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

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

(submitted by the evaluating Competent Authority)



STERIGENE IPA

Product type 2

Propan-2-ol

Case Number in R4BP: BC-DF025439-49

Evaluating Competent Authority: FR

Date: April 2018

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# CONCLUSION

***Conclusion for Physico-chemical properties:***

The product STERIGENE IPA 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 a homogeneous colourless limpid liquid with an isopropylic alcohol characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 35°C” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PET packaging material (commercial packaging material). The long term storage stability study (24 months) is on-going and has to be provided within two 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 AL formulation.

The product is not auto-flammable. It has no explosive and no oxidizing properties, but it is highly flammable Flam. Liq. 2, H225.

Method for detection and quantification of active substance in the product is considered in compliance with SANCO/3030/99 rev.4. According to EU, no residues are expected in soil and water. Analytical method for propan-2-ol residues in air is available in Assessment Report 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. 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.

***Conclusion for Efficacy***:

The product STERIGENE IPA is efficient against bacteria, yeasts and fungi by spraying and mopping on hard surfaces in industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C)

The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

***Conclusion 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 < 17 vol/h; or
* wearing gloves only in a room with a ventilation rate ≥ 17 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 < 17 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 ≥ 17 vol/h, the re-entry can occur during the aplication of the product.

***Conclusion for Environment***:

Based on the restricted uses of the product STERIGENE IPA 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.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Sterigene IPA | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Sterigene |
| **Address** | 2 rue André Citroën  95130 Franconville  FRANCE |
| **Authorisation number** | FR-2018-0023 | |
| **Date of the authorisation** | 12/04/2018 | |
| **Expiry date of the authorisation** | 11/04/2028 | |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | ECP – Entegris Cleaning Process |
| **Address of manufacturer** | 395 rue Louis Lépine  34000 Montpellier  FRANCE |
| **Location of manufacturing sites** | 395 rue Louis Lépine  34000 Montpellier  FRANCE |

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

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Ineos Solvents Germany GmbH |
| **Address of manufacturer** | Ineos Solvents Germany GmbH  Römerstraße 733  474433 Moers  GERMANY |
| **Location of manufacturing sites** | Ineos Solvents Grangemouth  PO Box 21  Grangemouth  Stirlingshire  FK3 9XH  UK  Ineos Solvents Germany GmbH, Werk Herne  Shamrockstraße 88  44623 Herne  GERMANY  Ineos Solvents Germany GmbH, Werk Moers  Römerstraße 733  474433 Moers  GERMANY |

### Product composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Propanol-2 |
| **IUPAC or EC name** | Propanol-2 |
| **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

The active substance Propanol-2 contained in the biocidal products is not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content**  **(% w/w)** |
| --- | --- | --- | --- | --- | --- |
| Propan-2-ol | Propan-2-ol | Active substance pure | 67-63-0 | 200-661-7 | 64.7 |

#### Information on technical equivalence

Not relevant.

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

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| Any other liquid |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  STOT SE 3  Flam. Liq. 2 |
| Hazard statement | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H225: Highly flammable liquid and vapour. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H225 - Highly flammable liquid and vapour. |
| 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  P210 – Keep away from heat/sparks/open flames/hot surfaces. — No smoking.  P233 – Keep container tightly closed.  P240 – Ground/bond container and receiving equipment.  P241 – Use explosion-proof electrical/ventilating/lighting/…/equipment.  P242 – Use only non-sparking tools.  P243 – Take precautionary measures against static discharge. |
| Note |  |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Surface disinfection in clean rooms

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product Sterigene IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in 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)** | Spraying  Mopping (damp mopping) |
| **Application rate(s) and frequency** | Ready-to-use  Contact time: 5 minutes  Temperature: 20°C  Use in clean rooms only (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging :  Bottle, Plastic: PET , 500.0 mL  Diameter – height: 78 mm – 172 mm  Transparent PETE (polyethylene terephtatalate) bottle fitted with trigger spray The nominal volume of the content is 500 mL.  Bottle, Plastic: PET , 750.0 mL  Transparent PETE (polyethylene terephtatalate) bottle fitted with trigger spray The nominal volume of the content is 750 mL.  Bottle, Plastic: PET , 1.0 L  Diameter – height: 93 mm – 228 mm  Transparent PETE (polyethylene terephtatalate) oblong bottle fitted with trigger spray. The nominal volume of the content is 1 L |
|  | Can, Plastic: HDPE, 5L |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use

#### Instructions for use

|  |
| --- |
| * Use only in clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C). * Always read the label or leaflet before use and respect all the instructions provided. * Remove the first packaging before entering the controlled atmosphere area. * Then remove the 2nd package on first use.- * For spraying application, hold bottle upright and spray directly from a distance of 10 to 20 cm. * Apply the product uniformly on the surface to be treated in sufficient quantity so that the surfaces remain wet during the indicated contact time. * Let the surfaces dry. * Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

#### Risk mitigation measures

|  |
| --- |
| * Avoid direct or indirect contact with food and feed. * In a room with a ventilation rate < 17 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 ≥ 17 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 < 17 vol/h during the application of the product. |

#### 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

|  |
| --- |
| * Shelf life 2 years. * Do not store at a temperature above 35°C. |

### Other information

|  |
| --- |
| * Final report of long term storage study has to be provided within 2 year. * The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle | 500 mL; 750 mL; 1L | PETE (polyethylene terephtatalate), spray trigger | / | Professional |  |
| Can | 5 L | HDPE | / | Professional |  |

### Documentation

#### Data submitted in relation to product application

***Physico-chemistry:***

Physico-chemical properties studies and analytical methods on the biocidal product Sterigene IPA were provided by Sterigene.

