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 NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



BACTY SP IPA

Product type 2

Propan-2-ol

Case Number in R4BP: BC-UK025489-17

Evaluating Competent Authority: France

Date: August 2018

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**Note to the reader**

This PAR has been updated with the post-authorisation data provided by the applicant and is based on the PAR of the first authorisation.

In this consolidated PAR, the assessments related to the post authorisation data of the product are at the end of the concerned section and are highlighted in grey.

The SPC (in the first section of the PAR) corresponds to the currently authorised uses in France.

**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-UK025489-17* | 03.10.2018 | Initial assessment |
| 2021 | Post authorisation data assessment |

# CONCLUSION

The biocidal product family BACTY SP IPA is to be used for disinfection in clean rooms by professional users. The BPF is composed from 3 META SPC. Products claimed in the different SPC differentiate mainly in the method of application and active substance (propan-2-ol) content.

* ***Physico-chemical properties***

***META SPC 1***

The META SPC 1 is an all other liquids (AL) formulation. All chemical and technical studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 30°” should be added.

The products BACTY SP IPA pulvérisateur, bidon and saches contain 70% w/w propan-2-ol, which is classified Flam. Liq. 2, H225, they are expected to be highly flammable and are classified Flam. Liq. 2 H225.

The long-term storage stability study is on-going and should be provided in post-authorisation within 2 years.

* **Post authorisation assessment (2021)**

Long-term storage stability study shows that after 3 years at ambient temperature in HDPE spray (double wrapped in PE bags), the product remains stable. Consequently, the shelf life of the product is maintained at 2 years.

***META SPC 2***

The META SPC 2 is an aerosol (AE) formulation. All chemical and technical studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 30°” should be added.

The product BACTY SP IPA aerosol is formulated as an aerosol containing 70% w/w of propan-2-ol, which is classified Flam. Liq. 2, H225, and as no ignition distance test and enclosed space ignition test was performed, it is classified Flam. Aerosol 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated).

The long term storage stability study is on-going and should be provided in post-authorisation within 2 years.

* **Post authorisation assessment (2021)**

Long-term storage stability study shows that after 3 years at ambient temperature in aluminium aerosol (double wrapped in PE bags), the product remains stable. Consequently, the shelf life of the product is maintained at 2 years.

***META SPC 3***

The META SPC 3 are wipes.

The appearance of the product is white tissues impregnated with alcoholic odour. There is no effect of high temperature on the appearance of the formulation. After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C. Its technical characteristics are acceptable for wipes.

The mention “do not store at temperatures above 40°” should be added.

The long term storage stability study is on-going and should be provided in post-authorisation within 2 years.

The product BACTY SP IPA tissu is formulated as wipes impregnated with a solution of 70 % w/w of propan-2-ol, which is classified Flam. Liq. 2, H225.

Based on the intended uses of the products and on the nature of the substance, on its physico-chemical properties and on its relations structure/function, limited contamination of the environment is foreseen (indoors use only). No residues are expected in soil and water.

* **Post authorisation assessment (2021)**

Long-term storage stability study shows that after 3 years at ambient temperature in white multi-layer (film layer = PET + vacuum metallized PET + metallocene-LLDPE) opaque bag, the product remains stable. Consequently, the shelf life of the product is maintained at 2 years.

* ***Efficacy assessment***

French competent authorities (FR CA) assessed that the product family (BACTY SP IPA) 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[[1]](#footnote-1), as:

* The liquid products of the BACTY SP IPA family (META SPC1) are efficient against bacteria, yeasts and fungi for hard surface disinfection without mechanical action; and only against bacteria and yeasts with mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by spraying, mopping (at 100 % v/v) and wiping (1 wipe/1-2 m²) by professional users.
* The in-can product of the BACTY SP IPA family (Meta SPC2) is efficient against bacteria, yeasts and fungi for hard surface disinfection without mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by spraying (at 100 % v/v) by professional users.
* The impregnated wipe products of the BACTY SP IPA family (META SPC 3) are efficient against bacteria and yeasts for hard surface disinfection with mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by wiping (1 wipe/1-2 m²) by professional users.

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

* ***Risk assessment for human health***

The risk is considered acceptable for professionals with the following RMMs:

* wearing gloves and RPE (with APF of 10) in a room with a ventilation rate < 21 vol/h; or
* wearing gloves only in a room with a ventilation rate ≥ 21 vol/h.

.

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.

For an adult entering a room with freshly treated surfaces (including soil), the time for re-entry is directly related to the ventilation rate of the room.

For rooms with a ventilation rate < 21 vol/h, the risk is considered acceptable if the re-entry occurs after the application.

Consequently a risk mitigation measure should be applied: “Do not enter the room during the application of the product”.

For rooms with a ventilation rate ≥ 21 vol/h, the re-entry can occur during the aplication of the product.

* ***Risk for consumers via residues***

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

* ***Risk assessment for environment***

Based on the restricted uses of the products of the BACTY SP IPA family in clean rooms (i.e. controlled atmosphere areas) where no wet cleaning or other releases are expected, no unacceptable risk to the environmental compartments has been identified.

* ***General conclusion***

According to the assessment performed for the product family BACTY SP IPA, two types of uses can be proposed for authorization:

* ready-to-use disinfectants used for the disinfection of industrial process equipment’s work plan (upper surface) and soil in clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) of industrial process (except in veterinary and food industry).

Products can either be sprayed using trigger spray (META SPC 1) or aerosol can (META SPC 2) on the surface to disinfect.

* ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) to disinfect hard surfaces. It can be used on walls, grounds, benches and equipments.

Products can be either applied by mopping uniformly on the surface to disinfect or applied uniformly with an impregnated wipe (META SPC 1) or with a ready to use impregnated wipe (META SPC 3) on the surfaces to disinfect.

# ASSESSMENT REPORT

## Summary of the product assessment

# Part I.- First information level

### Administrative information

#### Identifier of the product family

| **Identifier[[2]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| BACTY SP IPA | France  Belgium  Czech Republic  Switzerland |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Conformat |
| **Address** | 140 avenue Paul Doumer  92500 - RUEIL MALMAISON  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Conformat |
| **Address of manufacturer** | 140 avenue Paul Doumer  92500 - Rueil Malmaison  France |
| **Location of manufacturing sites** | SIMAGEC  54 Avenue de la Plaine  13106 Rousset  France |
| ARDEPHARM  Les iles ferays  07300 Tournon  France |

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

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | ExxonMobil Petroleum & Chemical B.V.B.A. |
| **Address of manufacturer** | Polderdijkweg 3B  B-2030 Antwerpen  Belgium |
| **Location of manufacturing sites** | Baton Rouge Chemical Plant (BRCP)  4999 Baton Rouge  Louisiana 70897  United-States |

### 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** | Isopropanol |
| **IUPAC or EC name** | Propan-2-ol |
| **EC number** | 200-661-7 |
| **CAS number** | 67-63-0 |
| **Index number in Annex VI of CLP** | 603-117-00-0 |
| **Minimum purity / content** | ≥ 99% w/w |
| **Structural formula** |  |

#### Candidate(s) for substitution

Not relevant

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

#### *With carrier*

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content**  **(% w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance  (pure) | 67-63-0 | 200-661-7 | 44.0 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance  (technical) | 67-63-0 | 200-661-7 | 44.4 | 70.7 |

#### *Without carrier*

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content**  **(% w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance  (pure) | 67-63-0 | 200-661-7 | 69.9 | 70.1 |
| Isopropanol | Propan-2-ol | Active Substance  (technical) | 67-63-0 | 200-661-7 | 70.6 | 70.8 |

#### Information on technical equivalence

Not relevant

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

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| AE – aerosol dispenser  AL – Any other liquid  Wipes |

# Part II.- Second information level - meta SPC 1

## Meta SPC 1 administrative information

## Meta SPC identifier

| **Identifier** | META SPC 1 |
| --- | --- |

## 

## Suffix to the authorisation number

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

## Product type(s)

| **Product type(s)** | PT02 |
| --- | --- |

## 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 (% w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance(pure) | 67-63-0 | 200-661-7 | 70.0 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.7 | 70.7 |

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

| **Formulation** | AL – Any other liquid |
| --- | --- |

## Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Flam. Liq. 2  Eye Irrit 2  STOT SE 3 |
| Hazard statement | H225: Highly flammable liquid and vapour  H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H225: Highly flammable liquid and vapour  H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness |
| Precautionary statements | P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing  P337 + P313: If eye irritation persists get medical advice/attention  P403 + P233: Store in a well ventilated place and keep container tightly closed  P405: Store locked up  P501: Dispose of contents/container in accordance with local/regional/national/international regulation |
|  | |
| Note | - |

## Authorised use(s) for the META SPC 1

## Use description

Table 1. Use # 1 – Spraying

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product BACTY SP IPA is a ready-to-use disinfectant used for the disinfection of industrial process equipment’s work plan (upper surface) and soil in clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) of industrial process (except in veterinary and food industry). |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is sprayed (trigger spray) on the surface to disinfect |
| **Application rate(s) and frequency** | Ready-to-use  Contact time 5 minutes  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Bottle with trigger spray in HDPE of 750 mL and 1L. |

### Use-specific instructions for use

|  |
| --- |
| * Hold the trigger upright and spray from a distance of 10 to 30 cm uniformly on the surface to be treated in sufficient quantity (50 mL/m²) so that surfaces remain wet during at least 5 minutes. If necessary, the product applied can be spread with a cloth. |

### 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 – Mopping

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product BACTY SP IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) to disinfect hard surfaces. It can be used on walls, grounds, benches and equipments. |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor use  Industries |
| **Application method(s)** | The product is applied by mopping uniformly on the surface to disinfect. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time 5 minutes  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Can in HDPE of 5L, 10L, 20L |

### Use-specific instructions for use

|  |
| --- |
| * Apply the product by mopping uniformly on the surface to be treated in sufficient quantity so that the surface remains wet during at least 5 minutes. |

### 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 3. Use # 3 – Wiping

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product BACTY SP IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) to disinfect hard surfaces. It can be used on walls, grounds, benches and equipment. |
| **Target organism (including development stage)** | Bacteria  Yeasts |
| **Field of use** | Indoor use  Industries |
| **Application method(s)** | The product is applied uniformly with an impregnated wipe on the surfaces to disinfect. |
| **Application rate(s) and frequency** | Ready-to-use  Application rate: depending on the size of the wipe. A 23\*23 cm wipe is sufficient to disinfect 1-2 m²  Contact time 5 minutes  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Sealed pouch (multi-layer zipper bag, LLDPE + PET + AL + LLDPE). Dry wipes and pouch are contained in a bag (multi-layer bag, PET + VMPET + metallocene-LLDPE) of 200 mL to 2 500 mL. |

### Use-specific instructions for use

|  |
| --- |
| * Apply the product with a wipe (impregnated just before use in the case of the product BACTY SP IPA saches) uniformly on the surface to be treated in sufficient quantity (one 23\*23 cm wipe for 1-2m²) so that the surface remains wet during at least 5 minutes. |

### 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

### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Let the surface dry. * Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C). * 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

|  |
| --- |
| * In a room with a ventilation rate < 21 vol/h, during the application of the product, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and RPE (with APF of 10). * In a room with a ventilation rate ≥ 21 vol/h, during the application of the product, wear protective chemical resistant gloves only (glove material to be specified by the authorisation holder within the product information). * 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; * Minimise number of staff exposed; * Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; * Training for staff on good practice; * Good standard of personal hygiene. * PPE for the spraying phase are as following: * Eye protection. * For people not applying the product, do not enter the room with a ventilation rate < 21 vol/h during the application of the product. * Avoid direct or indirect contact with food and feed. * Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed. |

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

|  |
| --- |
| **Impaired consciousness:** do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.  Keep the container or label available.  **Inhalation:** Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.  **Mouth contact/Ingestion:** Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.  **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention 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. |

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

|  |
| --- |
| * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Dispose of the product in accordance with local requirements. |

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

|  |
| --- |
| Do not store at temperatures above 30°C.  Shelf-life : 2 years |

## Other information

|  |
| --- |
| * The authorization holder should report any observed incidents related to 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)** | **BACTY SP Isopropyl alcohol 70% Trigger** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.7 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **BACTY SP Isopropyl alcohol 70% Bottle** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| Isopropanol | Propan-2-ol | Active Substance | 67-63-0 | 200-661-7 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.7 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **BACTY SP Isopropyl alcohol 70% BiB** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Isopropanol | Propan-2-ol | Active Substance | 67-63-0 | 200-661-7 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.7 |

# Part II.- Second information level - meta SPC 2

## Meta SPC 2 administrative information

## Meta SPC identifier

| **Identifier** | META SPC 2 |
| --- | --- |

## Suffix to the authorisation number

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

## Product type(s)

| **Product type(s)** | PT02 |
| --- | --- |

## 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 (% w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 70.0 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.7 | 70.7 |

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

| **Formulation** | AE – aerosol dispenser |
| --- | --- |

## Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Flam. Aerosol 1  Eye Irrit 2  STOT SE 3 |
| Hazard statement | H222: Extremely flammable aerosol  H229 : Pressurized container: may burst if heated  H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H319: Causes serious eye irritation  H222: Extremely flammable aerosol  H229 : Pressurized container: may burst if heated  H336: May cause drowsiness or dizziness |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P211: Do not spray on an open flame or other ignition source.  P251: Do not pierce or burn, even after use.  P280: Wear 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.  P410 + P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C.  P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P337 + P313: If eye irritation persists get medical advice/attention  P403 + P233: Store in a well ventilated place and keep container tightly closed  P405: Store locked up  P501: Dispose of contents/container in accordance with local/regional/national/international regulation |
|  | |
| Note | - |

## Authorised use(s) for the META SPC 2

## Use description

Table 4. Use # 1 – Spraying

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product BACTY SP IPA is a ready-to-use disinfectant used for the disinfection of industrial process equipment’s work plan (upper surface) and soil in clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) of industrial process (except in veterinary and food industry). |
| **Target organism (including development stage)** | Bacteria  Yeasts  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is sprayed (aerosol can) on the surface to disinfect |
| **Application rate(s) and frequency** | Ready-to-use  Contact time 5 minutes  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Aerosol in PP bag within an aluminium can of 400 mL |

### Use-specific instructions for use

|  |
| --- |
| * Hold the trigger upright and spray from a distance of 10 to 30 cm uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least 5 minutes. |

### 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

### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Let the surface dry. * Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C). * 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

|  |
| --- |
| * In a room with a ventilation rate < 21 vol/h, during the application of the product, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and RPE (with APF of 10). * In a room with a ventilation rate ≥ 21 vol/h, during the application of the product, wear protective chemical resistant gloves only (glove material to be specified by the authorisation holder within the product information). * 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; * Minimise number of staff exposed; * Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; * Training for staff on good practice; * Good standard of personal hygiene. * PPE for the spraying phase are as following: * Eye protection. * For people not applying the product, do not enter the room with a ventilation rate < 21 vol/h during the application of the product. * Avoid direct or indirect contact with food and feed. * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed. |

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

|  |
| --- |
| **Impaired consciousness:** do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.  Keep the container or label available.  **Inhalation:** Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.  **Mouth contact/Ingestion:** Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.  **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention 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. |

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

|  |
| --- |
| * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Dispose of the product in accordance with local requirements. |

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

|  |
| --- |
| Do not store at temperatures above 30°C.  Shelf-life : 2 years |

## Other information

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

# Part III - 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)** | **BACTY SP Isopropyl alcohol 70% Spray** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 70.0 |
| Isopropanol | Propan-2-ol | Active Substance(technical) | 67-63-0 | 200-661-7 | 70.7 |

# Part II.- Second information level - meta SPC 3

## Meta SPC 3 administrative information

## Meta SPC identifier

| **Identifier** | META SPC 3 |
| --- | --- |

## Suffix to the authorisation number

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

## Product type(s)

| **Product type(s)** | PT02 |
| --- | --- |

## Meta SPC 3 composition

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 44.0 | 49.4 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 44.4 | 49.9 |

## Qualitative and quantitative information on the composition of the meta SPC 3 without carrier.

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 69.9 | 70.1 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.6 | 70.8 |

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

| **Formulation** | Wipes |
| --- | --- |

## Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Flam. Liq. 2  Eye Irrit 2  STOT SE 3 |
| Hazard statement | H319: Causes serious eye irritation  H225: Highly flammable liquid and vapour  H336: May cause drowsiness or dizziness |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H225: Highly flammable liquid and vapour |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking  P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing  P337 + P313: If eye irritation persists get medical advice/attention  P403 + P233: Store in a well ventilated place and keep container tightly closed  P405: Store locked up  P501: Dispose of contents/container in accordance with local/regional/national/international regulation |
|  | |
| Note | - |

