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**



ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3

Product type 4

Hydrogen peroxide

Case Number in R4BP: BC-PN029668-12

Evaluating Competent Authority: FR

Date: October 2019

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# CONCLUSION

The biocidal product ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 is a hydrogen peroxide-based PT4 product intended to be used as a bactericidal, yeasticidal, sporicidal and virucidal agent (including bacteriophages) for the treatment of equipment in the food industry and milking parlours, for professional use only.

**Conclusion on physico-chemical properties and analytical methods**

The product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements and the results are considered to be not acceptable.

The appearance of the product is a colourless translucent liquid. The physico-chemical characteristics of the product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 have been described. Stability studies show that the biocidal product is not stable during 18 weeks at 30 °C and during the claimed shelf life (12 months). As no identification of degradation compounds has been given to FR-CA, based on stability data available, only a 2 months shelf life is accepted as the active substance degradation does not exceed 10% at this time point. The methods of analysis are considered as compliant.

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

Effects of light are not examined. Since the packaging is in HDPE and due to the sensitivity of hydrogen peroxide to light, the mitigation measure ”do not expose to direct sunlight” is stated on the label.

The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. Due to the acidic behaviour of the product, it should be classified as H290 according to CLP regulation.

Methods of analysis are considered as compliant.

Its technical characteristics are acceptable for an SL formulation.

**Conclusion on efficacy:**

In accordance with the submitted tests and the requirements of Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016) and EN 14885:2015 standard:

Efficacy of the product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 is demonstrated for:

* + Use 1: Closed circulation circuits in agri-food industry:
    - Mandatory target organisms:
      * Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
      * Bacterial spores: 4 % v/v, 15 min, 75 °C
  + Use 2: Closed circulation circuits in milking parlour system:
    - Mandatory target organisms:
      * Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
      * Bacterial spores: 4 % v/v, 15 min, 75 °C

* + Use 3: Automated spraying:
    - Mandatory target organisms:
      * Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
      * Bacterial spores: 4 % v/v, 15 min, 75 °C

It has to be noted that, for the yeasticidal efficacy when the product is applied at the temperature of 60 °C, the efficacy observed is due to the temperature.

**Conclusion on Human Health:**

The risk for professional users is not acceptable during mixing and loading (manual and automatic) without PPE. The risk is acceptable only when a respiratory mask APF10 is worn for mixing and loading (automatic loading with connecting lines and manual loading).

Regarding classification, chemical goggles, coverall and gloves must be worn during handling of the product in addition to the respiratory mask APF10.

No secondary exposure is expected due to the rinsing water step.

**Conclusion on Food Safety:**

For PT 4 uses (disinfection in food and feed areas, in milking parlour system and in agri-food industries), residues in food, feed, milk or drinking water might be expected based on intended uses.

Biocidal product ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 is composed of hydrogen peroxyde and contains few substances of concern (SoC): nitric acid, 2-(2-butoxyethoxy)ethanol and phosphoric acid.

Based on argumentation provided by the applicant for H2O2 and SoC, FR CA is of opinion that ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 intended use would not raise any risk for the consumer. Nevertheless, hydrogen peroxyde degradation can also lead to the formation of a wide range of Disinfection By Products (DBP). In the frame of this dossier, a rinsing step with tap water on treated surfaces are necessary to prevent food, feed, milk or drinking water contamination. Consequently, the following risk mitigation measure is proposed “*After required contact time, rinse treated surfaces with potable water before reusing the surfaces*”.

**Conclusion on Environment:**

The product ACIDE DETARTRANT DESINFECTION H2O2 + HNO3 has been assessed for all the intended uses covered by the scenarios entire plants and milking parlour systems.

Following the application of the product, the assessment shows no unacceptable risk for the different compartments when waste water is purified at least biologically before discharge to the environment.

Therefore the following RMM is proposed: “The product may only be used in installations where the waste water is treated biologically at least before being discharged into the environment”.

**OVERALL CONCLUSION**

FR CA considers that the product ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 shall be authorized according to Article 19(1) for the following uses:

|  |  |  |
| --- | --- | --- |
| **Target organisms** | **Application rates** | **Use conditions** |
| Bacteria  Bacterial spores  Yeasts Viruses  Bacteriophage | Content of the biocidal product in the treated system: 4% (v/v) | Dilute in drinking water through an automated dosing system for an automatic circulation application (CIP). |

With the following RMMs:

* After required contact time, rinse treated surfaces with potable water before reusing the surfaces.
* Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coverall, goggles and respiratory mask (minimum APF 10) during the handling of the product.
* The product may only be used in installations where the waste water is treated biologically at least before being discharged into the environment.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| Acide détartrant désinfectant H2O2 + HNO3 | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Commission 9 du GIE Groupement des Formulateurs de Biocides (GFB) |
| **Address** | 95 Cours Lafayette  69006 Lyon  FRANCE |
| **Authorisation number** | **FR-2020-0025** | |
| **Date of the authorisation** | **20/07/2020** | |
| **Expiry date of the authorisation** | **19/07/2030** | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | QUARON SAS |
| **Address of manufacturer** | 3 rue de la Buhotière – Saint-Jacques de la Lande  BP 89 152  35 091 Rennes CEDEX 9  France |
| **Location of manufacturing sites** | QUARON SAS  3 rue de la Buhotière  35136 Saint-Jacques de la Lande  France  QUARON SAS  Rue des Criquiers  60 220 Formerie  France |

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

|  |  |
| --- | --- |
| **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** | Zandvliet, Scheldelaan 600, Haven 725,  2040 Antwerp  Belgium |

### 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** | **-** |
| **EC number** | 231-765-0 |
| **CAS number** | 7722-84-1 |
| **Index number in Annex VI of CLP** | 008-003-00-9 |
| **Minimum purity / content** | 20% to 50% (commercial premix) |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance contained in the biocidal product is not candidate for substitution in accordance with Article 10 of BPR.

#### Qualitative and quantitative information on the composition of the biocidal product[[1]](#footnote-1)

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Technical Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Hydrogen peroxide | - | Active substance | 7722-84-1 | 231-765-0 | 5.0 |
| Nitric acid |  | Descaling agent | 7697-37-2 | 231-714-2 | 18.0 |
| 2-(2-butoxyethoxy)ethanol |  | Solubilizing agent | 112-34-5 | 203-961-6 | 5.0 |
| Phosphoric acid |  | Stabiliser | 7664-38-2 | 231-633-2 | 0.0048 |

#### 

#### Information on technical equivalence

Not relevant.

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

The product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 contains the following substances of concern: Nitric acid, 2-(2-Butoxyethoxy)ethanol and Phosphoric acid. Please see the confidential annex for further details.

#### Endocrine disrupting properties

According to our assessment, none of the formulants contained in the product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 are identified as endocrine disruptors.

However, there are indications that one co-formulant shows some effect on endocrine organs.

Base on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| SC: Soluble concentrate |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Metal Corrosion, category 1  Skin Corrosion, category 1  Serious eye damage, category 1 |
| Hazard statement | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage  H318: Causes serious eye damage |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H290: May be corrosive to metals.  H314: Causes severe skin burns and eye damage |
| Precautionary statements | P234: Keep only in original container.  P390: Absorb spillage to prevent material damage.  P264: Wash … thoroughly after handling.  P260: Do not breathe vapours.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P301 + P330 + P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.  P303 + P361 + P353: IF ON SKIN (or hair): Take off  immediately all contaminated clothing. Rinse skin with water [or shower].  P363: Wash contaminated clothing before reuse.  P304 + P340: If INHALED: Remove person to fresh air and keep comfortable for breathing.  P310: Immediately call a POISON CENTER/doctor.  P321: Specific treatment (see … on this label).  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P405: Store locked up.  P501: Dispose of contents/container to … |
|  | |
| Note | EUH071: Corrosive to the respiratory tract. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Closed circulation circuits in agri-food industry

|  |  |
| --- | --- |
| **Product Type** | PT04 |
| **Where relevant, an exact description of the authorised use** | Disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with foodstuffs and drinking water, in the agri-food industries. |
| **Target organism (including development stage)** | Bacteria  Bacterial spores  Yeasts  Viruses  Bacteriophages |
| **Field of use** | Agri-food industries |
| **Application method(s)** | Closed system, automatic circulation application (CIP) |
| **Application rate(s) and frequency** | Apply at 4% v/v, during 30 minutes, at 50°C minimum for bactericidal and yeasticidal efficacy.  Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy.  Apply at 4% v/v, during 5 minutes, at 50°C minimum for efficacy against bacteriophages.  Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy. |
| **Category(ies) of users** | Professionals in agri-food industries |
| **Pack sizes and packaging material** | - HDPE Bottle (1 L)  - HDPE Can (5 to 20 L)  - HDPE Drum (60 to 220 L)  - HDPE Bulk container (1000 L) |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

Table 2. Use # 2 – Closed circulation circuits in milking parlour system

|  |  |
| --- | --- |
| **Product Type** | PT04 |
| **Where relevant, an exact description of the authorised use** | Disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with milk, in milking parlour systems. |
| **Target organism (including development stage)** | Bacteria  Bacterial spores  Yeasts  Viruses  Bacteriophages |
| **Field of use** | Milking parlour system |
| **Application method(s)** | Closed system, automatic circulation application (CIP) |
| **Application rate(s) and frequency** | Apply at 4% v/v, during 30 minutes, at 50°C minimum for bactericidal and yeasticidal efficacy.  Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy.  Apply at 4% v/v, during 5 minutes, at 50°C minimum for efficacy against bacteriophages.  Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy. |
| **Category(ies) of users** | Professionals use in agri-food industries |
| **Pack sizes and packaging material** | - HDPE Bottle (1 L)  - HDPE Can (5 to 20 L)  - HDPE Drum (60 to 220 L)  - HDPE Bulk container (1000 L) |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### 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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

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| - |

Table 3. Use # 3 – Automated spraying

|  |  |
| --- | --- |
| **Product Type** | PT04 |
| **Where relevant, an exact description of the authorised use** | Disinfection of small equipments in contact with foodstuffs by automated spraying in closed washing machines, in the agri-food industries and institutional kitchens |
| **Target organism (including development stage)** | Bacteria  Bacterial spores  Yeasts  Viruses  Bacteriophages |
| **Field of use** | Agri-food industries and institutional kitchens |
| **Application method(s)** | Closed system |
| **Application rate(s) and frequency** | Apply at 4% v/v, during 30 minutes, at 50°C minimum for bactericidal and yeasticidal efficacy.  Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy.  Apply at 4% v/v, during 5 minutes, at 50°C minimum for efficacy against bacteriophages.  Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy. |
| **Category(ies) of users** | Professionals use in agri-food industries |
| **Pack sizes and packaging material** | - HDPE Bottle (1 L)  - HDPE Can (5 to 20 L)  - HDPE Drum (60 to 220 L)  - HDPE Bulk container (1000 L) |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

#### 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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| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.). * Apply only on non-porous surfaces * Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. * Prewash the system with hot water or with an alkaline product followed by a rinsing with drinking water. The product is a soluble concentrate (SL) to be diluted in drinking water via automatic proportional dosing system for automatic circulation application (CIP). |

#### Risk mitigation measures

|  |
| --- |
| * After required contact time, rinse treated surfaces with potable water before reusing the surfaces. * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coverall, goggles and respiratory mask (minimum APF 10) during the handling of the product. * The product may only be used in installations where the waste water is treated biologically at least before being discharged into the environment. |

#### 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

|  |
| --- |
| * 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

|  |
| --- |
| * Shelf-life : 2 months. * Do not expose to direct sunlight * Do not store at a temperature higher than 30°C |

### Other information

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| --- |
| * The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA) |

### 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 with integrated dosage nozzle | 1 L | HDPE |  | Professional | yes |
| Can | 5 L to 20 L | HDPE |  | Professional | yes |
| Drum | 60 to 220 L | HDPE |  | Professional | yes |
| Bulk container (tank) | 1000 L | HDPE |  | Professional | yes |

The product is also sold in bulk, delivery per road tanker emptied in client storage tank (only for use 1).

### Documentation

#### Data submitted in relation to product application

**Physico-chemical properties and analytical method Section:**

Physico-chemical properties studies and analytical methods on the biocidal product ACIDE DETERTRANT DESINFECTANT H2O2+HNO3 were provided by GFB.

**Residue Section:**

One study was provided to demonstrate rinsing post application efficiency on remaining residues on treated surfaces. Moreover, the applicant provided an argumentation to explain that intended H2O2 biocidal use would not raise any risk for the consumer.

**Efficacy Section:**

Studies with the product are submitted for the demonstration of the efficacy. Please refer to the list of references.

#### Access to documentation

GFB has access to data on the active substance hydrogen peroxide with a Letter of Access provided by Solvay SA, applicant of the active substance hydrogen peroxide.

**Efficacy data**

Studies with the product are submitted for the demonstration of the efficacy. Please refer to the list of references.

**Residue Section:**Yes

## 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 5% of technical active substance hydrogen peroxide.

The product does not contain PT6 preservative.

The end-use concentration of the product is: 4% product solution.

Formulation type: soluble concentrate (SL)

Hydrocarbon and H304 co-formulant content: <10%

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

Table 1. Intended use # 1 – Closed circulation circuits in agri-food industry

|  |  |
| --- | --- |
| Product Type(s) | PT04 - Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | Cleaning, descaling and disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with foodstuffs and drinking water, in the agri-food industries. |
| Target organism (including development stage) | Bacteria, Bacterial spores, Yeasts, Viruses and bacteriophages |
| Field of use | Indoor  Professional use in agri-food industries. |
| Application method(s) | Closed system  Cleaning, descaling and disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with foodstuffs and drinking water, in the agro-food industries.  Prewash the system with hot water or with an alkaline product followed by a rinsing with drinking water. The product is a soluble concentrate (SL) to be diluted in drinking water via automatic proportional dosing system for automatic circulation application (CIP).  Apply at 4% v/v, during 5 minutes, at 50°C minimum for bactericidal efficacy.  Apply at 4% v/v, during 30 minutes, at 50°C minimum for yeasticidal efficacy.  Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy.  Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy.  Apply at 4% v/v, during 5 minutes, at 50°C minimum for bacteriophagicidal efficacy.  After the appropriate contact time, rinse the treated surface with drinking water. |
| Application rate(s) and frequency | Final concentration of active substance in treated system 2.25 g/L - Final concentration of biocidal product in treated system is 4% (v/v)  Apply at an adequate frequency based on the hygiene plan in place. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | 5-10-20-60-200-1000L HDPE  Also sold in bulk, delivery per road tanker emptied in storage tank. |

Table 2. Use # 2 – Closed circulation circuits in milking parlour system

|  |  |
| --- | --- |
| Product Type(s) | PT04 - Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | Cleaning, descaling and disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with milk, in milking parlour systems. |
| Target organism (including development stage) | Bacteria, Bacterial spores, Yeasts, Viruses and bacteriophages |
| Field of use | Indoor  Professional use in milking parlour systems |
| Application method(s) | Closed system  Cleaning, descaling and disinfection of circuits, pumps, pipes, closed tanks and closed equipment in contact with foodstuffs and drinking water, in milking parlour systems.  Prewash the system with hot water. The product is a soluble concentrate (SL) to be diluted in drinking water via automatic proportional dosing system for automatic circulation application (CIP).  Apply at 4% v/v, during 5 minutes, at 50°C minimum for bactericidal efficacy.  Apply at 4% v/v, during 30 minutes, at 50°C minimum for yeasticidal efficacy.  Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy.  Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy.  Apply at 4% v/v, during 5 minutes, at 50°C minimum for bacteriophagicidal efficacy.  After the appropriate contact time, rinse the treated surface with drinking water. |
| Application rate(s) and frequency | Final concentration of active substance in treated system 2.25 g/L - Final concentration of biocidal product in treated system is 4% (v/v)  Apply at an adequate frequency based on the hygiene plan in place. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | 5-10-20-60-200-1000L HDPE  Also sold in bulk, delivery per road tanker emptied in storage tank |

Table 3. Use # 3 – Automated spraying

|  |  |
| --- | --- |
| Product Type(s) | PT04 - Food and feed area (Disinfectants) |
| Where relevant, an exact description of the authorised use | Cleaning, descaling and disinfection of small equipment in contact with foodstuffs by automated spraying in closed washing machines, in the agri-food industries and institutional kitchens |
| Target organism (including development stage) | Bacteria, Bacterial spores, Yeasts, Viruses and bacteriophages |
| Field of use | Indoor  Professional use in agro-food industries and institutional |
| Application method(s) | Closed system  Cleaning, descaling and disinfection of small equipment in contact with foodstuffs by automated spraying in closed washing machines, in the agri-food industries and institutional kitchens   Prewash the system with hot water or with an alkaline product followed by a rinsing with drinking water. The product is a soluble concentrate (SL) to be diluted in drinking water via automatic proportional dosing system or by manual dosing. Apply at 4% v/v, during 5 minutes, at 50°C minimum for bactericidal efficacy. Apply at 4% v/v, during 30 minutes, at 50°C minimum for yeasticidal efficacy. Apply at 4% v/v, during 15 minutes, at 50°C minimum for virucidal efficacy. Apply at 4% v/v, during 15 minutes, at 75°C minimum for sporicidal efficacy. Apply at 4% v/v, during 5 minutes, at 50°C minimum for bacteriophagicidal efficacy.  After the appropriate contact time, rinse with drinking water at medium-pressure. |
| Application rate(s) and frequency | Final concentration of active substance in treated system 2.25 g/L - Final concentration of biocidal product in treated system is 4% (v/v)  Apply at an adequate frequency based on the hygiene plan in place. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | 1-5-10-20-60-200-1000L HDPE |