***Efficacy:***

The product STERIGENE IPA (70% v/v propan-2-ol) has been tested in following efficacy studies:

* For bacteria:
* Laboratory study according to EN1276:2010 standard (phase 2, step 1).
* Laboratory study according to EN 13697:2015 standard (phase 2, step 2).
* For yeasts:
* Laboratory study according to EN1650 + A1:2013 standard (phase 2, step 1).
* Laboratory study according to EN 13697:2015 standard (phase 2, step 2).
* For fungi:
* Laboratory study according to EN1650+ A1:2013 standard (phase 2, step 1).
* Laboratory study according to EN 13697:2015 standard (phase 2, step 2).

***Residue:***

No specific residue data were submitted in the context of this dossier. By definition PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected. Considering the intended uses no data is required.

***Environment:***

None.

#### Access to documentation

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

## Assessment of the biocidal product

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

Intended use # 1 – Surface spraying

|  |  |
| --- | --- |
| Product Type(s) | PT02 – Disinfectant |
| Where relevant, an exact description of the authorised use | The product Sterigene IPA is a ready-to-use disinfectant used in industrial clean rooms to disinfect surfaces. It can be used on walls, benches and equipments. This product is to be used by professionals, indoors. |
| Target organism (including development stage) | Bacteria  Yeast  Fungi |
| Field of use | Indoor use |
| Application method(s) | Spraying -  The product is sprayed (trigger spray) on the surfaces to disinfect. The surfaces are then allowed to dry |
| Application rate(s) and frequency | 40.0 mL/m² - 100 -  The product is applied as needed, depending on the clean room's use |
| Category(ies) of user(s) | Professionals |
| Pack sizes and packaging material | Primary packaging :  Bottle, Plastic: PET , 500.0 mL  Diameter – height: 78 mm – 172 mm  Transparent PETE (polyethylene terephtatalate) bottle fitted with trigger spray The nominal volume of the content is 500 mL.  Bottle, Plastic: PET , 750.0 mL  Transparent PETE (polyethylene terephtatalate) bottle fitted with trigger spray The nominal volume of the content is 750 mL.  Bottle, Plastic: PET , 1.0 L  Diameter – height: 93 mm – 228 mm  Transparent PETE (polyethylene terephtatalate) oblong bottle fitted with trigger spray. The nominal volume of the content is 1 L  Can, Plastic: HDPE, 5L |

Intended use # 2 – Mopping

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The product Sterigene IPA is a ready-to-use disinfectant used in industrial clean rooms to disinfect surfaces. |
| **Target organism (including development stage)** | Bacteria Yeast Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The product is mopped on the surfaces to disinfect. |
| **Application rate(s) and frequency** | Application rate : 40 mL/m² Frequency : as needed |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section  12.3 of the IUCLID file). |

### Physical, chemical and technical properties

**Identity**

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 65.4% of technical active substance 2-propanol and 64.7% of pure active substance 2-propanol.

The product does not contain PT6 preservative.

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

Formulation type: AL (all other liquids)