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

## Use description

Table 5. Use # 1 – Wiping

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product BACTY SP IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 class 1 to 8, GMP EU grade A to C) to disinfect hard surfaces. It can be used on walls, grounds, benches and equipment. |
| **Target organism (including development stage)** | Bacteria  Yeasts |
| **Field of use** | Indoor use  Industries |
| **Application method(s)** | The product is applied uniformly with a ready to use impregnated wipe on the surfaces to disinfect. |
| **Application rate(s) and frequency** | Ready-to-use  Application rate: depending on the size of the wipe. A 23\*23 cm wipe is sufficient to disinfect 1-2 m²  Contact time 5 minutes  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Multi-layer bags (film layer = PET + VMPET + metallocene-LLDPE). |

### Use-specific instructions for use[[3]](#footnote-3)

|  |
| --- |
| * Apply the product with a wipe uniformly on the surface to be treated in sufficient quantity (one 23\*23 cm wipe for 1-2m²) so that the surface remains wet during at least 5 minutes. |

### 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

### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Let the surface dry. * 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. * Only use in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C). |

### Risk mitigation measures

|  |
| --- |
| * In a room with a ventilation rate < 21 vol/h, during the application of the product, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and RPE (with APF of 10). * In a room with a ventilation rate ≥ 21 vol/h, during the application of the product, wear protective chemical resistant gloves only (glove material to be specified by the authorisation holder within the product information). * 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; * Minimise number of staff exposed; * Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; * Training for staff on good practice; * Good standard of personal hygiene. * PPE for the spraying phase are as following: * Eye protection. * For people not applying the product, do not enter the room with a ventilation rate < 21 vol/h during the application of the product. * Avoid direct or indirect contact with food and feed. * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Dispose of the product in accordance with local requirements. * Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed. |

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

|  |
| --- |
| **Impaired consciousness:** do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.  Keep the container or label available.  **Inhalation:** Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.  **Mouth contact/Ingestion:** Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.  **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention 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. |

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

|  |
| --- |
| * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Dispose of the product in accordance with local requirements. |

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

|  |
| --- |
| Do not store at temperatures above 40°C.  Shelf-life : 2 years |

## Other information

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

# Part III - 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)** | **BACTY SP Isopropyl alcohol 70% Wipes P** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 44.0 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 44.4 |

Without carrier:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **BACTY SP Isopropyl alcohol 70% Wipes P** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 69.9 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.6 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **BACTY SP Isopropyl alcohol 70% Wipes C** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 49.4 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 49.9 |

Without carrier:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **BACTY SP Isopropyl alcohol 70% Wipes P** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%w/w)** |
| Isopropanol | Propan-2-ol | Active Substance (pure) | 67-63-0 | 200-661-7 | 70.1 |
| Isopropanol | Propan-2-ol | Active Substance (technical) | 67-63-0 | 200-661-7 | 70.8 |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Meta SPC 1 | Bottle with trigger spray | 750 mL  1L | HDPE | / | Professional |  |
| Meta SPC 1 | Can | 5L  10L  20L | HDPE | / | Professional |  |
| Meta SPC 1 | sealed pouch | 200 mL to 2500 mL | multi-layer zipper bag, LLDPE + PET + AL + LLDPE). Dry wipes and pouch are contained in a bag (multi-layer bag, PET + VMPET + metallocene-LLDPE) of 200 mL to 2 500 mL. | / | Professional |  |
| Meta SPC 2 | aerosol | 400 mL | PP bag within aluminium can. | / | Professional |  |
| Meta SPC 3 | Multi-layer bag | 200 mL to 2500 mL | film layer = PET + VMPET + metallocene-LLDPE | / | Professional |  |

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product BACTY SP IPA family were provided by CONFORMAT.

**Efficacy**

The product BACTY SP IPA (70 % w/w propan-2-ol) has been tested following efficacy studies:

* For bacteria:
* Laboratory study according to EN1276 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 yeasts:
* Laboratory study according to EN1650 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:
* Laboratory study according to EN1650 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)

#### Access to documentation

CONFORMAT has access to data on the active substance 2-propanol with a Letter of Access of STOCKMEIER Chemie GmbH & Co. KG, one applicant owner of the active substance 2-propanol.

## Assessment of the biocidal product family

The products of the biocidal product family are not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the products is confidential and is presented in a confidential annex. If counting the carrier for meta SPC 3, the products of the BPF contain 44.4-70.7% of technical active substance 2-propanol and 44-70% of pure active substance 2-propanol.

The product does not contain PT6 preservative.

The product is not diluted for use: it is ready-to-use.

Formulation types: AL, AE and wipes ready-to-use.

Hydrocarbon and H304 co-formulant content: /

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

#### **META SPC 1**

Table 1. Intended use # 1 – Spraying

|  |  |
| --- | --- |
| Product Type(s) | PT2 |
| Where relevant, an exact description of the authorised use | The products of the BACTY SP IPA family are ready-to-use disinfectants to be used in industrial clean rooms. |
| Target organism (including development stage) | Bacteria-No data-Bacteria  yeast-No data-Yeasts  fungi-No data-Fungi |
| Field of use | Indoor |
| Application method(s) | Spraying |
| Application rate(s) and frequency | 50 mL/m2 - 100 - as needed |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE bottle with trigger spray.  750 mL and 1 L |

Table 2. Intended use # 2 – Mopping

|  |  |
| --- | --- |
| Product Type(s) | PT2 |
| Where relevant, an exact description of the authorised use | The products of the BACTY SP IPA family are ready-to-use disinfectants to be used in industrial clean rooms. |
| Target organism (including development stage) | Bacteria-No data-Bacteria  yeast-No data-Yeasts  fungi-No data-Fungi |
| Field of use | Indoor |
| Application method(s) | Mopping |
| Application rate(s) and frequency | 50 mL/m2 - 100 - as needed |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | HDPE jerry can 5, 10 and 20 L |

Table 3. Intended use # 3 – Wiping

|  |  |
| --- | --- |
| Product Type(s) | PT2 |
| Where relevant, an exact description of the authorised use | The products of the BACTY SP IPA family are ready-to-use disinfectants to be used in industrial clean rooms. |
| Target organism (including development stage) | Bacteria-No data-Bacteria  yeast-No data-Yeasts  fungi-No data-Fungi |
| Field of use | Indoor |
| Application method(s) | Wiping |
| Application rate(s) and frequency | depending on the size of the wipe. 1 wipe for 1-2 m² - 100 -  as needed |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | sealed pouch (multi-layer zipper bag, LLDPE + PET + AL + LLDPE). Dry wipes and pouch are contained in a bag (multi-layer bag, PET + VMPET + metallocene-LLDPE) of 200 mL to 2 500 mL. |

#### **META SPC 2**

Table 1. Intended use # 1 – Spraying aerosol

|  |  |
| --- | --- |
| Product Type(s) | PT2 |
| Where relevant, an exact description of the authorised use | The products of the BACTY SP IPA family are ready-to-use disinfectants to be used in industrial clean rooms. |
| Target organism (including development stage) | Bacteria-No data-Bacteria  yeast-No data-Yeasts  fungi-No data-Fungi |
| Field of use | Indoor |
| Application method(s) | Spraying |
| Application rate(s) and frequency | 50 mL/m2 - 100 - as needed |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Aerosol can 400 mL.  The product is in a sterile pouch in PP and is not un contact with the propellant. |

#### **META SPC 3**

Table 1. Intended use # 1 – Wiping wipes

|  |  |
| --- | --- |
| Product Type(s) | PT2 |
| Where relevant, an exact description of the authorised use | The products of the BACTY SP IPA family are ready-to-use disinfectants to be used in industrial clean rooms. |
| Target organism (including development stage) | Bacteria-No data-Bacteria  yeast-No data-Yeasts  fungi-No data-Fungi |
| Field of use | Indoor |
| Application method(s) | Wiping |
| Application rate(s) and frequency | 1 wipe for 1-2m2 - 100 -  as needed |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Multi-layer bags: film layer = PET + VMPET + metallocene-LLDPE), 200 mL to 2 500 mL.  Each bag can contain 20 to 200 wipes (100% polyester or 55% cellulose/45% polyester). |

### Physical, chemical and technical properties

#### Meta SPC 1 - BACTY SP IPA pulvérisateur / bidon / saches

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA pulvérisateur  Batch 031215 | Homogeneous colourless limpid liquid | Demangel B., 2016  Report N° 16-903061-001 |
| Colour at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA pulvérisateur  Batch 031215 | Homogeneous colourless limpid liquid | Demangel B., 2016  Report N° 16-903061-001 |
| Odour at 20 °C and 101.3 kPa |  |  | All the products of the BACTY SP IPA family contain > 42% w/w propan-2-ol and the other co-formulants are not expected to have any odour (please refer to the detailed compositions in Section 13 or Section 2 of the IUCLID file). Therefore, these products are expected to have an alcoholic odour. |  |
| Acidity / alkalinity | CIPAC MT 75.3 | BACTY SP IPA pulvérisateur  Batch 031215 | At 21°C 5.93 |  |
| Relative density / bulk density | EC A3 OECD 109 | BACTY SP IPA pulvérisateur  Batch 031215 | D204=0.858 at 20.6°C | Demangel B., 2016  Report N° 16-903061-001 |
| Storage stability test – **accelerated storage** | Validated method study No.16-903061-004 |  | |  |  |  | | --- | --- | --- | |  | T = 0 | T = 18 weeks at 30°C | | Appearance | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | No change | | Packaging | HDPE spray | No change | | Isopropanol | 70.8 | 70.0 | | Variation | / | -1.1% | | pH | At 21°C pure: 5.93 | At 21°C pure: 6.13 | | Spray volume | 0.62 mL  Nozzles of the sprays were checked and no blocking was observed | 0.63 mL  Nozzles of the sprays were checked and no blocking was observed |   Study is acceptable and the product is stable 18 weeks at 30°C. The mention “Do not store at temperatures above 30°C” should be added. | Demangel B., 2016  Report N° 16-903061-002 |
| Storage stability test – **long term storage at ambient temperature** |  |  | Shelf-life study is on-going and should be provided in post-authorisation within 2 years.  **Post authorisation assessment (2021)**  Long-term storage stability study has been provided in post-authorisation. See below |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | BACTY SP IPA pulvérisateur  Batch 031215 | Homogeneous colourless limpid liquid.  The aspect of the test item was considered to be stable after 7 days at 0°C, no change was observed. | Demangel B., 2016  Report N° 16-903061-001 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | According to the Assessment Report of propan-2-ol, PT02, (January 2015), this substance is not accessible for direct photodegradation in sunlight. Indeed, the molecular structure of propan-2-ol has no chromophore and a cut-off point of 210 nm is given for propan-2-ol in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 nm cannot undergo direct photolysis in sunlight. Also, the packaging of the BACTY SP IPA saches product is opaque and the product is protected from the light.  Acceptable. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | see accelerated storage. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | see accelerated storage. |  |
| Wettability |  |  | Not required because BP is a ready-to-use. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required because BP is a ready-to-use. |  |
| Wet sieve analysis and dry sieve test |  |  | Not required because BP is a ready-to-use. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required because BP is a ready-to-use. |  |
| Disintegration time |  |  | Not required because BP is a ready-to-use. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Particle size distribution is below with spray pattern. |  |
| Persistent foaming |  |  | Not required because BP is a ready-to-use. |  |
| Flowability/Pourability/Dustability |  |  | Not required because BP is a liquid or saches. |  |
| Burning rate — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Burning completeness — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Composition of smoke — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Spraying pattern — aerosols | PSD method 30/217-01 | BACTY SP IPA pulvérisateur  Batch 310117 |  | Metrat L. 2017  Study 43689 |
| Physical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required because BP is a ready-to-use. |  |
| Surface tension | EC A5 OECD 115 | BACTY SP IPA pulvérisateur  Batch 031215 | At 20.1°C 22.8mN/m | Demangel B., 2016  Report N° 16-903061-001 |
| Viscosity | OECD 114 | BACTY SP IPA pulvérisateur  Batch 031215 | At 20°C 3.54 mPa.s  At 40°C 1.94 mPa.s  It is a newtonian liquid. | Demangel B., 2016  Report N° 16-903061-001 |

#### Meta SPC 2 - BACTY SP IPA aérosol

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA aérosol  Batch | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | Demangel B., 2016  Report N° 16-903061-005 |
| Colour at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA aérosol  Batch | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | Demangel B., 2016  Report N° 16-903061-005 |
| Odour at 20 °C and 101.3 kPa |  |  | All the products of the BACTY SP IPA family contain > 42% w/w propan-2-ol and the other co-formulants are not expected to have any odour (please refer to the detailed compositions in Section 13 or Section 2 of the IUCLID file). Therefore, these products are expected to have an alcoholic odour. |  |
| Acidity / alkalinity |  |  | At 20.9°C pure: 6.18 |  |
| Relative density / bulk density | EC A3 OECD 109 | BACTY SP IPA aérosol  Batch 031215 | At 20,6°C= 0.858 | Demangel B., 2016  Report N° 16-903061-001 |
| Storage stability test – **accelerated storage** | Method validated study No.16-903061-004 |  | |  |  |  | | --- | --- | --- | |  | T = 0 | T = 18 weeks at 30°C | | Appearance | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | No change | | Packaging | Aluminium aerosol | No change | | Isopropanol | 70.0 | 69.0 | | Variation | / | -1.5% | | pH | At 20.9°C pure: 6.18 | At 20.3°C pure: 5.87 | | Spray volume | Mean volume of 5-s pulverisation= 28.26 mL  Nozzles of the sprays were checked and no blocking was observed | Mean volume of 5-s pulverisation= 27.68 mL  Nozzles of the sprays were checked and no blocking was observed | | Spray dimeter and pattern | Mean spray diameter = 30 cm  The shape of the spray on the wetted patch was circular. | Mean spray diameter = 30 cm  The shape of the spray on the wetted patch was circular. | |  |  |  |   The product is stable 18 weeks at 30°C. The mention “Do not store at temperatures above 30°C” should be added. | Demangel B., 2016  Report N° 16-903061-005 |
| Storage stability test – **long term storage at ambient temperature** |  |  | Shelf-life study is on-going and should be provided in post-authorisation within 2 years.  **Post authorisation assessment (2021)**  Long-term storage stability study has been provided in post-authorisation. See below |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | BACTY SP IPA pulvérisateur  Batch 031215 | Homogeneous colourless limpid liquid.  The aspect of the test item was considered to be stable after 7 days at 0°C, no change was observed. | Demangel B., 2016  Report N° 16-903061-001 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | According to the Assessment Report of propan-2-ol, PT02,  (January 2015), this substance is not accessible for direct photodegradation in sunlight. Indeed, the molecular structure of propan-2-ol has no chromophore and a cut-off point of 210 nm is given for propan-2-ol in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 nm cannot undergo direct photolysis in sunlight. Also, the packaging of the BACTY SP IPA saches product is opaque and the product is protected from the light.  Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | See accelerated storage. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See accelerated storage. |  |
| Wettability |  |  | Not required because BP is a ready-to-use. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required because BP is a ready-to-use. |  |
| Wet sieve analysis and dry sieve test |  |  | Not required because BP is a ready-to-use. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required because BP is a ready-to-use. |  |
| Disintegration time |  |  | Not required because BP is a ready-to-use. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Particle size distribution is below with spray pattern |  |
| Persistent foaming |  |  | Not required because BP is a ready-to-use. |  |
| Flowability/Pourability/Dustability |  |  | Not required because BP is a liquid |  |
| Burning rate — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Burning completeness — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Composition of smoke — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Spraying pattern — aerosols | PSD method 30/217-01 |  |  | Metrat L. 2017  Study 43690 |
| Physical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required because BP is a ready-to-use. |  |
| Surface tension | EC A5 OECD 115 | BACTY SP IPA pulvérisateur  Batch 031215 | At 20.1°C 22.8mN/m | Demangel B., 2016  Report N° 16-903061-001 |
| Viscosity | OECD 114 | BACTY SP IPA pulvérisateur  Batch 031215 | At 20°C 3.54 mPa.s  At 40°C 1.94 mPa.s  It is a newtonian liquid. | Demangel B., 2016  Report N° 16-903061-001 |