### Physical, chemical and technical properties

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state, Colour and Odour at 20 °C and 101.3 kPa | standardized internal method | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | Translucent colorless liquid | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |
| Acidity / alkalinity | CIPAC method MT 75.3.  CIPAC method MT 191 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | At 20°C:  Neat formulation: -0.4  pH at 1% w/v: 1.5  Free acidity of the formulation is 14.2% H2SO4 w/w | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |
| Relative density / bulk density | OECD method 109 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | The relative density is 1.126 | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3. (30 °C ± 2 °C for 18 weeks) CIPAC MT 75.3  CIPAC MT 191  CIPAC MT 47.2  CIPAC MT 41.1 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP  Method for quantification was validated in section 2.4.1 | 18 weeks at 30 °C, 1 L Bottle in HDPE packaging:   |  |  |  | | --- | --- | --- | |  | T0 | T18w at 30°C | | AS content: hydrogen peroxide | 45.4 g/kg | 6.9 g/kg | | % Variation | / | -85% | | Nitric acid | 179.9 g/kg | 179.5 g/kg | | % Variation | / | -0.3% | | Sum of peracids\* | 0.29 g/kg | 0.18 g/kg | | % Variation | / | -38% | | Appearance | Colourless translucent liquid | Colourless translucent liquid | | pH neat at 20°C | -0.4 | -0.3 | | pH at 1%w/v at 20°C | 1.5 | 1.6 | | Free acidity H2SO4 at 20°C | 14.2 % H2SO4 | 15.6% H2SO4 | | Persistent foaming | At 0.5% v/v:  10”: 6 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL  At 5% v/v:  10”: 0 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL | At 0.5% v/v:  10”: 4 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL  At 5% v/v:  10”: 4 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL | | Dilution stability in water after 24h | At 0.5% v/v:  No separated materials  At 5% v/v:  No separated materials | At 0.5% v/v:  No separated materials  At 5% v/v:  No separated materials |   \*only almost Pernitric acid | Not acceptable  Accelerated study shows a loss of 85% of active substance, stability. An acceptable stability study with a defined time/temperature couple has not been provided in order to determine a shelf life product. | SERVAJEAN, 2017  Report 16-35-016-ES |
| Storage stability test – **long term storage at ambient temperature** | CIPAC MT 46.3  CIPAC MT 75.3  CIPAC MT 191  CIPAC MT 47.2  CIPAC MT 41.1 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP  Method for quantification was validated in section 2.4.1 | 12 months at room temperature, 1 L Bottle in HDPE packaging:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  | T0 | T2 m | T3 m | T4 m | T6 m | T9 m | T12 m | | AS content: hydrogen peroxide | 45.4 g/kg | 41.6 g/kg | 37.3 g/kg | 36.7 g/kg | 29.9 g/kg | 18.6 g/kg | 12.0 g/kg | | % Variation | / | -8.4% | -17.9% | -19.2% | -34.2% | -59.1% | -73.6% | | Nitric acid | 179.9 g/kg | 170 g/kg | 180.4 | 182.3 | 183.5 | 184.2 | 172.2 | | % Variation | / | -5.5% | 0.2% | 1.3% | 2.0% | 2.4% | -4.3% | | Sum of peracids\* | 0.29 g/kg | / | / | 0.38 g/kg | 0.38 g/kg | 0.35 g/kg | 0.33 g/kg | | % Variation | / | / | / | 31% | 31% | 20.7% | 13.8% | | Appearance | Colourless translucent liquid | / | / | No change | No change | No change | No change | | pH neat at 20°C | -0.4 | / | / | -0.3 | -0.3 | -0.3 | 0.0 | | pH at 1%w/v at 20°C | 1.5 | / | / | 1.6 | 1.5 | 1.7 | 1.6 | | Free acidity H2SO4 at 20°C | 14.2 % H2SO4 | / | / | 14.5% H2SO4 | 15.3% H2SO4 | 15.1% H2SO4 | 15.3% H2SO4 | | Persistent foaming | At 0.5%  10”:6mL  1’: 0mL  3’:0mL  12’: 0mL  At 5%  10”:0mL  1’: 0mL  3’:0mL  12’: 0mL | / | / | At 0.5%  1’:0mL  At 5%  1’:0mL | At 0.5%  1’:0mL  At 5%  1’:0mL | At 0.5%  1’:0mL  At 5%  1’:0mL | At 0.5%  1’:0mL  At 5%  1’:0mL | | Dilution stability in water after 24h | At 0.5%v/v  No separated materials  At 5%v/v  No separated materials |  |  | At 0.5%v/v  No separated materials  At 5%v/v  No separated materials | | | |   \*only almost Pernitric acid  Argument of the notifier of the product:  During the storage stability test (long term storage at ambient temperature), a loss of 73.6% of active substance was observed. The concentration of nitric and pernitric acid and the physicochemical properties of the product and its packaging remained stable during the storage procedure.  Since the loss in active substance H2O2 was observed to be > 10%, efficacy tests were performed on samples stored 6, 9 and 12 months at ambient temperature. It was shown during these tests that the product is still efficacious against the intended target organisms after 12 months of storage.  Based on the physical-chemical properties stability results and on the fact that the product is still efficacious after 12 months of storage at ambient temperature, a shelf-life of 12 months is claimed for the product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3. | Not acceptable.  Stability studies show that the biocidal product is not stable (intended: 12 months). Since no data has been provided in the dossier on degradation products, only a two-month life is accepted. | SERVAJEAN, 2018  Report 16-35-016-ES part 2 shelf-life determination |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 46.3. (30 °C ± 2 °C for 18 weeks) | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | 7 days at 0°C, 50 mL bottle in HDPE:   |  |  |  | | --- | --- | --- | |  | T0 | T7d | | Appearance | Colourless translucent liquid | Colourless translucent liquid | | AS content | 45.4 | 44.1 | | % variation | / | -2.9% | | pH neat at 20°C | -0.4 | -0.4 | | pH at 1%w/v at 20°C | 1.5 | 1.5 | | Free acidity H2SO4 at 20°C | 14.2 % H2SO4 | 14.2% H2SO4 | | Persistent foaming | At 0.5% v/v:  10”: 6 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL  At 5% v/v:  10”: 0 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL | At 0.5% v/v:  10”: 6 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL  At 5% v/v:  10”: 0 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL | | Dilution stability in water | At 0.5%v/v:  No separated materials  At 5%v/v:  No separated materials | At 0.5%v/v:  No separated materials  At 5%v/v:  No separated materials | | Acceptable  The preparation is stable 7 days at 0°C. | SERVAJEAN, 2017  Report 16-35-016-ES |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | / | All products will be sold in opaque packages. Thus, the light sensitivity during storage was not addressed. | Acceptable.  Effects of light are not examined. Since commercial packaging (HDPE) is not considered as totally opaque and due to the sensitivity of hydrogen peroxide to light, the mitigation measure ”do not expose to direct sunlight” is stated on the label. | */* |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | / | / | Acceptable. The product should not be stored at a temperature higher than 30°C. Concerning humidity, as the product is water base, effect of humidity is not relevant. | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | / | / | / | Compatibility of the product with the commercial packaging (HDPE) has been demonstrated with the accelerated storage (18 weeks at 30°C).  Since no loss of weight was noticed during storage, it can be reasonably conclude that the product is not reactive towards container material. | / |
| Wettability | / | / | / | Not relevant for an SL formulation | / |
| Suspensibility, spontaneity and dispersion stability | / | / | / | Not relevant for an SL formulation | / |
| Wet sieve analysis and dry sieve test | / | / | / | Not relevant for an SL formulation | / |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | / | Not relevant for an SL formulation | / |
| Disintegration time | / | / | / | Not relevant for an SL formulation | / |
| Particle size distribution, content of dust/fines, attrition, friability | / | / | / | Not relevant for an SL formulation | / |
| Persistent foaming | CIPAC method MT 47.3 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | At 0.5% v/v:  10”: 6 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL  At 5% v/v:  10”: 0 mL  1’: 0 mL  3’: 0 mL  12’: 0 mL | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |
| Flowability/Pourability/Dustability | / | / | / | Not relevant for an SL formulation | / |
| Solution stability | CIPAC method MT 41.1. | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | At 0.5% v/v:  No separated materials  At 5% v/v:  No separated materials | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |
| Burning rate — smoke generators | / | / | / | Not relevant for an SL formulation | / |
| Burning completeness — smoke generators | / | / | / | Not relevant for an SL formulation | / |
| Composition of smoke — smoke generators | / | / | / | Not relevant for an SL formulation | / |
| Spraying pattern — aerosols | / | / | / | Not relevant for an SL formulation | / |
| Physical compatibility | / | / | / | / | / |
| Chemical compatibility | Statement | / | This parameter is not required as a combined application with another product is not recommended or foreseen by the applicant | Acceptable | / |
| Degree of dissolution and dilution stability | / | / | / | Not relevant for an SL formulation | / |
| Surface tension | OECD method 115 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | The surface tension of the 0.1% dilution of formulation is 51.4 mN/m. | Acceptable.  The preparation is surface active.  Surface tension at highest concentration of use will be required for renewal application. | SERVAJEAN, 2017  Report 16-35-016-ES |
| Viscosity | OECD method 114 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | The kinematic viscosity of the formulation is 1.31 mm²/s at 20°C and 0.90mm²/s at 40°C. | Acceptable | SERVAJEAN, 2017  Report 16-35-016-ES |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements and the results are considered to be not acceptable.  The appearance of the product is a colourless translucent liquid. The physico-chemical characteristics of the product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 have been described. Stability studies show that the biocidal product is not stable during 18 weeks at 30 °C nor during the claimed shelf life (12 months). As no identification of degradation compounds has been given to FR-CA, based on stability data available, only a 2 months shelf life is accepted. The methods of analysis are considered as compliant.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Effects of light are not examined. Since the packaging is in HDPE and due to the sensitivity of hydrogen peroxide to light, the mitigation measure ”do not expose to direct sunlight” is stated on the label.  Its technical characteristics are acceptable for an SL formulation.  **Labelling mention:** Do not store at a temperature higher than 30°C, store away from direct sunlight  **Shelf life:** 2 months |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | DSC  +  UN Manual of Tests and Criteria Part I: Classification procedures, test methods and criteria relating to explosives of Class 1.  Test series 2. | Acide détartrant désinfectant H2O2 + HNO3 Com09 batches n° : QUA-ML-HD10355-FR17002732 and QUA-ML-HD10355HEDP | Experimental techniques are available for the classification of a substance or preparation as explosive. These are described in EC Test A14. However, according to the OECD testing methods publication, test A14 need not be carried out when examination of the structural formula establishes beyond reasonable doubt that the substance has no explosive properties (i.e. it is not capable of rapid gas or heat release).  The sample was observed to undergo an exothermic event from 48.7°C which had a heat of decomposition of- 1106.2 J.g-1.this is above the criteria for consideration (500J.g-1)  As the onset temperature of the exothermic event (48.7°C) is below the use temperature of the product (50°C), a new DSC test was performed to ensure that no modification in the product was expected under its in-use conditions. This new DSC analysis was performed on a 5% dilution of the product in water, which corresponds to a worst-case dilution of the product compared with the intended use dilutions.  The results show that no event is observable until 114°C, temperature at which the start of a very small exothermic event (corresponding to 14J/g of sample) can be seen. No danger or modification in the product composition is therefore expected at the in-use temperature | Due to the positive result to DSC test, a test CLP has been requested and presented below. | Younis S., 2017 report GLP3016000963R1V1/2017  Mak W.A., 2018 report 060.31886/01.01, draft. |
|  | Test 2 (a): UN gap test;  Test 2 (b): Koenen test;  Test 2 (c) (i): Time/Pressure test. |  | The explosive properties of the biocidal product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 were assessed according to the UN Manual of Tests and Criteria Part I: Classification procedures, test methods and criteria relating to explosives of Class 1.  Based on the results of the study, it is concluded that the investigated sample of ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 has no explosive properties in the sense of the United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. | Acceptable  The preparation has no explosive properties according to CLP test. | Neal P., 2018  report  GLP3016003239R1V1/2018 |
| Flammable gases | / | / | / | Not relevant for an SL formulation | / |
| Flammable aerosols | / | / | / | Not relevant for an SL formulation | / |
| Oxidising gases | / | / | / | Not relevant for an SL formulation | / |
| Gases under pressure | / | / | / | Not relevant for an SL formulation | / |
| Flammable liquids | EEC A9 | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | The formulation degraded above 115°C without flashing | Acceptable  The preparation has no flammable properties according CLP test. | SERVAJEAN, 2017  Report 16-35-016-ES |
| Flammable solids | / | / | / | Not relevant for an SL formulation | / |
| Self-reactive substances and mixtures | Statement | */* | The formulation is predominantly composed of water. In addition, the mixture is not classified as an oxidizer and has a flash point > 115 ° C. | Acceptable | */* |
| Pyrophoric liquids | Statement | */* | Experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)). Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing. | Acceptable | */* |
| Pyrophoric solids | / | / | / | Not relevant for an SL formulation | / |
| Self-heating substances and mixtures | / | / | / | Not relevant for an SL formulation | / |
| Substances and mixtures which in contact with water emit flammable gases | Statement | / | Experience in handling and use shows that the mixture does not react with water. The formulation contains water and can be mixed with water to form a stable mixture. Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be excluded without further testing. | Acceptable | / |
| Oxidising liquids | Test UN O.2 (CLP test) | Acide détartrant désinfectant H2O2 + HNO3  Batch N°QUA-ML-HD10355HEDP | The mean pressure rise time measured for the biocidal product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 (7562 ms) was greater than the mean pressure rise time of a reference solution of 65% nitric acid (2795 ms).  Based on this result, it can be concluded that the product does not meet the criteria for classification as an oxidising liquid. | Acceptable  The preparation has no oxidizing properties. | Petit L.,2018 report: INERIS-DRA-18-174833-03213C |
| Oxidising solids | / | / | / | Not relevant for an SL formulation | / |
| Organic peroxides | Statement | */* | The study does not need to be conducted because the formulation does not contain organic peroxides. | Acceptable | / |
| Corrosive to metals | Statement | */* | Experience in handling and use shows that the mixture is corrosive to metals. Thus, based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1), this classification can be applied without further testing. The product is thus classified as Met. Corr. 1 | Acceptable  Due to the acidic behaviour of the product, it should be classified as H290 according to CLP regulation. | */* |
| Auto-ignition temperatures of products (liquids and gases) | Statement | */* | Flash point testing showed that the formulation degraded above 115°C without flashing. Moreover, the formulation is predominantly composed of water.  We therefore consider that there is no auto-ignition below 115°C. | Acceptable | */* |
| Relative self-ignition temperature for solids | / | / | / | Not relevant for an SL formulation | / |
| Dust explosion hazard | / | / | / | Not relevant for an SL formulation | / |

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| --- |
| **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 acidic behaviour of the product, it should be classified as H290 according to CLP regulation.  **Classification related to physical hazards and respective characteristics of the product:** H290 as mentioned in CLP regulation |

### Methods for detection and identification

#### Dosage of H2O2 and nitric acid

Report: SERVAJEAN, 2017, Physico-chemical properties, stability and shelf-life of Acide détartrant disinfectant H2O2 + HNO3 Com09

Report no 16-35-016-ES

Test facilities:

Phytosafe s.a.r.l.

2 rue Marx Dormoy

64000 Pau

Principle of the method:

The liquid formulation is dissolved in H3PO40.1% is analysed by HPLC-UV (ƛ=228nm) for hydrogen peroxide and ionic chromatography for nitric acid.

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

Validation data:

|  |  |  |
| --- | --- | --- |
|  | Hydrogen peroxide | Nitric acid |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Reference item of the active substance H2O2 and nitric acid * Test item of the product   No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms (and mass spectra) were available. | |
| Linearity | Linearity was studied by carrying out 11 concentrations between 1.0-261.1 mg H2O2/L.  Calibration curve has been provided with a r2 higher than 0.99. | Linearity was studied by carrying out 10 concentrations between 0.2-63.0 mg nitric acid/L.  Calibration curve has been provided with a r2 higher than 0.99. |
| Precision | Repeatability was evaluated by analyzing 3 levels of concentration (n=4 or 6) test item solutions. | Repeatability was evaluated by analyzing 3 levels of concentration (n=4 or 6) test item solutions. |
| Repeatability (RSD) | Repeatability (RSD) |
| RSD = 0.68-2.04% | RSD = 0.25-1.15% |
| Accuracy | Accuracy was determined by analysis of 3 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level mg/L | Recovery rate | Mean recovery rate | RSD (%) | n | | 1.04 | 99.2;96.4;94.6;99;96.1 | 97.1 | 2.04 | 6 | | 45.4 | 98.9;99.5;99.1;98.2;101;102 | 99.8 | 1.43 | 6 | | 48.9 | 100.2;99.9;99;98.8 | 99.5 | 0.68 | 4 | | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level mg/L | Recovery rate | Mean recovery rate | RSD (%) | n | | 40 | 100.2;99.8;100.1;99.7;99.8 | 100 | 0.25 | 6 | | 200 | 100.1;100.1;100.1.100.99.1 | 99.9 | 0.40 | 6 | | 1 | 99.6;101.1;99.5;98.3 | 99.6 | 1.15 | 4 | |

The analytical method is fully validated for the determination of the active substance hydrogen peroxide and nitric acid in the product.

#### Dosage of peracids

Report: SERVAJEAN, 2016, GLP validation of analytical methods for the determination of pernitric acid of Acide détartrant disinfectant H2O2 + HNO3 Com09

Report no 15-35-083-ES

Test facilities:

Phytosafe s.a.r.l.

2 rue Marx Dormoy

64000 Pau

Principle of the method:

Because pernitric acid is not available as a certified analytical standard, the analytical method was developed and validated using other peracids (persulfuric acid, peracetic acid,and/or perchloric acid). Persulfuric acid was found to react with quaternary ammonium bromide such as cetyltrimethylammonium bromide and develops yellow coloration which is proportional to the amount of reacting persulfuric acid. Spectrophotometric determination at 325 nm was found to be convenient for further determination of 7.8-195.0µg persulfuric acid in 200µL aliquot volumes.

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

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, each single compound of the test substance showed that no coloration developed with butyldiglycol or ethylene and propylene oxide block polymer after addition of the reaction solution. The DO at 325 nm was stable.  Method is selective to sum of peracids. | |
| Linearity | Linearity was studied by carrying out 6 concentrations between 7.6-76.4 µg nitric acid.  Linearity was studied by carrying out 12 concentrations between 7.9-196.7 µg persulphuric acid and 11 concentrations between 9.5 and 189.3 µg peracetic acid. The relationship between active oxygen content and measured absorbance at 325 nm was proven to be linear for both reference peracids.  Calibration curve has been provided with a r2 higher than 0.99. | |
| Precision | Repeatability was evaluated by analyzing 3 levels of concentration (n= 6) test item solutions. | |
| Compound | Repeatability |
| pernitric acid     |  |  |  |  | | --- | --- | --- | --- | | Fortification level µL | Mean recovery rate | RSD (%) | n | | 40 | 84.5 | 6.32 | 6 | | 100 | 93.3 | 5.01 | 6 | | 200 | 114 | 3.88 | 6 | | RSD= 3.88-6.32 |
| Accuracy | As there is no available analytical standard for pernitric acid, the measurement was not feasible. | |

The analytical method is fully validated for the determination of the total peracids.

Analytical methods for H2O2 residues in soil, air, water (drinking water) and sediment are available in Assessment Report of active substance Product-type 1-6, March 2015. The applicant GFB has a Letter of Access from Solvay for these data.

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



|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance H2O2 in the product.  Analytical methods were provided at EU level for the determination of active substance residue in water with LOQ = 740 µg/L.  Active substance H2O2 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.  Regarding PT 4 uses, given the reactivity of the active substance, residue in food, feed and drink are expected to be negligible. Analytical method for the determination of hydrogen peroxide in food/feed of plant and animal origin is not required. |

#### Validation of the method for the determination of hydroxyl radicals formed from hydrogen peroxide in water used in preregistration studies

Validation of the method 18-35-001-ES used in the Servajean E. 2018, Determination of hydroxyl/peroxyl residues from “Acide détartrant disinfectant H2O2 + HNO3 ” after rinsing by spraying report no: 18-35-007-ES

Report: Servajean E. 2018, Validation of analytical methods for the determination of hydroxyl radicals formed from hydrogen peroxide in water, and peroxyl radicals formed from peroxoacids in water - Application to the determination of residues in water for hydrogen peroxide and/or peroxoacid containing biocidal products. Part 1: Determination of hydroxyl radicals formed from hydrogen peroxide in water

Report no 18-35-001-ES

Test facilities: PHYTOSAFE S .a .r .l

2 rue Marx Dormoy

64000 PAU

Principle of the method:

Hydrogen peroxide reacts for the determination with DMSO (dimethylsulfoxide) in water at the neutral pH, using FeSO4 as catalyst. The oxidation product is methanesulfinic acid.

