface water, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission- No data on degradation products and concentrations | | | | | **Unacceptable** . | | 40 | | 20 | | Scenario 4.2 (Tier 1): Direct release to soil –”above-ground” small pools | 80 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Unacceptable** | **Unacceptable** | | 40 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Unacceptable** | **Unacceptable** | | 20 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Unacceptable** | **Unacceptable** | | Scenario 4.2 (Tier 2a): Direct release to soil, after 40 days of degradation –”above-ground” small pools | 80 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Acceptable** | **Unacceptable** | | 40 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Acceptable** | **Unacceptable** | | 20 | Not relevant | Not relevant | Not relevant | **Unacceptable** | **Acceptable** | **Unacceptable** | | Scenario 4.2 (Tier 2b): Direct release to soil, with a neutralizer – ”above-ground” small pools | 80 | Qualitative assessment – No emission –No data on degradation products and concentrations | | | | | **Unacceptable** | | 40 | | 20 |   \* risk ratio are slightly above 1 (1.01) at the treatment concentration of 40 mg.L-1  Conclusion:  Following the application of the product PEROXYDE D’HYDROGENE 34.9% in permanent pools (municipal or private pools) **with releases into the STP compartment**:   * levels of exposure for non-target species of aquatic and terrestrial compartments are lower than the PNEC of the active substance. * Concentrations of hydrogen peroxide in groundwater related to the use of product PEROXYDE D’HYDROGENE 34.9% are also lower than the threshold value set by the Directive 98/83/EC.   For the application of the product PEROXYDE D’HYDROGENE 34.9% in private "above-ground" small pools not permanently installed **with direct release into the surface water**:   * levels of exposure for non-target species of the aquatic compartment are higher than the PNEC of the active substance, except for the treatment at 20 mg/L which presents a risk characterization ratio below 1, with the recommendation of the applicant not to drain pool waters directly to surface water in the 40 days following the treatment. At the application rate of 40 mg/L the risk ratio is really closed to 1 (1.01) considering the delay of 40 days.   In the case of the use of PEROXYDE D’HYDROGENE 34.9% in private "above-ground" small pools not permanently installed **with direct release into the soil**:   * levels of exposure for non-target species of soil compartment are higher than the PNEC of the active substance, even with the recommendation of the applicant not to drain pool waters directly to soil in the 40 days following the treatment. * Concentrations of hydrogen peroxide in groundwater related to the use of product PEROXYDE D’HYDROGENE 34.9% are only lower than the threshold value set by the Directive 98/83/EC with the recommendation of the applicant not to drain pool waters directly to soil in the 40 days following the treatment.   As explained in the infobox 23, the addition of sodium thiosulfate pentahydrate to mitigate the risk related to the drainage of above-ground pools directly to the environment, provided by the applicant, is not fully satisfactory. First, the proposal to use 8.4 kg of sodium thiosulfate pentahydrate as an oxidizer neutralizer able to reduce the totality of hydrogen peroxide in the pool is based on the assumption that there are no other compounds that could be reduced in the pool water. No provided data can confirm this hypothesis. On the other hand, no risk assessment is available for the product of the reaction, the tetrathionate anion (S4O62-). Regarding the lack of information on the degradation products and their concentrations in the pool water, the safe use of the sodium thiosulfate pentahydrate as an oxidizer neutralizer cannot be demonstrated.  Disinfection by-products (DBP) exposure  H2O2 is a highly reactive active substance that will react with organic matter present on the water leading to the formation of Disinfectant By-Product (DBP). The number of DBP formed is very high and neither identification nor quantification is possible.  In the absence of validated methodology, DBPs were not taken into account in the risk assessment.  **In conclusion, based on the available information related to the use of the product PEROXYDE D’HYDROGENE 34.9%, the environmental assessment is acceptable when pool waters are released into the STP compartment.**  **In the context of private "above-ground" small pools not permanently installed, risks following the direct releases to surface water or soil are considered unacceptable. Concerning the use of PEROXYDE D’HYDROGENE 34.9% with the addition of a risk mitigation measure to neutralize H2O2 before direct release to surface water or soil, the safe use of the sodium thiosulfate pentahydrate as an oxidizer neutralizer cannot be demonstrated.** |

### Measures to protect man, animals and the environment

See the SPC.

