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

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

(submitted by the evaluating Competent Authority)



**Christeyns’ Propan-1/2-ol Biocidal Product Family**

Product types 02-04

**Propan-1-ol (CAS N° 71-23-8)**

**Propan-2-ol (CAS N° 67-63-0)**

Case Number in R4BP: BC-MX051084-15

Evaluating Competent Authority: Belgium

Date : 03/12/2021**Table of Contents**

[History of the dossier (updated PAR 2023) 4](#_Toc127961115)

[1 CONCLUSION 4](#_Toc127961116)

[2 ASSESSMENT REPORT 6](#_Toc127961117)

[2.1 Summary of the product assessment 6](#_Toc127961118)

[2.1.1 Administrative information 6](#_Toc127961119)

[2.1.1.1 Identifier of the product family 6](#_Toc127961120)

[2.1.1.2 Authorisation holder 6](#_Toc127961121)

[2.1.1.3 Manufacturer(s) of the products of the family 7](#_Toc127961122)

[2.1.1.4 Manufacturer(s) of the active substance(s) 8](#_Toc127961123)

[2.1.2 Product family composition and formulation 9](#_Toc127961124)

[2.1.2.1 Identity of the active substances 9](#_Toc127961125)

[2.1.2.2 Candidate(s) for substitution 10](#_Toc127961126)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product family2 11](#_Toc127961127)

[2.1.2.4 Information on technical equivalence 11](#_Toc127961128)

[2.1.2.5 Information on the substance(s) of concern 11](#_Toc127961129)

[2.1.2.6 Type of formulation 11](#_Toc127961130)

[2.1.3 Hazard and precautionary statements 12](#_Toc127961131)

[2.1.4 Authorised use(s) 12](#_Toc127961132)

[2.1.4.1 Use description 12](#_Toc127961133)

[2.1.4.2 Use-specific instructions for use 23](#_Toc127961134)

[2.1.4.3 Use-specific risk mitigation measures 23](#_Toc127961135)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 26](#_Toc127961136)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 26](#_Toc127961137)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 26](#_Toc127961138)

[2.1.5 General directions for use 27](#_Toc127961139)

[2.1.5.1 Instructions for use 27](#_Toc127961140)

[2.1.5.2 Risk mitigation measures 27](#_Toc127961141)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 27](#_Toc127961142)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 28](#_Toc127961143)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 28](#_Toc127961144)

[2.1.6 Other information 28](#_Toc127961145)

[2.1.7 Packaging of the biocidal product 28](#_Toc127961146)

[2.1.8 Documentation 30](#_Toc127961147)

[2.1.8.1 Data submitted in relation to product application 30](#_Toc127961148)

[2.1.8.2 Access to documentation 30](#_Toc127961149)

[2.2 Assessment of the biocidal product family 31](#_Toc127961150)

[2.2.1 Intended use(s) as applied for by the applicant 31](#_Toc127961151)

[2.2.2 Physical, chemical and technical properties 32](#_Toc127961152)

[2.2.3 Physical hazards and respective characteristics 53](#_Toc127961153)

[2.2.4 Methods for detection and identification 60](#_Toc127961154)

[2.2.5 Efficacy against target organisms 67](#_Toc127961155)

[2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected) for the products of the family 67](#_Toc127961156)

[2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering 67](#_Toc127961157)

[2.2.5.3 Efficacy data 68](#_Toc127961158)

[2.2.5.4 Occurrence of resistance and resistance management 80](#_Toc127961159)

[2.2.5.5 Known limitations 80](#_Toc127961160)

[2.2.5.6 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 80](#_Toc127961161)

[2.2.6 Risk assessment for human health 81](#_Toc127961162)

[2.2.6.1 Assessment of effects on Human Health 81](#_Toc127961163)

[2.2.6.2 Exposure assessment 85](#_Toc127961164)

[2.2.6.3. Risk characterisation for human health 148](#_Toc127961165)

[2.2.7 Risk assessment for animal health 159](#_Toc127961166)

[2.2.8 Risk assessment for the environment 159](#_Toc127961167)

[2.2.8.1 Effects assessment on the environment 160](#_Toc127961168)

[2.2.8.2 Exposure assessment 165](#_Toc127961169)

[2.2.8.3 Risk characterisation 179](#_Toc127961170)

[2.2.9 Assessment of endocrine disrupting properties 185](#_Toc127961171)

[2.2.10 Measures to protect man, animals and the environment 186](#_Toc127961172)

[2.2.11 Assessment of a combination of biocidal products 187](#_Toc127961173)

[2.2.12 Comparative assessment 187](#_Toc127961174)

[3 Annexes 188](#_Toc127961175)

[3.1 List of studies for the biocidal product (family) 188](#_Toc127961176)

[3.2 Output tables from exposure assessment tools 188](#_Toc127961177)

[3.3 New information on the active substance 201](#_Toc127961178)

[3.4 Residue behaviour 201](#_Toc127961179)

[3.5 Summaries of the efficacy studies 201](#_Toc127961180)

[3.6 Confidential annex 201](#_Toc127961181)

[3.7 Other 201](#_Toc127961182)

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# History of the dossier (updated PAR 2023)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | BE | **BC-MX051084-15** | 20/01/2022 | First authorisation |
| NA-AAT | BE | **BC-XS084750-02** | 22/02/2023 | Amendments following MRS process |

# CONCLUSION

All the biocidal products within this family, divided into 4 Meta SPCs, do contain Propan-2-ol (CAS N° 67-63-0) & Propan-1-ol (CAS N° 71-23-8) as active substance, used at a concentration range 9.77 – 19.54 % w/w and 24.54 – 49.07 % w/w respectively.

All the biocidal products within this family are intended to be used indoors by professional and/or industrial users, according to the product and the intended use.

**Overall conclusion regarding physical, chemical and technical properties:**

Products in Meta SPC 1-4 are ready-to-use products. Meta SPC 1-3 are aqueous dilutions of propan-1-ol and propan-2-ol. Meta SPC 4 is wet wipes and the formulation of Meta SPC 3 is used as a liquid to impregnate the wet wipes.

The pH of all products are between 6.80 and 8.74. Their density is lower than 1 g/mL. Their surface tension varies between 24.6 and 25.6 mN/m. At 20°C, the viscosity is between 3.2 and 3.7 mm2/s and at 40°C it’s between 1.66 and 1.95 mm2/s

Based on the results of accelerated storage and the intermediate results (3 months) of long term storage at ambient temperature, it can be assumed that all products of Meta SPCs 1-3 should be still stable after 24 months in HDPE packaging. A shelf-life of 24 months is granted. The results of the long term storage at ambient temperature for Meta SPC 1-3 have to be evaluated during a post-authorization stage.

Moreover, the triggers sprayer packaging are claimed for the products in Meta SPCs 1-3. Therefore, the sprayability characteristics and particle size are investigated. These properties are adequately addressed.

The accelerated storage and long-term storage tests shows that the product in Meta SPC 4 is stable in different HDPE packaging except in plastic bag package (lost weight >10%). A shelf-life of 24 months is granted.

Storage conditions should include restrictions for all products in Meta SPCs 1-4 (“Protect from direct sunlight” and “Protect from frost”).

**Overall conclusion regarding physical hazards and respective characteristics:**

Regarding the assessment of physical hazards, it could be concluded that all Meta SPCs have to be classified as Flam. Liq. 3.

Implication concerning the labelling: H226 - Flammable liquid and vapour.

**Overall conclusion regarding methods of detection and identification:**

The provided GC-FID method is adequately validated for determination of the content of the propan-1-ol and propan-2-ol in the biocidal products in Meta SPCs 1-3. The liquid used to impregnate the wipes in Meta SPC 4 is the same as the liquid in Meta SPC 3 and therefore a specific, additional study on the analytical method for this liquid is not considered necessary.

Methods for monitoring residues in the environment are not required because residues are not expected. Methods for monitoring in food or feeding stuff are not available, and are also not considered to be required, taking into account the fact that no significant residues in food are to be expected according to the CARs of the active substances.

A residues test in rinse water was nevertheless conducted, and the amounts of residues were max. 2.9 g/kg 2-propanol and 7.1 g/kg 1-propanol in the first rinse water and max. 11 mg/kg 2-propanol and 25 mg/kg 1-propanol.

**Overall conclusion regarding efficacy:**

All the biocidal products within this family are intended to be used ***UNDILUTED*** as PT2 & PT4 hard/non-porous surface disinfectant via spraying, wiping or dipping disinfection procedures (with ***PRIOR*** cleaning):

* **META SPC 1** : related to product ***MIDA San 335 RV*** (50% dilution in water of ***MIDA San 311 KZ***) :

Active against bacteria & yeasts in 5 min contact time (PT2/PT4 via trigger or low-pressure spraying – PT4 via dipping).

* **META SPC 2** : related to product ***MIDA San 334 MF*** (70% dilution in water of ***MIDA San 311 KZ***) :

Active against bacteria & yeasts in 5 min contact time (PT2/PT4 via trigger or low-pressure spraying – PT4 via dipping).

* **META SPC 3** : related to product ***MIDA San 311 KZ :***

(PT2/PT4 via trigger or low-pressure spraying & dipping).

Active against bacteria, mycobacteria & yeasts : 5 min contact time

Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time

* **META SPC 4** : related to disinfection procedures by wiping with commercial pre-impregnated wipes (with undiluted product ***MIDA San 311 KZ***) or with a wipe/cloth dipped in a bucket containing the undiluted product ***MIDA San 311 KZ*** :

Active against bacteria, mycobacteria & yeasts : 5 min contact time

Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time

**It can be concluded that all products in the family are efficacious, when used in accordance with the use instructions mentioned above and proposed in the SPC.**

**Overall conclusion regarding human health:**

All the products in the family are classified as Eye Dam. 1 (H318), STOT SE 3 (H336) and EUH066.

The intended uses of the different products in Christeyns’ Propan-1/2-ol BPF do not pose an unacceptable risk to human health, when the directions of use and the required PPE are respected.

**Overall conclusion regarding residues:**

Exposure of the consumers could occur via transfer of residues on treated surfaces into food. However, due to the very high volatility of the active substances no significant residues are expected on surfaces or on food or feeding stuffs. It is therefore not considered necessary to assess exposure to the consumers.

**Overall conclusion regarding environment:**

No unacceptable effect to the environment is expected for the Christeyns’ Propan-1/2-ol BPF, neither for the STP, the aquatic compartment nor for the terrestrial compartment. No unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected. The threshold value was exceeded for groundwater, nevertheless, no unacceptable risk to the groundwater is expected based on expert judgement.

**Overall conclusion regarding endocrine disruptors:**

The assessment of the endocrine disrupting (ED) properties of the substances used in the biocidal product family Christeyns’ Propan-1/2-ol was performed according to the Regulation (EU) 528-2012 and Regulation (EU) 2017-2100. Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product family Christeyns’ Propan-1/2-ol.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| Christeyns’ Propan-1/2-ol BPF dossier | National Authorization with mutual recognitions in the European Union |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Christeyns N.V, |
| **Address** | Christeyns N.V., Afrikalaan 182, 9000 Gent, Belgium |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

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

|  |  |  |
| --- | --- | --- |
| **Name of manufacturer** | Christeyns N.V.  Christeyns s.r.o.  Christeyns France Food Hygiene sas  Betelgeux sl  Christeyns France sa  Christeyns Professional Hygiene srl  Christeyns UK Ltd.  Christeyns Food Hygiene Ltd.  Clover Chemicals Ltd. |  |
| **Address of manufacturer** | Christeyns N.V.: Afrikalaan 182, 9000 Gent, Belgium  Christeyns s.r.o.: Vítovská 453/7, 742 35 Odry, Czech Republic  Christeyns France Food Hygiene sas: ZA Les Farges, 24580 Rouffignac St. Cernin, France  Betelgeux sl: Poligono Industrial Raconc, Parcelas 2 y 3, CP 46729 Ador – Valencia, Spain  Christeyns France sa: 31 rue de la Maladrie, 44120 VERTOU, FRANCE  Christeyns Professional Hygiene srl.: Via Aldo Moro 30, 20060 Pessano conBornago, Italy  Christeyns UK Ltd.: Rutland Street, Bradford BD4 7EA, UK  Christeyns Food Hygiene Ltd.: 2 Cameron Court, Winwick Quay, Warrington, WA2 8RE, UK  Clover Chemicals Ltd. Clover House, Macclesfield Road, Whaley Bridge, High Peak. SK23 7DQ, UK |  |
| **Location of manufacturing sites** | Christeyns N.V.: Afrikalaan 182, 9000 Gent, Belgium  Christeyns s.r.o.: Vítovská 453/7, 742 35 Odry, Czech Republic  Christeyns France Food Hygiene sas: ZA Les Farges, 24580 Rouffignac St. Cernin, France  Betelgeux sl: Poligono Industrial Raconc, Parcelas 2 y 3, CP 46729 Ador – Valencia, Spain  Christeyns France sa: 31 rue de la Maladrie, 44120 VERTOU, FRANCE  Christeyns Professional Hygiene srl.: Via Aldo Moro 30, 20060 Pessano conBornago, Italy  Christeyns UK Ltd.: Rutland Street, Bradford BD4 7EA, UK  Christeyns Food Hygiene Ltd.: 2 Cameron Court, Winwick Quay, Warrington, WA2 8RE, UK  Clover Chemicals Ltd. Clover House, Macclesfield Road, Whaley Bridge, High Peak. SK23 7DQ, UK |  |

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

|  |  |
| --- | --- |
| **Active substance** | Propan-1-ol |
| **Name of manufacturer** | OQ Chemicals GmbH(Formerly OXEA GmbH)  Sasol Chemie GmbH & Co. KG |
| **Address of manufacturer** | OQ Chemicals GmbH **:** Otto-Roelen-Str. 3, 46147 Oberhausen, Germany.  Sasol Chemie GmbH & Co. KG, Anckelmannsplatz 1,  20537 Hamburg, Germany |
| **Location of manufacturing sites** | OQ Chemicals GmbH **:** Oxea corporation. 2001 FM 3057, Bay City, TX 77404 – USA (T.E. EU-0018321-0000 - TAP-D-1289063-14-00/F)  Secunda Chemical Operations, Sasol Place, 50 Katherine Street, Sandton 2090, South Africa |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Brenntag GmbH  Alcoholes Montplet S.A. |
| **Address of manufacturer** | Brenntag GmbH: Stinnes Platz 1, 45472 - Mülhelm an der Ruhr, Germany  Alcoholes Montplet S.A.: NOVAPEX, NOVACAP, Le Carré Joannès, 29 avenue Joannès Masset, CS 10619, 69258 Lyon Cedex 09, France. |
| **Location of manufacturing sites** | Via Brenntag GmbH:   * Shell Nederland Raffinaderij BV, Vondelingenweg 601, 3196 KK Rotterdam, Netherlands.” * Exxon Mobil, 4045 Scenic Hwy, Baton Rouge 70805 LA United States   Alcoholes Montplet S.A.: NOVAPEX, Rue Gaston Monmousseau, 38150 Salaise-sur-Sanne, France |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substances

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Isopropanol |
| **IUPAC or EC name** | Propan-2-ol |
| **EC number** | 200-661-7 |
| **CAS number** | 67-63-0 |
| **Index number in Annex VI of CLP** | 603-117-00-0 |
| **Minimum purity / content** | 99.0% |
| **Structural formula** | isopropanol |

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Propan-1-ol |
| **IUPAC or EC name** | Propan-1-ol |
| **EC number** | 200-746-9 |
| **CAS number** | 71-23-8 |
| **Index number in Annex VI of CLP** | 603-003-00-0 |
| **Minimum purity / content** | 99.5% w/w |
| **Structural formula** | propan-1-ol |

#### Candidate(s) for substitution

Not applicable: the active substances are not candidates for substitution*.*

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| n-propanol | Propan-1-ol | Active substance | 71-23-8 | 200-746-9 | 24.54 (TECH)  24.42 (PURE) | 49.07  (TECH)  48.82 (PURE) |
| Isopropanol | Propan-2-ol | Active substance | 67-63-0 | 200-661-7 | 9.77  (TECH)  9.67 (PURE) | 19.54  (TECH)  19.34 (PURE) |

#### 

#### Information on technical equivalence

The active substance suppliers are all listed on the Article 95 list. At the moment of submission of the BPR product dossier, there is confirmation from Oxea that their propan-1-ol and from Shell and Exxon that propan-2-ol (supplied via Brenntag) is technically equivalent.

Regarding Propan-1-ol, TE for Oxea:

Decision number: TAP-D-1289063-14-00/F

Asset number: EU-0018321-0000

Case number: BC-JS035760-24.

Regarding Propan-2-ol, TE for Brenntag GmbH

Decision number: TAP-D-1236889-07-00/F and TAP-D-1236892-12-00/F

Asset number: EU-0014505-0000 and EU-0014506-0000

Case number: BC-HN025225-42 and BC-LD025340-64

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

There are no substances of concern.

#### Type of formulation

|  |
| --- |
| AL – Other liquids to be applied undiluted (Meta SPC 1, 2 and 3)  XX – Other (Meta SPC 4) |

### Hazard and precautionary statements[[1]](#footnote-2)

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

**All Meta SPCs**

| **Classification** | |
| --- | --- |
| Hazard category | Flam. Liq. 3  Eye Dam. 1 H318  STOT SE 3 H336 |
| Hazard statement | H226 - Flammable liquid and vapour  H318 - Causes serious eye damage  H336 - May cause drowsiness or dizziness |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H226 - Flammable liquid and vapour  H318 - Causes serious eye damage  H336 - May cause drowsiness or dizziness |
| Supplemental hazard information | EUH066 - Repeated exposure may cause skin dryness or cracking |
| Precautionary statements | P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking  P261 - Avoid breathing spray and vapour  P271 - Use only outdoors or in a well-ventilated area.  P280 - Wear protective gloves/protective clothing/eye protection/face protection  P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  P310 - Immediately call a POISON CENTER or doctor/physician  P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  P501 - Dispose of contents/container in accordance with local/regional/national/international regulations |
|  | |
| Note |  |

### Authorised use(s)

#### Use description

**Meta SPC 1**

Table 1. Use 1.1 – PT2 Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors - Pharmaceutical industries, non-food industries  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying  After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 30 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 1 L flasks with separate trigger spraying device (HDPE)  5, 10, 22, 25 L refill cans (HDPE) |

Table 2. Use 1.2 – PT2 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning. |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 200 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 3. Use 1.3 – PT4 Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying : After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 30 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 1 L flasks with separate trigger spraying device (HDPE)  5, 10, 22, 25 L refill cans (HDPE) |

Table 4. Use 1.4 – PT4 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 200 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 5. Use 1.5 – PT4 Object Disinfection by dipping

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning |
| **Application method(s)** | Disinfection of instruments or equipment by means of dipping (entering objects in a pre-filled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

**Meta SPC 2**

Table 6. Use 2.1 – PT2 Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying : After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 30 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 1 L flasks with separate trigger spraying device (HDPE)  5, 10, 22, 25 L refill cans (HDPE) |

Table 7. Use 2.2 – PT2 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning. |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 200 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 8. Use 2.3 – Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying : After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 30 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 1 L flasks with separate trigger spraying device (HDPE)  5, 10, 22, 25 L refill cans (HDPE) |

Table 9. Use 2.4 – PT4 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Application rate: 200 ml / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 10. Use 2.5 –PT4 Object Disinfection by dipping

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Yeasts |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning |
| **Application method(s)** | Disinfection of instruments or equipment by means of dipping (entering objects in a pre-filled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed. |
| **Application rate(s) and frequency** | Active against bacteria & yeasts :  Ready-to-use  At Room Temperature  With 5 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

**Meta SPC 3**

Table 11. Use 3.1 – PT2 Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying : After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Application rate: 30 ml / m2  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 750 ml and 1 L flasks with separate trigger spraying device (HDPE), 5, 10, 22, 25 L refill cans (HDPE) |

Table 12. Use 3.2 – PT2 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning. |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Application rate: 200 ml / m2  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 13. Use 3.3 – PT4 Surface disinfection, trigger spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of small hard/non-porous surfaces by trigger spraying, with prior cleaning |
| **Application method(s)** | By trigger spraying : After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth. |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Application rate: 30 ml / m2  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 750 ml and 1 L flasks with separate trigger spraying device (HDPE). 5, 10, 22, 25 L refill cans (HDPE) |

Table 14. Use 3.4 – PT4 Surface disinfection, low-pressure spraying

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – In large-scale kitchens, restaurants, food industry:  Disinfection of hard/non-porous surfaces by low-pressure spraying, with prior cleaning |
| **Application method(s)** | By Low-pressure spraying : after low-pressure spraying, the product is left to dry but not wiped off. |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Application rate: 200 ml / m2  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE), 220 L vessels (HDPE)  1000 L IBCs (HDPE) |

Table 15. Use 3.5 – PT2 Object Disinfection by dipping

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of hard/non-porous surfaces (objects) by dipping, with prior cleaning |
| **Application method(s)** | Disinfection of instruments or equipment by means of dipping (entering objects in a pre-filled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed. |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE) |

Table 16. Use 3.6 – PT4 Object Disinfection by dipping

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organisms** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Disinfection of instruments or equipment by means of dipping (entering objects in a pre-filled bath) or filling (filling an empty bath, which already contains the objects). In both cases, objects are completely immersed. |
| **Application method(s)** | Dipping |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - Industrial |
| **Pack sizes and packaging material** | 5, 10, 22, 25 L cans (HDPE) |

**Meta SPC 4**

Table 17. Use 4.1 – PT2 Surface disinfection, wet wipes

|  |  |
| --- | --- |
| **Product Type** | PT2 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – Pharmaceutical industries, non-food industries  Disinfection of small hard/non-porous surfaces by wiping, with prior cleaning |
| **Application method(s)** | By wiping with commercial pre-impregnated wipes |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Surface disinfection: 1 wipe / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - industrial |
| **Pack sizes and packaging material** | 150 wipes/pack: opaque white 1L HDPE pack  800 wipes/bucket: opaque white 15L polypropylene bucket  1500 wipes/bucket: opaque white 15L polypropylene bucket |

Table 18. Use 4.2 – PT4 Surface disinfection, wet wipes

|  |  |
| --- | --- |
| **Product Type** | PT4 |
| **Where relevant, an exact description of the authorised use** | Not relevant |
| **Target organism (including development stage)** | Bacteria  Fungi  Yeasts  Mycobacteria  Viruses |
| **Field of use** | Indoors – In Kitchens, restaurants, food industry :  Disinfection of small hard/non-porous surfaces by wiping, with prior cleaning |
| **Application method(s)** | By wiping with commercial pre-impregnated wipes |
| **Application rate(s) and frequency** | Ready-to-use  At Room Temperature  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time  Surface disinfection: 1 wipe / m2  Frequency: 1 application per day |
| **Category(ies) of users** | Professional - industrial |
| **Pack sizes and packaging material** | 150 wipes/pack: opaque white 1L HDPE pack  800 wipes/bucket: opaque white 15L polypropylene bucket  1500 wipes/bucket: opaque white 15L polypropylene bucket |

#### Use-specific instructions for use

|  |
| --- |
| Please see general instructions for use. |

#### Use-specific risk mitigation measures

|  |
| --- |
| The following risk mitigation measures shall be applied unless they can be replaced by technical and/or organisational measures: Technical and organisational protection measures have to be considered by preference (personal protection measures shall not be permanent measures).  **Disinfection by trigger spraying**  **All room types:**   * Wear protective chemical resistant gloves during product handling phase. * Wear a face shield during product handling phase.   **Unspecified rooms (20m3) and small rooms (10m3):**   * Max 1 application per day. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 9 hours after treatment.   **Pharmaceutical and cosmetics manufacturing facilities:**   * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\*   **Kitchen and canteens:**   * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\*   **Disinfection by low-pressure spraying**  **All room types:**   * Wear protective chemical resistant gloves during product handling phase. * The use of eye protection (full face mask) during handling of the product is mandatory. * A protective coverall which is impermeable for the biocidal product shall be worn.   **Unspecified rooms (20m3):**   * Max 1 application per day for a maximum of 8 m2. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 12 hours after treatment.   **Small rooms (10m3):**   * Max 1 application per day for a maximum of 4 m2. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 12 hours after treatment.   **Cleanrooms:**   * Max 1 application per day for a maximum of 10 m2. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * A ventilation rate of 20/h required during application * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Laboratories and biotechnology:**   * Max 1 application per day for a maximum of 10 m2.   Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\*   * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Pharmaceutical and cosmetics manufacturing facilities:**   * Max 1 application per day for a maximum of 10 m2. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Institutional kitchens and canteens:**   * Max 1 application per day for a maximum of 10 m2. * Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during application. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).\* * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Industrial kitchens:**   * Max 1 application per day for a maximum of 10 m2. * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Industrial production rooms:**   * Max 1 application per day for a maximum of 10 m2. * Unprotected bystanders should not be present during application. * Leave room after treatment and do no re-enter before 1 hour after treatment.   **Disinfection by RTU wipes**  **All room types:**   * Wear protective chemical resistant gloves during product handling phase.   **Unspecified rooms (20m3) and small rooms (10m3):**   * Max 1 application per day * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 6 hours after treatment   **Disinfection by dipping**  **All room types:**   * Wear protective chemical resistant gloves during product handling phase. * Wear a face shield during product handling phase.   **Unspecified rooms (20m3):**   * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 1 hour after treatment.   **small rooms (10m3):**   * Unprotected bystanders should not be present during application. * Leave room after treatment & do not re-enter before 3 hours after treatment.   **\*** Organic vapor filter, combination filter, type A2/P2(RPE10) |

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

|  |
| --- |
| Disinfection by Dipping : The product can be safely flushed to the municipal sewer connected to a sewage treatment plant. |

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

|  |
| --- |
| Please see general directions for use. |

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

|  |
| --- |
| Please see general directions for use. |

### General directions for use

#### Instructions for use

|  |
| --- |
| - Disinfection procedures **by spraying, wiping or dipping** :  All the surfaces to be disinfected should be cleaned/rinsed/dried before the disinfection procedure : the user should thoroughly clean, rinse and drain the cleaning liquids from the surfaces to be disinfected.  - Disinfection cycle :  All the products must be used UNDILUTED.  Please refer to the description of application method related to each use to duly know the required CONTACT TIME and if a FINAL RINSE (with potable water) after disinfection is required.  - For the disinfection procedures **by trigger spraying** : Make sure to wet the surfaces completely, allow to take effect for the specified contact time.  After trigger spraying & required contact time achieved, the product may be wiped off with a tissue or cloth.  - For the disinfection procedures **using RTU pre-impregnated wipes** : Make sure to wet the surfaces completely, allow to take effect for the specified contact time.  - Disinfection procedures **by dipping** : The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily. |

#### Risk mitigation measures

|  |
| --- |
| Use in well ventilated areas.  Provide adequate ventilation before entering treated rooms.  Not for use in areas accessible for the general public.  Avoid contact with eyes. |

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

|  |
| --- |
| First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).  IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.  IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.  IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if  present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.  IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.  Most important symptoms and effects, both acute and delayed  Symptoms/injuries: Irritation of the respiratory tract and the other mucous membranes. Risk of serious damage to eyes. Vapours may cause drowsiness and dizziness.  Indication of any immediate medical attention and special treatment needed: Prompt action is critical.  Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters. |

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

|  |
| --- |
| Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or surface waters |

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

|  |
| --- |
| Technical measures:  Proper grounding procedures to avoid static electricity should be followed.  Storage conditions:  Keep only in the original container in a cool, well-ventilated place.  Avoid high temperatures.  Protect from direct sunlight.  Protect from frost.  Incompatible products:  Strong acids. Strong bases.  Shelf-life for all Meta SPCs: 2 years |

### Other information

|  |
| --- |
| The product contains Propan-2-ol, for which an AEC inhalation for the professional user was agreed and used for the risk assessment of the product. |

### 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)** |
| **Liquid** | | | | | |
| Trigger spray flasks | 750 mL | HDPE | HDPE | Professional | Yes |
| Trigger spray flasks | 1 litre | HDPE | HDPE | Professional | Yes |
| Cans | 5 litres | HDPE | HDPE | Professional | Yes |
| Cans | 10 litres | HDPE | HDPE | Professional | Yes |
| Cans | 22 litres | HDPE | HDPE | Professional - Industrial | Yes |
| Cans | 25 litres | HDPE | HDPE | Professional - Industrial | Yes |
| Vessels | 220 litres | HDPE | HDPE | Professional - Industrial | Yes |
| IBCs | 1000 litres | HDPE | HDPE | Professional - Industrial | Yes |
| **Wet wipes** | | | | | |
| Plastic bags | 150 wipes  Blue  100% Polypropylene  probe wipes | Opaque white HDPE pack of 1 L containing 150 wipes, height of ± 16 cm, diameter of ± 8 cm. | Closing with a white clipping cap. The cap contains a dispensing stopper of wipes. Sealing: plastic seal, heat sealed. | Professional | Yes |
| Buckets | 800 wipes  Blue  100% Polypropylene | Opaque white polypropylene bucket of  10 L. | Closing with a reclosable clip red cap. The cap contains a dispensing stopper of wipes. | Professional | Yes |
| Buckets | 1500 wipes  Blue  100% Polypropylene | Opaque white polypropylene bucket of  15 L. Height of ± 25.5 cm, diameter of ± 27 cm. | Closing with a reclosable clip red cap. The cap contains a dispensing stopper of wipes. | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

No new data on the product or on the active substances have been submitted.