Under conditions of excess DMSO, the concentration of produced methanesulfinic acid is used for back determination of native hydrogen peroxide. Methanesulfinic acid was assessed by HPLC-MS (SIM: one transition *m/z*=79>64) and external calibration.

The validation of this method was considered in compliance with SANCO/3029/99 rev.4.

Validation data:

|  |  |  |  |
| --- | --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Methanesulfinic acid produced from oxidation of DMSO by H2O2 * Blank matrix: water * Hydrogen peroxide   No interference was found: no peak appears in the reaction blank and in the, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available. | | |
| Linearity | Linearity was studied by carrying out 10 levels of concentrations (n=1) between 0.006-5.787 mg/L of methanesulfinic acid.  Calibration curve has been provided with a r higher than 0.99. | | |
| Compound | | Linearity % |
| methanesulfinic acid | | Log(methanesulfinic acid)) = 1.009xLog(Area) – 4.828 R2 = 0.9999 |
| Linearity was studied by carrying out 3 levels of concentrations (n=6) between 2.6 – 255.1 µg/L of hydrogen peroxide. The method was found to be linear with hydrogen peroxide levels ranging from 2.6 to 26.0 µg/L The equation of the curve should have been of the form y = ax + b.  Calibration curve has been provided with a r higher than 0.99. | | |
| Compound | | Linearity % |
| Active substance | | Log(methanesulfinic acid)) = 1.009xLog(Area) – 4.828 R2 = 0.9999 |
| Precision | Repeatability was evaluated by analyzing 5 times test item solutions at 1 level of concentration for **Methanesulfinic acid.** | | |
| Compound | Repeatability (RSD) | |
| Methanesulfinic acid | RSD = 1.80% % for 0.014 mg/L | |
| Repeatability was evaluated by analyzing 6 times test item solutions at 3 levels of concentration for **H2O2 alone.** | | |
| Compound | Repeatability (RSD) | |
| Hydrogen peroxide | At 2.6µg/L: RSD = 1.14%  At 25.5 µg/L: RSD = 1.81%  At 255.1 µg/L: RSD = 3.32 % | |
| Repeatability was evaluated by analyzing 6 times test item solutions at 3 levels of concentration for ACIDE DETERTRANT DESINFECTANT H2O2+HNO3. | | |
| Compound | Repeatability (RSD) | |
| Hydrogen peroxide | At 48.0 µg/L of biocidal product (3.8 µg H2O2/L) : RSD = 3.38% | |
| Accuracy | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | *Matrix* | *fortification level* | *n* | *recovery range (%)* | | *mean recovery (%)* | *RSD (%)* | | H2O2 alone | 2.6 µg/L | 6 | 93,6 | 96,8 | 94,8 | 1,14 | | 25.5 µg/L | 6 | 97,4 | 102,6 | 100,1 | 1,81 | | 255.1 µg/L | 6 | 65,8 | 70,7 | 68,4 | 3,32 | | Methanesulfinic acid | 0.014 mg/L | 5 | 97,3 | 101,7 | 99,8 | 1,80 | | Peroxyde d’hydrogene solution 7,4% PAE | 3.8µg H  H2O2/L | 6 | 94,2 | 103,7 | 98,2 | 3,88 | | | |

The analytical method is validated for the determination of the active substance H2O2 in water at traces level.

#### Validation of the method for the determination of peroxyl radicals formed from hydrogen peroxide in water used in preregistration studies

Validation of the method 18-35-001-ES used in the Servajean E. 2018, Determination of hydroxyl/peroxyl residues from ACIDE DETERTRANT DESINFECTANT H2O2+HNO3 report no: 18-35-007-ES.

Report: Servajean E. 2018, Validation of analytical methods for the determination of hydroxyl radicals formed from hydrogen peroxide in water, and peroxyl radicals formed from peroxoacids in water - Application to the determination of residues in water for hydrogen peroxide and/or peroxoacid containing biocidal products. Part 2: Determination of peroxyl radicals formed from hydrogen peroxide in water.

Report no 18-35-001-ES

Test facilities: PHYTOSAFE S .a .r .l

2 rue Marx Dormoy

64000 PAU

Principle of the method:

Peroxoacids react for the determination with DMSO (dimethylsulfoxide) in water at the neutral pH, using FeSO4 as catalyst. The reaction produces methanesulfinic acid and dimethyldulfone.

Under conditions of excess DMSO, the concentration of produced methanesulfinic acid and dimethyl suflone are used for back determination of native peroxoacids. Methanesulfinic acid was assessed by HPLC-MS (SIM -: one transition *m/z*=79>64; dimethyl sulfone SIM + one ion: *m/z*=95) and external calibration.

The validation of this method was considered in compliance with SANCO/3029/99 rev.4.

Validation data:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Methanesulfinic acid produced from oxidation of DMSO by H2O2 * Dimethyl sulfone * Blank matrices: un-reacted blank H2O2 + HNO3; un-reacted blank peracetic acid; un-reacted xone * Hydrogen peroxide * Test item   No interference was found: no peak appears in the reaction blank and in the, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available. | | | |
| Linearity | Linearity was studied by carrying out 8 levels of concentrations (n=1) between 0.008-2.54 mg/L of **dimethyl sulfone.**  Calibration curve has been provided with a r higher than 0.99. | | | |
| Compound | | | Linearity % |
| methanesulfinic acid | | | Log(dimethyl sulfone)) = 0.965xLog(Area) – 5.137  r2 = 0.9999 |
| Linearity was studied by carrying out 9 levels of concentrations (n=1) between 0.006-1.9 mg/L of **methanesulfinic acid.**  Calibration curve has been provided with a r higher than 0.99. | | | |
| Compound | | | Linearity % |
| methanesulfinic acid | | | Log(methanesulfinic acid)) = 1.078xLog(Area) – 5.186 r2 = 0.9999 |
| Linearity was studied by carrying out 5 levels of concentrations (n=2) between 0.03 – 0.304 mg/L of **peracetic acid** and considered as linear (equation has not been provided).  1 mole of peracetic acid would produce 1 mole of reaction product, methanesulfinic acid or dimethyl sulfone.  H2O2 is entirely converted into methanesulfinic acid (MESU) at such low concentrations. The measured values for MESU were corrected so that the contribution of H2O2 was subtracted:  Corrected value = measured MESU – [H2O2 \* 2 \* 80/34]  2\* 80/34: conversion factor for MESU derived from H2O2 based on molecular weight.  Results presented below showed that both MESU and Dimethyl sulfone DMSO2 were produced by the oxidation of DMSO by peracetic acid.  The distribution between the two reaction products ranged between 46-59% for MESU and 39-44% for dimethyl sulfone. | | | |
| Linearity was studied by carrying out 5 levels of concentrations (n=2) between 0.028 – 0.27 mg/L of **persulphuric acid** and considered as linear (equation has not been provided). Recoveries were acceptable in the range 0.028 – 0.084 mg/L persulphuric acid.  The measured values for MESU and DMSO2 were calculated.  Equivalent persulphuric acid = measured MESU \* 114/80  Where 114: molecular weight for persulphuric acid  94 = molecular weight for DMSO2  80 = molecular weight for MESU | | | |
| Precision  and Accuracy | Repeatability was evaluated by analyzing 5 times test item solutions at 1 level of concentration for **dimethyl sulfone.** | | | |
| Compound | | Repeatability (RSD) | |
|  | | RSD = 2.67% for 0.018 mg/L | |
| Repeatability was evaluated by analyzing 5 times test item solutions at 3 levels of concentration for **Peracetic acid.** | | | |
| Compound | Repeatability (RSD) | | |
| Peracetic acid | RSD = 4.27%for 0.03mg/L  RSD = 2.4% for 0.09mg/L  RSD = 2.97% for 0.3mg/L | | |
| Repeatability was evaluated by analyzing 6 times test item solutions at 3 levels of concentration for **persulphuric acid.** | | | |
| Compound | Repeatability (RSD) | | |
| persulphuric acid | RSD = 3.6% for 0.0279 mg/L  RSD = 14.7% for 0.0836 mg/L | | |

The analytical method is validated for the determination of the peroxoacid in water at traces level. The method is validated for the quantification of hydroxyl and peroxyl radicals residues in water.

### Efficacy against target organisms

#### Function and field of use

MG 01: Disinfectants

PT4: Food and feed area

The product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is a PT4 biocide used as a disinfectant cleaner for equipment in the food industry and milking parlours. It is for professional use only.

According to the applicant, the product can be applied in two different manners:

* by CIP (cleaning in place) in the agri- industry and in milking parlours: The product is applied in circuits, pumps, pipes, closed tanks and closed equipements that are in contact with foodstuffs and drinking water. Product application takes place in agri-food industries, facilities and equipment used for production / storage / processing / transportation / transformation / marketing of foodstuff. Disinfection by CIP also takes place in milking parlours, for the disinfection of milking equipment by CIP.
* by automated-spraying in closed washing machines: The product is used in professional dishwashers / washing tunnels / washing chambers / industrial washing machines for the disinfection of small equipment that is in contact with food and foodstuffs in the agri-industry and institutional kitchens.

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

The product is intended to be used for disinfection of equipments that are in contact with food and foodstuffs, which includes systems, pumps, pipes, closed tanks and closed devices (when the product is applied by CIP), as well as surfaces of small equipments (when the product is applied by spraying in industrial dishwashers).

Target organisms include bacteria, yeasts, viruses, phages and bacterial spores, relevant to the product’s areas of use and in-use conditions.

The product is used for the purpose of the protection of human health.

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

The product is able to produce, under defined conditions, a reduction in the number of viable bacterial cells (bactericidal activity), viable bacterial endospores (sporicidal activity), yeast cells (yeasticidal activity) and of infectious bacteriophage particles (phagocidal activity) of relevant test organisms.

#### 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.

Contact times for the different activities claimed are determined in the efficacy tests (see table below).

#### Efficacy data

* **Efficacy of the product**

Laboratory studies were conducted with the product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 according to the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016) and EN 14885:2015 standard. The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the tables below.

An application rate of 4% is claimed for all activities, whereas conditions of uses (temperatures and contact time) depends on the activity.

Use 1: application by CIP (cleaning in place) in the agri-food industry:

* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), at 50°C with a contact time of 5 minutes, and at 60°C with a contact time of 1 minute, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown at the concentration of 0.5 % v/v;
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 50°C, with a contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the concentration of 4 % v/v. Additional study has been submitted with a temperature of 60°C but only an effect of the temperature is proven.
* Phagocidal activity is demonstrated in phase 2, step 1 test (EN 13610), at 50 °C, with a contact time of 5 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, phagocidal activity is shown at the concentration of 0.5 % v/v.
* Virucidal activity is demonstrated according to the methodology of a phase 2, step 1 test (EN 14476), at 50 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, virucidal activity is shown at the concentration of 2 % v/v.
* Sporicidal activity is demonstrated in phase 2, step 1 test (EN 13704), at 75°C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, sporicidal activity is shown at the concentration 2% v/v.

=>The data presented below support the demonstration of the efficacy of the product when applied by CIP in the agri-food industry (dirty conditions) for all the activities in the conditions claimed, at the application rate of 4% v/v.

It has to be noted that for the yeasticidal efficacy when applied at the temperature of 60 °C, the control A of the efficacy test is not validated, then yeasticidal reduction observed in this test at 60 °C is due to the effect of the temperature.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **USE 1 :**  Product application by CIP in agri-food industry | | | | | | |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **50**°C  Contact time: 5 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1228/1116  RI = 1 |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **60**°C  Contact time: 1 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1227/1116  RI = 1 |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN1650+A1:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **50**°C  Contact time: 30 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 4 % v/v | RE-1336/1216  RI = 2 |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN1650+A1:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **60**°C  Contact time: 1 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Control A is not valid  Effect of the temperature only | RE-1235/1116  RI = 3 |
| Virucide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Murine parvovirus | EN14476+A1:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50** °C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 2% v/v | RE-1301/1216  RI = 1 |
| Sporicide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Bacillus cereus* | EN13704:2002 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **75** °C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 103 reduction | Sporicidal activity demonstrated at 2% v/v | RE-1296/1216  RI = 1 |
| Phagocide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Bacteriophage P001  Bacteriophage P008 | EN13610:2003 | Phase 2 step 1 test (suspension test)  Concentration tested:  Temperature: 50°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Phagocidal activity demonstrated at 0.5 % v/v. | RE-1247/1116  RI = 1 |

Use 2: application by CIP (cleaning in place) in milking parlours system:

* Bactericidal activity is demonstrated in phase 2, step 1 test (EN 1276), at 50°C with a contact time of 5 minutes and, at 60°C with a contact time of 1 minute, in presence of milk soiling (1 g/l milk powder). In these conditions, bactericidal activity is shown at the concentration of 0.5 % v/v;
* Yeasticidal activity is demonstrated in phase 2, step 1 test (EN 1650), at 50°C, with a contact time of 30 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, yeasticidal activity is shown at the concentration of 4 % v/v. The same study has been submitted with a temperature of 60°C but the test is not validated so the claim cannot be accepted.
* Phagocidal activity is demonstrated in phase 2, step 1 test (EN 13610), at 50 °C, with a contact time of 5 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, phagocidal activity is shown at the concentration of 0.5 % v/v.
* Virucidal activity is demonstrated according to the methodology of a phase 2, step 1 test (EN 14476), at 50 °C, with a contact time of 15 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, virucidal activity is shown at the concentration of 2 % v/v.
* Sporicidal activity is demonstrated in phase 2, step 1 test (EN 13704), at 75°C, with a contact time of 15 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, sporicidal activity is shown at the concentration of 3 % v/v.

=>The data presented below support the demonstration of the efficacy of the product when applied by CIP in milking parlours for all the activities in the conditions claimed, at the application rate of 4 % v/v.

It has to be noted that for the yeasticidal efficacy when applied at the temperature of 60 °C, the control A of the efficacy test is not validated, then yeasticidal reduction observed in this test at 60 °C is due to the effect of the temperature.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | | | | | | |
| **Function** | | **Test substance** | **Test organism(s)** | | **Test method** | | **Test system / concentrations applied / exposure time** | | **Test results: effects** | | | **Reference** |
| **USE 2 :** Product application by CIP in milking parlour system | | | | | | | | | | | | |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | *Enterococcus faecium* | | EN1276:2010 | | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **50**°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 5 log reduction | | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1230/1116  RI = 1 | |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | *Enterococcus faecium* | | EN1276:2010 | | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **60**°C  Contact time: 1 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 5 log reduction | | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1229/1116  RI = 1 | |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | *Candida albicans* | | EN1650+A1:2013 | | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **50**°C  Contact time: 30 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | | Yeasticidal activity demonstrated at 4 % v/v | RE-1335/1216  RI = 2 | |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | *Candida albicans* | | EN1650+A1:2013 | | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **60**°C  Contact time: 1 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | | Control A is not valid  Effect of the temperature only | RE-1238/1116  RI = 3 | |
| Virucide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | Murine parvovirus | | EN14476+A1:2015 | | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50** °C  Contact time: 15 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | | Virucidal activity demonstrated at 2% v/v | RE-1300/1216  RI = 1 | |
| Sporicide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | *Bacillus cereus* | | EN13704:2002 | | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **75** °C  Contact time: 15 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 103 reduction | | Sporicidal activity demonstrated at 3% v/v | RE-1297/1216  RI = 1 | |
| Phagocide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | | | Bacteriophage P001  Bacteriophage P008 | | EN13610:2003 | | Phase 2 step 1 test (suspension test)  Concentration tested:  Temperature: 50°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | | Phagocidal activity demonstrated at 0.5 % v/v. | RE-1247/1116  RI = 1 | |

Use 3: application by automated spraying in closed washing machines (agri-food industries and institutional kitchens):

- Bactericidal activity is demonstrated both in phase 2 steps 1 and 2 tests (EN 1276 and EN 13697), at 50°C with a contact time of 5 minutes and, at 60°C with a contact time of 1 minute, in dirty conditions (3.0 g/L BSA). In these conditions, bactericidal activity is shown respectively at the concentration of 1 % v/v at 50°C with a contact time of 5 minutes, and at 2% v/v at 60°C with a contact time of 1 minute;

- Bactericidal activity is demonstrated both in phase 2 steps1 and 2 tests (EN 1276 and EN 13697), at 50°C with a contact time of 5 minutes and, at 60°C with a contact time of 1 minute, in presence of milk soiling (1 g/l milk powder in the final test sample). In these conditions, bactericidal activity is shown respectively at the concentration of 1 % v/v at 50°C with a contact time of 5 minutes, and at 2% v/v at 60°C with a contact time of 1 minute;

* Yeasticidal activity is demonstrated in both phase 2, steps 1 and 2 (EN 1650 and EN 13697), at 50°C, with a contact time of 30 minutes, in dirty conditions (3.0 g/L BSA). In these conditions, yeasticidal activity is shown at the concentration of 4 % v/v.
* Yeasticidal activity is demonstrated in both phase 2, steps 1 and 2 (EN 1650, EN 13697), at 50°C, with a contact time of 30 minutes, in presence of milk soiling (1 g/l milk powder). In these conditions, yeasticidal activity is shown at the concentration of 4 % v/v.
* Phagocidal activity is demonstrated in phase 2, step 1 test (EN 13610) - (no surface test exist until now for food, industrial, domestic and institutional areas), at 50 °C, with a contact time of 5 minutes, in presence of milk soiling (1 g/l milk powder in the final test sample). In these conditions, phagicidal activity is shown at the concentration of 0.5 % v/v.
* Virucidal activity is demonstrated according to the methodology of a phase 2, step 1 test (EN 14476) - (no surface test exist until now for food, industrial, domestic and institutional areas), at 50 °C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA) and in presence of milk soiling (1 g/l milk powder in the final test sample). In these conditions, virucidal activity is shown at the concentration of 2 % v/v.
* Sporicidal activity is demonstrated in phase 2, step 1 test (EN 13704) - (no surface test exist until now for food, industrial, domestic and institutional areas), at 75°C, with a contact time of 15 minutes, in dirty conditions (3.0 g/L BSA) and in presence of milk soiling (1 g/l milk powder in the final test sample). In these conditions, sporicidal activity is shown at the concentration of 3 % v/v in presence of milk soiling and at 2% v/v in dirty conditions.