Hydrocarbon and H304 co-formulant content: 0%

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Reference** | **Results** | **FR comments** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual observation | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | The test item was a homogeneous colourless limpid liquid. | Acceptable |
| Colour at 20 °C and 101.3 kPa | Visual observation | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | The test item was a homogeneous colourless limpid liquid. | Acceptable |
| Odour at 20 °C and 101.3 kPa | Visual observation | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | The test item has isopropylic alcohol characteristic odour. | Acceptable |
| Acidity / alkalinity |  | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report N° 16-919077-022 | At 20°C, pH=7.64 | Acceptable |
| Relative density / bulk density | EC A3 OECD 109 | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | At 18.7°C, D= 0.875 | Acceptable |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Method validated in study No.16-919077-004 | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report N° 16-919077-002 | |  |  |  | | --- | --- | --- | |  | T=0 | After 12 weeks at 35°C | | Physical state | Homogeneous colourless limpid  liquid with an isopropylic alcohol  characteristic smell | No change | | Packaging | Transparent PET spray (double  wrapped in plastic bags) | No change | | AS content | 63.4 | 66.1 | | Variation (%) | - | +4.3% | | pH pure test item | 7.64 at 20°C | 7.71 at 18.7°C | | Spray volume | 1.015 mL  No blocking of the nozzles and the pump | 1.036 mL  No blocking of the nozzles and the pump | | Weight of packaging | 517.3 | 514.5 | | Variation of weight % | / | -0.55% |   Bottle of 500mL in PET. | Acceptable  The preparation is stable 12 weeks at 35°C. |
| Storage stability test – **long term storage at ambient temperature** |  |  | Demangel B. 2016  Report N° 16-919077-003 | On-going  In transparent PET sprays (double wrapped in plastic bag)s:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T=0 | After 6 months at 20°C | After 12 months at 20°C |  | | Physical state | Homogeneous colourless limpid  liquid with an isopropylic alcohol  characteristic smell | No change | No change |  | | Packaging | Transparent PET spray (double  wrapped in plastic bags) | No change | No change |  | | AS content | 63.4 | 64.8 | 62.9 |  | | Variation (%) | - | +2.2% | -0.8% |  | | pH pure test item | 7.64 at 20°C |  |  |  | | Spray volume | 1.015 mL  No blocking of the nozzles and the pump | 1.019 mL No blocking of the nozzles and the pump | 0.999 mL No blocking of the nozzles and the pump |  | | Weight | 517.3 |  |  |  | | Variation of weight of packaging% | / | -0.2% | -0.5% |  | | On-going,  Final report of long term storage study has to be provided when is available. |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | The test item was a homogeneous colourless limpid liquid.  The aspect of the test item was considered to be stable after low temperature stability for 7 days at 0 ± 2°C, no change was observed in the test item aspect. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  |  | Not required. According to the Assessment Report of Propan-2-ol, Product-type 02 (private area and public health area disinfectants and other biocidal products), 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. Acceptable |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report N° 16-919077-002 | The individual commercial packagings are sealed. With this closure system, the packaging is leak-tight.  The preparation is stable 12 weeks at 35°C and after 7 days at 0°C. | Acceptable |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  |  | See the storage stability test –accelerated storage procedure and long term storage at ambient temperature. | Acceptable |
| Wettability |  |  |  | Not required, BP is a ready-to-use spray liquid. |  |
| Suspensibility, spontaneity and dispersion stability |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Wet sieve analysis and dry sieve test |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Disintegration time |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Particle size distribution, content of dust/fines, attrition, friability | PSD method  30/2017-01-MS | Sterigene IPA  Batch 160315COMSTER | Metrat 2016, Report No. 43783 Lab-Service | |  |  |  |  | | --- | --- | --- | --- | | Sample N° | Dv (10%) µm | Dv (50%) µm | Dv (90%) µm | | 1 | 10.8 | 66 | 120 | | 1 | 11.0 | 63.6 | 121 | | 2 | 12.1 | 64.7 | 128 | | 2 | 9.41 | 60.2 | 109 | | 3 | 8.71 | 59.4 | 115 | | 3 | 8.75 | 56.6 | 115 | | **mean** | **10.1** | **61.8** | **118** | | **SD** | **1.37** | **3.57** | **6.69** | | **RSD (%)** | **13.5** | **5.8** | **5.7** | | Acceptable |
| Persistent foaming |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Flowability/Pourability/Dustability |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Burning rate — smoke generators |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Burning completeness — smoke generators |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Composition of smoke — smoke generators |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Spraying pattern — aerosols | In-house  methods for the  determination  of satisfactory  operation of the  spray and  spray volume | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report N° 16-919077-002  Demangel B. 2016  Report N° 16-919077-003 | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T=0 | After 6 months at 20°C | After 12 months at 20°C |  | | Spray volume | 1.015 mL  No blocking of the nozzles and the pump | 1.019 mL No blocking of the nozzles and the pump | 0.999 mL No blocking of the nozzles and the pump |  | | On-going,  Final report of long term storage study has to be provided when available. |
| Physical compatibility |  |  |  | Not applicable. STERIGENE IPA is a ready-to-use product and is not  intended to be used in conjunction with any other products or active  substances. |  |
| Chemical compatibility |  |  |  | Not applicable. STERIGENE IPA is a ready-to-use product and is not  intended to be used in conjunction with any other products or active  substances. |  |
| Degree of dissolution and dilution stability |  |  |  | Not required, BP is a ready-to-use liquid. |  |
| Surface tension | EC A5 OECD 115 | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | At 19.9°C 23.3 mN/m |  |
| Viscosity | OECD 114 | Sterigene IPA  Batch 160315COMSTER | Demangel B. 2016  Report n°16-919077-001 | At 20°C 3.78 mPa.s  At 40°C 2.03 mPa.s |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product STERIGENE IPA 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 a homogeneous colourless limpid liquid with an isopropylic alcohol characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 12 weeks at 35°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 35°C” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in PET packaging material (commercial packaging material). The long term storage stability study (24 months) is on-going.  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 AL formulation.  Final report of long term storage study has to be provided when available. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **FR comments** |
| --- | --- | --- | --- | --- | --- |
| Explosives | D.S.C.  EC A14 | Sterigene IPA  Batch 160315COMSTER | 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 1to 3 described in Part I of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria should not be performed In the temperature used range, no exothermic reaction was observed. This thermodynamic information allows knowing that the test item shall not be classified as explosive. | Demangel B. 2016  Report n°16-919077-001 | Acceptable  The preparation has no explosive properties according to CLP criteria. |
| Flammable gases |  |  | Not required, BP is a liquid. |  |  |
| Flammable aerosols |  |  | Not required, BP is a liquid. |  |  |
| Oxidising gases |  |  | Not required, BP is a liquid. |  |  |
| Gases under pressure |  |  | Not required, BP is a liquid. |  |  |
| Flammable liquids | Statement |  | As the product STERIGENE IPA contains 64.7% w/w propan-2-ol which is classified Flam. Liq. 2, H225, it is expected to be highly flammable and classified Flam. Liq. 2, H225. |  | Acceptable,  The preparation is classified Flam. Liq. 2, H225. |
| Flammable solids |  |  | Not required, BP is a liquid. |  |  |
| Self-reactive substances and mixtures |  |  | Not relevant |  |  |
| Pyrophoric liquids | Statement |  | The product is not a pyrophoric liquid. Test is not required as STERIGENE IPA contains more than 34% 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 Product-type 02, January 2015, the active substance propan-2-ol is stable in air at room temperature and is not pyrophoric. |  | Acceptable,  The preparation has no pyrophoric properties. |
| Pyrophoric solids |  |  | Not required, BP is a liquid. |  |  |
| Self-heating substances and mixtures |  |  | Not required, the product does not contain self-heating substance. |  | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases |  |  | The product does not emit flammable gases when in contact with water. Test is not required as STERIGENE IPA contains more than 34% w/w water and forms a stable mixture. |  | Acceptable |
| Oxidising liquids | Statement |  | The product is not oxidising. Test is not required as STERIGENE IPA contains 64.7% 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 34% water, an inert component. |  | Acceptable,  The preparation has no oxidising properties, test CLP is not required. |
| Oxidising solids |  |  | Not required, BP is a liquid. |  |  |
| Organic peroxides |  |  | Not relevant. |  |  |
| Corrosive to metals |  |  | The product is not corrosive to metals. Test is not required as the product STERIGENE IPA does not contain any ingredients classified as corrosive to metals. |  | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) | Statement |  | Test is not required on the liquid formulation as the product STERIGENE IPA contains more than 29% w/w water, and as propan-2-ol 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).  auto-ignition temperature is 425°C acceptable. |  | Acceptable,  The preparation is no auto-flammable at ambient temperature, test CLP is not required. |
| Relative self-ignition temperature for solids |  |  | Not required, BP is a ready-to-use liquid. |  |  |
| Dust explosion hazard |  |  | Not required, BP is a ready-to-use liquid. |  |  |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not auto-flammable. It has no explosive and no oxidizing properties.  Implication concerning labelling:  Highly flammable: classified Flam. Liq. 2, H225. |

### Methods for detection and identification

Report: Ricau H. 2016

Report no 16-919077-004

Test facility:

Défitraces

Z.A. des Andrés

150, rue Pré-Magne

69126 BRINDAS

FRANCE

Principle of the method:

Propan-2-ol is analysed after extraction from the formulation and quantified by gas chromatography using a flame ionisation detector (GC-FID).

