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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR MINOR CHANGE APPLICATION OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



SANYTOL FRESH

Product type(s) 2, 4

Hydrogen peroxide

NA-APP Case Number: BC-XF029273-37

NA-MIC Case Number: BC-KB061210-70

Evaluating Competent Authority: FR

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**Note to the reader:**

This consolidated PAR, for the minor change change application of biocidal product family SANYTOL FRESH authorisation, is based on the PAR of the first authorisation, granted by FR on 2020.

In part 2.1. of the consolidated PAR the “Summary of the product assessment” corresponds to the summary of the product characteristics (SPC) proposed for the minor chage application.

In part 2.2. and 3 of this consolidated PAR:

* the assessments related to the minor change of the biocidal product family are at the end of each section and are highlighted in grey.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-XF029273-37 | 21/04/2020 | National authorisation |
| NA-MIC | *FR* | BC-KB061210-70 | 22/04/2022 | Minor change application of a national authorisation:   * addition of the activity against enveloped virus (including *Coronavirus E229E*, *SARS COV2, Influenza A* H1N1, *Herpes simplex virus type 1*), * addition of “pouring and wiping” application method and new packaging for meta-SPC2 use, * submission of requested post-authorisation data. |

# CONCLUSION

SANYTOL FRESH containing hydrogen peroxide is a PT2 and TP4 biocidal product family with 3 meta SPCs, currently authorised for the disinfection of hard surfaces and /or textiles in commercial premises (food, industrial and institutional areas) and households / private areas (domestic areas), against bacteria, yeasts and fungi. The products of the SANYTOL FRESH family are applied by professional and non-professional users, and according to the case, through:

* manual spaying (meta SPC 1 and 2),
* manual spraying and wiping (meta SPC 1 and 2),
* pouring and wiping (meta SPC 3).
* **Minor Change (2021)**

The minor change application for the biocidal product family SANYTOL FRESH concerns the addition of the activity against enveloped virus (including *Coronavirus E229E*, *SARS COV2, Influenza A* H1N1 and *Herpes simplex virus type 1*), the addition of pouring and wiping application methods as well as new packaging for the use of meta-SPC2, and the submission of requested post-approval data (long-term storage stability studies, acidity and metal corrosion test studies for the biocidal product family).

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

Regarding the physico-chemical properties for the family product SANYTOL FRESH, all studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of products from meta SPC 1 and meta SPC 3 is a blue transparent liquid moderately perfumed. There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature (protect from frost) when stored in trigger spray PE bottle (commercial packaging material). The long-term storage stability study is on-going.

For the meta SPC 2, the appearance of the products is a liquid colourless. There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature (do not store at temperatures above 35°C and protect from frost) when stored in trigger spray PE bottle (commercial packaging material). The long-term storage stability study is on-going.

The analytical methods for meta SPC 1, meta SPC 2 and meta SPC 3 are fully validated.

Data required for meta SPC 1, meta SPC 2 and meta SPC 3: The studies of long term storage stability, acidity of the product and test for corrosion to metal UN Test C.1 should be provided within two years at post-authorisation.

Implication concerning labelling:

Protect from frost

Protect from light

For meta SPC 2: do not store at temperature above 35°C.

* **Minor Change (2021)**

**Post-Authorization data and minor change dossier:**

Regarding the physico-chemical properties for the family product SANYTOL FRESH, all studies have been performed in accordance with the current requirements and the results are deemed acceptable.

Acidity was prodided on all META SPC (0.245% w/w HCl for META SPC 1&3 and 0.273% w/w HCl for META SPC 2).

New long term storage studies were provided. The stability data indicate a shelf life of 2 years at ambient temperature when stored in HDPE bottle packaging material (commercial packaging material with trigger). Sprayer properties change significantly after 3 years storage, therefore, the shelf-life is kept at 2 years.

**Shelf life: 2 years**

Corrosion to metal test was provided. The products of BPF SANYTOL FRESH are classified **H290 – Mays be corrosive to metals.**

**Conclusion on Efficacy**

French competent authorities (FR CA) assessed that the products of the family SANYTOL FRESH, separated in 3 META-SPC, have shown a sufficient efficacy in accordance with the requirements of the transitional Guidance on Efficacy for product type PT1-5, Disinfectants (2016) for the following uses:

META SPC1

* Use 1, PT2 and 4 hard surface disinfection, by manual spraying or by manual spraying and wiping (100 % v/v) against bacteria with a contact time of 5 minutes and, against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.
* Use 2, PT2 soft surface disinfection, by manual spraying (100 % v/v) against bacteria, yeasts and fungi, with a contact time of 45 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

META SPC 2

* Use 1, PT2 and 4 hard surface disinfection, by manual spraying, by manual spraying and wiping, and by manual pouring and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

META SPC 3

* Use 1, PT2 and 4 hard surface disinfection, by manual pouring and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

Regarding the virucidal activity claimed for all uses under META SPC 1, 2 and 3, tests against only enveloped viruses were performed. However, according to the requirements of EN 14476+A1:2015 norm, efficacy of products intended to be used against viruses in PT2 and 4 should be proven against both enveloped and non-enveloped viruses.

Efficacy against virus of products of the SANYTOL FRESH BPF is thus not validated.

* **Minor Change (2021)**

With regard to the addition mode of application of pouring and wiping for META-SP2, this is covered by the efficacy data submitted for the first authorisation.

Virucidal activity against respectively enveloped virus (including *Coronavirus E229E* and *SARS COV2*, influenza A and *Herpes simplex virus type 1)* has been demonstrated for Meta SPC1 and 3, and against enveloped virus (including *Coronavirus E229E* and *SARS COV2)* has been demonstrated for Meta SPC2*,* with a contact time of 5 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

**Conclusion on risk assessment for human health**

The risk is considered acceptable for professionals for product application by spraying and pouring.

For spray application, due to the classification of products, facial exposure to generated aerosols has to be limited by the use of PPE (goggles) and application of technical and organisational RMMs.

The risk is considered acceptable for non-professionals for product application by spraying and pouring. In order to minimize any facial exposure, the spray application should be done downward.

**Conclusion on risk for consumers via residues**

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

Regarding PT 4 uses, considering properties of lactic acid, ethanol and hydrogen peroxide, no significant exposure via food is expected. Based on the low concentration of hydrogen peroxide and the authorised uses of this active substance in other regulated areas (PPP and technological aid in France), significant indirect exposure via Disinfection By Products in food is not expected.

**Conclusion on risk assessment for the environment**

The products of SANYTOL FRESH BPF contain two substances of concern for the environment (L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide).

Following the application of products of SANYTOL FRESH BPF,

* levels of exposure for non-target species of aquatic (surface water and sediment) and terrestrial compartments are lower than the reference values of the active substance and substances of concern.
* Concentrations of hydrogen peroxide and 1-Decanamine, N,N-dimethyl, N-oxide in groundwater are also lower than the threshold value set by Directive 98/83/EC.
* Whereas, concentrations of the substance of concern L(+) Lactic acid in groundwater are higher than the threshold value set by Directive 98/83/EC.

Nonetheless, as reported in the opinion of the BPC for approval of the active substance L(+) lactic acid for product type 2 and 4: “the current assessment of the biodegradation behaviour in soil of lactic acid is most likely too conservative: based on the information submitted in the application a default degradation half-live of 90 days was estimated. Additional information obtained via a literature search shows that in reality the degradation half-life may be lower.”

In this framework, additional data to refine the groundwater risk assessment may be required for authorisations of L(+) lactic acid-based biocidal products. However, in the case of SANYTOL FRESH, the L(+) lactic acid is not a biocide active substance but a co-formulant. Quantitative refinement is not possible based on up-to-date aivailable data presented in the doc II-B of the CAR of L-(+) lactic acid*.*

It should be noted that concentration of L(+) lactic acid in the groundwater are all below 0.1 µg/L when considering a degradation half-live of 30 days.

In the absence of validated refined reference values for L(+) lactic degradation half-live, the assessment of estimated concentrations of L(+) lactic acid in groundwater cannot be refined. However, given the highly conservative hypothesis for estimatiing concentrations in soil, risk for groundwater is not considered as unacceptable.

**Overall conclusion : Update 2021**

FR CA considers that authorisation can be granted for SANYTOL FRESH BPF with 3 meta SPCs, intended for the disinfection of hard surfaces and /or textiles in commercial premises (food, industrial and institutional areas) and households / private areas (domestic areas), against bacteria, yeasts,fungi and Enveloped virus (including *H1N1, Herpes simplex virus type 1*, *Coronavirus E229E* and *SARS COV2*). The products of the SANYTOL FRESH family can be applied by professional and non-professional users through:

* manual spaying (meta SPC 1 and 2),
* manual spraying and wiping (meta SPC 1 and 2),
* pouring and wiping (meta SPC 3).
* manual pouring and wiping (meta SPC2 and 3)

Risk mitigation measures have to be implemented.

Some of SANYTOL FRESH BPF product names directly refer to odor destructor efficacy, which is not in line with efficacy claims. In accordance with article 69.3, those names cannot be accepted for authorisation.

Some SANYTOL FRESH BPF product names refer to anti-allergen property, which is considered as misleading considering that the product is a disinfectant. In accordance with article 69.2 and 72.3, those names cannot be accepted for authorisation.

|  |  |  |
| --- | --- | --- |
| **Meta SPC** | **Target organism** | **Conditions of use** |
| **1** | Bacteria  Yeasts  Fungi  Enveloped virus (including *H1N1, Herpes simplex virus type 1*, *Coronavirus E229E* and *SARS COV2*) | TP2 and TP4 disinfection of hard surfaces by manual spray application, with or without wiping.  TP2 and TP4 disinfection of textile surfaces, by manual spray application. |
| **2** | Bacteria  Yeasts  Fungi  Enveloped virus (including *Coronavirus E229E* and *SARS COV2)* | TP2 and TP4 disinfection of hard surfaces by manual spraying application, with or without wiping, or by manual pouring and wiping. |
| **3** | Bacteria  Yeasts  Fungi  Enveloped virus (including *H1N1, Herpes simplex virus type 1*, *Coronavirus E229E* and *SARS COV2*) | TP2 and TP4 disinfection of hard surfaces by pouring and wiping application. |

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| SANYTOL FRESH | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | GRUPO AC MARCA S.L. |
| **Address** | Avda Carrilet 293-297  08907 L’Hospitalet de Llobregat  Barcelona – Spain |
| **Authorisation number** | **FR-2020-0018** | |
| **Date of the authorisation** | **21/04/2020** | |
| **Expiry date of the authorisation** | **20/04/2030** | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | GRUPO AC MARCA S.L. |
| **Address of manufacturer** | Avda Carrilet 293-297  08907 L’Hospitalet de Llobregat  Barcelona – Spain |
| **Location of manufacturing sites** | 1. Polígono Industrial Can Serra III, Parcela I   08791 Sant Llorenç d’Hortons  Barcelona – Spain   1. Polígono Industrial Can Barri. C/ Esqueis S/N   08415 Bigues i Riells  Barcelona – Spain   1. Jana Čermáka 124   282 01 Přišimasy,  Czech Republic |

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

|  |  |
| --- | --- |
| **Active substance** | Hydrogen Peroxide (H2O2) |
| **Name of manufacturer** | PeroxyChem Spain s.l.u |
| **Address of manufacturer** | C/ Afueras s/n  50784 La Zaida  Zaragoza - Spain |
| **Location of manufacturing sites** | C/ Afueras s/n  50784 La Zaida  Zaragoza - Spain |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Hydrogen peroxide |
| **IUPAC or EC name** | Hydrogen peroxide |
| **EC number** | 231-765-0 |
| **CAS number** | 7722-84-1 |
| **Index number in Annex VI of CLP** | 008-003-00-9 |
| **Minimum purity / content** | Hydrogen peroxide is always directly produced as an aqueous solution and these aqueous solutions of hydrogen peroxide range from 35 % to <70 % (by wt). Min purity on a calculated dry weight basis is ca 99.5% Detailed specification of the content of hydrogen peroxide in the Confidential Doc A2.\* |
| **Structural formula** |  |

#### Candidate(s) for substitution

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

#### Qualitative and quantitative information on the composition of the biocidal product family

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Hydrogen peroxide | Hydrogen peroxide | active substance | 7722-84-1 | 231-765-0 | 1.5 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 | 0.96 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | [D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.](https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.231.802) | Co-formulant | - | 940-284-1 | 0.00 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

#### Information on technical equivalence

GRUPO AC MARCA has access to data on the active substance hydrogen peroxide.

Source: PeroxyChem Spain, S.L.U.

Manufacturer Adress:C/Afueras s/no, La Zaida 5078 Saragosse Spain

Location site: PeroxyChem Bayport Plant – 1200 Bay Area Blvd, TX 77507 Pasadena USA

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

SANYTOL FRESH product family contains five substances of concern:

* L-(+)-lactic acid;
* 1-Decanamine, N,N-dimethyl, N-oxide;
* Ethanol;
* D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides;
* 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol.

#### Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products

According to our assessment, none of the co-formulants contained in the product of SANYTOL FRESH are regulatory identified as endocrine disruptors. However, some co-formulants are currently being evaluated in the frame of REACH for their potential ED properties.

In addition, based on screening, several co-formulants show indications of endocrine activity and this should be further assessed in the frame of REACH Regulation.

Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### Type of formulation

|  |
| --- |
| AL (any other liquid) ready-to-use |

**Part II - Second information level - meta SPC 1**

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 1 |
| --- | --- |

#### Suffix to the authorisation number

| **Number 1** |  |
| --- | --- |

#### Product type (s)

| **Product type(s)** | PT2, 4 |
| --- | --- |

### Meta SPC 1 composition

#### Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Hydrogen peroxide | Hydrogen peroxide | active substance  \* | 7722-84-1 | 231-765-0 | 1.5 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-frmulant | 79-33-4 | 201-196-2 | 0.49 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.67 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

#### Type(s) of formulation of the meta SPC 1

|  |
| --- |
| AL (any other liquid) ready-to-use |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  Met Corr 1 |
| Hazard statement | H319: Causes serious eye irritation  H290: May be corrosive to metals |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation  H290: May be corrosive to metals |
| Precautionary statements | P101\*: If medical advice is needed, have product container or label at hand.  P102\*: Keep out of reach of children.  P103\*: Read label before use.  P234: Keep only in original packaging.  P264: Wash… thoroughly after handling.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.  P337 + P313: If eye irritation persists get medical advice/attention.  P390: Absorb spillage to prevent material damage. |
| \*For non professional users | |
| Note |  |

### Authorised use(s) fort he META SPC 1

#### Use description

Table 1. Use # 1 – Hard surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Hard surface |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi  Enveloped virus |
| **Field of use** | Indoor use.  To be used in Commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas) |
| **Application method(s)** | Manual spraying  Manual spraying and wiping |
| **Application rate(s) and frequency** | Ready to use  Contact time:  Bacteria and enveloped virus : 5 min  Fungi and yeasts: 15 min  Temperature: 20°C |
| **Category(ies) of users** | Non-professional and professional |
| **Pack sizes and packaging material** | HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL  HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL |

#### Use-specific instructions for use

|  |
| --- |
| * Manual spray and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and virucidal efficacy and, for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry. * Manual spray on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and virucidal efficacy and, for 15 minutes for yeasticidal and fungicidal efficacy. Let the surface dry. |

#### 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

|  |
| --- |
| - |

#### Use description

Table 2. Use # 2 – Soft surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Soft surface |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi  Enveloped virus |
| **Field of use** | Indoor use.  To be used in commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas) |
| **Application method(s)** | Manual spraying |
| **Application rate(s) and frequency** | Ready to use  Contact time:  Bacteria, yeasts, fungi and enveloped virus : 45 minutes  Temperature: 20°C |
| **Category(ies) of users** | Non-professional and professional |
| **Pack sizes and packaging material** | HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL  HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL |

#### Use-specific instructions for use

|  |
| --- |
| * Manual spray on soft surfaces: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 45 minutes. Let the surface dry. |

#### 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

|  |
| --- |
| - |

### General directions for use of the meta SPC 1

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Products have been tested against enveloped virus, including the strains *Coronavirus 229E* and *SARS COV2* (representative strain of Coronavirus outbreak), *influenza A* (representative strain of Influenza H1N1 outbreak) and *Herpes simplex virus type 1* (representative strain of orofacial herpes).   **For professionals users:**   * Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| **For professional users:**  During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:   * Minimisation of splashes and spills; * Downward spray application in order to avoid any facial exposure; * Minimise number of staff exposed. * PPE for the spraying phase are as following: * Eye protection.   **For non-professional users:**  The spray application should be done downward in order to avoid any facial exposure. |

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

|  |
| --- |
| * Inhalation (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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and 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. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * 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 years. * Protect from frost and light. * Keep away from children and pets. |

### Other information

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

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[2]](#footnote-3)** | SANYTOL DESINFECTANT MULTI-USAGE EUCALYPTUS FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-01** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[3]](#footnote-4)** | SANYTOL DESINFECTANT MULTI-USAGE PAMPLEMOUSSE FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-02** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[4]](#footnote-5)** | SANYTOL DESINFECTANT MULTI-USAGE PIN FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-03** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[5]](#footnote-6)** | SANYTOL DESINFECTANT MULTI-USAGE NEUTRAL FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-04** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[6]](#footnote-7)** | SANYTOL DESINFECTANT MULTI-USAGE POMME FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-05** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[7]](#footnote-8)** | SANYTOL DESINFECTANT MULTI-USAGE GRAND AIR FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-06** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-ormulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[8]](#footnote-9)** | SANYTOL NETTOYANT DESINFECTANT SALLE DE BAINS FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-07** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[9]](#footnote-10)** | SANYTOL DESINFECTANT ODEUR FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-08** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[10]](#footnote-11)** | SANYTOL DESODORISANT DESINFECTANT SPECIAL TEXTILE FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-09** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[11]](#footnote-12)** | SANYTOL DÉSINFECTANT TEXTILE NEUTRAL FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-01-10** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[12]](#footnote-13)** | SANYTOL DESINFECTANT MULTI-USAGE FRESH EUCALYPTUS PROFESSIONNEL | | | | |
| **Authorisation number** | **FR-2020-0018-01-11** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[13]](#footnote-14)** | SANYTOL NETTOYANT DESINFECTANT SANITAIRES FRESH PROFESSIONNEL | | | | |
| **Authorisation number** | FR-2020-0018-01-12 | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

**Part IV - Second information level - meta SPC 2**

### Meta SPC 2 administrative information

#### Meta SPC identifier

| **Identification** | Meta SPC 2 |
| --- | --- |

#### Suffix to the authorisation number

| Number 2 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT2, 4 |
| --- | --- |

### Meta SPC 2 composition

#### Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 | 2.88 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 | 0.275 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.50 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 | 0.60 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.1 | Co-formulant | - | 940-284-1 | 0.50 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

#### Type(s) of formulation of the meta SPC 2

|  |
| --- |
| AL (any other liquid) ready-to-use |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  Met Corr 1 |
| Hazard statement | H319: Causes serious eye irritation  H290: May be corrosive to metals |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation  H290: May be corrosive to metals |
| Precautionary statements | P101\*: If medical advice is needed, have product container or label at hand.  P102\*: Keep out of reach of children.  P103\*: Read label before use  P234: Keep only in original packaging.  P264: Wash… thoroughly after handling  P280: Wear protective gloves/protective clothing/eye protection/face protection  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.  P337 + P313: If eye irritation persists get medical advice/attention  P390: Absorb spillage to prevent material damage. |
| \*For non professional users | |
| Note |  |

### Authorised use(s) fort he META SPC 2

#### Use description

Table 3. Use # 1 – Hard surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Hard surface |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi  Enveloped virus |
| **Field of use** | Indoor use.  To be used in Commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas) |
| **Application method(s)** | Manual spraying  Manual spraying and wiping  Manual pouring and wiping |
| **Application rate(s) and frequency** | Ready to use  Contact time:  Bacteria and enveloped virus: 5 minutes  Fungi and yeasts: 15 min  Temperature: 20°C |
| **Category(ies) of users** | Non-professional and professional |
| **Pack sizes and packaging material** | HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL  HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL  HDPE bottle: 750, 1000, 1200, 1500, 2000 mL  HDPE can: 5000 mL  Multi-layer PET/PE doy pack: 70, 140 mL |

#### Use-specific instructions for use

|  |
| --- |
| * Manual spray/pouring and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and virucidal efficacy and, for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry. * Manual spray on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and virucidal efficacy and, for 15 minutes for yeasticidal and fungicidal efficacy. Let the surface dry. |

#### 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

|  |
| --- |
| - |

### General directions for use of the meta SPC 2

#### Instructions for use

|  |
| --- |
| - Always read the label or leaflet before use and respect all the instructions provided.   * Products have been tested against enveloped virus, including the strains *Coronavirus 229E* and *SARS COV2* (representative strain of Coronavirus outbreak).   **For professionals users:**  - Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| **For professional users:**  During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:   * Minimisation of splashes and spills; * Downward spray application in order to avoid any facial exposure; * Minimise number of staff exposed. * PPE for the spraying phase are as following: * Eye protection.   **For non-professional users:**  The spray application should be done downward in order to avoid any facial exposure. |

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

|  |
| --- |
| * Inhalation (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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and 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. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * 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 years. * Protect from frost and light. * Do not store at temperature above 35°C. * Keep away from children and pets. |

### Other information

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

**PART V - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[14]](#footnote-15)** | SANYTOL DESINFECTANT CUISINE FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-02-01** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hydrogen peroxide |  |  |  |  | | Hydrogen peroxide | Active substance\* | |  |  |  | | --- | --- | --- | | 7722-84-1 |  |  | | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.11- | Co-formulant | - | 940-284-1 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[15]](#footnote-16)** | SANYTOL NETTOYANT DESINFECTANT 4 ACTIONS FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-02-02** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hydrogen peroxide |  |  |  |  | | Hydrogen peroxide | Active substance\* | |  |  |  | | --- | --- | --- | | 7722-84-1 |  |  | | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.11- | Co-formulant | - | 940-284-1 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[16]](#footnote-17)** | SANYTOL DESINFECTANT CUISINE FRESH PROFESSIONNEL | | | | |
| **Authorisation number** | **FR-2020-0018-02-03** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hydrogen peroxide |  |  |  |  | | Hydrogen peroxide | Active substance\* | |  |  |  | | --- | --- | --- | | 7722-84-1 |  |  | | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.11- | Co-formulant | - | 940-284-1 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[17]](#footnote-18)** | SANYTOL NETTOYANT DESINFECTANT 4 ACTIONS FRESH PROFESSIONNEL | | | | |
| **Authorisation number** | **FR-2020-0018-02-04** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Hydrogen peroxide |  |  |  |  | | Hydrogen peroxide | Active substance\* | |  |  |  | | --- | --- | --- | | 7722-84-1 |  |  | | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 2.88 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.275 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.50 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.42 |
| 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol | D-Glucitol, 1-deoxy-1-(methylamino)-, N-[C8-10(even numbered) acyl] derivs.11- | Co-formulant | - | 940-284-1 | 0.50 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

**Part VI - Second information level - meta SPC 3**

### Meta SPC 3 administrative information

#### Meta SPC identifier

| **Identification** | Meta SPC 3 |
| --- | --- |

#### Suffix to the authorisation number

| Number 3 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | PT 2,4 |
| --- | --- |

### Meta SPC 3 composition

#### Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.67 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

#### Type(s) of formulation of the meta SPC 3

|  |
| --- |
| AL (any other liquid) ready-to-use |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  Met Corr 1 |
| Hazard statement | H319: Causes serious eye irritation  H290: May be corrosive to metals |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation  H290: May be corrosive to metals |
| Precautionary statements | P101\*: If medical advice is needed, have product container or label at hand.  P102\*: Keep out of reach of children.  P103\*: Read label before use.  P234: Keep only in original packaging.  P264: Wash… thoroughly after handling.  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.  P337 + P313: If eye irritation persists get medical advice/attention.  P390: Absorb spillage to prevent material damage. |
| \*For non professional users | |
| Note |  |

### Authorised use(s) for the META SPC 3

#### Use description

Table 4. Use # 1 – Hard surface disinfection

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Hard surface |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi  Enveloped virus |
| **Field of use** | Indoor use.  To be used in Commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas) |
| **Application method(s)** | Manual pouring and wiping |
| **Application rate(s) and frequency** | Ready to use  Contact time:  Bacteria and enveloped virus: 5 min  Fungi and yeasts: 15 min  Temperature: 20°C |
| **Category(ies) of users** | Non-professional and professional |
| **Pack sizes and packaging material** | HDPE bottle: 750, 1000, 1200, 1500, 2000 mL  HDPE can: 5000 mL  Multi-layer PET/PE doy pack: 70, 140 mL |

#### Use-specific instructions for use

|  |
| --- |
| * Manual pouring and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and virucidal efficacy and, for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry. |

#### 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

|  |
| --- |
| - |

### General directions for use of the meta SPC 3

#### Instructions for use

|  |
| --- |
| - Always read the label or leaflet before use and respect all the instructions provided.   * Products have been tested against enveloped virus, including the strains *Coronavirus 229E* and *SARS COV2* (representative strain of Coronavirus outbreak), *influenza A* (representative strain of Influenza H1N1 outbreak) and *Herpes simplex virus type 1* (representative strain of orofacial herpes).   **For professionals users:**  - Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective. |

#### Risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| * Inhalation (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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and 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. * In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting. * 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 years. * Protect from frost and light. * Keep away from children and pets. |

### Other information

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

**PART VII - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[18]](#footnote-19)** | SANYTOL NETTOYANT DESINFECTANT EUCALYPTUS FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-01** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[19]](#footnote-20)** | SANYTOL NETTOYANT DESINFECTANT PAMPLEMOUSSE FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-02** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[20]](#footnote-21)** | SANYTOL NETTOYANT DESINFECTANT CITRON FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-03** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[21]](#footnote-22)** | SANYTOL NETTOYANT DESINFECTANT PIN FRESH | | | | |
| **Authorisation number** | FR-2020-0018-03-04 | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[22]](#footnote-23)** | SANYTOL NETTOYANT DESINFECTANT OCEÁN FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-05** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-ormulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[23]](#footnote-24)** | SANYTOL NETTOYANT DESINFECTANT NEUTRAL FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-06** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[24]](#footnote-25)** | SANYTOL NETTOYANT DESINFECTANT POMME FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-07** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[25]](#footnote-26)** | SANYTOL NETTOYANT DESINFECTANT GRAND AIR FRESH | | | | |
| **Authorisation number** | **FR-2020-0018-03-08** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[26]](#footnote-27)** | SANYTOL NETTOYANT DESINFECTANT EUCALYPTUS FRESH PROFESSIONNEL | | | | |
| **Authorisation number** | **FR-2020-0018-03-09** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)[[27]](#footnote-28)** | SANYTOL NETTOYANT DESINFECTANT CITRON FRESH PROFESSIONNEL | | | | |
| **Authorisation number** | **FR-2020-0018-03-10** | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Hydrogen peroxide | Hydrogen peroxide | Active substance\* | 7722-84-1 | 231-765-0 | 1.5 |
| Ethanol | Ethanol | Co-formulant | 64-17-5 | 200-578-6 | 3.00 |
| L-(+)-lactic acid | 2- Hydroxy propanoic acid | Co-formulant | 79-33-4 | 201-196-2 | 0.49 |
| 1-Decanamine, N,N-dimethyl, N-oxide | N,N-Dimethyldecylamine N-oxide | Co-formulant | 2605-79-0 | 220-020-5 | 0.48 |
| D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides | Co-formulant | - | 483-960-7 | 0.96 |

\*The technical active substance and the pure active substance are not different due to the very high purity of AS (99%).