=>The data presented below support the demonstration of the efficacy of the product when applied by spraying for all the activities in the conditions, at the application rate of 4% v/v.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **USE 3**: application by automated spraying in the presence of high level PT4 soiling | | | | | | |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **50**°C  Contact time: 5 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1228/1116\*  RI = 1  *\* also referenced for use 1* |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **60**°C  Contact time: 1 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1227/1116  RI = 1  *\* also referenced for use 1* |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 0.5/1/1.5 % v/v  Temperature: **50**°C  Contact time: 5 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1 % v/v. | RE-1232/1116  RI = 1 |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 0.5/1/1.5 % v/v  Temperature: **60**°C  Contact time: 1 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 2 % v/v. | RE-1234/1116  RI = 1 |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN1650+A1:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **50**°C  Contact time: 30 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Yeasticidal activity demonstrated at 4 % v/v | RE-1336/1216  RI = 2  *\* also referenced for use 1* |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN1650+A1:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **60**°C  Contact time: 1 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Control A not valid  Effect of the temperature only | RE-1235/1116  RI = 2  *\* also referenced for use 1* |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50**°C  Contact time: 30 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 2 % v/v | RE-1346/1216  RI = 2 |
| Virucide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Murine parvovirus | EN14476+A1:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50** °C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 2% v/v | RE-1301/1216  RI = 1  *\* also referenced for use 1* |
| Sporicide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Bacillus cereus* | EN13704:2002 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **75** °C  Contact time: 15 min  Dirty conditions (3 g/L BSA)  Criteria: at least a 103 reduction | Sporicidal activity demonstrated at 2% v/v | RE-1296/1216  RI = 1  *\* also referenced for use 1* |
| Phagocide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Bacteriophage P001  Bacteriophage P008 | EN13610:2003 | Phase 2 step 1 test (suspension test)  Concentration tested:  Temperature: 50°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Phagocidal activity demonstrated at 0.5 % v/v. | RE-1247/1116  RI = 1  *\* also referenced for use 1* |
| **USE 3:** application by automated spraying in the presence of milk soiling | | | | | | |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **50**°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1230/1116  RI = 1  *\* also referenced for use 2* |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN1276:2010 | Phase 2 step 1 test (suspension test)  Concentration tested: 0.1/0.5/1 % v/v  Temperature: **60**°C  Contact time: 1 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 5 log reduction | Bactericidal activity demonstrated at 0.5 % v/v. | RE-1229/1116  RI = 1  *\* also referenced for use 2* |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 0.5/1 /1.5 % v/v  Temperature: **50**°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 1 % v/v. | RE-1231/1116  RI = 1 |
| Bactericide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Enterococcus faecium* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 0.5/1/1.5 % v/v  Temperature: **60**°C  Contact time: 1 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Bactericidal activity demonstrated at 2 % v/v. | RE-1233/1116  RI = 1 |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN13697:2015 | Phase 2 step 2 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50**°C  Contact time: 30 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 3 log reduction | Yeasticidal activity demonstrated at 2 % v/v | RE-1347/1216  RI = 2 |
| Yeasticide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Candida albicans* | EN1650+A1:2013 | Phase 2 step 1 test (suspension test)  Concentration tested: 2/3/4 % v/v  Temperature: **60**°C  Contact time: 1 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Control A is not valid  Effect of the temperature only | RE-1238/1116  RI = 3  *\* also referenced for use 2* |
| Virucide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Murine parvovirus | EN14476+A1:2015 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **50** °C  Contact time: 15 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Virucidal activity demonstrated at 2% v/v | RE-1300/1216  RI = 1  *\* also referenced for use 2* |
| Sporicide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | *Bacillus cereus* | EN13704:2002 | Phase 2 step 1 test (suspension test)  Concentration tested: 1/2/3 % v/v  Temperature: **75** °C  Contact time: 15 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 103 reduction | Sporicidal activity demonstrated at 3% v/v | RE-1297/1216  RI = 1  *\* also referenced for use 2* |
| Phagocide | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 | Bacteriophage P001  Bacteriophage P008 | EN13610:2003 | Phase 2 step 1 test (suspension test)  Concentration tested:  Temperature: 50°C  Contact time: 5 min  Interfering substance: 1 g/l milk powder  Criteria: at least a 4 log reduction | Phagocidal activity demonstrated at 0.5 % v/v. | RE-1247/1116  RI = 1  *\* also referenced for use 2* |

* **Inactivity of coformulant**

The product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 contains 18 % w/w of nitric acid (CAS 7697-37-2) which is cited in the literature has having a biocidal activity[[2]](#footnote-2). So, additional efficacy tests were carried out, in order to demonstrate the non-activity of this coformulant at the product’s in-use concentration.

1. **Inactivity of coformulant nitric acid alone (phase 1 tests)**

Efficacy tests (EN 1040, EN 1275 and EN 14347) were carried out with an aqueous solution of 18% HNO3, in order to assess its biocidal properties at the product’s in-use concentrations. However, these tests have been performed in conditions (20°C, in absence of interfering substances) that are not representative of the in-use conditions of the product (50 to 75°C, dirty conditions) and have been considered as not relevant.

Another efficacy study was carried out with an aqueous solution of HNO3 18% in order to assess the biological properties at the product’s in-use concentrations of 4 % v/v. This test has been performed without soiling (worst-case for coformulants) on yeasts, and demonstrated that nitric acid do not achieve efficacy criteria against yeasts in the product’s in-use conditions.

|  |  |  |
| --- | --- | --- |
| **Co-formulants tested** | **Conditions**  (EN1650) | **Results** |
| HNO3 18% w/w at 4 % v/v | T°C: 50°C CT: 30 min  without interfering substance  *Yeasts (C. albicans)* | 3.48 log |

1. **Inactivity of coformulant according to the TAB[[3]](#footnote-3)11 (not applicable at the submission data of the dossier)**

Tests have been performed according to the recommendations of the TAB, test 2 (“each co-formulant under question is tested alone”) and test 3 (“the biocidal product without the co-formulant is tested”):

* **Test 2:** performed on a test item composed of 18% w/w HNO3 and distilled water. The chosen test organisms were *E. faecium* (strain model temperature > 40°C)and *S. aureus* (shown to be one of the least sensitive strains to the action of HNO3[[4]](#footnote-4)).

According to the TAB, to demonstrate in test 2 that the co-formulant under question is not an active substance the log reduction should be at least 2 log lower than the required log reduction in the EN Phase 2 step 1 test performed.

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Conditions** | **Results** | **Conclusion** |
| ADD HNO3  5% w/w H2O2 and 18% w/w HNO3 | *E. faecium*  dirty conditions  50°C, 5 min | 0,50% v/v=>> 5 log | Efficacy demonstrated for the entire product |
| **Test 2**  HNO3 alone(18% w/w) | *E. faecium*  dirty conditions  40°C, 5 min | **0,5% v/v => 3,61 log** **1% v/v => 5,12 log** 2% v/v => >5,32 log | HNO3 effective at 1% v/v at 40°C |
| *S. aureus*  dirty conditions  40°C, 5 min | 0,5% v/v => 0,59 log **1% v/v => >5,29 log** |

Comparison with the product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 (to demonstrate a difference of 2 log R) cannot be made as test conditions are not the same (40°C vs 50°C); but for the same test organism, *E. faecium*, efficacy criteria is achieved at 1% v/v with HNO3 alone.

Therefore test 3 has been carried out in order to demonstrate that at the claimed application rate, the active substance alone is efficient in the claimed conditions.

* **Test 3**: performed with the same composition as the commercial product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, except the coformulant HNO3. The concentration of HNO3 in the test item was 1/8th of the concentration in the commercial product, i.e. 2.25% w/w. According to the applicant, the reason for which the concentration in this ingredient was not set to 0% was to reach a pH value as close as possible to the one of the intended use conditions, as recommended in the TAB. The applicant has also decided to test the product in clean conditions, because in the absence of acid the product is not expected to demonstrate detergent properties. The product has been tested at the claimed application rates on *E. faecium* (strain model temperature > 40°C).

According to the TAB, for test 3, the log reduction of the two products (the biocidal product and the same product, but without the co-formulant) should be similar, i.e. showing no more than 1.50 log difference.

|  |  |  |  |
| --- | --- | --- | --- |
| **Product** | **Conditions** | **Results** | **Conclusion** |
| ADD HNO3  5% w/w H2O2 and 18% w/w HNO3 | *E. faecium*  dirty conditions  50°C, 5 min | 0,50% v/v=>> 5 log | Efficacy demonstrated for the entire product |
| **Test 3**  Product containing only H2O2 (5% w/w H2O2 with1/8 HNO3) | *E. faecium*  clean conditions 50°C, 5 min | **4% v/v => 5.12 log** | Efficacy demonstrated at 4% v/v |
| **Test 3**  Product containing only H2O2 (5% w/w H2O2 with1/8 HNO3) | *C.albicans*  clean conditions 50°C, 30 min | **4% v/v => 3.89 log** | Efficacy demonstrated at 4% v/v |

Regarding yeasticidal activity, 3.89 is lower than 4, nevertheless this value is very close to 4. FR CA is of the opinion that a slight tolerance is acceptable when testing on living organisms. Moreover according to Technical Agreement of Biocides, for the demonstration of the inactivity of co-formulants, test 3 should be performed with Bacteria. Therefore, FR CA consider that as this minimal requirement is fulfilled, efficacy of the AS alone is sufficiently demonstrated.

Thus, according to the tests provided, it can be confirmed that the active substance H2O2 alone is efficacious against bacteria and yeasts at the application rate of 4 % v/v.

FR CA has the opinion that at least the efficacy should be demonstrated for the active substance alone and that the efficacy should not be brought only by the co-formulants.

* **Efficacy after storage**

Furthermore, it has to be noted that the product ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 presents a loss of nearly 73% of H2O2 after a long term storage stability test. The applicant has therefore provided efficacy tests with aged product demonstrating that the product is still efficacious after 6, 9 and 12 months storage.

Considering the efficacy results against bacteria and yeasts, after a storage of 1 year, FR CA assume that the product applied at 4 % v/v will be still efficient after 2 months storage.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | | |
| **Function** | **Test substance** | **Test organism(s)** | | **Test method** | | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| **Efficacy assessment of the ingredient “nitric acid”** | | | | | | | | |
|  | Nitric acid solution 18% | *Pseudomonas aeruginosa*  *Staphylococcus aureus* | | EN 1040 : 2006  Phase 1 | | Phase 1 test (suspension test)  Concentration tested: 2/1.5/1/0.5/0.1%  Temperature: 20°C  Contact time: 5 min  No interfering substances  Criteria: at least a 5 log reduction | *P. aeruginosa*: >5 log reduction at 0.5%  *S. aureus*: 4.77 reduction at 2%  No basic bactericidal activity demonstrated at 2 % v/v | LDA67 – 161013-012599-01  RI = 3 |
|  | Nitric acid solution 18% | *Candida albicans*  *Aspergillus niger* | | EN 1275 : 2006  Phase 1 | | Phase 1 test (suspension test)  Concentration tested: 5/4/3/2/1%  Temperature: 20°C  Contact time: 15 min  No interfering substances  Criteria: at least a 4 log reduction | No basic yeasticidal/fungicidal activity demonstrated at 5 % v/v | LDA67 – 161013-012599-02  RI = 3 |
|  | Nitric acid solution 18% | *Candida albicans* | | EN 1275 : 2006  Phase 1 | | Temperature: 50°C  Contact time: 30 min  No interfering substances  Concentration tested: 2, 3, 4%  Criteria: at least a 4 log reduction | Not efficacious at 4 % v/v only 2.98 log reduction | RE19-196-1  RI=2 |
|  | Nitric acid solution 18% | *Bacillus cereus*  *Bacillus subtilis* | | EN 14347 : 2005  Phase 1 | | Phase 1 test (suspension test)  Concentration tested: 5/4/3/2/1%  Temperature: 20°C  Contact time: 30 min  No interfering substances  Criteria: at least a 5 log reduction | No basic sporicidal activity demonstrated at 5 % v/v  Test not validated for *B. cereus*. | LDA67 – 161013-012599-03  RI = 3 |
| TAB test 2 | Nitric acid solution 18% | *Enterococcus faecium* | | EN 1276 | | 40°C  5 min  3 g/L bovine albumin | 1% v/v | RE-2025/0318  RI = 1 |
| TAB Test 2 | Nitric acid solution 18% | *Staphylococcus aureus* | | EN 1276 | | 40°C  5 min  3 g/L bovine albumin | 1% v/v | RE-2055/0418  RI = 1 |
| TAB Test 2 | Nitric acid solution 18% | *Candida albicans* | | EN 1650 | | Temperature: 50°C  Contact time: 30 min  No interfering substance  Concentration tested: 2, 3, 4%  Criteria: at least a 4 log reduction | Not efficacious at 4%v/v  only 3.48 log reduction | 5565-1  RI=1 |
| TAB Test 3 | Product with H2O2 alone (with 1/8th HNO3 | *Enterococcus faecium* | | EN 1276 | | Temperature: 50 °C  Contact time: 5 minutes  0.3 g/L albumin bovine  Concentration tested: 2, 3, 4 %  Criteria: at least a 5 log reduction | 4 % v/v | 5563-1  RI=1 |
| TAB Test 3 | Product with H2O2 alone (with 1/8th HNO3) | *Candida albicans* | | EN 1650 | | Temperature: 50°C  Contact time: 30 min  0.3 g/L albumin bovine  Concentration tested: 2, 3, 4%  Criteria: at least a 4 log reduction | 3.89 log reduction at 4% v/v | 5567-1  RI=1 |
| **Efficacy assessment of the product “Acide détartrant désinfectant H2O2 + HNO3” after 6 months of storage at ambient temperature** | | | | | | | | |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 6 months old | *Enterococcus faecium* | EN 1276 | | 50°C  5 min  3 g/L bovine albumin | | 0.5% v/v | RE-1263/0517  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 6 months old | *Enterococcus faecium* | EN 13697 | | 50°C  5 min  3 g/L bovine albumin | | 1% v/v | RE-1265/0517-1  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 6 months old | *Candida albicans* | EN 1650 | | 50°C  30 min  3 g/L bovine albumin | | 4% v/v | RE-1264/0517  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 6 months old | *Candida albicans* | EN 13697 | | 50°C  30 min  3 g/L bovine albumin | | 1% v/v | RE-1265/0517-2  RI = 1 |
| **Efficacy assessment of the product “Acide détartrant désinfectant H2O2 + HNO3” after 9 months of storage at ambient temperature** | | | | | | | | |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 9 months old | *Enterococcus faecium* | EN 1276 | | 50°C  5 min  3 g/L bovine albumin | | 0.5% v/v | RE-1359/0817  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 9 months old | *Enterococcus faecium* | EN 13697 | | 50°C  5 min  3 g/L bovine albumin | | 1% v/v | RE-1360/0817-2  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 9 months old | *Candida albicans* | EN 1650 | | 50°C  30 min  3 g/L bovine albumin | | 3% v/v | RE-1358/0817  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 9 months old | *Candida albicans* | EN 13697 | | 50°C  30 min  3 g/L bovine albumin | | 1% v/v | RE-1360/0817-1  RI = 1 |
| **Efficacy assessment of the product “Acide détartrant désinfectant H2O2 + HNO3” after 12 months of storage at ambient temperature** | | | | | | | | |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 12 months old | *Enterococcus faecium* | EN 1276 | | 50°C  5 min  3 g/L bovine albumin | | 1% v/v | RE-1433/1017  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 12 months old | *Enterococcus faecium* | EN 13697 | | 50°C  5 min  3 g/L bovine albumin | | 1% v/v | RE-1435/1017  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 12 months old | *Candida albicans* | EN 1650 | | 50°C  30 min  3 g/L bovine albumin | | 4% v/v | RE-1436/1017  RI = 1 |
|  | ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, 12 months old | *Candida albicans* | EN 13697 | | 50°C  30 min  3 g/L bovine albumin | | 1% v/v | RE-1434/1017  RI = 1 |

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| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the submitted tests and the requirements of Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016) and EN 14885:2015 standard:   * Efficacy of the product ACIDE DÉTARTRANT DÉSINFECTANT H2O2 + HNO3 is demonstrated for:   + Use 1: Closed circulation circuits in agri-food industry against:     - Bacteria:       * 4% v/v, 5 min, 50 °C     - Yeast:       * 4% v/v, 30 min, 50 °C     - Virus:       * 4% v/v, 15 min, 50 °C     - Bacteriophages:       * 4 % v/v, 5 min, 50 °C     - Bacterial spores:       * 4 % v/v, 15 min, 75 °C   + Use 2: Closed circulation circuits in milking parlour system:     - Bacteria:       * 4% v/v, 5 min, 50 °C     - Yeast:       * 4% v/v, 30 min, 50 °C     - Virus:       * 4% v/v, 15 min, 50 °C     - Bacteriophages:       * 4 % v/v, 5 min, 50 °C     - Bacterial spores:       * 4 % v/v, 15 min, 75 °C   + Use 3: Automated spraying:     - Bacteria:       * 4% v/v, 5 min, 50 °C     - Yeast:       * 4% v/v, 30 min, 50 °C     - Virus:       * 4% v/v, 15 min, 50 °C     - Bacteriophages:       * 4 % v/v, 5 min, 50 °C     - Bacterial spores:       * 4 % v/v, 15 min, 75 °C   It has to be noted that, for the yeasticidal efficacy when applied from the temperature of 60 °C, the efficacy observed is due to the effect of the temperature. |

#### 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)[[5]](#footnote-5), Christman et al (1985)[[6]](#footnote-6)). The resistance to oxidative stress that *E.coli* develops when exposed to H202, as reported in literature papers, demonstrates an adaptive response only. Hydrogen peroxide has been intensively used as a disinfectant and preservative for more than 3 decades and has not lead to the development of significant resistance levels among field populations. Genetically inherited resistance is not expected when the products are used as recommended.”

#### Known limitations

None

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product ACIDE DÉTARTRANT DESINFECTANT H2O2 + HNO3 has shown a sufficient efficacy in accordance with the requirement of the transitional Guidance in Efficacy for product type PT1-5, Disinfectants (2016) and the EN 14885:2015 standard for the following uses:

* + Use 1: Closed circulation circuits in agri-food industry against:
    - Mandatory target organisms:
    - Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
    - Bacterial spores: 4 % v/v, 15 min, 75 °C
  + Use 2: Closed circulation circuits in milking parlour system:
    - Mandatory target organisms:
    - Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
    - Bacterial spores: 4 % v/v, 15 min, 75 °C

* + Use 3: Automated spraying:
    - Mandatory target organisms:
    - Bacteria and yeasts: 4% v/v, 30 min, 50 °C
    - Other target organisms:
      * Virus: 4% v/v, 15 min, 50 °C
      * Bacteriophages: 4 % v/v, 5 min, 50 °C
    - Bacterial spores: 4 % v/v, 15 min, 75 °C

It has to be noted that, for the yeasticidal efficacy when applied from the temperature of 60 °C, the efficacy observed is due to the effect of the temperature.

Only for non-porous surfaces

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

The product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is not intended to be used with another biocidal product.