#### Access to documentation

The applicant has submitted a letter of access to the dossiers on the active substances.

## Assessment of the biocidal product family

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

Please refer to Section 2.1.4: the intended uses as applied for by the applicant are the same as the authorised uses.

### 

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **BE remark** | |
| --- | --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual Observation | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | Homogeneous transparent liquid | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | Homogeneous transparent liquid | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | Homogeneous transparent liquid | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | Impregnated wipes: roll of 150 wipes soaked in solvent  Wrung out liquid: transparent liquid | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Colour at 20 °C and 101.3 kPa | Visual Observation | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | colourless | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | colourless | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | colourless | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Visual Observation | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | Impregnated wipes: blue  Wrung out liquid: light yellow | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Odour at 20 °C and 101.3 kPa | Sensory observation | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | Chemical odour (alcohol) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Sensory observation | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | Chemical odour (alcohol) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Sensory observation | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | Chemical odour (alcohol) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Sensory observation | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | Chemical odour | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| pH | CIPAC MT 75.3 | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | pH : 8.50 (at 23°C) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| CIPAC MT 75.3 | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | pH : 8.74 (at 23°C) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| CIPAC MT 75.3 | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | pH : 7.86 (at 23°C) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| CIPAC MT 75.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | pH of wrung liquid of the test item: 6.80 (at 20°C – 21°C) | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Acidity / alkalinity | According to the ECHA Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0 (May 2018), Section 3.6.2 Point 3.2 Acidity/alkalinity: Point 3.2 of Annex III of the BPR states that the test is applicable when the pH of the biocidal product or its dispersion in water (1%) is outside the pH range 4-10. The pH of the products in this Biocidal Product Family is not outside the pH range 4-10 and therefore, this test is not required. | | | | | Not applicable | |
| Density at 20°C | EEC A.3 | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | 0.9427 g/mL | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| EEC A.3 | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | 0.9127 g/mL | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| EEC A.3 | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 0.8676 g/mL | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| EEC A.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | 0.8719 g/mL | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Content AS:* Validated GC-FID method MET/25115  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3 | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | 14 days at 54°C in commercial type packaging:   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | 24.38% w/w | 24.18% w/w (-0.8%) | | Propan-2-ol content | 9.73% w/w | 9.67% w/w (-0.6%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE of 1L with separated hand held sprayer. Closing with a green screw cap. | No change  No significant pack weight change  (-0.3%) | | pH | 8.50 (at 23°C) | 8.55 (at 23°C) | | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Content AS:* Validated GC-FID method MET/25115  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3 | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | 14 days at 54°C in commercial type packaging:   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | 34.43% w/w | 33.97% w/w (-1.4%) | | Propan-2-ol content | 13.99% w/w | 14.10% w/w (+0.8%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE of 1L with separated hand held sprayer. Closing with a green screw cap. | No change except a small panelling but the bottle regains its original shape after returning at room temperature  No significant pack weight change  (-0.1%) | | pH | 8.74 (at 23°C) | 8.35 (at 23°C) | | De Ryckel B., 2020  Study N°25116  (Interim report) | The small panelling observed after the accelerated storage has a negligible impact on the results.  The test is considered as acceptable. | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  pH: CIPAC MT 75.3  *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 14 days at 54°C in 750 mL trigger spray flask (unsterilized):   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | 49.21% w/w | 49.31% w/w (+0.2%) | | Propan-2-ol content | 19.08% w/w | 19.05% w/w (-0.1%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Translucent white HDPE bottle of 750 mL with an held sprayer. Closing with a screw white plastic spout (trigger spray) | No change except a small panelling but the bottle regains its original shape after returning at room temperature  No significant pack weight change  (-0.1%) | | pH | 7.86 (at 23°C) | 7.93 (at 23°C) | | Blockage of nozzle | No | No | | Number of pressures necessaty to start the system | 2 | 2 | | Grams per discharge from the spray using the different of weight of the sprayer | 0.5g | 0.5g | | Grams per discharge from the spray using the amount of the test item sprayed in the flask | 0.51g | 0.51g | | Spray diameter | 16 cm (no splash) | 16 cm (no splash) | | De Ryckel B., 2020  Study N°25116  (Interim report) | The small panelling observed after the accelerated storage has a negligible impact on the results.  The test is considered as acceptable. | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3 | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 14 days at 54°C in 750 mL trigger spray flask (sterilized):   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | 49.65% w/w | 50.00% w/w (+0.7%) | | Propan-2-ol content | 19.26% w/w | 19.39% w/w (-0.7%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Translucent white HDPE bottle of 750 mL with an held sprayer. Closing with a screw white plastic spout (trigger spray) | No change  No significant pack weight change  (-0.1%) | | pH | 7.52 (at 23°C) | 7.58 (at 22°C) | | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3617001 | 14 days at 54°C in HDPE bottle 1L with separated hand held sprayer:   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | - | - | | Propan-2-ol content | - | - | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE bottle of 1L with separated hand held sprayer. Closing whit a screw white plastic spout (trigger spray) | No change  No significant pack weight change  (-0.2%) | | De Ryckel B., 2020  Study N°25116  (Interim report) | The study shows the evolution of HDPE bottle 1L after the accelerated storage.  The study is considered as a supporting data for the evaluation of Milda San 311 KZ. | |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3.2  *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Density:* EEC A.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | 14 days at 54°C in 150 wipes/pack:   |  |  |  | | --- | --- | --- | |  | Before | After | | Propan-1-ol content | 48.80% w/w | 48.23% w/w (-1.2%) | | Propan-2-ol content | 19.66% w/w | 19.52% w/w (-0.7%) | | Appearance of impregnated wipes | Roll of 150 wipes soaked in solvent | No change | | Appearance of wrung out liquid | Transparent light yellow liquid | No change | | Appearance of the commercial package | Opaque white HDPE pack of 1L containing 150 wipes. Closing with a white clipping cap. The cap contains a dispensing stopper of wipes. | No change  No significant pack weight change  (between -0.7% and -1.0%) | | pH of wrung liquid of the test item | 6.80 (at 20°-21°C) | 6.78 (at 20°-21°C) | | Density at 20°C | 0.8719 g/mL | 0.8694 g/mL | | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method MET/25115  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  Batch: RV004-8 | 3 months at 20°C in commercial type packaging (not used before storage):   |  |  |  | | --- | --- | --- | |  | Before | After 3 months | | Propan-1-ol content | 24.38% w/w | 24.46% w/w (+0.3%) | | Propan-2-ol content | 9.73% w/w | 9.60% w/w (-1.4%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE of 1L with separated hand held sprayer. Closing with a green screw cap | No change  No significant pack weight change  (-0.0%) | | pH | 8.50 (at 23°C) | 8.51 (at 20°C) | | Blockage of nozzle | No | No | | Number of pressures necessaty to start the system | 6 | 2 | | Grams per discharge from the spray using the different of weight of the sprayer | 0.9g | 1.1g | | Grams per discharge from the spray using the amount of the test item sprayed in the flask | 0.90g | 1.04g | | Spray diameter | 18 cm (no splash) | 19 cm (no splash) |   \*\* 12 and 24 months pending\*\* | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable  The results of the long term storage storage at ambient temperature for Meta SPC 1 have to be evaluated during a post-authorization stage. However, the results of the accelerated storage showed Meta SPC 1 was stable and a shelf-life of 2 years can be authorized. | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method MET/25115  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  Batch: MF002-8 | 3 months at 20°C in commercial type packaging (not used before storage):   |  |  |  | | --- | --- | --- | |  | Before | After 3 months | | Propan-1-ol content | 34.43% w/w | 34.12% w/w (-0.9%) | | Propan-2-ol content | 13.99% w/w | 13.90% w/w (-0.6%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE of 1L with separated hand held sprayer. Closing with a green screw cap | No change  No significant pack weight change  (-0.0%) | | pH | 8.74 (at 23°C) | 8.65 (at 20°C) | | Blockage of nozzle | No | No | | Number of pressures necessaty to start the system | 6 | 2 | | Grams per discharge from the spray using the different of weight of the sprayer | 1.0g | 1.1g | | Grams per discharge from the spray using the amount of the test item sprayed in the flask | 1.00g | 1.03g | | Spray diameter | 19 cm (no splash) | 19 cm (no splash) |   \*\* 12 and 24 months pending\*\* | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable  The results of the long term storage storage at ambient temperature for Meta SPC 2 have to be evaluated during a post-authorization stage. However, the results of the accelerated storage showed Meta SPC 2 was stable and a shelf-life of 2 years can be authorized. | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  pH: CIPAC MT 75.3  Relative density:  EEC A.3, OECD 109 | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 133025 MT | 12 months at 20°C in 150 wipes/pack:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | Before | After 3 months | After 6 months | After 9 months | After 12 months | | Propan-1-ol content | 49.3%  w/w | 49.3%  w/w  (-0.0%) | 48.6% w/w  (-1.4%) | 49.5% w/w  (+0.4%) | 49.0% w/w  (-0.6%) | | Propan-2-ol content | 19.8% w/w | 19.8% w/w  (-0.0%) | 19.9% w/w (+0.5%) | 20.4% w/w (+3.0%) | 18.7% w/w  (-5.6%) | | Appearance | Clear, non-viscous and colourless liquid | No change | No change | No change | No change | | Appearance of the original container | The test item containersconsisting of a white opaque 1L polyethylene screw-top, screw cap with ventillation and locking ring. | No change but the labelling faded, a few bottles were illegible.  No significant pack weight change  (-0.08%) | No change but the labelling faded, a few bottles were illegible.  No significant pack weight change  (-0.13%) | No change but the labelling faded, a few bottles were illegible.  No significant pack weight change  (-0.20%) | No change but the labelling faded, a few bottles were illegible.  No significant pack weight change  (-0.25%) | | pH at 20°C | 6.88 | 6.70 | 6.69 | 6.81 | 6.78 | | Relative density at 20°C | 0.8654 | 0.8654 | 0.8654 | 0.8654 | 0.8654 |   Note: The containers used for the stability study were not commercial containers, but samples prepared specifically for the stability study. The attached labels were also not commercial labels, but labels prepared by the lab.  The current commercial labelling setup has been in place since 2012 with no issues. After the many years of using this label setup, the only cause for these labels to fade has been direct sunlight over a period of months. This has always occurred when a customer has stored the products outside with no cover. This is against the storage recommendation described on the TDS. | Sperling T. 2016,  Study : S13-04199 | Data don’t be generated in a commercial packaging to support the ambient storage of Mida San 311 KZ for the claimed shelf-life.  The study is considered as a supporting data for the evaluation of Milda San 311 KZ.  However, the study S13-04199 shows that the light could have an impact on the legibility of the label.  “Protect from direct sunlight” will be added to the label for all products | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  pH: CIPAC MT 75.3  *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 3 months at 20°C in 750 mL trigger spray flask (unsterilized):   |  |  |  | | --- | --- | --- | |  | Before | After 3 months | | Propan-1-ol content | 49.21% w/w | 49.59% w/w (+0.8%) | | Propan-2-ol content | 19.08% w/w | 18.97% w/w (-0.6%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Translucent white HDPE bottle of 750 mL with an held sprayer. Closing with a screw white plastic spout (trigger spray) | No change  No significant pack weight change  (between -0.0% and -0.1%) | | pH | 7.86 (at 23°C) | 8.65 (at 20°C) | | Blockage of nozzle | No | No (already used)  No (not used before storage) | | Number of pressures necessaty to start the system | 2 | 2 (already used)  3 (not used before storage) | | Grams per discharge from the spray using the different of weight of the sprayer | 0.5g | 0.5g (already used)  0.6g (not used before storage) | | Grams per discharge from the spray using the amount of the test item sprayed in the flask | 0.51g | 0.51g (already used)  0.53g (not used before storage) | | Spray diameter | 16 cm (no splash) | 16 cm (no splash)  (already used)  17 cm (no splash)  (not used before storage) |   \*\* 12 and 24 months pending\*\* | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable  The results of the long term storage storage at ambient temperature for Meta SPC 3 have to be evaluated during a post-authorization stage. However, the results of the accelerated storage showed Meta SPC 3 was stable and a shelf-life of 2 years can be authorized. | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3 | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 3 months at 20°C in 750 mL trigger spray flask (sterilized):   |  |  |  | | --- | --- | --- | |  | Before | After 3 months | | Propan-1-ol content | 49.65% w/w | 49.93% w/w (+0.6%) | | Propan-2-ol content | 19.26% w/w | 19.11% w/w (-0.8%) | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Translucent white HDPE bottle of 750 mL with an held sprayer. Closing with a screw white plastic spout (trigger spray) | No change  No significant pack weight change  (-0.0%) | | pH | 7.52 (at 23°C) | 8.28 (at 20°C) |   \*\* 12 and 24 months pending\*\* | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable  The results of the long term storage storage at ambient temperature for Meta SPC 3 have to be evaluated during a post-authorization stage. However, the results of the accelerated storage showed Meta SPC 3 was stable and a shelf-life of 2 years can be authorized. | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 3616428 | 3 months at 20°C in HDPE bottle 1L with separated handheld sprayer (not used before storage):   |  |  |  | | --- | --- | --- | |  | Before | After 3 months | | Propan-1-ol content | - | 49.42% w/w | | Propan-2-ol content | - | 19.05% w/w | | Appearance of the test item | Homogeneous transparent uncoloured liquid | No change | | Appearance of the commercial package | Opaque white HDPE bottle of 1L with separated handheld sprayer. Closing with a screw white plastic spout (trigger spray) | No change  No significant pack weight change  (-0.0%) | | Blockage of nozzle | No | No | | Number of pressures necessaty to start the system | 3 | 1 | | Grams per discharge from the spray using the different of weight of the sprayer | 0.8g | 0.8 | | Grams per discharge from the spray using the amount of the test item sprayed in the flask | 0.80g | 0.81g | | Spray diameter | 38 cm (no splash) | 40 cm (no splash) |   \*\* 12 and 24 months pending\*\* | De Ryckel B., 2020  Study N°25116  (Interim report) | The study was amended by the applicant to determine the content of AS in Milda San 311 KZ after 3 months (HDPE bottle of 1L)  The study is considered as a supporting data for the evaluation of Milda San 311 KZ. | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Density:* EEC A.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 182328 GH | 24 months at 20°C in 150 wipes/pack:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Before | After 3 months | After 12 months | After 24 months | | Propan-1-ol content | 48.80% w/w | 47.98% w/w (-1.7%) | 47.33% w/w (-3.1%) | 48.72% w/w (-0.2%) | | Propan-2-ol content | 19.66% w/w | 19.40% w/w (-1.3%) | 19.31 w/w (-1.8%) | 19.04% w/w (-3.1%) | | Appearance of impregnated wipes | Roll of 150 wipes soaked in solvent | No change | No change | No change | | Appearance of wrung out liquid | Transparent light yellow liquid | No change | No change | No change | | Appearance of the commercial package | Opaque white HDPE pack of 1L containing 150 wipes. Closing with a white clipping cap. The cap contains a dispensing stopper of wipes. | No change  No significant pack weight change (between -0.7% and -1.0%) | No change  No significant pack weight change  (between -1.6% and - 1.9%) | No change  Significant pack weight change  (between -2.0% and – 2.8%) | | pH of wrung liquid of the test item | 6.80 (at 20-21°C) | 6.74 (at 21°C) | 6.59 (at 23°C) | 5.99 (at 21-22°C) | | Density at 20°C | 0.8719 g/mL | 0.8706 g/mL | 0.8703 g/mL | 0.8700 g/mL | | De Ryckel B., 2020  Study N°24815 | Acceptable | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Density:* EEC A.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 174229 | 24 months at 20°C in 400 wipes/pack:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Before | After 3 months | After 12 months | After 24 months | | Propan-1-ol content | 48.00% w/w | 48.44% w/w (+0.9%) | 49.24% w/w (+2.6%) | 50.17% w/w (+4.5%) | | Propan-2-ol content | 19.42% w/w | 19.42% w/w | 19.61% w/w (+1.0%) | 18.37% w/w (-5.4%) | | Appearance of impregnated wipes | Roll of 400 wipes soaked in solvent | No change | No change | No change | | Appearance of wrung out liquid | Transparent colourless liquid | No change | No change | No change | | Appearance of the commercial package | Opaque blue plastic bag of 3.5 kg containing 400 wipes. Closing with a reclosable clip blue cap. The cap contains a dispensing stopper of wipes. | No change  The cap is not watertight (very strong odour discernible)  No significant pack weight change  (-1.2%) | No change  The cap is not watertight (very strong odour discernible)  Significant pack weight change  (-5.8%) | No change  The cap is not watertight (very strong odour discernible)  Significant pack weight change  (-10.7%) | | pH of wrung liquid of the test item | 5.66 (at 23°C) | 5.54 (at 24°C) | 5.56 (at 21-22°C) | 5.53 (at 21-22°C) | | Density at 20°C | 0.8713 g/mL | 0.8712 g/mL | 0.8715 g/mL | 0.8698 g/mL |   Note: A significant pack weight change of maximum -10.7% occurred for the "400 wipes/plastic bag" package only. The packaging in plastic bags appeared to be not stable and will not be used for commercial purposes. | De Ryckel B., 2020  Study N°24700 | The results after 24 months at ambient temperature show that plastic bag is not appropriate for the wipes.  The **plastic bag** is not authorized for Meta SPC 4 (Mida San 311 KZ wipes). | |
| Storage stability test – **long term storage at ambient temperature** | *Content AS:* Validated GC-FID method (Study N°514-03895)  *Appearance of the test item:* Visual observation  *Appearance of packaging:* Visual observation  *pH:* CIPAC MT 75.3  *Density:* EEC A.3 | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54%  Batch: 181111GH | 24 months at 20°C in 1500 wipes/pack:   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | Before | After 3 months | After 12 months | After 24 months | | Propan-1-ol content | 47.76% w/w | 47.80% w/w (+0.1%) | 48.86% w/w (+2.3%) | 49.01% w/w (+2.6%) | | Propan-2-ol content | 19.37% w/w | 19.22% w/w (-0.8%) | 20.34% w/w (+5.0%) | 18.86% w/w (-2.7%) | | Appearance of impregnated wipes | Roll of 1500 wipes soaked in solvent | No change | No change | No change | | Appearance of wrung out liquid | Transparent slightly pink liquid | No change | No change | No change | | Appearance of the commercial package | Opaque white polypropylene bucket of 15L containing 1500 wipes. Closing with a reclosable clip red cap. The cap contains a dispensing stopper of wipes. | No change  No significant pack weight change  (-0.4%) | No change  No significant pack weight change  (-1.3%) | No change  Significant pack weight change  (-3.8%) | | pH of wrung liquid of the test item | 7.25 (at 22-23°C) | 6.97 (at 24-25°C) | 7.06 (at 21-22°C) | 7.01 (at 21-22°C) | | Density at 20°C | 0.8705 g/mL | 0.8697 g/mL | 0.8704 g/mL | 0.8709 g/mL | | De Ryckel B., 2020  Study N°24700 | Acceptable | |
| Storage stability test – **low temperature stability test for liquids** | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0, May 2018, Section 3.6.4.1.3 Point 3.4.1.3 Low temperature stability test (liquids): If the label gives clear instructions that the product must not be stored under conditions of ≤ 0°C (e.g. a phrase like ‘protect from frost’ on the label) then the low temperature storage does not need to be addressed.  It will be indicated on the labels that the products must be protected from frost. | | | | Acceptable  “Protect from frost” will be added to the label for all products | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | The products are packed in opaque, non-transparent HDPE containers. Furthermore, the active substances are not susceptible to photodegradation. And finally, the stability studies indicate that the active substances do not degrade for more than 10% during the stability studies. | | | | Acceptable  However, the study S13-04199 (please refer to the long term storage for META SPC 3) shows that the light could have an impact on the legibility of the label.  “Protect from direct sunlight” will be added to the label for all products | |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0, May 2018, Section 3.6.4.2 Point 3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product, Where relevant the effects of light, temperature and humidity must be investigated as part of the storage stability studies. Effects of temperature are already addressed by performing stability studies at accelerated and ambient temperatures described above in this Table.  Testing effects of humidity does not appear to be relevant for liquid products and wet wipes, as the products are liquids and contain water. Moreover, they are stored in closed containers. Any effects of humidity would be observed by changes in container weight, which are described in the stability studies conducted at room temperature and accelerated conditions. | | | | Acceptable | |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | Accelerated studies were conducted on all Meta SPC's, and indicated that the products are stable during 14 days at 54°C.  Long-term stability test at ambient temperature are performed for all Meta SPC's in the worst-case packagings, i.e. pre-filled trigger sprayer flasks. No significant changes in composition, density or appearance were observed during these tests so far. The worst-case packaging sizes were used for the studies: 750 ml (sterilized and non-sterilized) and 1 litre trigger sprayers. The material of the larger packagings is the same as that of the trigger sprayers (HDPE) and therefore the products are expected to show the same or a better stability profile in the larger packagings. So far there doesn’t appear to be a stability difference between sterilized and non-sterilized trigger sprayer flasks.  Real time stability studies on all products are still ongoing but results indicate that the products in trigger sprayers are stable for at least 1 year.  The results after 1 and 2 year on the wipes show a change in active substance content of maximum 5% and 5.4 % respectively, indicating that we can expect that the products are stable for 2 years. A significant pack weight change of maximum -10.7% occurred for the "400 wipes/plastic bag" package only. The packaging in plastic bags appeared to be not stable and will not be used for commercial purposes.  At the time of submission of the dossier the full results are not available, but the intermediate results indicate that the products will be stable for at least 2 years in any type of packaging. | | | | The results of the accelerated storage and the intermediate results of long-term storage show that all products are stable in different type of packaging.  A shelf-life of 2 years is granted for all products except for the plastic bag of Meta SPC 4 (Milda San 311 KZ wipes) | |
| Wettability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018), Section 3.6.5.1 Point 3.5.1 Wettability, Wettability is determined to ensure the preparation is readily wetted in use. The data are required for solid preparations which are to be dispersed in water. The products in this Biocidal Product Family are not solid preparations which are to be dispersed in water and therefore this test is not required. | | | | Not applicable | |
| Suspensibility, spontaneity and dispersion stability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.2 Point 3.5.2 Suspensibility, spontaneity and dispersion stability, applicability depends on the formulation type (nature) of the biocidal product. This test is required for wettable or water dispersible powders. The products in this Biocidal Product Family are not wettable or water dispersible powders and therefore this test is not required. | | | | Not applicable | |
| Wet sieve analysis and dry sieve test | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.3 Point 3.5.3 Wet sieve analysis and dry sieve test, applicability depends on the formulation type (nature) of the biocidal product. This test is required for wettable powders, suspension concentrates, capsule suspensions and water dispersible granules. The products in this Biocidal Product Family are not wettable powders, suspension concentrates, capsule suspensions or water dispersible granules and therefore this test is not required. | | | | Not applicable | |
| Emulsifiability, re-emulsifiability and emulsion stability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.4 Point 3.5.4 Emulsifiability, re-emulsifiability and emulsion  stability, applicability depends on the formulation type (nature) of the biocidal product.  This test is required for emulsions and suspo-emulsions. The products in this Biocidal Product Family are not emulsions or suspo-emulsions and therefore this test is not required. | | | | Not applicable | |
| Disintegration time | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.5 Point 3.5.5 Disintegration time, the disintegration time is applicable to all products that are tablets and depend on disintegration of the tablet in a solvent (water) for optimal efficacy. Applicable to ST (water soluble tablets) and WT (water dispersible tablets) formulations. The products in this Biocidal Product Family are not tablets and therefore this test is not required. | | | | Not applicable | |
| Content of dust/fines, attrition, friability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.6 Point 3.5.6 Particle size distribution, content of dust/fines  attrition, friability:  Dust  The dust content of solid preparations (granules and powders) must be determined. The products in this Biocidal Product Family are not powders or granules and therefore this test is not required.  Attrition, friability  These data are required to determine whether a granular material is robust under  normal conditions of use and transport. The products in this Biocidal Product Family are not powders or granules and therefore this test is not required. | | | | Not applicable | |
| Particle size distribution | Laser diffraction | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  (1 litre trigger spray flask) | |  |  | | --- | --- | | Parameter | Average of samples | | Dv(10), µm | 33.79 | | Dv(50), µm | 66.49 | | Dv(90), µm | 136.33 | | D[4,3], µm | 78.46 | | D[3.2], µm | 55.96 | | %V<50µm,% | 30.98 | | %V<10µm,% | 0.5 | | %V<5µm,% | 0.1 |   The average weight for the single actuation is 1.18g | Mazzei A. and Lunghi A. 2020  REPORT Nº RPT-SSC-200157 | Acceptable | |
| Laser diffraction | Meta SPC 2  MIDA SAN 334 MF  Batch: 2020-76NC  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  (1 litre trigger spray flask) | |  |  | | --- | --- | | Parameter | Average of samples | | Dv(10), µm | 32.58 | | Dv(50), µm | 59.12 | | Dv(90), µm | 106.79 | | D[4,3], µm | 67.03 | | D[3.2], µm | 51.58 | | %V<50µm,% | 35.37 | | %V<10µm,% | 0.47 | | %V<5µm,% | 0.10 |   The average weight for the single actuation is 1.15g | Mazzei A. and Lunghi A. 2020  REPORT N° RPT-SSC-200210 | Acceptable | |
| Laser diffraction | Meta SPC 3  Mida San 311 KZ  Batch: 3617001  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | 1 litre trigger spray flask   |  |  | | --- | --- | | Parameter | Average of samples | | Dv(10), µm | 28.98 | | Dv(50), µm | 53.88 | | Dv(90), µm | 99.92 | | D[4,3], µm | 61.22 | | D[3.2], µm | 46.37 | | %V<50µm,% | 44.37 | | %V<10µm,% | 0.14 | | %V<5µm,% | 0.056 |   The average weight for the single actuation is 0.841g  750 ml trigger spray flask   |  |  | | --- | --- | | Parameter | Average of samples | | Dv(10), µm | 46.17 | | Dv(50), µm | 91.96 | | Dv(90), µm | 213.41 | | D[4,3], µm | 113.49 | | D[3.2], µm | 77.75 | | %V<50µm,% | 13.45 | | %V<10µm,% | 0.27 | | %V<5µm,% | 0.017 |   The average weight for the single actuation is 0.54g  Note: In 1-litre trigger sprayers, the % particles smaller than 50 µm is 44% in meta SPC 3. The % particles smaller than 50 µm in the 750 ml trigger sprayer flask for meta SPC 3 was only 13%. So the particle size distribution not only depends on the product but also on the trigger sprayer. | Mazzei A. and Lunghi A. 2020  REPORT N° RPT-SSC-200563  And  Mazzei A. and Lunghi A. 2020  REPORT N° RPT-SSC-200785 | Acceptable | |
| / | Meta SPC 4  Mida San 311 KZ wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | Not applicable: wet wipes | / | Not applicable | |
| Persistent foaming | According to the ECHA Guidance on the Biocidal Products Regulation, Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C. Version 2.0 (May 2018), Section 3.6.5.7 Point 3.5.7 Persistent foaming: Applicability depends on the formulation type (nature) of the biocidal product. The data are required when the product is applied in water for use.  All products in this Biocidal Product Family are ready-to-use and should not be diluted with water. The test is therefore not required. | | | | Not applicable | |
| Flowability/Pourability/Dustability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.8 Point 3.5.8 Flowability / Pourability / Dustability, applicability depends on the formulation type (nature) of the biocidal product.  Flowability  Data are only required for granular formulations applied through application equipment  that would subject the granules to pressure and/or heat. The products in this Biocidal Product Family are not granules and therefore this test is not required.  Pourability (rinsability)  The data are required to demonstrate that the user can make use of the maximum  amount of the preparation and that an excessive amount of the material does not remain  in the container. The method is appropriate to suspension concentrates, capsule  suspensions and suspoemulsions. The products in this Biocidal Product Family are not suspension concentrates, capsule suspensions or suspoemulsions and therefore this test is not required.  Dustability  Data are required showing the preparation may be satisfactorily applied as a dust through the proposed application equipment and that there is no unacceptable compaction or caking following a heat test under pressure. The products in this Biocidal Product Family are not solid preparations and therefore this test is not required. | | | | Not applicable | |
| Burning rate — smoke generators | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.9 Point 3.5.9 Burning rate - smoke generators, evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness (see also sections 3.7.5.10 and 3.7.5.11  of this guidance) support the proposed use. The products in this Biocidal Product Family are not smoke generators and therefore this test is not required. | | | | Not applicable | |
| Burning completeness — smoke generators | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.10 Point 3.5.10 Burning completeness - smoke generators, burning completeness must be determined by weighing the preparation before and after use.  The products in this Biocidal Product Family are not smoke generators and therefore this test is not required. | | | | Not applicable | |
| Composition of smoke — smoke generators | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.5.11 Point 3.5.11 Composition of smoke - smoke generators, the smoke composition must be analysed for the concentration of the active substance  and decomposition products, if any, to guarantee that the produced smoke does indeed  contain the active substance and no decomposition products.  The products in this Biocidal Product Family are not smoke generators and therefore this test is not required. | | | | Not applicable | |
| Spraying pattern | *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77%  (1 litre trigger sprayer flask) | Blockage of nozzle : No  Number of pressures necessary to start the system : 6  Grams per discharge from the spray using the different of weight of the sprayer: 0.9g  Grams per discharge from the spray using the amount of the test item sprayed in the flask: 0.90g  Spray diameter: 18 cm (no splash) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68%  (1 litre trigger sprayer flask) | Blockage of nozzle : No  Number of pressures necessaty to start the system : 6  Grams per discharge from the spray using the different of weight of the sprayer: 1.0g  Grams per discharge from the spray using the amount of the test item sprayed in the flask: 1.00g  Spray diameter: 19 cm (no splash) | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| *Sprayability:* PA-U10-METSPRAY  *Spray diameter:* Internal method (30cm 1 spray actuation) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | 1L bottle  Blockage of nozzle : No  Number of pressures necessary to start the system : 3  Grams per discharge from the spray using the different of weight of the sprayer: 0.8g  Grams per discharge from the spray using the amount of the test item sprayed in the flask: 0.80g  Spray diameter: 38 cm (no splash)  750 mL bottle  Blockage of nozzle : No  Number of pressures necessary to start the system : 2  Grams per discharge from the spray using the different of weight of the sprayer: 0.5g  Grams per discharge from the spray using the amount of the test item sprayed in the flask: 0.50g  Spray diameter: 16 cm (no splash)  Note: The differences between 1L bottle and the 750mL bottle are explained by different types of trigger spray heads. | De Ryckel B., 2020  Study N°25116  (Interim report) | Acceptable | |
| */* | Meta SPC 4  Mida San 311 KZ wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | Not applicable: wet wipes | / | Not applicable | |
| Physical compatibility | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes).  For the products in this Biocidal Product Family there are no label recommendations made to co-apply the biocidal products with other substances, mixtures or biocidal or non-biocidal products and therefore this test is not required. | | | | Not applicable | |
| Chemical compatibility | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.6 Point 3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised, data to address the physical and chemical compatibility must be provided when label recommendations are made to co-apply the biocidal product with other substances, mixtures or biocidal or non-biocidal products (e.g. dyes).  For the products in this Biocidal Product Family there are no label recommendations made to co-apply the biocidal products with other substances, mixtures or biocidal or non-biocidal products and therefore this test is not required. | | | | Not applicable | |
| Degree of dissolution and dilution stability | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 3.6.7 Point 3.7 Degree of dissolution and dilution stability, applicability depends on the formulation type (nature) of the biocidal product. Degree of dissolution. The information is required for products used in a water-soluble bag and for all tablets.  The products in this Biocidal Product Family are not water-soluble bags or tablets and therefore this test is not required.  Dilution stability  The dilution stability is determined to ensure that water-soluble preparations dissolve readily and/or, when diluted, produce stable solutions without precipitation, flocculation,etc. The products in this Biocidal Product Family are not to be diluted with water and therefore this test is not required. | | | | Not applicable | |
| Surface tension | ASTM D1331  (ring method) | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77% | 25.6 mN/m | Laurent F., (2020)  Certificate of analysis  BEANTJ20105358-XX882833 | Acceptable | |
| ASTM D1331  (ring method) | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68% | 25.2 mN/m | Laurent F., (2020)  Certificate of analysis  BEANTJ20105358-XX882832 | Acceptable | |
| EC A.5, OECD 115  (harmonized ring method) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | 24.6 mN/m | Giorgio di Piano S. (2020)  Certificate of Analysis No. 003/18 – Laboratorio control | Acceptable | |
| / | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | The surface tension can’t be determined on wet wipes, for the liquid used to impregnate the wipes please refer to meta SPC 3 | / | Not applicable | |
| Viscosity | EN ISO 3104  (capillary viscometer) | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77% | Kinematic Viscosity is at:  20ºC: 3.206 mm2/s  40ºC: 1.655 mm2/s | Laurent F., (2020)  Certificate of analysis  BEANTJ20105358-XX882833 | Acceptable | |
| EN ISO 3104  (capillary viscometer) | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68% | Kinematic Viscosity is at:  20ºC: 3.661 mm2/s  40ºC: 1.905 mm2/s | Laurent F., (2020)  Certificate of analysis  BEANTJ20105358-XX882832 | Acceptable | |
| EN ISO 3104  (capillary viscometer) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | Kinematic Viscosity is at:  20ºC: 3.700 mm2/s  40ºC: 1.950 mm2/s | Kerhofs N., (2020)  Certificate of analysis  BEANTJ20105358-XX882834 | Acceptable | |
| / | Meta SPC 4  MIDA SAN 311 KZ Wipes  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | The viscosity can’t be determined on wet wipes, for the liquid used to impregnate the wipes please refer to meta SPC 3 | / | Not applicable | |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| **Meta SPC 1**  Mida San 335 RV (Meta SPC 1) is a ready-to-use product (AL). The product is a homogeneous transparent uncoloured liquid with a density at 20°c of 0.9427 g/mL and a surface tension of 25.6 mN/m. The pH of the pure product is 8.50 (at 23°C). It has a kinetic viscosity of 3.206 mm2/s (at 20°C) and 1.655 mm2/s (at 40°C).  Based on the results of accelerated storage and the intermediate results (3 months) of long term storage at ambient temperature studies, it can be assumed that Mida San 335 RV should be still stable after 24 months in HDPE packaging. A shelf-life of 24 months is granted for Mida San 335 RV. However, the data after 12 and 24 months have to be evaluated during a post-authorization stage.  With regard to product stability, no low temperature data are available, which is addressed by storage condition restrictions (“Protect from frost”). Another restriction is applied on the packaging (“Protect from direct sunlight”) based on the results from study S13-041199. Indeed, few bottles were illegible after 3 months in long term storage at ambient temperature.  All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  Shelf-life for Mida San 335 RV (Meta SPC 1): 24 months  **Meta SPC 2**  Mida San 334 MF (Meta SPC 2) is a ready-to-use product (AL). The product is a homogeneous transparent uncoloured liquid with a density at 20°c of 0.9127 g/mL and a surface tension of 25.2 mN/m. The pH of the pure product is 8.74 (at 23°C). It has a kinetic viscosity of 3.661 mm2/s (at 20°C) and 1.905 mm2/s (at 40°C).  Based on the results of accelerated storage and the intermediate results (3 months) of long-term storage at ambient temperature studies, it can be assumed that Mida San 334 MF should be still stable after 24 months in HDPE packaging. A shelf-life of 24 months is granted for Mida San 334 MF. However, the data after 12 and 24 months have to be evaluated during a post-authorization stage.  With regard to product stability, no low temperature data are available, which is addressed by storage condition restrictions (“Protect from frost”). Another restriction is applied on the packaging (“Protect from direct sunlight”) based on the results from study S13-041199. Indeed, few bottles were illegible after 3 months in long term storage at ambient temperature.  All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  Shelf-life for Mida San 334 MF (Meta SPC 2): 24 months  **Meta SPC 3**  Mida San 331 KZ (Meta SPC 3) is a ready-to-use product (AL). The product is a homogeneous transparent uncoloured liquid with a density at 20°c of 0.8676 g/mL and a surface tension of 24.6 mN/m. The pH of the pure product is 7.86 (at 23°C). It has a kinetic viscosity of 3.700mm2/s (at 20°C) and 1.950 mm2/s (at 40°C).  Based on the results of accelerated storage and the intermediate results (3 months) of long-term storage at ambient temperature studies, it can be assumed that Mida San 334 MF should be still stable after 24 months in HDPE packaging. A shelf-life of 24 months is granted for Mida San 334 MF. However, the data after 12 and 24 months have to be evaluated during a post-authorization stage.  With regards to product stability, no low temperature data are available, which is addressed by storage condition restrictions (“Protect from frost”). Another restriction is applied on the packaging (“Protect from direct sunlight”) based on the results from study S13-041199. Indeed, few bottles were illegible after 3 months in long term storage at ambient temperature.  The sprayability, spray diameter and MMAD were performed with 750 mL and 1L trigger sprayers. Some differences between the sprayers were observed and were explained by different types of trigger spray heads.  All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  Shelf-life for Mida San 311 KZ (Meta SPC 3): 24 months  **META SPC 4**  Mida San 311 KZ wipes (Meta SPC 4) is a ready-to-use product (AL). The wipes are impregnated with Mida San 311 KZ (Meta SPC 3). The wrung out liquid of the test item is a transparent light yellow liquid with a density at 20°c of 0.8719 g/mL. The pH of wrung liquid is 6.80 (at 20°C – 21°C).  The results of accelerated storage and long-term storage at ambient temperature studies showed that Mida San 311 KZ wipes was stable in HDPE packaging except in plastic bag package. Indeed, a significant pack weight change (-10.7%) was observed and the cap wasn’t watertight during the long-term storage at ambient temperature.  With regard to product stability, no low temperature data are available, which is addressed by storage condition restrictions (“Protect from frost”). Another restriction is applied on the packaging (“Protect from direct sunlight”) based on the results from study S13-041199. Indeed, few bottles were illegible after 3 months in long term storage at ambient temperature.  All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  Shelf-life for Mida San 311 KZ wipes (Meta SPC 4): 24 months |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **BE remark** |
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| Explosives | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.1 Point 4.1 Explosives, test according to UN Test series 1 to 3 (further test series 4 to 6 are necessary for classification) described in Part I of the UN-MTC is required.  There are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG ◄ , Manual of Tests and Criteria ; or (…)      None of the chemical groups listed within Tables A6.1 & A6.2 in Appendix 6 of the UN RTDG are applicable to IPA/n-propanol isomers. The test is therefore not required. | | | | Acceptable |
| Flammable gases | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.2 Point 4.2 Flammable gases  Criteria for flammable gases are described in the section 2.2 of Annex I to the CLP  Regulation, Test according to ISO 10156 and EN 1839.  The products in this Biocidal Product Family are not gases and therefore this test is not required. | | | | Not applicable |
| Flammable aerosols | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.3 Point 4.3 Flammable aerosols  Criteria for flammable aerosols are described in the section 2.36 of Annex I to the CLP Regulation. Test according to 75/324/EC amended by 2008/47/EC which are harmonised with UNMTC Section 31.  The products in this Biocidal Product Family are not aerosols and therefore this test is not required. | | | | Not applicable |
| Oxidising gases | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.4 Point 4.4 Oxidising gases  Criteria for oxidising gases are described in the section 2.4 of Annex I to the CLP  Regulation. Tests or calculation methods as described in ISO 10156 (Gases and gas mixtures. Determination of fire potential and oxidising ability for the selection of cylinder valve outlets) as amended should be performed.  The products in this Biocidal Product Family are not gases and therefore this test is not required. | | | | Not applicable |
| Gases under pressure | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.5 Point 4.5 Gases under pressure, Criteria for gases under pressure are described in the section 2.5 of Annex I to the CLP Regulation.  The products in this Biocidal Product Family are not gases and therefore this test is not required. | | | | Not applicable |
| Flammable liquids | ISO 2719:2002 (Pensky-Martens closed cup method) | Meta SPC 1  MIDA SAN 335 RV  Propan-1-ol: 24.54%  Propan-2-ol: 9.77% | 31ºC | Report n°  EHT19036/RWLExplosion Hazard Testing Limited, 2019. | Acceptable  Mida San 335 RV is classified as Flam Liq 3  H226: Flammable liquid and vapour |
| ISO 2719:2002 (Pensky-Martens closed cup method) | Meta SPC 2  MIDA SAN 334 MF  Propan-1-ol: 34.35%  Propan-2-ol: 13.68% | 29ºC | Report n°  EHT19036/RWLExplosion Hazard Testing Limited, 2019. | Acceptable  Mida San 334 MF is classified as Flam Liq 3  H226: Flammable liquid and vapour |
| ISO 13736:2008 (Abel closed cup method) | Meta SPC 3  Mida San 311 KZ  Propan-1-ol: 49.07%  Propan-2-ol: 19.54% | Mida San 311 KZ:  28.5ºC | Report n° EHT18151/RWL Explosion Hazard Testing Limited, 2018. | Acceptable  Mida San 311 KZ is classified as Flam Liq 3  H226: Flammable liquid and vapour |
| / | Meta SPC 4  Mida San 311 KZ wipes | The flash point can’t be determined on wet wipes, for the liquid used to impregnate the wipes please refer to meta SPC 3 | / | Acceptable  Mida San 311 KZ wipes is classified as Flam Liq 3  H226: Flammable liquid and vapour |
| Flammable solids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.7 Point 4.7 Flammable solids, Criteria for flammable solids are described in the section 2.7 of Annex I to the CLP. Regulation.  Test according to UN Test N.1 as described in Section 33.2.1 of the UN-MTC.  The products in meta SPC 1-3 of this Biocidal Product Family are not solids and therefore this test is not required. The classification of meta SPC 4 is based on the classification of the liquid used to impregnate the wipes in meta SPC 3. | | | | Not applicable |
| Self-reactive substances and mixtures | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.8 Point 4.8 Self-reactive substances and mixtures  Criteria for self-reactive substances and mixtures are described in the section 2.8 of  Annex I to the CLP Regulation.  The products in this Biocidal Product Family do not contain any self-reactive substances and there are also no chemical reactions between the ingredients or between the ingredients and air, and therefore this test is not required.  Under CLP Annex I 2.8.4 Additional Classification Considerations, Section 2.8.4.2 The classification procedures for self-reactive substances and mixtures need not be applied if:  (a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties. Examples of such groups are given in Tables A6.1 and A6.2 in Appendix 6 of the UN RTDG ◄ , Manual of Tests and Criteria ; or (…)      None of the chemical groups listed within Tables A6.1 & A6.2 in Appendix 6 of the UN RTDG are applicable to IPA/n-propanol isomers. The test is therefore not required. | | | | Acceptable |
| Pyrophoric liquids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.9 Point 4.9 Pyrophoric liquids, Criteria for pyrophoric liquids are described in the section 2.9 of Annex I to the CLP Regulation, a test according to UN Test N.3 as described in Section 33.3.1.5 of the UN-MTC should be conducted. However, according to the additional classification considerations in CLP Annex I, 2.9.4, the classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days)). From experience with manufacture and handling, it is known that the products in this BPF do not ignite spontaneously on coming into contact with air at normal temperatures. From the stability studies presented in this assessment report it is demonstrated that the liquids are stable at room temperature for prolonged periods of time (up to 24 months). | | | | Acceptable |
| Pyrophoric solids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.10 Point 4.10 Pyrophoric solids, Criteria for pyrophoric solids are described in the section 2.10 of Annex I to the CLP Regulation.  Test according to UN Test N.2 as described in Section 33.3.1.4 of the UN-MTC.  The products in meta SPC 1-3 of this Biocidal Product Family are not solids and therefore this test is not required. The classification of meta SPC 4 is based on the classification of the liquid used to impregnate the wipes in meta SPC 3. | | | | Not applicable |
| Self-heating substances and mixtures | According to the ECHA guidance on the Application of the CLP criteria Version 5.0 (July ’17) Section 2.11.4.2, The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore, liquids are not classified as self-heating. However, if liquids are adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered. The products in this BPF are not used to be adsorbed on large surfaces or solids, and therefore this test is not relevant and the products should not be classified for self-heating properties.  According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.5.3.1, the classification procedure for pyrophoric solids and liquids need not be applied when experience, in production or handling, shows that the substance does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time). The absence of self-heating properties of the products in this BPF is confirmed by experience in production and handling, and by stability studies. | | | | Acceptable |
| Substances and mixtures which in contact with water emit flammable gases | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.12 Point 4.12 Substances and mixtures which in contact with water emit flammable gases, Criteria for substances and mixtures which in contact with water emit flammable gases are described in section 2.12 of Annex I to the CLP Regulation. Test according to UN Test N.5 as described in Section 33.4.1.4 of the UN-MTC  The products in this Biocidal Product Family do not contain any substances which emit flammable gases in contact with water and therefore this test is not required. | | | | Acceptable |
| Oxidising liquids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.13 Point 4.13 Oxidising liquids, Criteria for oxidising liquids are described in the section 2.13 of Annex I to the CLP Regulation.  Test according to UN Test O.2 as described in Section 34.4.2 of the UN-MTC.  The products in this Biocidal Product Family do not contain any substances which are classified as oxidising liquids and therefore this test is not required.  Furthermore, experience in the handling of these products indicates that they are not oxidizing.  According to the UN Manual of Tests and Criteria, 7th revised edition (2019) Appendix 6, A6.6.1.1, for organic compounds the classification procedure need not be applied if the compound does not contain oxygen, fluorine or chlorine. Some constituents of the products do contain oxygen. However, oxygen is bound only to carbon or hydrogen and therefore a test is not required. | | | | Acceptable |
| Oxidising solids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.14 Point 4.14 Oxidising solids, Criteria for oxidising solids are described in the section 2.14 of Annex I to the CLP Regulation.  Test according to UN Test O.17 as described in Section 34.4.1 of the UN-MTC.  The products in meta SPC 1-3 of this Biocidal Product Family are not solids and therefore this test is not required. The classification of meta SPC 4 is based on the classification of the liquid used to impregnate the wipes in meta SPC 3. | | | | Not applicable |
| Organic peroxides | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.15 Point 4.15 Organic peroxides, Criteria for organic gases are described in the section 2.15 of Annex I to the CLP Regulation. Test according to UN Test series A to H as described in Section 28 of the UN-MTC.  The products in this Biocidal Product Family do not contain any substances which are classified as organic peroxides and therefore this test is not required. | | | | Acceptable |
| Corrosive to metals | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.16 Point 4.16 Corrosive to metals, Criteria for corrosive to metals are described in the section 2.16 of Annex I to the CLP Regulation.  Test according to UN Test C.1 as described in Section 37.4 of the UN-MTC.  The products contain only propan-1-ol, propan-2-ol and no other components that are classified as corrosive to metals, and fulfill all the requirements mentioned in the Technical Agreements for Biocides - APCP:  -halogen-free  -no acid  -no base  -no complexing agents  -pH-neutral  The components propan-1-ol and propan-2-ol show no functional groups which are associated with dissociation behaviour and are therefore not acid or base, and to be considered as pH neutral. The products are halogen-free and contain no complexing agents.  Based on these properties the products are not expected to be corrosive to metals and a test is not required. | | | | Acceptable |
| Auto-ignition temperatures of products (liquids and gases) | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17 Point 4.17 Additional physical indicators for hazards, 2.7.17.1 Point 4.17.1 Auto-ignition temperature (liquids and gases), The test procedure is applicable to gases, liquids and vapours which, in the presence of air, can be ignited by a hot surface.  The products in this Biocidal Product Family do not contain any pyrophoric liquids: the auto-ignition temperature of isopropanol is ca. 399°C, and the auto-ignition temperature of 1-propanol is 360°C. There are no other components in the mixtures with auto ignition properties. It can therefore be assumed that the products are not auto ignitable. | | | | Acceptable |
| Relative self-ignition temperature for solids | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17.2 Point 4.17.2 Relative self-ignition temperature for solids, Criteria for self-heating substances are described in Section 2.11 of Annex I to the CLP Regulation. Test according to UN Test N.4 as described in Section 33.3.1.6 of the UN-MTC.  The products in meta SPC 1-3 of this Biocidal Product Family are not solids and therefore this test is not required. The classification of meta SPC 4 is based on the classification of the liquid used to impregnate the wipes in meta SPC 3. | | | | Not applicable |
| Dust explosion hazard | According to the ECHA Guidance on the Biocidal Products Regulation Volume I: Identity of the active substance/physico-chemical properties/analytical methodology – Information Requirements, Evaluation and Assessment. Parts A+B+C, Version 2.0 (May 2018) Section 2.7.17.3 Point 4.17.3 Dust explosion hazard, A dust explosion hazard is applicable to all powders and products containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air (relevant for particulates up to 1 mm in diameter).  The products in this Biocidal Product Family are not powders or contain/produce powders and therefore this test is not required. | | | | Not applicable |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| **All Meta SPCs**  The products presented in the dossier have no explosive properties, they are not classified as oxidising liquids or organic peroxides, they are not corrosive to metals, have no self-heating properties, do not emit flammable gases in contact with water and are not pyrophoric or self-reactive. From experience with manufacturing, transportation and use, it is known that the products in this BPF have no physical hazards other than their flammability.  The flashpoints of the products are 31°C for Meta SPC 1, 29°C for Meta SPC 2 and 28.5°C for Meta SPC 3 and 4.  All product is classified as Flam Liq 3 according to CLP table 2.6.1. Therefore, H226 is assigned. |