#### Meta SPC 3 - BACTY SP IPA tissu

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA tissu  Batch | White tissues impregnated with alcoholic odour | Demangel B., 2016  Report N° 16-903061-007 |
| Colour at 20 °C and 101.3 kPa | Visual observation | BACTY SP IPA tissu  Batch | White tissues impregnated with alcoholic odour | Demangel B., 2016  Report N° 16-903061-007 |
| Odour at 20 °C and 101.3 kPa |  |  | All the products of the BACTY SP IPA family contain  > 42% w/w propan-2-ol and the other co-formulants are  not expected to have any odour (please refer to the  detailed compositions in Section 13 or Section 2 of the  IUCLID file). Therefore, these products are expected to  have an alcoholic odour. |  |
| Acidity / alkalinity |  |  | The products BACTY SP IPA tissu are ready-to-use solid  formulation, therefore no pH determination is required.  Nevertheless, studies on the liquid formulation which impregnates the wipes of the products are still ongoing, results will be provided when available. |  |
| Relative density / bulk density | EC A3 OECD 109 | BACTY SP IPA tissu  Batch 031215 | The calculated density of the product BACTY SP IPA tissu  (100% polyester) is 0.644 g/cm3.  The calculated density of the product BACTY SP IPA tissu  (55% cellulose/ 45% polyester) is 0.628 g/cm3. | Demangel B., 2016  Report N° 16-903061-001 |
| Storage stability test – **accelerated storage** | Visual observation | BACTY SP IPA tissu  Batch | |  |  |  | | --- | --- | --- | |  | T = 0 | T = 8 weeks at 40°C | | Appearance | White tissues impregnated with alcoholic odour | No change | | Weight  Variation of weight | 674.3 g  / | 666.4  -1.2% | | Packaging | White multi-layer (film layer = PET + Vacuum metallized PET + metallocene-LLDPE) opaque bag | No change |   The AS is not degradable as demonstrated in meta SPC 1&2, the variation of weight is negligible during accelerated storage, we can consider that the biocide product is stable during accelerated storage, no more data required.  The product is stable 8 weeks at 40°C. The mention “Do not store at temperatures above 40°C” should be added. | Demangel B., 2016  Report N° 16-903061-007 |
| Storage stability test – **long term storage at ambient temperature** |  |  | Shelf-life study is on-going and should be provided in post-authorisation within 2 years.  **Post authorisation assessment (2021)**  Long-term storage stability study has been provided in post-authorisation. See below |  |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | BACTY SP IPA pulvérisateur  Batch 031215 | The product BACTY SP IPA tissu is solid formulation, therefore no low temperature stability test is required.  Nevertheless, a study on the liquid formulation which  impregnates the wipes of the products has been provided.  The liquid formulation is considered to be stable after a  storage procedure for 7 days at 0 ± 2°C: no deposit or phase partition was observed. No change in the appearance of the test item was observed. | Demangel B., 2016  Report N° 16-903061-001 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | According to the Assessment Report of propan-2-ol, PT02, (January 2015), this substance is not accessible for direct photodegradation in sunlight. Indeed, the molecular structure of propan-2-ol has no chromophore and a cut-off point of 210 nm is given for propan-2-ol in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 nm cannot undergo direct photolysis in sunlight.  Also, the packaging of the BACTY SP IPA tissu products opaque and the product is protected from the light.  Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | See accelerated storage |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See accelerated storage |  |
| Wettability |  |  | Not required because BP is a ready-to-use. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required because BP is a ready-to-use. |  |
| Wet sieve analysis and dry sieve test |  |  | Not required because BP is a ready-to-use. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required because BP is a ready-to-use. |  |
| Disintegration time |  |  | Not required because BP is a ready-to-use. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required because BP is a tissue. |  |
| Persistent foaming |  |  | Not required because BP is a ready-to-use. |  |
| Flowability/Pourability/Dustability |  |  | Not required because BP is a tissue. |  |
| Burning rate — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Burning completeness — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Composition of smoke — smoke generators |  |  | Not required because BP is a ready-to-use. |  |
| Spraying pattern — aerosols |  |  | Not required |  |
| Physical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in  conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. BACTY SP IPA family products are ready-to-use products and are not intended to be used in  conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required because BP is a ready-to-use. |  |
| Surface tension | EC A5 OECD 115 | BACTY SP IPA pulvérisateur  Batch 031215 | The product BACTY SP IPA tissu is solid formulation,  therefore no surface tension determination is required.  Nevertheless, a study on the liquid formulation which  impregnates the wipes of the products has been provided.  The surface tension of the liquid formulation impregnated in BACTY SP IPA tissu is found to be 22.8 ±0.1 mN/m at a temperature of 20.1°C. The test items are considered as surface-active in the experimental conditions used. | Demangel B., 2016  Report N° 16-903061-001 |
| Viscosity | OECD 114 | BACTY SP IPA pulvérisateur  Batch 031215 | The product BACTY SP IPA tissu is solid formulation,  therefore no viscosity determination is required.  Nevertheless, a study on the liquid formulation which  impregnates the wipes of the products has been provided.  At 20°C 3.54 mPa.s  At 40°C 1.94 mPa.s  It is a newtonian liquid. | Demangel B., 2016  Report N° 16-903061-001 |

* **Post authorization data provided on 01/2021 (3 years storage stability)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **Comment** |
| Technical Monograph No. 17  Method GC-FID (Ricau H. 2016, already validated)  CIPAC MT 75.3 | Bacty SP IPA pulvérisateur  70 %w/w | |  |  |  | | --- | --- | --- | |  | **Initial** | **After 36 months in HDPE sprays (double wrapped in PE bags)** | | Appearance | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | No change | | Packaging | HDPE spray | No change | | Isopropanol content (%w/w) | 70.8 | 70.1 | | Variation | / | -1% | | pH | At 21°C pure: 5.93 | At 19.1°C pure: 5.55 | | Spray volume | 0.631 mL  Nozzles of the sprays were checked and no blocking was observed | 0.635 mL  Nozzles of the sprays were checked and no blocking was observed | | Report No.16-903061-003  DETRIMONT, 2019 | Acceptable  Product is stable after 3 year in HDPE packaging. |
| Technical Monograph No. 17  Method GC-FID (Ricau H. 2016, already validated)  CIPAC MT 75.3  FEA 644F (2009) | Bacty SP IPA aerosol  70 %w/w | |  |  |  | | --- | --- | --- | |  | **Initial** | **After 36 months in Aluminium aerosol (double**  **wrapped in PE bags)** | | Appearance | Homogeneous colourless limpid liquid with an isopropylic alcohol odour | No change | | Packaging | Aluminium aerosol | No change | | Isopropanol content (%w/w) | 70 | 69 | | Variation | / | -1.4 % | | pH | At 20.9°C pure: 6.18 | At 20.2°C pure: 5.9 | | Spray volume | Mean volume of 5-s pulverisation= 28.18mL  Nozzles of the sprays were checked and no blocking was observed | Mean volume of 5-s pulverisation= 25.7mL  Nozzles of the sprays were checked and no blocking was observed | | Spray diameter and pattern | Mean spray diameter = 29 cm  The shape of the spray on the wetted patch was circular. | Mean spray diameter = 35 cm  The shape of the spray on the wetted patch was circular. | | Report No.16-903061-006  DETRIMONT, 2018 | Acceptable  Product is stable after 3 years in aluminium aerosol. |
| Technical Monograph No. 17  Method GC-FID (Ricau H. 2016, already validated)  CIPAC MT 75.3  FEA 644F (2009) | Bacty SP IPA tissu | |  |  |  | | --- | --- | --- | |  | **Initial** | **After 36 months in white multi-layer opaque bag** | | Appearance | White tissues impregnated with alcoholic odour | No change | | Weight  Variation of weight | 673.3 g  / | 647.6  -3.7% | | Packaging | White multi-layer (film layer = PET + Vacuum metallized PET + metallocene-LLDPE) opaque bag | No change | | Report No.16-903061-008  DETRIMONT, 2019 | Acceptable  Product is stable after 3 years in white multi-layer opaque bag.  The product used in the impregnated wipes has been shown to be stable in the study report No.16-903061-003.  No change of weight was observed. Thus the product is considered as stable. |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The META SPC 1 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.  The appearance of the product is an homogeneous colourless limpid liquid with an isopropylic alcohol odour. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The mention “Do not store at temperatures above 30°C” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE spray packaging material (commercial packaging material). The long term storage stability study is on-going and should be provided in post-authorisation within 2 years.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an SL formulation.  The META SPC 2 is an aerosol (AE) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is an homogeneous colourless limpid liquid with an isopropylic alcohol odour. There is no effect of high temperature on the stability of the formulation, since after 18 weeks at 30°C, neither the active ingredient content nor the technical properties were changed. The mention “Do not store at temperatures above 30°C” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium can packaging material (commercial packaging material). The long term storage stability study is on-going and should be provided in post-authorisation within 2 years.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AE formulation.  The products of the META SPC 3 are wipes.  The appearance of the product is white tissues impregnated with alcoholic odour. There is no effect of high temperature on the appearance of the formulation.  The mention “Do not store at temperatures above 40°C” should be added.  The long term storage stability study is on-going and should be provided in post-authorisation within 2 years.  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for wipes.   * **Post authorisation assessment (2021)**   For Meta SPC1: Long-term storage stability study shows that after 3 years at ambient temperature in HDPE spray (double wrapped in PE bags), the product remains stable.  For Meta SPC2: Long-term storage stability study shows that after 3 years at ambient temperature in aluminum aerosol (double wrapped in PE bags), the product remains stable.  For Meta SPC3: Long-term storage stability study shows that after 3 years at ambient temperature in white multi-layer (film layer = PET + vacuum metallized PET + metallocene-LLDPE) opaque bag, the product remains stable.  Consequently, the shelf life of products of the BACTY SP IPA family are kept at 2 years. Shelf life can only be increased in the frame of a minor change application. |

### Physical hazards and respective characteristics

#### Meta SPC 1 BACTY SP IPA pulvérisateur, Meta SPC 2 BACTY SP IPA aérosol, BACTY SP IPA 3 BACTY SP IPA tissu

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | EC A14  D.S.C/ (Q) SAR | BACTY SP IPA pulvérisateur  Batch 031215 | The explosive properties of the products of BACTY SP IPA family were determined by Differential Scanning Calorimetry (DSC) on the liquid formulation containing 70.0% w/w propan-2-ol.  According to Differential Scanning Calorimetry (DSC) graphs, no  exothermic reaction was observed in the temperature range from 25°C to 600°C. Therefore, the test item is unlikely to be explosive and the test on explosive properties according to UN Test series 1 to 3 described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria should not be performed.  Meta SPC 1:  As the products BACTY SP IPA pulvérisateur, BACTY SP IPA bidon and  BACTY SP IPA saches have the same composition, the explosive  properties were only determined for the product BACTY SP IPA  pulvérisateur.  Meta SPC 2:  In the product BACTY SP IPA aérosol, the liquid formulation is contained in a PP bag and is not in contact with the gaz. The aerosol is not concerned by the explosive classification and the liquid formulation has the same composition as BACTY SP IPA pulvérisateur which is not explosive.  Meta SPC 3:  As the product BACTY SP IPA tissu is a wipe impregnated with the liquid formulation BACTY SP IPA, and as the 100% polyester wipes and 55% cellulose/ 45% polyester wipes have no explosive properties, its explosive properties are expected to be the same as for the product BACTY SP IPA pulvérisateur. | Demangel B., 2016  Report N° 16-903061-001 |
| Flammable gases |  |  | Not required, BP is a liquid or a solid. |  |
| Flammable aerosols |  | BACTY SP IPA aérosol | Meta SPC 2:  As the product BACTY SP IPA aérosol is formulated as an aerosol containing 70% w/w of propan-2-ol, which is classified Flam. Liq. 2, H225, and as no ignition distance test and enclosed space ignition test was performed, it is classified Flam. Aerosol 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated). | Annex classification, labelling and packaging |
| Oxidising gases |  |  | Not required, BP is a liquid or a solid. |  |
| Gases under pressure |  |  | Not required, BP is a liquid or a solid. |  |
| Flammable liquids |  | BACTY SP IPA pulvérisateur, bidon et saches | Meta SPC 1 and 3:  Flam. Liq. 2, H225: highly flammable  Note for Meta SPC3:  Despite the fact that wipe is a solid, according to CA-Nov16-Doc.4.3-Final document, the products in form of wipe have to be classified according to the lotion impregnating the wipe. The product BACTY SP IPA tissu is therefore classified according to its lotion impregnating the wipe: the solution of 70% w/w propan-2-ol. | Annex classification, labelling and packaging |
| Flammable solids |  | BACTY SP IPA tissu | Meta SPC3:  Despite the fact that wipes is a solid, according to CA-Nov16-Doc.4.3-Final document, the products in form of wipe have to be classified according to the lotion impregnating the wipe. Refer to the  flammable liquid section above. | Annex classification, labelling and packaging |
| Self-reactive substances and mixtures | D.S.C. | BACTY SP IPA pulvérisateur  Batch 031215 | The self-reactivity of the products of BACTY SP IPA family were  determined by Differential Scanning Calorimetry (DSC) on the liquid formulation containing 70.0% w/w propan-2-ol.  According to Differential Scanning Calorimetry (DSC) graphs, no  exothermic reaction was observed in the temperature range from 25°C to 600°C. Therefore, the test item is unlikely to be self-reactive and the test on self-reactive properties according to UN Test series A to H described in Part II of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria should not be performed.  As the products BACTY SP IPA pulvérisateur, BACTY SP IPA bidon and BACTY SP IPA saches have the same composition, the self-reactive properties were only determined for the product BACTY SP IPA pulvérisateur.  In BACTY SP IPA aérosol, the liquid formulation is contained in a PP bag and is not in contact with the gaz. The aerosol is not concerned by the self-reactivity classification and the liquid formulation has the same composition as BACTY SP IPA pulvérisateur, which is not self-reactive.  As the product BACTY SP IPA tissu is a wipe impregnated with the liquid formulation BACTY SP IPA, and as the 100% polyester wipes and 55% cellulose/ 45% polyester wipes have no self-reactive properties, its self-reactivity is expected to be the same as for the product BACTY SP IPA pulvérisateur. |  |
| Pyrophoric liquids |  | BACTY SP IPA pulvérisateur, bidon, aérosol et saches | Meta SPC 1 and 2:  Not required as BACTY SP IPA pulvérisateur, BACTY SP IPA aérosol, BACTY SP IPA bidon and BACTY SP IPA saches contain more than 29% w/w water, and as experience in manufacture and handling shows that the products do not ignite spontaneously on coming into contact with air at normal temperature. Moreover, according to Assessment Report propan-2-ol PT02 (January 2015), the active substance propan-  2-ol is stable in air at room temperature and is not pyrophoric. |  |
| Pyrophoric solids |  | BACTY SP IPA tissu | Not required as BACTY SP IPA tissu contains more than 18.5% w/w water, and as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. Moreover, according to Assessment Report propan-2-ol PT02 (January 2015), the active substance propan-2-ol is stable in air at room temperature and is not pyrophoric. |  |
| Self-heating substances and mixtures |  |  | Not required as the family products do not contain self-heating substances. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The products of the BACTY SP IPA family do not emit flammable gases when in contact with water. Test is not required as the products of BACTY SP IPA family contain ≥ 18.5% w/w water and form stable mixtures. |  |
| Oxidising liquids |  | BACTY SP IPA pulvérisateur, bidon, aérosol et saches | Test is not required on the liquid formulation as the products BACTY SP IPA pulvérisateur, BACTY SP IPA aérosol, BACTY SP IPA bidon and BACTY SP IPA saches contain 70% w/w propan-2-ol, which is not expected to have oxidising properties due to its chemical structure (the substance contains an oxygen atom and this one is only chemically bonded to carbon and hydrogen atoms), and more than 29% w/w water, an inert component. Therefore, the products BACTY SP IPA pulvérisateur, BACTY SP IPA aérosol, BACTY SP IPA bidon and BACTY SP IPA saches are not oxidising. |  |
| Oxidising solids |  | BACTY SP IPA tissu | Test is not required on the impregnated wipes as the product BACTY SP IPA tissu contains ≥ 44% w/w of propan-2-ol which is not expected to have oxidising properties due to its chemical structure (the substance contains an oxygen atom and this one is only chemically bonded to carbon and hydrogen atoms), and more than 50% w/w water, polyester and cellulose which are inert components. Therefore, the product BACTY SP IPA tissu is not oxidising. |  |
| Organic peroxides |  |  | Not required as the products do not contain organic peroxides. |  |
| Corrosive to metals |  |  | Meta SPC 1, 2 and 3:  The products of BACTY SP IPA family are not corrosive to metals. Test is not required as products of BACTY SP IPA family do not contain any ingredients classified as corrosive to metals. |  |
| Auto-ignition temperatures of products (liquids and gases) |  | BACTY SP IPA pulvérisateur, bidon, aérosol et saches | Test is not required on the liquid formulation as the products BACTY SP IPA pulvérisateur, BACTY SP IPA aérosol, BACTY SP IPA bidon and BACTY SP IPA saches contain more than 29% w/w water, and as propan-2-ol (70.0% w/w) is not considered to be auto-flammable based on available data found in literature (its auto-ignition temperature is 425°C according to the safety data sheet of the supplier). Therefore, the products BACTY SP IPA pulvérisateur, BACTY SP IPA aérosol, BACTY SP IPA bidon and BACTY SP IPA saches are not expected to present a significant hazard for auto-flammability. |  |
| Relative self-ignition temperature for solids |  | BACTY SP IPA tissu | Test is not required on the impregnated wipes as the product BACTY SP IPA tissu contains more than 18.5 % w/w water, and as propan-2-ol (≥ 44.0% w/w) is not considered to be auto-flammable based on available data found in literature (its auto-ignition temperature is 425°C according to the safety data sheet of the supplier). Therefore, the product BACTY SP IPA tissu is not expected to present a significant hazard for auto-flammability. |  |
| Dust explosion hazard |  |  | Not required as BACTY SP IPA family products are ready-to-use liquid or impregnated wipes. |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The active substance propan-2-ol is classified Flam. Liq. 2, H225.  The products of the META SPC 1: BACTY SP IPA pulvérisateur, bidon and saches contain 70% w/w of propan-2-ol (pure). Consequently they are expected to be highly flammable and are classified Flam. Liq. 2 H225.  The product BACTY SP IPA aérosol (META SPC 2) is formulated as an aerosol containing 70% w/w of propan-2-ol (pure). As no ignition distance test and enclosed space ignition test was performed, it is classified Flam. Aerosol 1, H222 (Extremely flammable aerosol) and H229 (Pressurised container: May burst if heated).  The 2 products of the META SPC 3: BACTY SP IPA tissue are formulated as impregnated wipes. Despite the fact that wipes is a solid, according to CA-Nov16-Doc.4.3-Final document, the products in form of swipe have to be classified according to the lotion impregnating the wipe. Refer to the flammable liquid section above. |

### Methods for detection and identification

Report: Ricau H. 2016

Report no 16-903061-004

Test facilities: Défitraces (Brindas, France)

Principle of the method:

A quantity of about 0.36 g (to the nearest 0.01 mg) of the test item BACTY SP IPA pulvérisateur was weighed into a 50mL volumetric flask and the volume was made up with 1-propanol. The solution was manually homogenised then diluted 5 times with 1-propanol before analysis.