### 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. |
| Classification of the product according to CLP | Classification Skin Corrosion, category 1; H314 Causes severe skin burns and eye damage is required, according to Regulation (EC) N°1272/2008. |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Corrosive to the eye. |
| Justification for the value/conclusion | According to Guidance on the Application of the CLP Criteria (Version 5.0 – July 2017): *”It should be noted that if a substance or mixture is classified as Skin corrosion Category 1 then serious damage to eyes is implicit as reflected in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). Thus, the corrosive substance or mixture is also classified, but the corresponding hazard statement (H318: Causes serious eye damage) is not indicated on the label to avoid redundancy”*. See also CLP Article 27. |
| Classification of the product according to CLP | The hazard statement H318 ‘Causes serious eye damage’ is not indicated on the label because of redundancy. |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The classification has been determined according to the CLP Regulation. |
| Classification of the product according to CLP | Since the product may be inhaled and that no acute inhalation study is available whereas it is classified for corrosivity: a hazard of respiratory tract corrosion may exist. As a consequence, the sentence ‘EUH071 Corrosive to the respiratory tract’ should be mentioned on the labelling. |

***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 and DSD | 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 | Not acutely toxic via the oral route. |
| Justification for the selected value | The classification has been determined using the calculation method.  Therefore, ATEmix (oral) of 8400 mg/kg bw is calculated. |
| Classification of the product according to CLP | No classification for acute oral toxicity is required. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not 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 toxicity category 4; H332, however no clear LC50 was determined. Calculation was performed considering a generic ATE of 1.5 mg/L.  Therefore, ATEmix (inhalation) is 100 x 1.5/5 = 30 mg/L. |
| Classification of the product according to CLP | No classification for acute inhalation toxicity is required. |

*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***

Considering the classification skin Corrosion, category 1; H314 Causes severe skin burns and eye damage, 100 % dermal penetration should be used. However, in the absence of clear systemic effects of hydrogen peroxide and only local effects at the site of first contact, no dermal penetration value was needed in order to conclude on human health risks from the presented uses of the biocidal products. Only a qualitative exposure and risk assessment for the dermal route of exposure will be performed by taking into account appropriate risk mitigation measures.

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

**Reaction production exposure**

H2O2 is a highly reactive active substance that will react with organic matter leading to a reaction production of pernitric acid. Currently, no information related to toxicity (environmental and human) is listed for pernitric acid. Neither REACH dossier nor toxicological data sheet are available.

Maximum quantity is equal to 0.18 g/kg, which corresponds to 0.018% of pernitric acid before the dilution.

According to the notifier, concentration of pernitric acid is considered negligible (0.033% w/w), taking into account a dilution of 4%.

**Substance of concern**

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, four co-formulants have been identified as substances of concern: Nitric acid, 2-(2-Butoxyethoxy)ethanol and Phosphoric acid. Summary is available in the following table:

| **Name and CAS**  **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** | **Community workplace exposure limit** (mg/m3) [[7]](#footnote-7) |
| --- | --- | --- | --- | --- |
| **Nitric Acid**  CAS 7697-37-2 | Contribution to the CLP classification of the biocidal product as “Skin corrosion cat. 1”  Substances for which there are Community workplace exposure limits. | Band B  Band C | Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.  Quantitative inhalation risk assessment for the professional | 2.6  (short term exposure) |
| **2-(2-Butoxyethoxy)ethanol**  CAS 112-34-5 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional | 67.5 |
| **Phosphoric acid**    CAS 7664-38-2 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional | 1 |

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

Not applicable.

#### Exposure assessment

ACIDE DETERTRANT DESINFECTANT H2O2+HNO3 is a water-soluble concentrated liquid disinfectant detergent packaged in bottle (1L), in jerrycan (5L to 20L), in drum (60 to 220L) and in bulk container (1000L) for professional use only.

It is intended for use as a bactericidal, yeasticidal, sporicidal and virucidal agent (including bacteriophages) for the treatment of closed-system pipework and surfaces in contact with foodstuffs.

This product is used:

1. In the agri-food industry or in the livestock of dairy production, in closed facilities using appropriate **Cleaning-In-place (CIP)** structures, after an automatic mixing and loading.

Examples of descaling and disinfection in CIP (agri-food industry):

|  |  |
| --- | --- |
| Fig.1: CIP (for 7 phases and 3 phases) | Fig.2: Closed IBC connected to automatic pumping system of CIP or stored on retention container |
|  |  |

Examples of descaling and disinfection in CIP (milking parlour system):

|  |  |
| --- | --- |
| Fig.3: Milking parlour and process description | Fig.4: Milking tank with temperature control |
|  |  |

Fig.3 & 4: The various stages of pre-wash, cleaning (with or without disinfection) and rinsing are automated.

1. In the agri-food industry, in the livestock of dairy production, or in the institutional kitchens, for the disinfection of materials by **automatic spraying** in closed systems after an automatic or a manual mixing and loading,

Examples of descaling and disinfection by automatic spraying:

|  |  |
| --- | --- |
| Fig.5: Professional dishwashing machine in open position | Fig.6: Washing tunnel with prewashing, cleaning and rinsing zones |
|  |  |

Fig.5: The product is automatically topped up at each dish washing cycle.

Fig.6: Pre-wash and rinsing with water after the cleaning and disinfection of the product.

**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 | n.a | n.a | yes | no | n.a. |
| Dermal | n.a | yes | n.a | n.a | yes | no | n.a. |
| Oral | n.a | no | n.a | n.a | no | no | yes |

*n.a.: not applicable*

**Primary exposure:**

Professional users may be potentially dermally and respiratory exposed to hydrogen peroxide, but also to the other substances identified as substances of concern during the mixing and loading of a concentrate solution

No exposure during the CIP or spraying application are expected since these applications are performed in closed systems.

The mixing and loading can be automated (connecting line) or manual, pending of the packaging size.

**Inhalation exposure**

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

**Dermal exposure**

Professionals will be exposed by dermal route during mixing and loading.

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

**Oral exposure**

Not relevant.

**Secondary exposure:**

No secondary exposure is expected due to the rinsing water step.

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Mixing/ loading | Mixing and loading: manual | Professionals |
| 2. | Mixing/ loading | Mixing and loading: automatic | Professionals |

***Industrial exposure***

ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is used by professionals only.

***Professional exposure***

*Scenario [1]*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| Professional users are exposed during the manual mixing and loading operations.  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 SoCs, and that only toxicological reference values for inhalation exposure are available, exposures assessment for the dermal route is not considered. Nevertheless, 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:  *Exposure duration/Emission duration*  According to ECHA Recommendation no.6, 2017[[8]](#footnote-8): exposure duration of 10 minutes by event is considered during mixing and loading operations for PT2 and PT6, which can be considered for PT4 for CIP and agri-food industries. 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. For jerrycans, different packagings from 5L to 20L are claimed. Considering a 20L jerrycan, an amount of product of 10L with a density of 1.126 (11260 g) is considered in ConsExpo.  *Room volume and ventilation rate*  Room volume and ventilation rate is taken into account.  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 5 hours-1.  *Release area*  It is assumed that evaporation takes place from a can with a not-too-small circular opening with a 4.9 cm diameter as referred to the packagings, which gives a release area of 18.86 cm². | | | |
|  | Parameters | Value | Reference |
| Tier 1 | *Model settings* | | |
| Product amount (gram) | 11260 | Corrected by density 1.198 |
| Exposure duration (minutes) | 10 | Recommendation no.6, 2017 |
| Molecular weight matrix (g/mol) | 18 | ConsExpo value |
| Room volume (m3) | 1 | Disinfectant Products Fact Sheet, 2006 |
| Ventilation rate (1/hour) | 5 | Expert judgement |
| Inhalation rate (m3/hour) | 1.25 | Recommendation no. 14, 2017[[9]](#footnote-9) |
| Application temperature (°C) | 25 | CAR of the active substance |
| Mass transfer coefficient (m/hour) | Thibodeaux’s method | |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| *Release area mode: constant* | | |
| Realease area (cm2) | 18.86 |  |
| Emission duration (min) | 10 | Recommendation no.6, 2017 |
| *Concentration values* | | |
| Hydrogen peroxide concentration (% w/w) | 5% | Applicant data |
| Nitric acid concentration (% w/w) | 18% | Applicant data |
| 2-(2-Butoxyethoxy)ethanol concentration (% w/w) | 5% | Applicant data |
| Phosphoric acid concentration (% w/w) | 0.009% | Applicant data |
| *Mass molecular values* | | |
| Hydrogen peroxide (g/mol) | 34.01 | CAR of the active substance |
| Nitric acid (g/mol) | 63.01 |  |
| 2-(2-Butoxyethoxy)ethanol (g/mol) | 160.21 |  |
| Phosphoric acid (g/mol) | 97.99 |  |
| *Vapour pressure values* | | |
| Hydrogen peroxide (Pa) | 299 | CAR of the active substance (25°C) |
| Nitric acid (Pa) | 6200 | Registered dossier (25°C) |
| 2-(2-Butoxyethoxy)ethanol (Pa) | 2.9 | Registered dossier (25°C) |
| Phosphoric acid (Pa) | 80\* | Registered dossier (25°C) |
| Tier 2 | PPE: mask AFP10 factor | 10 |  |

\* The vapour pressure at 25°C was extrapolated from the curve to be 80Pa for the supercooled liquid. Nevertheless this value is not accurate and applicable as the complete estimation of the vapour pressure of inorganic liquid by calculation is not solved yet.

**Calculations for Scenario [1]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [1] –  Hydrogen peroxide | 1 | 3.3 × 10⁻¹ | n.a | n.a | 3.3 × 10⁻¹ |
| Scenario [1] –  Hydrogen peroxide | 2 | 3.3 × 10⁻2 | n.a | n.a | 3.3 × 10⁻2 |
| Scenario [1] –  Nitric acid | 1 | 22 | n.a | n.a | 22 |
| Scenario [1] –  Nitric acid | 2 | 2.2 | n.a | n.a | 2.2 |
| Scenario [1] –  2-(2-Butoxyethoxy)ethanol | 1 | 1.9 × 10⁻³ | n.a | n.a | 1.9 × 10⁻³ |
| Scenario [1] –  2-(2-Butoxyethoxy)ethanol | 2 | 1.9 × 10⁻4 | n.a | n.a | 1.9 × 10⁻4 |
| Scenario [1] –  Phosphoric acid | 1 | 1.1 × 10⁻⁴ | n.a | n.a | 1.1 × 10⁻⁴ |
| Scenario [1] –  Phosphoric acid | 2 | 1.1 × 10⁻5 | n.a | n.a | 1.1 × 10⁻5 |

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

For local effects, please see section 2.2.6.3.

*Scenario [2]*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| Professional users are exposed during the automated mixing and loading.  Inhalation exposure could also occur due to evaporation from drum or bulk container, considering the high vapour pressure of the active substance (214 Pa at 20°C, 299 Pa at 25°C) during the connection to a line.  It has to be noted that, since no systemic effect has been identified for Hydrogen Peroxide and SoCs, and that only toxicological reference values for inhalation exposure are available, exposures assessment for the dermal route is not considered. Nevertheless, 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:  *Exposure duration/Emission duration*  Exposure duration of 1 minute by event is considered during the connection of lines. 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. Different packagings from 60L to 1000L are claimed. Considering a 1000L bulk container, an amount of product of 500L with a density of 1.126 (563000g) is considered in ConsExpo.  *Room volume and ventilation rate*  Room volume and ventilation rate is taken into account.  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 5 hours-1.  *Release area*  It is assumed that evaporation takes place from a can with a not-too-small circular opening with a 6-cm diameter, which gives a release area of 20 cm². | | | |
| Tier 1 | Parameters | Value | Reference |
| *Model settings* | | |
| Product amount (gram) | 563000 | Corrected by density 1.198 |
| Exposure duration (minutes) | 1 |  |
| Molecular weight matrix (g/mol) | 18 | ConsExpo value |
| Room volume (m3) | 1 | Disinfectant Products Fact Sheet, 2006 |
| Ventilation rate (1/hour) | 5 |  |
| Inhalation rate (m3/hour) | 1.25 | Recommendation no. 14, 2017[[10]](#footnote-10) |
| Application temperature (°C) | 25 | CAR of the active substance |
| Mass transfer coefficient (m/hour) | Thibodeaux’s method | |
| Body weight (kg) | 60 | Recommendation no. 14, 2017 |
| *Release area mode: constant* | | |
| Realease area (cm2) | 20 |  |
| Emission duration (min) | 1 |  |
| *Concentration values* | | |
| Hydrogen peroxide concentration (% w/w) | 5% | Applicant data |
| Nitric acid concentration (% w/w) | 18% | Applicant data |
| 2-(2-Butoxyethoxy)ethanol concentration (% w/w) | 5% | Applicant data |
| Phosphoric acid concentration (% w/w) | 0.009% | Applicant data |
| *Mass molecular values* | | |
| Hydrogen peroxide (g/mol) | 34.01 | CAR of the active substance |
| Nitric acid (g/mol) | 63.01 |  |
| 2-(2-Butoxyethoxy)ethanol (g/mol) | 160.21 |  |
| Phosphoric acid (g/mol) | 97.99 |  |
| *Vapour pressure values* | | |
| Hydrogen peroxide (Pa) | 299 | CAR of the active substance (25°C) |
| Nitric acid (Pa) | 6200 | Registered dossier (25°C) |
| 2-(2-Butoxyethoxy)ethanol (Pa) | 2.9 | Registered dossier (25°C) |
| Phosphoric acid (Pa) | 80\* | Registered dossier (25°C) |
| Tier 2 | PPE: mask AFP10 factor | 10 |  |

\* The vapour pressure at 25°C was extrapolated from the curve to be 80Pa for the supercooled liquid. Nevertheless this value is not accurate and applicable as the complete estimation of the vapour pressure of inorganic liquid by calculation is not solved yet.

**Calculations for Scenario [2]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/m3)** |
| Scenario [2] –  Hydrogen peroxide | 1 | 4.4 × 10⁻2 | n.a | n.a | 4.4 × 10⁻2 |
| Scenario [2] –  Hydrogen peroxide | 2 | 4.4 × 10-3 | n.a | n.a | 4.4 × 10-3 |
| Scenario [2] –  Nitric acid | 1 | 3.0 | n.a | n.a | 3.0 |
| Scenario [2] –  Nitric acid | 2 | 3.0 × 10⁻¹ | n.a | n.a | 3.0 × 10⁻¹ |
| Scenario [2] –  2-(2-Butoxyethoxy)ethanol | 1 | 2.6 × 10⁻⁴ | n.a | n.a | 2.6 × 10⁻⁴ |
| Scenario [2] –  2-(2-Butoxyethoxy)ethanol | 2 | 2.6 × 10⁻5 | n.a | n.a | 2.6 × 10⁻5 |
| Scenario [2] –  Phosphoric acid | 1 | 1.4 × 10⁻⁵ | n.a | n.a | 1.4 × 10⁻⁵ |
| Scenario [2] –  Phosphoric acid | 2 | 1.4 × 10⁻6 | n.a | n.a | 1.4 × 10⁻6 |

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

For local effects, please see section 2.2.6.3.

***Non-professional exposure***

ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is used by professionals only.

***Secondary Exposure of the general public***

No secondary exposure is expected due to the rinsing water step.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total uptake (mg/m3)** |
| Scenario [1] – Hydrogen peroxide | Professionals | 1 | 3.3 × 10⁻¹ |
| Scenario [1] – Hydrogen peroxide | Professionals | 2 | 3.3 × 10⁻2 |
| Scenario [1] – Nitric acid | Professionals | 1 | 22 |
| Scenario [1] – Nitric acid | Professionals | 2 | 2.2 |
| Scenario [1] – 2-(2-Butoxyethoxy)ethanol | Professionals | 1 | 1.9 × 10⁻³ |
| Scenario [1] – 2-(2-Butoxyethoxy)ethanol | Professionals | 2 | 1.9 × 10⁻4 |
| Scenario [1] – Phosphoric acid | Professionals | 1 | 1.1 × 10⁻⁴ |
| Scenario [1] – Phosphoric acid | Professionals | 2 | 1.1 × 10⁻5 |
| Scenario [2] – Hydrogen peroxide | Professionals | 1 | 4.4 × 10⁻2 |
| Scenario [2] – Hydrogen peroxide | Professionals | 2 | 4.4 × 10-3 |
| Scenario [2] – Nitric acid | Professionals | 1 | 3.0 |
| Scenario [2] – Nitric acid | Professionals | 2 | 3.0 × 10⁻¹ |
| Scenario [2] – 2-(2-Butoxyethoxy)ethanol | Professionals | 1 | 2.6 × 10⁻⁴ |
| Scenario [2] – 2-(2-Butoxyethoxy)ethanol | Professionals | 2 | 2.6 × 10-5 |
| Scenario [2] – Phosphoric acid | Professionals | 1 | 1.4 × 10⁻⁵ |
| Scenario [2] – Phosphoric acid | Professionals | 2 | 1.4 × 10-6 |

***Dietary exposure***

As PT 4, ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 is intended to be used as disinfectant in the agri-food industries, in milking parlour system and in institutional kitchen. Therefore, residues in food, feed, milk or drinking water might be expected based on intended uses. ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 is applied in closed facilities using appropriate Cleaning-In-Place (CIP) equipment in agri-food industries and milking parlour. In instutitional kitchens, this product is used for cleaning and disinfection of equipment (moulds, trays, dishes, kitchenware, removable parts of equipment, ...) in self-contained facilities such as professional dishwashers, washing tunnels and other types of professional dishwashing machines.

Biocidal product ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 is composed of hydrogen peroxyde only and contains few substances of concern: nitric acid, 2-(2-butoxyethoxy)ethanol and phosphoric acid.

For hydrogen peroxide, no dietary exposure is foreseen. Indeed, “*hydrogen peroxide is reactive and it degrades rapidly in contact with organic material. A significant proportion of hydrogen peroxide decomposes to water and oxygen*” (Finland, 2015). Therefore, this active substance is not expected to remain on surfaces, and no residues in food which may enter into contact with treated surface are expected.

Nevertheless, in the CAR (Finland, 2015), it is also stated : ”*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 range of by-products is considered wide and not well characterise*d*”*. Therefore, hydrogen peroxyde degradation can also lead to the formation of free radicals which are highly reactive components. Free radicals can therefore react with (in) organic components present on surfaces and lead to the formation of a wide range of by-products, potentially toxic (Disinfection By Products (DBP)). The range of DBP is considered wide and not well characterised. Therefore, it would be very difficult to provide analytical methods and toxicological data to cover the low level concentrations of the enormous variety of DBP.

European guidance on the assessment of Disinfection by products is finalised and available[[11]](#footnote-11). Nevertheless, this guidance was “*developed to be applicable to biocides in PT 2 (…) for the other PTs future development of an adapted guidance is needed to ensure a harmonised approach across the EU*” (ECHA, 2017). Therefore, in the frame of this dossier, in order to assess consumer risk assessment via DBP, no finalised or draft guidance is available.