### Packaging of the biocidal product

**Meta SPC 1 and 2:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 + trigger TS3 SO SPRAY | 500, 600, 700, 750, 900, 1000 mL | HDPE | HDPE | Professional and non-professional | yes |
| Bottle + trigger TS3 SO FOAM V20 | 500, 600, 700, 750, 900, 1000 mL | HDPE | HDPE | Professional and non-professional | Yes |
| Bottle + trigger TS3 FOX SP | 300, 375, 500, 600, 750 mL | HDPE | HDPE | Professional and non-professional | No |

trigger TS3 SO includes two different nozzle : Spray and Foam

trigger TS3 FOX SP is the spray device for Sanytol Deo Textil: soft surfaces

**Meta SPC 3**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | 750, 1000, 1200, 1500, 2000 mL | HDPE | PP | Professional and non-professional | Yes |
| Can | 5000 mL | HDPE | PP | Professional and non-professional | Yes |
| Doy pack | 70, 140 mL | Multi-layer PET/PE |  | Professional and non-professional | Yes |

New packaging for the Minor change:

**Meta SPC 2**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | 750, 1000, 1200, 1500, 2000 mL | HDPE | PP | Professional and non-professional | Yes |
| Can | 5000 mL | HDPE | PP | Professional and non-professional | Yes |
| Doy pack | 70, 140 mL | Multi-layer PET/PE |  | Professional and non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Physico-chemical data**

Physico-chemical properties studies and analytical methods on the biocidal product sanytol were provided by grupo AC marca S.L.

**Efficacy data**

Phase 1 tests that have been performed to demonstrate non activity of the co-formulants (solvent, pH regulator and perfumes) are listed below:

The following studies were submitted with the solvent alone:

* Laboratory study according to EN 1040 standard (phase 1), on bacteria
* Laboratory study according to EN 1275 standard (phase 1) on yeasts/fungi

The following studies were submitted with the pH regulator alone:

* Laboratory study according to EN 1040 standard (phase 1), on bacteria
* Laboratory study according to EN 1275 standard (phase 1) on yeasts/fungi

The following studies were submitted with different perfumes alone:

* Laboratory study according to EN 1040 standard (phase 1), on bacteria
* Laboratory study according to EN 1275 standard (phase 1) on yeasts/fungi

The following efficacy studies were submitted with the product MU 3049-91 (Meta SPC 1 & 3):

* For bacteria :
* Laboratory study according to EN 1276 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 13697 standard modified on soft surface (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For fungi and yeasts:
* Laboratory study according to EN 1650 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 13697 standard modified on soft surface (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For virus:
* 3 laboratory studies according to EN 14476 standard (phase 2, step 1)

The following efficacy studies were submitted with the product COC ref 35 (Meta SPC 2):

* For bacteria :
* Laboratory study according to EN 1276 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For fungi and yeasts:
* Laboratory study according to EN 1650 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For virus:
* Laboratory study according to EN 14476 standard (phase 2, step 1)
* **Minor change -2021:**

New studies have been submitted (see Reference list)

**Toxicological / Risk for human health data**

No toxicological data was submitted for this dossier.

No specific residue data were submitted in the context of this dossier.

**Ecotoxicological / Risk for the environment data**

No ecotoxicolocigal data was submitted for this dossier.

#### Access to documentation

GRUPO AC MARCA has access to data on the active substance hydrogen peroxide with a Letter of Access of PeroxyChem, one applicant of the active substance hydrogen peroxide.

Source: PeroxyChem Spain, S.L.U.

Manufacturer Adress:C/Afueras s/no, La Zaida 5078 Saragosse Spain

Location site: PeroxyChem Bayport Plant – 1200 Bay Area Blvd, TX 77507 Pasadena USA

## Assessment of the biocidal product (family)

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

Table 5. Intended use # 1 – Hard surface disinfection (covers Meta SPC 1 and 2)

|  |  |
| --- | --- |
| Product Type(s) | PT2, PT4 |
| Where relevant, an exact description of the authorised use | Spray  Spray and wiping |
| Target organism (including development stage) | Bacteria:   * *Pseudomonas aeruginosa* * *Escherichia coli* * *Staphylococcus aureus* * *Enterococcus hirae*   *Fungi:*   * *Candida albicans* * *Aspergillus brasiliensis*   *Virus:*   * *Virus Influenza A (H1N1) (Meta SPC1 only)* * *Herpes simplex virus type 1 (Meta SPC1 only)* * *Vaccinia Poxvirus* * *Coronavirus 229E* * *SARS COV2* |
| Field of use | IV.1 Indoor use.  IV 1.3 To be used in / at:  IV 1.3.1 Commercial premises (Food, Industrial and Institutional areas)  IV 1.3.2 Households / private areas (Domestic areas) |
| Application method(s) | Manual spraying (trigger spray)  Manual spraying and wiping |
| Application rate(s) and frequency | As often as the consumer needs to use it |
| Category(ies) of user(s) | V.1 Non-professional user / consumer (General public)  V.2 Professional |
| Pack sizes and packaging material | Please see the relevant section. |

Table 6. Intended use # 2 – Hard surface disinfection (covers Meta SPC 2 and 3)

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Pouring and wiping |
| **Target organism (including development stage)** | Bacteria:   * *Pseudomonas aeruginosa* * *Escherichia coli* * *Staphylococcus aureus* * *Enterococcus hirae*   *Fungi:*   * *Candida albicans* * *Aspergillus brasiliensis*   *Virus:*   * *Virus Influenza A (H1N1) (Meta SPC3 only)* * *Herpes simplex virus type 1(Meta SPC3 only)* * *Vaccinia Poxvirus* * *Coronavirus 229E* * *SARS COV2* |
| **Field of use** | IV.1 Indoor use.  IV 1.3 To be used in / at:  IV 1.3.1 Commercial premises (Food, Industrial and Institutional areas)  IV 1.3.2 Households / private areas (Domestic areas) |
| **Application method(s)** | Manual pouring and wiping |
| **Application rate(s) and frequency** | As often as the consumer needs to use it |
| **Category(ies) of users** | V.1 Non-professional user / consumer (General public)  V.2 Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

Table 4. Intended use # 3 – Soft surface disinfection (covers Meta SPC 1)

|  |  |
| --- | --- |
| **Product Type** | PT2, PT4 |
| **Where relevant, an exact description of the authorised use** | Spray |
| **Target organism (including development stage)** | Bacteria:   * *Pseudomonas aeruginosa* * *Escherichia coli* * *Staphylococcus aureus* * *Enterococcus hirae*   *Fungi:*   * *Candida albicans* * *Aspergillus brasiliensis*   *Virus:*   * *Virus Influenza A (H1N1)* * *Herpes simplex virus type 1* * *Vaccinia Poxvirus* * *Coronavirus 229E* * *SARS COV2* |
| **Field of use** | IV.1 Indoor use.  IV 1.3 To be used in / at:  IV 1.3.1 Commercial premises (Food, Industrial and Institutional areas)  IV 1.3.2 Households / private areas (Domestic areas) |
| **Application method(s)** | Manual spraying (trigger spray) |
| **Application rate(s) and frequency** | As often as the consumer needs to use it |
| **Category(ies) of users** | V.1 Non-professional user / consumer (General public)  V.2 Professional |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use

|  |
| --- |
| **Manual spray and wiping**: Spray the product directly on the surface to be treated with a distance of 20 cm, wipe the surface with a wet and clean cloth and let dry. It is not necessary to rinse.  **Manual spray**: Spray the product directly on the surface to be treated with a distance of 20 cm and let act until it dries. It is not necessary to rinse.  **Manual spray on soft surfaces**: Spray the product directly on the textile to be treated with a distance of 20 cm and let act until it dries.  Dose: 12 sprays/m2.  **Manual pouring and wiping**: For a surface disinfection, apply the product directly on the surface with a wet clean cloth and wipe. It is not necessary to rinse. |

### Physical, chemical and technical properties

#### Meta SPC 1 and 3 (ref. 3049-91 MOD1)

Meta SPC 1 and 3 are identical: reference of the product used is SANYTOL MULTIUSOS FRESH (ref 3049-91 MOD1) (purity of AS is 99%) (worst-case; same as Meta SPC 1).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w))** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 3049-91 MOD1 | Liquid | Acceptable | Pijuan (2016), study number EST319 |
| Colour at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 3049-91 MOD1 | Blue transparent for information | Acceptable,  Depending on used dye | Pijuan (2016), study number EST319 |
| Odour at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 3049-91 MOD1 | Moderately perfurmed, eucalyptus fresh from information | Acceptable  Depending on used perfum | Pijuan (2016), study number EST319 |
| Acidity / alkalinity | CIPAC MT 46.3, CIPAC MT72.3 | 3049-91 MOD1 | pH = 2.99 at 20°C | Acceptable. However as the pH is below 4 the acidity of the product should be provided at post-authorisation. | Pijuan (2016), study number EST319 |
| CIPAC MT 191 | 3049-91 MOD1 | Test was provided in post-autorisation :  Acidity: mean of 0.245% w/w HCl | Acceptable | Pijuan (2020), study number EST694 |
| Relative density / bulk density | CIPAC MT 46.3, 440/2008 (Annex A.3) | 3049-91 MOD1 | 1.0032 at 20°C | Acceptable | Pijuan (2016), study number EST319 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Validated method BPL-MA-025 for quantitation of AS (study EST322) | 3049-91 MOD1 | |  |  |  | | --- | --- | --- | | **Test** | **T=0** | **T=2 weeks at 54°C** | | **Active Ingredient Content (%w/w)** | 1.54 ± 0.00 | 1.52 ± 0.01 | | **Variation of AS content** | / | -1,3% | | **pH Value** | 2.99 ± 0.00 at 20°C | 3.05 ± 0.04 at 20°C | | **Relative Density** | 1.0032 ± 0.0000 | N.D. | | **Flash Point** | No flash point (>100ºC) | N.D. | | **Viscosity 20ºC (cP)** | 4.95 ± 0.40 | N.D. | | **Viscosity 40ºC (cP)** | 4.22 ± 0.22 | N.D. | | **Appearance, Colour and Odour** | Homogeneous liquid. Blue Transparent.  Moderately perfumed, eucalyptus fresh | Homogeneous liquid. Slightly perfumed, eucalyptus fresh.  Slight loss of odour intensity compared to the reference | | **Stability of Packaging** | No leakages observed | No leakages observed. Width increase of 7.50% | | **Spray Characterization: TS3 SO SPRAY** | Amount delivered per spray = 1.154 g  Dmax= 20.4 cm  Dmin = 18.6 cm | Amount delivered per spray = 1.074 g  Dmax= 36.4 cm  Dmin = 29.4 cm | | **Weight Change** | 0.16% loss of weight during the storage stability. | |   Tested commercial packaging: 500 mL trigger spray PE bottle.  Due to time constrains and to meet the deadlines, the second study, EST319 was planned and started using the quickest and default combination of 54ºC/2weeks. The formulations would be stable even at this more severe condition. | According to Guidance on the BPR Vol 1 3.6.4.2 page 71 analysis of the aversive agent should be required to assess its stability However, Based on the fact that the presence of the aversive agent has not been referenced in the risk assessment, the analysis of it after storage is not necessary in this case.  Acceptable,  The products are stable two weeks at 54°C. | Pijuan (2016), study number EST319 |
| Storage stability test – **long term storage at ambient temperature** | CIPAC MT 46.3 | / | Study planned.  Experimental Starting date: 26th week, 2018  Final report: 34th week 2021. | Final results of long term storage stability (including particle size distribution and the quantity of delivered liquid by spray for each spray devices) should be provided in post registration. | Pijuan (2016), study number EST320 |
|  | CIPAC MT 46.3  Validated method BPL-MA-025 for quantitation of AS (study EST322) | 3049-91 MOD1 with trigger | New storage study was provided:   |  |  |  | | --- | --- | --- | | **Test** | **T=0** | **T=3years at 26°C** | | **Active Ingredient Content (%w/w)** | 1.54 | 1.45 | | **Variation of AS content** | / | -6% | | **pH Value** | 2.99 at 20°C | 3.14 at 20°C | | **Appearance, Colour and Odour** | Homogeneous liquid. Blue Transparent.  Moderately perfumed, eucalyptus fresh | Homogeneous liquid. Blue Transparent.  Slight loss of odour/colour intensity compared to the reference. Freshness and Eucalyptus note | | **Stability of Packaging** | No leakages observed | No leakages observed.  Width difference: 8.95% | | **Spray Characterization: TS3 SO SPRAY** | Amount delivered per spray = 1.042 g  Dmax= 39 cm  Dmin = 26 cm | Amount delivered per spray = 0.874 g  Dmax= 35.8 cm  Dmin = 23.8 cm | | **Weight Change of packaging** | 0.34% loss of weight during the storage stability. | | | The sprayer properties decreased after 3 years storage at ambient temperature.  **Therefore, the shelf-life is kept at 2 years.** | Pijuan (2020), study number EST320 |
|  |  |  |  |  |  |
| Storage stability test – **low temperature stability test for liquids** | / | / | Not provided | As study of storage stability at low temperature was not provided, the mention « protect from frost » is added to mitigation measure in SPC | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | / | / | In the accelerated storage stability study there is no indication that the study was performed in the dark. | The mention « protect from light » is added to mitigation measure | / |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | / | Not relevant it is an AL. | / | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | CIPAC MT 46.3 | 3049-91 MOD1 | No leakages observed. Width increase of 7.50% | Acceptable | Pijuan (2016), study number EST319 |
| Wettability | / | / | Not applicable | / | / |
| Suspensibility, spontaneity and dispersion stability | / | / | Not applicable | / | / |
| Wet sieve analysis and dry sieve test | / | / | Not applicable | / | / |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | Not applicable | / | / |
| Disintegration time | / | / | Not applicable | / | / |
| Particle size distribution, content of dust/fines, attrition, friability | Guala internal test specification | Ref. 35 with triggers TS3 SO SPRAY and TS3 SO V20 FOAM | The spray pattern of triggers TS3 SO SPRAY and TS3 SO V20 FOAM at ambient temperature in a 500 mL white bottle in HDPE.   |  |  |  | | --- | --- | --- | |  | **Drop mean diameter (µm)** | | |  | **TS3 SO SPRAY** | **TS3 SO V20 FOAM** | | D (v, 0.1) | 51 | 104 | | D (v, 0.5) | 148 | 296 | | D (v, 0.9) | 377 | 521 | |  | **Drop size volume under** | | | < 10 µm | 1.1% | 0.6% | | The particle size distribution for each spray devices have been provided but this test should be provided before and after long term storage. | Gobbi C., 2016 |
| Guala internal test specification | Ref. 3049-91 with trigger TS3 FOX SP | The spray pattern of trigger TS3 FOX SP at ambient temperature in a 500 mL white bottle in HDPE. | Gobbi C., 2016 |
| Persistent foaming | / | / | Not applicable | / | / |
| Flowability/Pourability/Dustability | / | / | Not applicable | / | / |
| Burning rate — smoke generators | / | / | Not applicable | / | / |
| Burning completeness — smoke generators | / | / | Not applicable | / | / |
| Composition of smoke — smoke generators | / | / | Not applicable | / | / |
| Spraying pattern | CIPAC MT 46.3 | 3049-91 MOD1 | |  |  |  | | --- | --- | --- | | **Test** | **T=0** | **T=2 weeks at 54°C** | | **Spray Characterization: TS3 SO SPRAY** | Amount delivered per spray = 1.154 g  Dmax= 20.4 cm  Dmin = 18.6 cm | Amount delivered per spray = 1.074 g  Dmax= 36.4 cm  Dmin = 29.4 cm |   Tested commercial packaging: 500 mL trigger spray PE bottle. | The quantity of delivered liquid by spray for each spray devices was provided see below. | Pijuan (2016), study number EST319 |
| Guala internal test specification | Ref. 35 with triggers TS3 SO SPRAY and TS3 SO FOAM V20 | The spray pattern of triggers TS3 SO SPRAY and TS3 SO FOAM V20 at ambient temperature in a 500 mL white bottle in HDPE.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **characteristic** | **Target** | **T=0** | **T=6 weeks** | **T= 12 weeks** | | Priming | 10 strokes max | 3 | - | - | | Dose | 1.2 mL | 1.2 | 1.2 | 1.2 | | Spray pattern (mm)-shape | 200±30 from 20 cm | 190 – A | 190 – A | 190 – D | | Foam pattern (mm)-shape | 200±30 from 20 cm | 220 – D | 220 – D | 220 – D | | Venting | No permanent deform | Ok | Ok | Ok | | Leakage | none | none | none | none | | The spray pattern is stable 12 weeks at ambient temperature.  It still needs to be provided before and after long term storage. | Gobbi C., 2016 |
| Guala internal test specification | Ref. 3049-91 with trigger TS3 FOX SP | The spray pattern of trigger TS3 FOX SP at ambient temperature in a 500 mL white bottle in HDPE.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **characteristic** | **Target** | **T=0** | **T=6 weeks** | **T= 12 weeks** | | Priming | 10 strokes max | 4 | - | - | | Dose | 1.2 mL | 1.2 | 1.2 | 1.2 | | Spray pattern (mm)-shape | 200±30 from 20 cm | 160 – C | 160 – C | 160 – D | | Venting | No permanent deform | Ok | Ok | Ok | | Leakage | none | none | none | none | | The spray pattern is stable 12 weeks at ambient temperature.  It still needs to be provided before and after long term storage. | Gobbi C., 2016 |
| Physical compatibility | / | / | Not applicable | / | / |
| Chemical compatibility | / | / | Not applicable | / | / |
| Degree of dissolution and dilution stability | / | / | Not applicable | / | / |
| Surface tension | EEC A.5  SOP6PR6043 | 3049-91 MOD1 | The surface tension is: 28,1 mN/m. | Acceptable,  The product is surface active. | Surface tensionA.5, Manka S., 2017  Study: Mo5936 |
| Viscosity | BPL-MA-13 internal procedure | 3049-91 MOD1 | At 20°C: 4,95 cP  At 40°C: 4,22 cP | Acceptable | Pijuan (2016), study number EST319  Eport number R-EST319-M1 |

#### Meta SPC 2 (ref. 35 MOD)

Meta SPC 2: reference of the product used is SANYTOL COCINAS FRESH (ref 35 mod) (worst case) (purity of AS is 99%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w))** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 35 MOD | Liquid | Acceptable | Pijuan (2016), study number EST228 |
| Colour at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 35 MOD | Colourless for information | Acceptable,  Depending on used dye | Pijuan (2016), study number EST228 |
| Odour at 20 °C and 101.3 kPa | CIPAC MT 46.3 | 35 MOD | Moderately perfurmed, sweet citrus for information | Acceptable  Depending on used perfum | Pijuan (2016), study number EST228 |
| Acidity / alkalinity | CIPAC MT 46.3, CIPAC MT72.3 | 35 MOD | pH = 2.98 at 20°C | Acceptable however as the pH is below 4 the acidity of the product should be provided at post-authorisation. | Pijuan (2016), study number EST228 |
| CIPAC MT 191 | 35 MOD | Test was provided in post-autorisation :  Acidity: mean of 0.273% w/w HCl | Acceptable | Pijuan (2020), study number EST694 |
| Relative density / bulk density | CIPAC MT 46.3, 440/2008 (Annex A.3) | 35 MOD | 1.0018 at 20°C | Acceptable | Pijuan (2016), study number EST228 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Validated method BPL-MA-025 for quantitation of AS (study EST263) | 35 MOD with trigger **TS3 SO FOAM V20** | |  |  |  | | --- | --- | --- | | **Test** | **T=0** | **T=12 weeks at 35°C** | | **Active Ingredient Content (%w/w)** | 1.52 ± 0.00 | 1.44 ± 0.00 | | **Variation of AS content** | / | -5.2% | | **pH Value** | 2.98 ± 0.01 at 20°C | 3.20 ± 0.07 at 20°C | | **Relative Density** | 1.0018 ± 0.0001 | 1.0021 ± 0.0000 | | **Viscosity 20ºC (cP)** | 5.30 ± 0.42 | 5.21 ± 0.44 | | **Viscosity 40ºC (cP)** | 4.59 ± 0.36 | 4.63 ± 0.31 | | **Appearance, Colour and Odour** | Homogeneous liquid. Colourless.  Slightly perfumed, sweet citrus | Homogeneous liquid. Colourless.  Moderately perfumed, sweet citrus. Slight loss of odour intensity compared to the reference | | **Stability of Packaging** | No leakages observed | No leakages observed.  Width increase of 3.25% | | **Spray Characterization: TS3 SO FOAM V20** | Amount delivered per spray = 1.11 g  Dmax= 40.8 cm  Dmin = 18.4 cm | Amount delivered per spray = 1.08 g  Dmax= 40.0 cm  Dmin = 16.3 cm | | **Weight Change** | 0.15% loss of weight during the storage stability. | |   Tested commercial packaging: 500 mL trigger spray bottle in PE.  Due to time constrains and to meet the deadlines, the second study, EST319 was planned and started using the quickest and default combination of 54ºC/2weeks. The formulations would be stable even at this more severe condition. | According to Guidance on the BPR Vol 1 3.6.4.2 page 71 analysis of the aversive agent is required to assess its stability. However, based on the fact that the presence of the aversive agent has not been referenced in the risk assessment, the analysis of it after storage is not necessary in this case.  Acceptable  Do not store at temperatures above 35°C. | Pijuan (2016), study number EST228 |
| Storage stability test – **long term storage at ambient temperature** | CIPAC MT 46.3 | / | Study planned. Experimental Starting date: 26th week, 2018  Final report: 34th week 2021 | Final results of long term storage stability (including particle size distribution and the quantity of delivered liquid by spray for each spray devices) should be provided in post registration. | Pijuan (2016), study number EST228 |
|  | CIPAC MT 46.3  Validated method BPL-MA-025 for quantitation of AS (study EST322) | 35 MOD | New storage study was provided:   |  |  |  | | --- | --- | --- | | **Test** | **T=0** | **T=3years at 26°C** | | **Active Ingredient Content (%w/w)** | 1.52 | 1.41 | | **Variation of AS content** | / | -7% | | **pH Value** | 2.98 at 20°C | 3.34 at 20°C | | **Relative Density** | 1.0018 | 1.0021 | | **Viscosity (cP)** | 5.3 (20°C)  4.6 (40°C) | 5.3 (20°C)  4.4 (40°C) | | **Appearance, Colour and Odour** | Homogeneous liquid. Colourless. Slightly perfumed, sweet citrus | Homogeneous liquid. Colourless and clear. Total loss of citric note and instensity | | **Stability of Packaging** | No leakages observed | No leakages observed.  Width difference: 6.4% | | **Spray Characterization: TS3 SO SPRAY** | Amount delivered per spray = 0.974 g  Dmax= 37.4 cm  Dmin = 21.2 cm  Ratio: 1.76 | Amount delivered per spray = 0.598 g  Dmax= 30 cm  Dmin = 19.8 cm  Ratio: 1.52 | | **Weight Change of packaging** | 0.27% loss of weight during the storage stability. | | | The sprayer properties decrases after 3 years at ambient temperature.  **Therefore, the shelf-life is kept at 2 years.**  The trigger was covered by META SPC 3 packaging. | Pijuan (2020), study number EST229 |
|  |  |  |  |  |  |
| Storage stability test – **low temperature stability test for liquids** | / | / | Not provided | As study of storage stability at low temperature was not provided, the mention « protect from frost » is added to mitigation measure in SPC | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | / | / | In the accelerated storage stability study there is no indication that the study was performed in the dark. | The mention « protect from light » is added to mitigation measure in SPC. | / |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | / | / | See Storage stability test – **accelerated storage** | / | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | / | / | See Storage stability test – **accelerated storage** | / | / |
| Wettability | / | / | Not applicable | / | / |
| Suspensibility, spontaneity and dispersion stability | / | / | Not applicable | / | / |
| Wet sieve analysis and dry sieve test | / | / | Not applicable | / | / |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | Not applicable | / | / |
| Disintegration time | / | / | Not applicable | / | / |
| Particle size distribution, content of dust/fines, attrition, friability | Guala internal test specification | Ref. 35 with triggers TS3 SO SPRAY and TS3 SO FOAM V20 | The spray pattern of triggers TS3 SO SPRAY and TS3 SO FOAM V20 at ambient temperature in a 500 mL white bottle in HDPE.   |  |  |  | | --- | --- | --- | |  | **Drop mean diameter (µm)** | | |  | **TS3 SO SPRAY** | **TS3 SO V20 FOAM** | | D (v, 0.1) | 65 | 120 | | D (v, 0.5) | 315 | 462 | | D (v, 0.9) | 480 | 628 | |  | **Drop size volume under** | | | < 10 µm | 1% | 0.4% | | The particle size distribution for each spray devices have been provided but this test should be provided before and after long term storage. | Gobbi C., 2016 |
| Persistent foaming | / | / | Not applicable | / | / |
| Flowability/Pourability/Dustability | / | / | Not applicable | / | / |
| Burning rate — smoke generators | / | / | Not applicable | / | / |
| Burning completeness — smoke generators | / | / | Not applicable | / | / |
| Composition of smoke — smoke generators | / | / | Not applicable | / | / |
| Spraying pattern | CIPAC MT 46.3 | 3049-91 MOD1 | |  |  |  | | --- | --- | --- | | **Spray Characterization: TS3 SO FOAM V20** | Amount delivered per spray = 1.11 g  Dmax= 40.8 cm  Dmin = 18.4 cm | Amount delivered per spray = 1.08 g  Dmax= 40.0 cm  Dmin = 16.3 cm |   Tested commercial packaging: 500 mL trigger spray PE bottle. | The quantity of delivered liquid by spray for each spray device should be provided before and after long term storage. | Pijuan (2016), study number EST319 |
| Guala internal test specification | Ref. 35 with triggers TS3 SO SPRAY and TS3 SO FOAM V20 | The spray pattern of triggers TS3 SO SPRAY and TS3 SO FOAM V20 at ambient temperature in a 500 mL white bottle in HDPE.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **characteristic** | **Target** | **T=0** | **T=6 weeks** | **T= 12 weeks** | | Priming | 10 strokes max | 3 | - | - | | Dose | 1.2 mL | 1.2 | 1.2 | 1.2 | | Spray pattern (mm)-shape | 200±30 from 20 cm | 190 – A | 190 – A | 190 – D | | Foam pattern (mm)-shape | 200±30 from 20 cm | 220 – D | 220 – D | 220 – D | | Venting | No permanent deform | Ok | Ok | Ok | | Leakage | none | none | none | none | | The spray pattern is stable 12 weeks at ambient temperature.  It still needs to be provided before and after long term storage. |  |
| Physical compatibility | / | / | Not applicable | / | / |
| Chemical compatibility | / | / | Not applicable | / | / |
| Degree of dissolution and dilution stability | / | / | Not applicable | / | / |
| Surface tension | EEC A.5  SOP6PR6043 | 35 MOD | The surface tension is: 27,8 mN/m. | Acceptable,  The product is surface active. | Surface tensionA.5, Manka S., 2017  Study: Mo5936 |
| Viscosity | BPL-MA-13 internal procedure | 35 MOD | Viscosity 20ºC: 5.30 cP  Viscosity 40ºC: 4.59 cP | / | Pijuan (2016), study number EST228 report n° : R-EST228-M1 |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product SANYTOL FRESH is an all other liquids (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable for the accelerated storage stability study.  There is no effect of high temperature on the stability of the formulation, since after 2 weeks at 54°C for meta SPC 1 and 3, neither the active ingredient content nor the technical properties were changed. After 12 weeks at 35°C for meta SPC 2, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 2 years at ambient temperature when stored in HDPE bottle packaging material (commercial packaging material). The long term storage stability study (24 months) is on-going.  There are no stability data (accelerated or long term) on the spray device TS3 FOX. This device is therefore not acceptable.  The acidity of the product should be provided at post-authorisation.  The low temperature storage stability has not been provided, so a mention “protect from frost” should be added on the label.  For meta SPC 2: the mention “do not store at temperature above 35°C” should be added on the label.  Implication concerning labelling:  Protect from frost  Protect from light  For meta SPC 2: do not store at temperature above 35°C.  **Post-Authorization data and minor change dossier:**  Acidity was prodided on all META SPC (0.245% w/w HCl for META SPC 1&3 and 0.273% w/w HCl for META SPC 2).  New long term storage studies were provided. The stability data indicate a shelf life of 2 years at ambient temperature when stored in HDPE bottle packaging material (commercial packaging material with trigger) as sprayer properties change significantly after 3 years.  **Shelf life: 2 years** |