### Methods for detection and identification

**Meta SPC 1 - Mida San 335 RV**

MET/25115 - analytical GC-FID method to develop and to validate by the test facility with validated GC-FID method supplied by the sponsor (Study N° S14-03895 of Eurofins) as general base.

Validation in compliance with Document SANCO/3030/99, rev.5, as general base.

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Precision** | **Reference** |
| Range | Mean | RSD |
| *Propan-2-ol* | GC-FID  Weigh about (to the nearest 0.1 mg) 500 mg of test item into a 50 mL volumetric flask. Add internal standard solution and fill up the volumetric flask to volume with internal standard solution, at 20°C ± 1°C. Mix thoroughly and inject in GC. | 4 fortification levels with 2 measurements (90%, 100% 140% and 154% of the nominal content) | Linear response between 5.02% - 50.16% w/w propan-1-ol  (0.5015 – 5.016 mg/mL)  6 levels, duplicate,  y= 1.4132x-0.0601  r2=0.9998  r=0.9999 | No interference.  The method is specific. | 90.2% - 103.0% | 99.1% | 4.64% | / | 6 samples determination  Mean of Propan-2-ol : 9.73% w/w  SD: 0.07  RSD: 0.76%  RSDr<RSD Horwitz x 0.67 (1.90%)  Horrat (Hr): 0.40 | Validation of an analytical method for determination of propan-1-ol and propan-2-ol in Mida San 334 MF and Mida San 335 RV.  (Study N°25115)  De Ryckel (2020) |
| *Propan-1-ol* | GC-FID  Weigh about (to the nearest 0.1 mg) 500 mg of test item into a 50 mL volumetric flask. Add internal standard solution and fill up the volumetric flask to volume with internal standard solution, at 20°C ± 1°C. Mix thoroughly and inject in GC. | 4 fortification levels with 2 measurements (90%, 100% 140% and 154% of the nominal content) | Linear response between 10.00% - 99.97% w/w propan-2-ol  (0.997 – 9.997 mg/mL)  6 levels, duplicate,  y= 1.1037x-0.0113  r2=1.0000  r=1.0000 | No interference.  The method is specific. | 94.5% - 101.8% | 98.8% | 2.64% | / | 6 samples determination  Mean of Propan-1-ol : 24.38% (w/w)  SD: 0.18  RSD: 0.72%  RSDr<RSD Horwitz x 0.67 (1.66%)  Horrat (Hr): 0.44 | Validation of an analytical method for determination of propan-1-ol and propan-2-ol in Mida San 334 MF and Mida San 335 RV.  (Study N°25115)  De Ryckel (2020) |
| **Meta SPC 2 - Mida San 334 MF**  MET/25115 - analytical GC-FID method to develop and to validate by the test facility with validated GC-FID method supplied by the sponsor (Study N° S14-03895 of Eurofins) as general base.  Validation in compliance with Document SANCO/3030/99, rev.5, as general base. | | | | | | | | | | |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Precision** | **Reference** |
| Range | Mean | RSD |
| *Propan-2-ol* | GC-FID  Weigh about (to the nearest 0.1 mg) 500 mg of test item into a 50 mL volumetric flask. Add internal standard solution and fill up the volumetric flask to volume with internal standard solution, at 20°C ± 1°C. Mix thoroughly and inject in GC. | 4 fortification levels with 2 measurements (64%, 71%, 100%, 110% of the nominal content) | Linear response between 5.02% - 50.16% w/w propan-2-ol  (0.5113 – 5.1135 mg/mL)  6 levels, duplicate,  y=1.3936x – 0.0398  r2=0.9999  r=0.9999 | No interference.  The method is specific. | 90.2% - 103.0% | 99.1% | 4.64% | / | 6 samples determination  Mean of Propan-2-ol : 13.99% (w/w)  SD: 0.20  RSD: 1.41%  RSDr<RSD Horwitz x 0.67 (1.80%)  Horrat (Hr): 0.78 | Validation of an analytical method for determination of propan-1-ol and propan-2-ol in Mida San 334 MF and Mida San 335 RV.  (Study N°25115)  De Ryckel (2020) |
| *Propan-1-ol* | GC-FID  Weigh about (to the nearest 0.1 mg) 500 mg of test item into a 50 mL volumetric flask. Add internal standard solution and fill up the volumetric flask to volume with internal standard solution, at 20°C ± 1°C. Mix thoroughly and inject in GC. | 4 fortification levels with 2 measurements (64%, 71%, 100%, 110% of the nominal content) | Linear response between 10.00% - 99.97% w/w propan-1-ol  (1.0208 – 10.2078 mg/mL)  6 levels, duplicate,  y=1.1052x -0.0102  r2=1.0000  r=1.0000 | No interference.  The method is specific. | 94.5% - 101.8% | 98.8% | 2.64% | / | 6 samples determination  Mean of Propan-1-ol : 34.43% (w/w)  SD: 0.47  RSD: 1.35%  RSDr<RSD Horwitz x 0.67 (1.57%)  Horrat (Hr): 0.86 | Validation of an analytical method for determination of propan-1-ol and propan-2-ol in Mida San 334 MF and Mida San 335 RV.  (Study N°25115)  De Ryckel (2020) |

**Meta SPC 3 - Mida San 311 KZ**

*Propan-2-ol and propan-1-ol were determined with a GC system and flame ionisation detection (FID). The method was validated with regard to specificity, linearity, precision and accuracy according to SANCO/3030/99 rev 4.*

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Precision** | **Reference** |
| Range | Mean | RSD |
| *Propan-2-ol* | GC-FID  About 100 mg of the test item were given into a 10 mL volumetric flask and the flask were filled up to the mark with the solvent. After mixing the solution was measured by GC-FID | 2 fortification levels with 5 measurements (50% and 150% of the nominal content) | Linear response between 5.05% - 50.55% w/w propan-2-ol  (507.1 - 5070.5 mg/L)  6 levels, duplicate,  y= 0.00042x – 0.01401  r: 0.9996 | No interference.  The method is specific. | 96.7% - 104% | 100.1% | 2% | 1010.7 mg/L | 5 samples determination  Mean of Propan-2-ol : 19.8% (w/w)  SD: 0.2  RSD: 1.0%  RSDr: 1.7% | Development and Validation of an Analytical Method for Determination of Isopropanol and Propan-1-ol in Mida San 311 (S14-03895)  P. Schaudt (2014) |
| *Propan-1-ol* | GC-FID  About 100 mg of the test item were given into a 10 mL volumetric flask and the flask were filled up to the mark with the solvent. After mixing the solution was measured by GC-FID | 2 fortification levels with 5 measurements (50% and 150% of the nominal content) | Linear response between 10.09% w/w and 100.89% w/w propan-1-ol (1013.4 - 10134 mg/L)  8 levels, duplicate,  y= 0.00052x-0.07185  r: 0.9998 | No interference.  The method is specific. | 99.6% - 103% | 101% | 0.9% | 2498.9 mg/L | 5 samples determination  Mean of Propan-1-ol : 49.3% (w/w)  SD: 0.5  RSD: 1.0%  RSDr: 1.5% | Development and Validation of an Analytical Method for Determination of Isopropanol and Propan-1-ol in Mida San 311 (S14-03895)  P. Schaudt (2014) |

**Meta SPC 4 - Mida San 311 KZ wipes**

The liquid used to impregnate the wipes in meta SPC4 is the same as the liquid in Meta SPC3 and therefore a specific, additional study on the analytical method for this liquid is not considered necessary.