Without any indication on how to perform an exposure assessment of the DBP formed during H2O2 application, the applicant provided a reliable argumentation to explain that intended H2O2 biocidal use would not raise any risk for the consumer:

”*So, if we also refer to other legislation as PPP and veterinary regulations, the next information is also found:*

* *According to the EFSA report on the outcome of the consultation with Member States and EFSA on the basic substance application for hydrogen peroxide for use in plant protection as fungicide and bactericide in seed treatment and for disinfecting cutting tool (EFSA Technical report, 2016), it is indicated that expected residue of hydrogen peroxide are only water and oxygen. So, EFSA set no MRL for this substance stating it was not required.*
* *« The European Agency for the Evaluation of Medicinal Products Veterinary Medicines Evaluation Unite – Committee for veterinary medicinal products – hydrogen peroxide (1) and (2) – summary report » (EMEA, 1996) also provides the following observations:*
  + *“Following treatment with H2O2, residues in fish and other products of animal origin cannot distinguished from the endogenous levels. Spectrophotometric methods are available for the determination of residues of H2O2 down to 0.01 mg/l (0.01mg/kg).*
  + *Although H2O2 is toxic to some aquatic organisms including marine phytoplankton and crustacea, the rated of dilution and dissociation encountered on fish farms ensure that harmful effects on the environment are minimized.*
  + *For reasons stated in the preceding paragraphs, the Working Group on the Safety of Residues agreed that it was not necessary to set MRLs for hydrogen peroxide and agreed that the substance should be included in Annex II of Regulation N°2377/90.*
  + *Therefore, the Committee for Veterinary Medicinal Products considers that there is no need to establish MRL for H2O2 for animal species other than fish and recommends its inclusion into Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table: H2O2 pharmacologically active substance is authorized in all food producing animal species”.*

*Besides this, literature research on the possible toxicity of hydrogen peroxide in food and feed reveals the following information in the EFSA Scientific opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat (EFSA Journal, 2014)[[12]](#footnote-12).*

* *“On the basis of the previous EFSA exposure scenarios including short term baths that were not evaluated previously, it was concluded no toxicity concerns were identified with regards to residues of peroxyacids, to HEDP and to possible reaction products of hydrogen peroxide and peroxyacids with lipids and proteins of the poultry carcasses.”*

*If we extrapolate this observation and conclusion, it can be assumed that hydrogen peroxide, even in the case it would be present at a sufficient level to lead to food exposure, would not raise any level of toxicity for the consumer.*

*(…)*

*And finally, in the Council Directive 2011/84/EU[[13]](#footnote-13), amending Directive 76/768/EEC concerning cosmetic products, also referenced in the Assessment report of hydrogen peroxide (Official Journal of the European Union, 2011), the Scientific Committee on Consumer Products (SCCS) has confirmed that a maximum concentration of 0,1 % of hydrogen peroxide present in oral products or released from other compounds or mixtures in those products is safe.”*

Moreover, hydrogen peroxide is also authorised in France as processing aid (i.e. components of washing solution for vegetables)[[14]](#footnote-14)  and no risk for consumer was identified. In those kind of H2O2 application, a rinsing step has to be done after washing.

About identified SoC in ACIDE DETARTRANT DESINFECTAN H2O2+HNO3 product, Nitric acid, 2-(2-Butoxyethoxy)ethanol and Phosphoric acid, the applicant provided a reliable argumentation to explain that these SoCs would not raise any risk for the consumer after ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 treatment:

”(...) *even if those substances of concern were still present on the treated surface after treatment, it can be considered they will not affect the dietary exposure and lead to any unacceptable risk for dietary. Indeed, the reason of their identification is:*

* *They have European community workplace limits.*
  + *So, it means they could only be of potential hazard for professional users that are directly exposed by the inhalation route. So, it would not have any toxicological effects to consumers and would not lead to unacceptable risk related to the dietary exposure for which the oral route is the only route involved in the dietary exposure.*

*The substances of concern present in the formulation of the biocidal product “Acide détartrant désinfectant H2O2 + HNO3” are only identified because of their inhalation local effects for professional. So, they do not fall into the scope of a Dietary exposure and would not lead to any unacceptable risk related to the dietary exposure*.”

Moreover, some of these SoCs were also assessed in other European or national regulations:

- Phytosanitary regulation (Reg. EU 1107/2009): phosphoric acid not approved with default MRL at 0.01\* mg/kg.

- Food additives regulation (Reg EU 1129/2011): phosphoric acid (E 338) approved.

- French regulation about cleaning products used on surfaces in contact with food[[15]](#footnote-15) with a rinsing step after treatment: nitric acid and phosphoric acid approved.

Based on these argumentations for H2O2 and SoC, FR is of opinion that ACIDE DETARTRANT DESINFECTANT H2O2+HNO3 intended use would not raise any risk for the consumer.

Moreover, rinsing of treated surfaces is intended by the applicant : ”*After the appropriate contact time, rinse with drinking water”*.

The applicant provided the following study: ”*Determination of hydroxyl/peroxyl residues from ACIDE DETARTRANT DISINFECTANT H2O2+HNO3 COM 09 after rinsing by spraying*.”. This study was aimed at the determination of hydroxyl/peroxyl residues on different materials previously treated with the test item at 4% v/v in water by soaking or spraying (at 50°C), and then rinsed with tap water by spraying at room temperature. Moreover, in this study, a pH determination was also done in solution treatment and in rinsing solutions. A short summary of this study is detailed below and a full description of this study is provided in Annex 3.4.

In this study, biocidal product was sprayed at 4 % v/v (representative of highest intended application rate) onto different materials representative of surfaces commonly present in food and feed industries: glass, inox and polypropylene. Inox and polypropylene were tested in the soaking application because these surfaces are well representative of the surfaces used in cleaning-in-place for PT4 applications. The three surfaces were tested in the spraying protocol because they are well representative of the material usually sprayed with the product in industrial or institutional washing machines for example.

Determination of hydroxyl/peroxyl residues, that could be in contact with organic matter or food and so could lead to the possible production of DBP, was performed on rinsing solution volume. Hydroxyl residues occur from the degradation of hydrogen peroxide. Peroxyl residue can occur from reaction of hydroxyl residues on organic matter or comes from acids and peracids. These two kind of residues (hydroxyl and peroxyl) were measured and quantified as hydroxyl/peroxyl residues expressed in mg H2O2/L of rinsing solution.

pH of rinsing solution was also analysed in the study. Through pH determination, it can be estimated ”acid” residues quantity. Indeed, if the observed pH shows a value below 7, the presence of acids is suspected. Moreover as all the substances of concerns present in the formulated biocidal product are acids, this measure gives clear elements to answer if SoCs could be present on rinsed surfaces and so could be in potential contact with food. It has to be noted that no measurement of residue on treated surfaces took place in this study.

The verification of the treatment applications showed that nominal value of 2248 mg H2O2/L was recovered in every case in the test solutions soon after treatment for soaking and spraying.

After container treatment by soaking and then container rinsing, hydroxyl/peroxyl residues were always:

- lower than 0.08 mg H2O2/l after the fourth rinsing volume for polypropylene surfaces.

- lower than 0.16 mg H2O2/l after the fourth rinsing volume for inox surfaces.

After spray surface treatment and then surface rinsing, hydroxyl/peroxyl residues were always:

- lower than 0.42 mg H2O2/l after the fourth rinsing volume for glass surfaces.

- lower than 0.42 mg H2O2/l after the fourth rinsing volume for inox surfaces

- lower than 0.17 mg H2O2/l after the fourth rinsing volume for polypropylene surfaces.

Moreover, as pH was restored at 7 after rinsing, no “acid” residues are expected in rinsing water whatever the scenario (spraying or soaking) and whatever the treated surfaces.

Assumption can be made that residue transfer to food is similar to residue transfer to rinsing water. This is in many cases not true, e.g. the transfer of a lipophilic substance into fatty food will be much higher than that same substance’s transfer into rinsing water. Nevertheless, due to lack of data, this assumption is used in the frame of this dossier.

Therefore, for soaking, it can be expected that hydroxyl/peroxyl residues were always lower than 0.16 mg H2O2/kg of food after the fourth rinsing volume (equivalent to a total rinsing volume of 800 mL). For the spraying, it can be expected that hydroxyl/peroxyl residues were always lower than 0.42 mg H2O2/kg after the fourth rinsing volume (equivalent to a rinsing volume of 800 mL).

In agri-food industries, milking parlour or institutional kitchens, rinsing volume used after disinfection can be expected to be much more higher than 800 mL used in the experimental study. Therefore, remaining residues on treated surfaces and therefore eventually in food, feed, milk or drinking water is not expected and considered to be really low.

Therefore, in the frame of this dossier, a rinsing step is necessary to prevent food, feed or drinking water contamination. As a conclusion, after required contact time, rinse treated surfaces with potable water, before reusing the surfaces.

*List of scenarios*

Not relevant.

*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) |
| 3. | Processing aid – National regulation in France | Hydrogen peroxide – directly used on food or in rinsing water for food3 | Maximum concentration of H2O2 in washing solution for salads: 2mM (68 ppm),  Remaining level: Technically unavoidable content |
| 4. | Processing aid | Solutions of peroxyacetic acid, hydrogen peroxide and 1-hydroxyethylidene-1,1-diphosphonic acid for reduction of pathogens on poultry carcasses and meat4 | None |
| 5. | Para-pharmaceutical product | Hydrogen peroxide in oral dental products (Council Directive 2011/84/EU)5 | Maximum concentration of 0,1 % of hydrogen peroxide present in oral products |

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

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

3 Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires

4 EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599

5 Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36

*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** | **NOAEL (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 | ADI not established, the substance is not systemically available. The agreed acceptable max concentration is 0.1 mg/L in human drinking water | | | | |

1 Assessment factor (AF): Reduced interspecies AF of 2.5 + interspecies AF of 2.5 + interspecies AF of 3.2

**Community workplace exposure limits identified for SoC (see page 59)**

According to Guidance on the BPR: Volume III Parts B+C (version 4.0 December 2017), for SoCs for which Community workplace exposure limits (IOELVs – Indicative Occupational Exposure Limit Values) have been set, a quantitative inhalation risk assessment for the professional operator against the IOELV should always be conducted:

| **Name and CAS**  **SOC** | **Reason(s) for identification** | **Relation to band** | **Consequences on the Human Risk assessment** | **Community workplace exposure limit** (mg/m3) [[16]](#footnote-16) |
| --- | --- | --- | --- | --- |
| **Nitric Acid**  CAS 7697-37-2 | Contribution to the CLP classification of the biocidal product as “Skin corrosion cat. 1”  Substances for which there are Community workplace exposure limits. | Band B  Band C | Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.  Quantitative inhalation risk assessment for the professional | 2.6  (short term exposure) |
| **2-(2-Butoxyethoxy)ethanol**  CAS 112-34-5 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional | 67.5 |
| **Phosphoric acid**    CAS 7664-38-2 | Substances for which there are Community workplace exposure limits. | Band C | Quantitative inhalation risk assessment for the professional | 1 |

**Maximum residue limits or equivalent**

Not relevant.

***Risk for professional users***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/Scenario** | **Tier** | **AEC**  **and OELs**  **(mg/m3)** | **Estimated uptake**  **(mg/m3)** | **Estimated uptake/ AEC (%)** | **Acceptable**  **(yes/no)** |
| Scenario [1] – Hydrogen peroxide | 1 | 1.25 | 3.3 × 10⁻¹ | 26% | Yes |
| Scenario [1] – Hydrogen peroxide | 2 | 1.25 | 3.3 × 10⁻2 | 2.6% | Yes |
| Scenario [1] – Nitric acid | 1 | 2.6\* | 22 | 846% | No |
| Scenario [1] – Nitric acid | 2 | 2.6\* | 2.2 | 84.6% | yes |
| Scenario [1] – 2-(2-Butoxyethoxy)ethanol | 1 | 67.5 | 1.9 × 10⁻³ | < 1.0% | Yes |
| Scenario [1] – 2-(2-Butoxyethoxy)ethanol | 2 | 67.5 | 1.9 × 10⁻4 | < 1.0% | Yes |
| Scenario [1] – Phosphoric acid | 1 | 1 | 1.1 × 10⁻⁴ | < 1.0% | Yes |
| Scenario [1] – Phosphoric acid | 2 | 1 | 1.1 × 10⁻5 | < 1.0% | Yes |
| Scenario [2] – Hydrogen peroxide | 1 | 1.25 | 4.4 × 10-2 | 4% | Yes |
| Scenario [2] – Hydrogen peroxide | 2 | 1.25 | 4.4 × 10-3 | < 1.0% | Yes |
| Scenario [2] – Nitric acid | 1 | 2.6\* | 3.0 | 231% | No |
| Scenario [2] – Nitric acid | 2 | 2.6\* | 3.0 × 10⁻¹ | 23% | Yes |
| Scenario [2] – 2-(2-Butoxyethoxy)ethanol | 1 | 67.5 | 2.6 × 10⁻⁴ | < 1.0% | Yes |
| Scenario [2] – 2-(2-Butoxyethoxy)ethanol | 2 | 67.5 | 2.6 × 10-5 | < 1.0% | Yes |
| Scenario [2] – Phosphoric acid | 1 | 1 | 1.4 × 10⁻⁵ | < 1.0% | Yes |
| Scenario [2] – Phosphoric acid | 2 | 1 | 1.4 × 10-6 | < 1.0% | Yes |

\* The occupational exposure limit value of 2.6 g/m3 corresponds to short-term exposure. No long-term value is available at EU level.

**Local effects (dermal and inhalation exposure)**

The product is corrosive to the skin and to the respiratory tract, therefore skin and inhalation effects are expected. According to the guidance on the BPR for human health[[17]](#footnote-17), a qualitative local risk assessment is performed:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | Skin Corr. Category 1 | - | 2 | Professional | Mixing and loading | Dermal | Less than few minutes per day | Sources for contamination being from:  - splashes;  - hand to eye transfer. | RMM Technics:  - Minimisation of manual phases;  - Regular cleaning of equipment and work area;  - Avoidance of contact with contaminated tools and objects;  RMM Organisation:  - Control staff entry to work area;  - Ensure all equipment well maintained;  - Permit to work for maintenance work;  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice;  - Procedures and training for emergency decontamination and disposal;  - Good standard of personal hygiene  - Recording of any 'near miss' situations.  Sensitisers - Pre-employment screening and appropriate health surveillance.  PPE:  - Gloves;  - protection coverall (EN 13034, 13962, 14605 or 943 according to pattern of exposure);  - 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. |
| High | EUH071 | - | 2 | Professional | Mixing and loading | Inhalation | Less than few minutes per day | - splashes;  - aerosol formation. | See above  PPE:  - Substance/task appropriate respirator; | See above |

**Conclusion**

The risk for professional users is not acceptable during mixing and loading (manual and automatic) without PPE. The risk is acceptable only when a respiratory mask APF10 is worn for mixing and loading (automatic loading with connecting lines and manual loading).

Regarding classification, chemical goggles, coverall and gloves are worn during handling of the product in addition to the respiratory mask APF10.

No secondary exposure is expected due to the rinsing water step.

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

Not relevant.

See paragraph 2.6.2.2 (dietary exposure).

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

Not relevant.

### Risk assessment for animal health

Not relevant.

### Risk assessment for the environment

|  |
| --- |
| 1. - FR CA :   Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes**.  The product does not contain substances of concern, therefore the assessment of the product ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is based on the active substance hydrogen peroxide. |

The ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is a PT4 disinfectant cleaner. It is used for the disinfection of equipment in the food industry and in milking parlours. In agri-food businesses, ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is applied by CIP and by spraying in professional washing machines. In milking parlours, ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is used to disinfect the milking equipment by CIP.

The specific uses and applications of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 are not covered by the hydrogen peroxide assessment report. A complete risk assessment for the environment was therefore carried out for ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3.

The risk assessment was conducted considering a final concentration of 2.5g/L of active substance in the treated system. This concentration is a worst case compare to the actual in use concentration of 2.25g/L. This safety margin was used because the density of the product was unknown at the time.

ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 does not contain any environmental SOCs that would need to be addressed in a risk evaluation for the environment and no relevant metabolites are formed in the environment.

#### Effects assessment on the environment

No new environmental studies have been carried out with the ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3. All data pertaining to the active substance is therefore derived from the hydrogen peroxide assessment report.

Ecotoxicological studies on the active substance were carried out for aquatic organisms and activated sewage sludge. The measured endpoints are summarized in the following table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table of ecotoxicological studies from the hydrogen peroxide assessment report** | | | |
| **Species** | **Time-scale** | **Endpoint** | **Toxicity** |
| **Fish** | | | |
| *Pimephales promelas* | 96 h, semi-static | Mortality, LC50 | 16.4 mg a.s./L |
| **Invertebrates** | | | |
| *Daphnia pulex* (crustaceans) | 48 h, semi-static | Immobility, EC50 | 2.34 mg a.s./L |
| *Daphnia magna* (crustaceans) | 21 d, flow-through | Reproduction, NOEC | 0.63 mg a.s./L |
| **Algae** | | | |
| *Skeletonema costatum* (marine diatom) | 72 h, static | Growth rate, NOEC | 1.69 mg a.s./L |
| **Microorganisms** | | | |
| Activated sewage sludge from sewage treatment plant | 0.5 hours and 3 hours, static | Respiration inhibition, EC50 | 466 mg a.s./l |

Corresponding PNEC values for each environmental compartment were calculated with EUSES 2.1.2. and are indicated in the table hereunder.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on PNEC values** | | | | | | | |
| **PNECSTP** | **PNECwater** | **PNECsed** | **PNECseawater** | **PNECseased** | **PNECsoil** | **Trigger value GW** | **PNECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/ kgwwt] | [g/l] | [mg/m3] |
| 4.66 | 0.0126 | 0.0101 | 0.00126 | 0.00101 | 0.0017 | 0.1 | - |

|  |
| --- |
| Infobox 2 - FR CA :  The PNEC values 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 risk assessment for the sediment has to be carried out.  Moreover concerning the marine compartment, it is considered covered by the assessment of the freshwater compartment.  Concerning the PNEC soil, a slightly different value is indicated in the CAR and will be used for the risk assessment (1.84E-03 mg/kg wwt). |

For the STP and aquatic compartments, PNEC values were derived from the ecotoxicological endpoints reported in the hydrogen peroxide assessment report.

No ecotoxicological data was generated for sediment dewelling and soil organisms as the physico-chemical properties of hydrogen peroxide do not point towards a risk for their corresponding environmental compartments. PNEC values for both these compartments were therefore derived through equilibrium partitioning.

The 0.1 μg/L trigger value for pesticides was applied for the groundwater compartment, as indicated in the Guidance on the BPR. Vol. IV Part B Risk Assessment (2015).

No PNEC value can be derived for the air compartment. However, a typical natural background value for air is available and indicated in the hydrogen peroxide assessment report. Natural background values are also available for surface water and groundwater. This data is useful for a more qualitative assessment of the risk for these compartments.