### Assessment of a combination of biocidal products

No information

# Annexes[[23]](#footnote-23)

## List of studies for the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Servajean E. | *2017* | Stability of Eau oxygénée GIE Hydrachim over accelerated storage and shelf life determination  Servajean E., 2016 Phytosafe s.a.r.l.. N° report: 16-33-032-ES | yes | The study is the full property of the 4 members of the GIE H2O-BIOCIDES / COMMISSION PEROX: GIE made from  - MAREVA PISCINES & FILTRATIONS (F-13310 Saint-Martin de Crau), leader company  - OCEDIS S.A.S.U. (F-01600 Trévoux),  - HYDRAPRO (F-35370 Etrelles), and  - GACHES CHIMIE SPECIALITES (F-31084 Toulouse) |
| Krebs F. | *2017* | Determination of the corrosion of metals by Hydrogen Peroxide solution 34.9% following method 37.4 C.1 of the UN Handbook, Laüs  Krebs F., 2017. Laüs Report n°: 16081201G979 | yes | The study is the full property of the 4 members of the GIE H2O-BIOCIDES / COMMISSION PEROX: GIE made from  - MAREVA PISCINES & FILTRATIONS (F-13310 Saint-Martin de Crau), leader company  - OCEDIS S.A.S.U. (F-01600 Trévoux),  - HYDRAPRO (F-35370 Etrelles), and  - GACHES CHIMIE SPECIALITES (F-31084 Toulouse) |
| GIE H2O BIOCIDE | 2017 | In situ cells numeration in several swimming pool water samples. A data collection document.  GIE H2O BIOCIDE. GIE/PEROX/201612/01 | Yes | GIE H2O BIOCIDE - Commission PEROX |
| Boiseillier M. et al. | 2017 | Essai d’efficacité d’un produit algicide. Essai préliminaire. Produit : PEROXYDE HYDROGENE 34,9%.  IRM Report N° 1332/1216 | Yes | GIE H2O BIOCIDE |
| Boiseillier M et al. | 2017 | Algicide efficacy testing. Product: PEROXYDE D'HYDROGENE 34.9%.  IRM Report N° 1025/0117 | Yes | GIE H2O BIOCIDE |
| Boiseillier M. IRM | 2018 | Test of the compatibility of 34.9% hydrogen peroxide with sodium hypochlorite"  Preliminary test # 1 - Test report No. 1007 / 0118-1, March 2018 | yes | GIE H2O BIOCIDE |
| Eftekhari A. et al | 2018 | Evaluation de l’impact de certains paramètres  sur le taux de H2O2 dans une eau standardisée  Assessment of the impact of certain parameters on the rate of H2O2 in standardized water  Preliminary-test # 2. GACHES / essai 31012018 | yes | GIE H2O BIOCIDE |
| Boiseillier M. IRM | 2018 | Test of the compatibility of product: Peroxyde Hydrogene 34.9% with two chlorine based disinfectants.  Test report N° RE-1007/0118-2/A | yes | GIE H2O BIOCIDE |

## Output tables from exposure assessment tools

ConsExpo sheet: 

## Residue behaviour

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected.

## Summaries of the efficacy studies (B.5.10.1-xx)[[24]](#footnote-24)

A IUCLID-6 file is available.

## Confidential annex

See the separate confidential annex.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. As cited in: Anses, Mars 2012. Évaluation des risques sanitaires liés aux piscines Partie I : piscines réglementées Avis de l’Afsset, Rapport d’expertise collective, 252 p. [↑](#footnote-ref-3)
4. Freshwater algae and Cyanobacteria, Growth Inhibition Test (July 2011) [↑](#footnote-ref-4)
5. Non-food products: How to assess children’s exposure?, RIVM Report 320005001/2004 [↑](#footnote-ref-5)
6. Disinfectant Products Fact Sheet, RIVM report 320005003/2006 [↑](#footnote-ref-6)
7. Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products [↑](#footnote-ref-7)
8. Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products [↑](#footnote-ref-8)
9. Disinfectant Products Fact Sheet, RIVM report 320005003/2006 [↑](#footnote-ref-9)
10. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-10)
11. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-11)
12. Emission scenario document for biocides, Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC), P. van der Poel and J. Bakker, RIVM report 601450009, 2001. [↑](#footnote-ref-12)
13. Emission scenario document for biocides, Emission scenarios for all 23 product types of the Biocidal Products Directive (EU Directive 98/8/EC), P. van der Poel and J. Bakker, RIVM report 601450009, 2001. [↑](#footnote-ref-13)
14. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, EC Document Reference SANCO/4802/2001-rev2. [↑](#footnote-ref-14)
15. « Évaluation des risques sanitaires liés aux piscines. Partie I : piscines réglementées » - Avis de l’AFSSET - Rapport d’expertise collective - Édition de juin 2010 avec addendum de mars 2012 (ISBN 978-2-11-129542-1), Parts 4.1.5 (pages 68) and 4.1.7 (page 70). [↑](#footnote-ref-15)
16. “Handbook of Chemistry & Physics”, CRC Press inc., 75th edition (1995) [↑](#footnote-ref-16)
17. « Évaluation des risques sanitaires liés aux piscines. Partie I : piscines réglementées » - Avis de l’AFSSET - Rapport d’expertise collective - Édition de juin 2010 avec addendum de mars 2012 (ISBN 978-2-11-129542-1), Parts 4.1.5 (pages 68) and 4.1.7 (page 70). [↑](#footnote-ref-17)
18. “Handbook of Chemistry & Physics”, CRC Press inc., 75th edition (1995) [↑](#footnote-ref-18)
19. SANCO/321/2000 rev.2: FOCUS groudwater scenarios in the EU review of active substances. [↑](#footnote-ref-19)
20. FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp [↑](#footnote-ref-20)
21. FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater assessments, Version 2.0, January 2011. [↑](#footnote-ref-21)
22. Qappl values can be found in annex 3.2.2. [↑](#footnote-ref-22)
23. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-23)
24. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-24)