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| **Analytical methods for monitoring** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Not required, no residues expected (see CAR 1-propanol[[2]](#footnote-3) and Propan-2-ol[[3]](#footnote-4)) | | | | | | | | | |

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| **Analytical methods for soil** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| No residues are expected (CAR 1-propanol[[4]](#footnote-5) and Propan-2-ol[[5]](#footnote-6)). | | | | | | | | | |

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| **Analytical methods for air** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Propan-1-ol* | GC-FID | - | - | - | - | - | - | 0.5 µg/m3 | CAR Propan-1-ol (Germany, 2017, p. 49) |
| *Propan-1-ol* | GC-MS | - | - | - | - | - | - | 1 µg/m3 | CAR Propan-1-ol (Germany, 2017, p. 49) |
| *Propan-2-ol* | GC-FID | - | - | - | - | - | - | 0.109 mg/m3 | CAR Propan-2-ol (Germany, 2015, p. 46) |

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| **Analytical methods for water** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Although no residues are expected (CAR 1-propanol[[6]](#footnote-7) and CAR Propan-2-ol[[7]](#footnote-8)), a test was performed with Mida San 311 KZ (worst-case product with the highest concentration of active substances) in rinse water which was collected after treating surfaces of different materials (stainless steel, glass and PVC[[8]](#footnote-9)). The method used was GC-MS, with a LOD of 2.4 mg/kg for both substances.  The average dose of disinfectant per m2 was 181 g on stainless steel, 195 g on glass and 123 g on plastic. The dosages in these tests are at a slightly lower rate than what is described in the used descriptions (200 g / m2), so the test is a worst-case approach. The products are normally applied on flat surfaces instead of beakers. For stainless steel and glass, the dosage was somewhat lower, but for plastic the dosage was significantly lower. This could be explained by the shape of the containers, or the surfaces itself. The residue in the first rinse water over all surfaces was max. 2.9 g/kg 2-propanol and 7.1 g/kg 1-propanol. Compared with the concentration in the product, this is a reduction of 66 and 69 times, respectively. In the second rinse water, the residues were max. 11 mg/kg 2-propanol and 25 mg/kg 1-propanol. | | | | | | | | | |

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| **Analytical methods for animal and human body fluids and tissues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| According to the assessment reports of the active substances, analytical methods for animal and human body fluids and tissues are not required, the active substances are not classified as toxic or very toxic (CAR 1-propanol[[9]](#footnote-10) and CAR Propan-2-ol[[10]](#footnote-11)). | | | | | | | | | |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| No residues are expected (CAR 1-propanol[[11]](#footnote-12) and CAR Propan-2-ol[[12]](#footnote-13)), therefore analytical methods for monitoring residues in food and feedingstuff are not required. | | | | | | | | | |

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| **Conclusion on the methods for detection and identification of the product** |
| **All Meta SPCs**  The provid GC-FID method is adequately validated for determination of the content of the propan-1-ol and propan-2-ol in the biocidal products Mida San 335 RV (Meta SPC1), Mida San 334 MF (Meta SPC 2), Mida San 311 KZ (Meta SPC 3). The liquid used to impregnate the wipes in Mida San 311 KZ wipes (Meta SPC 4) is the same as the liquid in Meta SPC3 and therefore a specific, additional study on the analytical method for this liquid is not considered necessary.  Methods for monitoring residues in the environment are not required because residues are not expected. Methods for monitoring in food or feeding stuff are not available, and are also not considered to be required, taking into account the fact that no significant residues in food are to be expected according to the CARs of the active substances.  A residues test in rinse water was nevertheless conducted, and the amounts of residues were max. 2.9 g/kg 2-propanol and 7.1 g/kg 1-propanol in the first rinse water and max. 11 mg/kg 2-propanol and 25 mg/kg 1-propanol. |

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### Efficacy against target organisms

#### Function (organisms to be controlled) and field of use (products/objects to be protected) for the products of the family

Main group 01: DISINFECTANTS

Product types :

* PT2 (*Disinfectants and algaecides not intended for direct applications to humans or animals*)
* PT4 (*Food & feed Area*)

All the biocidal products within this family, divided into 4 Meta SPCs, do contain Propan-2-ol (CAS N° 67-63-0) & Propan-1-ol (CAS N° 71-23-8) as active substance, used at a concentration range 9.77 – 19.54 % w/w and 24.54 – 49.07 % w/w respectively.

They are intended to be used indoors by professional and/or industrial users, according to the product and the intended use.

The products are intended to be used UNDILUTED as hard/non-porous surface disinfectant (PT2 & PT4) for institutions, industries and food :

* META SPC 1 : related to product ***MIDA San 335 RV*** (50% dilution in water of ***MIDA San 311 KZ***)
* META SPC 2 : related to product ***MIDA San 334 MF*** (70% dilution in water of ***MIDA San 311 KZ***)
* META SPC 3 : related to product ***MIDA San 311 KZ***
* META SPC 4 : related to pre-impregnated wipes with undiluted product ***MIDA San 311 KZ***

The products aim to eliminate vegetative bacteria and yeasts & in addition fungi, mycobacteria and viruses (for Meta SPCs 3 & 4).

The objects or organisms to be protected are hard surfaces.

#### Mode of action and effects on target organisms, including unacceptable suffering

Effects on target organisms are lethal.

Propan-1-ol :

“Propan-1-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.” (CAR Propan-1-ol, Germany, 2017, p. 6)

Propan-2-ol :

“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.” (CAR Propan-2-ol, Germany, 2015, p. 6)

#### Efficacy data

Efficacy tests performed according to suspension and surface standards have been submitted : Phase 2/Step 1 and Step 2 efficacy tests are mandatory for products intended to be used for surface disinfection via spraying and dipping procedures.

Please note that all the efficacy studies have been performed on the products ***MIDA San 311 KZ*** which contains 49.07% Propan-1-ol & 19.54% Propan-2-ol and ***MIDA San 311*** which contains 52% Propan-1-ol & 17.5% Propan-2-ol.

In addition, please note that there is no co-formulant likely to have an impact on the efficacy of the products, since active substances are diluted in water.

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| **Experimental data on the efficacy of the biocidal product against target organisms** | | | | |
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| **Test product** | **Function &**  **Test organism(s)** | **Test method / Test system / concentrations applied / exposure time** | **Test results : effects** | **Reference & R.I.** |
| ***Mida San 311***  Batch N°SO 14/006 | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 8 – 40 - 80% * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **8%** | **40%** | **80%** | | *P. aeruginosa* | < 3.90 | > 5.27 | | | *S. aureus* | < 3.83 | > 5.20 | | | *E. coli* | < 3.87 | > 5.24 | | | *E. hirae* | < 3.89 | > 5.26 | |  * Bactericidal activity at 40% in 5 min at +20°C in clean conditions | Doc. 2 - “Mida San 311 EN1276 0-3gL 40% - 14037-2 - EN”  Test report N°14-037-2  **R.I. 1**  **Key study** |
| ***Mida San 311*** (125% concentrated)  Batch N°SO 15/159 | ***Bactericidal activity***  *Campylobacter jejuni* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 10 – 20 – 40% * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **10%** | **20%** | **40%** | | *C. jejuni* | < 4.05 | > 5.08 | |  * Active against *C. jejuni* at 20% in 5 min at +20°C in clean conditions. | Doc. 1 - “EN1276\_Mida San 311 KZ\_Test report n.295-0715-M1”  Test report N°295/0715/M1  **R.I. 1**  **Key study** |
| ***Mida San 311*** (125% concentrated)  Batch N°SO 14/276  ***Mida San 311*** (125% concentrated)  Batch N°SO 14/220 | ***Bactericidal activity***  *Listeria monocytogenes*  *Salmonella typhimurium* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 8 – 40 – 80 – 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **8%** | **40%** | **80%** | **100%** | | *S. typhimurium* | < 3.90 | > 5.27 | | | | *L. monocytogenes* | < 3.89 | > 5.26 | | |  * Active against *Listeria monocytogenes* and *Salmonella typhimurium* at 40% in 5 min at +20°C in clean conditions. | Doc. 3 - “Mida San 311 EN1276 5 min 20Â°C 14377-3 - EN”  Test report N°RE14377-3  **R.I. 1**  **Key study** |
| ***Mida San 311*** (125% concentrated)  Batch N°SO 14/220 | ***Bactericidal activity***  *Listeria monocytogenes*  *Salmonella typhimurium* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 8 – 40 – 80 – 100 %   I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **8%** | **40%** | **80%** | | *S. typhimurium* | < 3.84 | > 5.21 | | | *L. monocytogenes* | < 3.92 | > 5.29 | |  * Active against *Listeria monocytogenes* and *Salmonella typhimurium* at 40% in 5 min at +20°C in clean conditions. | Doc. 4 - “Mida San 311 EN1276 sal & list 40% 0\_3g\_L alb - 14344-3 - EN”  Test report N°RE14344-3  **R.I. 1**  **Key study** |
| ***Mida San 311***  Batch N°170106 | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : 20 - 50 – 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **50%** | **80%** | | *P. aeruginosa* | < 4.12 | > 5.49 | | | *S. aureus* | < 3.86 | > 5.23 | | | *E. coli* | < 2.11 | > 5.48 | | | *E. hirae* | < 3.72 | > 5.09 | |  * Bactericidal activity at 50% in 1 min at +20°C in clean conditions | Doc.21 - “MidaSan 311 EN1276 1min”  Test report N°MB/REP/141478/2  **R.I. 1**  **Key study** |
| ***Mida San 311***  Batch N°170814 | ***Bactericidal activity***  *E. coli O157*  *Yersinia enterocolitica*  *Listeria monocytogenes*  *Salmonella typhimurium* | **EN 1276 (2010)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : 20 - 50 – 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **50%** | **80%** | | *S. typhimurium* | < 4.32 | > 5.69 | | | *E. coli O157* | < 4.01 | > 5.38 | | | *L. monocytogenes* | < 4.12 | > 5.49 | | | *Y. enterocolitica* | < 4.01 | > 5.38 | |  * Active against *E. coli O157, Yersinia enterocolitica, Listeria monocytogenes and Salmonella typhimurium* at 50% in 1 min at +20°C in clean conditions. | Doc.20 - “MidaSan 311 EN1276 1min +4bacteria”  Test report N°MB/REP/141715/1  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Bactericidal activity***  *Enterococcus hirae*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 13727 (2012 + AC 2015)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 - 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *P. aeruginosa* | 5.25 | > 5.50 | | | *S. aureus* | < 4.45 | > 5.54 | | | *E. hirae* | < 0.63 | > 5.37 | |  * Bactericidal activity at 40% in 5 min at +20°C in clean conditions | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311*** (125% concentred)  Batch N°SO 15/016 | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 1650 (2013)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 15 min * Concentrations tested : 1 – 50 – 80 - 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **1%** | **50%** | **80%** | **100%** | | *A. brasiliensis* | - | 3.55 | > 4.11 | | | *C. albicans* | < 2.27 | > 4.14 | | |  * Yeasticidal activity at 50% in 15 min at +20°C in clean conditions. * Fungicidal/yeasticidal activity at 80% in 15 min at +20°C in clean conditions. | Doc. 5 - “Mida San 311 EN1650 15028-2 - EN”  Test report N°RE15028-2  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 13624 (2013)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 - 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *A. brasiliensis* | 0 | 2.42 | > 4.41 | | *C. albicans* | 0.49 | > 4.45 | |  * Yeasticidal activity at 40% in 5 min at +20°C in clean conditions. * Fungicidal/yeasticidal activity at 80% in 5 min at +20°C in clean conditions. | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Mycobactericidal activity***  *Mycobacterium avium*  *Mycobacterium terrae* | **EN 14348 (2005)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 - 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *M. avium* | 2.08 | 4.38 | > 5.17 | | *M. terrae* | 0.92 | 4.68 | > 5.55 |  * Mycobactericidal activity at 40 % in 5 min at +20°C in clean conditions. | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Virucidal activity***  Adenovirus  Murine norovirus  Poliovirus | **EN 14476 (2014)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 – 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *Adenovirus* | 2.83 | 4.17 | 4.33 | | *Norovirus* | 2.00 | 2.67 | 3.17 | | *Poliovirus* | 3.00 | 4.00 | 4.50 |  * Active against Adenovirus and Poliovirus at 40% in 5 min at +20°C in clean conditions. * NON-active against Murine norovirus at 80% in 5 min at +20°C in clean conditions. | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°174214 | ***Virucidal activity***  Murine Norovirus | **EN 14476 (2014)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 20 min * Concentrations tested : 20 – 40 - 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **100%** | | *Norovirus* | 3.50 | 4.00 | > 5.00 |  * Active against Murine Norovirus at 40% in 20 min at +20°C in clean conditions. | Doc. 12 - “Mida San 311 EN14562 fungi - EN14476 Norovirus 20 min. - S163-2018 EN”  Test report N°180090243 |
| ***Mida San 311 KZ***  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Virucidal activity***  Murine Norovirus | **EN 14476 (2014)**  **Quantitative suspension test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 0.1 – 50 – 80 - 97 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **0.1%** | **50%** | **80%** | **97%** | | *Norovirus* | 0.33 | 2.75 | 3.08 | 5.41 |  * Active against *Murine norovirus* at 97% in 5 min at +20°C in clean conditions | Doc. 25 - “Mida San 311 KZ EN-14476 Norovirus”  **R.I. 1**  **Key study** |
|  |  |  |  |  |
| ***Mida San 311***  Batch N°SO 13/224\*  *\* Supported by Certificate of Analysis : Propan-1-ol (CAS N° 71-23-8) 52%*  *+ Propan-2-ol (CAS N° 67-63-0) 17.5%* | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 13697 (2001)**  **Quantitative carrier test – hard & non-porous surfaces (performed in Feb. 2014)**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 10 – 20 – 80 – 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **10%** | **20%** | **80%** | **100%** | | *P. aeruginosa* | < 0.64 | > 5.12 | | | | *E. hirae* | - | < 1.36 | > 5.84 | | | *E. coli* | < 1.26 | > 5.74 | | | | *S. aureus* | < 1.25 | 1.92 | > 5.73 | |  * Bactericidal activity at 80% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 6 - “Mida San 311 EN13697 4bact 80% 0\_3gL 13533-4 - EN”  Test report N°13533-4  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 – 50 - 70 % * I.S. : 0.3g/L BSA (clean conditions) & skimmed milk 0.85% for *P. aeruginosa* | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **50%** | **70%** | | *P. aeruginosa* | < 1.24 | > 6.66 | | | *E. coli* | 3.74 | > 6.62 | | | *S. aureus* | < 1.25 | > 6.67 | | | *E. hirae* | < 1.16 | > 6.58 | |  * Bactericidal activity at 50% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 16 - “MIDA SAN 311 KZ EN13697 BACT - 180105990 - EN”  Test report N°180105990  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus*  *+*  *E. coli O157*  *Yersinia enterocolitica*  *Listeria monocytogenes*  *Salmonella typhimurium* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : 20 – 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) & skimmed milk 0.85% for *P. aeruginosa* | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *P. aeruginosa* | 2.20 | > 6.64 | | | *E. coli* | > 6.52 | | | | *S. aureus* | < 1.19 | > 6.61 | | | *E. hirae* | < 1.23 | > 6.65 | | |  | | | | | *S. typhimurium* | 2.25 | > 6.60 | | | *E. coli O157* | 4.32 | > 6.61 | | | *L. monocytogenes* | 2.45 | > 6.58 | | | *Y. enterocolitica* | < 1.14 | > 6.56 | |  * Bactericidal activity (including *E. coli O157, Yersinia enterocolitica, Listeria monocytogenes and Salmonella typhimurium* ) at 40% in 1 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 9 - “Mida San 311 EN13697 bacteria 1 min 20°C - EN\_Test report n180090242”  Test report N°180090242  **R.I. 1**  **Key study** |
| ***Mida San 311***  Batch N°SO 14/220  *\* Supported by Certificate of Analysis : Propan-1-ol (CAS N° 71-23-8) 52%*  *+ Propan-2-ol (CAS N° 67-63-0) 17.5%* | ***Bactericidal activity***  *Listeria monocytogenes*  *Salmonella typhimurium*  *Campylobacter jejuni* | **EN 13697 (2001)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 0.1 => 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **0.1%** | **1%** | **10%** | **20%** | | *S. typhimurium* | < 0.72 | | | > 6.10 |  |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **10%** | **20%** | **80%** | **100%** | | *C. jejuni* | < 0.35 | 2.44 | > 5.73 | | | *L. monocytogenes* | 3.89 | > 6.72 | | |  * Active against *Listeria monocytogenes and Salmonella typhimurium* at 20% in 5 min on hard/non-porous surfaces with prior * Active against *C. jejuni* at 80% in 5 min on hard/non-porous surfaces with prior | Doc. 7 - “Mida San 311 EN13697 5 min 21Â°C - 14347-2 - EN”  Test report N°RE14347-2  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°3613579 | ***Bactericidal activity***  *Campylobacter jejuni* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : 10 – 50 - 100 % * I.S. : Skimmed milk at 0.85 g/L ( clean conditions according to the Applicant) | |  |  |  |  | | --- | --- | --- | --- | |  | **10%** | **50%** | **100%** | | *C. jejuni* | 2.94 | > 5.50 | |   Active against *Campylobacter jejuni*  at 50% in 1 min at +20°C on hard/non-porous clean surfaces | Doc. 24 - “Mida San 311 KZ EN13697 CJ BT-CYT-02 1 min. - EN”  **R.I. 2** |
| ***Mida San 311*** (125% concentred)  Batch N°133025MT  *Propan-1-ol (CAS N° 71-23-8) 52%*  *+ Propan-2-ol (CAS N° 67-63-0) 17.5%* | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**  **Performed in Feb. 2014**   * Temperature : +20 ± 1°C * Contact time : 15 min * Concentrations tested : 10 => 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **10%** | **25%** | **100%** | | *C. albicans* | < 0.14 | > 5.52 | |  * Yeasticidal activity at 25% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning.  |  |  |  |  | | --- | --- | --- | --- | |  | **50%** | **75%** | **100%** | | *A. brasiliensis* | 2.47 | 3.27 | > 5.72 |  * Fungicidal/yeasticidal activity at 75% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 8 - “Mida San 311 EN13697 15 min 20Â°C 180-0214-M3 - EN”  Test report N°180/0214/M3  **R.I. 2** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 15 min * Concentrations tested : 10 => 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **10%** | **80%** | **100%** | | *C. albicans* | < 1.07 | > 5.61 | | | *A. brasiliensis* | < 0.42 | > 5.54 | |  * Yeasticidal activity at 80% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. * Fungicidal/yeasticidal activity at 80% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 10 - “Mida San 311 EN13697 fungi 15 min 20°C - EN\_TEST REPORT Nº 180091118”  Test report N°180091118  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Yeasticidal activity***  *Candida albicans* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : 20 – 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **10%** | **40%** | **80%** | | *C. albicans* | 1.90 | > 5.50 | |  * Yeasticidal activity at 40% in 1 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 11 - “Mida San 311 EN13697 yeasts 1 min 20°C - EN\_TEST REPORT Nº 180090243”  Test report N°180090243  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Fungicidal activity***  *Aspergillus brasiliensis* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 50 – 80 - 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **50%** | **80%** | **100%** | | *A. brasiliensis* | 2.86 | > 5.56 | |  * Active against *Aspergillus brasiliensis* at 80 % in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 11 - “MIDA SAN 311 KZ EN13697 A. brasiliensis 5 min - 200027171 - EN”  Test report N°200027171  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 15 min * Concentrations tested : 20 – 50 - 70 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **20%** | **50%** | | **70%** | | *C. albicans* | 1.66 | > 5.59 | | | | *A. brasiliensis* | < 0.42 | 2.76 | > 5.54 | |  * Yeasticidal activity at 50% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. * Fungicidal/yeasticidal activity at 70% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 17 - “MIDA SAN 311 KZ EN13697 FUNG - 180106590 - EN”  Test report N°180106590  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Yeasticidal activity***  *Candida albicans* | **EN 13697 (2015)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 15 min * Concentrations tested : 20 – 50 - 70 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **50%** | **70%** | | *C. albicans* | 1.66 | > 5.59 | |  * Yeasticidal activity at 50% in 15 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 18 - “MIDA SAN 311 KZ EN13697 LEV - 180106591 - EN”  Test report N°180106591  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°184429  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Virucidal activity***  *Adenovirus Type 5*  Murine Norovirus | **prEN 16777 (2017)**  **Quantitative carrier test – hard & non-porous surfaces**   * Temperature : +20 ± 1°C * Contact time : 20 min * Concentrations tested : 0.1 – 50 - 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **0.1%** | **50%** | **100%** | | *Adenovirus* | < 0.32 | > 5.15 | | | *Norovirus* | < 0.59 | > 5.07 | |  * Virucidal activity at 50% in 20 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 15 - “Mida San 311 KZ EN 16777”  Test report N°D/18/346  **R.I. 1**  **Key study** |
|  |  |  |  |  |
| ***Mida San 311 KZ***  Batch N°180145 | ***Bactericidal activity***  *Enterococcus hirae*  *Pseudomonas aeruginosa Staphylococcus aureus* | **EN 14561 (2006)**  **Quantitative carrier test / immersion**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 - 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | *P. aeruginosa* | > 5.19 | | | | *S. aureus* | 3.14 | > 5.71 | | | *E. hirae* | 2.89 | > 5.02 | |  * Bactericidal activity at 40% in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 14562 (2006)**  **Quantitative carrier test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 20 - 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **20%** | **40%** | **80%** | | | *C. albicans* | 2.67 | > 4.89 | | | | *A. brasiliensis* | 0.46 | 2.54 | | 3.51 |  * Yeasticidal activity at 40 % in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. * **NO** Fungicidal/yeasticidal activity at 80 % in 5 min at +20°C on clean carriers**.** | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°174214 | ***Fungicidal activity***  *Candida albicans*  *Aspergillus brasiliensis* | **EN 14562 (2006)**  **Quantitative carrier test**   * Temperature : +20 ± 1°C * Contact time : 20 min * Concentrations tested : 20 – 40 - 80 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **20%** | **40%** | **100%** | | *C. albicans* | > 4.03 | | | | *A. brasiliensis* | 0.01 | > 4.36 | |  * Yeasticidal activity at 20 % in 20 min at +20°C on hard/non-porous surfaces with prior cleaning. * Fungicidal/Yeasticidal activity at 40 % in 20 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 12 - “Mida San 311 EN14562 fungi - EN14476 Norovirus 20 min. - S163-2018 EN”  Test report N°180090243  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°3613568 | ***Mycobactericidal activity***  *Mycobacterium avium*  *Mycobacterium terrae* | **EN 14563 (2009)**  **Quantitative carrier test**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : 40 – 80 - 100 % * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  |  | | --- | --- | --- | --- | |  | **40%** | **80%** | **100%** | | *M. avium* | 4.49 | > 5.13 | | | *M. terrae* | 4.42 | > 4.92 | |  * Mycobactericidal activity at 40 % in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc.22 - “Mida San 311 KZ EN14563 Mycobacteria D-19-267 - EN”  Test report N°D/19/267  **R.I. 2** |
|  |  |  |  |  |
| ***Mida San 311 KZ***  Batch N°183703  *Propan-1-ol (CAS N° 71-23-8) 49%*  *+ Propan-2-ol (CAS N° 67-63-0) 19.5%* | ***Bactericidal activity***  *Enterococcus hirae*  *E.coli*  *Pseudomonas aeruginosa Staphylococcus aureus*  *+*  *E. coli O157*  *Yersinia enterocolitica*  *Listeria monocytogenes*  *Salmonella enterica* | **EN 16615 (2015)**  **Quantitative test –non-porous surfaces with mechanical action**   * Temperature : +20 ± 1°C * Contact time : 1 min * Concentrations tested : pure * I.S. : 0.3g/L BSA (clean conditions) | |  |  |  | | --- | --- | --- | |  | | **100% on wipes** | | *S. aureus* | | > 5.80 | | *P. aeruginosa* | | > 5.77 | | *E. hirae* | | > 5.77 | | *E. coli* | | > 5.77 | |  | | *S. enterica* | | > 5.94 | | *Y. enterocolitica* | | > 5.84 | | *L. monocytogenes* | | > 5.79 | | *E. coli O157* | | > 5.76 |  * Bactericidal activity (including *E. coli O157, Yersinia enterocolitica, Listeria monocytogenes and Salmonella typhimurium* ) in 1 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 13 - “Mida San 311 EN16615 1 min. contact time signed”  Test report N°D/18/265  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Fungicidal activity***  *Aspergillus brasiliensis* | **EN 16615 (2015)**  **Quantitative test –non-porous surfaces with mechanical action**   * Temperature : +20 ± 1°C * Contact time : 20 min * Concentrations tested : 50 - 100% * I.S. : 0.3g/L BSA (clean conditions)   With 55% cellulose/45%PET wipes (17 cm x 29.5 cm) soaked 30 min in 16 mL undiluted product. | |  |  |  | | --- | --- | --- | |  | **50%** | **100%** | | *A. brasiliensis* | > 4.00 | |  * Active against *Aspergillus brasiliensis*   at 50% in 20 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 14 - “Mida San 311 EN16615 fungi 20 min 20Â°C - EN - S13-2-2018”  Test report N°S163-2/2018  **R.I. 1**  **Key study** |
| ***Mida San 311 KZ***  Batch N°180145 | ***Bactericidal activity***  ***+ Yeasticidal activity***  *Enterococcus hirae*  *Pseudomonas aeruginosa Staphylococcus aureus*  *Candida albicans* | **EN 16615 (2015)**  **Quantitative test –non-porous surfaces with mechanical action**   * Temperature : +20 ± 1°C * Contact time : 5 min * Concentrations tested : RTU * I.S. : 0.3g/L BSA (clean conditions)   With 55% cellulose/45%PET wipes (17 cm x 29.5 cm) soaked 30 min in 16 mL undiluted product. | |  |  |  | | --- | --- | --- | |  | | **RTU** | | *S. aureus* | | > 5.17 | | *P. aeruginosa* | | > 5.52 | | *E. hirae* | | > 5.29 | | *E. coli* | | > 5.77 | |  | | *C. albicans* | | > 4.05 |  * Bactericidal & yeasticidal activity in 5 min at +20°C on hard/non-porous surfaces with prior cleaning. | Doc. 19 - “Mida San 311 KZ EN13727-EN14561-EN13624-EN14562-EN14348-EN14476-EN16615”  Test report N°S7/2018  **R.I. 1**  **Key study** |
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| **Conclusion on the efficacy of the representative product *Mida San 311 KZ* (with 49.07% Propan-1-ol + 19.54% Propan-2-ol) :**  Summary of the results from the EFF studies submitted, validated after evaluation | | | |
| EN 1276 | 40% - 5 min - +20°C - CLEAN | EN 13697 - B | 50% - 5 min - +20°C - CLEAN |
| EN 13727 | 40% - 5 min - +20°C – CLEAN |
| EN 1276 | 50% - 1 min - +20°C - CLEAN | EN 13697 - B | 40% - 1 min - +20°C - CLEAN |
|  | | | |
| EN 1650 – Y | 50% - 15 min - +20°C – CLEAN | EN 13697 – Y | 25% - 15 min - +20°C – CLEAN |
| EN 13624 - Y | 40% - 5 min - +20°C – CLEAN |  | 40% - 1 min - +20°C – CLEAN |
|  | | | |
| EN 1650 – F/Y | 80% - 15 min - +20°C – CLEAN | EN 13697 – F/Y | 75% - 15 min - +20°C – CLEAN |
| EN 13624 – F/Y | 100% - 5 min - +20°C – CLEAN | EN 13697 – F/Y | 80% - 5 min - +20°C – CLEAN |
|  | | | |
| EN 14476 – Full | 100% - 5 min - +20°C - CLEAN | EN 16777 | 50% - 20 min - +20°C - CLEAN |
| EN 14476 – Full | 40% - 20 min - +20°C - CLEAN |  |  |
|  | | | |
| EN 14348 - MycoB | 40% - 5 min - +20°C - CLEAN | EN 14561 | 40% - 5 min - +20°C - CLEAN |
|  | | EN 14562 - Y | 40% - 5 min - +20°C - CLEAN |
| EN 14562 – F/Y | 40% - 20 min - +20°C - CLEAN |
| EN 14563 MycoB | 40% - 5 min - +20°C - CLEAN |
| EN 16615 - B | 1 min – 20°C - CLEAN |
| EN 16615 – B + Y | 5 min – 20°C - CLEAN |
| EN 16615 – B + F/Y | 20 min – 20°C - CLEAN |

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| **Conclusion on the efficacy of the products of the Family and validated label claims** | | |
| **AS A REMINDER :**  *- For “surface disinfection by spraying/mopping or immersion, P2S1 and all P2S2 tests are necessary and both tests must be taken into account and therefore the higher concentration & contact time required is the limiting one and thus be set up as the necessary concentration.*  *- Please note that one single Use concentration/Contact Time will be validated for basic requirements (see Annex IV in ECHA EFF guidance from May 2016/April 2018).* | | |
| **Meta SPC-1  *MIDA San 335 RV*** (50% dilution of ***MIDA San 311 KZ***) | | **Validated label claims** |
| **PT2** | **Use #1.1** : RTU Surface disinfection via trigger-spraying | On hard/non-porous surfaces with prior cleaning  at Room Temperature  Ready-to-Use   * Active against bacteria & yeasts : 100% - 5 min contact time |
| **Use #1.2** : RTU Surface disinfection via low-pressure spraying |
| **PT4** | **Use #1.3** : RTU Surface disinfection via trigger-spraying |
| **Use #1.4 :** RTU Surface disinfection via low-pressure spraying |
| **Use #1.5** : RTU Surface disinfection via dipping |
| **Meta SPC-2\*  *MIDA San 334 MF*** (70% dilution of ***MIDA San 311 KZ***) | | **Validated label claims** |
| **PT2** | **Use #2.1** : RTU Surface disinfection via trigger-spraying | On hard/non-porous surfaces with prior cleaning  at Room Temperature  Ready-to-Use  Active against bacteria & yeasts : 100% - 5 min contact time |
| **Use #2.2** : RTU Surface disinfection via low-pressure spraying |
| **PT4** | **Use #2.3** : RTU Surface disinfection via trigger-spraying |
| **Use #2.4 :** RTU Surface disinfection via low-pressure spraying |
| **Use #2.5** : RTU Surface disinfection via dipping |
| **Meta SPC-3  *MIDA San 311 KZ*** | | **Validated label claims** |
| **PT2** | **Use #3.1** : RTU Surface disinfection via trigger-spraying | On hard/non-porous surfaces with prior cleaning  at Room Temperature  Ready-to-Use  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time |
| **Use #3.2** : RTU Surface disinfection via low-pressure spraying |
| **Use #3.5** : RTU Surface disinfection via dipping |
| **PT4** | **Use #3.3** : RTU Surface disinfection via trigger-spraying |
| **Use #3.4** : RTU Surface disinfection via low-pressure spraying |
| **Use #3.6** : RTU Surface disinfection via dipping |
| **Meta SPC-4  *MIDA San 311 KZ by wiping*** | | **Validated label claims** |
| **PT2** | **Use #4.1 :** RTU Surface Disinfection | On hard/non-porous surfaces with prior cleaning  at Room Temperature  Active against bacteria, mycobacteria & yeasts : 5 min contact time  Active against bacteria, fungi/yeasts, mycobacteria and viruses : 20 min contact time |
| **PT4** | **Use #4.2 :** RTU Surface Disinfection |

**\*** Even if there is no difference between these two Meta SPC 1 & 2, except that Meta SPC 2 is with higher concentrations of the AS, the representative product for Meta-SPC2 can be authorised anyway, considering the justification provided by the Applicant i.e. “*meta SPC 2 has a shorter drying time than meta SPC 1. In practice this is useful because surfaces can be used again faster after disinfection.*

#### Occurrence of resistance and resistance management

Given the unspecific mode of action of both 1-propanol and isopropanol, the development of resistance is not expected and not reported in the scientific literature. A natural resistance against sporulated bacteria is known where 1-propanol and isopropanol are ineffective at any concentration. Likewise, both 1-propanol and isopropanol are more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods. (CAR PROPAN-1-OL, Germany, June 2017 & CAR ISOPROPANOL, Germany, January 2015).