Isopropanol is analysed by Gas Chromatography with flame ionisation detector (GC-FID) by external standard calibration, at retention time of about 7.7 min for isopropanol peak.

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

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (1-propanol) * blank Formulation * Reference item of the active substance isopropanol std * Test item of the product: BACTY SP IPA pulvérisateur   No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  All chromatograms were available. | |
| Linearity | Linearity was studied by carrying out five concentrations between 50% and 150% of the reference item (n=2).  Calibration curve has been provided with a R2 higher than 0.999. | |
| Compound | Linearity % |
| Active substance | 50% to 100%  Y = 2,56.102 x – 7600 R2 = 0.9998  n=2 5 levels |
| Precision | Repeatability was evaluated by analyzing twice five test item solutions. | |
| Compound | Repeatability (RSD) |
| Ispropanol | RSD = 0.37% |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 70% | 70.78%; 71.14%; 70.98%; 71.40%; 71.35% | 71.1% | 0.37% | 5 | | |
| Accuracy | Accuracy was determined by analysis of 2 reconstituted samples. The accuracy results are expressed as the recovery rate.   |  |  |  |  | | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | n | | 1005.12 | 98.9%; 99.2% | 99.1% | 2 | | 998.92 | 100%; 98.6% | 99.3% | 2 | | |

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

Based on

* the intended uses of the products,
* the nature of the substance,
* its physico-chemical properties and
* its relations structure/function,

limited contamination of the environment is foreseen (indoor use only). No residues are expected in soil and water. Analytical method for propan-2-ol residues in air is available in the Assessment Report of propan-2-ol, Product-type 02 (private area and public health area disinfectants and other biocidal products), January 2015.

Please, refer to Letter of Access from STOCKMEIER Chemie GmbH & Co. KG.

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

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| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance propan-2-ol in the product.  Analytical methods were provided at EU level for the determination of isopropanol residue in air with respectively LOQ = 0.109 mg/m3.  Propan-2-ol is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin, consequently an analytical method for the determination of propan-2-ol 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

Products of the BACTY SP IPA family are ready-to-use disinfectants used for hard surfaces disinfection, disinfection of industrial process equipment’s, upper surfaces of work plan and soil in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C).

This product is to be used by professionals, indoor.

The family is separated in three META-SPCs.

* For META-SPC1, there are 3 products claimed, intended to be used for hard surface disinfection by spraying, mopping and wiping by professional users.
* For META-SPC2, there is one product claimed to be used for hard surface disinfection by spraying by professional users.
* For META-SPC3, there are 2 products claimed, intended to be used for hard surface disinfection by wiping impregnated wipes by professional users.

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

The products supported in the BACTY SP IPA family are used to disinfect surfaces. They irreversibly inactivate vegetative bacteria, yeasts and fungi.

The aim of using these products is to keep the surfaces free of microorganisms, in order to protect human health.

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

The products are able to produce a reduction in the number of viable bacterial cells (bactericidal activity), of yeast cells (yeasticidal activity), and of fungal cells (fungicidal activity) of relevant test organisms under defined conditions.

#### Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm’s proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes’ coagulation lead to a loss of cellular activity resulting in the cell’s death.

Propan-2-ol is used as disinfectant in 70% aqueous solution, and not pure. When the bacterial cell walls proteins come in contact with the 70% propan-2-ol aqueous solution, coagulation of proteins takes places, proteins are denaturated and propan-2-ol can penetrate in the cell which causes lysis or death of the cell. Protein coagulation also happens in case of pure propan-2-ol, but with very fast rate and because of this very fast protein coagulation process, denatured protein forms protective layer outside of the cell. When this happens, propan-2-ol cannot penetrate inside the cell and the microbe is not killed. Microorganisms become dormant in those conditions.

Another factor is contact time, 70% propan-2-ol aqueous solution takes longer time to evaporate from any surface hence get enough contact time and in this mean time it shows its efficacy but in case of pure propan-2-ol, evaporation will be very fast, contact time will be less and it will not be so effective against microbes.

#### Efficacy data

For all the META-SPCs, the laboratory studies were conducted with the product BACTY SP IPA (70 % w/w propan-2-ol) and with wipes impregnated with the product BACTY SP IPA, according to the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, (May 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.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | EN1276:2010 Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1). | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions  Concentration tested: 1%, 40% and 80% v/v  Criteria: at least a 5 log reduction | Bactericidal  concentration: 40% v/v | S6.7\_01  Carre A. and  Strohl P.,  2016  RI=1 |
| Yeasticide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w) | *Candida albicans* | EN1650+A1:2013  Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1). | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions  Concentration tested: 1%, 40% and 80% v/v  Criteria: at least a 4 log reduction | Yeasticidal concentration:  40% v/v | S6.7\_02  Carre A. and  Strohl P.,  2016  RI=1 |
| Fungicide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w) | *Aspergillus brasiliensis* | EN1650+A1:2013 (phase 2, step 1) | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions  Concentration tested: 1%, 40% and 80% v/v  Criteria: at least a 5 log reduction | No effective concentration tested | S6.7\_03  Carre A. and  Strohl P.,  2016  RI=1 |
| Bactericide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | EN 13697:2015  Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2, step 2) | Contact time: 5 minutes  Temperature: 18°C – 25°C  Soiling: clean condition (0.3g /L BSA and reconstituted skimmed milk for *P. aeruginosa*  Concentration tested: 100% v/v  Criteria: at least a 4 log reduction | **Bactericidal**  **concentration: 100% v/v** | S6.7\_04  Carre A. and  Strohl P.,  2016  RI=1 |
| Fungicide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w) | *Candida albicans*  *Aspergillus brasiliensis* | EN 13697:2015 (phase 2, step 2) | Contact time: 5 minutes  Temperature: 18°C – 25°C  Soiling:  -clean conditions for *C. albicans*,  -distilled water for *A. brasiliensis*  Concentration tested: 100% (v/v)  Criteria: at least a 3 log reduction | **Fungicidal concentration:**  **100% v/v** | S6.7\_05  Carre A. and  Strohl P.,  2016  RI=1 |
| Bactericide  Yeasticide | Industrial clean rooms (indoors) | Wipe standard impregnated with BACTY SP IPA  (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Staphylococcus aureus*  *Enterococcus hirae*  *Candida albicans* | EN16615 :2015  chemical Quantitative test method for the evaluation of bactericidal action employing wipes in the medical area (4-field test) (phase 2, step 2) | Contact time 5 minutes  Temperature:  18°c – 25°C  soiling  distilled water for *S. aureus* and *E. hirae*  clean conditions (0.3 g/L BSA) for *P. aeruginosa* and *C. albicans* | R (logarithmic reduction of the viable cells number , efficacy threshold R>5 for bacteria and R>4 for yeast and average accumulation on fields 2 to 4 lower than 50 cfu/25 cm²  *P. aeruginosa* : 6.19  *S. aureus* : > 5.93  E. hirae: 5.86  C. albicans: 5.63  average accumulation (2-4)  *P. aeruginosa*: 16  *S. aureus :* <5  *E. hirae*: 39  *C. albicans*: 14  **bactericidal and yeasticidal concentration:**  **100% v/v** | S6.7\_06  Carre A; and Strohl P.,  2017  RI=1 |
| Bactericide  Yeasticide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w)  impregnated on BACTY SP IPA tissue 100 % polyester wipe (BACTY SP IPA REF. KW SP 8023-IPA) | *Pseudomonas aeruginosa*  *Staphylococcus aureus*  *Enterococcus hirae*  *Candida albicans* | EN16615 :2015  chemical Quantitative test method for the evaluation of bactericidal action employing wipes in the medical area (4-field test) (phase 2, step 2) | Contact time 3 minutes  Temperature:  18°c – 25°C  soiling  clean conditions (0.3g/L BSA) | R (logarithmic reduction of the viable cells number , efficacy threshold R>5 for bacteria and R>4 for yeast and average accumulation on fields 2 to 4 lower than 50 cfu/25 cm²  *P. aeruginosa* : 5.54  *S. aureus* : 4.58  *E. hirae*: >5.86  C. albicans: > 4.32  average accumulation (2-4)  *P. aeruginosa*: <5  *S. aureus :* 12  *E. hirae*: <5  *C. albicans*: <5  **Bactericidal concentration:**  **100% v/v.**  **efficient against *P. aeruginosa* and *E. hirae***  ***Yeasticidal concentration***  **100 % v/v** | S6.7\_07  Carre A; and Strohl P.,  2016  RI=1 |
| Bactericide | Industrial clean rooms (indoors) | BACTY SP IPA  (propan-2-ol 70 % w/w)  impregnated on BACTY SP IPA tissue 100% polyester wipe (BACTY SP IPA REF. KW SP 8023-IPA) | *Staphylococcus aureus* | EN16615 :2015  (phase 2, step 2)  chemical Quantitative test method for the evaluation of bactericidal action employing wipes in the medical area (4-field test) | Contact time 5 minutes  Temperature:  18°c – 25°C  soiling  clean conditions (0.3g/L BSA) | R (logarithmic reduction of the viable cells number , efficacy threshold R>5 average accumulation on fields 2 to 4 lower than 50 cfu/25 cm²  *S. aureus* : >6.02  average accumulation (2-4)  *P. aeruginosa*: 18 cells/25 cm² (<50 viable cells/25 cm²)  Activity *against S. aureus* with a contact time of 5 minutes at 100 % v/v | S6.7\_08  Carre A; and Strohl P.,  2017  RI=1 |

The product BACTY SP IPA has been tested in representative conditions of industrial uses, with clean conditions or considering no soiling, since the product is to be used in clean rooms only:

* Bactericidal activity is demonstrated in phase 2 step 1 test according to the EN 1276 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in use concentration of 40 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 2 test according to the EN 13697 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA and reconstitutes skimmed milk 8.5 g/L for *P. aeruginosa*). In these conditions, bactericidal activity is shown at the in-use concentration of 100 % v/v.
* Bacterial activity is demonstrated in phase 2 steps 2 test according to the EN 16615 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in use concentration of 100 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test according to the EN 1650 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions the yeasticidal activity is shown at the in use concentration of 40 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 2 tests according to the EN 13697 standard, at the temperature of 20 °C, for a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In this condition, Yeasticidal activity is shown at the in-use concentration of 100 % v/v for non-porous surface.
* Yeasticidal activity is demonstrated in Phase 2, step 2 tests according to the EN 16615 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions the yeasticidal activity is shown at the in-use concentration of 100 % v/v.
* Fungicidal activity is only demonstrated in phase 2, step 2 tests according to the EN 13697 standard, at the temperature of 20 °C, with a contact time of 5 minutes, sterile water as interfering substance. In these conditions, fungicidal activity is shown at the in-use concentration of 100 % v/v.

The product BACTY SP IPA passed all the standards with 5 minutes of contact time and clean conditions for bacterial and yeast strains.

Concerning the tests against *A. brasiliensis*, representative of fungi, the product failed the EN 1650 suspension test with clean conditions. However, it passed the EN 13697 surface test with sterile water as interfering substances. This deviation is possible for products used in clean rooms, as stated in the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016), part 3.2.3 "As an exception to the rule, products to be used in cleanrooms do not require additional soiling in the test".

Nevertheless, regarding the disinfection by wiping, no efficacy test against *A. brasiliensis*, according to the methodology of the EN 16615, nor surface test with liquid extracted from the wipes (not the original liquid) has been submitted. Then for fungi, the hard surface disinfection with mechanical action (wiping) is not validated.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product family (BACTY SP IPA) 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[[4]](#footnote-4).   * The liquid products of the BACTY SP IPA family (META SPC1) are efficient against Bacteria, yeasts and fungi for hard surface disinfection without mechanical action; and only against bacteria and yeasts with mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by spraying, mopping (at 100 % v/v) and wiping (1 wipe/1-2 m²) by professional users. * The in-can product of the BACTY SP IPA family (Meta SPC2) is efficient against bacteria, yeasts and fungi for hard surface disinfection without mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by spraying (at 100 % v/v) by professional users. * The impregnated wipe products of the BACTY SP IPA family (META SPC 3) are efficient against bacteria and yeasts for hard surface disinfection with mechanical action, with a contact time of 5 minutes, at the temperature of 20 °C, in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) by wiping (1 wipe/1-2 m²) by professional users. |

#### Occurrence of resistance and resistance management

*See propan-2-ol Assessment Report, PT02, January 2015.*

Due to the unspecific mode of action of propan-2-ol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known, in that case propan-2-ol is ineffective at any concentration. No specific data has been found in the literature regarding occurrence of resistance to propan-2-ol when used in industrial clean rooms. Strategies such as alternate with other disinfectant active substances and avoidance of over frequent use are efficient standard practices and should be applied also to biocide uses of propan-2-ol, in order to combat any potential for the onset of resistance.

#### Known limitations

None

#### Evaluation of the label claims

French competent authorities (FR CA) assessed the products of the BACTY SP IPA family (ready to use disinfectant) which have shown sufficient efficacy for the following claimed uses:

* By spraying (at 100 % v/v) regarding the disinfection (bacteria, yeasts and fungi)
  + of industrial process equipment’s work plan (upper side),
  + of soil in clean room (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) and
  + on clean surfaces,

at the temperature of 20 °C, with a contact time of 5 minutes.

This use is considered for META SPC 1 and META SPC 2 using either trigger spray or aerosol.

* By mopping uniformly the surface (at 100 % v/v) regarding the disinfection (bacteria, yeasts and fungi) of
  + of industrial process equipment’s work plan (upper side),
  + of soil in clean room (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) and
  + on clean surface,

at the temperature of 20 °C, with a contact time of 5 minutes.

This use is considered only for META SPC 1.

* By wiping uniformly the surface (with a wipe impregnated just before use in the case of the product BACTY SP IPA saches), one wipe of 23\*23 cm is sufficient for 1-2 m²) for the disinfection (bacteria and yeasts)
  + of industrial process equipment’s work plan (upper side),
  + of soil in clean room (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) and
  + on clean surface,

at the temperature of 20 °C, with a contact time of 5 minutes.

This use is considered either for META SPC 1 using wipes to be impregnated before use or for META SPC 3 using impregnated wipes.

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

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

Products claimed in the frame of the BACTY SP IPA family are not intended to be used with another biocidal product.

### Risk assessment for human health

The products of the BACTY SP IPA family are ready-to-use disinfectants containing 70% w/w propan-2-ol for Meta SPC 1 and 2 or 44.4-49.9% w/w of propan-2-ol for Meta SPC 3.

They are intended to be applied for the disinfection of industrial process equipment, work plan (upper surfaces) and soil, in clean rooms. These treatments are done by professionals by spraying, mopping or wiping.

For the META SPC 1 and 2, products are applied indoors at the dose of 50 mL product/m2. For META SPC3, product is applied as wipes, 1 wipe for 1 to 2 m².

#### Assessment of effects on Human Health

Neither acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study, nor skin sensitisation study have been performed on any product of the product family BACTY SP IPA.