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: STERIGENE IPA   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 0.99. | |
| Compound | Linearity % |
| Active substance | 50% to 100%  Y = 1.89.102 x – 892 R2 = 0.9986  n=2 x 5 levels |
| Precision | Repeatability was evaluated by analyzing twice five test item solutions. | |
| Compound | Repeatability (RSD) |
| Ispropanol | RSD = 0.96% |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 64% | 64.15%; 64.10%; 62.83%; 63.03%; 63.73% | 63.6% | 0.96% | 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 | | 988.16 mg/L | 98.0%; 99.1% | 98.5% | 2 | | 1019.04 mg/L | 98.5%; 98.1% | 98.3% | 2 | | |

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

According to EU, no residues are expected in soil and water.

Analytical method for propan-2-ol residues in air is available in Assessment Report 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. Analytical methods were provided at EU level for the determination of isopropanol residue in air with respectively LOQ = 0.109 mg/m3.

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.

|  |
| --- |
| **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, 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

The product STERIGENE IPA is a ready-to-use disinfectant used in industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C) to disinfect hard surfaces, by spraying and by mopping. It can be used on walls, grounds, benches and equipment.

This product is to be used by professionals, indoors.

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

The product STERIGENE IPA is used to disinfect surfaces. It irreversibly inactivates vegetative bacteria, yeasts and fungi.

The aim of using this product is to keep the surfaces free of microorganisms, to finally protect human health.

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

The product is 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 leads to a loss of cellular activity resulting in the cell’s death.

Propan-2-ol is used as disinfectant as 70% aqueous solution, and not pure. When the bacterial cell walls proteins comes 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 cause 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.

The product STERIGENE IPA used in clean rooms is effective after a contact time of 5 minutes (please refer to the results of the tests in the following table).

#### Efficacy data

Laboratory studies were conducted with STERIGENE IPA, according to the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants (2016) and EN 14885:2015 standard.

The results are summarized in Section 6.7 of the IUCLID file and the main points are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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) | STERIGENE IPA  (propan-2-ol, 64.7% w/w) | Bacteria  *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 | Effective concentration:  *P. aeruginosa*: 40% v/v  *E. coli*: 40% v/v  *S. aureus*: 80% v/v  *E. hirae*: 80% v/v  **Bactericidal**  **concentration: 80% v/v** | S6.7\_01  Carre A. and  Strohl P.,  2016  RI=1 |
| Yeasticide | Industrial clean rooms (indoors) | STERIGENE IPA  (propan-2-ol, 64.7% w/w) | Yeast  *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 | Effective concentration:  *C. albicans*: 80% v/v  **Yeasticidal concentration:**  **80% v/v** | S6.7\_02  Carre A. and  Strohl P.,  2016  RI=1 |
| Fungicide | Industrial clean rooms (indoors) | STERIGENE IPA  (propan-2-ol, 64.7% w/w) | Mold  *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 | **No effective concentration.** | S6.7\_03  Carre A. and  Strohl P.,  2016  RI=1 |
| Bactericide | Industrial clean rooms (indoors) | STERIGENE IPA  (propan-2-ol, 64.7% w/w) | Bacteria  *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 conditions  Concentration tested: 100% v/v | R (logarithmic reduction of the viable cells number, efficacy threshold R > 4):  *P. aeruginosa*: > 6.35  *E. coli*: > 6.26  *S. aureus*: > 6.81  *E. hirae*: > 6.51  **Bactericidal**  **concentration: 100% v/v** | S6.7\_04  Carre A. and  Strohl P.,  2016  RI=1 |
| Fungicide | Industrial clean rooms (indoors) | STERIGENE IPA  (propan-2-ol, 64.7% w/w) | Fungi  *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) | R (logarithmic reduction of the viable cells number, efficacy threshold R > 3):  *C. albicans*: > 5.90  *A. brasiliensis*: 3.44  **Fungicidal concentration:**  **100% v/v** | S6.7\_05  Carre A. and  Strohl P.,  2016  RI=1 |

These trials show that the product STERIGENE IPA is an effective disinfectant against bacteria, yeasts and fungi when applied on non-porous surfaces. The product has been tested in conditions representative of industrial uses, with clean conditions or even no soiling, since the product is to be used in clean rooms only.

The product has been tested with phase 2, step 1 (EN 1276 and EN 1650) and phase 2, step 2 (EN 13697) tests. In the absence of phase 2 step 2 standards for the mopping application, the EN 13697 standard is acceptable for both types of application, spraying and mopping.

STERIGENE IPA passed all the standards with 5 minutes of contact 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 (May 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".* Against bacteria and yeasts, STERIGENE IPA is effective to disinfect clean surfaces, within 5 minutes of contact, at 20 °C.

Against fungi, STERIGENE IPA is effective to disinfect surfaces only inside clean rooms, within 5 minutes of contact.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product STERIGENE IPA, ready to use, has shown a sufficient efficacy, for the following use:   * By spraying and mopping for the disinfection (bacteria, yeasts and fungi) of hard surfaces in industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C), at 20 °C, with a contact time of 5 minutes. |

#### 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 where 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.

The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the ready to use product STERIGENE IPA showed a sufficient efficacy, for the disinfection (bacteria, yeasts and fungi) of industrial clean rooms (ISO 14644-1 in class 1 to 8, GMP EU in grade A to C), by spraying and mopping of hard surfaces, at 20 °C, with a contact time of 5 minutes.

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)

The product STERIGENE IPA is not intended to be used with another biocidal product.