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of the product.

#### Known limitations

Nothing to mention.

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

Not applicable : the products are not intended to be used together with other biocidal products.

### Risk assessment for human health

New data/information on human health and exposure is for the product due to differences in product composition and/or intended use compared to representative product(s) for the active substance(s) listed in the Union list of approved active substances under Regulation No. 528/2012.

#### Assessment of effects on Human Health

The products included in the biocidal product family are classified according to CLP mixture rules. The classification is identical for all metaSPC’s.

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not skin corrosive/irritant.  Repeated exposure may cause skin dryness or cracking, EUH066 |
| Justification for the value/conclusion | There are no substances classified for skin corrosion or irritation in the BPF. |
| Classification of the product according to CLP | Classification for skin corrosion or irritation is not required.  Supplemental hazard statement: EUH066 (Repeated exposure may cause skin dryness or cracking) |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Eye Dam. 1, H318 |
| Justification for the value/conclusion | All metaSPC’s contain more than 3% Propan-1-ol which is classified as Eye Dam. 1; H318 |
| Classification of the product according to CLP | Eye Dam. 1; H318 |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | The BPD does not contain any substances classified for respiratory tract irritation. |
| Classification of the product according to CLP | Not classified. |

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| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation. |
| Justification | The BPF does not contain any substances classified for respiratory tract irritation. |

***Skin sensitization***

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not skin sensitising. |
| Justification for the value/conclusion | The BPF does not contain any substances classified for skin sensitisation. |
| Classification of the product according to CLP | Not classified. |

***Respiratory sensitization (ADS)***

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| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not respiratory sensitising. |
| Justification for the value/conclusion | The BPF does not contain any substances classified for respiratory sensitisation. |
| Classification of the product according to CLP | Not classified. |

***Acute toxicity***

*Acute toxicity by oral route*

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| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Propan-1-ol: LD50 =6500 mg/kg (CAR)  Propan-2-ol: LD50 =4400 mg/kg (CAR) |
| Justification for the selected value | The BPF does not contain any substances classified for acute oral toxicity. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by inhalation*

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| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Propan-1-ol: LC50=>33.9 mg/L air x 4h (whole body, vapour) (CAR)  Propan-2-ol: LC50=17100 mg/kg bw (47.5 mg/L air for 8h; whole body, vapour (CAR) |
| Justification for the selected value | The BPF does not contain any substances classified for acute inhalation toxicity.  Both propan-1-ol as propan-2-ol are classified as STOT SE 3, H336. Following the additivity rule, the general concentration limit of 20% is exceeded in all metaSPC’s, therefore the BPF is classified as STOT SE 3. |
| Classification of the product according to CLP | STOT SE 3, H336 |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Propan-1-ol: LD50 rabbit 4000-10000 mg/kg (MSDS)  Propan-2-ol: LD50 rabbit 13900 mg/kg (MSDS) |
| Justification for the selected value | The BPF does not contain any substances classified for acute dermal toxicity. |
| Classification of the product according to CLP | Not classified. |

***Information on dermal absorption***

Please refer to the active substance dossier of Propan-1-ol and Propan-2-ol via Letter of Access. No dermal absorption tests have been performed on the products.

|  |  |  |
| --- | --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | | |
| Substance | Propan-1-ol | Propan-2-ol |
| Value(s)\* | 0.85 mg/cm2 | 0.85 mg/cm2 |
| Justification for the selected value(s) | “Based on in vivo rat study for propan-2-ol. Proposal of the eCA to apply this rate to the isomer propan-1-ol.” (Assessment report for Propan-1-ol”. | Assessment report for Propan-2-ol |

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

There are no substances of concern in the BPF.

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

No toxicological test data are available on the products.

#### Exposure assessment

For all scenarios the worst-case product corresponds to the most concentrated product in the family which is Mida San 311 KZ with 49% Propan-1-ol and 19.5% Propan-2-ol. In the last scenario, for the assessment of the wet-wipes the worst-case in terms of product content, corresponds to 3.75 g of solution per wipe and is the one used in the assessment.

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| **Uses**  **PTs** | **Users** | **Use Areas** | **Meta SPC** | | | |
| **1**  **Mida San 335 RV** | **2**  **Mida San 334 MF** | **3**  **Mida San 311 KZ** | **4**  **Mida San**  **311 KZ wipes**  **Saniwipes 311** |
| Trigger spraying  PT2 | Professional Industrial | Indoors  Cleanrooms, pharmaceuticals and cosmetics manufacturing facilities, laboratories and biotechnology, unspecified rooms, small rooms - small surfaces | Use 1.1 | Use 2.1 | Use 3.1 | - |
| Low-pressure spraying  PT2 | Industrial | Indoors  Cleanrooms, pharmaceuticals and cosmetics manufacturing facilities, laboratories and biotechnology, unspecified rooms, small rooms - small surfaces | Use 1.2 | Use 2.2 | Use 3.2 | - |
| Trigger spraying  PT4 | Professional Industrial | Indoors  Unspecified rooms, kitchens and canteens and food processing machinery - small surfaces | Use 1.3 | Use 2.3 | Use 3.3 | - |
| Low-pressure spraying  PT4 | Industrial | Indoors  Unspecified rooms, Institutional kitchens and canteens; industrial kitchens and industrial production rooms - small surfaces | Use 1.4 | Use 2.4 | Use 3.4 | - |
| Dipping  PT 2 | Professional Industrial | Indoors  Cleanrooms, pharmaceuticals and cosmetics manufacturing facilities, laboratories and biotechnology, unspecified rooms, small rooms | - | - | Use 3.5 |  |
| Dipping  PT4 | Professional Industrial | Indoors  Unspecified rooms, kitchens and canteens and food processing machinery - smaller surfaces | Use 1.5 | Use 2.5 | Use 3.6 | - |
| Wiping  PT2 | Professional industrial | Indoors  Cleanrooms, pharmaceuticals and cosmetics manufacturing facilities, laboratories and biotechnology, unspecified rooms, small rooms - smaller surfaces | - | - | - | Use 4.1 |
| Wiping  PT4 | Professional industrial | Indoors  Unspecified rooms, kitchens and canteens and food processing machinery - smaller surfaces | - | - | - | Use 4.2 |

**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 | Yes | Yes | No | Yes | Yes | yes | No |
| Dermal | Yes | Yes | No | Yes | Not expected | No | No |
| Oral | No | No | No | No | No | No | No |

***List of scenarios***

Based on expert judgement eCA, HEAdhoc recommendation 15 and after refinement by the applicant, a list of parameters was agreed upon per room type, see tables below.

For the scenario’s trigger spraying (PT2/PT4), wiping (PT2/PT4) and dipping (PT4) in which small surface disinfection is claimed, the following parameters were used:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume** | **Ventilation rate** | **Area treated** | **Application durationa** | **Exposure duration** | **Frequency** |
| **Cleanrooms** | 55 m3 | Tier 1: 8/h  Tier 2: 20/h | 0.5 m2 | 1 min | 45 min | 10 |
| **Pharmaceutical and cosmetics manufacturing facilities** | 80 m3 | 8/h | 0.5 m2 | 1 min | 6 minf | 80 |
| **Laboratories and biotechnology** | 25 m3 | 8/h | 0.5 m2 | 1 min | 45 min | 10 |
| **Unspecified rooms** | 20 m3 | 0.6/h | 2 m2 | 5 min | 48 minb/60 minc | 10/5d/1e |
| **Small roomsg** | 10 m3 | 0.6/h | 1 m2 | 5 min | 60 min | 1 |
| **Kitchen and canteens** | 25 m3 | 15/h | 1 m2 | 2 min | 48 minb | 10a |
| **Food processing machinery** | 300 m3 | 20/h | 4.6 m2 | 5 min | 48 minb | 10a |

aFor dermal exposure the application duration was used as the exposure duration to calculate the dermal exposure.

bWith a frequency of 10 times per day and an 8-hour working day, the exposure duration is max. 48min.

cFor wipes and trigger sprayers, the duration in unspecified rooms is 60 min.

dFor dipping, the frequency in unspecified rooms is 5

eFor wipes and trigger sprayers, the frequency in unspecified rooms is 1. Since the assessment does not include use frequencies higher than 1/day for this room type, the use frequency will be included as RMM for this room type.

fWith a frequency of 80 times per day and an 8-hour working day, the exposure duration is max. 6 min.

gSmall rooms: as unspecified rooms do not cover smaller rooms in a house, calculations were also performed for the smallest room (besides toilets) in a house, which are bath rooms (see Consexpo general fact sheet). The selected default treated area is 1m2. This is based on the following defaults:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Surface (m2) | Volume (m3) | Treated area (m2) |
| Unspecified room | 8 | 20 | 2 |
| Kitchen | 6 | 15 | 1 |
| Bath room | 4 | 10 | 1 |

The treated area of a bath room is considered to be the same as a kitchen which has a larger surface and volume.

For the scenario low pressure spraying (PT2/PT4) in which large surface disinfection is claimed, the following parameters were used:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume** | **Ventilation rate** | **Area treated** | **Application durationb** | **Exposure duration** | **Frequency** |
| **Cleanrooms** | 55 m3 | Tier 1: 8/h  Tier 2: 20/h | max. 10 m2a | 1 L/min.: 2’  3 L/min.: 40” | max. 20 min | 1c |
| **Pharmaceutical and cosmetics manufacturing facilities** | 80 m3 | 8/h | max. 10 m2a | 1 L/min.: 2’  3 L/min.: 40” | max. 20 min | 1c |
| **Laboratories and biotechnology** | 25 m3 | 8/h | 10 m2 | 1 L/min.: 2’  3 L/min.: 40” | max. 20 min | 1c |
| **Unspecified rooms** | 20 m3 | 0.6/h | 8 m2 | 1 L/min.: 1’36”  3 L/min.: 32” | max. 20 min | 1c |
| **Small roomsg** | 10 m3 | 0.6/h | 4 m2 | 1 L/min.: 1’36”  3 L/min.: 32” | max. 20 min. | 1c |
| **Institutional kitchens and canteens** | 25 m3 | 15/h | 10 m2 | 1 L/min.: 2’  3 L/min.: 40” | max. 20 min | 1c |
| **Industrial kitchen** | 2400 m3 | 15/h | max. 10 m2a | 1 L/min.: 2’  3 L/min.: 40” | max. 120 min | 1c |
| **Industrial production room** | 300 m3 | 20/h | max. 10 m2a | 1 L/min.: 2’  3 L/min.:40’’ | max. 60 | 1c |

aApplicant’s judgement: the area treated was decreased for these room types as propanol is not applied on such big surfaces as it is too expensive for large surface applications. The maximum treated area will be indicated in the SPC in the use instructions.

bFor dermal exposure the application duration was used as the exposure duration to calculate the dermal exposure.

cSince the assessment does not include use frequencies higher than 1/day for low pressure spraying, the use frequency will be included as RMM for this use.

The exposure and risk assessments were performed for all room types indicated in the tables above. The calculations below are presented only for the worst-case room types. The calculations for the other room types can be found in the excel sheet in annex (see Annex 3.2).

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| Uses 1.1-1.3-2.1-2.3-3.1-3.3: Small surface disinfection by trigger spraying (Ready to use products) – PT2/PT4 (Trigger spray) | | | |
| 1.1 | Loading | Loading of ready-to-use solution in application equipment. | Professionals |
| 1.2-a | Application | Application of product on surfaces by spraying / wiping in unspecified rooms and small rooms | Professionals |
| 1.2-b | Application | Application of product on surfaces by spraying / wiping in kitchen and canteens | Professionals |
| 1.2-c | Application | Application of product on surfaces by spraying / wiping in pharmaceutical and cosmetics manufacturing facilities | Professionals |
| 1.3 | Post-application | Cleaning of application equipment. | Professionals |
| Uses 1.2-1.4-2.2-2.4-3.2-3.4: Small surface disinfection by low-pressure spraying (Ready to use products) – PT2/PT4 (Low Pressure Spraying) | | | |
| 2.1 | Loading | Loading of ready-to-use solution in application equipment. | Professionals |
| 2.2-a | Application | Application of product on surfaces by spraying / wiping in unspecified rooms and small rooms | Professionals |
| 2.2-b | Application | Application of product on surfaces by spraying / wiping in laboratories and biotechnology | Professionals |
| 2.2-c | Application | Application of product on surfaces by spraying / wiping in industrial production room | Professionals |
| 2.2-d | Application | Application of product on surfaces by spraying / wiping in cleanrooms | Professionals |
| 2.2-e | Application | Application of product on surfaces by spraying / wiping in institutional kitchen and canteens | Professionals |
| 2.3 | Post-application | Cleaning of application equipment. | Professionals |
| Uses 1.5-2.5-3.5-3.6: Surface disinfection by dipping (Ready to use products) - PT2/PT4 | | | |
| 3.1 | Loading | Loading of ready-to-use solution in dipping bath. | Professionals |
| 3.2-a | Application | Submersion of equipment into ready-to-use solution in unspecified rooms | Professionals |
| 3.2-b | Application | Submersion of equipment into ready-to-use solution in small rooms | Professionals |
| 3.3 | Post-application | Emptying and dipping bath. Rinsing of dipping bath. | Professionals |
| Uses 4.1-4.2: Small surface disinfection RTU wet wipes - PT2/PT4 | | | |
| 4.1 | Loading | Not applicable: ready-to-use wet wipes. | Professionals |
| 4.2-a | Application | Pick up a wipe from the packaging and wipe off surface with the wet wipe in unspecified rooms and small rooms | Professionals |
| 4.3 | Post-application | Disposal of used wipe into waste bin. | Professionals |
| Secondary exposure | | | |
| 5.1 | Application | Adult bystander present during application | Professionals |
| 5.2 | Post-application | Contact with treated surfaces. | Professionals |

***Industrial exposure***

The products are for professional and industrial use, both applications are assessed as professional exposure.

***Professional exposure***

*Scenario [1.1] Loading of ready-to-use solution in application equipment*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [1.1] – Loading of ready-to-use solution in application equipment** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The products are either sold as pre-filled trigger spray flasks (750mL-1 litre) or as refill containers (5-10-18-20-25 litres). The products are only used indoors. The loading phase consists of removing the cap of a trigger spray flask and inserting the spraying device or removing the spraying device of an empty spray flask and refill it with liquid from a larger container up to 25 litres.  One pouring/loading operation (10 min) is assumed for a professional user per day.  Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa |
| Propan-2-ol: 5780 Pa |
| Body weight | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: mixing & loading model 42** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value mixing & loading model 4 | 0.5 ml/loading | HEAdhoc recommendation 6, Nr. 9 + HEEG opinion 1 – Mixing loading model 7 alternatives |
| Number of operations | 1 per day | Expert judgement eCA |
| PPE | none |  |
| **Inhalation exposure to vapour: ART 1.51** | | | |
| Tier 1 | Exposure duration | 10 min | Expert judgement eCA |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAdhoc recommendation 14 |
| Activity coefficient | Propan-1-ol: 1.5 | AIOMFAC-web, version 2.32 |
| Propan-2-ol: 1.34 |
| Activity class | Falling liquids | ART 1.5 |
| Situation | Transfer of liquid product with flow of 0.1 - 1 l/minute |
| Containment level | Open process |
| Loading type | Splash loading |
| Room size | Any size workroom |
| Ventilation rate | Only good natural ventilation |
| General control measures | No localized controls |
| PPE | none |  |

1It is agreed in the CAR of peracetic acid PT11 & 12 and approved union authorizations to use ART for the calculation of inhalation exposure of volatile substances during manual mixing and loading.

2 According to HEAdhoc recommendation 6 & HEEG opinion 1, mixing and loading model 4 can be used for simple loading of smaller quantities (the volume of a trigger sprayer flask is max 1 L).

**Calculations for scenario 1.1**

Dermal exposure

The indicative value from Mixing and Loading Model 4 is 0.5 ml/loading. Assuming that 1 pouring/loading operation is performed in a day, the amount of propan-1-ol on the skin is 211.925 mg, and the amount of propan-2-ol on the skin is 84.3375 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (both hands): 820 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 211.925 | 84.3375 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 11.88 s | 2.37 s |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 12 s for propan-1-ol and 2 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h, this leads to a total absorbed amount of 0.0383 mg/kg bw/d propan-1-ol and 0.0076 mg/kg bw/d propan-2-ol.

Inhalation exposure to vapour

Propan-1-ol: The predicted 95th percentile full-shift exposure is 190 mg/m³. With an exposure time of 10 minutes and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.6597 mg/kg bw/d.

Propan-2-ol: The predicted 95th percentile full-shift exposure is 140 mg/m3. With an exposure time of 10 minutes and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.4861 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 1.1** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake**  **/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 0.6597 | 0.0383 | 0.698 | 9.2 | 7 |
| Propan-2-ol | 1 (no PPE) | 0.4861 | 0.0076 | 0.494 | 17.9 | 2 |

The cumulative risk of propan-1-ol and propan-2-ol was too high for the combined tasks: loading of the trigger spray + trigger spraying in **kitchen & canteens**. Therefore gloves and RPE 4 were added as a tier 2 during mixing and loading for trigger spraying in kitchen & canteens.

The cumulative risk of propan-1-ol and propan-2-ol was too high for the combined tasks: loading of the trigger spray + trigger spraying in **pharmaceutical and cosmetics manufacturing facilities.** Therefore RPE 4 was added as a tier 2 during mixing and loading for trigger spraying in pharmaceutical and cosmetics manufacturing facilities.   
Since there is no appropriate P1 filter for very small molecules like propan-1-ol and propan-2-ol, a mask with an organic vapor filter, combination filter, type A2/P2 (RPE 10) will be required.

*Scenario [1.2-a] Application of products on surfaces by trigger spraying in unspecified rooms and small rooms*

The calculations cover both unspecified and small rooms as:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Surface (m2) | Volume (m3) | Treated area (m2) |
| Unspecified room | 8 | 20 | 2 |
| Kitchen | 6 | 15 | 1 |
| Ratio | **2** | **2** | **2** |

As the ratio of surface/volume/treated area is always 2, the exposure in the small room will be identical to the exposure in the unspecified room.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [1.2-a] – Application of products on surfaces by trigger spraying in unspecified room** | | | |
| The scenario covers rapid disinfection of small surfaces. Exposed workers are trained professionals or industrial users in unspecified room. The application method is by trigger spraying + wiping. The products are only used indoors in unspecified rooms. Tier 1: No PPE Tier 2: Mask (APF4) | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: BEAT3** | | | |
| Tier 1 | Exposed surface area | Hand palms:  205 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value BEAT | 0,214 ml/min | HEAdhoc recommendation 15 + Expert judgement eCA |
| Frequency of use | 1/day |
| Application/exposure duration | 5 min |
| Area treated | 2 m2 unspecified room  1 m3 – small room |
| PPE | none |  |
| **Inhalation exposure to vapour : ConsExpo – evaporation4** | | | |
| Tier 1 | Application rate | 30 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
|  | 0.05 Propan-2-ol |
| Release area | 2 m2  - unspecified room1 m3 – small room |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Event exposure duration | 60 min | HEAdhoc recommendation 15 + Expert judgement eCA |
| Frequency of use | 1/day |
| Application duration | 5 min |
| Room Volume | 20 m3- unspecified room10 m3 – small room |
| Ventilation rate | 0.6 /h |
| Area disinfected | 2 m2- unspecified room1 m3 – small room |
| Product amount per application (= density x application rate x area disinfected) | 51.9 g- unspecified room25.95 g – small room | Product specific data |
| PPE | none |  |
| Tier 2 | PPE | Mask (APF4) | Since there is no appropriate P1 filter for very small molecules like propan-1-ol and propan-2-ol, a mask with an organic vapor filter, combination filter, type A2/P2 (APF 10) will be required. |

3 In the CAR of propan-1-ol the BEAT model is considered to be sufficiently conservative to assess the dermal exposure during small scale wiping. Therefore BEAT has been considered also to be sufficiently conservative to assess the dermal exposure for small scale wiping in the assessment of Christeyn’s propan1-2-ol BPF, since similar or even identical parameters were used.

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 1.2-a**

Dermal exposure

The indicative value from BEAT is 0,214 ml/min. Assuming an exposure duration of 5 minutes, the amount of propan-1-ol on the skin is 453.52 mg, and the amount of propan-2-ol is 180.48 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 453.52 | 180.48 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 102 | 20 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 102 s for propan-1-ol and 20 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.082 mg/kg bw/d propan-1-ol and 0.016 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 850 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 17.70 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 350 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 7.29 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 1.2-a** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 17.70 | 0.082 | 17.782 | 9.2 | 193 |
| Propan-2-ol | 1 (no PPE) | 7.29 | 0.016 | 7.306 | 17.9 | 40 |
| Propan-1-ol | mask (APF4) | 4.43 | 0.082 | 4.5 | 9.2 | 49 |
| Propan-2-ol | mask (APF4) | 1.82 | 0.016 | 1.83 | 17.9 | 10 |

*Scenario [1.2-b] Application of products on surfaces by trigger spraying in kitchen and canteens*

Please refer to the calculation excel sheet for cleanrooms, laboratories and biotechnology and food processing machinery.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [1.2-b] – Application of products on surfaces by trigger spraying in kitchen and canteens** | | | |
| The scenario covers rapid disinfection of small surfaces. Exposed workers are trained professionals or industrial users in kitchen and canteens. The application method is by trigger spraying + wiping. The products are only used indoors in kitchen and canteens.  Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: BEAT3** | | | |
| Tier 1 | Exposed surface area | Hand palms:  205 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value BEAT | 0,214 ml/min | Expert judgement eCA + refinement applicant |
| Frequency of use | 10 /day |
| Application/exposure duration | 2 min |
| Area treated | 1 m2 |
| PPE | none |  |
| **Inhalation exposure to vapour : ConsExpo – evaporation4** | | | |
| Tier 1 | Application rate | 30 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
|  | 0.05 Propan-2-ol |
| Release area | 1 m2 |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Event exposure duration | 48 min | Expert judgement eCA + refinement applicant |
| Frequency of use | 10 /day |
| Application duration | 2 min |
| Room Volume | 25 m3 |
| Ventilation rate | 15 /h |
| Area disinfected | 1 m2 |
| Product amount per application (= density x application rate x area disinfected) | 25.95 g | Product specific data |
| PPE | none |  |

3 In the CAR of propan-1-ol the BEAT model is considered to be sufficiently conservative to assess the dermal exposure during small scale wiping. Therefore BEAT has been considered also to be sufficiently conservative to assess the dermal exposure for small scale wiping in the assessment of Christeyn’s propan1-2-ol BPF, since similar or even identical parameters were used.

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 1.2-b**

Dermal exposure

The indicative value from BEAT is 0,214 ml/min. Assuming an exposure duration of 2 minutes, the amount of propan-1-ol on the skin is 181.40 mg, and the amount of propan-2-ol is 72.20 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 181.40 | 72.20 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 41 | 8 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 41 s for propan-1-ol and 8 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 10, the total absorbed amount is 0.328 mg/kg bw/d propan-1-ol and 0.065 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 42 mg/m3. With an exposure time of 48 minutes, a frequency of 10 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 7.0 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 17 mg/m3. With an exposure time of 48 minutes, a frequency of 10 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 2.83 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 1.2-b** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 7.0 | 0.328 | 7.33 | 9.2 | 80 |
| Propan-2-ol | 1 (no PPE) | 2.83 | 0.065 | 2.89 | 17.9 | 16 |

*Scenario [1.2-c] Application of products on surfaces by trigger spraying in pharmaceutical and cosmetics manufacturing facilities*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [1.2-c] – Application of products on surfaces by trigger spraying in pharmaceutical and cosmetics manufacturing facilities** | | | |
| The scenario covers rapid disinfection of small surfaces. Exposed workers are trained professionals or industrial users in unspecified rooms. The application method is by trigger spraying + wiping. The products are only used indoors in pharmaceutical and cosmetics manufacturing facilities Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: BEAT3** | | | |
| Tier 1 | Exposed surface area | Hand palms:  205 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value BEAT | 0,214 ml/min | Expert judgement eCA + refinement applicant |
| Frequency of use | 80 /day |
| Application/exposure duration | 1 min |
| Area treated | 0.5 m2 |
| PPE | none |  |
| **Inhalation exposure to vapour : ConsExpo – evaporation4** | | | |
| Tier 1 | Application rate | 30 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
|  | 0.05 Propan-2-ol |
| Release area | 0.5 m2 |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Event exposure duration | 6 min (=8h/80) | Expert judgement eCA + refinement applicant |
| Frequency of use | 80 /day |
| Application duration | 1 min |
| Room Volume | 80 m3 |
| Ventilation rate | 8 /h |
| Area disinfected | 0.5 m2 |
| Product amount per application (= density x application rate x area disinfected) | 12.97 g | Product specific data |
| PPE | none |  |

3 In the CAR of propan-1-ol the BEAT model is considered to be sufficiently conservative to assess the dermal exposure during small scale wiping. Therefore BEAT has been considered also to be sufficiently conservative to assess the dermal exposure for small scale wiping in the assessment of Christeyn’s propan1-2-ol BPF, since similar or even identical parameters were used.