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

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion and irritation |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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 skin irritation. |

***Eye irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Eye irritation |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, a classification Eye Irrit 2 – H319 is required for products in Meta SPC 1, 2 and 3. |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | - |
| Justification for the value/conclusion | In meta SPC 1, 2 and 3, the content of a.s classified H319 is higher than 10% (general concentration limit), leading to a classification of the products as irritant to eyes. |
| Classification of the product according to CLP | Eye Irrit 2 – H319 |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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 skin sensitization. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | No study has been performed on any products of the BACTY SP IPA family.  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***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | As defined in the EFSA guidance on dermal absorption (2012), if a product or in use dilution contains more than 5% of active substance, a default dermal absorption value of 25% should be used.  The **25% dermal absorption value** is used for the Human risk assessment of propan-2-ol in the products of the BACTY SP IPA family. |

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

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, BACTY SP IPA family does not contain any substance of concern.

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

Not applicable.

***Other***

Not applicable.

#### 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** | **Via food** |
| Inhalation | n.a | yes | n.a | n.a | yes | no | no |
| Dermal | n.a | yes | n.a | n.a | no | no | no |
| Oral | n.a | no | n.a | n.a | no | no | no |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| **1** | **Spray application – Meta SPC 1 and 2** | | |
| 1a. | Spraying application  (trigger spray or aerosol) | **Primary exposure – Dermal and inhalation (aerosols) exposure**  Products of Meta SPC 1 and Meta SPC 2 are sprayed on small surfaces using a trigger spray or an aerosol leading to dermal and inhalation exposure during application. | 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 wiped with a tissue leading to dermal exposure. | Professionals |
| 1c. | Exposure to volatilized residues during application (spraying + wiping) | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product (spraying and wiping). | Professionals |
| **2** | **Application by mopping – META SPC 1** | | |
| 2a. | Mopping application | **Primary exposure – Dermal exposure**  The product is loaded into a bucket and applied by mopping on the floor. | Professionals |
| 2b. | Exposure to volatilized residues during mopping | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product (mopping) | Professionals |
| **3** | **Application with wipes – META SPC 1 and META SPC 3** | | |
| 3a. | Mixing and loading | **Primary exposure – Dermal exposure**  In Meta SPC 1, one product is presented in a sache containing wipes and the biocidal product in a separated sealed pouch. Before use, the sealed pouch is open in order to impregnate the wipes. | Professionals |
| 3b. | Wiping (using pre-impregnated wipes) | **Primary exposure – Dermal exposure**  The product is applied on small surfaces with pre-impregnated wipes (Meta SPC 3). | Professionals |
| 3c. | Exposure to volatilized residues during application (wiping) | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product (wiping) | Professionals |
| **4** | **Secondary exposure** | | |
| **4.** | Exposure to volatilized residues after application | **Secondary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs if persons enter rooms after the use of the product. | 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 small surfaces at an application rate of 50 mL of product/m2. After spraying, products can be wiped on the 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 during the application of the product.

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

| **Description of Scenario [1a]** | | | |
| --- | --- | --- | --- |
| The products are applied by spraying to a small surface to disinfect it using a trigger spray (Meta SPC 1) or an aerosol (Meta SPC 2). Only indoor use is considered.  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 te model are as follows:   * 36.1 mg/min (hands/forearms); * 9.7 mg/min (feet/legs/face); * 10.5 mg/m3 (inhalation).   For the spray application using an aerosol, the “Consumer Spraying and Dusting model 2 (aerosol spray can)” 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:   * 64.7 mg/min (hands/forearms); * 45.2 mg/min (feet/legs/face); * 35.9 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** | |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data | |
| Task duration (min) | 30 | Recommendation 6 of HEAd Hoc | |
| Gloves penetration factor | 100% | HEEG Opinion 9 | |
| AEL long term (mg/kg bw/d) | 17.9 | - | |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 | |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 | |
| Dermal absorption | 25% | EFSA default value (2012) | |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 | |
| Coverall penetration factor | 10% | HEEG Opinion 9 | |
| Respiratory penetration factor (APF) | 10 | HEEG Opinion 9 | |

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

**Calculations for Scenario [1a]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake (aerosols)**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Trigger spray (Meta SPC 1)** | | | | | |
| Scenario [1a] | Tier 1/no PPE | 7.66 x 10-2 | 4.01 | - | 4.08 |
| Scenario [1a] | Tier 2/ PPE (gloves) | 7.66 x 10-2 | 1.16 | - | 1.24 |
| Scenario [1a] | Tier 2/ PPE (gloves + coated coverall) | 7.66 x 10-2 | 4.01 x 10-1 | - | 4.77 x 10-1 |
| Scenario [1a] | Tier 2/ PPE (gloves + coated coveral + RPE) | 7.66 x 10-3 | 4.01 x 10-1 | - | 4.08 x 10-1 |
| **Aerosol (Meta SPC 2)** | | | | | |
| Scenario [1a] | Tier 1/no PPE | 2.62 x 10-1 | 9.62 | - | 9.88 |
| Scenario [1a] | Tier 2/ PPE (gloves) | 2.62 x 10-1 | 4.52 | - | 4.78 |
| Scenario [1a] | Tier 2/ PPE (gloves + coated coverall) | 2.62 x 10-1 | 9.62 x 10-1 | - | 1.22 |
| Scenario [1a] | Tier 2/ PPE (gloves + coated coveral + RPE) | 2.62 x 10-2 | 9.62 x 10-1 | - | 9.88 x 10-1 |

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

| **Description of Scenario [1b]** | | | |
| --- | --- | --- | --- |
| After spray application, the product can be wiped in order of keeping the surface sterile.  To assess dermal exposure, the model of application by wiping from the BEAT data base has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure value from the model is 214 µL/min (hands) with 10 wiping/events and 1 min/events. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 10 | UA discussions |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

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

**Calculations for Scenario [1b]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1b] | Tier 1/no PPE | - | 4.9 | - | 4.9 |
| Scenario [1b] | Tier 2/ PPE (gloves) | - | 4.9 x 10-1 | - | 4.9 x 10-1 |

*Scenario [1c] Exposure to volatilized residues during application (spraying + wiping)*

| **Description of Scenario [1c]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, 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 or an aerosol is 50 mL/m2.  Considering a density of 0.858 and a treated surface of **5m2**, the amount of product deposited on the treated surface is of **214.5g** (50 mL/m2 x 0.858 x 5 m2 = 214.5g).  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 the other parameters, ConsExpo default values have been kept. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 40 | Spraying + wiping |
| Release area (m2) | 5 | UA discussions |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) | 5780 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 8/h |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |

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 uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1c] | Tier 1/no PPE | 15 | - | - | 15 |

*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) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Application using a trigger spray** | | | | |
| **Scenarios [1a,1b,1c]**  **Tier 1** | 7.66 x 10-2 | 8.91 | 15 | 23.98 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves)** | 7.66 x 10-2 | 1.65 | 15 | 16.73 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + coated coverall)** | 7.66 x 10-2 | 8.91 x 10-1 | 15 | 15.97 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + RPE)** | 7.66 x 10-3 | 1.65 | 1.5 | 3.16 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + coated coverall + RPE)** | 7.66 x 10-3 | 8.91 x 10-1 | 1.5 | 2.40 |
| **Application using an aerosol** | | | | |
| **Scenarios [1a,1b,1c]**  **Tier 1** | 2.62 x 10-1 | 14.5 | 15 | 29.78 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves)** | 2.62 x 10-1 | 5.01 | 15 | 20.27 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + coated coverall)** | 2.62 x 10-1 | 1.45 | 15 | 16.71 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + RPE)** | 2.62 x 10-2 | 5.01 | 1.5 | 6.54 |
| **Scenarios [1a,1b,1c]**  **Tier 2 (gloves + coated coverall + RPE)** | 2.62 x 10-2 | 1.45 | 1.5 | 2.98 |

\* Please include the Tier where relevant

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

Products of Meta SPC 1 are available in bottles of 5, 10 and 20L to be applied at an application rate of 50 mL product/m2. The product is loaded into a bucket and mopped on the floor using a cleaning fabric.

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 2 different scenarios in order to clarify the assessment:

* Scenario [2a] 🡪 professional exposure during mopping (dermal exposure including the mixing and loading phase);
* Scenario [2b] 🡪 professional exposure to volatilized residues generated due to the high volatility of the a.s during the application of the product.

*Scenario [2a] – Primary exposure during mopping*

| **Description of Scenario [2a]** | | | |
| --- | --- | --- | --- |
| The product is loaded into a bucket in order to be applied on the floor by mopping using a cleaning fabric.  To assess dermal exposure during mopping, the “Surface disinfection model 1” has been used according to the Recommendation 6 of HEAd Hoc. The model includes the mixing and loading phase.  In the Recommendation 6 of HEAd Hoc, a time duration of 110 min is presented for mopping in relation with a time duration of 220 min for wiping for large surfaces.  Taking into account this recommendation, a factor exists between both duration that has been agreed at EU level.  For small surfaces, a time duration of 10 minutes has been retained for wiping (10 events per day, 1 min per event) leading to a time duration of 5 min for mopping of small rooms (10 m2).  The indicative exposure values from the model are as follows:   * 87.6 mg/min (body); * 1030 mg/min (hands); * 10.3 mg/min (hands with gloves). | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 5 | Recommendation 6 HEAd Hoc adapted with the time duration retained for wiping |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

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

**Calculations for Scenario [2a]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2a] | Tier 1/no PPE | - | 16.30 | - | 16.30 |
| Scenario [2a] | Tier 2/ PPE (gloves) | - | 1.29 | - | 1.29 |

*Scenario [2b]* Exposure to volatilized residues during mopping

| **Description of Scenario [2b]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during mopping has been assessed using ConsExpo web and the model for disinfectant (wiping).  The application rate claimed by the applicant for application with an application rate of 50 mL/m2.  Considering a density of 0.858 and a treated surface of **10m2**, the amount of product deposited on the treated surface is of **429g** (50 mL/m2 x 0.858 x 10 m2 = 429.0g).  An exposure duration of **5 min** is considered for mopping.  For the other parameters, ConsExpo default values have been kept. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 5 | mopping |
| Release area (m2) | 10 | Surface of a room with a volume of 25m3 (default value ConsExpo) with a height of 2.5m |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) | 5780 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 8/h |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |

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 uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2b] | Tier 1/no PPE | 13 | - | - | 13 |

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

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Scenarios [2a,2b]**  **Tier 1** | - | 16.30 | 13.0 | 29.30 |
| **Scenarios [2a,2b]**  **Tier 2 (gloves)** | - | 1.29 | 13.0 | 14.29 |

**Scenario [3] – Application by wiping (using pre-impregnated wipes or wipes to be impregnated)**

According to Meta SPC 1 and 3, the product can be applied directly by wiping using pre-impregnated wipes (Meta SPC 3) or wipes to be impregnated (Meta SPC 1).

In Meta SPC 1, the product is presented in a sache containing 20 wipes and the biocidal product in a separated sealed pouch. Before use, the pouch containing the biocidal product must be opened and poured on the wipes in order to impregnate them.

In Meta SPC 3, wipes are already impregnated and can be directly used to disinfect small surfaces.

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 3 different scenarios in order to clarify the assessment:

* Scenario [3a] 🡪 professional exposure during mixing and loading to impregnate wipes with b.p;
* Scenario [3b] 🡪 professional exposure during the use of impregnated wipes;
* Scenario [3c] 🡪 professional exposure to volatilized residues generated due to the high volatility of the a.s during the application of the product.

*Scenario [3a] – Primary exposure during mixing and loading for impregnation of wipes*

| **Description of Scenario [3a]** | | | |
| --- | --- | --- | --- |
| The product is available in a sache containing 20 wipes and the biocidal product in a separated pouch of 500 mL.  In order to impregnate the wipes, the pouch is open and loaded on the wipes.  To asses dermal exposure during the loading of the biocidal product, the ”Mixing and Loading model 4” from the TNsG 2008 has been used.  The indicative exposure value for the loading of 1L of product is 0.01 mL/event for hands.  It has to be noted that this exposure scenario is a worst case approach considering that, with this particular packaging, no exposure is expected according to the applicant. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Number of event | 1 |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

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

**Calculations for Scenario [3a]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3a] | Tier 1/no PPE | - | 2.3 x 10-2 | - | 2.3 x 10-2 |
| Scenario [3a] | Tier 2/ PPE (gloves) | - | 2.3 x 10-3 | - | 2.3 x 10-3 |

*Scenario [3b] – Primary exposure during wiping with a pre-impregnated wipe*

| **Description of Scenario [3b]** | | | |
| --- | --- | --- | --- |
| The product can be directly applied using pre-impregnated wipes.  According to the efficacy data presented in the dossier, it is assumed that a wipe contains 25 mL of b.p (correlated with the pouch of 500 mL of b.p loaded on 20 wipes (see scenario M&L above)) and that 1 wipe can be used to disinfect 1 m2.  For this mode of application, an application rate of 25mL b.p/m2 is therefore assumed leading to an amount of product deposited on surfaces of 107.25g (25 mL/m2 x 0.858 x 5m2) by taken into account a density of 0.858 and a tretaed surface of 5m2.  To assess dermal exposure during the use of treated wipes, the data of ConsExpo web and the factsheet of cleaning and washing/wet tissues application have been used. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Exposure duration (min) | 10 | UA discussions |
| Ventilation rate | 8/h | UA discussions |
| Release area (m2) | 5 | UA discussions |
| Exposed area (cm2) | 205 | HEAD Hoc recommendation 14  (palm of one hand) |
| Product amount transfered to the skin (g) | 0.047 | Default value from the factsheet |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

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

**Calculations for Scenario [3b]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3b] | Tier 1/no PPE | - | 1.4 x 10-1 | - | 1.4 x 10-1 |
| Scenario [3b] | Tier 2/ PPE (gloves) | - | 1.4 x 10-2 | - | 1.4 x 10-2 |

*Scenario [3c]*

| **Description of Scenario [3c]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during wiping has been assessed using ConsExpo web and the model for disinfectant (wiping).  The application rate assumed for application with a pre-impregnated wipe is 25 mL/m2.  Considering a density of 0.785 and a treated surface of **5m2**, the amount of product deposited on the treated surface is of **107.25g** (25 mL/m2 x 0.858 x 5 m2 = 107.25g).  An exposure duration of **10 min** is considered for wiping.  For the other parameters, ConsExpo default values have been kept. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 10 | UA discussions |
| Release area (m2) | 5 | UA discussions |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) | 5780 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 8/h |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |

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

**Calculations for Scenario [3c]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3c] | Tier 1/no PPE | 5.4 | - | - | 5.4 |
| Scenario [3c] | Tier 2/RPE | 0.54 | - | - | 0.54 |

*Combined exposure - Scenario [3]: Total exposure during application by wiping [3a + 3b + 3c]*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation (generated aerosols) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Scenarios [3a,3b,3c]**  **Tier 1** | - | 1.4 x 10-1 | 5.4 | 5.56 |
| **Scenarios [3a,3b,3c]**  **Tier 2 (gloves)** | - | 1.4 x 10-2 | 5.4 | 5.41 |
| **Scenarios [3a,3b,3c]**  **Tier 2 (gloves+RPE)** | - | 1.4 x 10-2 | 0.54 | 5.54 x 10-1 |

*Combined scenarios*

| **Description of combined scenarios** | | | |
| --- | --- | --- | --- |
| Professionals may use the different formulations of product to clean the same room.  Exposure may occur during the spraying of surfaces, followed by a wiping phase and a mopping phase. Therefore, a combined scenario has been envisaged.  Dermal exposure and inhalation exposure to aerosols generated during the application have already been estimated in the different scenarios presented above.  The exposure to vapor during **spraying, wiping and mopping** has been assessed using ConsExpo web and the model for disinfectant (wiping).  The application rate of 50 mL/m2 has been taken into account as a worst-case situation.  Considering a density of 0.785 and a treated surface of **15m2** (5m2 for surfaces and 10m2 for soil), the amount of product deposited on the treated surface is of **643.5g** (50 mL/m2 x 0.858 x 15 m2 = 643.5g).  An exposure duration of **45 min** is considered (30 min for spraying + 10 min for wiping +5 min for mopping).  For the other parameters, ConsExpo default values have been kept. | | | |
|  | **Parameters1** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 45 | Spraying + wiping + mopping |
| Release area (m2) | 15 | Surface + soil |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) | 5780 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 8/h |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg bw/d) | 17.9 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 |
| Dermal absorption | 25% | EFSA default value (2012) |
| **Tier 2** | Gloves penetration factor | 10% | HEEG Opinion 9 |
| Coverall penetration factor | 10% | HEEG Opinion 9 |
| Respiratory penetration factor APF | 10 | HEEG Opinion 9 |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

**Calculations for combined scenarios**

| **Summary table: estimated exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (aerosols) and dermal uptakes**  **(mg/kg bw/d)** | **Estimated inhalation uptake (evaporation)**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Application with a trigger spray + wiping + mopping** | | | | |
| **[1,2,3]** | Tier 1/no PPE | 25.3 | 46.00 | 71.28 |
| **[1,2,3]** | Tier 2/PPE (Gloves) | 3.02 | 46.00 | 49.02 |
| **[1,2,3]** | Tier 2/PPE (Gloves + coated coverall) | 2.26 | 46.00 | 48.26 |
| **[1,2,3]** | Tier 2/PPE (Gloves + RPE) | 1.87 | 4.60 | 6.47 |
| **[1,2,3]** | Tier 2/PPE (Gloves + coated coverall + RPE) | 2.19 | 4.60 | 6.79 |
| **Application with an aerosol + wiping + mopping** | | | | |
| **[1,2,3]** | Tier 1/no PPE | 31.08 | 46.00 | 77.08 |
| **[1,2,3]** | Tier 2/PPE (Gloves) | 6.57 | 46.00 | 52.57 |
| **[1,2,3]** | Tier 2/PPE (Gloves + coated coverall) | 3.01 | 46.00 | 49.01 |
| **[1,2,3]** | Tier 2/PPE (Gloves + coated coverall + RPE) | 5.24 | 4.60 | 9.84 |
| **[1,2,3]** | Tier 2/PPE (Gloves + coated coverall + RPE) | 2.77 | 4.60 | 7.37 |
| **Application by wiping (including M&L to impregnate the wipes) + mopping** | | | | |
| **[2,3]** | Tier 1/no PPE | 16.46 | 46.00 | 62.46 |
| **[2,3]** | Tier 2/PPE (Gloves) | 1.31 | 46.00 | 47.31 |
| **[2,3]** | Tier 2/PPE (Gloves + RPE) | 1.31 | 4.60 | 5.91 |

***Non-professional exposure***

Not applicable.