### Physical hazards and respective characteristics

**All meta SPC**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | / | According to the classification of all present ingredients in this biocidal product family under the Regulation 1272/2008 (CLP), which do not classify as Explosives, it is not necessary to determine the explosive properties of any of the biocidal products within the family. H2O2 is an explosives precusor according to Reg. 98/2013. However the content of H2O2 in the product is lower than 12% (limit value reported in the reg 98/2103). The H2o2 is considered as explosive precursor in the product Regarding H2O2 the predominant hazard is the oxidising property. | Acceptable | / |
| Flammable gases | / | / | Not applicable it is a liquid. | / | / |
| Flammable aerosols | / | / | Not applicable it is a liquid. | / | / |
| Oxidising gases | / | / | Not applicable it is a liquid. | / | / |
| Gases under pressure | / | / | Not applicable it is a liquid. | / | / |
| Flammable liquids | ASTM D93 | 3049-91 MOD1  35 MOD | The flash points of the reference formulations for the physico-chemical properties of the Meta SPC 1, 2 and 3 are greater than 100ºC, in accordance with ASTM D93 method. The formulations are therefore not flammables according to the CLP criteria. | Acceptable | Pijuan (2016), study number EST228  Pijuan (2016), study number EST319 |
| Flammable solids | / | / | Not applicable it is a liquid. | / | / |
| Self-reactive substances and mixtures | / | / | Not applicable it is a liquid. | / | / |
| Pyrophoric liquids | Statement | / | Inorganic oxidising liquids are not flammable and therefore do not have to be subjected to the classification procedures for the hazard classes flammable liquids or pyrophoric liquids. | Acceptable | / |
| Pyrophoric solids | / | / | Not applicable it is a liquid. | / | / |
| Self-heating substances and mixtures | / | / | Not applicable it is a liquid. | / | / |
| Substances and mixtures which in contact with water emit flammable gases | / | / | Not applicable it is a liquid. | / | / |
| Oxidising liquids | Statement |  | All formulations contain an important quantity of water, quantity of Hydrogen peroxide is below the oxidising classification threshold. Other co-formulants are not classified as oxidising. | Acceptable | / |
| Oxidising solids | / | / | Not applicable it is a liquid. | / | / |
| Organic peroxides | Statement | / | As there is a low content of H2O2 (1.5%) and there is a low content of organic acids in the product. Therefore, even if peracids could be formed the content obtained will be very low. | Acceptable | / |
| Corrosive to metals | UNE-EN 13442 | MU 3049-91 and COC REF 35 | No visible changes. | The test for corrosion to metal UN Test C.1 should be provided at post-authorisation | IUCLID |
| Test C.1 of UN RTDG Manual | 3049-91 MOD1 | A new test was provided for META SPC 1&3 in pot-authorization:   |  |  |  | | --- | --- | --- | | **Metal tested** | **Plate** | **Loss of weight (%)** | | Aluminium | Headspace | 0.14 | | Partly immersed | 6.6 | | Fully immersed | 12.33 | | Steel | Headspace | 0.37 | | Partly immersed | 2.93 | | Fully immersed | 5.42 |   **Localized corrosion:**  The maximum depth for fully immersed aluminium was 1079µm and 699µm for steel. | Loss of weight after 28 days exposure at 55°C is far from the limit of 51.5%. Nevertheless, localized corrosion shows that maximum depth holes are higher than the limit of 480µm in both metals. Therefore, the META SPC 1&3 are classified H290-corrosive to metal. | K. Czornik, 2020 |
| Test C.1 of UN RTDG Manual | 35-MOD | A new test was provided for META SPC 2 in pot-authorization:   |  |  |  | | --- | --- | --- | | **Metal tested** | **Plate** | **Loss of weight (%)** | | Aluminium | Headspace | 0.11 | | Partly immersed | 15.48 | | Fully immersed | 25.19 | | Steel | Headspace | 1.22 | | Partly immersed | 4.12 | | Fully immersed | 7.75 |   **Localized corrosion:**  The maximum depth for fully immersed aluminium was 1841µm and 517µm for steel. | Loss of weight after 28 days exposure at 55°C is far from the limit of 51.5%. Nevertheless, localized corrosion shows that maximum depth holes are higher than the limit of 480µm in both metals. Therefore, the META SPC 2 is also classified H290-corrosive to metal. | K. Czornik, 2020 |
| Auto-ignition temperatures of products (liquids and gases) | statement |  | None of the products of the biocidal product family is auto-igniting. | Acceptable |  |
| Relative self-ignition temperature for solids | / | / | Not applicable it is a liquid. | / | / |
| Dust explosion hazard | / | / | Not applicable it is a liquid. | / | / |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties. The test for corrosion to metal UN Test C.1 should be provided at post-authorisation.  **Post-Authorization data and minor change dossier:**  The products of BPF SANYTOL FRESH are classified H290 – May be corrosive to metals. |

### Methods for detection and identification

**For meta SPC 1 and 3:**

Report: Pijuan 2016, report n : EST322

Test facilities:

Analytical Laboratory

Grupo AC Marca

Pol. Ind. Can Serra – Parc. 1

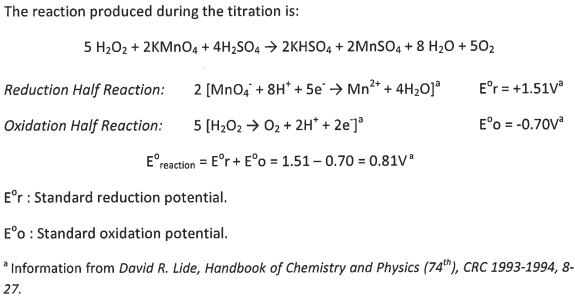
08791 – Sant Lorenç d’Hortons

Barcelona

Spain

Principle of the method:

The determination of hydrogen peroxide in this analytical method is based on a potentiometric titration using Potassium Permanganate as reagent.



The titration is done with an automatic potentiometric titrator wich follows the reaction measuring the electric potential difference with a redox electrode to find the equivalence point.

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

Validation data:

|  |  |  |
| --- | --- | --- |
| Matrix effect |  | |
| Linearity | Linearity was studied by carrying out five concentrations between 0.85-2.37 % w/w.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance | Y = 6.0112x + 0.7101 R2 = 0.9997  n=1 for five levels of concentration |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 0.145% |
| Accuracy | Accuracy was determined by analysis of 1 reconstituted sample. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 0.31 | 100.37; 99.29; 100.04; 104.82; 99.85; 101.48; 99.83; 102.33; 105.81 | 101.53% | 2.31 | 9 | | |

The analytical method is fully validated for the determination of the active substance hydrogen peroxide in the product of meta SPC 1 and 3.

**For meta SPC2:**

Report: Pijuan 2016, report n : EST263

Test facilities:

Analytical Laboratory

Grupo AC Marca

Pol. Ind. Can Serra – Parc. 1

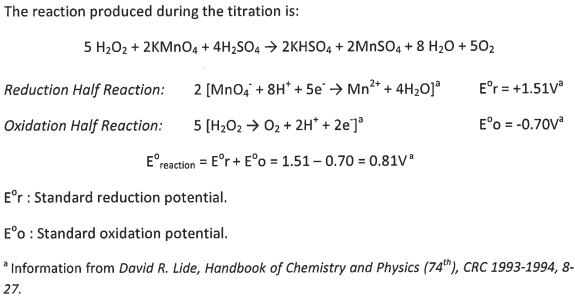
08791 – Sant Lorenç d’Hortons

Barcelona

Spain

Principle of the method:

The determination of hydrogen peroxide in this analytical method is based on a potentiometric titration using Potassium Permanganate as reagent.



The titration is done with an automatic potentiometric titrator wich follows the reaction measuring the electric potential difference with a redox electrode to find the equivalence point.

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

Validation data:

|  |  |  |
| --- | --- | --- |
| Matrix effect |  | |
| Linearity | Linearity was studied by carrying out five concentrations between 0.85-2.37 % w/w.  Calibration curve has been provided with a R2 higher than 0.99. | |
| Compound | Linearity % |
| Active substance | Y = 6.0481x + 0.8736 R2 = 1.0000  n=1 for five levels of concentration |
| Precision | Repeatability was evaluated by analyzing five test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 0.198% |
| Accuracy | Accuracy was determined by analysis of 1 reconstituted sample. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 0.31 | 100.37; 100.07; 100.25; 100.27; 100.63 | 100.32% | 0.2 | 5 | | |

The analytical method is fully validated for the determination of the active substance hydrogen for meta SPC 2.

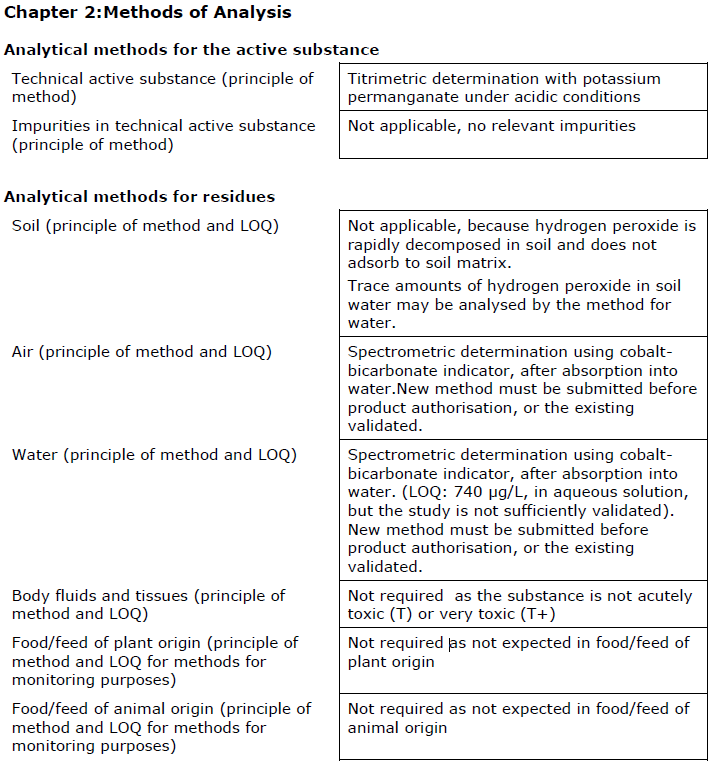
Analytical methods for determination of hydrogen peroxide residues in air, water (drinking water) are available in Assessment Report of hydrogen peroxide Product-type 1-6, march 2015. The applicant GRUPO AC MARCA has a Letter of Access from PeroxyChem for these data.

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

No analytical method in soil is required according to the Assessment report of hydrogen peroxide.

As the family product SANYTOL FRESH is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of hydrogen peroxide residue in food/feed of plant and animal origin is unnecessary.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance hydrogen peroxide in the product.  Analytical methods were provided at EU level for the determination of hydrogen peroxide residue in water and air with respectively LOQ= 740 µg/L and 139 µg/m3.  Hydrogen peroxide is not toxic (T) or very toxic (T+) active substance. Therefore, no analytical method in biological matrices is required.  No analytical method in soil is required.  Regarding PT 4 uses, given the ractivity 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. |



### Efficacy against target organisms

#### Function and field of use

Main Group 01: Disinfectants

Product Type 02: Disinfectants and algaecides not intended for direct application to humans or animals.

Product Type 04: Food and feed area

The products of the SANYTOL FRESH family are ready to use products used for surfaces disinfection, indoor in private areas and commercial premises.

The family was separated in three META-SPC:

* + META-SPC1: the products are intended to be used for hard surface disinfection by manual spraying or by manual spraying and wiping, and for soft surface disinfection by manual spraying, by professional and non-professional users.
  + META-SPC2: the products are intended to be used for hard surface disinfection by manual spraying, by manual spraying and wiping, by professional and non-professional users.
  + META-SPC3: the products are intended to be used for hard surface disinfection by manual pouring and wiping, by professional and non-professional users.

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

The products of SANYTOL FRESH family are intended to disinfect surfaces. The applicant claimed the disinfection activity against bacteria, yeasts, fungi and viruses.

The products are used for the purpose of the protection of human.

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

The products are intended to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), of moulds spores (fungicidal activity) and of infectious virus particles (virucidal activity) of relevant test organisms under defined conditions.

#### 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.”

(Source: Assessment Report. Hydrogen peroxide. Product-types 1-6. March 2015. Finland)

#### Efficacy data

* **Inactivity of co-formulants**

The products of the SANYTOL FRESH family contain a pH regulator and a solvent in the formulation. As these ingredients are also active substance that are approved for main group 1, phase 1 tests (EN 1040 and EN 1275 standards) were performed with these coformulants alone at the highest concentrations in order to demonstrate that they do not have any basic bactericidal and fungicidal activities (see table of experimental data in confidential annex of the PAR).

At in-use concentrations claimed, the coformulants pH regulator and solvent do not possess any basic bactericidal and fungicidal activities according to respectively EN 1040 and EN 1275 standards.

The products of the SANYTOL FRESH family contain also some perfumes that can potentially influence the efficacy of the products. According to phase 1 tests performed (EN 1040 and EN 1275), any of them possess bactericidal and fungicidal activities at the in-use concentrations of the products (see table of experimental data in confidential annex of the PAR).

* **First authorisation**
* **Efficacy of the SANYTOL FRESH product family**

Laboratory studies were conducted with reference formulations 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 table below.

Two reference formulations for efficacy covering all Meta SPC have been tested according to the EN norms:

-The reference formulation for efficacy named “**MU 3049-91**” covers all products contained in Meta SPC 1 and Meta SPC 3 as their compositions similar.

-The reference formulation for efficacy named “**Coc ref 35**” covers all products contained in Meta SPC 2.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / active concentrations / exposure time** | **Test results: effects** | **Reference** |
| Bactericidal | PT2/PT4 Disinfection of hard surfaces  PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | *P. aeruginosa*,  *E. coli*,  *S. aureus* and  *E. hirae* | EN1276 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  80%, 50%, 25% and 5 % v/v | Bactericidal  concentration: 25 % v/v  ≥ 5 log unit reduction | IUCLID  Section 6.7  Study record 003  R.I = 1 |
| Bactericidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  (Meta SPC 1 & 3) | *P. aeruginosa*,  *E. coli*,  *S. aureus* and  *E. hirae* | EN 13697 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested: 100%, 50%, 25 % and 5 % v/v | Bactericidal  concentration: 50% v/v  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 001  R.I = 1 |
| Fungicidal | PT2/PT4 Disinfection of hard surfaces  PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | *C. albicans*,  *A. brasiliensis* | EN 1650 | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  80%, 50%, 25% and 5 % v/v | Fungicidal concentration : 50 % v/v  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 004  R.I = 1 |
| Fungicidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  (Meta SPC 1 & 3) | *C. albicans*,  *A. brasiliensis* | EN 13697 | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  100%, 50%, 25 % and 5 % v/v | Fungicidal concentration : 100 % v/v  ≥ 3 log unit reduction | IUCLID  Section 6.7  Study record 002  R.I = 1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces  PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | Influenza A (H1N1)  (enveloped virus) | EN 14476 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Clean and dirty conditions  Concentration tested:  80%, 50%, 25%, 5 % v/v | Virucidal concentration : 80 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 005  R.I = 1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces  PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | Herpes simplex virus type 1  (enveloped virus) | EN 14476 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Clean and dirty conditions  Concentration tested:  80%, 50%, 25%, 5 % v/v | Virucidal concentration : 25 % v/v  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 006  R.I = 1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces  PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | Vaccinia Poxvirus  (enveloped DNA virus) | EN 14476 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Clean and dirty conditions  Concentration tested:  80%, 50%, 25%, 5 % v/v | Virucidal concentration : 80 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 007  R.I = 1 |
| Bactericidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  (Meta SPC 1 & 3) | *P. aeruginosa*,  *S. aureus,*  *E. hirae* | EN 16615 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: 3 g/L BSA  Concentration tested: 100 % v/v  Mechanical action employing wipes | Bactericidal  concentration: 100 % v/v  ≥ 5 log unit reduction | IUCLID  Section 6.7  Study record 008  R= 1 |
| Yeasticidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  (Meta SPC 1 & 3) | *C. albicans* | EN 16615 | Contact time: 5, 15 minutes  Temperature: 20°C ± 1°C  Soiling: 3 g/L BSA  Concentration tested: 100 %, 10 % v/v  Mechanical action employing wipes | Yeasticidal concentration: 100 % within 15 min  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 008  R=1 |
| Fungicidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  (Meta SPC 1 & 3) | *A. brasiliensis* | EN 16615 | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: 3 g/L BSA  Concentration tested: 100 %, 10 % v/v  Mechanical action employing wipes | Fungicidal concentration: 100 %  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 008  R=1 |
| Bactericidal | PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | *P. aeruginosa*,  *E. coli*,  *S. aureus,*  *E. hirae* | EN 13697  Adapted to porous surfaces | Contact time: 45 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Test surface: Cotton carrier according to specifications of EN16616:2015  Concentration tested:  100%, 50%, 10% v/v | Bactericidal  concentration: 50 % v/v  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 009  R=1 |
| Yeasticidal | PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | *C. albicans* | EN 13697  Adapted to porous surfaces | Contact time: 45 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Test surface: Cotton carrier according to specifications of EN16616:2015  Concentration tested:  100%, 50%, 10% v/v | Yeasticidal concentration: 50 % v/v  ≥ 3 log unit reduction | IUCLID  Section 6.7  Study record 009  R=1 |
| Fungicidal | PT2/PT4 Disinfection of soft surfaces | MU 3049-91  (Meta SPC 1 & 3) | *A. brasiliensis* | EN 13697  Adapted to porous surfaces | Contact time: 45 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Test surface: Cotton carrier according to specifications of EN16616:2015  Concentration tested:  100%, 50%, 10% v/v | Fungicidal concentration: 100 %  ≥ 3 log unit reduction | IUCLID  Section 6.7  Study record 009 |
| Bactericidal | PT2/PT4 Disinfection of hard surfaces | Coc ref 35  (Meta SPC 2) | *P. aeruginosa*,  *E. coli*,  *S. aureus* and  *E. hirae* | EN1276 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  80%, 50%, 25%, 5 % v/v | Bactericidal  concentration: 25 % v/v  ≥ 5 log unit reduction | IUCLID  Section 6.7  Study record 012  R=1 |
| Bactericidal | PT2/PT4 Disinfection of hard surfaces  surfaces | Coc ref 35  (Meta SPC 2) | *P. aeruginosa*,  *E. coli*,  *S. aureus* and  *E. hirae* | EN 13697 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  100%, 50%, 25%, 5 % v/v | Bactericidal  concentration: 25 % v/v  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 010  R=1 |
| Fungicidal | PT2/PT4 Disinfection of hard surfaces | Coc ref 35  (Meta SPC 2) | *C. albicans*,  *A. brasiliensis* | EN 1650 | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  80%, 50%, 25% and 5 % v/v | Fungicidal concentration: 50 %  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 013  R=1 |
| Fungicidal | PT2/PT4 Disinfection of hard surfaces | Coc ref 35  (Meta SPC 2) | *C. albicans*,  *A. brasiliensis* | EN 13697 | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: Dirty conditions  Concentration tested:  100%, 50%, 25 %, 5 % v/v | Fungicidal concentration: 100 %  ≥ 3 log unit reduction | IUCLID  Section 6.7  Study record 011  R=1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces | Coc ref 35  (Meta SPC 2) | Vaccinia Poxvirus  (enveloped DNA virus) | EN 14476 | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: Clean and dirty conditions  Concentration tested:  80 % v/v | Virucidal concentration : 80 % (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7  Study record 015  R=1 |

**META SPC 1**

META-SPC1 contains products at 1.5 % w/w Hydrogen peroxide, with range of variations for wetting agent, perfumes, solvent and bittering agents. Laboratory studies were conducted with only one representative product MU 3049-91 (1.5 % w/w Hydrogen peroxide):

Taking into account the variations of the co-formulants presented in the META-SPC1, it can be assumed that they have no impact on efficacy and the efficacy results of the representative product MU 3049-91 covers the whole META-SPC1 claims.

* Regarding the use 1, **hard surface disinfection in PT2 and 4, by manual spraying and wiping or by manual spraying**:

The formulationMU 3049-91 has been tested against bacteria, yeasts and fungi. For tests conditions and results, see efficacy data table above.

The bactericidal, yeasticidal and fungicidal activities were demonstrated according to the requirements of the PT1-5 guidance [[28]](#footnote-29) for hard surfaces in PT 2 and 4 with:

* Quantitative suspension tests (EN 1276 and EN 1650);
* Quantitative surface tests: EN 13697 test for the application by manual spraying, and EN 16615 test for the application by manual spraying and wiping.
* Regarding the use 2, **soft surface disinfection in PT2 and 4, by manual spraying**:

The formulationMU 3049-91 has been tested against bacteria, yeasts and fungi. For tests conditions and results, see table of efficacy data above.

The bactericidal, yeasticidal and fungicidal activities were demonstrated according to the requirements of the PT1-5 guidance for soft surfaces in PT 2 and 4:

* Quantitative suspension tests (EN 1276 and EN 1650),
* Quantitative surface test: as the products of the META-SPC1 are not intended to be used in washing machines, EN 13697 test adapted to porous surface (cotton as carrier) was performed.

**META SPC 2**

META-SPC2 contains products at 1.5 % w/w Hydrogen peroxide, with range of variations for wetting agent, perfumes, solvent and bittering agents. Laboratory studies were conducted with only one representative product Coc ref 35 (1.5 % w/w Hydrogen peroxide):

Taking into account the variations of the co-formulants presented in the META-SPC2, it can be assumed that they have no impact on efficacy and the efficacy results of the representative product Coc ref 35 covers the whole META-SPC2 claims.