No data is derived for primary poisoning as product use is not expected to lead to direct exposure of birds and mammals. No secondary poisoning is expected for hydrogen peroxide either. The log Kow is -1.57, indicating that hydrogen peroxide has a negligible potiential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the foodchain is therefore expected.

***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:   |  |  | | --- | --- | | **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 ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3** | | | Value/conclusion | The product is not classified. | |

***Further Ecotoxicological studies***

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

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

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

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

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

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

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

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

|  |
| --- |
| Infobox 9 - FR CA :  No data is available. |

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

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

***Leaching behaviour (ADS)***

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

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

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

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

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

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

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

#### Exposure assessment

The ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is a PT4 biocide used as a disinfectant cleaner for equipment in the food industry and milking parlours. The product can be applied in two different ways:

* by CIP (cleaning in place) in the food-drink-milk industry and in milking parlours: The product is applied in systems, pumps, pipes, closed tanks and closed devices that are in contact with foodstuffs, food and drinking water. Product application takes place in agri-food industries, facilities and equipment used for production / storage / processing / transportation / transformation / marketing of foodstuff. The product is also applied in milking parlours for the disinfection of milking equipment by CIP.
* by spraying in industrial dishwashers: The product is used in professional dishwashers / washing tunnels / washing chambers for the disinfection of small equipment that is in contact with food and foodstuffs in the food industry.

Two different scenarios were selected to cover the various product uses. The two scenarios are detailed in the Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (2011).

* Scenario 1 “Assessment of entire plants” (ESD PT4, p.13): Product use in the food industry by CIP and spraying in industrial dishwashers is assessed via the single scenario “assessment of entire plants” (ESD PT4, p.13). The ESD for this scenario indicates that “disinfection takes place in several different units (e.g. CIP, disinfection of storage tanks by automated spraying/foaming, disinfection of surfaces, membrane filters or bottles etc.) partly simultaneously and often using the same disinfectant. […] A scenario was developed which considers a model food processing plant as local point source. The release of disinfectants from this local point source covers all disinfection processes which take place in the model plant”. The two application processes of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 can both take place in different units of an industrial plant. It is therefore considered for this risk assessment that both methods of product application in the agri-food industry are taken into account when assessing the product use “in an entire plant”.
* Scenario 2 “Disinfection of milking parlour systems” (ESD PT4, p.24): Product use by CIP in milking parlours is assessed via the scenario “disinfection of milking parlour systems” (ESD PT4, p.24).

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 4 |
| Assessed scenarios | Scenario 1: Assessment of entire plants (ESD PT4, p.13)  Scenario 2: Disinfection of milking parlour systems (ESD PT4, p.24) |
| ESD(s) used | Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011 |
| Approach | Scenario 1: Average consumption  Scenario 2: Average consumption |
| Distribution in the environment | Estimated according to :   * Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), April 2015. * Assessment report: Hydrogen peroxide, Product-types 1-6, March 2015 |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1: product use  Scenario 2: product use |
| Remarks | - |

|  |
| --- |
| 1. - FR CA :   We agree with the proposed scenarios. |

***Emission estimation***

**Scenario 1: Assessment of entire plants (ESD PT4, p.13)**

When used in the agri-food industry, ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 can be applied by CIP and by spraying in industrial dishwashers. The waste water produced in the different industrial plant units following the application of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is collected and released to an on-site STP or to the sewer system. The main release pathway of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is therefore to waste water. The local emission of hydrogen peroxide to waste water was calculated using the following input parameters.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario 1: Assessment of entire plants (ESD PT4, p.13)* | | | |
| Amount of biocidal active substance used per year in the local plant [*Qai*] | 191 | kg/y | Default value (average annual amount of active substance (100%) applied for hydrogen peroxide) |
| Number of emission days per year [*Temission*] | 220 | d/y | Product specific value (worst-case value) |
| Fraction released to wastewater [*Fwater*] | 1 | - | Default value (worst-case value) |
| Fraction of substance eliminated due to on-site pre-treatment of the plant waste water [*Felim*] | 0 | - | Default value (worst-case value) |
| Fraction of substance disintegrated during or after application (before release to the sewer system) [*Fdis*] | 0 | - | Default value (worst-case value) |

Calculations for Scenario 1

The ESD PT4 scenario for the assessment of entire plants indicates that the waste water produced in the different industrial plant units will either be released to the communal STP, or will be treated in an on-site STP. As discussed during the pre-submission meeting on 5-9-2016, only the off-site treatment of waste water in the communal STP will be evaluated in this risk assessment as a worst case scenario.

Local emission to waste water (communal STP) [*Elocal*] :

*Elocal = (Qa.i. / Temission) • (1 - Fdis) • (1 – Felim) • Fwater [kg/d]*

= (191 / 220) • (1 – 0) • (1 – 0) • 1

= 0.8681 kg/d

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.868 |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   Please note that the number of emission days per year proposed by the applicant is 220 days instead of 231 days. This value of 220 days is a worst-case approach compared to the default value according to the ESD PT4.  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 revised local emission value is summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 1 (Assessment of entire plants)** | | | **Compartment** | **Elocal [kg/d]** | | STP | 2.08E-02 |   The risk assessment is based on an off-site STP. Please note that the risk assessment for the on-site STP shows no acceptable risk for the aquatic compartment. Therefore application is only allowed when waste water is purified at least biologically before discharge to the environment. |

**Scenario 2: Disinfection of milking parlour systems (ESD PT4, p.24)**

Disinfection of milking parlour systems with ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is carried out by circulating the product in the milking equipment via CIP. The Emission Scenario Document for PT4 indicates that the emissions from use of disinfectants in milking parlour systems will occur mainly to the sewer system and not to the manure pit. Indeed, in the case of bigger farms, milking carousels are directly connected to the sewer system. And in the case of smaller farms, the waste water exiting milking parlours is diverted towards the sewer system in order to avoid a high liquid influx into the manure storage system. The Emission Scenario Document for PT4 also indicates that emissions to air are negligible for this application, so the main release pathway of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 will therefore be to waste water.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Scenario 2 : Disinfection of milking parlour systems (ESD PT4, p.24)* | | | |
| Concentration of active ingredient [*Cform*] | 2.5 | g/l | Product specific value |
| Amount of disinfectant used for cleaning of the milking installation [*Vforminst*] | 130 | l/d | Default value |
| Amount of disinfectant used for cleaning of the milk storage tank [*Vformtank*] | 45 | l/d | Default value |
| Fraction of substance disintegrated during or after application (before release to the sewer system) [*Fdis*] | 0 | - | Default value (worst-case value) |
| Fraction of the emission to waste water [*Fwater*] | 1 | - | Default value (worst-case value) |

Calculations for Scenario 2

Quantity of active ingredient used [*Qai*]:

*Qa.i. = Cform. • (Vforminst + Vformtank) [g/d]*

= 2.5 \* (130 + 45)

= 437.5 g/d

Local emission to waste water [*Elocalwater*]:

*Elocalwater = Qa.i. • (1 - Fdis) • Fwater / 1000 [kg/d]*

= 437.5 / 1000

= 0.437 kg/d

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.437 |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   Please note that the assessment has been performed before the new efficacy study was provided by the applicant which led to a slight decrease of the concentration of the active substance. Therefore, the current assessment is a worst-case approach. As the risk is acceptable for the relevant compartment, the assessment was not modified.  Moreover 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 revised local emission value for the disinfection in institutional areas is summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 2 (Milking parlour)** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 1.05E-02 | |

***Fate and distribution in exposed environmental compartments***

For both scenarios, the primary receiving compartment is the STP. After entering the STP, the active substance will then distribute to the different environmental compartments. The fate and distribution of hydrogen peroxide in the exposed environmental compartments was calculated via EUSES 2.1.

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | + | + | + | + | ++ | + | + | + |  |
| Scenario 2 | + | + | + | + | ++ | + | + | + |  |

*++: direct exposure +: indirect exposure -: no exposure*

Input parameters for calculating the fate and distribution of the active substance in the environment were selected from the hydrogen peroxide assessment report.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 31.04 | g/mol | EUSES set to minimum value: 40 g/mol |
| Melting point | -0.43 | °C |  |
| Boiling point | 150.2 | °C |  |
| Vapour pressure (at 20°C) | 214 | Pa |  |
| Water solubility | Miscible with water in all proportions | mg/l | EUSES set to maximum value: 105 mg/l |
| Log Octanol/water partition coefficient | -1.57 | Log 10 | EUSES set to minimum value: -1 |
| Organic carbon/water partition coefficient (Koc) | 0.2036 | l/kg | EUSES set to minimum value: 1 l/kg |
| Henry’s Law Constant (at 20°C) | 7.5 x 10-4 | Pa/m³/mol |  |
| Biodegradability | Readily biodegradable |  |  |
| BCF earthworm | 0.84 | l/kg |  |
| BCF fish | 1.4 | l/kg |  |
| DT50 for biodegradation in STP | 2 | minutes | EUSES set to minimum value: 0.5545 hours |
| DT50 for biodegradation in surface water | 5 | d (at 12ºC) |  |
| DT50 for degradation in soil | 12 | hr (at 12ºC) | EUSES set to minimum value: 0.99 days |
| DT50 for photolysis in air | 24 | hr |  |
| Use or bypass marine STP | Use marine STP | - | Based on its high levels of degradation in the sewer and in the STP, it is considered that H2O2 will undergo degradation before reaching water compartments. |

|  |
| --- |
| 1. - FR CA :   The input parameters are correct. However according to the CAR of hydrogen peroxide, the QSAR calculated the log Koc of 0.2036 ml/g and Koc of 1.598 ml/g.  Moreover, the DT50 value of 22.8 hours for degradation in soil at 12°C will be considered according to the CAR of the active substance. |

Hydrogen peroxide shows high levels of degradation both in the sewer and in the STP. Data provided in the hydrogen peroxide active substance report Doc IIB indicates a 97.6% reduction in the sewer (based on the publication by Spain J. *et al*, 1989[[18]](#footnote-18)) and a 99.3% removal in the STP by degradation (based on on the study by Groenevel A. and de Groot W., 1999[[19]](#footnote-19)).

In view of these high degradation values, it is considered that the marine STP is not bypassed for product use on industrial plants in coastal areas (scenario 1). Indeed, it is unlikely that waste water effluents in the agri-food industry will not undergo treatment in an STP. This treatment will occur either in a communal STP or in an on-site STP. In the worst case event that the STP is indeed bypassed following the release of waste water to the sewer system, hydrogen peroxide will undergo intense degradation in the sewer, as indicated in the the study by Spain J. *et al*. When used in coastal areas, hydrogen peroxide will therefore degrade before reaching marine waters. For the purpose of simplifying this risk assessment, and considering the similarity of the degradation values in the STP and in the sewer, it is considered that the industrial effluents are all treated in an STP and the degradation values in the STP are applied accordingly.

In the case of product use in milking parlours (scenario 2), it is considered that all waste water is released to the sewer system and will undergo treatment in an STP.

For both scenarios, the default values of active substance fractioning within the STP were readjusted according to the degradation value of 99.3%. The two following tables indicate the percentages of distribution in the STP. The first table lists the default distribution of the active substance in the STP, as calculated by EUSES 2.1. The second table indicates the readjusted fractioning, after applying a degradation percentage of 99.3% and redistributing the remaining fractions accordingly.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP**  **(default values)** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario 2 |
| Air | 1.87 x 10-4 | 1.87 x 10-4 |  |
| Water | 10.4 | 10.4 |  |
| Sludge | 9.37 x 10-3 | 9.37 x 10-3 |  |
| Degraded in STP | 89.6 | 89.6 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP**  **(with 99.3% degradation in the STP)** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario 2 |
| Air | 1.25 x 10-5 | 1.25 x 10-5 |  |
| Water | 0.7 | 0.7 |  |
| Sludge | 6.3 x 10-4 | 6.3 x 10-4 |  |
| Degraded in STP | 99.3 | 99.3 |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   According to the CAR of hydrogen peroxide, the distribution in the STP is slighty different for the air and sludge compartment. The values that should be used in the assessment are presented in the table below:   |  |  |  | | --- | --- | --- | | **Calculated fate and distribution in the STP** | | | | Compartment | Percentage [%] | Remarks | | Air | 0.001 |  | | Water | 0.685 |  | | Sludge | 1.6 x 10-2 |  | | Degraded in STP | 99.3 |  | |

Hydrogen peroxide shows rapid biodegradation in sewage sludge with a DT50 of 2 minutes (at 20°C). The main fraction of active substance is therefore degraded in the STP (99.3% degraded in STP). Because of hydrogen peroxide’s physico-chemical properties, only negligible amounts of the active substance will evaporate to air or partition to solid phases. The 0.7% of active substance remaining in the STP after degradation will therefore mainly fraction to the water phase, and distribute in the aquatic compartments.

The PEC values resulting from the active substance distribution in the environment are indicated in the following table.

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW** | **PECair** |
| [mg/m3] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/m3] | [μg/l] | [mg/m3] |
| Scenario 1 | 3.04 x 10-3 | 3.04 x 10-4 | 2.44 x 10-4 | 3.04 x 10-5 | 2.44 x 10-5 | 4.77 x 10-7 | 5.88 x 10-4 | 8.26 x 10-14 |
| Scenario 2 | 1.53 x 10-3 | 1.53 x 10-4 | 1.23 x 10-4 | 1.53 x 10-5 | 1.23 x 10-5 | 2.4 x 10-7 | 2.96 x 10-4 | 4.46 x 10-14 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   The revised PEC values are summarized in the following table with degradation refinement:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Scenario 1 | 7.14E-05 | 7.14E-06 | 5.83E-06 | 6.20E-06 | 3.12E-04 | | Scenario 2 | 3.60E-05 | 3.60E-06 | 2.94E-06 | 3.13E-06 | 1.57E-04 | |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not likely to occur as the ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for hydrogen peroxide. The log Kow is -1.57, indicating that hydrogen peroxide has a negligible potential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the foodchain is therefore expected.

|  |
| --- |
| 1. - 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 PEC for air was calculated to be 8.26 x 10-14 mg/m³ in the scenario 1 and 4.16 x 10-14 mg/m³ in the scenario 2. No PNEC value exists for the air compartment, however natural background concentrations are available for hydrogen peroxide.

The hydrogen peroxide assessment reports indicates that typical natural background concentrations for air are 0.14-1.4 μg/m3 (0.1-1 ppb), maximum 10 μg/m3 (7 ppb). The PECair calculated for the ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 uses is negligible compared to these background values. No unacceptable risk for the air compartment is therefore expected following the product uses of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3.

|  |
| --- |
| 1. - FR CA :   Emission of hydrogen peroxide to air is considered negligible or not to occur at all. Therefore, no unacceptable risk for the air compartment is expected. |

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

The calculated PEC/PNEC values for the STP compartment are indicated in the following table.

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 6.52 x 10-4 |
| Scenario 2 | 3.28 x 10-4 |

For both scenario 1 and scenario 2, the PEC/PNEC values are < 1 and no unacceptable risk is therefore identified for STP microorganisms.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   The revised PEC/PNEC values for the STP compartment are presented in the following table :   |  |  | | --- | --- | | **Summary table on calculated PEC/PNEC values** | | |  | **PEC/PNECSTP** | | Scenario 1 | 1.53E-05 | | Scenario 2 | 7.72E-06 |   The risk is acceptable for both scenarios. |

***Aquatic compartment***

The calculated PEC/PNEC values for the aquatic compartments and their respective sediment compartments are indicated in the following table.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | 0.0241 | 0.0241 | 0.0241 | 0.0241 |
| Scenario 2 | 0.0121 | 0.0121 | 0.0121 | 0.0121 |

For both scenarios, PEC/PNEC values are <1 for the aquatic compartment. Typical natural background concentrations of hydrogen peroxide in water range from 1 to 30 μg/L (maximum > 100 μg/L), which is a higher value than the PEC measured for the freshwater compartment. No unacceptable risks are identified for the aquatic compartment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   The revised PEC values are summarized in the following table:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values** | | | | | |  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseaded** | | Scenario 1 | 5.66E-04 | Not relevant\* | Not relevant\* | Not relevant\* | | Scenario 2 | 2.85E-04 | Not relevant\* | Not relevant\* | Not relevant\* |   \* Covered by the assessment of the water compartment  For both scenarios, the PEC/PNEC values are < 1 for the aquatic compartment. |

***Terrestrial compartment***

The calculated PEC/PNEC values for the soil compartment are indicated in the following table

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 | 2.8 x 10-4 |
| Scenario 2 | 1.41 x 10-4 |

For both scenarios, PEC/PNEC values are <1 and no unacceptable risks are identified for the soil compartment.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. - FR CA :   The revised PEC values are summarized in the following table:   |  |  | | --- | --- | | **Summary table on calculated PEC values** | | |  | **PEC/PNECsoil** | | Scenario 1 | 3.37E-03 | | Scenario 2 | 1.70E-03 |   For both scenarios, the PEC/PNEC values are < 1 for the soil compartment. |

***Groundwater***

No unacceptable risk is identified for the groundwater compartment as the calculated PECGW of 5.88 x 10-4 μg/L in scenario 1 and 2.96 x 10-4 μg/L in scenario 2is below the EU trigger value of 0.1 μg/L. Furthermore, typical natural background concentrations of hydrogen peroxide in groundwater are 0.7 μg/L, maximum 2.3 μg/L.

|  |
| --- |
| 1. - FR CA :   The calculated PEC groundwater for the scenario 1 and scenario 2 are respectively 3.12 x 10-4 and 1.57 x 10-4 µg/L which are below the EU trigger value of 0.1µg/L. Therefore, there is no unacceptable risk for the groundwater compartment. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not likely to occur as the ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 is intended for an indoor use. No direct exposure of birds or mammals is therefore expected.

Secondary poisoning

No secondary poisoning is expected for hydrogen peroxide. The log Kow is -1.57, indicating that hydrogen peroxide has a negligible potential for bioconcentration in biota. The BCFs for fish and earthworms are 1.4 and 0.84 respectively, indicating that the risk of secondary poisoning for aquatic and terrestrial predators will be negligible. No accumulation of hydrogen peroxide in the food chain is therefore expected.

|  |
| --- |
| 1. - FR CA :   We agree with the conclusion of the primary and secondary poisoning. |

***Mixture toxicity***

Not relevant as the product contains only one active substance and no substance of concern.

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

As indicated in the hydrogen peroxide assessment report, an aggregated risk assessment is not relevant for this substance due to its high reactivity.



|  |
| --- |
| 1. - FR CA :   An aggregated risk assessment is not relevant as all the industrial installations using the biocidal products will not release waste water in the same STP. |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Based on this risk assessment and on available data, no unacceptable risk to the environment has been identified for the ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3, when applied according to the intended uses. |

|  |
| --- |
| 1. - FR CA :   We agree with the overall conclusion on the risk assessment for the environment of the product.  Nevertheless, for the scenario 1 (assessment of entire plants) the risk assessment is based on an off-site STP only (while on-site treatment should also have been assessed). Please note that the risk assessment for the on-site STP shows no acceptable risk for the aquatic compartment. Therefore application is only allowed when waste water is purified at least biologically before discharge to the environment. |

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

**Environment:**

Application is only allowed when waste water is purified at least biologically before discharge to the environment.