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 1.2-c**

Dermal exposure

The indicative value from BEAT is 0,214 ml/min. Assuming an exposure duration of 6 minutes, the amount of propan-1-ol on the skin is 90.70 mg, and the amount of propan-2-ol is 36.10 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 90.70 | 36.10 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 20 | 4 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 20 s for propan-1-ol and 4 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 80, the total absorbed amount is 1.31 mg/kg bw/d propan-1-ol and 0.26 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 27 mg/m3. With an exposure time of 6 minutes, a frequency of 80 disinfections per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 4.5 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 15 mg/m3. With an exposure time of 6 minutes, a frequency of 80 disinfections per day and an inhalation rate of 1.25 m3/h are assumed, the inhalation exposure is 2.5 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 1.2-c** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 4.5 | 1.31 | 5.81 | 9.20 | 63 |
| Propan-2-ol | 1 (no PPE) | 2.5 | 0.26 | 2.76 | 17.90 | 15 |

*Scenario [1.3] Cleaning of application equipment*

| **Description of Scenario [1.3] – Cleaning of application equipment** |
| --- |
| Exposure during the post-application phase is considered to be negligible. |

*Scenario [2.1] Loading of ready-to-use solution in application equipment*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.1] – Loading of ready-to-use solution in application equipment** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The product is loaded manually into low-pressure sprayers. The products are only used indoors. One pouring/loading operation (10 min) is assumed for a professional user per day.  Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** | |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data | |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR | |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa |
| Propan-2-ol: 5780 Pa |
| Body weight | 60 kg | HEAdhoc recommendation 14 | |
| **Dermal exposure: mixing & loading model 7** | | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 | |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 | |
| Indicative value mixing & loading model 7 | 101 mg/min | HEAdhoc recommendation 6, Nr. 9 | |
| Number of operations | 1 per day, 10 min | Expert judgement eCA | |
| PPE | none |  | |
| **Inhalation exposure to vapour: ART 1.51** | | | | |
| Tier 1 | Exposure duration | 10 min | Expert judgement eCA | |
| Absorption value | 100% | Default value | |
| Inhalation rate | 1.25 m3/h | HEAdhoc recommendation 14 | |
| Activity coefficient | Propan-1-ol: 1.5 | AIOMFAC-web, version 2.32 | |
| Propan-2-ol: 1.34 |
| Activity class | Falling liquids | ART 1.5 | |
| Situation | Transfer of liquid product with flow of 0.1 - 1 l/minute |
| Containment level | Open process |
| Loading type | Splash loading |
| Room size | Any size workroom |
| Ventilation rate | Only good natural ventilation |
| General control measures | No localized controls |
| PPE | none |  | |

1 It is agreed in the CAR of peracetic acid PT11 & 12 and approved union authorizations to use ART for the calculation of inhalation exposure of volatile substances during manual mixing and loading.

**Calculations for scenario 1.1**

Dermal exposure

The indicative value from Mixing and Loading Model 7 is 101 mg/min. Assuming that 1 pouring/loading operation of 10 minutes is performed in a day, the amount of propan-1-ol on the skin is 494.9 mg, and the amount of propan-2-ol on the skin is 196.95 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (both hands): 820 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 494.9 | 196.95 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 28 s | 5.5 s |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 28 s for propan-1-ol and 5.5 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h, this leads to a total absorbed amount of 0.09 mg/kg bw/d propan-1-ol and 0.02 mg/kg bw/d propan-2-ol.

Inhalation exposure to vapour

Propan-1-ol: The predicted 95th percentile full-shift exposure is 190 mg/m³. With an exposure time of 10 minutes and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.6597 mg/kg bw/d.

Propan-2-ol: The predicted 95th percentile full-shift exposure is 140 mg/m3. With an exposure time of 10 minutes and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.4861 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 1.1** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake**  **/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 0.6597 | 0.0903 | 0.75 | 9.2 | 8 |
| Propan-2-ol | 1 (no PPE) | 0.4861 | 0.0178 | 0.50 | 17.9 | 2.8 |

*Scenario [2.2-a] Application of products on surfaces**by low-pressure spraying in Unspecified rooms and small rooms*

Similar as for 1.2-a, as the ratio of surface area/volume/treated area is identical for an unspecified room and a small room, the exposure is covering both room types.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.2-a] - Application of products on surfaces by low-pressure spraying in unspecified rooms** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by low pressure spraying in unspecified rooms.  The products are sold in containers of 1, 5, 10, 18, 20, 22, 25, 33 litre cans, 200, 210, 220, 230, 250 L vessels (HDPE), 600, 1000, 1050, 1100, 1200 L IBCs (HDPE), then transferred to a low- pressure spraying system. It is assumed that a staff person carries out 1 disinfection per day. Tier 1: No PPE Tier 2: Mask (APF 10) | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure:** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value spraying model 1 | 181 mg/min | HEAdhoc recommendation 6, nr. 3 |
| Frequency of use | 1 | Applicant’s info |
| Application/exposure duration | 1.6 min | Applicant’s info |
| PPE | none |  |
| **Inhalation exposure to vapour: ConsExpo – evaporation4** | | | |  |  | |
| Tier 1 | Application rate | 200 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Frequency of use | 1 | Applicant’s info |
| Event exposure duration | 20 min | Applicant’s info |  | |
| Application duration | 1.6 min | Applicant’s info |
| Room Volume | 20 m3 - unspecified room10 m3 – small room | HEAhoc recommendation 15 |
| Ventilation rate | 0.6 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Area disinfected | 8 m2- unspecified room  4 m2– small room | Expert judgement eCA |
| Release area | 8 m2- unspecified room  4 m2– small room |
| Product amount per application (= density x application rate x area disinfected) | 1384 g- unspecified room  692 g- unspecified room | Product specific data |
| PPE | none |  |
| Tier 2 | PPE | Mask (APF 10) | Organic vapor filter, combination filter, type A2/P2 (APF 10) |

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 2.2-a**

Dermal exposure

The indicative value from spraying model 1 is 181 mg/min. Assuming an exposure duration of 1.6 minutes, the amount of propan-1-ol on the skin is 141.90 mg, and the amount of propan-2-ol is 56.47 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 141.90 | 56.47 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 8 | 1.6 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 8 s for propan-1-ol and 1.6 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.026 mg/kg bw/d propan-1-ol and 0.005 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 6600 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 45.83 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 4500 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 31.25 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 2.2-a** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 45.83 | 0.026 | 45.86 | 9.2 | 498 |
| Propan-2-ol | 1 (no PPE) | 31.25 | 0.005 | 31.26 | 17.90 | 174 |
| Propan-1-ol | Mask (APF 10) | 4.583 | 0.026 | 4.6 | 9.20 | 50 |
| Propan-2-ol | Mask (APF 10) | 3.125 | 0.005 | 3.1 | 17.90 | 17 |

*Scenario [2.2-b] Application of products on surfaces by low-pressure spraying in laboratories and biotechnology*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.2-b] - Application of products on surfaces by low-pressure spraying in laboratories and biotechnology** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by low pressure spraying in laboratories and biotechnology.  The products are sold in containers of 1, 5, 10, 18, 20, 22, 25, 33 litre cans, 200, 210, 220, 230, 250 L vessels (HDPE), 600, 1000, 1050, 1100, 1200 L IBCs (HDPE), then transferred to a low- pressure spraying system. It is assumed that a staff person carries out 1 disinfection per day. Tier 1: No PPE  Tier 2: Mask (APF 10) | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure:** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
|  | Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
|  | Indicative value spraying model 1 | 181 mg/min | HEAdhoc recommendation 6, nr. 3 |
|  | Frequency of use | 1 | Applicant’s info |
|  | Application/exposure duration | 2 min | Applicant’s info |
|  | PPE | none |  |
| **Inhalation exposure to vapour: ConsExpo – evaporation4** | | | |  |  | |
| Tier 1 | Application rate | 200 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Frequency of use | 1 | Applicant’s info |
| Event exposure duration | 20 min | Applicant’s info |  | |
| Application duration | 2 min | Applicant’s info |
| Room Volume | 25 m3 | Expert judgement eCA |
| Ventilation rate | 8 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Area disinfected | 10 m2 | Expert judgement eCA |
| Release area | 10 m2 |
| Product amount per application (= density x application rate x area disinfected) | 1730 g | Product specific data |
| PPE | none |  |
| Tier 2 | PPE | Mask (APF 10) | organic vapor filter, combination filter, type A2/P2 (APF 10) |

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 2.2-b**

Dermal exposure

The indicative value from spraying model 1 is 181 mg/min. Assuming an exposure duration of 2 minutes, the amount of propan-1-ol on the skin is 177.38 mg, and the amount of propan-2-ol is 70.59 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 177.38 | 70.59 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 10 | 2 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 10 s for propan-1-ol and 2 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.032 mg/kg bw/d propan-1-ol and 0.006 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 3800 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 26.4 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 2500 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 17.36 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 2.2-b** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 26.38 | 0.032 | 26.41 | 9.20 | 287 |
| Propan-2-ol | 1 (no PPE) | 17.36 | 0.006 | 17.37 | 17.90 | 97 |
| Propan-1-ol | Mask (APF 10) | 2.638 | 0.032 | 2.67 | 9.20 | 29 |
| Propan-2-ol | Mask (APF 10) | 1.736 | 0.006 | 1.74 | 17.90 | 9.7 |

*Scenario [2.2-c] Application of products on surfaces**by low-pressure spraying in industrial production room*

This scenario covers also industrial kitchens.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.2-c] - Application of products on surfaces by low-pressure spraying in industrial production room** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by low pressure spraying in industrial production room.  The products are sold in containers of 1, 5, 10, 18, 20, 22, 25, 33 litre cans, 200, 210, 220, 230, 250 L vessels (HDPE), 600, 1000, 1050, 1100, 1200 L IBCs (HDPE), then transferred to a low- pressure spraying system. It is assumed that a staff person carries out 1 disinfection per day. Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure:** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value spraying model 1 | 181 mg/min | HEAdhoc recommendation 6, nr. 3 |
| Frequency of use | 1 | Applicant’s info |
| Application/exposure duration | 2 min | Applicant’s info |
| PPE | none |  |
| **Inhalation exposure to vapour: ConsExpo – evaporation4** | | | |  |  | |
| Tier 1 | Application rate | 200 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Frequency of use | 1 | Applicant’s info |
| Event exposure duration | 60 min | Applicant’s info |  | |
| Application duration | 2 min | Applicant’s info |
| Room Volume | 300 m3 | Expert judgement eCA |
| Ventilation rate | 20 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Area disinfected | 10 m2 | Refinement applicant |
| Release area | 10 m2 | Refinement applicant |
| Product amount per application (= density x application rate x area disinfected) | 1730 g | Product specific data |
| PPE | none |  |

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 2.2-c**

Dermal exposure

The indicative value from spraying model 1 is 181 mg/min. Assuming an exposure duration of 2 minutes, the amount of propan-1-ol on the skin is 177.38 mg, and the amount of propan-2-ol is 70.59 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 177.38 | 70.59 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 10 | 2 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 10 s for propan-1-ol and 2 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.032 mg/kg bw/d propan-1-ol and 0.006 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 139.2 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 2.9 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 57.6 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 1.2 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 2.2 -c** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 2.90 | 0.032 | 2.93 | 9.20 | 32 |
| Propan-2-ol | 1 (no PPE) | 1.20 | 0.006 | 1.21 | 17.90 | 7 |

*Scenario [2.2-d] Application of products on surfaces**by low-pressure spraying in cleanrooms*

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.2-d] - Application of products on surfaces by low-pressure spraying in cleanrooms** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by low pressure spraying in cleanrooms.  The products are sold in containers of 1, 5, 10, 18, 20, 22, 25, 33 litre cans, 200, 210, 220, 230, 250 L vessels (HDPE), 600, 1000, 1050, 1100, 1200 L IBCs (HDPE), then transferred to a low- pressure spraying system. It is assumed that a staff person carries out 1 disinfection per day. Tier 1: No PPE Tier2: Mask (APF 4) + ventilation rate 20/h | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure:** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
|  | Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
|  | Indicative value spraying model 1 | 181 mg/min | HEAdhoc recommendation 6, nr. 3 |
|  | Frequency of use | 1 | Applicant’s info |
|  | Application/exposure duration | 2 min | Applicant’s info |
|  | PPE | none |  |
| **Inhalation exposure to vapour: ConsExpo – evaporation4** | | | |  |  | |
| Tier 1 | Application rate | 200 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Frequency of use | 1 | Applicant’s info |
| Event exposure duration | 20 min | Applicant’s info |  | |
| Application duration | 2 min | Applicant’s info |
| Room Volume | 55 m3 | HEAhoc recommendation 15 |
| Ventilation rate | 8 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Area disinfected | 10 m2 | Refinement applicant |
| Release area | 10 m2 | Refinement applicant |
| Product amount per application (= density x application rate x area disinfected) | 1730 g | Product specific data |
| PPE | none |  |
| Tier 2 | Ventilation rate | 20 /h | HEAhoc recommendation 15 |
| PPE | Mask APF 4 | Since there is no appropriate P1 filter for very small molecules like propan-1-ol and propan-2-ol, a mask with an organic vapor filter, combination filter, type A2/P2 (APF 10) will be required. |

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 2.2-d**

Dermal exposure

The indicative value from spraying model 1 is 181 mg/min. Assuming an exposure duration of 2 minutes, the amount of propan-1-ol on the skin is 177.38 mg, and the amount of propan-2-ol is 70.59 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 177.38 | 70.59 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 10 | 2 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 10 s for propan-1-ol and 2 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.032 mg/kg bw/d propan-1-ol and 0.006 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 1900 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 13 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 1200 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 8 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 2.2-d** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL** |
| Propan-1-ol | 1 (no PPE) | 13.19 | 0.032 | 13.23 | 9.20 | 144 |
| Propan-2-ol | 1 (no PPE) | 8.33 | 0.006 | 8.34 | 17.90 | 46 |
| Propan-1-ol | Mask (APF 4) + ventilation rate 20/h | 3.3 | 0.032 | 3.33 | 9.20 | 36 |
| Propan-2-ol | Mask (APF 4) + ventilation rate 20/h | 2 | 0.006 | 2 | 17.90 | 11.6 |

*Scenario [2.2-e] Application of products on surfaces**by low-pressure spraying in institutional kitchens and canteens*

This scenario covers also pharmaceuticals and cosmetics manufacturing facilities.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [2.2-e] - Application of products on surfaces by low-pressure spraying in institutional kitchens and canteens** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by low pressure spraying in institutional kitchens and canteens.  The products are sold in containers of 1, 5, 10, 18, 20, 22, 25, 33 litre cans, 200, 210, 220, 230, 250 L vessels (HDPE), 600, 1000, 1050, 1100, 1200 L IBCs (HDPE), then transferred to a low- pressure spraying system. It is assumed that a staff person carries out 1 disinfection per day. Tier 1: No PPE Tier2: Mask (APF 4) | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure:** | | | |
| Tier 1 | Exposed surface area | Hands: 820 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value spraying model 1 | 181 mg/min | HEAdhoc recommendation 6, nr. 3 |
| Frequency of use | 1 | Applicant’s info |
| Application/exposure duration | 2 min | Applicant’s info |
| PPE | none |  |
| **Inhalation exposure to vapour: ConsExpo – evaporation4** | | | |  |  | |
| Tier 1 | Application rate | 200 ml/m2 | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAhoc recommendation 14 |
| Release mode | Increasing |  |
| Frequency of use | 1 | Applicant’s info |
| Event exposure duration | 20 min | Applicant’s info |  | |
| Application duration | 2 min | Applicant’s info |
| Room Volume | 25 m3 | Expert judgement eCA |
| Ventilation rate | 15 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Area disinfected | 10 m2 | Expert judgement eCA |
| Release area | 10 m2 |
| Product amount per application (= density x application rate x area disinfected) | 1730 g | Product specific data |
| PPE | none |  |
| Tier 2 | PPE | Mask (APF 4) | Since there is no appropriate P1 filter for very small molecules like propan-1-ol and propan-2-ol, a mask with an organic vapor filter, combination filter, type A2/P2 (APF 10) will be required. |

4 Because of the high vapour pressure of the active substances, evaporation is considered as the exposure relevant process, not aerosol forming, in accordance with approved union authorisations.

**Calculations for scenario 2.2-e**

Dermal exposure

The indicative value from spraying model 1 is 181 mg/min. Assuming an exposure duration of 2 minutes, the amount of propan-1-ol on the skin is 177.38 mg, and the amount of propan-2-ol is 70.59 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 177.38 | 70.59 |
| P (Pa) | 3774 at 30°C | 7544 at 30°C |
| t (s) | 10 | 2 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 10 s for propan-1-ol and 2 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.032 mg/kg bw/d propan-1-ol and 0.006 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 2600 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 18 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 1700 mg/m3. With an exposure time of 20 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 12 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 2.2-e** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL** |
| Propan-1-ol | 1 (no PPE) | 18 | 0.032 | 18 | 9.20 | 197 |
| Propan-2-ol | 1 (no PPE) | 12 | 0.006 | 12 | 17.90 | 66 |
| Propan-1-ol | Mask (APF 4) | 4.5 | 0.032 | 4.5 | 9.20 | 50 |
| Propan-2-ol | Mask (APF 4) | 3 | 0.006 | 3 | 17.90 | 16.5 |

*Scenario [3.1] Loading of ready-to-use solution into dipping bath or bucket*

|  |
| --- |
| **Description of Scenario [3.1] – Loading of ready-to-use solution into dipping bath or bucket** |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The products are poured into a dipping bath or bucket manually, 5 times per day.  The products are only used indoors. According to TNsG 2002, dipping model 1 covers a range of dipping activities, including mixing and loading. Exposure during loading of the dipping bath is covered by scenario [3.2]. |

*Scenario [3.2-a] Disinfection of objects by dipping in unspecified rooms*

This scenario covers all room types (cleanrooms, pharmaceutical and cosmetics manufacturing facilities, laboratories and biotechnology, kitchens and canteens, food processing machinery).

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3.2-a] – Disinfection of objects by dipping in unspecified rooms** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The objects to be disinfected are brought into the disinfection bath or bucket. After the required contact time, the objects are removed from the disinfection bath or bucket and left to dry. The products are only used indoors, in unspecified rooms, 5 times per day. Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: Dipping model 1** | | | |
| Tier 1 | Exposed surface area | Hands + forearms: 1948.8 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Exposure/application duration | 5 min | Applicant’s info |
| Frequency of use | 5 | Applicant’s info |
| Indicative value dipping model 1 | 25.7 mg/min | HEAdhoc recommendation 6, Nr. 8 |
| PPE | none |  |
| **Inhalation exposure to vapour : ConsExpo - evaporation** | | | |
| Tier 1 | Applied amount per application | 25 l x 0.865 g/l = 21 625 g | Applicant’s info |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol | Product specific data |
| Release area | 25 l, bath height 10 cm = 2500 cm2 | Applicant’s info |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAdhoc recommendation 14 |
| Release mode | Constant |  |
| Event exposure duration | 5 min | Efficacy contact time |
| Frequency of use | 5 | Applicant’s info |
| Application duration | 5 min | Efficacy contact time |
| Room Volume | 20 m3 | HEAdhoc recommendation 15 |
| Ventilation rate | 0.6 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| PPE | none |  |

**Calculations for scenario 3.2-a**

Dermal exposure

The indicative value from dipping model 1 is 25.7 mg/min. Assuming an exposure duration of 5 minutes per day, the amount of propan-1-ol on the skin is 62.96 mg, and the amount of propan-2-ol on the skin is 25.06 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (both hands): 1948.8 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 62.96 mg | 25.06 mg |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 1.5 | 0.29 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 1.5 s for propan-1-ol and 0.29 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 5, this leads to a total absorbed amount of 0.057 mg/kg bw/d propan-1-ol and 0.011 mg/kg bw/d propan-2-ol.

Inhalation exposure to vapour

Propan-1-ol: the mean event concentration is 98 mg/m3. With an exposure time of 5 minutes, a frequency of 5 times a day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.85 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 82 mg/m3. With an exposure time of 5 minutes, a frequency of 5 times a day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 0.71 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 3.2-a** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake**  **/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 0.85 | 0.057 | 0.90 | 9.2 | 9 |
| Propan-2-ol | 1 (no PPE) | 0.71 | 0.011 | 0.72 | 17.9 | 4 |

*Scenario [3.2-b] Disinfection of objects by dipping in small rooms*

The amount of product used in dipping scenario is the same for all room types, however the volume of small rooms is lower than the unspecified rooms, therefore only the inhalation exposure is higher in small rooms compared to the unspecified rooms. This scenario is the worst case compared to the unspecified room, but for the reason of completeness this scenario is added. This scenario covers all room types (cleanrooms, pharmaceutical and cosmetics manufacturing facilities, laboratories and biotechnology, kitchens and canteens, food processing machinery).

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [3.2-b] – Disinfection of objects by dipping in small rooms** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The objects to be disinfected are brought into the disinfection bath or bucket. After the required contact time, the objects are removed from the disinfection bath or bucket and left to dry. The products are only used indoors, in unspecified rooms, 5 times per day. Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.865 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: Dipping model 1** | | | |
| Tier 1 | Exposed surface area | Hands + forearms: 1948.8 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Exposure/application duration | 5 min | Applicant’s info |
| Frequency of use | 5 | Applicant’s info |
| Indicative value dipping model 1 | 25.7 mg/min | HEAdhoc recommendation 6, Nr. 8 |
| PPE | none |  |
| **Inhalation exposure to vapour : ConsExpo - evaporation** | | | |
| Tier 1 | Applied amount per application | 25 l x 0.865 g/l = 21 625 g | Applicant’s info |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol | Product specific data |
| Release area | 25 l, bath height 10 cm = 2500 cm2 | Applicant’s info |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAdhoc recommendation 14 |
| Release mode | Constant |  |
| Event exposure duration | 5 min | Efficacy contact time |
| Frequency of use | 5 | Applicant’s info |
| Application duration | 5 min | Efficacy contact time |
| Room Volume | 10 m3 | HEAdhoc recommendation 15 |
| Ventilation rate | 0.6 /h |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| PPE | none |  |

**Calculations for scenario 3.2-b**

Dermal exposure

The indicative value from dipping model 1 is 25.7 mg/min. Assuming an exposure duration of 5 minutes per day, the amount of propan-1-ol on the skin is 62.96 mg, and the amount of propan-2-ol on the skin is 25.06 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (both hands): 1948.8 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 62.96 mg | 25.06 mg |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 1.5 | 0.29 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 1.5 s for propan-1-ol and 0.29 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 5, this leads to a total absorbed amount of 0.057 mg/kg bw/d propan-1-ol and 0.011 mg/kg bw/d propan-2-ol.

Inhalation exposure to vapour

Propan-1-ol: the mean event concentration is 200 mg/m3. With an exposure time of 5 minutes, a frequency of 5 times a day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 1.73 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 160 mg/m3. With an exposure time of 5 minutes, a frequency of 5 times a day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 1.39 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 3.2-b** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake**  **/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 1.74 | 0.057 | 1.79 | 9.2 | 19.49 |
| Propan-2-ol | 1 (no PPE) | 1.39 | 0.011 | 1.40 | 17.9 | 7.82 |

*Scenario [3.3] Emptying and cleaning of dipping bath or bucket*

|  |
| --- |
| **Description of Scenario [3.3] – Emptying and cleaning of dipping bath or bucket** |
| According to TNsG 2002, dipping model 1 covers a range of dipping activities, including mixing and loading. Exposure during emptying and cleaning of the dipping bath is covered by scenario [3.2] |

*Scenario [4.1] Single use wet wipes - loading*

| **Description of Scenario [4.1] – Single use wet wipes - loading** |
| --- |
| Not applicable: the pre-wetted wipes are ready-to-use and there is no loading phase. |

*Scenario [4.2-a] Single use wet wipes – application in unspecified rooms and small rooms*

Similar as for 1.2-a, as the ratio of surface area/volume/treated area is identical for an unspecified room and a small room, the exposure is covering both room types. Moreover, this scenario covers cleanrooms, pharmaceutical and cosmetics manufacturing facilities, laboratories and biotechnology, kitchens and canteens, food processing machinery.

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of Scenario [4.2-a] – Single use wet wipes – application in unspecified rooms and small rooms** | | | |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. The application method is by wiping. The products are single-use pre-wetted wipes. The user removes the wipe from the packaging and proceeds to wipe a surface with it. The worst-case product amount in wipes is 3.75 g per wipe using in unspecified rooms  Tier 1: No PPE | | | |
|  | **Parameters** | **Value** | **Reference** |
| Concentration of Active Substances | Propan-1-ol: 49% | Product specific data |
| Propan-2-ol: 19.5% |
| Density of product: | 0.8729 g/mL |
| Molecular weight of Active Substance | Propan-1-ol: 60.096 g/mol | CAR |
| Propan-2-ol: 60.096 g/mol |
| Vapour pressure | Propan-1-ol: 2760 Pa at 25°C |
| Propan-2-ol: 5780 Pa at 25°C |
| Body weight: | 60 kg | HEAdhoc recommendation 14 |
| **Dermal exposure: BEAT3** | | | |
| Tier 1 | Exposed surface area | Hand palms:  205 cm2 | HEAdhoc recommendation 14 |
| Dermal flux rate | 0.85 mg/cm2/h | Boatman et al. 1998 |
| Indicative value BEAT | 0,214 ml/min | Expert judgement eCA |
| Frequency of use | 1/day |
| Application/exposure duration | 5 min |
| Area treated | 2 m2- unspecified room1 m2 – small room |
| PPE | none |  |
| **Inhalation exposure: ConsExpo** | | | |
| Tier 1 | Application rate | 1 wipe / m2  3.75 g / wipe | Product specific data |
| Molecular weight matrix | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol | Product specific data |
| Kow (10 log) | 0.25 Propan-1-ol | CAR |
| 0.05 Propan-2-ol |
| Absorption value | 100% | Default value |
| Inhalation rate | 1.25 m3/h | HEAdhoc recommendation 14 |
| Release mode | Increasing |  |
| Mass transfer rate | 10 m/hr | Consexpo Cleaning Products Fact Sheet |
| Event exposure duration | 60 min | Expert judgement eCA |
| Frequency of use | 1 /day |
| Application duration | 5 min |
| Room Volume | 20 m3- unspecified room10 m3 – small room | HEAdhoc recommendation 14 |
| Ventilation rate | 0.6 /h |
| Release area | 2 m2- unspecified room1 m2 – small room | Expert judgement eCA |
| Area disinfected | 2 m2- unspecified room1 m2 – small room |
| Product amount per application (= 3.75 g x area disinfected) | 7.5 g | Product specific data |
| PPE | 7.5 g- unspecified room3.75 g – small room |  |

3 In the CAR of propan-1-ol the BEAT model is considered to be sufficiently conservative to assess the dermal exposure during small scale wiping. Therefore BEAT has been considered also to be sufficiently conservative to assess the dermal exposure for small scale wiping in the assessment of Christeyn’s propan1-2-ol BPF, since similar or even identical parameters were used.

**Calculations for scenario 4.2-a**

Dermal exposure

The indicative value from BEAT is 0,214 ml/min. Assuming an exposure duration of 5 minutes, the amount of propan-1-ol on the skin is 457.66 mg, and the amount of propan-2-ol is 182.13 mg. Following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

t = m x R x T / (M x β x p x A) x K

t: time [s]

m: mass of propan-1-ol and propan-2-ol on surface: see table

R: gas constant: 8.314 J/K/mol

T: skin/surface temperature: 303.15 K

M: molar mass: 60.1 g/mol

β: mass transfer coefficient, for calculation see TGD: 8.7 m/h

p: vapour pressure of the pure substance: see table

A: surface area (hands): 205 cm2

K: conversion factor: 36000

|  |  |  |
| --- | --- | --- |
|  | **propan-1-ol** | **propan-2-ol** |
| m (mg) | 457.66 | 182.13 |
| P (Pa)\* | 3774 at 30°C | 7544 at 30°C |
| t (s) | 103 | 20 |

\* obtained by calculation and the Clausius-Clapeyron equation

According to this equation the evaporation time is 103 s for propan-1-ol and 20 s for propan-2-ol. Using the dermal flux rate 0.85 mg/cm2/h and assuming a use frequency of 1, the total absorbed amount is 0.083 mg/kg bw/d propan-1-ol and 0.016 mg/kg bw/d propan-2-ol.

Inhalation exposure

Propan-1-ol: the mean event concentration is 130 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 2.7 mg/kg bw/d.