* Regarding the use 1, **hard surface disinfection in PT2 and 4, by manual spraying, by manual spraying and wiping:**

The formulation Coc ref 35 has been tested against bacteria, yeast and fungi. For tests conditions and results, see efficacy data table above.

The bactericidal, yeasticidal and fungicidal activities were demonstrated according to the requirements of PT1-5 guidance for hard surfaces in PT 2 and 4:

* Quantitative suspension tests (EN 1276 and EN 1650);
* Quantitative surface tests: EN 13697 test for the application by manual spraying, and EN 16615 test (adapted to food, industrial, domestic and institutional areas) for both application by manual spraying and wiping, and, by pouring and wiping.

**META SPC 3**

META-SPC3 contains products at 1.5 % w/w Hydrogen peroxide, with range of variations for wetting agent, perfumes, solvent; dye’s preservative and bittering agents. Laboratory studies were conducted with only one representative product MU 3049-91 (1.5 % w/w Hydrogen peroxide):

Taking into account the variations of the co-formulants presented in the META-SPC3, it can be assumed that they have no impact on efficacy and the efficacy results of the representative product MU 3049-91 covers the whole META-SPC3 claims.

* Regarding the use 1, **hard surface disinfection in PT2 and 4, by manual pouring and wiping**:

The formulationMU 3049-91 has been tested against bacteria, yeast and fungi. For tests conditions and results, see efficacy data table above.

The bactericidal, yeasticidal and fungicidal activities were demonstrated according to the requirements of PT1-5 guidance for hard surfaces in PT 2 and 4:

* Quantitative suspension tests (EN 1276 and EN 1650);
* Quantitative surface test: as the products of the META SPC 3 are intended to be used by pouring and wiping, EN 16615 (adapted to food, industrial, domestic and institutional areas) test was performed.

Regarding the virucidal activity claimed for all uses under META SPC 1, 2 and 3, tests against enveloped viruses only were performed. For viruses species tested, tests conditions and results, see efficacy data table above.

According to the PT1-5 guidance:

* For products against viruses in PT2 (§ 3.2.4): “*product against viruses must be effective against virus with and without an “envelope”. Products can claim virucidal efficacy if efficacy against non-enveloped viruses has been proven. Such product can be regarded as efficacious against enveloped and non-enveloped viruses*”.
* For products against viruses in PT4 (§ 5.2.2.2) “*To demonstrate a general virus claim a modified EN phase 2, step 1 test (medical area test with food area soiling) can be provided with Adenovirus and Murine Norovirus as test organism*”

An E-consultation on limited virucidal claims for PT 2 and PT 4 was also launched in 2017, and it was agreed by the Efficacy WG, that “*Regarding biocidal products used in PT 2: Disinfectants and algaecides not intended for direct application to humans or animals and in PT 4: Food and feed area, it is necessary to point out that for the time being a claim against enveloped viruses is not accepted. For biocidal products used in other PTs a virucidal activity within the meaning of full virucidal activity can only be claimed, i.e. against both enveloped and non-enveloped viruses*” (§ 5-Limited virucidal activity – WGII2016-Technical Agreement for Biocides (TAB)[[29]](#footnote-30) version 1.3 -August, 2017). Therefore, studies provided by the applicant to demonstrate an activity against envelopped virus have been evaluated and considered as satisfaying by the eCA, but taken into account the requirement of EN 14476+A1:2015 norm, confirmed by the e-consultation, the claims against envelopped virus have been rejected in the frame of this dossier.

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the products of the family SANYTOL FRESH, separated in 3 META-SPC, have shown a sufficient efficacy in accordance with the requirements of the transitional Guidance on Efficacy for product type PT1-5, Disinfectants (2016) for the following uses:  META SPC1   * Use 1, PT2 and 4 hard surface disinfection, by manual spraying or by manual spraying and wiping (100 % v/v) against bacteria with a contact time of 5 minutes and, against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C. * Use 2, PT2 soft surface disinfection, by manual spraying (100 % v/v) against bacteria, yeasts and fungi, with a contact time of 45 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.   META SPC 2   * Use 1, PT2 and 4 hard surface disinfection, by manual spraying and by manual spraying and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.   META SPC 3   * Use 1, PT2 and 4 hard surface disinfection, by manual pouring and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.   Regarding the virucidal activity claimed for all uses under META SPC 1, 2 and 3, tests against only enveloped viruses were performed. However, according to the requirements of EN 14476+A1:2015 norm, efficacy of products intended to be used against viruses in PT2 and 4 should be proven against bothenveloped and non-enveloped viruses. |

* **Minor Change (2021)**

The minor change application for the biocidal product family SANYTOL FRESH concerns the addition of enveloped virus including *Coronavirus E229E*, *SARS COV2, H1N1*, and *Herpes simplex virus type 1* and, the addition of the mode of application pouring and wiping for META SPC2.

With regard to the addition of the mode of application pouring and wiping for META-SPC2, this is covered by the efficacy data submitted for the first authorisation.

With regard to the claim against enveloped virus for all uses for META SPC1, 2 and 3, Technical agreement for Biocides version 2.2 clarified that activity against enveloped virus can be claimed for professional and non professional users, for surfaces disinfection in non healthcare areas. Only PT2 is considered at the section 19, because until now this splitting of virucidal claims has only been discussed at WG Eff in the frame of PT2 dossiers. Nevertheless, in the frame of this dossier, it makes sense that such claim against enveloped virus is also valid for PT4 hard surfaces for non-professionals.

Therefore virucidal activity against enveloped virus is demonstrated according to the requirements of efficacy guidance:

* Quantitative suspension tests (EN 14476)

Virucidal activity had been also demonstrated against strain H1N1 and Herpes simplex virus type 1, for META SPC1 and 3.

With regard to the claim against the target organism *Coronavirus E229E* and *SARS COV2,* the applicant has submitted additional EN 14476 tests modified, with dirty conditions (3 g/l BSA+3 ml/L sheep erythrocytes)*.* The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / active concentrations / exposure time** | **Test results: effects** | **Reference** |
| Virucidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  1,5% H2O2  (Meta SPC 1 & 3) | Coronavirus 229E | EN 14476 modified | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: dirty conditions (3 g/l BSA+3 ml/L sheep erythrocytes)  Concentration tested:  80%, 50%, 0,1 % v/v | Virucidal concentration : 50 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7\_018  R.I = 1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces | COC.REF.35  1,5 % H2O2  (Meta SPC 2) | Coronavirus 229E | EN 14476 modified | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: dirty conditions (3 g/l BSA+3 ml/L sheep erythrocytes)  Concentration tested:  80%, 50%, 1 % v/v | Virucidal concentration : 50 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7\_019  R.I = 1 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces | MU 3049-91  1,5% H2O2  (Meta SPC 1 & 3) | Sars-Cov2 | EN 14476 modified | Contact time: 1 and 5 minutes  Temperature: 20°C ± 1°C  Soiling: dirty conditions (3 g/l BSA+3 ml/L sheep erythrocytes)  Concentration tested:  80%, 50%, 1 % v/v | Virucidal concentration : 50 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7\_020  R.I = 2 |
| Virucidal | PT2/PT4 Disinfection of hard surfaces | COC.REF.35  1,5 % H2O2  (Meta SPC 2) | Sars-Cov2 | EN 14476 modified | Contact time: 1 and 5 minutes  Temperature: 20°C ± 1°C  Soiling: dirty conditions (3 g/l BSA+3 ml/L sheep erythrocytes)  Concentration tested:  80%, 50%, 1 % v/v | Virucidal concentration : 80 % v/v (dirty conditions)  ≥ 4 log unit reduction | IUCLID  Section 6.7 021  R.I = 2 |

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| **Conclusion on the efficacy of the product (Minor change (2021):** |
| Products of the family SANYTOL FRESH, separated in 3 META-SPCs, have shown a sufficient efficacy in accordance with the requirements of the Efficacy guidanceVol II part B/C for the following uses:  META SPC1   * PT2 and 4 hard surface disinfection, by manual spraying or by manual spraying and wiping (100 % v/v), with dirty conditions (3 g/L BSA), at the temperature of 20 °C:   against enveloped virus (including *H1N1*, *Herpes simplex virus type 1*, *Coronavirus 229E* and *SARS COV2*), with a contact time of 5 min  META SPC 2   * PT2 and 4 hard surface disinfection, by manual spraying, by manual spraying and wiping, and by manual pouring and wiping (100 % v/v), with dirty conditions (3 g/L BSA), at the temperature of 20 °C:   against enveloped virus (including *Coronavirus 229E* and *SARS COV2*) with a contact time of 5 min  META SPC 3   * PT2 and 4 hard surface disinfection, by manual pouring and wiping (100 % v/v), with dirty conditions (3 g/L BSA), at the temperature of 20 °C:   against enveloped virus (including *H1N1*, *Herpes simplex virus type 1*, *Coronavirus 229E* and *SARS COV2*), with a contact time of 5 min |

#### Occurrence of resistance and resistance management

“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)[[30]](#footnote-31), Christman et al (1985)[[31]](#footnote-32)). 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.” (Source: Assessment Report. Hydrogen peroxide. Product-types 1-6. March 2015. Finland).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

#### Known limitations

None

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the products of the family SANYTOL FRESH has shown a sufficient efficacy in accordance with the requirements of the transitional Guidance on Efficacy for product type PT1-5, Disinfectants (2016) and the EN 14885:2015 standard for the following uses:

**First authorisation**

META SPC1

* Use 1, PT2 and 4 hard surface disinfection, by manual spraying or by manual spraying and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.
* Use 2, PT2 and 4 soft surface disinfection, by manual spraying (100 % v/v) against bacteria, yeasts and fungi, with a contact time of 45 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

META SPC 2

* Use 1, PT2 and 4 hard surface disinfection, by manual spraying and by manual spraying and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

META SPC 3

* Use 1, PT2 and 4 hard surface disinfection, by manual pouring and wiping (100 % v/v) against bacteria with a contact time of 5 minutes, and against yeasts and fungi with a contact time of 15 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

Some of SANYTOL FRESH BPF product names directly refer to anti-allergen or odor destructor efficacy, which is not in line with efficacy claim. In accordance with article 69.3, those names cannot be accepted for authorisation.

**Minor change (2021):**

Virucidal activity against against enveloped virus has been demonstrated for Meta SPC1 and META-SPC3 (including including *H1N1*, *Herpex simplex virus type 1*, *Coronavirus 229*E and *SARS COV2*) and META-SPC 2 (including *Coronavirus 229E* and *SARS COV2*), with a contact time of 5 minutes, with dirty conditions (3 g/L BSA), at the temperature of 20 °C.

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

The products of the SANYTOL FRESH family are not intended to be used with another biocidal product.

### Risk assessment for human health

Products of the SANYTOL FRESH family are ready-to-use disinfectants containing 1.51% w/w (technical a.s) hydrogen peroxide (H2O2) for Meta SPC 1, 2 and 3.

They are intended to be applied for the disinfection of hard and soft surfaces. These treatments are done by professionals and non-professionals by spraying or wiping.

The product is applied indoors at the following application dose (claimed by the applicant):

* 12 sprays/m2 (for spray application);
* As often as consumers need to use (for application by pouring and wiping).

#### Assessment of effects on Human Health

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on any product of the product family SANYTOL FRESH.

Classification of the products in meta SPC has been carried out according to the calculation rules laid down in the CLP regulation.

***Skin corrosion and irritation***

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| **Data waiving** | |
| Information requirement | Skin corrosion and irritation |
| Justification | According to CLP regulation, the relevant ingredients of a mixture are those which are present in concentrations of 1% or greater. Therefore, the only substance considered relevant for the purpose of classification according to CLP generic cut-off values is H2O2. This substance is present at 1.51% in the reference formulations. As there is a specific concentration limit for skin irritation/corrosivity which is >35%, no classification is triggeredfor skin irritation. |

***Eye irritation***

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| **Data waiving** | |
| Information requirement | Eye irritation |
| Justification | In the case of SANYTHOL FRESH, D-pentose & D-glucose, oligomeric, C8-10-alkyl glycosides and 1-Decanamine, N,N-dimethyl, N-oxide are wetting agent classified H318. They both fulfil the definition of ingredients that have to taken into account in mixture classification even if their content is below 1%.(please refer to CLP § 3.3.3.3.4.1)  Ingredients considered relevant for the purpose of classification according to CLP are   * H2O2 (1.5%), * ethanol (3% for meta SPC 1 and 3, 2.88% for meta SPC 2), * D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides (0.96% for meta SPC 1 and 3, 0.42% for meta SPC 2), * 1-Deoxi-1-(metil-(C8-10-alcanoil)amino)-D-Glucitol (0.5% only for meta SPC 2), * 1-Decanamine, N,N-dimethyl, N-oxide (0.48% for meta SPC 1 and 3 and 0.5% for meta SPC 2).   A specific concentration limit for eye irritation of > 5% (H319) is available for H2O2.  For ethanol, classified H319, the generic concentration limit (GCL) for eye irritation (H319) is of > 10%.  For 1-Decanamine, N,N-dimethyl, N-oxide, 1-Deoxi-1-(metil-(C8-10-alcanoil)amino)-D-Glucitol and D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides, classified H318, the generic concentration limit for eye irritation (H319) is of > 1%.  Taking into account:   * the content of a.s and the SCL of 5%; * the content of co-formulant (wetting agent + ethanol) with GCL of 1% for 1-Decanamine, N,N-dimethyl, N-oxide, 1-Deoxi-1-(metil-(C8-10-alcanoil)amino)-D-Glucitol and D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides classified H318; * 10% for ethanol;   a classification H319 is triggered according to the classification rules and calculations of CLP.  Considering this, a **classification H319 is required** for the three meta SPC. |

***Respiratory tract irritation***

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| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, **no classification is required** for respiratory tract irritation. |

***Skin sensitization***

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| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | In the different formulations, perfumes classified as Skin Sens 1 or 1B – H317 are present at a content of ≤ 0.5%, which is below the general concentration limit of 1%.  Moreover, in the detailed formulation of each perfume classified H317, no sensitizing ingredient is present at a content higher than the threshold value for specific labelling of 0.1%.  Considering this and according to the classification rules laid down in the CLP regulation, **no classification and no specific labelling are required** for skin sensitization. |

***Respiratory sensitization (ADS)***

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| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

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| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for oral acute toxicity. |

*Acute toxicity by inhalation*

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| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity. |

*Acute toxicity by dermal route*

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| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

***Information on dermal absorption***

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| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | According to the information presented in the CAR of the a.s, no clear systemic effect has been observed for H2O2, and then no dermal penetration parameter is needed in order to conclude on human health risks. Only quantitative local risk assessment is performed for H2O2. |

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

Considering the detailed formulations of the products of the family SANYTOL FRESH, five co-formulants have been identified as substances of concern: Ethanol, L(+) Lactic Acid, D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides, 1-Deoxi-1-(metil-(C8-10-alcanoil)amino)-D-Glucitoland 1-Decanamine, N,N-dimethyl, N-oxide.

**Ethanol**

Ethanol is under the BPR review program. No agreed reference value is available under BPR.

OELs exist in the different member states.

The presence of ethanol in the formulation triggers a classification of the products Eye Irrit 2 – H319, it is considered as a SoC.

A local risk assessment will be performed taking into account this classification.

**L(+) Lactic acid**

L(+) Lactic acid is a biocidal active substance agreed and peer-reviewed at the EU level with a draft final Competent Authority Report (CAR) for PT 1 and concentration > 0.1%.

It is classified as Skin irritant 2 – H315 (with a SCL > 24%) and Eye damage 1 – H318 (with a GCL for Eye irrit 2 – H319 of 1%).

A NOAEC for dermal irritant effects has been set at 10%.

No systemic effect has been observed for L(+) Lactic acid, The concentration of L(+) lactic Acid in the formulation is of 0.5%; inferior to the NOAEC of 10% set for the irritation potential of this active substance.

Therefore, no local effects is expected due to the presence of L(+) lactic Acid.

**1-Decanamine, N,N-dimethyl, N-oxide**

The presence of a mixture containing 1-Decanamine, N,N-dimethyl, N-oxide in the formulation triggers a classification of the products Eye Irrit 2 – H319, it is considered as a SoC.

A local risk assessment will be performed taking into account this classification.

**D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides**

The presence of a mixture containing D-pentose and D-glucose, oligomeric, C8-10-alkyl glycosides in the formulation triggers a classification of the products Eye Irrit 2 – H319, it is considered as a SoC.

A local risk assessment will be performed taking into account this classification.

**1-Deoxi-1-(metil-(C8-10-alcanoil)amino)-D-Glucitol**

The presence of a mixture containing 1-Decanamine, N,N-dimethyl, N-oxide in the formulation triggers a classification of the products Eye Irrit 2 – H319, it is considered as a SoC only for meta SPC 2.

A local risk assessment will be performed taking into account this classification.

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

Not relevant.

***Other***

Not relevant.

#### Exposure assessment

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

| **Summary table: relevant paths of human exposure** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** |
| Inhalation | n.a | yes | yes | n.a | yes | yes |
| Dermal | n.a | yes | yes | n.a | yes | yes |
| Oral | n.a | n.a | n.a | n.a | no | no |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| **1** | **Spray application** | | |
| 1a. | Spray application | **Primary Exposure - Dermal and inhalation (aerosols) routes**  Products of Meta SPC 1 and Meta SPC 2 are sprayed on hard and soft surfaces using a trigger spray and leading to dermal and inhalation exposure during application. | Professionals and non-professionals |
| 1b. | Wiping the treated surfaces after spraying | **Primary exposure – Dermal exposure**  After application of the product by spraying (Meta SPC 1 and 2), the treated surfaces can be wipped with a wet cloth leading to dermal exposure. | Professionals and non-professionals |
| 1c. | Exposure to volatilized residues during application (spraying + wiping) | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance and ethanol, exposure to volatilized residues occurs during the application of the product (spraying and wiping) | Professionals and non-professionals |
| **2** | **Application by pouring** | | |
| 2a. | Application by pouring and wiping | **Primary exposure – Dermal exposure**  Product of Meta SPC 2 and 3 are poured on hard surfaces and wipped with a wet cloth leading to dermal exposure. | Professionals and non-professionals |
| 2b. | Exposure to volatilized residues during application (spraying + wiping) | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance and ethanol, exposure to volatilized residues occurs during the application of the product (pouring and wiping) | Professionals and non-professionals |
| **3.** | Exposure to volatilized residues after application | **Secondary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance and ethanol, exposure to volatilized residues occurs if persons enter rooms after the use of the product. | Bystanders |
| **4** | Exposure to treated surfaces (hard and soft) | **Secondary exposure – Dermal exposure**  After the application of the product by spray (hard and soft surfaces) or directly poured on hard surfaces, the product may be wiped or it is let dry.  Secondary dermal exposure may occur during the contact with the treated surfaces (dry or wet). | Bystanders |

***Industrial exposure***

Not applicable.

***Professional exposure***

**Scenario [1] – Spray application**

Products of Meta SPC 1 and Meta SPC 2 are applied by spraying on hard and soft surfaces at an application rate of 12 sprays/m2. After spraying, products can be wiped on hard surfaces to disinfect.

Considering this mode of application, professionals are exposed to the product *via* dermal and inhalation routes simultaneously during the application of the product. The different phases of exposure have been split in three different scenarios in order to clarify the assessment:

* Scenario [1a] 🡪 professional exposure during spray application (dermal exposure + inhalation exposure to generated aerosols);
* Scenario [1b] 🡪 professional exposure during wiping (dermal exposure);
* Scenario [1c] 🡪 professional exposure to volatilized residues generated due to the high volatility of the a.s and ethanol during the application of the product.

This scenario represents a worst-case for non-professional exposure; therefore non-professional uses are considered covered by this assessment.

*Scenario [1a] – Primary exposure during spray application (using a trigger spray)*

| **Description of Scenario [1a]** | | | |
| --- | --- | --- | --- |
| The products are applied by indoors spraying to a hard or soft surface to disinfect it using a trigger spray (Meta SPC 1 and 2).  To assess the exposure during the spray application with a trigger spray, the ”Consumer Spraying and Dusting model 2 (hand held trigger spray)” from the TNsG 2008 has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure values from the model are as follows:   * 36.1 mg bp/min (hands/forearms); * 9.7 mg bp/min (feet/legs/face); * 10.5 mg bp/m3 (inhalation).   It has to be noted that, since no systemic effect has been identified for Hydrogen Peroxide and that only toxicological reference value for inhalation exposure (mg/m3) is available, exposure assessment for the dermal route is not considered.  A local risk assessment will be performed for the dermal route.  In this context, only the indicative exposure value for inhalation is used. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 1.51% | Applicant’s data |
| Concentration of Ethanol in the product | 3% | Applicant’s data |

**Calculations for Scenario [1a]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure**  **(mg/m3)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | | |
| Scenario [1a] | Tier 1/no PPE | 0.16 | - | - | 0.16 |

*Scenario [1b] – Primary exposure during wiping hard surfaces*

After spray application, the product can be wiped on hard surfaces.

As already mentioned above, no systemic effect has been identified for Hydrogen Peroxide and only toxicological reference value for inhalation exposure (mg/m3) is available. A systemic exposure assessment for the dermal route is therefore not considered.

A local risk assessment will be performed for the dermal route.

*Scenario [1c] – Primary exposure to volatilized residues during spray application*

| **Description of Scenario [1c]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance and ethanol, the exposure to vapor during spraying and wiping has been assessed using ConsExpo web and the model for disinfectant (wiping).  The application rate claimed by the applicant for application with a trigger spray is 12 spray/m2.  Considering the following parameters:   * a density of 1.0032 for Meta SPC 1 and 1.0018 for Meta SPC 2; * an amount of product delivered per spray of 1.154g for Meta SPC 1 and 1.11g for Meta SPC 2; * and a treated surface of **5m2;**   The amount of product deposited on the treated surface is of **69g** (12 spray/m2 x 1.15g/spray x 5 m2 = 196.25g).  An exposure duration of **40 min** is considered in order to take into account the time duration of the spraying and the wiping, 30 min and 10 min respectively. For wiping, 10 events/d and 1 min/event for a professional using a wipe for disinfection of small surfacesare considerd (UA discussion on propan-2-ol)  For the other parameters, ConsExpo default values have been kept.  This scenario represents a worst-case approach. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 1.51% | Applicant’s data |
| Concentration of Ethanol in the product | 3.00% | Applicant’s data |
| Task duration (min) | 40 | Spraying + wiping |
| Release area (m2) | 5 | UA discussions on porpan-2-ol |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) of a.s | 214 | Substance data |
| Vapor pressure (Pa) of Ethanol | 5950 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 2/h | Available value for kitchen or bathroom[[32]](#footnote-33) |

2 Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [1c]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure**  **(mg/m3)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | | |
| Scenario [1c] | Tier 1/no PPE | 6.27 | - | - | 6.27 |

*Combined exposure - Scenario [1]: Total exposure during spray application [1a + 1b + 1c]*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) exposure**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [1a,1b,1c]**  **Tier 1** | 0.16 | - | 6.27 | 6.43 |

**Scenario [2] – Application by pouring**

Products of Meta SPC 2 and Meta SPC 3 are applied by pouring on hard surfaces and wiped with a wet cloth. The application dose claimed by the applicant is ”as often as the consumer needs to use”.

Considering this mode of application, professionals are exposed to the product *via* dermal and inhalation routes simultaneously during the application of the product. The different phases of exposure have been split in three different scenarios in order to clarify the assessment:

* Scenario [2a] 🡪 professional exposure during the pouring and the wiping of the product (dermal exposure);
* Scenario [2b] 🡪 professional exposure to volatilized residues generated due to the high volatility of the a.s and ethanol during the application of the product.

This scenario represents a worst-case for non-professional exposure; therefore non-professional uses are considered covered by this assessment.

*Scenario [2a] – Primary exposure during pouring and wiping on hard surfaces*

The product is poured on hard surfaces and wiped with a wet cloth.

As already mentioned above, no systemic effect has been identified for Hydrogen Peroxide and only toxicological reference value for inhalation exposure (mg/m3) is available. A systemic exposure assessment for the dermal route is therefore not considered.

A local risk assessment will be performed for the dermal route.

*Scenario [2b] – Primary exposure to volatilized residues during pouring application*

| **Description of Scenario [2b]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during pouring and wiping has been assessed using ConsExpo web and the model for disinfectant (wiping).  Since no real application rate has been claimed by the applicant for this type of application, the product amount of **69g** calculated for spray application (see. Scenario [1c]) has been used.  An exposure duration of **20 min** is considered in order to take into account the time duration of the pouring and the wiping, 10 min and 10 min respectively.  For the other parameters, ConsExpo default values have been kept.  This scenario represents a worst-case approach. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 1.51% | Applicant’s data |
| Concentration of Ethanol in the product | 3.00% | Applicant’s data |
| Task duration (min) | 20 | pouring + wiping |
| Release area (m2) | 5 | UA discussions |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) of a.s | 214 | Substance data |
| Vapor pressure (Pa) of Ethanol | 5950 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 2/h | Available value for kitchen or bathroom |

2 Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [2b]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation exposure**  **(mg/m3)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | | |
| Scenario [2b] | Tier 1/no PPE | 4.8 | - | - | 4.8 |

*Combined exposure - Scenario [2]: Total exposure during spray application [2a + 2b]*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [2a, 2b]**  **Tier 1** | - | - | 4.8 | 4.8 |

**Combined exposure: Scenario [1] + Scenario [2]**

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [1 + 2]**  **Tier 1** | 0.16 | - | 11.07 | 11.23 |

**Further information and considerations on scenarios [1] and [2]**

TNsG and ConsExpo models make an overestimation of the inhalation exposure due to the generated aerosols and of the air concentration of H2O2 generated by evaporation from a film of product deposited in a surface after application by spraying or pouring.

Therefore, a series of experimental determinations and alternative models have been applied in order to do a more accurate exposure assessment in a Tier 3 approach.