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes[[20]](#footnote-20)

## List of studies for the biocidal product (family)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Section No.** | **Author(s)** | **Year** | **Title Source (laboratory) Report No. GLP; (un)published Doc. No.** | **Data**  **Protection (Yes/No)** | **Owner** | **Date of submission** |
|  | Dr E. Servajean | 2018 | FINAL REPORT  Determination of hydroxyl/peroxyl residues from Acide détartrant disinfectant H2O2+HNO3 COM09” after rinsing by soaking and spraying  PHYTOSAFE s.a.r.l  18-35-007-ES  GLP, Unpublished | Yes | GFB Commission 9 | 09/2018 |
|  | Dr E.  Servajean | 2017 | Physical-chemical properties, stability and shelf-life of Acide détartrant désinfectant H2O2 + HNO3 Com09 – Part 1: Physical-chemical properties upon receipt, after cold storage and after accelerated storage 16-35-016-ES GLP, Unpublished | Yes | GFB Commission 9 |  |
|  | Dr E.  Servajean | 2018 | Physical-chemical properties, stability and shelf-life of Acide détartrant disinfectant H2O2 + HNO3 Com09 – Part 2: Shelf-life determination  16-35-016-ES  GLP, Unpublished | Yes | GFB Commission 9 |  |
|  | Shajad Younis | 2017 | Explosive Properties Testing on a Sample of Acide Detartrant Desinfectant H2O2+HNO3 COM09  DEKRA on behalf of Chilworth Technology Limited  Report GLP3016000963R1V1/2017  GLP, Unpublished | Yes | GFB Commission 9 |  |
|  | Peter Neal | 2018 | Differential Scanning Calorimetry Testing on a sample of Acide Detartrant Desinfectant H2O2 + HNO3 COM 09 5% w/w dilution in water  Chilworth Technology Ltd.  GLP3016003239R1V1/2018  GLP; Unpublished | Yes | GFB Commission 9 |  |
|  | W.A. Mak | 2018 | Explosive properties of ACIDE DETARTRANT DESINFECTANT H2O2 + HNO3 COM 09  TNO  060.31886/01.01  Non-GLP; Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2016 | Rapport d'essai - N°RE-1228/1116 RE-1228/1116 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1332/1116  RE-1232/1116  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test report - N°RE-1336/1216 RE-1336/1216 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1346/1216  RE-1346/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1301/1216  RE-1301/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2016 | Rapport d'essai - N°RE-1230/1116 RE-1230/1116 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1231/1116  RE-1231/1116  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1335/1216-1  RE-1335/1216-1  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1347/1216  RE-1347/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1300/1216  RE-1300/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1247/1116  RE-1247/1116  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2016 | Rapport d'essai - N°RE-1227/1116 RE-1227/1116 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1234/1116-1  RE-1234/1116-1  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1335/1116  RE-1235/1116  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2016 | Rapport d'essai - N°RE-1229/1116 RE-1229/1116 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1233/1116-1  RE-1233/1116-1  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1238/1116  RE-1238/1116  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1296/1216  RE-1296/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré P. Strohl | 2017 | Test Report – N°RE-1297/1216  RE-1297/1216  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | F. Paté | 2016 | Requested research: Evaluation of the activity according to NF EN 1040 (april 2006) LDA 67-161013-012599-01 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | F. Paté | 2016 | Recherche(s) demandée(s) LDA67 161013-012599-02 Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | F. Paté | 2017 | Requested research: Evaluation of the activity according to NF EN 14347  LDA 67-161013-012599-03  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2018 | Test Report N°RE-1078/0218  IRM Institut de Recherche Microbiologique  RE-1078/0218  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2018 | Test Report N°RE-2024/0318  IRM Institut de Recherche Microbiologique  RE-2024/0318  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2018 | Test Report N°RE-2025/0318  IRM Institut de Recherche Microbiologique  RE-2025/0318  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2018 | Test Report N°RE-2055/0418  IRM Institut de Recherche Microbiologique  RE-2055/0418  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1263/0517  IRM Institut de Recherche Microbiologique  RE-1263/0517  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1265/0517-1  IRM Institut de Recherche Microbiologique  RE-1265/0517-1  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1264/0517  IRM Institut de Recherche Microbiologique  RE-1264/0517  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1265/0517-2  IRM Institut de Recherche Microbiologique  RE-1265/0517-2  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1359/0817  IRM Institut de Recherche Microbiologique  RE-1359/0817  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1360/0817-2  IRM Institut de Recherche Microbiologique  RE-1360/0817-2  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1358/0817  IRM Institut de Recherche Microbiologique  RE-1358/0817  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré, P. Strohl | 2017 | Test Report N°RE-1360/0817-1  IRM Institut de Recherche Microbiologique  RE-1360/0817-1  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1433/1017  IRM Institut de Recherche Microbiologique  RE-1433/1017  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1435/1017  IRM Institut de Recherche Microbiologique  RE-1435/1017  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1436/1017  IRM Institut de Recherche Microbiologique  RE-1436/1017  Non GLP, Unpublished | Yes | GFB Commission 9 |  |
| 6 | A. Carré | 2017 | Test Report N°RE-1434/1017  IRM Institut de Recherche Microbiologique  RE-1434/1017  Non GLP, Unpublished | Yes | GFB Commission 9 |  |

## Output tables from exposure assessment tools

Consexpo sheet: 

## New information on the active substance

## Residue behaviour

The applicant provided the following study:”*Determination of hydroxyl/peroxyl residues from ACIDE DETARTRANT DISINFECTANT H2O2+HNO3 COM 09 after rinsing by spraying*”. This study was aimed at the determination of hydroxyl/peroxyl residues on different materials previously treated with the test item at 4% v/v in water by soaking or spraying (at 50°C), and then rinsed with tap water by spraying at room temperature.

Two representative scenarios of treatment and rinsing were developped:

- soaking in the treatment solution (4% v/v) for 30 minutes at 50°C and then rinsing: this procedure was tested with inox and polypropylene containers,

- spraying of the test solution (4% v/v) + standing for 30 min at room temperature and then rinsing: the procedure was tested with glass, inox and polypropylene surfaces.

Determination of hydroxyl/peroxyl residues was performed in treatment solution and in solution after rinsing.

1. **Protocol:**
2. For treatment by soaking and rinsing by spraying

The treatment solutions were prepared directly in the containers by adding the required volume of test item and then adding pre-heated water up to volume. 2 types of containers were tested: polypropylene of 1.7 L capacity and inox of 2L, 3L and 5L. A sample of the treatment solution was assessed for hydroxyl/peroxyl radical concentration (two replicate determinations). The filled containers were kept in the climatic chamber at 50°C for 30 minutes. Again a sample was taken for further determination of hydroxyl/peroxyl radical concentration (two replicate determinations). At the end of the period, the pH of the treatment solution was measured, and the containers were emptied.

For rinsing, the empty container was maintained over a large container and tap water was sprayed all over the surface. The volume for each rinse correspond to 1/10 of the container. The receiving container was emptied and the rinsing volume was assessed for pH value and hydroxyl/peroxyl radical concentrations. Four successive rinsing were performed.

1. For treatment by spraying and rinsing by spraying

Before application, small objects of known dimensions (inserts) were placed onto glass plates and were used for further determination of residual hydroxyl/peroxyl radicals. Three materials were selected as representative of the variability of the surfaces on which the product ”ACIDE DETARTRANT DISINFECTANT H2O2+HNO3” can be applied (glass for mineral surfaces, inox for metals and polypropylene (PP) for plastic polymers). After placing inserts on plates, the test item was evenly sprayed onto 20x20 cm glass plates. Application rate of test item was of 200 mL/m2. The application rate was checked by weighing.

The spray deposit on the glass plate was used for further determination of the pH value and hydroxyl/peroxyl radical concentration in the draining volume. The other inserts were allowed to stand for 30 minutes at room temperature. Care was taken to avoid evaporation of the spray deposit during the period.

To be noted that: prelimininary test were performed at 50°C for the standing period: the treated glass plates and the inserts were maintained for 30 minutes in the climatic chamber at 50°C. The results showed that the spray deposit had dried. In the actual conditions of use, the treatment is continuoulsy in contact with the surfaces without drying. Furthermore, no information is available as referred to the stability of hydroxyl/peroxyl radicals through drying. Thus the procedure was changed and the standing period was performed at room temperature in order to avoid drying. This was considered as a worst case scenario.

At the end of the period, the inserts and the glass plate were dimantled and placed vertically for a few minutes so as to allow draining of the deposit. The draining solution was sampled for further assessment of pH value and hydroxyl/peroxyl radical concentration. The inserts were placed back onto the glass plate and then rinsed by spraying tap water at 200 mL/m2. Again the rinsing solution was sampled for further assessment of pH value and hydroxyl/peroxyl radical concentration. Four successive rinsing were performed.

1. **Results:**
2. Soaking/rinsing procedure:

The verification of the treatment applications showed that 2248 mg H2O2/Lwas recovered in every case in the test solutions soon after treatment: the measured concentrations ranged between 86% and 133% of the nominal value.

Recoveries of more than 100% were observed for the inox containers soon after the treatment and then 30 minutes of standing. The hypothesis was that the exceeding part was to be attributed to peroxyl radicals which formed in contact with the inox surfaces.

The pH value of the drained volume after 30 minutes was 0 in every case. The pH was restored to 7 in the first rinsing volume and then remained at the same value in the subsequent volumes.

The measured concentrations for hydroxyl/peroxyl radicals are presented in table below:

**Table: Measured hydroxyl/peroxyl radicals (mg/L) in the test solution and in the rinsing solution**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Residue results** | | **Polypropylene (PP)** | | | | | **Inox** | | | | |
| **Replicate 1** | **Replicate 2** | **Replicate 3** | **Mean** | **Median** | **Inox 2L** | **Inox 3L** | **Inox 5L** | **Mean** | **Median** |
| **After product application** | Initial (mg H2O2/L) | 2157.58 | 1921.02 | 2198.19 | 2092.26 | 2157.58 | 2345.94 | 2564.25 | 2329.92 | 2413.37 | 2345.94 |
| after 30 minutes (mg H2O2/L) | 2345.94 | 2564.25 | 2329.92 | 2413.37 | 2345.94 | 2372.49 | 2567.98 | 2584.13 | 2508.20 | 2567.98 |
| **After rinsing** | Rinsing 1 (mg H2O2/L) | 5.16 | 5.14 | 5.84 | 5.38 | 5.16 | 7.47 | 7.26 | 4.56 | 6.43 | 7.26 |
| Rinsing 2 (mg H2O2/L) | 0.17 | 0.19 | 0.20 | 0.19 | 0.19 | 0.17 | 0.13 | 0.11 | 0.13 | 0.13 |
| Rinsing 3 (mg H2O2/L) | 0.06 | 0.06 | 0.06 | 0.06 | 0.06 | 0.10 | 0.03 | 0.02 | 0.05 | 0.03 |
| Rinsing 4 (mg H2O2/L) | 0.08 | 0.07 | 0.05 | 0.07 | 0.07 | 0.16 | 0.09 | 0.02 | 0.09 | 0.09 |

1. Spraying/rinsing procedure:

The verification of the treatment applications showed that nominal value of 2248 mg H2O2/L was recovered in every case in the test solutions soon after treatment: the measured concentrations ranged between 73% and 78% of the nominal value. Recovery values still remained after 30 minutes of standing, without sign of peroxyl radical formation.

The pH values for the initial test treatments and for the drained volumes after 30 minutes were 0 in every case. In the rinsing solution 1, pH was of 2 or 3 and the pH was restored to 7 in the second and third rinsing volume respectively for glass, inox surface and for polypropylene surface.

The measured concentrations for hydroxyl/peroxyl radicals are presented in table below:

**Table: Measured hydroxyl/peroxyl radicals (mg/L) in the test solution and in the rinsing solution**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Residue results** | | **Glass** | | | | | **Inox** | | | | | **Polypropylene** | | | | |
| **Rep 1** | **Rep 2** | **Rep 3** | **Mean** | **Median** | **Rep 1** | **Rep 2** | **Rep 3** | **Mean** | **Median** | **Rep 1** | **Rep 2** | **Rep 3** | **Mean** | **Median** |
| **After product application** | Initial (mg H2O2/L) | 1635.51 | 1741.52 | - | 1688.51 | 1688.51 | 1759.65 | 1728.62 | - | 1744.13 | 1744.13 | 1707.69 | 1725.02 | - | 1716.36 | 1716.36 |
| after 30 minutes (mg H2O2/L) | 1845.41 | 1846.62 | - | 1846.01 | 1846.01 | 1777.19 | 1720.53 | - | 1748.86 | 1748.86 | 1842.11 | 1804.63 | - | 1823.37 | 1823.37 |
| **After rinsing** | Rinsing 1 (mg H2O2/L) | 120.06 | 64.07 | 43.62 | 75.91 | 64.07 | 96.64 | 140.98 | 166.63 | 134.75 | 140.98 | 136.65 | 200.93 | 139.84 | 159.14 | 139.84 |
| Rinsing 2 (mg H2O2/L) | 3.47 | 1.34 | 21.25 | 8.69 | 3.47 | 16.96 | 13.45 | 21.62 | 17.34 | 16.96 | 7.44 | 3.19 | 6.23 | 5.62 | 6.23 |
| Rinsing 3 (mg H2O2/L) | 0.99 | 0.56 | 0.81 | 0.79 | 0.81 | 1.46 | 1.13 | 1.07 | 1.22 | 1.13 | 0.35 | 0.27 | 0.32 | 0.31 | 0.32 |
| Rinsing 4 (mg H2O2/L) | 0.40 | 0.39 | 0.42 | 0.40 | 0.40 | 0.42 | 0.34 | 0.28 | 0.35 | 0.34 | 0.16 | 0.16 | 0.17 | 0.16 | 0.16 |

1. **Conclusion**

This study was aimed at the determination of residues for ACIDE DETARTRANT DISINFECTANT H2O2+HNO3on different materials previously treated with the test item at 4% v/v in water under representative scenario of treatment application (soaking or spraying at 50°C). The treated surfaces were then rinsed by spraying of tap water, 1/10 volume of the soaked containers or 200 mL/m2 for the surfaces treated by spraying.Through hydroxyl/peroxyl residues determination, it can be estimated potential DBP quantity. Through pH determination, it can be estimated ”acid” residues quantity.

After container treatment by soaking and then container rinsing by spray, hydroxyl/peroxyl residues were always:

- lower than 0.08 mg H2O2/l (mean value of 0.05 mg H2O2/l) after the fourth rinsing volume for polypropylene surfaces.

- lower than 0.16 mg H2O2/l (mean value of 0.09 mg H2O2/l) after the fourth rinsing volume for inox surfaces.

After spray surface treatment and then surface rinsing by spray, hydroxyl/peroxyl residues were always:

- lower than 0.42 mg H2O2/l (mean value of 0.40 mg H2O2/l) after the fourth rinsing volume for glass surfaces.

- lower than 0.42 mg H2O2/l (mean value of 0.35 mg H2O2/l) after the fourth rinsing volume for inox surfaces

- lower than 0.17 mg H2O2/l (mean value of 0.06 mg H2O2/l) after the fourth rinsing volume for polypropylene surfaces.

Moreover, as pH was restored at 7 after rinsing, no “acid” residues are expected in rinsing water.

## Summaries of the efficacy studies (B.5.10.1-xx)

See IUCLID files

## Confidential annex

## Other

1. [↑](#footnote-ref-1)
2. MARTIN H., MARIS P., JEHANNIN G., RAULT A. and FRESNEL R. (2005). An assessment of the bactericidal and fungicidal efficacy of seventeen mineral and organic acids on bacterial and fungal food industry contaminants. Sciences des aliments, 25, 105-127. [↑](#footnote-ref-2)
3. 11 https://echa.europa.eu/fr/about-us/who-we-are/biocidal-products-committee/working-groups [↑](#footnote-ref-3)
4. MARTIN H., MARIS P., JEHANNIN G., RAULT A. and FRESNEL R. (2005). An assessment of the bactericidal and fungicidal efficacy of seventeen mineral and organic acids on bacterial and fungal food industry contaminants. Sciences des aliments, 25, 105-127. [↑](#footnote-ref-4)
5. Hypochlorous Acid Stress in *Escherichia coli*: Resistance, DNA Damage, and Comparison with Hydrogen Peroxide Stress [↑](#footnote-ref-5)
6. Positive Control of a Regulon for Defenses against Oxidative Stress and Some Heat-Shock Proteins in *Salmonella* Typhimurium [↑](#footnote-ref-6)
7. Gestis database: <http://limitvalue.ifa.dguv.de/> [↑](#footnote-ref-7)
8. Recommendation 6 - Methods and models to assess exposure to biocidal products in different product types, Version 3, 2017 [↑](#footnote-ref-8)
9. Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products [↑](#footnote-ref-9)
10. Recommendation 14 - Default human factor values for use in exposure assessments for biocidal products [↑](#footnote-ref-10)
11. ECHA (European Chemicals Agency) - Guidance on the Biocidal Products Regulation – Volume V, guidance on disinfection by-products – Version 1.0 – January 2017. [↑](#footnote-ref-11)
12. EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2014. Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat. EFSA Journal 2014;12(3):3599, 60 pp. doi:10.2903/j.efsa.2014.3599 [↑](#footnote-ref-12)
13. Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress – Official Journal of The European Union - L 283/36 [↑](#footnote-ref-13)
14. Arrêté du 19 octobre 2006 relatif à l'emploi d'auxiliaires technologiques dans la fabrication de certaines denrées alimentaires [↑](#footnote-ref-14)
15. Arrêté du 8 septembre 1999 pris pour l'application de l'article 11 du décret no 73-138 du 12 février 1973 modifié portant application de la loi du 1er août 1905 sur les fraudes et falsifications en ce qui concerne les procédés et les produits utilisés pour le nettoyage des matériaux et objets destinés à entrer en contact avec des denrées, produits et boissons pour l'alimentation de l'homme et des animaux [↑](#footnote-ref-15)
16. Community workplace exposure limits has been identified from Gestis database: <http://limitvalue.ifa.dguv.de/> [↑](#footnote-ref-16)
17. Guidance on the Biocidal Products Regulation ,Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0 December 2017 [↑](#footnote-ref-17)
18. Spain JC, Milligan JD, Downey DC and Slaughter JK (1989), Excessive bacterial decomposition of H2O2 during enhanced biodegradation. Groundwater 27, 163-167. [↑](#footnote-ref-18)
19. Groeneveld AHC and de Groot WA (1999), Activated sludge, respiration inhibition test with hydrogen peroxide. Solvay Pharmaceuticals. A.SOL.S.003. [↑](#footnote-ref-19)
20. 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-20)