Propan-2-ol: the mean event concentration is 53 mg/m3. With an exposure time of 60 minutes, a frequency of 1 disinfection per day and an inhalation rate of 1.25 m3/h, the inhalation exposure is 1.1 mg/kg bw/d.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure scenario 4.2-a** | | | | | | |
|  | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated total uptake**  **(mg/kg bw/d)** | **AEL** | **Estimated total uptake/AEL (%)** |
| Propan-1-ol | 1 (no PPE) | 2.7 | 0.83 | 2.79 | 9.20 | 30 |
| Propan-2-ol | 1 (no PPE) | 1.1 | 0.016 | 1.12 | 17.90 | 6 |

*Scenario [4.3] Single use wiping tissue - disposal*

| **Description of Scenario [4.3] – Single use wiping tissue – disposal** |
| --- |
| Post-application exposure is considered negligible due to the high volatility of both active substances and possible exposure is included in the application assessment. |

*Scenario [5.1] Adult bystander present during disinfection*

| **Description of Scenario [5.1] – Adult bystander present during disinfection** |
| --- |
| For the applications and room types, where PPE is required, a re-entry time was determined for the bystander to enter the treated room safely.  Consexpo Web was used to model this re-entry period based on the air concentration present after the application. The model used was Exposure to vapour – instantaneous release using the air concentration of propan-1-ol and propan-2-ol present in the treated room after application. This concentration was compared with the acceptable air concentrations:   * **Propan-1-ol: 55.2 mg/m3** (based on the AEL of 9.2 mg/kg bw/day, a body weight of 60kg, inhalation rate of 1.25m3/h and an exposure duration of 8h) * **Propan-2-ol: 52.6 mg/m3** (based on the AEC)   If the air concentration after application exceeds the acceptable air concentration, a re-entry time needs to be defined. The re-entry time per application per room type is listed in the tables below. |

*Scenario [5.1] Adult bystander present during disinfection – Trigger spraying*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Room volume (m3) | Ventilation rate (h-1) | Air concentration propan-1-ol after application (mg/m3) | Re-entry time (min) | Air concentration propan-2-ol after application (mg/m3) | Re-entry time (min) |
| **Cleanrooms** | 55 | 8 | 19 | 0 | 7.6 | 0 |
| **Pharmaceutical and cosmetics manufacturing facilities** | 80 | 8 | 27 | 0 | 15 | 0 |
| **Laboratories and biotechnology** | 25 | 8 | 42 | 0 | 17 | 0 |
| **Unspecified room** | 20 | 0,6 | 850 | **274**  **+ 60 min exposure duration**  **= 334 min** | 350 | **192**  **+ 60 min exposure duration**  **= 252 min** |
| **Kitchen and canteens** | 25 | 15 | 42 | 0 | 17 | 0 |
| **Food processing machinery** | 300 | 20 | 12 | 0 | 4.8 | 0 |
| **Small rooms** | 10 | 0.6 | 850 | **274**  **+ 60 min exposure duration**  **= 334 min** | 350 | **192**  **+ 60 min exposure duration**  **= 252 min** |

*Scenario [5.1] Adult bystander present during disinfection – Low pressure spraying*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Room volume (m3) | Ventilation rate (h-1) | Air concentration propan-1-ol after application (mg/m3) | **Re-entry time (min)** | Air concentration propan-2-ol after application (mg/m3) | **Re-entry time (min)** |
| **Cleanrooms** | 55 | 8 | 1900 | **28.8**  **+20 min exposure duration**  **= 48.8** | 1200 | **24**  **+20 min exposure duration**  **= 44** |
| **Pharmaceutical and cosmetics manufacturing facilities** | 80 | 8 | 1400 | **28.8**  **+20 min exposure duration**  **= 48.8** | 870 | **24**  **+20 min exposure duration**  **= 44** |
| **Laboratories and biotechnology** | 25 | 8 | 3800 | **33.6**  **+20 min exposure duration**  **= 53.6** | 2500 | **33.6**  **+20 min exposure duration**  **= 53.6** |
| **Unspecified room** | 20 | 0,6 | 6600 | **480**  **+20 min exposure duration**  **= 500** | 4500 | **446**  **+20 min exposure duration**  **= 466** |
| **Institutional kitchens and canteens** | 25 | 15 | 2600 | **19.2**  **+ 20 min exposure duration**  **= 39.2** | 1700 | **14.4**  **+20 min exposure duration**  **= 34.4** |
| **Industrial kitchens** | 2400 | 15 | 12 | **0** | 4.6 | **0** |
| **Industrial production rooms** | 300 | 20 | 130 | **4.8**  **+ 60 min exposure duration**  **= 64.8** | 55 | **4.8**  **+60 min exposure duration**  **= 64.8** |
| **Small rooms** | 10 | 0.6 | 6600 | **480**  **+20 min exposure duration**  **= 500** | 4500 | **446**  **+20 min exposure duration**  **= 466** |

*Scenario [5.1] Adult bystander present during disinfection – Wiping*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume (m3)** | **Ventilation rate (h-1)** | **Air concentration propan-1-ol after application (mg/m3)** | **Re-entry time (min)** | **Air concentration propan-2-ol after application (mg/m3)** | **Re-entry time (min)** |
| **Cleanrooms** | 55 | 8 | 2.8 | 0 | 1.1 | 0 |
| **Pharmaceutical and cosmetics manufacturing facilities** | 80 | 8 | 7.0 | 0 | 2.3 | 0 |
| **Laboratories and biotechnology** | 25 | 8 | 6.1 | 0 | 2.4 | 0 |
| **Unspecified room** | 20 | 0,6 | 130 | **81.6**  **+ 60 min exposure duration**  **= 141.6** | 53 | **4.8**  **+ 60 min exposure duration**  **= 64.8** |
| **Kitchen and canteens** | 25 | 15 | 6.1 | 0 | 2.4 | 0 |
| **Food processing machinery** | 300 | 20 | 1.7 | 0 | 0.7 | 0 |
| **Small rooms** | 10 | 0.6 | 130 | **81.6**  **+ 60 min exposure duration**  **= 141.6** | 53 | **4.8**  **+ 60 min exposure duration**  **= 64.8** |

*Scenario [5.1] Adult bystander present during disinfection – Dipping*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume (m3)** | **Ventilation rate (h-1)** | **Air concentration propan-1-ol after application (mg/m3)** | **Re-entry time (min)** | **Air concentration propan-2-ol after application (mg/m3)** | **Re-entry time (min)** |
| **Unspecified room** | 20 | 0,6 | 98 | **62.4** | 82 | **52.8** |
| **Kitchen and canteens** | 25 | 15 | 55 | 0 | 46 | 0 |
| **Food processing machinery** | 300 | 20 | 4.1 | 0 | 3.4 | 0 |
| **Small rooms** | 10 | 0.6 | 200 | **130** | 160 | **115** |

*Scenario [5.2] Re-entry of infants to treated rooms*

| **Description of Scenario [5.2] – Re-entry of infants to treated rooms** |
| --- |
| After disinfection of certain room types, namely unspecified rooms and small rooms by trigger spraying, low-pressure spraying and wiping, it is expected that infants enter those premises and be exposed to the product.  Consexpo Web was used to model this re-entry period based on the air concentration present after the application. The model used was Exposure to vapour – instantaneous release using the air concentration of propan-1-ol and propan-2-ol present in the treated room after application. This concentration was compared with the acceptable air concentrations:   * **Propan-1-ol: 10.95 mg/m3** (based on the AEL of 9.2 mg/kg bw/day, a body weight of 8kg, inhalation rate of 0.84m3/h and an exposure duration of 8h) * **Propan-2-ol: 52.6 mg/m3** (based on the AEC)   If the air concentration after application exceeds the acceptable air concentration, a re-entry time needs to be defined. The re-entry time per application per room type is listed in the tables below. |

*Scenario [5.2] Re-entry of infants to treated rooms – Trigger spraying*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume (m3)** | **Ventilation rate (h-1)** | **Air concentration propan-1-ol after application (mg/m3)** | **Re-entry time (min)** | **Air concentration propan-2-ol after application (mg/m3)** | **Re-entry time (min)** |
| **Unspecified rooms** | 20 | 0.6 | 850 | **446**  **+ 60 min exposure duration**  **= 506** | 350 | **202**  **+ 60 min exposure duration**  **= 262** |
| **Small rooms** | 10 | 0.6 |

*Scenario [5.2] Re-entry of infants to treated rooms – Low pressure spraying*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume (m3)** | **Ventilation rate (h-1)** | **Air concentration propan-1-ol after application (mg/m3)** | **Re-entry time (min)** | **Air concentration propan-2-ol after application (mg/m3)** | **Re-entry time (min)** |
| **Unspecified rooms** | 20 | 0.6 | 6600 | **648**  **+20 min exposure duration**  **= 668** | 4500 | **446**  **+20 min exposure duration**  **= 466** |
| **Small rooms** | 10 | 0.6 |

*Scenario [5.2] Re-entry of infants to treated rooms – wiping*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Room volume (m3)** | **Ventilation rate (h-1)** | **Air concentration propan-1-ol after application (mg/m3)** | **Re-entry time (min)** | **Air concentration propan-2-ol after application (mg/m3)** | **Re-entry time (min)** |
| **Unspecified rooms** | 20 | 0.6 | 130 | **259**  **+ 60 min exposure duration**  **= 319** | 53 | **14.4**  **+ 60 min exposure duration**  **= 74.4** |
| **Small rooms** | 10 | 0.6 |

*Scenario [5.3] Post-application contact with treated surfaces*

| **Description of Scenario [5.3] – Post-application contact with treated surfaces** |
| --- |
| Exposed workers are trained professionals or industrial users in institutions or in the food or other industry. Contact with treated surfaces can occur for users or bystanders. Due to the high volatility of both active substances, confirmed by residue studies, and the fact that there are no substances of concern, it is concluded that no significant secondary exposure to treated surfaces will occur and calculations are not performed. |

***Calculations for Scenarios [1-5]***

|  | **Summary table: estimated exposure from professional uses** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Room type** | **Tier/PPE** | | **Estimated inhalation uptake mg/kg bw/d (aerosol+vapour)** | | | **Estimated dermal uptake mg/kg bw/d** | **Estimated oral uptake** | **Estimated total uptake**  **mg/kg/d** |
| 1 trigger spraying | Unspecified rooms  And small rooms | Tier 2: mask (APF4) for application | | Propan-1-ol:  5.09 mg/kg bw/d  Propan-2-ol:  2.31 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  5.21 mg/kg bw/d  Propan-2-ol:  2.33 mg/kg bw/d |
| 1 trigger spraying | Kitchen and canteens | Tier 2: mask (APF 4) and gloves (APF 10) for mixing and loading | | Propan-1-ol:  7.16 mg/kg bw/d  Propan-2-ol:  2.95 mg/kg bw/d | | | Propan-1-ol:  0.33 mg/kg bw/d  Propan-2-ol:  0.07 mg/kg bw/d | Not relevant | Propan-1-ol:  7.50 mg/kg bw/d  Propan-2-ol:  3.02 mg/kg bw/d |
| 1 trigger spraying | Cleanroom | Tier 1: no PPE | | Propan-1-ol:  3.63 mg/kg bw/d  Propan-2-ol:  1.67 mg/kg bw/d | | | Propan-1-ol:  0.20 mg/kg bw/d  Propan-2-ol:  0.04 mg/kg bw/d | Not relevant | Propan-1-ol:  3.83 mg/kg bw/d  Propan-2-ol:  1.71 mg/kg bw/d |
| 1 trigger spraying | Laboratories and biotechnology | Tier 1: no PPE | | Propan-1-ol:  7.22 mg/kg bw/d  Propan-2-ol:  3.14 mg/kg bw/d | | | Propan-1-ol:  0.20 mg/kg bw/d  Propan-2-ol:  0.04 mg/kg bw/d | Not relevant | Propan-1-ol:  7.42 mg/kg bw/d  Propan-2-ol:  3.18 mg/kg bw/d |
| 1 trigger spraying | Food processing machinery | Tier 1: no PPE | | Propan-1-ol:  2.66 mg/kg bw/d  Propan-2-ol:  1.29 mg/kg bw/d | | | Propan-1-ol:  0.86 mg/kg bw/d  Propan-2-ol:  0.17 mg/kg bw/d | Not relevant | Propan-1-ol:  3.52 mg/kg bw/d  Propan-2-ol:  1.46 mg/kg bw/d |
| 1 trigger spraying | Pharmaceutical and cosmetics manufacturing facilities | Tier 2: mask (APF 4) for mixing and loading | | Propan-1-ol:  4.66 mg/kg bw/d  Propan-2-ol:  2.62 mg/kg bw/d | | | Propan-1-ol:  1.35 mg/kg bw/d  Propan-2-ol:  0.27 mg/kg bw/d | Not relevant | Propan-1-ol:  6.02 mg/kg bw/d  Propan-2-ol:  2.89 mg/kg bw/d |
| 2 low-pressure spraying | Unspecified rooms  and small rooms | Tier 2: Mask (APF 10) for application | | Propan-1-ol:  5.24 mg/kg bw/d  Propan-2-ol:  3.61 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  5.36 mg/kg bw/d  Propan-2-ol:  3.63 mg/kg bw/d |
| 2 low-pressure spraying | Laboratories and biotechnology | Tier 2: Mask (APF 10) for application | | Propan-1-ol:  3.30 mg/kg bw/d  Propan-2-ol:  2.22 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  3.42 mg/kg bw/d  Propan-2-ol:  2.25 mg/kg bw/d |
| 2 low-pressure spraying | Pharmaceutical and cosmetics manufacturing facilities | Tier 2: Mask (APF 4) for application | | Propan-1-ol:  3.39 mg/kg bw/d  Propan-2-ol:  2.57 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  3.51 mg/kg bw/d  Propan-2-ol:  2.59 mg/kg bw/d |
| 2 low-pressure spraying | Institutional kitchens and canteens | Tier 2: mask (APF4) for application | | Propan-1-ol:  5.17 mg/kg bw/d  Propan-2-ol:  3.44 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  5.3 mg/kg bw/d  Propan-2-ol:  3.46 mg/kg bw/d |
| 2 low-pressure spraying | Industrial production room | Tier 1: no PPE | | Propan-1-ol:  3.37 mg/kg bw/d  Propan-2-ol:  1.63 mg/kg bw/ | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  3.49 mg/kg bw/d  Propan-2-ol:  1.66 mg/kg bw/d |
| 2 low-pressure spraying | Cleanrooms | Tier 2: mask (APF 4)+ ventilation rate 20/h for application | | Propan-1-ol:  3.96 g/kg bw/d  Propan-2-ol:  2.57 mg/kg bw/d | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  4.08 mg/kg bw/d  Propan-2-ol:  2.59 mg/kg bw/d |
| 2 low-pressure spraying | Industrial kitchen | Tier 1: no PPE | | Propan-1-ol:  1.16 mg/kg bw/d  Propan-2-ol:  0.68 mg/kg bw/ | | | Propan-1-ol:  0.12 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  1.28 mg/kg bw/d  Propan-2-ol:  0.70 mg/kg bw/d |
| 3 Dipping | Unspecified rooms | Tier 1: No PPE | | Propan-1-ol:  0.85 mg/kg bw/d  Propan-2-ol:  0.71 mg/kg bw/d | | | Propan-1-ol:  0.06 mg/kg bw/d  Propan-2-ol:  0.01 mg/kg bw/d | Not relevant | Propan-1-ol:  0.91 mg/kg bw/d  Propan-2-ol:  0.72 mg/kg bw/d |
| 3 Dipping | Kitchen and canteens | Tier 1: No PPE | | Propan-1-ol:  0.48 mg/kg bw/d  Propan-2-ol:  0.40 mg/kg bw/d | | | Propan-1-ol:  0.06 mg/kg bw/d  Propan-2-ol:  0.01 mg/kg bw/d | Not relevant | Propan-1-ol:  0.53 mg/kg bw/d  Propan-2-ol:  0.41 mg/kg bw/d |
| 3 Dipping | Food processing machinery | Tier 1: No PPE | | Propan-1-ol:  0.04 mg/kg bw/d  Propan-2-ol:  0.03 mg/kg bw/d | | | Propan-1-ol:  0.06 mg/kg bw/d  Propan-2-ol:  0.01 mg/kg bw/d | Not relevant | Propan-1-ol:  0.09 mg/kg bw/d  Propan-2-ol:  0.04 mg/kg bw/d |
| 3 Dipping | Small rooms | Tier 1: No PPE | Propan-1-ol:  1.74 mg/kg bw/d  Propan-2-ol:  1.39 mg/kg bw/d | Propan-1-ol:  0.06 mg/kg bw/d  Propan-2-ol:  0.01 mg/kg bw/d | Not relevant | Propan-1-ol:  1.79 mg/kg bw/d  Propan-2-ol:  1.40 mg/kg bw/d |
| 4 Wiping | Unspecified rooms and small rooms | Tier 1: no PPE | | Propan-1-ol:  2.71 mg/kg bw/d  Propan-2-ol:  1.10 mg/kg bw/d | | | Propan-1-ol:  0.08 mg/kg bw/d  Propan-2-ol:  0.02 mg/kg bw/d | Not relevant | Propan-1-ol:  2.79 mg/kg bw/d  Propan-2-ol:  1.12 mg/kg bw/d |
| 4 Wiping | Pharmaceutical and cosmetics manufacturing facilities | Tier 1: no PPE | | Propan-1-ol:  1.17 mg/kg bw/d  Propan-2-ol:  0.48 mg/kg bw/d | | | Propan-1-ol:  1.32 mg/kg bw/d  Propan-2-ol:  0.03 mg/kg bw/d | Not relevant | Propan-1-ol:  2.49 mg/kg bw/d  Propan-2-ol:  0.52 mg/kg bw/d |
| 4 Wiping | cleanrooms | Tier 1: no PPE | | Propan-1-ol:  0.44 mg/kg bw/d  Propan-2-ol:  0.17 mg/kg bw/d | | | Propan-1-ol:  0.17 mg/kg bw/d  Propan-2-ol:  0.03 mg/kg bw/d | Not relevant | Propan-1-ol:  0.60 mg/kg bw/d  Propan-2-ol:  0.20 mg/kg bw/d |
| 4 Wiping | Laboratories and biotechnology | Tier 1: no PPE | | Propan-1-ol:  0.95 mg/kg bw/d  Propan-2-ol:  0.38 mg/kg bw/d | | | Propan-1-ol:  0.17 mg/kg bw/d  Propan-2-ol:  0.03 mg/kg bw/d | Not relevant | Propan-1-ol:  1.12 mg/kg bw/d  Propan-2-ol:  0.41 mg/kg bw/d |
| 4 Wiping | Kitchen and canteens | Tier 1: no PPE | | Propan-1-ol:  1.02 mg/kg bw/d  Propan-2-ol:  0.40 mg/kg bw/d | | | Propan-1-ol:  0.33 mg/kg bw/d    Propan-2-ol:  0.07 mg/kg bw/d | Not relevant | Propan-1-ol:  1.35 mg/kg bw/d  Propan-2-ol:  0.47 mg/kg bw/d |
| 4 Wiping | Food processing machinery | Tier 1: no PPE | | Propan-1-ol:  0.28 mg/kg bw/d  Propan-2-ol:  0.12 mg/kg bw/d | | | Propan-1-ol:  0.83 mg/kg bw/d    Propan-2-ol:  0.16 mg/kg bw/d | Not relevant | Propan-1-ol:  1.11 mg/kg bw/d  Propan-2-ol:  0.28 mg/kg bw/d |

***Further information and considerations on scenario [1-5]***

There is no further information.

*Combined scenarios*

The assessment of combined scenarios is not necessary because the different uses are not performed at the same time or by the same type of workers. Trigger spraying, wet wiping or dipping is typically done by workers in production (e.g. slaughters in slaughterhouses), but not all uses at the same time, whereas disinfection by low-pressure spraying is typically done by a dedicated cleaning / disinfection team.

Even if trigger spraying, wiping and dipping is combined by the same worker, since a full working day has been considered in the exposure calculations any combination of these uses is covered by the worst case exposure, in this case a full working day of trigger spraying.

***Non-professional exposure***

The products are only for professional use, there is no non-professional exposure.

***Exposure of the general public***

Exposure by inhalation route may occur when general public enters the treated area. Only the unspecified room and the small room are expected to be entered by general public. Therefore, re-entry times were calculated for infants for the unspecified and small room, and these were included in the RMM. Please refer to scenario 5.2 and annex for detailed calculations.

Regarding dermal and oral exposure (contact with treated surfaces) due to the very high volatility of active substances we can expect that the majority of these substances present on the surfaces will evaporate after the contact time. It is concluded that no significant secondary exposure to treated surfaces will occur. Therefore the calculations are not performed.

***Monitoring data***

Not relevant: there are no significant residues in food or feeding stuffs.

***Dietary exposure***

The biocidal product family “*Christeyns’ Propan-1/2-ol*” consist of PT4 type of products containing maximum 49.07% propan-1-ol of and 19.54% of propan-2-ol (corresponding to the product in the meta spc 3, Mida San 311 KZ). The products may come into direct contact with food or feed during professional surface disinfection of small surfaces in food/feed processing areas, kitchens or canteens. However, due to their high vapour pressure, the actives substances completely evaporate within the application time (5 or 20 min) of the biocidal product, so that no transfer of active substance residues from treated surfaces to food should take place. In the unlikely event that residue transfer occurs, the active substances evaporate from the food before being consumed. Therefore, dietary exposure to humans from the use of propan-2-ol and propan-1-ol as a biocide of PT 4 should be excluded.

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

The main use for isopropanol (IPA) is in solvents with outlets in cosmetics and personal care products, de-icers, paints and resins, pharmaceuticals, food, inks and adhesives. A pharmaceutical grade of IPA allows its use in the preparation of a number of pharmaceutical products such as medicinal tablets as well as disinfectants, sterilisers and skin creams. Little or no growth is expected in solvent applications due to stricter regulations on volatile organic compounds (VOCs).

IPA is used in the extraction and purification of natural products such as vegetable and animal oil and fats. Other applications include its use as a cleaning and drying agent in the manufacture of electronic parts and metals, and as an aerosol solvent in medical and veterinary products. It can also be used as a coolant in beer manufacture, a coupling agent, a polymerisation modifier, a de-icing agent and a preservative.[[13]](#footnote-14)

Propan-1-ol is used as a solvent in dyes, paints and coatings, in fuels and fuel additives, as a viscosity adjustor, in cleaning and furnishing care products, in food packaging, fuels and related products, in ink, toner and colorant products, paper products and personal care products.[[14]](#footnote-15)

Both isopropanol and 1-propanol are listed in Commission Implementing Regulation (EU) No 872/2012[[15]](#footnote-16) as flavouring substances intended to be used in or on foodstuffs.

Residue definitions

Not relevant: there are no significant residues in food or feeding stuffs.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use** | **Intended use** | **Reference value(s) 2** |
| 1. | Food industry | Food additive | - |
| 2. | Veterinary | Feeding additive | - |
| 3. | Dyes, paints, inks, pigments | Solvent, additive | - |
| 4. | Fuel | Solvent, additive | - |
| 5. | Cleaning products | Solvent, additive | - |
| 6. | Cosmetics | Solvent, additive | - |
| 7. | Pharmaceuticals | Solvent, additive | - |
| 8. | Paper products | Solvent, additive | - |

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

There is no livestock exposure from the products in this dossier, as they are not used in PT3.

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

Due to the high volatility of the active substances, no transfer into foods is expected. In the unlikely event that residue transfer occurs, the actives substances evaporate from the food before being consumed.

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

Not applicable: there is no non-professional use.

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

Exposure associated with production and formulation is regulated by national worker protection regulations and disposal of the biocidal product is regulated by national and local legislation. It is therefore not necessary to evaluate this exposure within the framework of a biocidal product authorisation dossier.

***Aggregated exposure***

Due to the low hazard profile of both active substances, it is not considered necessary to conduct an aggregated exposure assessment.

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| **Propan-1-ol** | | | | | |
| AELshort-term | Rat inhalation  developmental  toxicity studies  (foetal skeletal  malformations) | 1830 mg/kg bw/d | 100 | - | 27.6 mg/kg bw |
| AELmedium-term | Overall NOAEL from  rat 13-week  inhalation study  (impairment of male  fertility parameters) | 1830 mg/kg bw/d | 100 | - | 18.3 mg/kg bw/d |
| AELlong-term | Overall NOAEL from  rat 13-week rat  inhalation study  (impairment in male  fertility parameters) | 1830 mg/kg bw/d | 200 (In addition to default AF  of 100, application of  separate AF of 2 for  extrapolation from  medium-term to long-term  systemic toxicity) | - | 9.2 mg/kg bw/d |
| ARfD | 13-week inhalation studies (rat) | 1830 mg/kg bw/d | 100 | - | 27.6 mg/kg bw/d |
| ADI | 13-week inhalation studies (rat) | 1830 mg/kg bw/d | 200 | - | 9.2 mg/kg bw/d |
| **Propan-2-ol** | | | | | |
| AELshort-term/medium term/long-term (General Populaiton) | Human  volunteer  study  (Sethre et al.  2000a) | NOAEC 200 ppm | 6.4 (for intraspecies variability within the general population) |  | 10.7 mg/kg  bw/d  (31.25 ppm  for 8  hours/d) |
| AELshort-term/medium term/long-term (Professionals) | Human  volunteer  study  (Sethre et al.  2000a) | NOAEC 200 ppm | 3.8 (for intraspecies variability within the general population) | - | 17.9 mg/kg  bw/d  (52.6 ppm  for 8  hours/d) |
| ARfD | n.a. | n.a. | n.a. | n.a. | n.a.: Not necessary, no residues in food expected |
| ADI | Scientific Committee for Food | n.a. | n.a. | n.a. | 2.4 mg/kg/d |

**Maximum residue limits or equivalent**

No maximum residue limits have been set for propan-1-ol or. Due to the rapid degradation it is not considered necessary to establish such limits.

Regarding propan-2-ol is an approved active substance in the veterinary regulation and that no MRLs are required according to Regulation  (EU) 37/2010. Propan-2-ol is a non-approved active substance in the PPP regulation (Regulation (EC) N° 1107/2009) and default MRLs at 0.01 mg/kg are established according to article 18(1)(b) of Reg (EC) 396/2005.

**Specific reference value for groundwater**

Not applicable.

***Risk for industrial users***

The risk for industrial users is covered by the risk assessment for professional users.

***Risk for professional users***

**Systemic effects**

In the table below an overview of the risk assessment of all claimed room types per scenario is presented.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Room type** | **Tier** | **Active substance** | | **Systemic NOAEL**  **mg/kg bw/d** | | **AEL**  **mg/kg bw/d** | | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1 trigger spraying | Unspecified rooms and small rooms | Tier 2: mask (APF4) | Propan-1-ol | | 1830 | | 9.2 | | 5.21 | 56.60 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 2.33 | 13.03 | Yes |
| Kitchen and canteens | Tier 2: mask (APF 4) and gloves (APF 10) for mixing and loading | Propan-1-ol | | 1830 | | 9.2 | | 7.50 | 81.49 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 3.02 | 16.88 | Yes |
| Cleanrooms | Tier 1: no PPE | Propan-1-ol | | 1830 | | 9.2 | | 3.83 | 41.64 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 1.71 | 9.57 | Yes |
| Laboratories and biotechnology | Propan-1-ol | | 1830 | | 9.2 | | 7.42 | 80.70 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 3.18 | 17.78 | Yes |
| Food processing machinery | Propan-1-ol | | 1830 | | 9.2 | | 3.52 | 38.25 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 1.46 | 8.14 | Yes |
| Pharmaceutical and cosmetics manufacturing facilities | Tier 2: mask (APF 4) for mixing and loading | Propan-1-ol | | 1830 | | 9.2 | | 6.02 | 65.39 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 2.89 | 16.15 | Yes |
| 2 low-pressure spraying | Unspecified rooms and small rooms | Tier 2: Mask (APF 10) for application | Propan-1-ol | | 1830 | | 9.2 | | 5.36 | 58.25 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 3.63 | 20.30 | Yes |
| 2 low-pressure spraying | Laboratories and biotechnology | Tier 2: Mask (APF 10) for application | Propan-1-ol | | 1830 | | 9.2 | | 3.42 | 37.18 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 2.25 | 12.55 | Yes |
| 2 low-pressure spraying | Pharmaceutical and cosmetics manufacturing facilities | Tier 2: mask (APF4) for application | Propan-1-ol | | 1830 | | 9.2 | | 3.51 | 38.17 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 2.59 | 14.49 | Yes |
| 2 low-pressure spraying | Institutional kitchens and canteens | Propan-1-ol | | 1830 | | 9.2 | | 5.30 | 57.56 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 3.46 | 19.34 | Yes |
| 2 low-pressure spraying | Cleanrooms | Tier 2: Mask (APF 4) for application + ventilation rate 20/h | Propan-1-ol | | 1830 | | 9.2 | | 4.08 | 44.36 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 2.59 | 14.49 | Yes |
| 2 low-pressure spraying | Industrial production room | Tier 1: (No PPE) | Propan-1-ol | | 1830 | | 9.2 | | 3.49 | 37.94 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 1.66 | 9.25 | Yes |
| 2 low-pressure spraying | Industrial kitchen | Propan-1-ol | | 1830 | | 9.2 | | 1.28 | 13.94 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.70 | 3.92 | Yes |
| 3 Dipping | Unspecified rooms | Tier 1: No PPE | Propan-1-ol | | 1830 | | 9.2 | | 0.91 | 9.87 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.72 | 4.04 | Yes |
| 3 Dipping | Kitchen and canteens | Propan-1-ol | | 1830 | | 9.2 | | 0.53 | 5.81 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.41 | 2.29 | Yes |
| 3 Dipping | Food processing machinery | Propan-1-ol | | 1830 | | 9.2 | | 0.09 | 1.01 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.04 | 0.23 | Yes |
| 3 Dipping | Small rooms |  | Propan-1-ol  Propan-2-ol | 1830  200 ppm | 9.2  17.9 | 1.79  1.40 | 19.49  7.82 | Yes  Yes |
| 4 Wiping | Unspecified rooms and small rooms | Tier 1: No PPE | Propan-1-ol | | 1830 | | 9.2 | | 2.79 | 30.34 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 1.12 | 6.26 | Yes |
| 4 Wiping | Pharmaceutical and cosmetics manufacturing facilities | Propan-1-ol | | 1830 | | 9.2 | | 2.49 | 27.08 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.52 | 2.88 | Yes |
| 4 Wiping | Cleanrooms | Propan-1-ol | | 1830 | | 9.2 | | 0.60 | 6.56 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.20 | 1.14 | Yes |
| 4 Wiping | Laboratories and biotechnology | Propan-1-ol | | 1830 | | 9.2 | | 1.12 | 12.16 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.41 | 2.28 | Yes |
| 4 Wiping | Kitchen and canteens | Propan-1-ol | | 1830 | | 9.2 | | 1.35 | 14.65 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.47 | 2.60 | Yes |
| 4 Wiping | Food processing machinery | Propan-1-ol | | 1830 | | 9.2 | | 1.11 | 12.08 | Yes |
| Propan-2-ol | | 200 ppm | | 17.9 | | 0.28 | 1.57 | Yes |

**Combined scenarios**

The substances within one scenario were already combined for the calculations presented above. The combination of exposure from different scenarios is not relevant, as the different uses will not be performed by one worker at the same time/day or by the same type of worker.