***Secondary exposure***

*Scenario [4] exposure to vapor after application*

| **Description of Scenario [4]** |
| --- |
| The BACTY SP IPA biocidal products family is intended to be used for the disinfection of industrial process equipment’s, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry).  Inhalation of volatilized residues after indoor application is considered possible and, regarding the intended uses, this exposure only takes place to other professional workers that have not used the product.  It can be considered that this exposure is equal or lower than the direct exposure of the professional applying the product (combined exposure).  Furthermore, the dermal exposure is considered negligible because of the high volatility of the a.s containing in the product no residue will remains on surfaces.  Therefore, the same parameters used in combined exposure scenarios have been applied leading to similar exposure to volatilized residues for an adult entering a room with freshly treated surfaces;  For details please refer to the combined exposure scenarios. |

**Calculations for Scenario [4]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [4] | Tier 1/no PPE | 46 | - | - | 46 |

***Monitoring data***

None

***Dietary exposure***

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

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

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Plant protection product | 2-propanol: Not approved under PPP regulation (reg 2004/129/EC) | Default MRL of 0.01 mg/kg according to article 18(1)(b) of Reg 396/2005 |
| 2. | Veterinary use | Isopropanol: all food producing species | No MRL required (Reg 37/2010) |

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

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

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

Not relevant

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

Not relevant

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

Not relevant

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

Not applicable.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **1.** | Professionals  (trigger spray application) | Tier 1/no PPE | 23.98 |
| Tier 2/ PPE (Gloves) | 16.73 |
| Tier 2/ PPE (Gloves + coated coverall) | 15.97 |
| Tier 2/ PPE (Gloves + RPE) | 3.16 |
| Tier 2/ PPE (Gloves + coated coverall + RPE) | 2.40 |
| **1.** | Professionals  (aerosol application) | Tier 1/no PPE | 29.78 |
| Tier 2/ PPE (Gloves) | 20.27 |
| Tier 2 (Gloves + coated coverall) | 16.71 |
| Tier 2/ PPE (Gloves + RPE) | 6.54 |
| Tier 2/ PPE (Gloves + coated coverall + RPE) | 2.98 |
| **2.** | Professionals (mopping) | Tier 1/no PPE | 29.30 |
| Tier 2/ PPE (Gloves) | 14.29 |
| Tier 2 (Gloves + coated coverall) | 13.20 |
| Tier 2/ PPE (Gloves + RPE) | 2.59 |
| Tier 2/ PPE (Gloves + coated coverall + RPE) | 1.50 |
| **3.** | Professionals (wiping) | Tier 1/no PPE | 5.56 |
| Tier 2/ PPE (Gloves) | 5.42 |
| Tier 2 (Gloves + coated coverall) | 5.42 |
| Tier 2/ PPE (Gloves + RPE) | 0.56 |
| Tier 2/ PPE (Gloves + coated coverall + RPE) | 0.56 |
| **4.** | Bystanders | Tier 1/no PPE | 46 |

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Application with a trigger spray + wiping + mopping** | | | |
| **[1,2,3]** | Professionals | Tier 1/no PPE | 71.28 |
| Tier 2/PPE (Gloves) | 49.02 |
| Tier 2/PPE (Gloves + coated coverall) | 48.26 |
| Tier 2/PPE (Gloves + RPE) | 6.47 |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 6.79 |
| **Application with an aerosol + wiping + mopping** | | | |
| **[1,2,3]** | Professionals | Tier 1/no PPE | 77.08 |
| Tier 2/PPE (Gloves) | 52.57 |
| Tier 2/PPE (Gloves + coated coverall) | 49.01 |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 9.84 |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 7.37 |
| **Application by wiping (including M&L to impregnate the wipes) + mopping** | | | |
| **[2,3]** | Professionals | Tier 1/no PPE | 62.46 |
| Tier 2/PPE (Gloves) | 47.31 |
| Tier 2/PPE (Gloves + coated coverall) | 47.31 |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 5.91 |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 5.91 |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELshort, medium and long-term  (General population) | Inhalation, Human volunteer study | 200 ppm or 68.2 mg/kg bw/d | 6.4 | 100% | 10.7 mg/kg bw/d |
| AELshort,medium and long-term  (Professional workers) | 3.8 | 17.9 mg/kg bw/d |
| Inhalation OEL | 200 ppm or 0.49 mg/L air, 8h exposure\* | n.a | 200 ppm or 0.49 mg/L air, 8h exposure\* |
| ARfD | Not necessary | | | | |
| ADI |

1 Please explain background and reason for assessment factor.

\* Based on LOAEC of 400 ppm from study by Sethre *et al*. 2000a. For conversion to inhaled dose, default values for adult humans (average weight of 60 kg) and a respiratory volume of 1.044 m3/h (8.35 m3/8h) were employed.

**Maximum residue limits or equivalent**

Not relevant

***Risk for industrial users***

Not applicable

***Risk for professional users***

**Systemic effects**

| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| **Scenario [1]**  **Trigger spray** | Tier 1/no PPE | 17.9 | 23.98 | 133.99% | no |
| Tier 2/PPE (gloves) | 17.9 | 16.73 | 93.47% | yes |
| Tier 2/PPE (gloves + coated coverall) | 17.9 | 15.97 | 89.20% | yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 3.16 | 17.67% | yes |
| Tier 2/PPE (gloves + coated coverall + RPE) | 17.9 | 2.40 | 13.40% | yes |
| **Scenario [1]**  **Aerosol** | Tier 1/no PPE | 17.9 | 29.78 | 166.36% | no |
| Tier 2/PPE (gloves) | 17.9 | 20.27 | 113.26% | no |
| Tier 2/PPE (gloves + coated coverall) | 17.9 | 16.71 | 93.37% | yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 6.54 | 36.52% | yes |
| Tier 2/PPE (gloves + coated coverall + RPE) | 17.9 | 2.98 | 16.64% | yes |
| **Scenario [2]**  **Mopping** | Tier 1/no PPE | 17.9 | 29.30 | 163.68% | no |
| Tier 2/PPE (gloves) | 17.9 | 14.29 | 79.85% | yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 2.59 | 14.48% | yes |
| **Scenario [3]**  **Pre impregnated wipes or wipes to be impregnated before use** | Tier 1/no PPE | 17.9 | 5.56 | 31.08% | yes |
| Tier 2/PPE (gloves) | 17.9 | 5.42 | 30.26% | yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 0.56 | 3.11% | yes |

**Combined scenarios**

| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| **Application with a trigger spray + wiping + mopping** | | | | | |
| **[1,2,3]** | Tier 1/no PPE | 17.9 | 71.28 | **398.22%** | no |
| Tier 2/PPE (Gloves) | 17.9 | 49.02 | **273.88%** | no |
| Tier 2/PPE (Gloves + coated coverall) | 17.9 | 48.26 | **269.61%** | no |
| Tier 2/PPE (Gloves + RPE) | 17.9 | 7.55 | 42.21% | yes |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 17.9 | 6.79 | 37.94% | yes |
| **Application with an aerosol + wiping + mopping** | | | | | |
| **[1,2,3]** | Tier 1/no PPE | 17.9 | 77.08 | **430.59%** | no |
| Tier 2/PPE (Gloves) | 17.9 | 52.57 | **293.66%** | no |
| Tier 2/PPE (Gloves + coated coverall) | 17.9 | 49.01 | **273.78%** | no |
| Tier 2/PPE (Gloves + RPE) | 17.9 | 10.93 | **61.06%** | yes |
| Tier 2/PPE (Gloves + coated coverall + RPE) | 17.9 | 7.37 | **41.17%** | yes |
| **Application by wiping (including M&L to impregnate the wipes) + mopping** | | | | | |
| **[2,3]** | Tier 1/no PPE | 17.9 | 62.46 | **348.95%** | no |
| Tier 2/PPE (Gloves) | 17.9 | 47.31 | **264.30%** | no |
| Tier 2/PPE (Gloves + RPE) | 17.9 | 5.91 | **33.01%** | yes |

A specifc use in room with a high ventilation rate is claimed by the applicant (*i.e* clean rooms with a ventilation rate between 15 and 50 vol/h).

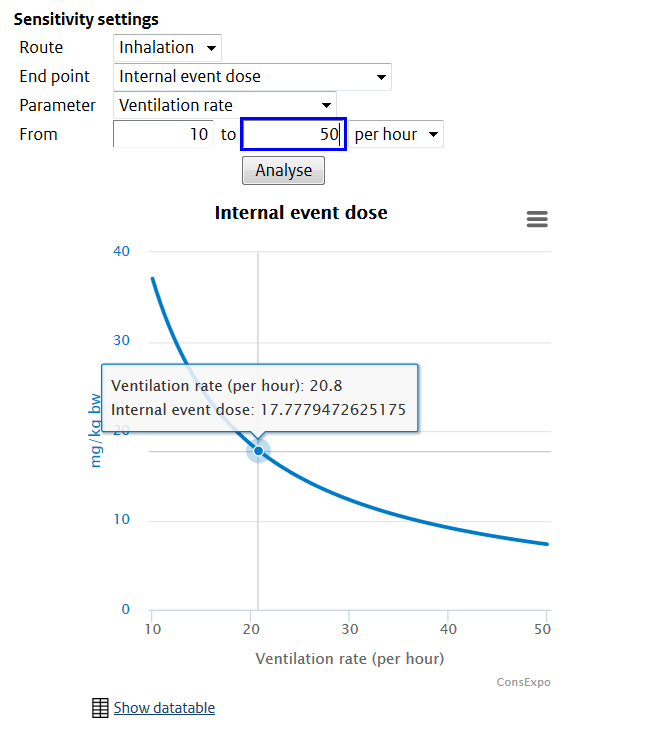
The ventilation rate being the parameter that can influence the risk assessment by triggering the wear of RPE for professional users and a re-entry period, a specific evaluation has been performed.

In order to determine the minimum ventilation rate necessary to avoid the wear of RPE during the cleaning of the room (considering a combined exposure with spraying + wiping + mopping), the ”sensitivity analysis” available in ConsExpo web has been used.

This function allows to vary a parameter taken into account in the exposure model and then to determine a threshold value for this parameter.

The limit exposure value (Internal event dose) to not be exceeded is the long term AEL of 17.9 mg/kg bw/d set for the a.s.

Considering the same parameters used for the combined exposure scenario [1,2,3] (see p 76) the following results are obtained:



As presented in the graph above, a ventilation rate of 20.8 vol/h is necessary to reach an internal dose of 17.77 g/kg bw/d.

Taking this into account, it is considered that the risk is acceptable for professionals with the following RMMs:

* With gloves and RPE (with APF of 10) in a room with a ventilation rate < 21 vol/h; or
* With gloves only in a room with a ventilation rate ≥ 21 vol/h.

**Local effects**

As the product is irritant for eyes (Eye Irrit 2 – H319), 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 | Professional | Spraying doward on small surfaces (desk, equipment materials...) in area with or without controlled atmosphere | ocular | Few minutes per day | Low | **RMM Technics:** - Minimisation of splashes and spills;  **RMM Organisation:** - Minimise number of staff exposed; -Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene  **PPE**  - Eye protection | The spray application should be done downward in order to avoid any facial exposure.  Considering that these recommendations can be followed during this task, the risk is acceptable according to RMM and PPE |

**Conclusion**

Regarding the results obtained for risk assessment of each mode of application and combined exposure (combination of the modes of application), the risk is considered acceptable for professionals:

* With gloves and RPE (with APF of 10) in a room with a ventilation rate < 21 vol/h; or
* With gloves only in a room with a ventilation rate ≥ 21 vol/h.

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***

Not applicable.

***Risk for Secondary exposure***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario [4] - bystander | Tier 1 | 17.9 | 46 | 257 | no |
| Scenario [4] - bystander | Tier 2 RPE | 17.9 | 4.6 | 26 | YES |

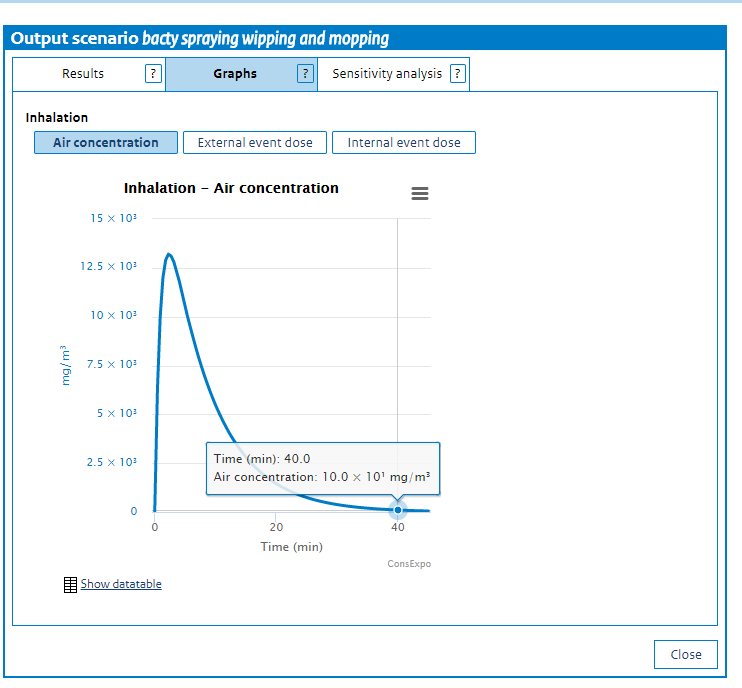
Exposure is not acceptable for another worker present during the application unless it wears the same level of RPE as the applicator.

So a time before re-entry without RPE is necessary.

Due to its high volatility, the product evaporates rapidly.

Considering the graph presented below (from ConsExpo) and representing the evaporation kinetic of the product in a room with a ventilation rate of 8 vol/h, it is assumed that, after 40 min, the product air concentration is considerably decreased and is of 100 mg/m3 air.

For the specific use in a room with a high ventilation rate, taking into account the results of the analysis presented above, with a ventilation rate ≥ 21 vol/h, the internal dose is below the long term AEL and then no time for re-entry is necessary.



According to the CAR of the a.s, the OEL set for propan-2-ol is 200 ppm corresponding to 0.49 mg/L air or 490 mg/m3. After 40 min, the concentration of propan-2-ol in the air is below the OEL leading to an acceptable risk. It is therefore recommended not to enter the room during the application of the product (corresponding to 45 minutes (spraying + wiping + mopping)) for rooms with a ventilation rate < 21 vol/h.

For rooms with a ventilation rate ≥ 21 vol.h, no time for re-entry is necessary.

**Local effects**

Not applicable.

**Conclusion**

For an adult entering a room with freshly treated surfaces (including soil), the risk is considered acceptable if the re-entry occurs after the application, considering a room with a ventilation rate < 21 vol/h. For rooms with a ventilation rate ≥ 21 vol.h, no time for re-entry is necessary.

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

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

### Risk assessment for animal health

Not applicable

### Risk assessment for the environment

|  |
| --- |
| **Box 1- FR CA position :**  Please notice that the environmental exposure assessment is reported as provided by the applicant. The FR CA position is presented **in green evaluation boxes at the end each part of the environmental risk assessment section.** |

#### Effects assessment on the environment

The products of the BACTY SP IPA family are ready-to-use disinfectant products containing 70% w/w propan-2-ol. A summary of the available ecotoxicity data on the active substance propan-2-ol and the Predictive No Effect Concentrations (PNECs) for the different compartments are presented in the tables below. All the data are coming from the Assessment Report of the active substance (see Assessment Report of propan-2-ol, PT02, 13 January 2015). Ecotoxicity data are available only for the aquatic compartment.