These experiments and models were planned and realized by SVS@CAP and are described in the annexed document SVS\_H2O2.pdf available in Annexe 3.2 of the PAR.

Experimental determinations of H2O2 in air after spray application of reference formulations were conducted to understand the levels of exposure during spray application. The reference formulations were applied with 3 different trigger spray devices considered similar to those claimed for SANYTOL FRESH products. Concentrations were monitorized at 25 cm of the spray plume during several minutes, in two different conditions of product temperature (30ºC and 40ºC corresponding to a worst-case situation). When possible, the obtained results were adjusted by quantitative models of evaporation of a substance from a spray plume (Model from INRS or BASF-MAURER).

*Material and Methods*

The products to be tested are three different formulations with a H202 content of 1.5% and coded with the names F1, F2 and F3.

These formulations are tested as regards two specific applications: -Manual spraying and direct surface inversion.

These three formulations are applied by 3 types of manual spray (or spray bomb), thereafter called: P1, P2 and P3.

The tested formulation-spray combinations are summarized below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Formulation/Spray** | **P1** | **P2** | **P3** |
| **F1** | X | X | X |
| **F2** |  | X | X |
| **F3** |  | X | X |

The technical characteristics of sprays are summarized in Table 1.

In positive control mode, the reference F4 is introduced, having 3.5% H202 and is tested under the P2, P3 and D1 (pouring) applications.

Table 1. Summary of the technical specifications of the tested sprays

|  |  |  |  |
| --- | --- | --- | --- |
|  | **P1** | **P2** | **P3** |
| **Supplier pump code** | TS3 SP FOX SPRAY | TS3 SOUS SPRAY | TS3 SOUS FOAM V20 |
| **Dose (ml)** | 1.2 ± 0.3 ml | 1.2 ± 0.3 ml | 1.2 ± 0.3 ml |
| **Spray pattern (mm)** | 250 mm ± 30 mm (25 cm) | 250 mm ± 30 mm (25 cm) | 250 mm ± 30 mm (25 cm) |
| **Supplier technical specifications document** | TS3 SNAP ON SP GENERAL CA FT TS3 66 01 00 | TS3 SNAP ON CA FT TS3 47 01 00 | TS3 SNAP ON CA FT TS3 47 01 00 |

The formulation F1, in addition to being applied by a spray, may be applied by direct inversion from its original packaging (bottle) on the surface to be treated or previously diluted to 25%. This application by inversion on a surface without dilution was called D5 and the diluted application was called D6.

*Environmental and application conditions*

The environmental and application conditions were selected by taking into account the parameters of the vaporization models and simulating the worst cases of exposure.

The environmental conditions in which measurements of H202 concentrations in air were conducted, were as follows:

* + - Room temperature: Tª = 21 to 22°C
    - Relative humidity: 52%
    - Ventilation in the vaporization area corresponding to a non-industrial atmosphere (≤2.5 V/h), since application for cleanliness and disinfection in domestic kitchens, baths (C2) and dormitories (C3) is considered as worst case ventilation (uncontrolled).

The application conditions took into account the temperature of the liquid at the time of application and the distance for the application of the product with respect to the surface in the case of spraying.

* + - The temperature of the liquid product: Tl = 40 and 30°C
    - The distance for application of the product during spraying: D = 30 cm

According to the applicant, the application dose of the products to cover 1 m2 of surface would be a maximum of 14 g (12 sprays x 1.15 g). To achieve this value, 12 consecutive sprayings would be necessary.

*Determination of H202 concentrations in atmosphere*

Measurements were made by considering two types of application:

* Direct manual spraying on a vertical surface;
* Direct inversion of product on a horizontal surface (application by pouring).

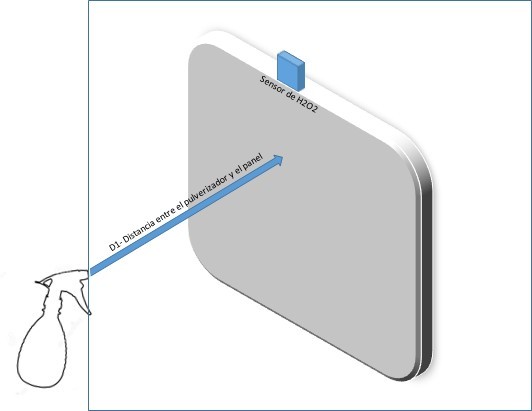
1. **Determination of H202 concentrations in atmosphere after manual spraying of the formulations F1, F2 and F3 by using the sprays P1, P2 and P3.**

Experimental measurements of H202 were performed as follows:

* + - * Experimental measurements were carried out in a 1m3 chamber, where there is a vertical metal wall of 1m2 and a sensor that determines continuously the H202 concentration in air for 15 minutes. The environmental temperature, relative humidity and ventilation are maintained under control throughout the study.
      * Product is sprayed after the manual bomb of the spray has been prepared or primed by a full spraying t1 = 1 s, outside the measurement area, to ensure that the spray tube is full of product.
      * During the measurements, a complete spraying is carried out at a distance of 30 cm from the vertical metal wall of 1m2 of surface. This distance of 30 cm corresponds to the maximum achieved coverage at the vertical panel. It is therefore the distance in which the spraying volume is the largest and therefore represents the worst case (see Figure 1 below).
      * During the tests, the measurements are carried out continuously at the H202 concentration in air by using the sensors that are described in the following section. These sensors have an accuracy of 0.1 ppm. The sensors are located on the spraying axis.

The sensor has a long saturation time, so to perform a new test, it is necessary to wait the time necessary so that the sensor is no longer saturated and returns to a value below the limit of detection (10-15 min).

* The tests were carried out three times.
* The data from all these tests (3 times for each combination formulation - spray) are those corresponding in each case to worst case.
* In those cases where the single spraying produces H202 values below the limit of detection, the spraying is repeated by 12 consecutive sprays in 1 second intervals and then the H202 concentration is estimated.



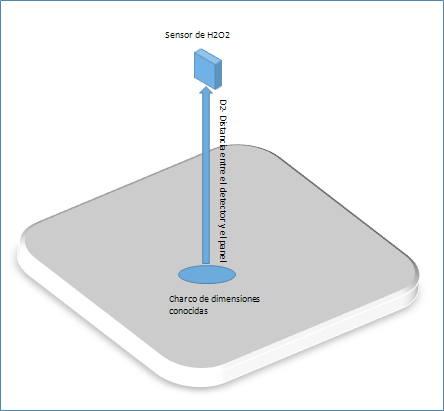
*Figure 1: Representation of the manual spraying on the vertical surface. The distance D1 is the distance from the spray to the panel.*

1. **Determination of H202 concentrations in atmosphere after inversion of the formulation F1 according to D5 and D6**
   * + - Measurements of H2O2 concentrations in air are carried out after having applied the formulation F1 in the form of a puddle (3 to 5 mm thick) on a horizontal metal surface of 1m2. The dimensions of these horizontal applications are made in accordance with the standard EN60079-10-1, relating to the classification of gaseous explosive atmospheres (taken here as a technical reference) and the UIC and INRS protocols for spraying during a product spillage in puddles.
       - The sizes correspond to:
         * 7cmx7cm
         * 14cmx14cm
         * 21cmx21cm
         * 28cmx28cm
       - The liquid to 30°C or 40°C is placed on the reference surface.
       - H2O2 in air is continuously measured at a distance of 1 cm and at 25cm from the application surface (Figure 2). The height of 25 cm corresponds to the user´s breathing distance.

The sensors that are used for the measurements are those described in the following section. These sensors have an accuracy of 0.1 ppm.

The sensor has a long saturation time, so to perform a new test, it is necessary to wait the time necessary so that the sensor indicates 0 ppm. Continuous measurements are carried out for 15 minutes.

* + - * Check the maximum value of H2O2 in ppm, at a distance of 1 cm and 25 cm above the surface, as well as the recorded data.
      * Check the time in seconds to reach the maximum H2O2 concentration in air.
      * Tests are always repeated 3 times.
      * Data of all the repetitions are used and the worst case is each time considered.



*Figure 2: Representation of the measuring system for evaluation of the application by inversion on the horizontal surface. The distance D2 is the distance from the sensor to the product puddle.*

1. **Sensors for measuring H202 in atmosphere**

To carry out continuous measurements of H2O2 in air, ATI sensors are used, which have the following characteristics:

* Sensor measuring low H2O2 concentrations (only calibrated for H2O2): 0 to 10/100 ppm.
* Measurements in 4-20mA are recorded by a Siemens automation system, having a 4-20mA input and a DELL laptop.
* Precision: ± 5% of the value
* Repeatability: ± 5% of the span
* Output: 4-20mA
* Power supply: 12-28 VDC
* Load resistance: 657 Ω max in 24 VDC
* Calibration: By using a potentiometer (zero and sensitivities) that is mounted on the electronic board.
* Operating temperature: 0°C to + +50°C



*Figure 3: ATI detector of H2O2*

ATI sensors have been calibrated by ATI's technical service unit. The calibration certificate is attached to the study report.

The reference F4, with 3.5% of H2O2, is used as positive control and tested by using the applications P2, P3 and D1.

*Results of measurements of H202 concentrations in atmosphere after application of the formulations under the provided experimental conditions*

1. **Results of measurements on the formulation F1**

Tables 2a and 2b summarize the values of the maximum H202 concentrations during application of the product F1 by the different sprays and by direct inversion on the surface.

*Table 2a: Maximum H202 concentrations during application of the formulation F1*

|  |  |  |  |
| --- | --- | --- | --- |
| **Spray** | **Tª** | **30cm 25cm** | |
| **Spray P1** | **40ºC** | <0.1  ppm |  |
| **30ºC** | <0.1  ppm |
| **Spray P2** | **40ºC** | <0.1  ppm |  |
| **30ºC** | <0.1  ppm |
| **Spray P3** | **40ºC** | <0.1  ppm |  |
| **30ºC** | <0.1  ppm |
| **D5, D6** | **40ºC** |  | <0.1  ppm |
| **30ºC** | <0.1  ppm |

*Table 2b: Maximum H202 concentrations after subsequent application of 12 sprays of the formulation F1*

|  |  |  |
| --- | --- | --- |
| **Spray** | **Tª** | **30cm** |
| **Spray P1** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |
| **Spray P2** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |
| **Spray P3** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |

1. **Results of measurements on the formulation F2**

Tables 3a and 3b summarize the values of the maximum H202 concentrations during application of the product F2 by the different sprays on the surface.

*Table 3a: Maximum H202 concentrations during application of the formulation F2*

|  |  |  |
| --- | --- | --- |
| **Spray** | **Tª** | **30cm** |
| **Spray P2** | **40ºC** | <0.1 ppm  <0.1 ppm |
| **30ºC** |
| **Spray P3 40ºC** | | <0.1 ppm |
|  | **30ºC** | <0.1 ppm |

*Table 3b: Maximum H202 concentrations after subsequent application of 12 sprays of the formulation F2*

|  |  |  |
| --- | --- | --- |
| **Spray** | **Tª** | **30cm** |
| **Spray P2** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |
| **Spray P3** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |

1. **Results of measurements on the formulation F3**

Tables 4a and 4b summarize the values of the maximum H202 concentrations during application of the product F3 by the different sprays on the surface.

*Table 4a: Maximum H202 concentrations during application of the formulation F3*

|  |  |  |
| --- | --- | --- |
| **Spray** | **Tª** | **30cm** |
| **Spray P2** | **40ºC** | <0.1 ppm  <0.1 ppm |
| **30ºC** |
| **Spray P3 40ºC** | | <0.1 ppm |
|  | **30ºC** | <0.1 ppm |

*Table 4b: Maximum H202 concentrations during application of the formulation F3*

|  |  |  |
| --- | --- | --- |
| **Spray** | **Tª** | **30cm** |
| **Spray P2** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |
| **Spray P3** | **30ºC** | <0.1 ppm |
|  | **40ºC** | <0.1 ppm |

1. **Results of measurements on the control formulation F4**

Table 5a summarizes the maximum H202 concentrations after application of the F4 control by using the different sprays (P2 and P3) and the direct inversion on the surface (D5 and D6).

*Table 5: Maximum H202 concentrations during application of the formulation F4*

|  |  |  |  |
| --- | --- | --- | --- |
| **Spray** | **Tª** | **30cm 25cm** | |
| **Spray P2** | **40ºC** | 0.8 ppm |  |
| **30ºC** | <0.1 ppm |
| **Spray P3** | **40ºC** | 0.3 ppm |  |
| **30ºC** | 0.2 ppm |
| **D5, D6** | **40ºC** |  | <0.1  ppm |
| **30ºC** | <0.1  ppm |

*Conclusions of the study*

* Spray application

All H202 measurements in air after spraying were performed in the worst-case scenario. This means, a spraying distance of 30 cm and a liquid temperature of 30°C and 40 °C on a vertical surface with the sensor at 25 cm above the spray pen.

It is observed that the H202 concentrations in air, that are produced after one or twelve spraying of the formulations F1, F2 and F3 are **less than 0.1 ppm (equivalent to 0.14 mg/m3 with a MM of 34 g/mol)** whatever the sprays used to apply the formulation (P1, P2 or P3).

* Application by inversion (pouring)

It is observed that after applying the product F1 (D5) over an area of 22 m2, the H202 concentration at 25 cm from the treated surface, when the air exchange will be minimal (2.5 renovations/hour), is **less than 0.1 ppm (equivalent to 0.14 mg/m3 with a MM of 34 g/mol)**.

***Overall conclusions on exposure asssessement for Scenario [1]***

| **Summary table: combined systemic exposure from professional uses – Spray application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [1a,1b,1c]**  **Tier 1** | 0.16 | - | 6.27 | 7.43 |
| **Scenarios [1a,1b,1c]**  **Tier 3** | 0.16 | - | 0.14 | 0.30 |

***Overall conclusions on exposure asssessement for Scenario [2]***

| **Summary table: combined systemic exposure from professional uses - Application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [2a, 2b]**  **Tier 1** | - | - | 4.8 | 4.8 |
| **Scenarios [2a, 2b]**  **Tier 3** |  |  | 0.14 | 0.14 |

***Combined exposure: Scenario [1] + Scenario [2]***

| **Summary table: combined systemic exposure from professional uses - Application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [1 + 2]**  **Tier 1** | 0.16 | - | 11.07 | 11.23 |
| **Scenarios [1 + 2]**  **Tier 3** | 0.16 |  | 0.28 | 0.44 |

***Non-professional exposure***

Non-professional exposure during the application of the product by spraying or pouring is considered covered by the professional exposure assessment described above.

Indeed, for the exposure assessment using the TNsG and ConsExpo models, no modification of the exposure parameters is expected. The exposure durations used in ConsExpo are considered suitable for a non-professional application. Moreover, due to the nature of the toxicological effects (local effects), the duration of exposure has no impact.

Regarding the experimental study (Tier 3), the experimental conditions tested represent a worst-case scenario and are in line with the application conditions expected for non-professional uses. Therefore, the results of the experimental study are considered extrapolable for non-professional application.

***Exposure of the general public***

*Scenario [3]*

| **Description of Scenario [3]** |
| --- |
| SANYTOL FRESH product is intended for use as surface disinfectants.  Inhalation of volatilized residues (H2O2) after indoor application is considered possible and, regarding the intended uses, this exposure takes place to general public entering a room with freshly treated surfaces.  It can be considered that this exposure is equal or lower than the direct exposure of the professionals/non-professionals applying the product. Moreover, due to the high reactivity of H2O2, inhalation exposure to a.s is not expected during a long time.  Therefore, the same parameters used in scenario 1 and 2 have been applied leading to similar exposure to volatilzed residues for a person (adult or child) entering a room with freshly treated surfaces  For details please refer to the scenario 1 and 2. |

**Calculations for Scenario [3]**

Spray application

| **Summary table: combined systemic exposure from professional uses – Spray application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [1a,1b,1c]**  **Tier 1** | - | - | 6.27 | 6.27 |
| **Scenarios [1a,1b,1c]**  **Tier 3** | - | - | 0.14 | 0.14 |

Application by pouring

| **Summary table: combined systemic exposure from professional uses - Application** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) exposure**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/m3)** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | | |
| **Scenarios [2a, 2b]**  **Tier 1** | - | - | 4.8 | 4.8 |
| **Scenarios [2a, 2b]**  **Tier 3** | - | - | 0.14 | 0.14 |

*Scenario [4]*

| **Description of Scenario [4]** |
| --- |
| Products of the SANYTOL FRESH family are intended for use as surface disinfectants.  Because of the high volatility of the a.s and ethanol containing in the product, dermal exposure to H2O2 and ethanol applied in the product is considered negligible.  However, H2O2 is a highly reactive active substance that will react with organic matter present on the surfaces to be treated (hard and soft) leading to the formation of Disinfectant By-Product (DBP).  The number of DBP formed is very high and no identification neither quantification is possible.  The guidance on the BPR Vol V on Disinfection By-Products doesn’t give many information on how to handle this exposure the priority being given to PT 2 (swimming-water) since this is considered the most relevant from the point of view of the degree of human exposure and possible health risk.  However, considering the low concentration of active substance in the products (1.5%), only exposure to very low levels of a wide variety of DBP is expected leading to no real concern for general public. |

***Monitoring data***

None

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

Not relevant

***Aggregated exposure***

None

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group** | **Tier/PPE** | **Estimated total exposure**  **(mg/m3)** |
| **H2O2** | | | |
| 1. | Professionals and Non-professionals | Tier 1/No PPE | 6.43 |
| Tier 3/No PPE | 0.30 |
| 2. | Professionals and Non-professionals | Tier 1/No PPE | 4.8 |
| Tier 3/No PPE | 0.14 |
| 1 + 2 | Professionals and Non-professionals | Tier 1/No PPE | 11.23 |
| Tier 3/No PPE | 0.44 |
| 3. | Bystanders | Tier 3/Spray application | 0.14 |
| Tier 3/Application by pouring | 0.14 |

***Dietary exposure***

By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residue in food or feed are not expected for SANYTOL FRESH PT 2 uses.

As PT 4, SANYTOL FRESH is intended to be used for surface disinfection in commercial premises (food, industrial and institutional areas) and in households/private areas (domestic areas). Therefore, residues in food or feed might be expected based on intended uses.

Biocidal product SANYTOL FRESH is composed of hydrogen peroxide and of several coformulants, especially ethanol (CAS number: 64-17-5) and L+ lactic acid (CAS n° 79-33-4). These two substances are biocidal active substances: L+ lactic acid is approved as PT 4 (Reg (EU) 2017/2002) and ethanol is under EU review at EU level for PT 4 (eCA Greece). Therefore, dietary assessment shall take into account hydrogen peroxide, ethanol and L+ lactic acid.

For ethanol, “*exposure via food is negligible due to environmental behaviour of ethanol:*

*- Ethanol is classified as readily biodegradable*

*- Bioaccumulation of ethanol in the food chain is not expected*” (CAR, Document I, Ethanol)[[33]](#footnote-34).

Regarding L+ lactic acid data, “*L(+) lactic acid is a naturally occurring alpha-hydroxy acid found in plants, animals, and humans. Major sources of L(+) lactic acid in the human organism are endogenous production (e. g. via anaerobic catabolism of glycogen and glucose) production by gastrointestinal microorganisms and uptake via food. The production of L(+) lactic acid as an intermediary metabolite in a 70 kg resting man is estimated to be in the range of 117- 230 g/d but can be much higher during exercise. The mean daily per capita intake of L(+) lactic acid and D(-) Lactic acid from milk and milk products has been estimated to be approximately 1 g in Switzerland (Walther, 2006). The estimated overall intake via food in the EU and the USA is estimated to be 1.65-2.76 g/person/day (DocIII6.2.01).*

*L(+) lactic acid has been approved in the EU as a food additive without an ADI or upper limit (quantum satis; Dir. 95/2/EC), as a cosmetics ingredient, and as veterinary medicinal product without the requirement for MRL setting (EMEA 2008)*” (Assessment Report, 2017[[34]](#footnote-35)).

Moreover, “*Because of the very low systemic toxicity of L(+) lactic acid, derivation of any systemic toxicological reference dose was regarded unnecessary. Considering the intended uses, exposure is estimated to be clearly below endogenous production (>100 g/person/day) and dietary exposure (>1 g/person/day). Therefore, neither an ADI nor an ARfD have been set*” (Assessment Report, 2017).

So, considering available knowledge about ethanol and L(+) lactic acid and for SANYTOL FRESH intended PT 4 uses, no concern for consumer are expected following indirect exposure via food.

According to the applicant “*for hydrogen peroxide, no indirect exposure is assumed via food because of its rapid degradation. Nevertheless, hydrogen peroxide degradation can lead to the formation of free radicals which are highly reactive components. Free radicals can therefore react with organic components present on surfaces and lead to the formation of a wide range of by-products, potentially toxic. The range of trace by-products 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 disinfection by-products*”.

Moreover, European guidance on the assessment of Disinfection by products is finalised and available[[35]](#footnote-36). 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, no finalised or draft guidance is available.

Without any indication on how to perform an exposure assessment of the DBP formed during H2O2 application, no proposal has been made. Considering the low concentration of hydrogen peroxide and the authorised uses of hydrogen peroxide in other regulated areas (PPP and processing aid in France), significant indirect exposure via Disinfection By-Products in food is not expected.

*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 | ie 68 mg/kg on salads, no limits on spinach, wheat, peas, |

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

*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** |
| AECshort-term | 90 d study in rats | 10 mg/m3 | 8 | n.r | 1.25 mg/m3 |
| AECmedium-term | n.r |
| AEClong-term | n.r |
| ARfD | n.a | | | | |
| ADI |

**L(+) Lactic acid**

L(+) Lactic acid is a biocidal active substance agreed and peer-reviewed at the EU level with a draft final Competent Authority Report (CAR) for PT 1 and concentration > 0.1%.

It is classified as Skin irritant 2 – H315 (with a SCL > 24%) and Eye damage 1 – H318 (with a GCL for Eye irrit 2 – H319 of 1%).

No systemic effect has been observed for L(+) Lactic acid, A NOAEC for dermal irritant effects has been set at 10%.

***Risk for industrial users***

Not applicable

***Risk for professional users***

**Local effect – Quantitative assessment**

**Scenarios – H2O2**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/m3** | **Estimated exposure**  **mg/m3** | **Estimated exposure / AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [1] – Spray application** | Tier 1 | 1.25 | 6.43 | 514 | No |
| Tier 3 | 1.25 | 0.30 | 24 | Yes |
| **Scenario [2] – Application by pouring** | Tier 1 | 1.25 | 4.8 | 384 | No |
| Tier 3 | 1.25 | 0.14 | 11.2 | Yes |
| **Scenario [1 + 2]** | Tier 1 | 1.25 | 11.23 | 898 |  |
| Tier 3 | 1.25 | 0.44 | 35.2 |  |

**Local effect – Qualitative assessment**

**L(+) Lactic acid**

The concentration of L(+) lactic Acid in the formulation is of 0.5%; inferior to the NOAEC of 10% set for the irritation potential of this active substance.

Therefore, no local effects is expected due to the presence of L(+) lactic Acid.

Moreover, a classification Eye irrit. 2 – H319 being required for the products of the SANYTOL FRESH family, a local risk assessment according to the guidance on the BPR: Volume III HH part B 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 |
| Low | Eye Irrit 2 | - | 2-4 | Professional | Spraying downward on small surfaces (desk, equipment materials...) in area without controlled atmosphere | ocular | More than few minutes per day but equal to or less than few hours per day | Low | **RMM Technics:** - Minimisation of splashes and spills;  **RMM Organisation:** -Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene  **PPE**  - Eye protection | The spray application should be downward in order to avoid any facial exposure.  Considering that these recommendations can be followed during this task, ,the risk is acceptable according to RMMs and PPE |

**Conclusion**

The risk is considered acceptable for professional users during the application of the product by spraying and pouring.

For spray application, due to the classification of products, facial exposure to generated aerosols has to be limited by the use of PPE (goggles) and application of technical and organisational RMMs.

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

**Local effects - Quantitative assessment**

The exposure assessment being similar to professional uses, the same conclusion applies for the risk assessment regarding H2O2 and Ethanol.

**Local effects - Qualitative assessment**

The concentration of L(+) lactic Acid in the formulation is of 0.5%; inferior to the NOAEC of 10% set for the irritation potential of this active substance.

Therefore, no local effects is expected due to the presence of L(+) lactic Acid.

Moreover, a classification Eye irrit. 2 – H319 being required for the products of the SANYTOL FRESH family, a local risk assessment according to the guidance on the BPR: Volume III HH part B is realised.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
| Low | Eye Irrit 2 | - | 2-4 | Non-professional | Spraying downward on small surfaces (desk, equipment materials...) in area without controlled atmosphere | ocular | Equal to or less than one hour per day | Low | Labelling, instructions of use that minimise exposure or possible health effects. | The spray application should be downward in order to avoid any facial exposure.  Considering that these recommendations can be followed during this task, ,the risk is acceptable. |

**Conclusion**

The risk is considered acceptable for non-professional users during the application of the product by spraying and pouring.

***Risk for the general public***

**Local effects - Quantitative assessment**

**Inhalation exposure**

**Scenarios – H2O2**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/m3** | **Estimated exposure**  **mg/m3** | **Estimated exposure / AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [3] – Spray application** | Tier 1 | 1.25 | 6.27 | 501.6 | No |
| Tier 3 | 1.25 | 0.14 | 11.2 | Yes |
| **Scenario [3] – Application by pouring** | Tier 1 | 1.25 | 4.8 | 384 | No |
| Tier 3 | 1.25 | 0.14 | 11.2 | Yes |

**Dermal exposure**

Because of the high volatility of the a.s and ethanol containing in the product, dermal exposure to H2O2 and ethanol applied in the product is considered negligible.

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

The number of DBP formed is very high and no identification neither quantification is possible.

However, considering the low concentration of active substance in the products (1.5%), only exposure to very low levels of a wide variety of DBP is expected leading to no real concern for general public.