### Risk assessment for human health

The product STERIGENE IPA is a ready-to-use disinfectant containing 70% v/v (equivalent to 64.7% w/w) propan-2-ol, and intended to be used in industrial clean rooms to disinfect surfaces. It can be used on walls, benches and equipment. These treatments are done by professionals by spraying (trigger spray) and mopping. The product is applied indoors at the dose of 40 mL product/m2.

#### Assessment of effects on Human Health

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on STERIGENE 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 STERIGENE IPA.  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 STERIGENE IPA.  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 the product. |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | - |
| Justification for the value/conclusion | The content of a.s classified H319 is higher thant 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 STERIGENE IPA.  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 STERIGENE IPA.  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 STERIGENE IPA.  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 STERIGENE IPA.  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 STERIGENE IPA.  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 STERIGENE IPA.  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 dilutions contains > 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 STERIGENE IPA. |

*]*

***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, STERIGENE IPA 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 | n.a | n.a |
| Dermal | n.a | yes | n.a | n.a | no | n.a | n.a |
| Oral | n.a | no | n.a | n.a | no | n.a | n.a |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | Spray application | **Primary exposure – Dermal and inhalation (aerosols + evaporation) exposure**  The product is sprayed on small surfaces and equipment using a trigger spray leading to dermal and inhalation (aerosols) exposure during application.  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product | Professionals |
| 2. | Mopping application | **Primary exposure – Dermal and inhalation (evaporation) exposure**  The product is loaded into a bucket and applied by mopping on the floor.  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product | Professionals |
| 3. | 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] – Primary exposure during spray application (using a trigger spray)*

| **Description of Scenario [1] – Dermal and inhalation (aerosols) exposure during spraying** | | | |
| --- | --- | --- | --- |
| The products are applied by indoors spraying to a small surface to disinfect it using a trigger spray.  After spraying, the surfaces are let dry, no wiping phase is necessary.  To assess the exposure during the spray application with a trigger spray, the ”Consumer Spraying and Dusting model 2 (hand held trigger spray)” from the TNsG 2008 has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure values from the model are as follows:   * 36.1 mg/min (hands/forearms); * 9.7 mg/min (feet/legs/face); * 10.5 mg/m3 (inhalation). | | | |
|  | **Parameters1** | **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 |
| 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.

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

| **Description of Scenario [1] – Inhalation exposure (evaporation) to volatilized residues during spraying** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during spraying has been assessed using ConsExpo web and the model for disinfectant (spraying).  The application rate claimed by the applicant for application with a trigger spray or an aerosol is 40 mL/m2.  Considering a density of 0.875 and a treated surface of **5m2**, the amount of product deposited on the treated surface is of **175g** (40 mL/m2 x 0.875 x 5 m2 = 175g).  An exposure duration of **30 min** is considered for the application by spraying.  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) | 30 | Time duration for spraying |
| 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) |

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.

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

**Calculations for Scenario [1]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (aerosols) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] | Tier 1/no PPE | 7.66 x 10-2 | 4.01 | 12.0 | 16.08 |
| Scenario [1] | Tier 1/PPE (Gloves) | 7.66 x 10-2 | 1.16 | 12.0 | 13.24 |
| Scenario [1] | Tier 1/PPE (Gloves + RPE) | 7.66 x 10-3 | 1.16 | 12.0 | 2.37 |

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

None

*Scenario [2] – Primary exposure during application by mopping*

| **Description of Scenario [2] – Demal exposure during mopping** | | | | |
| --- | --- | --- | --- | --- |
| The product (bottle of 5L) is loaded into a bucket in order to be applied on the floor by mopping.  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.  A time duration of 5 min for mopping of small rooms (10 m2) is considered.  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). | | | | |
|  | **Parameters1** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 5 | 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 |

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.

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

| **Description of Scenario [2] – Inhalation exposure (evaporation) to volatilized residues during spraying** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during spraying has been assessed using ConsExpo web and the model for disinfectant (spraying).  The application rate claimed by the applicant for application by mopping is 40 mL/m2.  Considering a density of 0.875 and a treated surface of **10m2**, the amount of product deposited on the treated surface is of **350g** (40 mL/m2 x 0.875 x 10 m2 = 350g).  During UA discussions for wipping application a duration of 10 min was set. According to HeadHoc recommendation 2, mopping duration is half the suration of wipping.  So an exposure duration of **5 min** is considered for the application by mopping.  For the other parameters, ConsExpo default values have benn kept. | | | |
|  | **Parameters1** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 5 | UA discussions |
| Release area (m2) | 10 | 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) |
| **Tier 2** | Respiratory penetration factor | 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.

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

**Calculations for Scenario [2]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (aerosols) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [2] | Tier 1/no PPE | - | 16.3 | 10 | 26.30 |
| Scenario [2] | Tier 1/PPE (Gloves) | - | 1.29 | 10 | 11.29 |
| Scenario [2] | Tier 1/PPE (Gloves + RPE) | - | 1.29 | x 10-1 | 2.29 |

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

None.

*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 mopping phase. Therefore, a combined scenario has been envisaged.  Dermal exposure during the application has already been estimated in scenario 2 presented above.  The exposure to vapor during **spraying and mopping** has been assessed using ConsExpo web and the model for disinfectant (wiping).  The application rate of 40 mL/m2 has been taken into account.  Considering a density of 0.875 and a treated surface of **15m2** (5m2 for surfaces and 10m2 for soil), the amount of product deposited on the treated surface is of **525g** (40 mL/m2 x 0.875 x 15 m2 = 525g).  An exposure duration of **35 min** is considered (30 min for spraying +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) | 35 | Spraying + 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 |
| Respiratory penetration factor (APF) | 10 | HEEG Opinion 9 |

**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)** |
| **[1,2]** | Tier 1/no PPE | 20.4 | 37 | 57.4 |
| **[1,2]** | Tier 2/PPE (Gloves) | 2.53 | 37 | 39.53 |
| **[1,2]** | Tier 2/PPE (Gloves + RPE) | 2.46 | 3.7 | 6.16 |

***Non-professional exposure***

Not applicable.