**Available ecotoxicity data on propan-2-ol**

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Time scale** | **Endpoint** | **Toxicity** |
| *Pimephales promelas* | 96h | LC50 | 8692 mg a.s./L |
| *Daphnia magna* | 48h | EC50 | 2285 mg a.s./L |
| *Daphnia magna* | 16 days | NOEC (growth) | 141 mg a.s./L |
| *Pseudokirchneriella  subspicata* | 48h | ErC50 | 10 500 mg a.s./L |
| Activated sludge | 3h (static) | EC50 (respiration inhibition) | > 1000 mg a.s./L (nominal) |

**Summary of PNECs for propan-2-ol**

|  |  |
| --- | --- |
| **Compartment** | **PNEC value** |
| STP | 10 mg/L (Assessment Factor, AF = 100) |
| Freshwater | 2.82 mg/L (AF = 50) |
| Freshwater sediment | 2.41 mg/kgwwt (equilibrium partitioning method) |
| Soil | 0.496 mg/kgwwt (equilibrium partitioning method) |

***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***

There is no ecotoxicological data available for the products of the BACTY SP IPA family. As the products contained a 70% w/w propan-2-ol aqueous solution, the classification of the product is based on data on the active substance.

Several aquatic ecotoxicological data on the active substance are available and are presented in the above. Based on these data, the active substance propan-2-ol is not classified for the environment according to Regulation (EC) No.1272/2008 (CLP).

Therefore, the products of the BACTY SP IPA family are not classified for the environment according to Regulation (EC) No.1272/2008 (CLP).

The classification of the product is presented in IUCLID, Section 12 Classification & labelling.

|  |  |
| --- | --- |
| Information relating to the ecotoxicity of the biocidal product | |
| Justification | The products of the BACTY SP IPA family are not classified for the environment based on active substance data, according to the rules laid down in Regulation 1272/2008 (CLP).  No further aquatic ecotoxicity data on the products of the BACTY SP IPA family is deemed necessary. |

***Further Ecotoxicological studies***

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies. |
| Justification | The products of the BACTY SP IPA family are intended to be used for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry).  As explained in details below, no emission into the aquatic ant the terrestrial compartments is foreseen following the use of the products of the BACTY SP IPA family. The risk of exposure of non-target organisms is negligible when using the products according to the label recommendations.  Moreover, several ecotoxicity data are available on the active substance propan-2-ol and are considered sufficient to assess the products as they contained a 70% w/w propan-2-ol aqueous solution.  Thus, no additional aquatic and terrestrial ecotoxicological study with the products of the BACTY SP IPA family was conducted to address this point. |
|  |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information | Effects on any other specific, non-target organisms (flora and fauna) believed to be |
| requirement | at risk. |
| Justification | Based on the intended uses of the products of the BACTY SP IPA family there is no concern regarding other specific non-target organisms like for instance, sediment dwelling organisms, aquatic macrophytes or brackish, estuarine or marine organisms. |
| As explained in details below, no emission into the aquatic ant the terrestrial compartments is foreseen following the use of products of the BACTY SP IPA family. The risk of exposure of non-target organisms is negligible when using the products according to the label recommendations. |
| Moreover, several ecotoxicity data are available on the active substance propan-2-ol and are considered sufficient to assess the product as it is a 70% w/w propan-2-ol aqueous solution. |
| Thus no additional ecotoxicological study on other specific, non-target organisms with the products was conducted. |

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

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Supervised trials to assess risks to non-target organisms under field conditions. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The products of the BACTY SP IPA family are a liquid or wipes. Therefore, no additional study is deemed necessary to address this point. |

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

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk. |
| Justification | This endpoint is relevant only for products in the form of bait or granules. The products of the BACTY SP IPA family are a liquid or wipes. Therefore, no additional study is deemed necessary to address this point. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Studies on secondary ecological effect. |
| Justification | The products of the BACTY SP IPA family are intended to be used indoor for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry).  As the product is for indoor use only, it is not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the products of the BACTY SP IPA family. It can therefore be concluded that no secondary ecological effect is expected when using the products of the BACTY SP IPA family according to the label recommendations. |

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

The foreseeable routes of entry in the environment are based on the uses envisaged and the behaviour of the products is extrapolated from the information on the active substance itself.

The products of the BACTY SP IPA family are intended to be used by professionals only for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry). The products can be applied by spraying, mopping or wiping.

The products BACTY SP IPA pulvérisateur and BACTY SP IPA aérosol are applied by spraying: the products are sprayed on upper surfaces with a trigger spray or a spray can. The products can be wiped with a fabric in order to distribute the product evenly on the surface, or also be sprayed directly on the fabric and applied evenly on the surface.

The product BACTY SP IPA bidon is applied by mopping: the product is loaded in a bucket; a cleaning fabric is soaked in the bucket and applied on the floor or the upper surface.

The product BACTY SP IPA tissu and saches are applied by wiping: the pre-impregnated wipes are used directly on surfaces.

All the products are non-rinse off products: the treated surfaces are always left for drying.

Based on the intended uses of the product, no direct or indirect contamination of the STP, the surface water (including sediment) and the soil (including groundwater) is foreseen and the expected concentrations of propan-2-ol in these compartments from the use of the products are expected to be negligible. The main emission pathway following the use of the products will be *via* the air. Explanations for each environmental compartment are presented below.

**Atmospheric compartment**

The main emission pathway following the use of the products will be *via* the air. Indeed, after application on surfaces, the products are left for drying. The high vapour pressure (5780 Pa at 25°C) and the Henry’s law constant (0.80 Pa.m3/mol at 25°C) indicate that direct evaporation of propan-2-ol is expected within a short time after application. It can be assumed that nearly the whole amount of propan-2-ol applied is released to the indoor air and then is emitted to the local outside air through ventilation of the clean room. However, based on the recommended application dose and the size of the treated surfaces, the quantity of products applied in a clean room is about 2 L per day at a maximum (see section on risk assessment for human health for more explanations on the quantities used). Considering this low volume of product applied, it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

**Aquatic compartment (Sewage Treatment Plant (STP), surface water and sediment**)

Considering the indoor use of the products of the BACTY SP IPA family, direct emission of propan-2-ol into the aquatic compartment does not occur.

As explained above, the products of the BACTY SP IPA family are applied indoors on surfaces by spraying, mopping or wiping and are left for drying. The treated surfaces are not rinsed after application of the products and there is no cleaning with water in clean rooms. Moreover, due to its high vapor pressure (5780 Pa at 25°C), propan-2-ol will evaporate shortly after application and will be distributed mainly into the indoor air. Furthermore, Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed.

Then, no emission into the STP and subsequent into surface water and sediment is expected when using the products of the BACTY SP IPA family according to the label recommendations.

**Terrestrial compartment (including groundwater)**

Considering the indoor use of the products of the BACTY SP IPA family, direct emission of propan-2-ol into the soil compartment does not occur.

Indirect release into agricultural soil as a result of sewage sludge application is not expected either as no release into waste water is expected (no rinse after application, no use of water in clean rooms, disposable PPE, wipes and fabrics).

Indirect release into the soil as a result of deposition from the atmosphere may be possible. However, contamination of the atmosphere is limited in time and restricted to a local scale. Moreover, as the active substance is highly volatile deposition on soil from the atmosphere can be regarded as negligible.

Therefore, the soil is not expected to be contaminated when using the products of the BACTY SP IPA family according to the label recommendations.

Please see section "Fate and distribution in exposed environmental compartments" for more information regarding propan-2-ol fate and distribution in the environment.

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further studies on fate and behavior in the environment. |
| Justification | As explained above, potential emissions to the atmosphere are limited in time and restricted to a local scale and there is no contamination of the aquatic and terrestrial compartments. |
| Moreover, several environmental data are available on propan-2-ol (see |
| Assessment Report, propan-2-ol, PT02, 13 January 2015) and are presented in the section "Fate and distribution in exposed environmental compartments". These data are considered sufficient to assess the product as it is a 70% w/w propan-2-ol aqueous solution. |
| Therefore, it can be concluded that there is no need to conduct additional environmental studies with the products of the BACTY SP IPA family. |

***Leaching behaviour (ADS)***

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Leaching behaviour. |
| Justification | The products of the BACTY SP IPA family are intended to be applied indoors in industrial clean rooms on process equipment's, work plan (upper surfaces) and soil. They are not intended to be used for the treatment of surfaces exposed to weathering. Therefore, leaching is not relevant for the products of the BACTY SP IPA family. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in soil. |
| Justification | Emissions into the soil (including groundwater) are not foreseen.  Moreover, environmental data are available on propan-2-ol (see Assessment |
|  |
|  | Report, propan-2-ol, PT02, 13 January 2015) and are presented in the section. |
|  | "Fate and distribution in exposed environmental compartments". These data are considered sufficient to assess the product as it is a 70% w/w propan-2-ol aqueous solution. |
|  | Based on the Koc value of 3.3 L/kg, propan-2-ol is expected to be weakly adsorbed in soils. It has a very high mobility in soil and a very low geo-accumulation potential. |
|  | Furthermore, propan-2-ol is classified as “readily biodegradable”. Additional studies on biodegradability in soil, water/sediment or sewage treatment plant were not deemed necessary. |
|  | Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in soil with the products of the BACTY SP IPA family. |
|  | Please see section "Fate and distribution in exposed environmental compartments" for more data regarding propan-2-ol fate and distribution in the environment. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in water and sediment. |
| Justification | Emissions into the surface water are not foreseen. Moreover, environmental data are available on propan-2-ol (see Assessment Report, propan-2-ol, PT02, 13 January 2015) and are presented in the section"Fate and distribution in exposed environmental compartments". These data are considered sufficient to assess the product as it is a 70% w/w propan-2-ol aqueous solution.  For the active substance authorisation, a fugacity model according to Mackay (level 1) has been used to estimate the distribution of propan-2-ol into the environment. The results are presented in the Assessment Report of propan-2-ol and demonstrate that the substance is preferentially distributed into water (77.8%) and air (22.1 %) in an equilibrium atmosphere. |
|  |
| Regarding the sediments, based on the low Koc value of 3.3 L/kg, adsorption of relevant amounts of propan-2-ol on sediments is not expected. |
| Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in water and sediment with the products of the BACTY SP IPA family. |
| Please see section "Fate and distribution in exposed environmental compartments" for more data regarding propan-2-ol fate and distribution in the environment. |

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

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Testing for distribution and dissipation in air. |
| Justification | The high vapour pressure (5780 Pa at 25°C) and the Henry’s law constant (0.80 |
| Pa.m3/mol at 25°C) indicates that direct evaporation of propan-2-ol is expected within a short time after application. The fugacity model has shown a distribution of 22.1% of propan-2-ol in air in an equilibrium atmosphere (see Assessment Report, propan-2-ol, PT02, 13 January 2015). |
|  |
| However, considering the indoor use of the product and the low volume of product applied per day (2 L at a maximum), it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale. |
| Propan-2-ol present in the atmosphere will react with photo-chemically produced  OH and NO3 radicals. The half-life of propan-2-ol in the troposphere was estimated to be 3.1 days considering a global 24-hours mean and a concentration of 5\*105 OH radicals cm-3. |
| Based on this assessment, there is no need to conduct additional studies on distribution and dissipation in air with the products of the BACTY SP IPA family. |
| Please see section "Fate and distribution in exposed environmental compartments" for more data regarding propan-2-ol fate and distribution in the environment. |

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

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to aquatic organisms or plants under field conditions. |
| Justification | The products of the BACTY SP IPA family are intended to be applied indoors in industrial clean rooms on surfaces such as walls, benches and equipment. It is therefore not intended to be sprayed in or near surface water. Therefore no overspray is foreseen.  Based on this assessment, an overspray study is not required for the products of the BACTY SP IPA family. |

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

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Overspray study to assess risks to bees and non-target arthropods under field conditions. |
| Justification | The products of the BACTY SP IPA family are intended to be applied indoors for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry).  The products are not intended to be sprayed into the outdoor environment. Moreover, as the products are liquid or wipes, formation of dust is not possible. Therefore there is no risk of exposure of honeybees and non-target arthropods.  Based on this assessment, no additional study with the products of the BACTY SP IPA family was conducted to address this point. |

|  |
| --- |
| **Box 2- FR CA position :**  FR CA agrees to use the endpoints from the Assessment Report of propan-2-ol (CAS no. 67-63-0) for the environmental risk assessment. |

#### Exposure assessment

The products of the BACTY SP IPA family are ready-to-use disinfectant containing 70% w/w propan-2-ol. They are intended to be used by professionals only for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry). The products can be applied by spraying, mopping or wiping.

The products BACTY SP IPA pulvérisateur and BACTY SP IPA aérosol are applied by spraying: the products are sprayed on upper surfaces with a trigger spray or a spray can. The products can be wiped with a fabric in order to distribute the product evenly on the surface, or also be sprayed directly on the fabric and applied evenly on the surface.

The product BACTY SP IPA bidon is applied by mopping: the product is loaded in a bucket; a cleaning fabric is soaked in the bucket and applied on the floor or the upper surface.

The product BACTY SP IPA tissu and saches are applied by wiping: the pre-impregnated wipes are used directly on surfaces.

All the products are non-rinse off products: the treated surfaces are always left for drying.

According to the intended uses of the products of the BACTY SP IPA family, it can be stated that no significant emissions into the outdoor environment is foreseen when using the products according to the label recommendations. Arguments for each environmental compartment are presented below.

**Atmospheric compartment**

The main emission pathway following the use of the products will be via the air. Indeed, after application on surfaces, the products are left for drying. The high vapour pressure (5780 Pa at 25°C) and the Henry’s law constant (0.80 Pa.m3/mol at 25°C) indicate that direct evaporation of propan-2-ol is expected within a short time after application. It can be assumed that nearly the whole amount of propan-2-ol applied is released to the indoor air and then is emitted to the local outside air through ventilation of the clean room. However, based on the recommended application dose and the size of the treated surfaces, the quantity of products applied in a clean room is about 2 L per day at a maximum (see section on risk assessment for human health for more explanations on the quantities used). Considering this low volume of product applied, it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

**Aquatic compartment (Sewage Treatment Plant (STP), surface water and sediment)**

Considering the indoor use of the products of the BACTY SP IPA family, direct emission of propan-2-ol into the aquatic compartment does not occur.

As explained above, the products of the BACTY SP IPA family are applied indoors in clean rooms by spraying, mopping or wiping on surfaces and are left for drying. The treated surfaces are not rinsed after application of the products and there is no cleaning with water in clean rooms. Moreover, due to its high vapour pressure (5780 Pa at 25°C), propan-2-ol will evaporate shortly after application and will be distributed mainly into the indoor air. Furthermore, Personal Protective Equipment (PPE) as well as wipes and fabrics used for the application are disposable and are not washed.

Then, no emission into the STP and subsequent into surface water and sediment is expected when using the products of the BACTY SP IPA family according to the label recommendations.

**Terrestrial compartment (including groundwater)**

Considering the indoor use of the products of the BACTY SP IPA family, direct emission of propan-2-ol into the soil compartment does not occur. Indirect release into agricultural soil as a result of sewage sludge application is not expected either as no release in waste water is expected (no rinse after application, no use of water in clean rooms, disposable PPE, wipes and fabrics). Indirect release into the soil as a result of deposition from the atmosphere may be possible. However, contamination of the atmosphere is limited in time and restricted to a local scale. Moreover, as the active substance is highly volatile deposition on soil from the atmosphere can be regarded as negligible.

**General information on exposure assessment**

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|  |  |
| --- | --- |
| Assessed PT | PT02 |
| Assessed scenarios | Scenario 1: indoor applications in industrial clean rooms |
| ESD(s) used | Not relevant (no emission foreseen) |
| Approach | Not relevant (no emission foreseen) |
| Distribution in the environment | Not relevant (no emission foreseen) |
| Groundwater simulation | Not relevant (no emission foreseen) |
| Confidential Annexes | No |
| Life cycle steps assessed | Scenario 1:  Production:No  Formulation No  Use: No  Service life: No |

***Emission estimation***

As explained above, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected when using the products of the BACTY SP IPA family according to the label recommendations.

Regarding the air compartment, based on the indoor application of the products and the low volume applied per day (2 L at a maximum), it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

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

**Identification of relevant receiving compartments based on the exposure pathway**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-  water | Freshwater sediment | Sea-  water | Seawater sediment | STP | Air | Soil | Groundwater |
| Indoor use | No | No | No | No | No | Limited  to local  scale | No | No |

Available data on the fate and the behaviour of propan-2-ol are summarized in the following table. These data are coming from the Assessment Report of propan-2-ol, PT02, January 2015.