**Local effects - Qualitative assessment**

The concentration of L(+) lactic Acid in the formulation is of 0.5%; inferior to the NOAEC of 10% set for the irritation potential of this active substance.

Therefore, no local effects is expected due to the presence of L(+) lactic Acid.

**Conclusion**

The risk is considered acceptable for general public (adult and child) entering a room with freshly treated surfaces.

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

Not applicable

**Maximum residue limits or equivalent**

Not relevant

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

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

Regarding PT 4 uses, considering properties of lactic acid, ethanol and hydrogen peroxide, no significant exposure via food is expected. Based on the low concentration of hydrogen peroxide and the authorised uses of this active substance in other regulated areas (PPP, processing aid in France), significant indirect exposure via Disinfection By-Products in food is not expected.

### Risk assessment for animal health

Not applicable

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

Not applicable.

Please refer to SPC.

### Assessment of a combination of biocidal products

Not applicable

### Risk assessment for the environment

|  |
| --- |
| 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**. |

#### Effects assessment on the environment

Every data on the environmental fate, behaviour and toxicity of the active substance and the SoC are derived from:

* Hydrogen peroxide CAR for PT1-6
* L-lactic acid MSDS provided for the supplier (attached file 09 PURAC 50- MASSO –EN ) and the available information available in "https://echa.europa.eu/es/registration-dossier/-/registered-dossier/14252/1"' (Source: European Chemicals Agency, http: //echa.europa)
* MSDS and ECHA database data of other minor ingredients (1-Decanamine, N.N-dimethyl,N-oxide) that surpass the cut-off values. (Source: European Chemicals Agency, http: //echa.europa).

**Active ingredient: Hydrogen peroxide**

|  |  |
| --- | --- |
| Hydrolisis | Not applicable. Descomposition catalysed by transition metal ions |
| Readiliy biodegradable | Yes. Half life in STP: 2 min |
| Biodegradation in freshwater | Half-life 5 days |
| Distribution water/sediments | Does not partition. No adsorption to sediment |
| Degradation in soil | Rapidily decomposed |
| Log Koc | 0.2036 |
| Photolysis in air | Half-life 24 h |
| Toxicity |  |
| Acute fish LC50 | 16.4mg/L |
| Acute Dapnia EC50 | 2.34 mg/L |
| Acute algae | 2.39 mg/ml |
| Chronic Daphnia NOEC | 0.63 mg/L |
| Algae 72 h NOEC | 1.69 mg/L |
| Microorganisms activated sludge EC50 | 466 mg/L |
| Bioconcentration | No required (Kow -1.5) |
|  |  |
| **PNECs** |  |
| **STP microorganims** | **4.66 mg/L (AF = 100)** |
| **freshwater** | **12.6E-3 mg/L (AF=50)** |
| **Freshwater sediments** | **0.0101 mg.kgwwt-1 (equilibrium)** |
| **soil** | **1.7E-03 mg.kgwwt-1 (equilibrium)** |

|  |
| --- |
| Infobox 1 - FR CA position:  The proposed endpoint values for the effect assessment of the active substance hydrogen peroxide are correct. However, for the PNEC freshwater sediment no value is set in the CAR of hydrogen peroxide (March,2015).  The following explanation is provided: ”*Considering the low n-octanol/water partition coefficient of hydrogen peroxide (log Kow –1.57), the expected low adsorption to organic matter (QSAR based log KOC 0.2036) and its generally rapid abiotic and biotic degradation in surface waters […], hydrogen peroxide is not expected to partition into the sediment. Because of the lack of exposure, a proposal for a PNEC for sediment-dwelling organisms is not considered necessary. Furthermore, any potential risk to sediment dwelling organisms is considered to be adequately covered by using the PNEC for the water phase.*” Therefore no risk assessment for the sediment has to be carried out.  Concerning the PNEC soil, a slightly different value is indicated in the CAR and will be used for the risk assessment (1.84E-3 mg/kg wwt). |

**SoC: L-Lactic acid**

|  |  |
| --- | --- |
| Hydrolisis | No hydrolysis |
| Readiliy biodegradable | Yes, but 10-day window not assessed |
| Biodegradation in freshwater |  |
| Distribution water/sediments |  |
| Degradation in soil |  |
| Log Koc | 20.9 |
| Photolysis in air | Not applicable |
| Toxicity |  |
| Acute fish LC50 | 130 mg/L (related to low pH; not valid) |
| Acute Dapnia EC50 | 156 mg/L (related to low pH; not valid) |
| Acute algae | 3.9 g/L |
| Chronic Daphnia NOEC |  |
| Algae 72 h NOEC | 1.1 g/L |
| Microorganisms activated sludge EC50 | >100 mg/L |
| Microorganisms activated sludge NOEC | >100 mg/L |
|  |  |
|  |  |
| **PNECs** |  |
| **STP microorganims** | **10 mg/L (AF = 10)** |
| **freshwater** | **3.9 mg/L (AF = 1000)** |
| **Freshwater sediments** | **4.8 mg/kg ww (equilibrium)** |
| **soil** | **1.9 mg/kg ww (equilibrium)** |

|  |
| --- |
| Infobox 2 - FR CA position:  The proposed endpoint values for the effect assessment of L-Lactic acid are the same as those presented in the CAR of L(+) Lactic acid (January, 2016). |

**Other relevant ingredients**

The "relevant components" of a mixture are those which are classified "Acute 1" (H400) or "Chronic 1" (H410) and present in a concentration of 0.1 % (w/w) or greater, and those which are classified "Chronic 2" (H411), "Chronic 3" (H412) or "Chronic 4" (H413) and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as "Acute 1" or "Chronic 1" the concentration to be taken into account is (0.1/M) %.

Applying these criteria:

|  |  |
| --- | --- |
| **1-Decanamine, N.N-dimethyl,N-oxide** (CAS 2605-79-0) is classified as H400 and H411; the final concentration is **0.5%** (> cut-off 0.1% for H400). | Relevant |
| **Fragrances** are mixtures classified as H411 or H412; the final concentration in the product is 0.5% (< cut-off 1%)  Furthermore, the sum of concentrations of H400 or H410 ingredients in any of the fragrances is lower than 11%. Therefore, the final concentration in the product of the sum of H400 or H410 ingredients in any of the fragrances is < 0.5%\*11% < 0.055% (< cut-off 0.1%)  The only exception is “New Pin Maritime” perfume that contains 22.5-30% of 1-Decanamine, N.N-dimethyl,N-oxide (CAS 2605-79-0) and 1-Dodecanamine, N.N-dimethyl,N-oxide (CAS 1643-20-5). Therefore, gives 0.5%\*30%= **0.15%** final concentration of the sum of two very similar substances classified as H400.  The first of these two substances is also present in the product formulation (0.5%) and has been considered as relevant.  The second has almost identical environmental properties. Therefore they will be considered in conjunction (**concentration 0.65%)** | Not relevant |

|  |
| --- |
| Infobox 3 - FR CA position:  In view of the low concentrations of substances classified for the environment such as 1-decanamine, N.N-dimethyl,N-oxide and fragrances, we agree with the applicant proposal to assess only the 1-decanamine, N.N-dimethyl,N-oxide considering a concentration of 0.65% of product SANYTOL FRESH.  A substance is under the BPR review program but no agreed reference values are available. Therefore, according to guidance on the BPR volume IV part B + C section 8.1.1, this substance could not be considered as SOC for the environment.  Another substance is not considered as a SoC for the environment.  The justification for the non-relevance of this co-formulants is presented in the Confidential PAR. |

**1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide)**

Data from ECHA database

|  |  |  |
| --- | --- | --- |
| Molecular weight (decanamine-N-oxide) | 201 | [g.mol-1] |
| Melting point (decanamine-N-oxide) | 135 | [oC] |
| Vapour pressure at test temperature | 1.00E-06 | [Pa] |
| Temperature at which vapour pressure was measured | 20 | [oC] |
| Octanol-water partition coefficient | 2.7 | [log10] |
| Water solubility at test temperature | 1.00E+05 | [mg.l-1] |
| Chemical class for Koc-QSAR | Non-hydrophobics (default QSAR) |  |
| Solids-water partition coefficient in soil  (mean from experimental data in three soils) | 13.8 | [l.kg-1] |
| Henry's law constant at test temparature | 7.50E-04 | [Pa.m3.mol-1] |
| Temperature at which Henry's law constant was measured | 20 | [oC] |
| Characterization of biodegradability | Readily biodegradable |  |
| Fraction of emission directed to water by STP  (Experimental) | <5 | [%] |
|  |  |  |
| PNEC for aquatic organisms | 0.0335 | [mg.l-1] |
| PNEC for fresh-water sediment organisms (equilibrium partitioning) | 0.22 | [mg.kgwwt-1] |
| PNEC for marine organisms | 3.35E-03 | [mg.l-1] |
| PNEC for micro-organisms in a STP | 4.59 | [mg.l-1] |
| PNEC for terrestrial organisms (equilibrium partitioning) | 0.373 | [mg.kgwwt-1] |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 4 - FR CA position:  Some values presented above seem to be not valid. In fact, the proposed Koc value of 13.8 corresponds to the Kd value. Thus, the PNEC calculations are impacted and have been recalculated with the correct Koc of 1517.  The following table summarizes the PNEC values for 1-decanamine, N.N-dimethyl,N-oxide.   |  |  |  |  | | --- | --- | --- | --- | | PNEC values used in the environmental exposure assessments according to the SDS and update data from ECHA web site. | | | | | PNEC values for each environmental compartment | | | | | Surface water | 3.35E-02 | [mg.L-1] | | STP | 4.59E+00 | [mg.L-1] | | Sediment | 1.14E+00 | [mg.kg-1 wwt] | | Soil | 9.00E-01 | [mg.kg-1 wwt] | |

***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 5 - FR CA position:   |  |  | | --- | --- | | **Classification of the Active Substance Hydrogen peroxide** | | | Value/conclusion | Active substance – Hydrogen peroxide is not classified for the environment according to the harmonised classification. Nevertheless, this active substance should be classified H 412 according to the available data of the CAR. This classification has no consequence on the product classification. | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest lowest chronic ecotoxicity endpoint (21d): NOEC= 0.63 mg/L and the substance is considered as rapidly degradable. |  |  |  | | --- | --- | | **Classification of the Substance of Concern: L(+) Lactic acid** | | | Value/conclusion | Substance of concern: L(+) Lactic acid has no harmonised classification. Nevertheless, according to the available data in the CAR of this substance, it should not be classified. |  |  |  | | --- | --- | | **Classification of the Substance of Concern: 1-Decanamine, N,N-dimethyl, N-oxide** | | | Value/conclusion | According to the SDS, the substance of concern: 1-Decanamine, N,N-dimethyl, N-oxide is classified H400-H411 (Mfactor=1). | | Justification for the value/conclusion | Algae were the most sensitive species with the lowest chronic ecotoxicity endpoint (28d): NOEC 67 µg/L, and the substance is considered readily biodegradable. |  |  |  | | --- | --- | | **Classification of the Product SANYTOL FRESH** | | | Value/conclusion | Not classified | |

***Further Ecotoxicological studies***

No data available

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

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

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

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

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

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

No data is available

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

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

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

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| H202 | yes | yes | n.r | n.r. | yes | no | n.r. | no |  |

|  |
| --- |
| Infobox 11 - FR CA position:  See the fate and distribution in exposed environmental compartments in infobox 25. |

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

No data is available

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

***Leaching behaviour (ADS)***

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

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

No data is available

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

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

No data is available

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

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

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

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

|  |
| --- |
| Infobox 17 - FR CA position:  No new data is available. |

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

|  |
| --- |
| Infobox 18 - FR CA position:  No new data is available. |

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | *PT 2 PT4* |
| Assessed scenarios | *Scenario 1: PT2 Private Disinfection of rooms, furniture and objects*  *Scenario 2: PT2 Disinfection in industrial areas*  *Scenario 3: PT2 Disinfection in institutional areas*  *Scenario 4: PT2 Disinfection for sanitary purposes in hospitals*  *Scenario 5: PT4 Disinfection in large scale catering, kitchens, …* |
| ESD(s) used | *Scenario 1*  *Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD RIVM 2001, Table 2.2, p.10).*  *Scenario 2*  *Emission scenario for calculating the releases of disinfectants used in industrial areas (ESD JRC 2011, Table 2, p.12 & TAB ENV 24, Sept 2015)*  *Scenario 3*  *Emission scenarios for calculating the releases of disinfectants used in institutional áreas. Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD JRC 2011, Table 4, p.16)*  *Scenario 4*  *Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD RIVM 2001, Table 3.6, p.20)*  *Scenario 5*  *Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, and canteens, (JRC 2011, ESD § 2.2, p.17)* |
| Approach | *Scenario 1-5 : Average consumption based* |
| Distribution in the environment | *Calculated based on TGD 2003* |
| Groundwater simulation | *No simulation for leaching to groundwater using a higher tier models it has been performed for any of the scenarios.* |
| Confidential Annexes | *No* |
| Life cycle steps assessed | *Scenario 1-5:*  *Production: No*  *Formulation No*  *Use: Yes*  *Service life: No* |
| Remarks | *All the scenarios assume indoor application. The products are aimed for disinfection of indoor hard surfaces and textile surfaces. Application of the products to outdoor surfaces (and direct emission to soil) is possible, but very occasional. Therefore outdoor applications have not been considered.* |

|  |
| --- |
| Infobox 19 - FR CA position:  We agree with the general information provided for the product SANYTOL FRESH. However, it is worth noting that a technical concentration of 1.51% of hydrogen peroxide (instead of the pure concentration taken by the applicant) is further considered in the following revised environmental assessment of the product SANYTOL FRESH. |

***Emission estimation***

**Scenario [1]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD RIVM 2001, Table 2.2, p.10). | | | |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.007 | *L/day/inhabitant* | Default for general+lavatory application |
| Concentration of **active substance** in the product | 0.015 | *Kg/L* | 1.5% |
| Concentration of **SoC (L-lactic acid)** in the product | 0.005 | *Kg/L* | 0.5% |
| Concentration of 1-Decanamine, N.N-dimethyl,N-oxide and Dodecanamine, N.N-dimethyl,N-oxide (DDMNO) | 0.0065 | *Kg/L* | 0.65% |
| Fraction released to wastewater | 1 | [-] | Default (1) |
| Number of emission days | 365 | [d] | Default |
| Penetration factor of disinfectant | 0.5 | [-] | Default |
| Number of inhabitants feeding one STP | 1.00E+04 | [eq] | Default |

1. *Hydrogen peroxide is volatile. Therefore, a major portion of the substance will be emited to air. The emission to air is of low environmental relevance. The half-live is very short and there are multiple natural sources that contributes to a natural background concentration. Furthermore, hydrogen peroxide is very reactive and decompose rapidily before being emited to the environmental comparments. As a worst scenario, we have assumed that 100% of the substance is emited to wastewater.*

Calculations for Scenario [*1*]

Elocal4,water = Nlocal \* Qproduct \* Cproduct \* Fpenetr \* F4,water

Nlocal = 10000

Qproduct = 0.007 L/cap\_day (General + lavatory)

Cproduct= 0.015 kg H2O2/L ; 0.005 kg lactic acid/L

Fpenetr= 0.5

F4,water = 1 (worst option)

**Elocal4,water = 10000 \* 0.007 \* 0.015 \* 0.5 \* 1 = 0.525 kg H2O2/d**

**Elocal4,water = 10000 \* 0.007 \* 0.005 \* 0.5 \* 1 = 0.175 kg lactic acid/d**

**Elocal4,water = 10000 \* 0.007 \* 0.0065 \* 0.5 \* 1 = 0.223 kg DDMNO/d**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.525 | Hydrogen peroxide |
| STP | 0.175 | L-Lactic acid (SoC) |
| STP | 0.223 | DDMNO |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 20 - FR CA position:  The input parameters and calculations provided for the scenario 1 “Private disinfection of rooms, furniture and objects” are relevant. It is worth noting that the density of the product is close to 1 kg/L (1.0032 kg/L).  However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP after a residence time in the sewage system of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR. The local emission values are summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 1** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 1.27E-02 | | L**(+)** Lactic acid | 1.75E-01 | | 1-Decanamine, N,N-dimethyl, N-oxide | 2.28E-01 | |

**Scenario [2]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emission scenario for calculating the releases of disinfectants used in industrial areas (ESD JRC 2011, Table 2, p.12 & TAB ENV 24, Sept 2015) | | | |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.1 | *L/m2* | maximum 0.1 L/ m² in the pharmaceutical industry |
| Concentration of active substance in the product | 0.015 | *Kg/L* | 1.5% |
| Concentration of **SoC (L-lactic acid)** in the product | 0.005 | *Kg/L* | 0.5% |
| Concentration of 1-Decanamine, N.N-dimethyl,N-oxide and Dodecanamine, N.N-dimethyl,N-oxide (DDMNO) | 0.0065 | *Kg/L* | 0.65% |
| Fraction released to wastewater | 1 | [-] | Default (1) |
| Area surface | 1000 | M2 | Large surface |
| N appl | 1 | Day-1 |  |

Calculations for Scenario [*2*]

Elocal4water = Vform \* Cform \* AREAsurface \* Nappl \* (1-Fdis) \* Fwater / 1000

Vform= 0.1 L/m2

Typical application rates for biocidal products found in the Internet (www.hygies.de) were

0.02 – 0.06 L/m², up to maximum 0.1 L/ m² in the pharmaceutical industry

Cform,= 15g H2O2/L, 5 g lactic acid/L, 6.5g DDMNO/L

AREA Surface = 1000 m2 (Large Surface application)

Nappl = 1 d-1

Fdis = 0 (worst option)

Fwater = 1 (worst option)

**Elocal4water = 0.1 \* 15 \* 1000 \* 1 \* (1-0) 1 /1000 = 1.5 kg H2O2/d**

**Elocal4water = 0.1 \* 5 \* 1000 \* 1 \* (1-0) 1 /1000 = 0.5 kg lactic acid/d**

**Elocal4water = 0.1 \* 6.5 \* 1000 \* 1 \* (1-0) 1 /1000 = 0.65 kg DDMNO/d**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | **1.5 kg /d** | Hydrogen peroxide |
| STP | **0.5 kg/d** | L-Lactic acid (SoC) |
| STP | **0.65 kg/d** | DDMNO |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 21 - FR CA position:  The input parameters and calculations provided for the scenario 2 “Disinfection in industrial areas” are relevant. However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP (after a residence time in sewage of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR). The local emission values are summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 2** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 3.62E-02 | | L**(+)** Lactic acid | 5.00 E-01 | | 1-Decanamine, N,N-dimethyl, N-oxide | 6.50E-01 | |

**Scenario [3]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emission scenarios for calculating the releases of disinfectants used in institutional áreas. Emission scenario for calculating the release of disinfectants used for sanitary purposes based on an average consumption (ESD JRC 2011, Table 4, p.16) | | | |
| Application rate of biocidal product *[alternative: annual tonnage in the EU]* | 0.007 | *L/day/inhabitant* | Default for general+lavatory application |
| Concentration of active substance in the product | 0.015 | *Kg/L* | 1.5% |
| Concentration of **SoC (L-lactic acid)** in the product | 0.005 | *Kg/L* | 0.5% |
| Concentration of 1-Decanamine, N.N-dimethyl,N-oxide and Dodecanamine, N.N-dimethyl,N-oxide (DDMNO) | 0.0065 | *Kg/L* | 0.65% |
| Fraction released to wastewater | 1 | [-] | Default (1) |
| Number of emission days | 365 | [d] | default |
| Penetration factor of disinfectant | 0.5 | [-] | default |
| Number of inhabitants feeding one STP | 1.00E+04 | [eq] | default |

Calculations for Scenario [*3*]

Elocal4,water = Nlocal \* Qproduct \* Cproduct \* Fpenetr \* F4,water

Nlocal = 10000

Qproduct = 0.007 L/cap\_day (General + lavatory)

Cproduct= 0.015 kg H2O2/L ; 0.005 kg lactic acid/L

Fpenetr= 0.5

F4,water = 1 (worst option)

**Elocal4,water = 10000 \* 0.007 \* 0.015 \* 0.5 \* 1 = 0.525 kg H2O2/d**

**Elocal4,water = 10000 \* 0.007 \* 0.005 \* 0.5 \* 1 = 0.175 kg lactic acid/d**

**Elocal4,water = 10000 \* 0.007 \* 0.0065 \* 0.5 \* 1 = 0.223 kg DDMNO/d**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.525 | Hydrogen peroxide |
| STP | 0.175 | L-Lactic acid (SoC) |
| STP | 0.223 | DDMNO |

|  |
| --- |
| Infobox 22 - FR CA position:  According to the ESD for PT02 (JRC 2011), the scenario for the disinfection in institutional areas covers both private use (households) and public domain (institutional sector). Therefore the scenario 3 (disinfection in institutional areas) is covered by the scenario 1 (Private disinfection of rooms, furniture and objects) presented above. |

**Scenario [4]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emission scenario for calculating the release of disinfectants used for sanitary purposes in hospitals based on the amount of solution of disinfectant used on a day (ESD RIVM 2001, Table 3.6, p.20) | | | |
| Qwater\_san | 25 | *L/day* | Default |
| Qwater\_obj | 25 | *L/day* | Default |
| Concentration of active substance in the product | 0.015 | *Kg/L* | 1.5% |
| Concentration of **SoC (L-lactic acid)** in the product | 0.005 | *Kg/L* | 0.5% |
| Concentration of 1-Decanamine, N.N-dimethyl,N-oxide and Dodecanamine, N.N-dimethyl,N-oxide (DDMNO) | 0.0065 | *Kg/L* | 0.65% |
| Fsan3,water | 0.55 | [-] | Default |
| Fobj3,water | 0.95 |  | Default |

Calculations for Scenario [*4]*

**Elocal3,water = Qwater\_san \* Csan \* Fsan3,water + Qwater\_obj \* Cobj \* Fobj3,water**

Qwater\_san = 25 L/d

Qwater\_obj = 25 L/d

Csan = Cobj = 0.015 kg H2O2/L ; 0.005 kg lactic acid/L

Fsan3,water = 0.55

Fobj3,water = 0.95

**Elocal3,water = 25 \* 0.015 \* 0.55 + 25 \* 0.015 \* 0.95= 0.5625 kg H2O2/d**

**Elocal3,water = 25 \* 0.005 \* 0.55 + 25 \* 0.005 \* 0.95= 0.1875 kg lactic acid/d**

**Elocal3,water = 25 \* 0.0065 \* 0.55 + 25 \* 0.0065 \* 0.95= 0.244 kg DDMNO/d**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 0.5625 kg /d | H2O2 |
| STP | 0.1875 kg/d | L(+)lactic acid |
| STP | 0.244 kg/d | DDMNO |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 23 - FR CA position:  The input parameters and calculations provided for the scenario 4 “Disinfection for sanitary purposes in hospitals” are relevant. However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP (after a residence time in sewage of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR). The local emission values are summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 4** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 1.36E-02 | | L**(+)** Lactic acid | 1.88E-01 | | 1-Decanamine, N,N-dimethyl, N-oxide | 2.44E-01 | |

**Scenario [5]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, (JRC 2011, ESD § 2.2, p.17) | | | |
| Application rate of biocidal product | 40 | *g/m2* | Default |
| Concentration of active substance in the product | 0.015 | *Kg/L* | 1.5% |
| Concentration of **SoC (L-lactic acid)** in the product | 0.005 | *Kg/L* | 0.5% |
| Concentration of 1-Decanamine, N.N-dimethyl,N-oxide and Dodecanamine, N.N-dimethyl,N-oxide (DDMNO) | 0.0065 | *Kg/L* | 0.65% |
| Fraction released to wastewater | 1 | [-] | Default (1) |
| Area surface | 2000 | m2 | Canteens, catering kitchens |

Calculations for Scenario [*5*]

**Elocalwater = Qaiappl \* AREAsurface \* Nappl \* (1-Fdis) \* (1-Felim) \* Fwater /1000**

Qaiappl = 40 g product/m2 \* 1.5% H2O2 = 0.6 g H2O2/ m2

40 g product/m2 \* 0.5% lactic= 0.2 g lactic acid/m2

40 g product/m2 \* 0.65% DDMNO= 0.26 g DDMNO/m2

40 g/m2 CONSEXPO default for liquid disinfectants

AREAsurface 2000 (large scale application)

Nappl= 1

Fdis = 0

Felim= 0

Fwater = 1

**Elocalwater = 0.6 \* 2000 \* 1 \* 1 \* 1 \* 1 /1000 = 1.2 kg H2O2/d**

**Elocalwater = 0.2 \* 2000 \* 1 \* 1 \* 1 \* 1 /1000 = 0.4 kg lactic acid/d**

**Elocalwater = 0.26 \* 2000 \* 1 \* 1 \* 1 \* 1 /1000 = 0.52 kg DDMNO/d**

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 1.2 kg /d | H2O2 |
| STP | 0.4 kg/d | L(+)Lactic acid |
| STP | 0.52 kg/d | DDMNO |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 24 - FR CA position:  The input parameters and calculations provided for the scenario 5 “Disinfection in large scale catering, kitchens, …” are relevant. However, according to the CAR of hydrogen peroxide only a fraction of 0.024 of the discharged hydrogen peroxide reaches the STP (after a residence time in sewage of 1 hour and considering a DT50 of 11.2 mins in this system according to the CAR). The local emission values are summarized in the table below:   |  |  | | --- | --- | | **Local emission before the release to the STP compartment for scenario 5** | | | **Substance** | **Elocal [kg/d]** | | Hydrogen peroxide | 2.90E-02 | | L**(+)** Lactic acid | 4.00E-01 | | 1-Decanamine, N,N-dimethyl, N-oxide | 5.20E-01 |   Applications in slaughter houses were not intended by the applicant. |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 25 - FR CA position:  For all scenarios and substances considered in the environmental assessment, the exposure pathways are presented in the following table.   | **Identification of relevant receiving compartments based on the exposure pathways** | | | | | | | | --- | --- | --- | --- | --- | --- | --- | |  | STP | Freshwater | Freshwater sediment | Air | Soil | Groundwater | | Scenario1 - 5 | ++ | + | + | - | + | + |   ++ Direct emissions expected  + Indirect emissions expected  - No emission expected |