***Secondary exposure***

*Scenario [4] – Secondary inhalation exposure to volatilized residues*

| **Description of Scenario [4]** |
| --- |
| The STERIGENE IPA biocidal product is intended to be used for the disinfection of surfaces in industrial clean rooms. It can be used on walls, benches and equipment.  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.  Therefore, the same parameters used in combined exposure scenario have been applied leading to similar exposure to volatilzed residues for an adult entering a room with freshly treated surfaces.  For details please refer to the combined exposure scenario. |

**Calculations for Scenario [4]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (evaporation)uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [4] | Tier 1/no PPE | 37 | - | - | 37 |

**Further information and considerations on scenario [4]**

None.

***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 | Tier 1/no PPE | 16.1 |
| Tier 2/ PPE (Gloves) | 13.2 |
| Tier 2/ PPE (Gloves + RPE) | 2.37 |
| **[2]** | Professionals | Tier 1/no PPE | 26.3 |
| Tier 2/ PPE (Gloves) | 11.3 |
| Tier 2/ PPE (Gloves + RPE) | 2.29 |
| **[3]** | Bystanders | Tier 1/no PPE | 37 |
| **[1,2]** | Professionals | Tier 1/no PPE | 57.4 |
| Tier 2/ PPE (Gloves) | 39.5 |
| Tier 2/ PPE (Gloves + RPE) | 6.16 |

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AEL short, medium and long-term  (General population) | Inhalation, Human volonteer study | 200 ppm or 68.2 mg/kg bw/d | 6.4 | 100% | 10.7 mg/kg bw/d |
| AEL short,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 |

\* 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]** | Tier 1/no PPE | 17.9 | 16.08 | 89.9% | Yes |
| Tier 2/PPE (gloves) | 17.9 | 13.24 | 74.0% | Yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 2.37 | 13.3% | Yes |
| **Scenario [2]** | Tier 1/no PPE | 17.9 | 26.30 | 146.9% | **no** |
| Tier 2/PPE (gloves) | 17.9 | 11.29 | 63.1% | Yes |
| Tier 2/PPE (gloves + RPE) | 17.9 | 2.29 | 12.8% | Yes |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **[1,2]** | Tier 1/no PPE | 17.9 | 57.38 | **320.6%** | **no** |
| Tier 2/PPE (Gloves) | 17.9 | 39.53 | **220.9%** | **no** |
| Tier 2/PPE (Gloves + RPE) | 17.9 | 6.16 | **34.4%** | 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 10 and 60 vol/h).

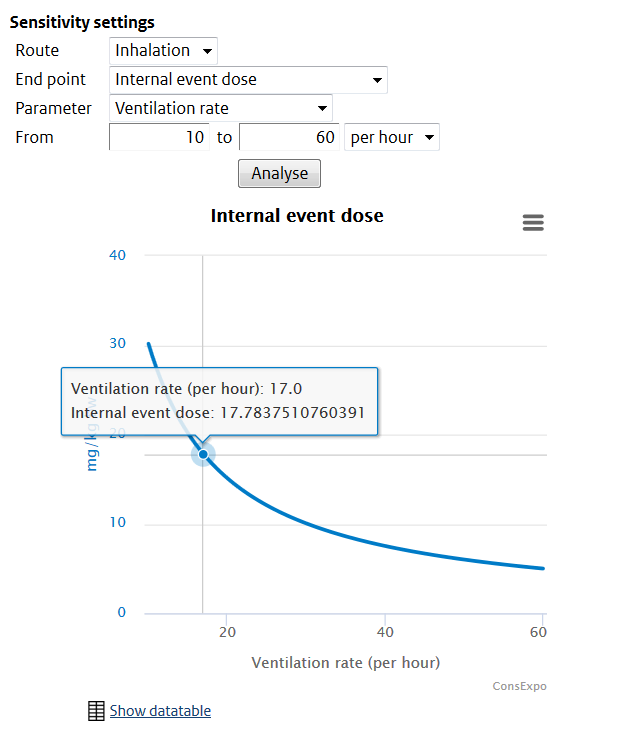
The ventilation rate being the parameter that can influence the risk assessment by triggering the wear of RPE for professional users and a re-entry period, a specific evaluation has been performed.

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 + 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] (see p 38) the following results are obtained:



As presented in the graph above, a ventilation rate of 17 vol/h is necessary to reach an internal dose of 17.78 g/kg bw/d. Taking this into account, it is considered that the risk is acceptable for professionals:

* With gloves and RPE (with APF of 10) in a room with a ventilation rate < 17 vol/h; or
* With gloves only in a room with a ventilation rate ≥ 17 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 realised.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | | Risk |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Eye Irri 2 | - | 2 | Professional | Spraying downward 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 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 (spraying + mopping), the risk is considered acceptable for professionals:

* With gloves and RPE (with APF of 10) in a room with a ventilation rate < 17 vol/h; or
* With gloves only in a room with a ventilation rate ≥ 17 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***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 | 37 | 207 | **No** |
| Scenario [4] bystander | Tier 2 with an RPE | 17.9 | 3.7 | 20.7 | Yes |