**Available fate and distribution data for the active substance propan-2-ol**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 60.09 | g/mol | - |
| Melting point | - 89.5 | °C | - |
| Boiling point | 82.5 | °C | at 1013 hPa |
| Vapour pressure (at 25 °C) | 5780 | Pa | at 25°C |
| Water solubility (at 25°C) | 1000 | g/L | Propan-2-ol is indefinitely miscible with water. |
| Log octanol/water partition coefficient | 0.05 | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | 3.3 (estimated) | L/kg | Adsorption of relevant amounts of propan-2-ol on soils and sediments is not expected. |
| Henry’s Law Constant (measured at 25°C) | 0.80 | Pa.m3/mol | Henry’s law constant indicates moderate volatility from water. |
| Biodegradability | Readily biodegradable |  | - |
| Rate constant for STP | 1 | h-1 | Extrapolated from the biodegradation screening test according to the Table  6 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015. |
| DT50 for biodegradation in surface water (at 12°C) | 15 | d | Extrapolated from the biodegradation screening test according to the Table  7 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015. |
| DT50 for hydrolysis in surface water | Experimentally data not  available | d | Hydrolysis under  environmental conditions is not expected. |
| DT50 for photolysis in surface water | Experimentally data not  available | d | Photolysis is not expected. |
| DT50 for degradation in soil (at 12°C) | 30 | d | Extrapolated from the biodegradation screening test according to the Table  8 of the guidance on BPR, volume IV – part B (active substances); v1.0, April 2015 |
| DT50 for degradation in air | 3.1 | d | Value obtained considering a global 24-hours mean and a concentration of 5\*105 OH radicals cm-3. |
| BCF in fish | 0.22 (estimated) | L/kg wwt | - |
| BCF in earthworms | 0.85 (estimated) | L/kg wwt | - |

***Calculated PEC values***

As explained above, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected when using the products of the BACTY SP IPA family according to the label recommendations.

Regarding the air compartment, considering the indoor application of the product and the low volume applied per day (2 L at a maximum), it is likely that the emissions to the atmosphere will be negligible.

Therefore, the expected concentrations of propan-2-ol are considered negligible in all compartments, when using the products of the BACTY SP IPA family according to the label recommendations.

|  |
| --- |
| **Box 3- FR CA position :**  FR CA agrees with the applicant, according to the uses of BACTY SP IPA, no risk assessment for environment is needed. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the products of the BACTY SP IPA family. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the products of the BACTY SP IPA family. Moreover, the products are for indoor use only.

Secondary poisoning

As the aquatic and terrestrial compartments are not intended to be contaminated, no risk of secondary poisoning via ingestion of potentially contaminated food (e.g. earthworm or fish) by birds or mammals is expected. Moreover, the active substance propan-2-ol has a low potential of bio-accumulation. Indeed, the bio-concentration factors are estimated to be 0.22 L/kg in fish and 0.85 L/kg in earthworms.

|  |
| --- |
| **Box 4- FR CA position :**  FR CA agrees with the applicant, according to the assessment report of propan-2-ol, no risk assessment for poisoning is needed. |

#### Risk characterisation

***Atmosphere***

The main emission pathway following the use of the product will be *via* the air. Indeed, after application on surfaces, the product is left for drying. The high vapour pressure (5780 Pa at 25°C) and the Henry’s law constant (0.80 Pa.m3/mol at 25°C) indicate that direct evaporation of propan-2-ol is expected within a short time. It can be assumed that nearly the whole amount of propan-2-ol applied is released to the indoor air and then is emitted to the local outside air through ventilation of the clean room. However, according to the applicant, the quantity of product applied in a clean room is about 2 L per day at a maximum. Considering this low volume of product applied, it is likely that emissions to the atmosphere will be limited in time and restricted to a local scale.

Methods for determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed. Therefore, no quantitative characterization of risk by comparison of the PECair to PNECair is possible. Only a qualitative assessment for air is feasible.

For the air compartment, ecotoxicological data on animal species other than mammals are not available. For volatile compounds, acute or short-term inhalation tests may give indications on adverse effect following an exposition *via* the atmosphere. Short-term LC50 data can be used for a coarse estimation of the risk a chemical poses for animals. For propan-2-ol, acute inhalation test is available, which shows a low toxicity with a LC50 inhalation on rat of 17 100 mg/kg b.w. (equivalent to 47.5 mg/L of air for 8 h; whole body vapour).

Moreover, according to the guidance on BPR, volume IV, part B (version 1.0, April 2015), a chemical may be dangerous for the atmospheric environment at a low concentration, if it is classified as R48 ("Danger of serious damage to health by prolonged exposure"), equivalent to H372 (“causes damage to organs through prolonged or repeated exposure”) or H373 (“may cause damage to organs through prolonged or repeated exposure”). Also, mutagenic effects and toxic effects on reproduction indicate a toxic potential for terrestrial vertebrates. These classifications don’t apply to propan-2-ol.

In conclusion, considering the low potential of exposition and the low toxicity of propan-2-ol, the risk for the atmospheric compartment can be considered as acceptable following the use of the products of the BACTY SP IPA family according to the label recommendations.

Regarding abiotic effects, effects on stratospheric and tropospheric ozone and acidification are not expected because propan-2-ol does not contain halogens, nitrogen or sulphur substituent and propan-2-ol is not listed as a substance of concern in the Regulation (EC) No 1005/2009 on substances that deplete the ozone layer. The potential for global warming cannot be characterised because there is no information available in the absorption spectrum in the range from 800 to 1200 nm.

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

As explained above, the products of the BACTY SP IPA family are applied indoors in clean rooms by spraying, mopping or wiping on surfaces and are left for drying. The treated surfaces are not rinsed after application of the products and there is no cleaning with water in clean rooms. Furthermore, due to its high vapour pressure (5780 Pa at 25°C), propan-2-ol will evaporate shortly after application and will be distributed mainly into the indoor air. Moreover, Personal Protective Equipments (PPE) as well as wipes and fabrics used for the application are disposable and are not washed.

Then, no emission into the STP is expected.

Moreover, it has to be reminded that propan-2-ol is readily biodegradable and practically non-toxic to aquatic organisms. Indeed, propan-2-ol shows low effects on microbial activity in STPs with a 3h EC50 > 1000 mg a.s/L obtained in a respiration inhibition test on activated sludge.

In addition, an environmental risk assessment with a product similar to the products of the BACTY SP IPA family (i.e a 70% w/w propan-2-ol aqueous solution) has been performed at the active substance authorization stage and is presented in the Assessment Report of propan-2-ol (see Assessment Report of propan-2-ol, PT02, 13 January 2015, p.37-39, point 2.2.7). Risk characterisation ratios were calculated for the application of the product for “disinfection of rooms, furniture and objects in the medical and sanitary sector” and are well below 1 in all compartments. This demonstrates that even if contamination of the STP compartment occurs, following cleaning of treated surfaces and objects in medical and sanitary areas, the risk for the STP remains acceptable.

Based on this assessment, the risk for the STP can be considered as negligible when using the products of the BACTY SP IPA family according to the label recommendations.

***Aquatic compartment***

As the products are for indoor use only, no direct contamination of the aquatic compartment is foreseen. Indirect contamination via the STP is not expected either as the STP is not exposed (no rinse of the products after application, no use of water in clean rooms and use of disposable PPE, wipes and fabrics).

Moreover, it has to be reminded that propan-2-ol is readily biodegradable and practically non-toxic to aquatic organisms. The most sensitive aquatic organism to propan-2-ol is Daphnia magna with an EC50 of 2 285 mg/L and a NOEC of 141 mg/L.

In addition, an environmental risk assessment with a product similar to the products of the BACTY SP IPA family (i.e a 70% w/w propan-2-ol aqueous solution) has been performed at the active substance authorization stage and is presented in the Assessment Report of propan-2-ol (see Assessment Report of propan-2-ol, PT02, 13 January 2015, p.37-39, point 2.2.7). Risk characterisation ratios were calculated for the application of the product for disinfection of rooms, furniture and objects in the medical and sanitary sector and are well below 1 in all compartments. This demonstrates that even if contamination of the aquatic compartment occurs, following cleaning of treated surfaces and objects in medical and sanitary areas, the risk for the aquatic compartment (including sediment) remains acceptable.

Based on this assessment, the risk for the aquatic compartment (including sediment) can be considered as negligible when using the products of the BACTY SP IPA family according to the label recommendations.

***Terrestrial compartment***

Considering the indoor use of the products of the BACTY SP IPA family, direct emission of propan-2-ol into the soil compartment does not occur. Indirect release into agricultural soil as a result of sewage sludge application is not expected either as no release into waste water is expected (no rinse of the products after application, no use of water in clean rooms and use of disposable PPE, wipes and fabrics). Indirect release into the soil as a result of deposition from the atmosphere may be possible. However, contamination of the atmosphere is limited in time and restricted to a local scale. Moreover, as the active substance is highly volatile deposition on soil from the atmosphere can be regarded as negligible.

Furthermore, an environmental risk assessment with a product similar to the products of the BACTY SP IPA family (i.e a 70% w/w propan-2-ol aqueous solution) has been performed at the active substance authorization stage and is presented in the Assessment Report of propan-2-ol (see Assessment Report of propan-2-ol, PT02, 13 January 2015, p.37-39, point 2.2.7). Risk characterisation ratios were calculated for the application of the product for disinfection of rooms, furniture and objects in the medical and sanitary sector and are well below 1 in all compartments. This demonstrates that even if contamination of the terrestrial compartment occurs, following cleaning of treated surfaces and objects in medical and sanitary areas, the risk for the soil remains acceptable

Based on this assessment, the risk for the terrestrial compartment is considered as acceptable when using the products of the BACTY SP IPA family according to the label recommendations.

***Groundwater***

As explained above, contamination of the soil is negligible. Therefore, no contamination of the groundwater is expected.

Moreover, an environmental risk assessment with a product similar to the products of the BACTY SP IPA family (i.e a 70% w/w propan-2-ol aqueous solution) has been performed at the active substance authorization stage and is presented in the Assessment Report of propan-2-ol (see Assessment Report of propan-2-ol, PT02, 13 January 2015, p.37-39, point 2.2.7). Risk characterisation ratios were calculated for the application of the product for “disinfection of rooms, furniture and objects in the medical and sanitary sector” and are well below 1 in all compartments, including groundwater. This demonstrates that even if contamination of the groundwater occurs, following cleaning of treated surfaces and objects in medical and sanitary areas, the risk for the groundwater remains acceptable.

Therefore, the foreseeable concentration in groundwater of propan-2-ol can be considered as negligible and is not expected to exceed the maximum permissible concentration of 0.1 μg/L laid down by Directive 98/83/EC.

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning, i.e. the direct consumption of the product by birds or mammals is not considered as relevant for the products of the BACTY SP IPA family. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the products of the BACTY SP IPA family. Moreover, the products are for indoor use only.

Secondary poisoning

As the aquatic and terrestrial compartments are not intended to be contaminated, no risk of secondary poisoning *via* ingestion of potentially contaminated food (*e.g*. earthworm or fish) by birds or mammals is expected. Moreover, the active substance propan-2-ol has a low potential of bio-accumulation. Indeed, the bio-concentration factors are estimated to be 0.22 L/kg in fish and 0.85 L/kg in earthworms.

|  |
| --- |
| **Box 5- FR CA position :**  FR CA agrees with the applicant, according to intended uses of the products, no risk assessment for environment is needed. |

***Mixture toxicity***

The mixture toxicity assessment is performed according to the Transitional guidance on mixture toxicity assessment for the environment of May 2014.

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

The products of the BACTY SP IPA family are ready-to-use disinfectant containing 70% w/w propan-2-ol. They are intended to be used by professionals only for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry). The products can be applied by spraying, mopping or wiping and are left for drying after application.

As explained in sections above, no contamination either directly or indirectly of the STP, the surface water (including sediment) and the soil (including groundwater) is expected.

Regarding the air compartment, considering the indoor application of the product and the low volume applied per day (2 L at a maximum), it is likely that the emissions to the atmosphere will be negligible.

Therefore, a significant exposure of environment is unlikely and a mixture toxicity assessment is not necessary for the products of the BACTY SP IPA family.

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

An assessment of aggregated exposure is judged not relevant for the products of the BACTY SP IPA family based on the decision scheme developed by UBA (see Figure 1). Indeed, as the emissions into the environment are negligible (see sections above), there is no need for an estimation of aggregated exposure.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

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

The products of the BACTY SP IPA family are ready-to-use disinfectant containing 70% w/w propan-2-ol. They are intended to be used by professionals only for the disinfection of industrial process equipment's, work plan (upper surfaces) and soil, in clean rooms of industrial process (except in veterinary and food industry). The products can be applied by spraying, mopping or wiping and are left for drying after application.

According to the intended uses of the products of the BACTY SP IPA family, no emissions into the aquatic and the terrestrial compartments are foreseen. Emissions into the outdoor air are possible but are limited in quantity and time and restricted to a local scale.

Therefore, the risk for all compartments (air, water, sediment, soil and groundwater) and the risk of primary and secondary poisoning are considered acceptable when using the products of the BACTY SP IPA family according to the label recommendations.

There is no need for conducting a mixture toxicity assessment and an estimation of aggregated exposure.

|  |  |  |
| --- | --- | --- |
| **Box 6- FR CA position :**   |  | | --- | | **Overall conclusion on the risk assessment for the environment of the product** | | Based on the restricted uses of the products of the BACTY SP IPA family in clean rooms (i.e. controlled atmosphere areas) where no wet cleaning or other releases are expected, no unacceptable risk to the environmental compartments has been identified. | |

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

*See Summary of Product Characteristics (SPC)*

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

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)** | **Date of first submission** |
| Carre A. and  Strohl P. | 2016 | European Standard NF EN 1276 (March 2010): chemical  disinfectants and antiseptics – Test method and requirements  (phase 2, step 1). Product: BACTY SP IPA  IRM, Report n°RE-179/0316-4  Unpublished | Yes | Conformat |  |
| Carre A. and  Strohl P. | 2016 | European Standard NF EN 1650 + A1 (July 2013): chemical  disinfectants and antiseptics – Test method and requirements  (phase 2, step 1). Product: BACTY SP IPA  IRM, Report n°RE-179/0316-2  Unpublished | Yes | Conformat |  |
| Carre A. and  Strohl P. | 2016 | European Standard NF EN 1650 + A1 (July 2013): chemical  disinfectants and antiseptics – Test method and requirements  (phase 2, step 1). Product: BACTY SP IPA  IRM, Report n°RE-179/0316-3  Unpublished | Yes | Conformat |  |
| Carre A. and  Strohl P. | 2016 | In accordance with the procedures of the EUROPEAN  STANDARD NF EN 13697 (June 2015): Chemical  disinfectants and antiseptics -Test method and requirements without mechanical action (phase 2 / step 2). Product  BATY SP IPA.  IRM, Report n°RE-179/0316-1  Unpublished | Yes | Conformat |  |
| Carre A. and  Strohl P. | 2016 | In accordance with the procedures of the EUROPEAN  STANDARD NF EN 13697 (June 2015): Chemical  disinfectants and antiseptics -Test method and requirements without mechanical action (phase 2 / step 2). Product  BACTY SP IPA.  IRM, Report n°RE-180/0316-5  Unpublished | Yes | Conformat |  |
| Carre A. and | 2017 | EUROPEAN STANDARD NF EN 16615 (May 2015): Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test)  BACTY SP IPA.  IRM, Report n°RE-1151/0317-1  **Unpublished** | Yes | Conformat |  |
| Strohl P. | 2016 | EUROPEAN STANDARD NF EN 16615 (May 2015): Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test)  BACTY SP IPA.  IRM, Report n°RE-231/0516  **Unpublished** | Yes | Conformat |  |
| Carre A. and | 2017 | EUROPEAN STANDARD NF EN 16615 (May 2015): Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test)  BACTY SP IPA.  IRM, Report n°RE-1152/0317  **Unpublished** | Yes | Conformat |  |

* **Post authorisation assessment (2021)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Demangel B. | 2019 | Physico-chemical tests and chemical stability  during and after a storage procedure at 20 ± 2°C  for 36 months on BACTY SP IPA pulvérisateur  Report No.16-903061-003  GLP |  | Conformat |  |
| Demangel B. | 2018 | Physico-chemical tests and chemical stability during  and after a storage procedure at 20 ± 2°C for  36 months on BACTY SP IPA aerosol  Report No.16-903061-006  GLP |  | Conformat |  |
| Demangel B. | 2019 | Appearance test after a storage procedure for  36 months at 20 ± 2°C on BACTY SP IPA TISSU  Report No.16-903061-008  GLP |  | Conformat |  |

## Output tables from exposure assessment tools

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## New information on the active substance

Not relevant

## Residue behaviour

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

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

See IUCLID file

## Confidential annex

See in an annex document

## Other

Not relevant

1. Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics [↑](#footnote-ref-1)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
3. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-3)
4. Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics [↑](#footnote-ref-4)