***1) Active ingredient: Hydrogen peroxide***

| **Identification of relevant receiving compartments based on the exposure pathway Active ingredient: Hydrogen peroxide** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1-5 | yes | yes | n.r | n.r. | yes | no | n.r. | no |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment. Active ingredient: Hydrogen peroxide** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 34.01 |  |  |
| Melting point | -0.43 | °C |  |
| Boiling point | 150.2 | °C |  |
| Vapour pressure (at 25C) | 299 | Pa |  |
| Water solubility (at X°C) | miscible | mg/l | In all proportions |
| Log Octanol/water partition coefficient | -1.57 | Log 10 |  |
| Henry’s Law Constant (at 20 C)*[if measured data available]* | 7.5E-4 | Pa/m3/mol |  |
| Biodegradability | *Ready biodegradable* |  |  |
| Rate constant for STP *[if measured data available]* | 21 | h-1 | Half-life: 2 min |
| DT50 for biodegradation in surface water | 5 | d (at 12ºC) |  |
| DT50 for degradation in soil | 12 | hr (at 12ºC) |  |
| DT50 for degradation in air | 24 | hr |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP**  **Active ingredient: Hydrogen peroxide** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1-5 | Scenario n |
| Air | 0.0001 |  |  |
| Water | 0.66 |  |  |
| Sludge | 0.01 |  |  |
| Degraded in STP | 99.33 |  |  |

Calculated by SimpleTreat4

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 26 - FR CA position:  Input parameters coming from the Hydrogen peroxide CAR presented above are accurate, except for the DT50 values which are measured at 20°C in CAR, and for the provided distribution of the substance in STP. Thus, to assess the fate and distribution of hydrogen peroxide in exposed environmental compartments, the DT50 value of 22.8 hours for degradation in soil at 12°C will be considered and the distribution of the active substance in the STP validated in the CAR of hydrogen peroxide will be used and presented in the following table.   |  |  | | --- | --- | | Calculated fate and distribution of Hydrogen peroxide in the STP (EUSES model 2.1) | | | Compartment | Percentage [%] | | Air | 1E-03 | | Water | 6.85E-01 | | Sludge | 1.6E-02 | | Degraded in STP | 99.3 | |

***2) SoC: L(+)Lactic acid***

| **Identification of relevant receiving compartments based on the exposure pathway SoC: L(+)Lactic acid** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1-5 | yes | yes | yes | yes | yes | no | yes | yes |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment SoC: L(+)Lactic acid** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 90.08 | [g.mol-1] |  |
| Melting point | 53 | [oC] |  |
| Boiling point | 204.2 | [oC] |  |
| Vapour pressure at test temperature | 0.4 | [Pa] |  |
| Temperature at which vapour pressure was measured | 20 | [oC] |  |
| Octanol-water partition coefficient | -0.74 | [log10] |  |
| Water solubility at test temperature | 1.00E+05 | [mg.l-1] |  |
| Organic carbon-water partition coefficient | 20.9 | [l.kg-1] |  |
| Henry's law constant at test temparature | 7.50E-04 | [Pa.m3.mol-1] |  |
| Temperature at which Henry's law constant was measured | 20 | [oC] |  |
| Characterization of biodegradability | Readily biodegradable |  |  |
| Rate constant for biodegradation in STP | 0.3 | [hr-1] |  |
|  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP SoC: L(+)Lactic acid** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario n |
| Air | 3.74E-04 |  |  |
| Water | 32.5 |  |  |
| Sludge | 0.211 |  |  |
| Degraded in STP | 67.3 |  |  |

Calculated by SimpleTreat4

|  |
| --- |
| Infobox 27 - FR CA position:  Input parameters and the distribution of substance in the STP coming from the L(+) Lactic acid CAR presented above are accurate, except for the Henry’s constant which is set to 3.6E10-5 at 20°C in the CAR. Moreover this substance is readily biodegradable but failing the 10-days window criterion, the Koc taken in the CAR for calculations is 20 L/kg and the DT50 in soil is 90 days. |

***3) SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)***

| **Identification of relevant receiving compartments based on the exposure pathway (DDMNO)** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1-5 | yes | yes | yes | yes | yes | no | yes | yes |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment (DDMNO)** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight (decanamine-N-oxide) | 201 | [g.mol-1] |  |
| Melting point (decanamine-N-oxide) | 135 | [oC] |  |
| Vapour pressure at test temperature | 1.00E-06 | [Pa] |  |
| Temperature at which vapour pressure was measured | 20 | [oC] |  |
| Octanol-water partition coefficient | 2.7 | [log10] |  |
| Water solubility at test temperature | 1.00E+05 | [mg.l-1] |  |
| Chemical class for Koc-QSAR | Non-hydrophobics (default QSAR) |  |  |
| Solids-water partition coefficient in soil | 13.8 | [l.kg-1] | Experimental data in three soils: 8.3; >16.9; >16.1 |
| Henry's law constant at test temparature | 7.50E-04 | [Pa.m3.mol-1] |  |
| Temperature at which Henry's law constant was measured | 20 | [oC] |  |
| Characterization of biodegradability | Readily biodegradable |  |  |
| Fraction of emission directed to water by STP | <5 | [%] | Experimental data |
|  |  |  |  |
| PNEC for aquatic organisms | 0.0335 | [mg.l-1] | SDS |
| PNEC for fresh-water sediment organisms | 5.24 | [mg.kgdwt-1] | SDS |
| PNEC for marine organisms | 3.35E-03 | [mg.l-1] | SDS |
| PNEC for marine sediment organisms | 0.524 | [mg.kgdwt-1] |  |
| PNEC for micro-organisms in a STP | 4.59 | [mg.l-1] | SDS |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP (DDMNO)** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario n |
| Air | 0.0002 |  |  |
| Water | 5 |  | experimental |
| Sludge | 2.42 |  |  |
| Degraded in STP | 92.6 |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 28 - FR CA position:  Substance of concern: 1-Decanamine, N,N-dimethyl, N-oxide  A detailed list of endpoints is presented in the table below.   |  |  |  | | --- | --- | --- | | Input parameters used in the environmental exposure assessments according to the SDS and update data from ECHA web site. | | | | Input | Value | Unit | | CAS number | 2605-79-0 | - | | Molecular weight | 201 | g.mol-1 | | Vapour pressure (at 20°C) | 7.5E-05 | Pa | | Water solubility (at 20°C) | 4.1E+5 | mg.L-1 | | Partition coefficient (log POW) (pH 7) | 2.7 | Log 10 | | Biodegradability | Readily biodegradable |  | | Degradation in soil (DT50) (at 12°C) | 30 | days | | Adsorption / desorption Koc | 1517 | L.kg-1 | | BCF fish | 39.4 | L.kg-1 | | BCF earthworms | 6.85 | L.kg-1 |   The following table shows the distribution of the substance of concern “1-Decanamine, N,N-dimethyl, N-oxide” in the STP to clarify the assessment of this substance.   |  |  | | --- | --- | | Calculated fate and distribution of “1-Decanamine, N,N-dimethyl, N-oxide” in the STP (EUSES model 2.1) | | | Compartment | Percentage [%] | | Air | 2.69E-08 | | Water | 11.3 | | Sludge | 11.9 | | Degraded in STP | 76.8 | |

***Calculated PEC values***

***1) Active ingredient: Hydrogen peroxide***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1**Summary table on calculated PEC values Active ingredient: Hydrogen peroxide** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1 | 1.73E-03 | 1.73E-04 | 1.39E-04 | n.r. | n.r. | 4.58E-06 | 5.65E-03 | n.r. |
| Scenario 2 | 4.95E-03 | 4.95E-04 | 3.98E-04 | n.r. | n.r. | 1.31E-05 | 0.016 | n.r. |
| Scenario 3 | 1.73E-03 | 1.73E-04 | 1.39E-04 | n.r. | n.r. | 4.58E-06 | 5.65E-03 | n.r. |
| Scenario 4 | 1.86E-03 | 1.86E-04 | 1.49E-04 | n.r. | n.r. | 4.91E-06 | 6.05E-03 | n.r. |
| Scenario 5 | 3.96E-03 | 3.96E-04 | 3.19E-04 | n.r. | n.r. | 1.05E-5 | 0.00129 | n.r. |
| 1 If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 29 - FR CA position:  The concentrations in the different environmental compartments following releases to the STP for the active substance (hydrogen peroxide) are summarized in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table on calculated PEC values for the Hydrogen Peroxide | | | | | | |  | PECSTP | PECwater | PECsed | PECsoil initial | PECGW | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Scenario 1 (covering Scenario 3) | 4.34E-05 | 4.34E-06 | Not relevant | 3.78E-06 | 1.90E-04 | | Scenario 2 | 1.24E-04 | 1.24E-05 | Not relevant | 1.08E-05 | 5.43E-04 | | Scenario 4 | 4.65E-05 | 4.65E-06 | Not relevant | 4.05E-06 | 2.04E-04 | | Scenario 5 | 9.93E-05 | 9.93E-06 | Not relevant | 8.63E-06 | 4.35E-04 | |

***2) SoC: L(+)Lactic acid***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values SoC: L(+)Lactic acid** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW1,2** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1 | 0.0284 | 2.84E-03 | 3.52E-03 | 2.84E-04 | 3.52E-04 | 4.78E-04 | 0.30 | n.r. |
| Scenario 2 | 0.0813 | 8.13E-03 | 0.0101 | 8.13E-04 | 1.01E-03 | 1.36E-03 | 0.85 | n.r. |
| Scenario 3 | 0.0284 | 2.84E-03 | 3.52E-03 | 2.84E-04 | 3.52E-04 | 4.78E-04 | 0.30 | n.r. |
| Scenario 4 | 0.0305 | 3.05E-03 | 3.77E-03 | 3.05E-04 | 3.77E-04 | 5.12E-04 | 0.32 | n.r. |
| Scenario 5 | 0.065 | 0.0065 | 0.0084 | 0.00065 | 8.4E-04 | 1.13-03 | 0.68 | n.r. |
| 1 If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.  2 Prior to the refinement of the exposure assessment for groundwater | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 30 - FR CA position:  The concentrations in the different environmental compartments following releases to the STP for the substance of concern (L(+) Lactic acid) are summarized in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table on calculated PEC values for the L**(+)** Lactic acid | | | | | | |  | PECSTP | PECwater | PECsed | PECsoil | PECGW | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Scenario 1 (covering Scenario 3) | 2.84E-02 | 2.84E-03 | 3.46E-03 | 5.69E-04 | **6.26E-01** | | Scenario 2 | 8.13E-02 | 8.12E-03 | 9.89E-03 | 1.62E-03 | **1.79** | | Scenario 4 | 3.05E-02 | 3.05E-03 | 3.71E-03 | 6.09E-04 | **6.71E-01** | | Scenario 5 | 6.50E-02 | 6.50E-03 | 7.91E-03 | 1.30E-03 | **1.43** | |

***3) SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (DDMNO)** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW1,2** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | [mg/m3] |
| Scenario 1 | 5.58E-03 | 5.57E-04 | 3.65E-03 | 5.57E-04 | 3.65E-04 | 7.24E-03 | 0.21 | n.r. |
| Scenario 2 | 1.63E-02 | 1.62E-03 | 1.06E-02 | 1.62E-03 | 1.06E-03 | 2.11E-02 | 0.61 | n.r. |
| Scenario 3 | 5.58E-03 | 5.57E-04 | 3.65E-03 | 5.57E-04 | 3.65E-04 | 7.24E-03 | 0.21 | n.r. |
| Scenario 4 | 5.6E-03 | 5.6 E-04 | 3.7E-03 | 5.6E-04 | 3.7E-04 | 7.4E-O3 | 0.23 | n.r. |
| Scenario 5 | 0.013 | 1.3E-03 | 8.52E-03 | 1.3E-04 | 8.52E-04 | 0.0169 | 0.45 | n.r. |
| 1 If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.  2 Prior to the refinement of the exposure assessment for groundwater | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 31 - FR CA position:  The concentrations in the different environmental compartments following releases to the STP for the substance of concern (1-Decanamine, N,N-dimethyl, N-oxide) are summarized in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table on calculated PEC values for the 1-Decanamine, N,N-dimethyl, N-oxide. | | | | | | |  | PECSTP | PECwater | PECsed | PECsoil | PECGW | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Scenario 1 (covering Scenario 3) | 1.29E-02 | 1.28E-03 | 4.33E-02 | 3.63E-02 | **4.43E-01** | | Scenario 2 | 3.67E-02 | 3.66E-03 | 1.24E-01 | 1.04E-01 | **1.27** | | Scenario 4 | 1.38E-02 | 1.37E-03 | 4.64E-02 | 3.89E-02 | **4.74E-01** | | Scenario 5 | 2.94E-02 | 2.93E-03 | 9.90E-02 | 8.30E-02 | **1.01** | |

***Primary and secondary poisoning***

Primary poisoning

Secondary poisoning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 32 - FR CA position:  Hydrogen peroxide, L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide have a log Kow <3 and a BCF <100. Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for these substances. The following table shows log Kow and BCF values for each substance assessed.   |  |  |  |  | | --- | --- | --- | --- | | Summary table on log Kow and BCF values | | | | |  | Log Kow | BCF fish | BCF earthworm | | **Hydrogen peroxide** | -1.57 | 1.4 | 0.84 | | **L(+) Lactic acid** | -0.74 | 4.80E-02 | 6.78 | | **1-Decanamine, N,N-dimethyl, N-oxide** | 2.70 | 39.4 | 6.85 | |

#### Risk characterisation

***Atmosphere***

1. *Active ingredient: Hydrogen peroxide*

Conclusion:Predicted Air concentration is very low. Furthermore, Hydrogen peroxide is rapidly decomposed in air.

1. *SoC: L(+)Lactic acid*

Conclusion: Predicted Air concentration is very low.

1. *SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)*

Conclusion: Predicted Air concentration is very low.

|  |
| --- |
| Infobox 33 - FR CA position:  Emissions of hydrogen peroxide, L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide to air from the biocidal uses are regarded negligible or not to occur at all.  Conclusion:Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product SANYTOL FRESH will not pose a significant risk to the atmospheric compartment. |

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

1. *Active ingredient: Hydrogen peroxide*

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 3.72E-04 |
| Scenario 2 | 1.06E-03 |
| Scenario 3 | 3.72E-04 |
| Scenario 4 | 3.98E-04 |
| Scenario 5 | 8.5E-04 |

Conclusion: *No risk is expected*

1. *SoC: L(+)Lactic acid*

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values L(+)Lactic acid** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 2.84E-03 |
| Scenario 2 | 8.13E-03 |
| Scenario 3 | 2.84E-03 |
| Scenario 4 | 3.05E-03 |
| Scenario 5 | 6.5E-03 |

Conclusion: No risk is expected

1. *SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)*

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values**  **(DDMNO)** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 1.21E-03 |
| Scenario 2 | 0.004 |
| Scenario 3 | 1.21E-03 |
| Scenario 4 | 1.3E-03 |
| Scenario 5 | 2.8E03 |

Conclusion: No risk is expected

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 34 - FR CA position:  Risk ratios for the STP are presented in the following table:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Summary table on calculated STP PEC/PNEC values for each substance assessed | | | | Conclusion | |  | Hydrogen peroxide PEC/PNECSTP | L(+) Lactic acid PEC/PNECSTP | 1-Decanamine, N,N-dimethyl, N-oxide PEC/PNECSTP | | Scenario 1 (covering Scenario 3) | 9.32E-06 | 2.84E-03 | 2.80E-03 | Acceptable | | Scenario 2 | 2.66E-05 | 8.13E-03 | 8.00E-03 | Acceptable | | Scenario 4 | 9.99E-06 | 3.05E-03 | 3.00E-03 | Acceptable | | Scenario 5 | 2.13E-05 | 6.50E-03 | 6.40E-03 | Acceptable |   **Conclusion:**  For all the assessed scenarios, risks to the STP compartment are acceptable for the use of the product SANYTOL FRESH. |

***Aquatic compartment***

1. *Active ingredient: Hydrogen peroxide*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | 0.0137 | 0.0137 | n.r. | n.r. |
| Scenario 2 | 0.0393 | 0.0393 | n.r. | n.r. |
| Scenario 3 | 0.0137 | 0.0137 | n.r. | n.r. |
| Scenario 4 | 0.0147 | 0.0147 | n.r. | n.r. |
| Scenario 5 | 0.0314 | 0.0314 | n.r. | n.r. |

Conclusion: No risk is expected. The marine compartment exposure is not relevant because the fast degradation of hydrogen peroxide*.*

1. *SoC: L(+)Lactic acid*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values L(+)Lactic acid** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | 7.29E-04 | 7.29E-04 | 7.29E-04 | 7.29E-04 |
| Scenario 2 | 2.08E-03 | 2.08E-03 | 2.08E-03 | 2.08E-03 |
| Scenario 3 | 7.29E-04 | 7.29E-04 | 7.29E-04 | 7.29E-04 |
| Scenario 4 | 7.81E-04 | 7.81E-04 | 7.81E-04 | 7.81E-04 |
| Scenario 5 | 1.67E-03 | 1.67E-03 | 1.67E-03 | 1.67E-03 |

Conclusion: No risk is expected.

1. *SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values**  **(DDMNO)** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1 | 0.0166 | 0.0032 | 0.0166 | 0.0166 |
| Scenario 2 | 0.048 | 0.0093 | 0.048 | 0.048 |
| Scenario 3 | 0.0166 | 0.0032 | 0.0166 | 0.0166 |
| Scenario 4 | 0.0182 | 0.0035 | 0.0182 | 0.0182 |
| Scenario 5 | 0.039 | 0.0075 | 0.039 | 0.039 |

Conclusion: No risk is expected.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 35 - FR CA position:  Risk ratios for the surface water compartment are presented in the following table:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Summary table on calculated freshwater PEC/PNEC values for each substance assessed | | | | Conclusion | |  | Hydrogen peroxide PEC/PNECFreshwater | L(+) Lactic acid PEC/PNECFreshwater | 1-Decanamine, N,N-dimethyl, N-oxide PEC/PNECFreshwater | | Scenario 1 (covering Scenario 3) | 3.45E-04 | 7.29E-04 | 3.82E-02 | Acceptable | | Scenario 2 | 9.85E-04 | 2.08E-03 | 1.09E-01 | Acceptable | | Scenario 4 | 3.69E-04 | 7.81E-04 | 4.10E-02 | Acceptable | | Scenario 5 | 7.88E-04 | 1.66E-03 | 8.75E-02 | Acceptable |   Considering that PNEC values for the active substance et for the substances of concern are derived from the PNECsw using the equilibrium partitioning method, risk ratios for surface water cover the sediment compartment.  **Conclusion:**  For all the assessed scenarios, risks to the aquatic compartment are acceptable for the use of the product SANYTOL FRESH. |

***Terrestrial compartment***

1. *Active ingredient: Hydrogen peroxide*

**No relevant.** Hydrogen peroxide if rapidly decomposed in presence of transition metal ions, organic matter and microbiota. Therefore, exposure of hydrogen peroxide to the soil via sludge application is negligible. In the worst scenario (scenario 2) the PEC/PNEC calculated was 0.008.

1. *SoC: L(+)Lactic acid*

Scenario 1 PEC/PNEC: 2.52E-04

Scenario 2 PEC/PNEC: 7.319E-04

Scenario 3 PEC/PNEC: 2.52E-04

Scenario 4 PEC/PNEC: 2.70E-04

Scenario 5 PEC/PNEC: 5.76E-04

1. *SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)*

Scenario 1 PEC/PNEC: 0.0081

Scenario 2 PEC/PNEC: 0.0235

Scenario 3 PEC/PNEC: 0.0081

Scenario 4 PEC/PNEC: 0.0088

Scenario 5 PEC/PNEC: 0.019

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| Infobox 36 - FR CA position:  Risk ratios for the soil compartment are presented in the following table:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Summary table on calculated soil PEC/PNEC values for each substance assessed | | | | Conclusion | |  | Hydrogen peroxide PEC/PNECsoil | L(+) Lactic acid PEC/PNECsoil | 1-Decanamine, N,N-dimethyl, N-oxide PEC/PNECsoil | | Scenario 1 (covering Scenario 3) | 2.10E-03 | 2.99E-04 | 4.04E-02 | Acceptable | | Scenario 2 | 6.00E-03 | 8.55E-04 | 1.15E-01 | Acceptable | | Scenario 4 | 2.25E-03 | 3.21E-04 | 4.32E-02 | Acceptable | | Scenario 5 | 4.80E-03 | 6.84E-04 | 9.23E-02 | Acceptable |   **Conclusion:**  For all the assessed scenarios, risks to the soil compartment are acceptable for the use of the product SANYTOL FRESH. |

***Groundwater***

1. *Active ingredient: Hydrogen peroxide*

Not relevant because the fast degradation of hydrogen peroxide. In the first tier approach the concentration for the worst scenario (scenario 5) was 0.077 μg/L, inferior to the the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 μg/L).

1. *SoC: L(+)Lactic acid*

The concentration in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 μg/L). Thus, the groundwater assessment must be refined with a second tier model.

Considering the following application parameters:

1. Application rate of dry sludge: 5000 kg/Ha/year
2. Concentration of Lactic acid in dry sludge: 1.34 mg/kg [EUSES output from Scenario #2 (worst option)]

Lactic acid application = 5000 kg sludge/Ha/year \* 1.34 mg/kg sludge = 6700 mg/Ha

|  |  |  |
| --- | --- | --- |
|  | **Lactic acid concentration (mg/kg dry sludge)** | **Lactic acid Application rate**  **(g/Ha)** |
| Scenario 1 | 0.468 | 2.34 |
| **Scenario 2** | **1.34** | **6.7** |
| Scenario 3 | 0.468 | 2.34 |
| Scenario 4 | 0.502 | 2.51 |
| Scenario 5 | 1.07 | 5.35 |