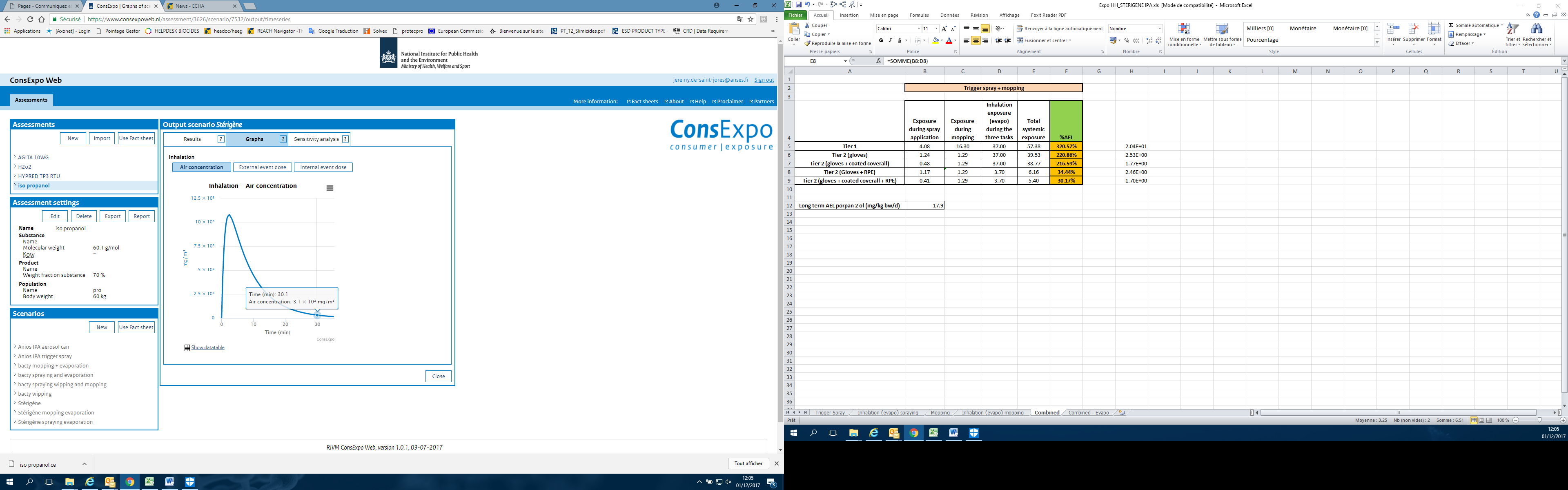
Exposure is not acceptable for another worker present during the application unless he wears the same level of RPE as the applicator.

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 30 min, the product air concentration is considerably decreased and is of 310 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 ≥ 17 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. It is then assumed that, after 30 min, the concentration of propan-2-ol in the air is below the OEL leading to an acceptable risk. It is therefore recommended to not enter the room during the application of the product (corresponding to 35 minutes (spraying + mopping)) for rooms with a ventilation rate < 17 vol/h.

For rooms with a ventilation rate ≥ 17 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 < 17 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 characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

Not relevant.

### Risk assessment for animal health

Not applicable.

### Risk assessment for the environment

|  |
| --- |
| **Box 1- FR CA position :**    Please notice that the environmental exposure assessment (section 2.8.4) 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 product Sterigene IPA is a ready-to-use disinfectant containing 64.7% w/w (70% v/v) 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 product Sterigene IPA. As the product is an aqueous solution containing 70% v/v of propan-2-ol, 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 Table 2.2.8.1-1 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 product Sterigene IPA is 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 product Sterigene IPA is 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 product Sterigene IPA is deemed necessary. |

***Further Ecotoxicological studies***

No data is available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Further ecotoxicological studies. |
| Justification | The product Sterigene IPA is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed or mopped on the surfaces to disinfect and is left for drying (non-rinse off product). |
| No emission into the aquatic and the terrestrial compartments is foreseen following the use of the product |
| Sterigene IPA. The risk of exposure of non-target organisms is negligible when using the product 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% v/v propan-2-ol aqueous solution. |
| Thus, no additional aquatic and terrestrial ecotoxicological study with the product |
|  | Sterigene IPA 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 product Sterigene IPA there is no concern regarding other specific non-target organisms like for instance, sediment dwelling organisms, aquatic macrophytes or brackish, estuarine or marine organisms. |
|  | No emission into the aquatic and the terrestrial compartments is foreseen following the use of the product |
|  | Sterigene IPA. The risk of exposure of non-target organisms is negligible when using the product 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% v/v propan-2-ol aqueous solution. |
|  | Thus no additional ecotoxicological study on other specific, non-target organisms with the product 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 product Sterigene IPA is a liquid. 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 product Sterigene IPA is a liquid. 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 product Sterigene IPA is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed or mopped on the surfaces to disinfect and is left for drying (non-rinse off product).  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 product Sterigene IPA. It can therefore be concluded that no secondary ecological effect is expected when using the product Sterigene IPA 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 product is extrapolated from the information on the active substance itself as it is a 70% v/v propan-2-ol aqueous solution.

The product Sterigene IPA is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed with a trigger spray or applied by mopping on the surfaces to disinfect and is left for drying (non-rinse off product).

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 product are expected to be negligible. The main emission pathway following the use of the product will be *via* the air.

Explanations for each environmental compartment are presented below.

**Atmospheric compartment**

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 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, according to the applicant, the quantity of product applied in a clean room is about 5 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.

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

Considering the indoor use of the product Sterigene IPA, direct emission of propan-2-ol into the surface water does not occur.

As explained above, the product Sterigene IPA is applied indoors on surfaces with a trigger spray or by mopping and is left for drying. The treated surfaces are not rinsed after application of the product and no cleaning with water is made 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, the mop and the Personal Protective Equipment (PPE) are disposable and are not washed.

Then, no emission into the STP and subsequent into surface water and sediment is expected when using the product Sterigene IPA according to the label recommendations.

**Terrestrial compartment (including groundwater)**

Considering the indoor use of the product Sterigene IPA, 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 mop and PPE).

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 product Sterigene IPA 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 behaviour 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% v/v propan-2-ol aqueous solution. |
| Therefore, it can be concluded that there is no need to conduct additional environmental studies with the product Sterigene IPA. |

***Leaching behaviour (ADS)***

Not relevant.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Leaching behaviour. |
| Justification | The product Sterigene IPA is a liquid intended to be applied indoor in industrial clean rooms on surfaces such as walls, benches and equipment. It is not intended to be used for the treatment of surfaces exposed to weathering. Therefore, leaching is not relevant for the product Sterigene IPA*.* |

***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% v/v 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 product Sterigene IPA. |
|  | 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% v/v 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 product Sterigene IPA. |
| 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 (5 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 product Sterigene IPA. |
| 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 product Sterigene IPA is 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 product Sterigene IPA. |

***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 product Sterigene IPA is intended to be applied indoors in industrial clean rooms on surfaces such as walls, benches and equipment. |

The product is not intended to be sprayed into the outdoor environment. Moreover, as the product is a liquid, 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 product STERIGENE IPA was conducted to address this point.

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| **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 product Sterigene IPA is a ready-to-use disinfectant containing 64.7% w/w (70% v/v) propan-2-ol. It is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed with a trigger spray or applied by mopping on the surfaces to disinfect and is left for drying (non-rinse off product).

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

**Atmospheric compartment**

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 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, according to the applicant, the quantity of product applied in a clean room is about 5 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.

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

Considering the indoor use of the product Sterigene IPA, direct emission of propan-2-ol into the surface water does not occur.

As explained above, the product Sterigene IPA is applied on surfaces with a trigger spray or by mopping and is left for drying. The treated surfaces are not rinsed after application of the product 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, the mop and the Personal Protective Equipment (PPE) are disposable and are not washed. Then, no emission into the STP and subsequent into surface water and sediment is expected when using the product Sterigene IPA according to the label recommendations.

**Terrestrial compartment (including groundwater)**

Considering the indoor use of the product Sterigene IPA, direct emission of propan-2-ol in 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 mop and PPE).

Indirect release to 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 product Sterigene IPA according to the label recommendations.

Regarding the air compartment, based on the indoor application of the product and the low volume applied per day (5 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 product Sterigene IPA according to the label recommendations.

Regarding the air compartment, considering the indoor application of the product and the low volume applied per day (5 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 product Sterigene IPA according to the label recommendations.

|  |
| --- |
| **Box 3- FR CA position :**  FR CA agrees with the applicant, according to the uses of STERIGENE IPA, no risk assessment for environment is needed as the product is applied in clean rooms (i.e. controlled atmosphere areas) where no wet cleaning or other releases are expected. |

***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 product Sterigne IPA. 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 product Sterigene IPA. Moreover, the product is 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 5 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 product Sterigene IPA 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 product Sterigene IPA is applied on surfaces with a trigger spray or by mopping and is left for drying. The treated surfaces are not rinsed after application of the product and there is no cleaning with water in clean rooms. 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, the mop and the personal protective equipment (PPE) 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 product Sterigene IPA (*i.e* a 70% w/w propan-2-ol aqueous solution, more concentrated in active substance than the product Sterigene IPA which is a 64.7% 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 product Sterigene IPA according to the label recommendations.

***Aquatic compartment***

As the product is 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 product after application, no use of water in clean rooms and use of disposable mop and PPE).

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 product Sterigene IPA (*i.e* a 70% w/w propan-2-ol aqueous solution more concentrated in active substance than the product Sterigene IPA which is a 64.7% 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 product Sterigene IPA according to the label recommendations.

***Terrestrial compartment***

Considering the indoor use of the product Sterigene IPA, 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 of the product after application, no use of water in clean rooms and mop and PPE disposable). 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.

Moreover, an environmental risk assessment with a product similar to the product Sterigene IPA (*i.e* a 70% w/w propan-2-ol aqueous solution more concentrated in active substance than the product Sterigene IPA which is a 64.7% 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 can be considered as negligible when using the product Sterigene IPA 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 product Sterigene IPA (*i.e* a 70% w/w propan-2-ol aqueous solution more concentrated in active substance than the product Sterigene IPA which is a 64.7% 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 when emissions to 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 product Sterigene IPA. 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 product Sterigene IPA. Moreover, the product is 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 product STERIGENE IPA, 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 product Sterigene IPA is a ready-to-use disinfectant containing 64.7% w/w (70% v/v) propan-2-ol. It is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed (trigger spray) or applied by mopping on the surfaces to disinfect and is left for drying (non-rinse off product).

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 (5 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 product Sterigene IPA.

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

An assessment of aggregated exposure is judged not relevant for the product Sterigene IPA 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**

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The product Sterigene IPA is a ready-to-use disinfectant containing 64.7% w/w (70% v/v) propan-2-ol. It is used in industrial clean rooms to disinfect surfaces such as walls, benches and equipment. The product is sprayed with a trigger spray or applied by mopping on the surfaces to disinfect and is left for drying (non-rinse off product).

According to the intended uses of the product Sterigene IPA, no emissions into the aquatic and the terrestrial compartments are foreseen. Emissions into the outdoor air are possible but are limited in quantity and in 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 product Sterigene IPA 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 product STERIGENE IPA 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

Not relevant.

### Assessment of a combination of biocidal products

Not relevant as the product is not intended to be used with other biocidal product.

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **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: Sterigene IPA  IRM, Report n°RE-180/0316-1  Unpublished | Yes | Sterigene | 2016.06.28 |
| 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: Sterigene IPA  IRM, Report n°RE-180/0316-3  Unpublished | Yes | Sterigene | 2016.06.28 |
| 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: Sterigene IPA  IRM, Report n°RE-180/0316-4  Unpublished | Yes | Sterigene | 2016.06.28 |
| 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  Sterigene IPA.  IRM, Report n°RE-180/0316-2  Unpublished | Yes | Sterigene | 2016.06.28 |
| 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  Sterigene IPA.  IRM, Report n°RE-180/0316-5  Unpublished | Yes | Sterigene | 2016.06.28 |

## Output tables from exposure assessment tools

None.

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## New information on the active substance

None.

## 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)[[3]](#footnote-3)

Not relevant (IUCLID file available).

## Confidential annex

Please refer to the Confidential annex file.

## Other

None.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Please delete as appropriate. [↑](#footnote-ref-2)
3. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-3)