1. One application/year during 25 years. Application by incorporation into soil (depth 5 cm).

Applying FOCUS\_PEARL.4.4.4 to a serie of locations/crops, the following results were obtained:

|  |  |  |
| --- | --- | --- |
| **Concentration (µg/L ) 80th percentile** | **LOCATION** | **CROP\_CALENDAR** |
| 0.000000 | SEVILLA | SEVI-CABBAGE |
| 0.000000 | SEVILLA | SEVI-MAIZE |
| 0.000000 | SEVILLA | SEVI-SPOTATOES |
| 0.000000 | SEVILLA | SEVI-TOMATOES |
| 0.000000 | SEVILLA | SEVI-WCEREALS |
| 0.000000 | SEVILLA | SEVI-STRAWBER |
| 0.000000 | THIVA | THIV-CARROTS |
| 0.000000 | THIVA | THIV-ONIONS |
| 0.000001 | SEVILLA | SEVI-SUNFLOWER |
| 0.000001 | THIVA | THIV-VEGBEANS |
| 0.000002 | CHATEAUDUN | CHAT-PEAS |
| 0.000002 | CHATEAUDUN | CHAT-SCEREALS |
| 0.000002 | SEVILLA | SEVI-COTTON |
| 0.000002 | THIVA | THIV-COTTON |
| 0.000002 | THIVA | THIV-SPOTATOES |
| 0.000002 | THIVA | THIV-TOBACCO |
| 0.000004 | THIVA | THIV-WCEREALS |
| 0.000005 | SEVILLA | SEVI-GRASS |
| 0.000005 | THIVA | THIV-TOMATOES |
| 0.000006 | SEVILLA | SEVI-SUGARBEET |
| 0.000006 | THIVA | THIV-GRASS |
| 0.000009 | PORTO | PORT-SPOTATOES |
| 0.000012 | PORTO | PORT-ONIONS |
| 0.000014 | PORTO | PORT-CARROTS |
| 0.000015 | THIVA | THIV-VINES |
| 0.000016 | PORTO | PORT-SCEREALS |
| 0.000017 | THIVA | THIV-MAIZE |
| 0.000018 | CHATEAUDUN | CHAT-ONIONS |
| 0.000020 | PORTO | PORT-CABBAGE |
| 0.000022 | PORTO | PORT-TOMATOES |
| 0.000024 | PORTO | PORT-VEGBEANS |
| 0.000024 | THIVA | THIV-SUGARBEET |
| 0.000028 | CHATEAUDUN | CHAT-CABBAGE |
| 0.000028 | PORTO | PORT-MAIZE |
| 0.000032 | PORTO | PORT-SOILSEED |
| 0.000042 | PORTO | PORT-SUGARBEET |
| 0.000066 | SEVILLA | SEVI-VINES |
| 0.000070 | CHATEAUDUN | CHAT-SPOTATOES |
| 0.000077 | THIVA | THIV-APPLES |
| 0.000079 | CHATEAUDUN | CHAT-CARROTS |
| 0.000082 | THIVA | THIV-CITRUS |
| 0.000121 | CHATEAUDUN | CHAT-MAIZE |
| 0.000137 | CHATEAUDUN | CHAT-WCEREALS |
| 0.000151 | KREMSMUENSTER | KREM-CABBAGE |
| 0.000153 | SEVILLA | SEVI-APPLES |
| 0.000160 | CHATEAUDUN | CHAT-TOMATOES |
| 0.000171 | PIACENZA | PIAC-SPOTATOES |
| 0.000180 | CHATEAUDUN | CHAT-GRASS |
| 0.000199 | CHATEAUDUN | CHAT-WOILSEED |
| 0.000203 | PIACENZA | PIAC-TOBACCO |
| 0.000204 | PIACENZA | PIAC-SUNFLOWER |
| 0.000207 | PIACENZA | PIAC-SUGARBEET |
| 0.000228 | KREMSMUENSTER | KREM-ONIONS |
| 0.000234 | KREMSMUENSTER | KREM-SUGARBEET |
| 0.000274 | KREMSMUENSTER | KREM-CARROTS |
| 0.000286 | KREMSMUENSTER | KREM-FLDBEANS |
| 0.000289 | KREMSMUENSTER | KREM-GRASS |
| 0.000290 | HAMBURG | HAMB-CARROTS |
| 0.000309 | PIACENZA | PIAC-SOYBEAN |
| 0.000329 | SEVILLA | SEVI-CITRUS |
| 0.000334 | PIACENZA | PIAC-MAIZE |
| 0.000381 | KREMSMUENSTER | KREM-SPOTATOES |
| 0.000397 | OKEHAMPTON | OKEH-FLDBEANS |
| 0.000413 | PIACENZA | PIAC-TOMATOES |
| 0.000417 | HAMBURG | HAMB-CABBAGE |
| 0.000428 | KREMSMUENSTER | KREM-MAIZE |
| 0.000443 | CHATEAUDUN | CHAT-VINES |
| 0.000469 | HAMBURG | HAMB-ONIONS |
| 0.000480 | KREMSMUENSTER | KREM-SCEREALS |
| 0.000481 | PORTO | PORT-VINES |
| 0.000486 | HAMBURG | HAMB-SUGARBEET |
| 0.000486 | OKEHAMPTON | OKEH-PEAS |
| 0.000490 | THIVA | THIV-CABBAGE |
| 0.000497 | PORTO | PORT-GRASS |
| 0.000502 | HAMBURG | HAMB-PEAS |
| 0.000507 | KREMSMUENSTER | KREM-STRAWBER |
| 0.000512 | PORTO | PORT-APPLES |
| 0.000514 | OKEHAMPTON | OKEH-LINSEED |
| 0.000516 | HAMBURG | HAMB-FLDBEANS |
| 0.000521 | OKEHAMPTON | OKEH-SUGARBEET |
| 0.000563 | HAMBURG | HAMB-SPOTATOES |
| 0.000566 | HAMBURG | HAMB-SCEREALS |
| 0.000568 | KREMSMUENSTER | KREM-VINES |
| 0.000583 | OKEHAMPTON | OKEH-SOILSEED |
| 0.000609 | CHATEAUDUN | CHAT-APPLES |
| 0.000677 | KREMSMUENSTER | KREM-APPLES |
| 0.000682 | OKEHAMPTON | OKEH-SPOTATOES |
| 0.000691 | OKEHAMPTON | OKEH-SCEREALS |
| 0.000726 | HAMBURG | HAMB-STRAWBER |
| 0.000737 | HAMBURG | HAMB-GRASS |
| 0.000775 | HAMBURG | HAMB-MAIZE |
| 0.000789 | HAMBURG | HAMB-VINES |
| 0.000800 | PIACENZA | PIAC-APPLES |
| 0.000852 | PIACENZA | PIAC-VINES |
| 0.000985 | PIACENZA | PIAC-GRASS |
| 0.001054 | CHATEAUDUN | CHAT-SUGARBEET |
| 0.001108 | KREMSMUENSTER | KREM-WCEREALS |
| 0.001125 | PIACENZA | PIAC-WCEREALS |
| 0.001134 | PORTO | PORT-CITRUS |
| 0.001172 | HAMBURG | HAMB-APPLES |
| 0.001193 | OKEHAMPTON | OKEH-GRASS |
| 0.001356 | PORTO | PORT-WCEREALS |
| 0.001413 | OKEHAMPTON | OKEH-MAIZE |
| 0.001613 | OKEHAMPTON | OKEH-APPLES |
| 0.002189 | PIACENZA | PIAC-CITRUS |
| 0.002345 | PIACENZA | PIAC-WOILSEED |
| 0.002470 | KREMSMUENSTER | KREM-WOILSEED |
| 0.004019 | HAMBURG | HAMB-WCEREALS |
| 0.004587 | OKEHAMPTON | OKEH-WOILSEED |
| 0.005066 | OKEHAMPTON | OKEH-WCEREALS |
| 0.005660 | PORTO | PORT-WOILSEED |
| 0.005985 | HAMBURG | HAMB-WOILSEED |

Some FOCUS\_PEARL.4.4.4 input and output files are annexed (Section 3.2).

All the 112 scenarios have the average 80th percentile concentration of L(+) Lactic under the trigger value of 0.1 μg/L.

As a whole, these results suggest that the application of sludge do not contribute to a significant risk on groundwater.

1. *SoC: 1-Decanamine, N.N-dimethyl,N-oxide (and Dodecanamine, N.N-dimethyl,N-oxide) (DDMNO)*

The concentration in groundwater exceeds the quality standard for pesticides and biocidal products according to Directive 2006/118/EC for drinking water (0.1 μg/L). Thus, the groundwater assessment must be refined with a second tier model.

Considering the following application parameters:

1. Application rate of dry sludge: 5000 kg/Ha/year
2. Concentration of DDMNO in dry sludge 19.9 mg/kg [EUSES output from Scenario #2 (worst option)]

DDMNO application = 5000 kg sludge/Ha/year \* 19.9 mg/kg sludge = 99.5 g/Ha

1. One application/year during 25 years. Application by incorporation into soil.
2. The experimental Kom of DDMNO were 307, > 2113 and > 619 L/kg in three different soils (ECHA database). The average value is used (1013 L/kg).

Applying FOCUS\_PEARL.4.4.4 to a serie of locations/crops, the results were 0.000 μg/L for all scenarios. These null water concentrations are a consequence of the high values of Kom. These results suggest that the application of sludge do not contribute to a significant risk associated to DDMNO on groundwater.

Some FOCUS\_PEARL.4.4.4 input and output files are annexed (Section 3.2).

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 37 - FR CA position:  Concentrations in groundwater are presented in the following tables:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Acceptable risks for PEC < the limit value of 0.1 µg/L** | | | | Conclusion | |  | Hydrogen peroxide PECGW | L(+) Lactic acid PECGW | 1-Decanamine, N,N-dimethyl, N-oxide PECGW | | Scenario 1 | 1.90E-04 | **6.27E-01** | **4.43E-01** | Unacceptable | | Scenario 2 | 5.43E-04 | **1.79** | **1.27** | Unacceptable | | Scenario 4 | 2.04E-04 | **6.71E-01** | **4.74E-01** | Unacceptable | | Scenario 5 | 4.35E-04 | **1.43** | **1.01** | Unacceptable |   ***High-tier assessment for groundwater***  The groundwater compartment presents PEC values > 0.1 µg/L for L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide. These values indicate a potential risk to groundwater. A more realistic, higher-tier assessment of the potential for groundwater contamination associated with the sludge applications of L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide has also been carried out using the simulation model FOCUS-PEARL 4.4.4.  As a worst case for each substance studied, the quantity considered in the model calculation is the sum of the 4 scenarios from this report.  The leaching potential of L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide were investigated by simulating applications to two standard crops (Maize and alfalfa). Simulations were performed for all nine FOCUS scenarios.  According to the TAB, an effective application rate per hectare with sludge contribution is given by:  Application rate for agricultural land (kg/ha) = 5000 x Σ[Cdry sludge of scenario 1-5] x 10-6  Application rate for grassland (kg/ha) = 1000 x Σ[Cdry sludge of scenario 1-5] x 10-6  The FOCUS-Pearl model considers 26 year of simulation, for the maize crops one application per year 20 days before crop emergence, and for the alfalfa crops one application per year on the 1st of march are simulated.   |  |  | | --- | --- | | **Relevant input variables in FOCUS PEARL 4.4.4** | | | **Parameter** | **Value** | | Scenario | | | Location | All 9 EU scenario | | Years of simulation | 26 | | Standard crop | Maize and alfalfa | | Application rate of STP sludge (kg/ha) | **Agricultural land (Maize):**  5000 x Cdry sludge x 10-6 = 0.016 for the L(+)Lactic acid and 1.235 for the decanamine  **Grassland (Alfalfa):**  1000 x Cdry sludge x 10-6 = 0.0032 for the L(+)Lactic acid and 0.247 for the decanamine | | Application depth | Incorporation 20 cm (maize)  Incorporation 10 cm (alfalfa) | | Date of application | **Maize:** One application per year, 20 days before crop emergence  **Grassland (alfalfa) :** One application per year on the 1st of March | | **Lactic acid** | | | Deposition | No deposition | | Molar mass (g.mol-1) | 90.1 | | Vapour pressure (Pa at 20°C) | 0.4 | | Water solubility (mg.L-1 at 20°C) | 1E+03 | | Kom (L.kg-1 at 20°C) | 11.6 | | Freundlich exponent | 0.9 | | DT50 soil (d) | 90 | | Coefficient for uptake for plant | 0 | | Molar activation energy | 54 kJ.mol-1 | | **1-Decanamine, N,N-dimethyl, N-oxide** | | | Deposition | No deposition | | Molar mass (g.mol-1) | 201 | | Vapour pressure (Pa at 20°C) | 7.5E-05 | | Water solubility (mg.L-1 at 20°C) | 4.1E+05 | | Kom (L.kg-1 at 20°C) | 879.9 | | Freundlich exponent | 0.9 | | DT50 soil (d) | 30 | | Coefficient for uptake for plant | 0 | | Molar activation energy | 54 kJ.mol-1 |   Results are presented in the following tables for the agricultural land.   |  |  |  |  | | --- | --- | --- | --- | | **Overview of result for maize crop from FOCUS PEARL** | | | | | **Result-text** | **L(+) Lactic** **acid** | **1-Decanamine, N,N-dimethyl, N-oxide** | **Location** | | Concentration closest to the 80th percentile(µg/L) | 0.401759 | 0 | CHATEAUDUN | | Concentration closest to the 80th percentile(µg/L) | 0.76673 | 0 | HAMBURG | | Concentration closest to the 80th percentile(µg/L) | 0.523175 | 0 | KREMSMUENSTER | | Concentration closest to the 80th percentile(µg/L) | 0.547898 | 0 | OKEHAMPTON | | Concentration closest to the 80th percentile(µg/L) | 0.326953 | 0 | PIACENZA | | Concentration closest to the 80th percentile(µg/L) | 0.173642 | 0 | PORTO | | Concentration closest to the 80th percentile(µg/L) | 0.049206 | 0 | SEVILLA | | Concentration closest to the 80th percentile(µg/L) | 0.251186 | 0 | THIVA |   Results are presented in the following tables for the grassland.   |  |  |  |  | | --- | --- | --- | --- | | **Overview of result for alfalfa crops from FOCUS PEARL** | | | | | **Result-text** | **L(+) Lactic** **acid** | **1-Decanamine, N,N-dimethyl, N-oxide** | **Location** | | Concentration closest to the 80th percentile(µg/L) | 0.069724 | 0 | CHATEAUDUN | | Concentration closest to the 80th percentile(µg/L) | 0.114758 | 0 | HAMBURG | | Concentration closest to the 80th percentile(µg/L) | 0.119264 | 0 | JOKIOINEN | | Concentration closest to the 80th percentile(µg/L) | 0.071873 | 0 | KREMSMUENSTER | | Concentration closest to the 80th percentile(µg/L) | 0.091598 | 0 | OKEHAMPTON | | Concentration closest to the 80th percentile(µg/L) | 0.074547 | 0 | PIACENZA | | Concentration closest to the 80th percentile(µg/L) | 0.042539 | 0 | PORTO | | Concentration closest to the 80th percentile(µg/L) | 0.021586 | 0 | SEVILLA | | Concentration closest to the 80th percentile(µg/L) | 0.028403 | 0 | THIVA |   **Conclusion:**  For several scenario test, concentrations of L(+) Lactic acid substance are above the threshold value of 0.1µg/L. |

***Primary and secondary poisoning***

Primary poisoning

1. *Active ingredient: Hydrogen peroxide*

Not relevant because the fast degradation of hydrogen peroxide.

1. *SoC: L(+)Lactic acid*

Not relevant because the lack of systemic toxicity.

Secondary poisoning

1. *Active ingredient: Hydrogen peroxide*

Not relevant because the fast degradation of hydrogen peroxide.

1. *SoC: L(+)Lactic acid*

Not relevant because the lack of systemic toxicity.

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| Infobox 38 - FR CA position:  As detailed in the infobox 32 above, Hydrogen peroxide, L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide have a log Kow <3 and a BCF <100. Thus, these values indicate a negligible potential for bioconcentration in biota and no accumulation of substances in the food chain is expected. The secondary poisoning assessment is not relevant for these substances. |

***Mixture toxicity***

*Screening step*

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

The calculated PEC/PNEC for hydrogen peroxide, L-lactic acid and DDMNO in the several environmental compartments and scenarios are very low. The summatory of PEC/PNEC ratios for the trhee substances is lower than 1 for all the environmental media.

These substances are characterized by very dissimilar physicochemical and ecotoxicological features. No synergistic interactions are expected. Therefore, mixture toxicity is expected to be not relevant.

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| Infobox 39 - FR CA position:  The result of mixture toxicity assessment of the product SANYTOL FRESH containing one active substance (Hydrogen peroxide) and two substances of concern is summarized in the following table.   |  |  |  |  | | --- | --- | --- | --- | | Summary table on calculated ΣPEC/PNEC values | | | | |  | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsoil | | Scenario 1 | 5.65E-03 | 3.94E-02 | 4.28E-02 | | Scenario 2 | 1.62E-02 | 1.12E-01 | 1.22E-01 | | Scenario 4 | 6.06E-03 | 4.22E-02 | 4.58E-02 | | Scenario 5 | 1.29E-02 | 9.00E-02 | 9.77E-02 |   Conclusion:  The PEC/PNEC sums are below 1 for all the assessed compartments. However regardless the scenario studied, the refinement described above (in the infobox 37) are above the threshold value of 0.1 µg/l for the substance of concern L(+) Lactic acid .  The risks related to the use of SANYTOL FRESH are acceptable for all environmental compartments except the groundwater compartment. |

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

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

Since the amount of L(+)Lactic acid that is used annually in biocidal products accounts for less than 10% compared to the annual production and import volume of L(+) Lactic acid in the EU, no aggregated risk assessment was performed.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 40 - FR CA position:  The result of aggregated exposure assessment of the product containing one active substance (Hydrogen peroxide) and two substances of concern is summarized in the following table.   |  |  |  |  | | --- | --- | --- | --- | | Summary table on calculated ΣPEC/PNEC values | | | | |  | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsoil | | Scenario 1-5 | 4.08E-02 | 2.84E-01 | 3.09E-01 |   Conclusion:  The PEC/PNEC sums are below 1 for all the assessed compartments except for the groundwater.  The risks related to the use of SANYTOL FRESH are acceptable for all environmental compartments except the groundwater compartment. |

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| **Overall conclusion on the risk assessment for the environment of the product** |
| acceptable |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Infobox 41 - FR CA position:  Overall conclusion on the risk assessment for the environment of the product SANYTOL FRESH.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Summary table for the risk assessment of the product SANYTOL FRESH | | | | | | |  | PEC/PNECSTP | PEC/PNECwater | PEC/PNECsed | PEC/PNECsoil | PECGW (mg/L) | | Scenario 1 | Acceptable | Acceptable | Acceptable | Acceptable | above 0.1µg/L\* | | Scenario 2 | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario 4 | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario 5 | Acceptable | Acceptable | Acceptable | Acceptable |   \* For L(+) Lactic acid  **Conclusion:**  The product SANYTOL FRESH contains two substances of concern for the environment (L(+) Lactic acid and 1-Decanamine, N,N-dimethyl, N-oxide.  Following the application of the product SANYTOL FRESH,   * levels of exposure for non-target species of aquatic (surface water and sediment) and terrestrial compartments are lower than the reference values of the active substance and substances of concern. * Concentrations of hydrogen peroxide and 1-Decanamine, N,N-dimethyl, N-oxide in groundwater related to the use of product SANYTOL FRESH are also lower than the threshold value set by Directive 98/83/EC. * Whereas, concentrations of the substance of concern L(+) Lactic acid in groundwater related to the use of product SANYTOL FRESH are higher than the threshold value set by Directive 98/83/EC.   Nonetheless, as reported in the opinion of the BPC for approval of the active substance L(+) lactic acid for product type 2 and 4: “the current assessment of the biodegradation behaviour in soil of lactic acid is most likely too conservative: based on the information submitted in the application a default degradation half-live of 90 days was estimated. Additional information obtained via a literature search shows that in reality the degradation half-life may be lower.”  In this framework, additional data to refine the current risk assessment may be required for product authorisation. However, in the case of SANYTOL FRESH, the L(+) lactic acid is not claimed as biocide active substance, it is a co-formulant used as a pH-regulator. Quantitative refinement of groundwater contamination is not possible for SANYTOL FRESH BPF based on up-to-date aivailable data presented in the doc II-B of the CAR of L-(+) lactic acid*.*  It should be noted that concentration of L(+) lactic acid in the groundwater are all below 0.1 µg/L when considering a degradation half-live of 30 days.  In the absence of validated refined reference values for L(+) lactic degradation half-live, the assessment of estimated concentrations of L(+) lactic acid in groundwater cannot be refined. However, given the highly conservative hypothesis for estimation of concentrations in soil, risk for groundwater is not considered as unacceptable. |

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

*See the SPC.*

### Assessment of a combination of biocidal products

Not relevant

# Annexes

## List of studies for the biocidal product family

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** |
| Pijuan | 2016 | SANYTOL COCINAS FRESH (ref 35 MOD) Determination of accelerated storage stability  study number EST228  report number R-EST228-M1 | Y | GRUPO AC MARCA |
| Pijuan | 2016 | SANYTOL MULTIUSOS FRESH (ref 3049-91 MOD1) Determination of accelerated storage stability  study number EST319  report number R-EST319-M1 | Y | GRUPO AC MARCA |
| Pijuan | 2016 | Validation of potentiometruc titration method (BPL-MA-025) for the determination of hydrogen peroxide (H2O2) in the test item SANYTOL COCINAS FRESH (ref 35 MOD)  study number EST363  report number R-EST263 | Y | GRUPO AC MARCA |
| Pijuan | 2016 | Validation of potentiometruc titration method (BPL-MA-025) for the determination of hydrogen peroxide (H2O2) in the test item SANYTOL MULTIUSOS FRESH (ref 3049-91 MOD1)  study number EST322  report number R-EST322 | Y | GRUPO AC MARCA |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| IVAMI | 2016 | Bactericidal activity with MU 3049-91 on non-porous surfaces (Phase 2, step 2). (European Standard UNE-EN 13697 :2015), Report Nº D/15/94 | Yes | ORG | 25-01-17 |
| IVAMI | 2016 | Fungicidal activity with MU 3049-91 on non-porous surfaces (Phase 2, step 2). (European Standard UNE-EN 13697 :2015), Report Nº D/15/95 | Yes | ORG | 25-01-17 |
| IVAMI | 2015 | Bactericidal activity test with the product MU 3049-91 (European Standard UNE-EN 1276 :2010), Report Nº D/15/92 | Yes | ORG | 25-01-17 |
| IVAMI | 2015 | Fungicidal/Yeasticidal activity of MU 3049-91 (European Standard UNE-EN 1650 :2008 + A1 :2013), IVAMI, Report Nº D/15/93 | Yes | ORG | 25-01-17 |
| IVAMI | 2017 | Virucidal test with the product MU 3049-91 against Influenza A (H1N1) pdm09, strain A/California/7/2009 (H1N1) pdm09, Report Nº D/15/98 | Yes | ORG | 21-12-17 |
| IVAMI | 2017 | Virucidal test with the product MU 3049-91 against Herpes simplex virus type 1 (Guideline EN 14476: 2013), Report Nº D/ 15 / 99 | Yes | ORG | 21-12-17 |
| IVAMI | 2017 | Virucidal test with the product 3049-91 against Vaccinia Poxvirus  (UNE EN 14476: 2014 Guideline), Report Nº D/16/40 | Yes | ORG | 21-12-17 |
| DR. BRILL + DR. STEINMANN | 2016 | Quantitative test method for the evaluation of bactericidal and yeasticidal activity of MU3049-91 on non-porous surfaces with mechanical action employing wipes in the medical area according to DIN EN 16615 :2015 (Phase 2, step 2), Test report no L16/0295.1 | Yes | ORG | 25-01-17 |
| DR. BRILL + DR. STEINMANN | 2016 | Modified Quantitative Non-Porous Surface Test for the evaluation of bactericidal and/or fungicidal activity of MU3049-91 in Food, Industrial, Domestic, and Institutional Areas following DIN EN 13697 :2015 (Phase 2, step 2), Test report no L16/0729.1 | Yes | ORG | 25-01-17 |
| IVAMI | 2016 | Bactericidal activity with COC.REF.35 on non-porous surfaces (Phase 2, step 2). (European Standard UNE-EN 13697 :2015). IVAMI, Report D/16/37 | Yes | ORG | 25-01-17 |
| IVAMI | 2016 | Fungicidal activity with COC.REF.35 on non-porous surfaces (Phase 2, step 2). (European Standard UNE-EN 13697 :2015), Report D/16/38 | Yes | ORG | 25-01-17 |
| IVAMI | 2016 | Bactericidal Activity Test with the product COC.REF.35, (European Standard UNE-EN 1276:2010.AC 2010), Report D/16/35 | Yes | ORG | 25-01-17 |
| IVAMI | 2016 | Fungicidal/Yeasticidal activity of COC.REF.35 (European standard UNE-EN 1650, Report D/16/36 | Yes | ORG | 25-01-17 |
| IVAMI | 2017 | Virucidal test with the product COC.REF.35 against Vaccinia Poxvirus (ATCC VR-1354) (UNE EN 14476: 2014 Guideline). Report D/16/39 | Yes | ORG | 21-12-17 |
| IVAMI | 2017 | Quantative test method for the evaluation of bactericidal and yeasticidal activity of COCREF35 on non-porous surfaces with mechanical action employing wipes in the medical area according to DIN EN 16615 :2015 (Phase 2, step 2) | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy – EtOH | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy – EtOH | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - Lactic Acid | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - Lactic Acid | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - SANYTOL LAST 47BM | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - SANYTOL LAST 47BM | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 773557 GRAPEFRUIT TEA TREE OXY | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - 773557 GRAPEFRUIT TEA TREE OXY | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - NEW PIN MARITIME 54.500.0544 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - NEW PIN MARITIME 54.500.0544 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 784765 NEUTRAL | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy- 784765 NEUTRAL | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 789740 OXYCOOL | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - 789740 OXYCOOL. | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 78784 OXY GREEN | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - 78784 OXY GREEN | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - BRISE DE PRINTEMPS E\_0912548.01 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - BRISE DE PRINTEMPS E\_0912548.01 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - DAL BLUE STONE G111 33212 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - DAL BLUE STONE G111 33212 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 951758 DESTROYER FREE | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - 951758 DESTROYER FREE | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - LEMON LIME FIZZ 28X | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - LEMON LIME FIZZ 28X | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - SANIKIT SC153420 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - SANIKIT SC153420 | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - 776773 FRAIS FREE | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - 776773 FRAIS FREE | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1040 Demonstration of non-efficacy - Generic perfume solvent | Yes | ORG | 25-01-17 |
| Grupo AC MARCA | 2016 | EN1275 Demonstration of non-efficacy - Generic perfume solvent | Yes | ORG | 25-01-17 |
| Orléat Laboratory | 2016 | Determination of H2O2 concentration in air after application by inversion and manual spraying of formulations for surface disinfection. | yes | AC MARCA | - |

## Output tables from exposure assessment tools

**Excel data sheets**



**Experimental data**





## Residue behaviour

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

Regarding PT 4 uses, considering properties of lactic acid, ethanol and hydrogen peroxide, no significant exposure via food is expected. Based on the low concentration of hydrogen peroxide and the authorised uses of this active substance in other regulated areas (PPP, processing aid in France), significant indirect exposure via Disinfection By-Products in food is not expected.

## Summaries of the efficacy studies

Not relevant (IUCLID file available)

## Confidential annex

*See confidential annex in a separated file*

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
2. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-3)
3. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-4)
4. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-5)
5. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-6)
6. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-7)
7. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-8)
8. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-9)
9. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-10)
10. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-11)
11. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-12)
12. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-13)
13. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-14)
14. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-15)
15. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-16)
16. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-17)
17. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-18)
18. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-19)
19. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-20)
20. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-21)
21. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-22)
22. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-23)
23. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-24)
24. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-25)
25. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-26)
26. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-27)
27. The trade names listed here are the names claimed. Authorized trade names will be defined for each national authorization. [↑](#footnote-ref-28)
28. Transitional Guidance on the Biocidal Products Regulation (May 2016) [↑](#footnote-ref-29)
29. https://publications.europa.eu/en/publication-detail/-/publication/f687a3a2-809b-11e7-b5c6-01aa75ed71a1 [↑](#footnote-ref-30)
30. Hypochlorous Acid Stress in *Escherichia coli*: Resistance, DNA Damage, and Comparison with Hydrogen Peroxide Stress [↑](#footnote-ref-31)
31. Positive Control of a Regulon for Defenses against Oxidative Stress and Some Heat-Shock Proteins in *Salmonella* Typhimurium [↑](#footnote-ref-32)
32. As a worst cas, a ventilation route of 0.6 /h and a room volume of 20 m3 could have been used for unspecified room. [↑](#footnote-ref-33)
33. Competent Authority Report – Programme for inclusion of Active substances in Annex I to Council directive 98/8/EC – Ethanol, CAS N°.: 64-17-5, PT 4 (Food and Feed area disinfectant) – Document I (July, 2013; Rapporteur: Hellas) [↑](#footnote-ref-34)
34. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products – Evaluation of active substances – Assessment Report – L(+) lactic acid – product types 02, 03 and 04 (June 2017, eCA: Germany) [↑](#footnote-ref-35)
35. ECHA (European Chemicals Agency) - Guidance on the Biocidal Products Regulation – Volume V, guidance on disinfection by-products – Version 1.0 – January 2017. [↑](#footnote-ref-36)