**Local effects for professional users**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Hazard effects** | **Uses** | **Frequency and duration of total exposure** | **Degree of potential exposure under best practice conditions** | **Relevant RMM** | **PPE** | **Acceptable (yes/no)** |
| **EUH066** | All | More than few  minutes but  equal to or less than few hours per day | Controlled exposure | **Technics**  - Minimisation of manual phases/work  tasks,  - Minimisation of splashes and spills;  - Avoidance of contact with contaminated  tools and objects;  - Regular cleaning of equipment and work area;  **Organisation**  - Management/supervision in place to check  that the RMMs in place are being used  correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene | **Mixing & loading:**  - Face shield;  - Substance/task appropriate gloves;  **Trigger spraying:**  - Face shield;  - Substance/task appropriate gloves;  **Low pressure sprayinga:**  - Substance/task appropriate gloves;  - protection coverall (EN  13034, 13962, 14605 or 943 according to pattern of exposure)  **Dipping bath:**  - Face shield;  - Substance/task appropriate gloves;  **RTU wipesb:**  - Substance/task appropriate gloves; | Yes  RMM & PPE are sufficiently protective for the use and exposure duration |
| **Eye dam. 1, H318** | Trigger spraying | Few minutes per task, circa 30 minutes per day | Controlled exposure | **Technics**  - Containment as appropriate;  - Segregation of the emitting process;  - Effective contaminant extraction;  - Good standard of general ventilation;  - Minimisation of manual phases;  - Regular cleaning of equipment and work  area;  - Avoidance of contact with contaminated  tools and objects;  **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. | Safety goggles (EN166)c | Yes  RMM & PPE are sufficiently protective for the use and exposure duration |
| Low pressure spraying | Circa 120 minutes per day | Controlled exposure | Full face mask | Yes  RMM & PPE are sufficiently protective for the use and exposure duration |
| Dipping bath | Few minutes per task, circa 30 minutes per day | Controlled exposure | Safety goggles (EN166)d | Yes  RMM & PPE are sufficiently protective for the use and exposure duration |
| RTU Wipes | Few minutes per task, circa 30 minutes per day | High level of containment,  practically no exposure; no  splashes, no hand to eye transfer,  no (liquid or solid) aerosol  formation | -b | Yes  RMM are sufficiently protective for the use and exposure duration |

a No face shield because already covered by full face mask

b Only exposure to hands expected

c Already covered by face shield

d Already covered by face shield

**Conclusion**

The risks for local effects are well under control by appropriate technics, organisation and personal protective equipment. The applied measures may depend on the individual situation of the users and is the responsibility of the employer.

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

Not applicable: the products are only for professional use.

***Risk for the general public***

Not applicable: the products are only for professional use.

The products are not for use in areas accessible for the general public.

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

The product is meant to be used for PT4 food hygiene. However due to the high volatility, there is no concern about residues in food.

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

Cumulative risk assessment of propan-1-ol and propan-2-ol:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Room type** | **Tier** | | **Active substance** | | **AEL**  **mg/kg bw/d** | | **Estimated uptake**  **mg/kg bw/d** | | **Estimated uptake/ AEL (%)** | **Hazard index** | **Acceptable (yes/no)** |
| 1 trigger spraying | Unspecified rooms and small rooms | Tier 2: mask (APF4) | | Propan-1-ol | | 9.2 | | 5.21 | | 56.60 | 69.63 | yes |
| Propan-2-ol | | 17.9 | | 2.33 | | 13.03 |
| 1 trigger spraying | Kitchen and canteens | Tier 2: mask (APF 4) and gloves (APF 10) for mixing and loading | | Propan-1-ol | | 9.2 | | 7.50 | | 81.49 | 98.37 | yes |
| Propan-2-ol | | 17.9 | | 3.02 | | 16.88 |
| 1 trigger spraying | Cleanrooms | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 3.83 | | 41.64 | 51.22 | yes |
| Propan-2-ol | | 17.9 | | 1.71 | | 9.57 |
| 1 trigger spraying | Laboratories and biotechnology | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 7.42 | | 80.70 | 98.48 | yes |
| Propan-2-ol | | 17.9 | | 3.18 | | 17.78 |
| 1 trigger spraying | Food processing machinery | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 3.52 | | 38.25 | 46.39 | yes |
| Propan-2-ol | | 17.9 | | 1.46 | | 8.14 |
| 1 trigger spraying | Pharmaceutical and cosmetics manufacturing facilities | Tier 2: mask (APF 4) for mixing and loading | | Propan-1-ol | | 9.2 | | 6.02 | | 65.39 | 81.54 | yes |
| Propan-2-ol | | 17.9 | | 2.89 | | 16.15 |
| 2 low-pressure spraying | Unspecified rooms and small rooms | Tier 2: Mask (APF 10) for application | | Propan-1-ol | | 9.2 | | 5.36 | | 58.25 | 78.55 | yes |
| Propan-2-ol | | 17.9 | | 3.63 | | 20.30 |
| 2 low-pressure  Spraying | Laboratories and biotechnology | Tier 2: Mask (APF 10) for application | | Propan-1-ol | | 9.2 | | 3.42 | | 37.18 | 49.73 | yes |
| Propan-2-ol | | 17.9 | | 2.25 | | 12.55 |
| 2 low-pressure spraying | Pharmaceutical and cosmetics manufacturing facilities | Tier 2: mask (APF4) for application | | Propan-1-ol | | 9.2 | | 3.51 | | 38.17 | 52.66 | yes |
| Propan-2-ol | | 17.9 | | 2.59 | | 14.49 |
| 2 low-pressure spraying | Institutional kitchens and canteens | Tier 2: mask (APF4) for application | | Propan-1-ol | | 9.2 | | 5.30 | | 57.56 | 76.90 | yes |
| Propan-2-ol | | 17.9 | | 3.46 | | 19.34 |
| 2 low-pressure spraying | Cleanrooms | Tier 2: Mask (APF 4) for application + ventilation rate 20/h | | Propan-1-ol | | 9.2 | | 4.08 | | 44.36 | 58.85 | yes |
| Propan-2-ol | | 17.9 | | 2.59 | | 14.49 |
| 2 low-pressure spraying | Industrial production room | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 3.49 | | 37.94 | 47.19 | yes |
| Propan-2-ol | | 17.9 | | 1.66 | | 9.25 |
| 2 low-pressure spraying | Industrial kitchen | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 1.28 | | 13.94 | 17.86 | yes |
| Propan-2-ol | | 17.9 | | 0.70 | | 3.92 |
| 3 Dipping | Unspecified rooms | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 0.91 | | 9.87 | 13.91 | yes |
| Propan-2-ol | | 17.9 | | 0.72 | | 4.04 |
| 3 Dipping | Kitchen and canteens | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 0.53 | | 5.81 | 8.10 | yes |
| Propan-2-ol | | 17.9 | | 0.41 | | 2.29 |
| 3 Dipping | Food processing machinery | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 0.09 | | 1.01 | 1.23 | yes |
| Propan-2-ol | | 17.9 | | 0.04 | | 0.23 |
| 3 Dipping | Small rooms | Tier 1: No PPE | Propan-1-ol  Propan-2-ol | 9.2  17.9 | 1.79  1.40 | | 19.49  7.82 | 27.31 | yes |
| 4 Wiping | Unspecified rooms and small rooms | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 2.79 | | 30.34 | 36.60 | yes |
| Propan-2-ol | | 17.9 | | 1.12 | | 6.26 |
| 4 Wiping | Pharmaceutical and cosmetics manufacturing facilities | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 2.49 | | 27.08 | 29.97 | yes |
| Propan-2-ol | | 17.9 | | 0.52 | | 2.88 |
| 4 Wiping | Cleanrooms | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 0.60 | | 6.56 | 7.70 | yes |
| Propan-2-ol | | 17.9 | | 0.20 | | 1.14 |
| 4 Wiping | Laboratories and biotechnology | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 1.12 | | 12.16 | 14.44 | yes |
| Propan-2-ol | | 17.9 | | 0.41 | | 2.28 |
| 4 Wiping | Kitchen and canteens | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 1.35 | | 14.65 | 17.25 | yes |
| Propan-2-ol | | 17.9 | | 0.47 | | 2.60 |
| 4 Wiping | Food processing machinery | Tier 1: No PPE | | Propan-1-ol | | 9.2 | | 1.11 | | 12.08 | 13.65 | yes |
| Propan-2-ol | | 17.9 | | 0.28 | | 1.57 |

There are no other active substances or substances of concern to consider in this product formulation.

### Risk assessment for animal health

The field of use is restricted to pharmaceutical industries, food- and non-food industry area, contact to animals is not expected.

### Risk assessment for the environment

The products within this Biocidal Product Family contain 2 active substances : Propan-1-ol (CAS n°71-23-8) and Propan-2-ol (CAS n°67-63-0). No substances of concern for the environment were identified.

Since the products contain more than one active substance, the assessment performed for the representative product(s) for the active substance(s) listed in the Union list of approved active substances under Regulation No.528/2012 could not be used and a new assessment for the environment is presented below.

The applicant submitted access to alternative dossiers for both active substances. They were evaluated and considered to satisfy to the requirements set out in Annex II of the regulation (EU) No 528/2012 by the German CA. They are both included in the ECHA’s list of alternative dossiers.

According to CG-17 document No. AP 13.1-CG-17-2016-13 “*Evaluation of alternative dossiers during product authorisation*”, “*the latest LoEP agreed by the BPC in the context of the (initial or reviewed) approval of the active substance should be taken into account for the product authorisation, regardless of the availability of new relevant data*”, unless the new data would “*significantly modify the conclusions of the hazard or risk assessment of the active substance*”. Since the data provided in the alternative dossiers does not significantly modify the conclusions of the hazard or risk assessment of the active substance, the evaluation of this Biocidal Product Family will be based on data that were agreed during the approval of the active substances propan-1-ol and propan-2-ol.

#### Effects assessment on the environment

Propan-1-ol (*active substance n°1*) :

**Sewage treatment plant**

In a test on the respiration inhibition of activated sludge conducted according to OECD

Guideline 209, the EC50 was calculated to be >1000 mg a.s./L. Therefore, an EC50 value of 1000 mg/L was used as a worst case. Considering an assessment factor of 100 a PNECSTP of 10 mg/L was derived.

**Aquatic compartment**

The lowest acute effect concentration was derived from a study with *Nitocra spinipes* resulting in an EC50 of 2300 mg/L after 48 hours. Since there are no valid long term studies with propan-1-ol available, an assessment factor of 1000 was applied resulting in a

PNECwater of 2.3 mg/L.

**Sediment**

Studies on sediment dwelling organisms were not available. By using the equilibrium partioning method a PNECsediment of 1.998 mg/kgwwt (9.19 mg/kgdwt) was estimated.

**Terrestrial compartment**

Based on PNECwater a PNECsoil of 0.432 mg/kgwwt (0.489 mg/kgdwt) was derived by using equilibrium partioning method.

**Non-compartment specific effects relevant to the food chain (secondary poisoning)**

With regard to the low estimated BCF values results (BCFFish = 0.33 L/kgwet fish and BCFEarthworm = 0.86 L/kgwet earthworm applying the experimentally derived logKOW of 0.25) propan-1-ol is not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

**Atmosphere**

A PNECair cannot be derived, but acute and subchronic inhalation studies with rats can be used as indication of adverse effects of chemicals on species arising from atmospheric contamination. Available results of these studies reveal that effect values are clearly above the environmental concentration in air. Therefore, no adverse effects on terrestrial organisms (mammals) are expected. A similar conclusion can be drawn for honeybees or terrestrial plants, for which negative effects as a result of the intended uses of the active substance are also not to be expected.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on PNEC values for Propan-1-ol** | | | |
| **PNECSTP** | **PNECwater** | **PNECsed** | **PNECsoil** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/ kgwwt] |
| 10 | 2.3 | 1.998 | 0.432 |

Propan-2-ol (*active substance n°2*) :

**Sewage treatment plant**

In a test on the respiration inhibition of activated sludge conducted according to OECD Guideline 209, the EC50 was calculated to be >1000 mg a.s./L. Therefore, an EC50 value of 1000 mg/L was used as a worst case. Considering an assessment factor of 100 a PNECSTP of 10 mg/L was derived.

**Aquatic compartment**

Acute data on effects of propan-2-ol are available on fish, invertebrates and algea. Chronic data on effects of propan-2-ol are available on invertebrates and algae. The lowest chronic effect value (NOEC = 141 mg a.s./L) was derived from a chronic study with *Daphnia magna*. By applying an assessment factor of 50, a PNECwater of 2.82 mg a.s./L was derived.

**Sediment**

Studies on sediment dwelling organisms are not available. By using equilibrium partitioning method a PNECsediment of 2.41 mg/kgwwt (11.1 mg/kgdwt) was estimated.

**Terrestrial compartment**

Based on PNECwater a PNECsoil of 0.496 mg/kgwwt (0.562 mg/kgdwt) was derived by using equilibrium partitioning method.

**Non-compartment specific effects relevant to the food chain (secondary poisoning)**

Applying the experimentally derived log KOW of 0.05 results in a BCFFish of 0.22 L/kgwwt and a BCFEarthworm of 0.85 L/kgwwt. With regard to the low estimated BCF values in aquatic and terrestrial indicator species, propan-2-ol is not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

**Atmosphere**

For the air compartment ecotoxicological data on animal species are not available and methods for determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed. Therefore, no quantitative estimation of PNECair for the active substance is possible.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on PNEC values for Propan-2-ol** | | | |
| **PNECSTP** | **PNECwater** | **PNECsed** | **PNECsoil** |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/ kgwwt] |
| 10 | 2.82 | 2.41 | 0.496 |

***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***

Classification of the products is based on ecotoxicological properties of the components, and CLP mixture rules. According to information available, Propan-1-ol and Propan-2-ol are not classified for the environment. The products within this BPF do not contain other substance(s) with such classification. Therefore, no classification for the environment is required.

|  |
| --- |
| **Conclusion on the environmental classification and labelling of the product** |
| ***Classification :***  Not required  ***Labelling :***  Not required |

***Further Ecotoxicological studies***

No further ecotoxicological studies are available.

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

No further studies on the effects on non-target organisms (flora and fauna) believed to be at risk are available.

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

Not relevant. The biocidal products do not come in the form of bait or granules so no such data is required.

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

Not relevant. The biocidal products do not come in the form of bait or granules so no such data is required.

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

No additional data are required. The biocidal products are for indoor use only.

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

The high vapour pressure of Propan-1-ol (2760 Pa at 25°C) and Propan-2-ol (5780 Pa at 25°C) indicates that the substances will be mainly released to indoor air when applied on surfaces, and then to local outdoor air. The Henry’s Law constants (respectively 0.76 Pa/m³/mol at 25°C and 0.80 Pa/m³/mol at 25°C) indicate a moderate volatility from water, it can therefore be assumed that a fraction of the substances will be also released to air from the dipping baths. The active substances may enter the aquatic and terrestrial environment due to deposition of airborne product.

It is also expected that the substances will be emitted to the environment via the waste water. It is assumed that waste water is emitted to the surface water after treatment in a local waste water treatment plant. Fresh water and fresh water sediments could thus be exposed. The soil can be then exposed through sludge application, leading to an emission to groundwater.

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

No further studies on fate and behaviour in the environment are available.

***Leaching behaviour (ADS)***

Leaching tests are not considered relevant to the proposed uses.

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

No data available or required.

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

No data available or required.

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

No data available or required.

***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. The products are not to be sprayed near to surface waters.

***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. The products are not to be sprayed outside.

#### Exposure assessment

The maximum concentrations of active substances in the family are of 49.07% for Propan 1-ol and 19.54% for Propan-2-ol. Therefore, the environmental risk assessment was performed on this worst-case. All the products are ready-to-use.

The products are intended for indoor use and for professionals only :

* PT2 in non-food industry, institutions, workplaces on small and large areas :
* Spraying (trigger or low-pressure) and wiping (wet wipes) for the disinfection of surfaces  scenario 1, 2 and 3.
* Object disinfection dipping  scenario 6.
* PT4 in large-scale kitchens, restaurants, food industry on small and large areas :
* Spraying (trigger or low-pressure) and wiping (wet wipes) for the disinfection of surfaces  scenario 4 and 5.
* Object disinfection dipping  scenario 6.

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Scenario 1: Emission scenario for calculating the releases of disinfectants used in industrial areas Table 2 p.12  Scenario 2: Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on the annual tonnage applied (Van der Poel 2001) Table 3 p.14  Scenario 3: Emission scenario for calculating the releases of disinfectants used for sanitary purposes based on an average consumption (Van der Poel 2001) Table 4 p.16 |
| ESD(s) used | Supplement to the ESD for PT 2: Emission scenarios for private and public health area disinfectants and other biocidal products (JRC Scientific and Technical Reports, 2011) |
| Approach | Scenario 1: Average consumption  Scenario 2: Tonnage  Scenario 3: Average consumption |
| Distribution in the environment | Calculated based on Simple Treat 4.0 |
| Groundwater simulation | Not relevant |
| Confidential Annexes | YES: tonnage calculations are provided in the confidential annex of this PAR*.* |
| Life cycle steps assessed | Scenario 1, 2 & 3:  Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | The emissions results from the scenario 2 won’t be used for PEC calculation and risk characterisation according to the break-even point method. See below in the “Emission estimation” section for further information. |

|  |  |
| --- | --- |
| Assessed PT | PT 4 |
| Assessed scenarios | Scenario 4: Emission scenario for calculating the releases of disinfectants used in entire plants (e.g. breweries, dairies, beverage processing plants) (IHO 2006) Table 5 p.15  Scenario 5: Emission scenario for calculating the releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries (IHO 2006) Table 10 p.22 |
| ESD(s) used | ESD for PT 4: Emission scenarios for Disinfectants used in food and feed areas (JRC Scientific and Technical Reports, 2011) |
| Approach | Scenario 4: Average consumption  Scenario 5: Average consumption |
| Distribution in the environment | Calculated based on Simple Treat 4.0 |
| Groundwater simulation | Not relevant |
| Confidential Annexes | NO |
| Life cycle steps assessed | Scenario 4 & 5:  Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | - |

|  |  |
| --- | --- |
| Assessed PT | PT 2 & 4 |
| Assessed scenarios | Scenario 6: Emission scenario for pre-disinfection dipping |
| ESD(s) used | Technical Agreements for Biocides (TAB) – ENV v.2.1  TAB entry : ENV45 |
| Approach | Scenario 6: Average consumption |
| Distribution in the environment | Calculated based on Simple Treat 4.0 |
| Groundwater simulation | Not relevant |
| Confidential Annexes | NO |
| Life cycle steps assessed | Scenario 6 :  Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | - |

***Emission estimation***

During the environmental risk assessment of the active substances Propan-1-ol and Propan-2-ol it was assumed that 90% of the a.s. is released to air and 10% of the a.s. is released to water. According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In this family the product is either wiped or left to dry after the treatment of the surfaces. The relatively high vapour pressures of both active substances indicate that a significant amount of substance applied will be released to indoor air, which will be emitted to the local outside air. Nevertheless, releases to waste water via leakages or rinse off cannot be excluded for liquid products. The distribution of 90% to air and 10% to water seems realistic and is maintained for the purpose of this evaluation.

According to the information provided by the applicant the worst-case application rate for spraying applications (PT2 and PT4) is 200 ml/m² with low-pressure spray one time per day. For trigger spray the application rate is 30ml/m². Up to 4 times per day i.e. 120 ml/m² which is less than 200 ml/m². Furthermore, the low-pressure spraying allows large surface to be disinfected and cannot be considered as RTU products like spraying flacons or wipes, therefore when a surface area had to be selected, the large scale was chosen as a worst-case.

**Scenario [1]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Releases of disinfectants used in industrial areas* | | | |
| Application rate of biocidal product (Vform) | 0.2 | L/m² | S |
| Concentration of active substance in the product (Cform) | Propan-1-ol : 424.45  Propan-2-ol : 169.02 | g/L | S |
| Surface area to be disinfected (AREAsurface) | 1000 | m² | D |
| Number of applications per day (Nappl) | 1 | d-1 | S |
| Fraction of substance disintegrated during or after application (before release to the sewer system) (Fdis) | 0 | [-] | D |
| Fraction of substance eliminated due to onsite pre-treatment of waste water (Felim) | 0 | [-] | D |
| Fraction released to wastewater (Fwater) | 0.1 | [-] | Propan-1-ol and Propan-2-ol CAR |
| Fraction released to air (Fair) | 0.9 | [-] | Propan-1-ol and Propan-2-ol CAR |

Calculations for Scenario [1]

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

**Elocalair** = Vform \* Cform \* AREAsurface \* Nappl \* (1 - Fdis) \* Fair / 1000

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocal) [kg/d]** | |
| Propan-1-ol | Propan-2-ol |
| STP | 8.49 | 3.38 |
| Air | 76.4 | 30.4 |

**Scenario [2]**

As explained in the confidential annex, based on the breakeven point, the “consumption-based” model should be used as the worst-case approach.

**Scenario [3]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Disinfectants used for sanitary purposes based on an average consumption* | | | |
| Number of inhabitants feeding one STP (Nlocal) | 10000 | [-] | D |
| Fraction released to waste water (Fwater) | 0.1 | [-] | Propan-1-ol and Propan-2-ol CAR |
| Fraction released to air (Fair) | 0.9 |  | Propan-1-ol and Propan-2-ol CAR |
| Active substance in product (Cproduct) | Propan-1-ol : 0.424  Propan-2-ol : 0.169 | kg/L | S |
| Consumption per capita (Qproduct) | General purposes (tiles, floors, sinks) + Lavatory : 0.007 | L/cap/d | D |
| Penetration factor of disinfectant (Fpenetr) | Propan-1-ol : 0.5  Propan-2-ol : 0.3 | [-] | Propan-1-ol : D  Propan-2-ol : CAR |

Calculations for Scenario [3]

**Elocalwater** = Nlocal \* Fwater \* Cproduct \* Qproduct \* Fpenetr

**Elocalair** = Nlocal \* Fair \* Cproduct \* Qproduct \* Fpenetr

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocal) [kg/d]** | |
| Propan-1-ol | Propan-2-ol |
| STP | 1.49 | 0.35 |
| Air | 13.4 | 3.19 |

**Scenario [4]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Releases of disinfectants used in entire plants* | | | |
| Amount of biocidal active substance used per year in the local plant (Qai) | 143 | kg/yr | P (same value for both AS) |
| Number of emission days per year (Temission) | 231 | d/yr | D |
| Fraction released to wastewater (Fwater) | 0.1 | [-] | Propan-1-ol and Propan-2-ol CAR |
| Fraction released to air (Fair) | 0.9 | [-] | Propan-1-ol and Propan-2-ol CAR |
| Fraction of substance eliminated due to onsite pre-treatment of waste water (Felim) | 0 | [-] | D |
| Fraction of substance disintegrated during or after application (before release to the sewer system) (Fdis) | 0 | [-] | D |
| Capacity of the On-site STP (CAPSTP-on-site) | 112.7 | m³/d | D |
| Capacity of the Off-site STP (CAPSTP-off-site) | 2000 | m³/d | D |
| Dilution factor in surface water (standard default according to the TGD) (DIL) | 160 | [-] | D |

Calculations for Scenario [4]

**Ceffluent\_on-site****= Clocalwater**= (Qai/Temission) \* 1000 \* (1-Fdis) \* (1-Felim) \* Fwater / (CAPSTP\_on-site \* DIL)

**Cinfluent\_off-site =** (Qai/Temission) \* 1000 \* (1-Fdis) \* (1-Felim) \* Fwater / CAPSTP\_off-site

| **Resulting concentrations in STP** | | |
| --- | --- | --- |
|  | **Concentration (C) [mg/L]** | |
| Propan-1-ol | Propan-2-ol |
| Effluent On-site | 3.43x10-3 | 3.43x10-3 |
| Influent Off-site | 3.10x10-2 | 3.10x10-2 |

**Elocalair** = (Qai/Temission) \* Fair

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocal) [kg/d]** | |
| Propan-1-ol | Propan-2-ol |
| Air | 0.557 | 0.557 |

**Scenario [5]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Releases of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries* | | | |
| Type of application | Spraying/Wiping | [-] | P |
| Size of the area treated | Large scale application | [-] | P |
| Application rate of active substance (Qaiappl) | Propan-1-ol : 84.89  Propan-2-ol : 33.8 | g/m² | S  Converted from % with relative density |
| Surface area to be disinfected (AREAsurface) | 10000 | m² | D |
| Number of applications per day (Nappl) | 1 | d-1 | D |
| Fraction of substance disintegrated during or after application (before release to the sewer system) (Fdis) | 0 | [-] | D |
| Fraction of substance eliminated due to the on-site pre-treatment of the plant waste water) (Felim) | 0 | [-] | D |
| Fraction released to waste water (Fwater) | 0.1 | [-] | Propan-1-ol and Propan-2-ol CAR |
| Fraction released to waste water (Fair) | 0.9 | [-] | Propan-1-ol and Propan-2-ol CAR |

Calculations for Scenario [5]

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

**Elocalair** =Qaiappl \* AREAsurface \* Nappl \* Fair / 1000

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocal) [kg/d]** | |
| Propan-1-ol | Propan-2-ol |
| STP | 84.9 | 33.8 |
| Air | 764 | 304 |

**Scenario [6]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: *Pre-disinfection dipping* | | | |
| Working concentration of active ingredient (Cdisinf) | Propan-1-ol : 49.07  Propan-2-ol : 19.54 | % | S |
| Volume of solution in  dipping bath (Qdipping\_bath) | 0.01 | m³ | D |
| Maximum number of dipping bath per day | 30 | d-1 | D |
| Fraction released to wastewater (Fwater) | 1 | [-] | D |

Calculations for Scenario [6]

**Elocalwater** = Cdisinf \* Qdipping\_bath \* Fwater \* Ndipping\_bath \* 10

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocal) [kg/d]** | |
| Propan-1-ol | Propan-2-ol |
| STP | 147 | 58.6 |

***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 | Ground-water | Other |
| All scenarios | Yes (+) | Yes (+) | No (-) | No (-) | Yes (++) | Yes(Q) | Yes(+) | Yes (+) | Not relevant |

++ compartment directly exposed; + compartment indirectly exposed; - compartment not exposed; Q will be assessed qualitatively

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment – *Propan-1-ol*** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 60.09 | g/mol | - |
| Melting point | -127 | °C | - |
| Boiling point | 97.2 | °C | 1013 hPa |
| Vapour pressure (at 25°C) | 2.76x103 | Pa |  |
| Water solubility (at 25°C) | 1x105 | mg/L | Completely miscible in water, set to maximum value in EUSES |
| Log Octanol/water partition coefficient | 0.25 | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | 3.96 | L/kg | - |
| Henry’s Law Constant (at 25°C) | 0.76 | Pa/m3/mol | - |
| Biodegradability | Readily biodegradable | - | - |
| Rate constant for STP | 1 | h-1 | No measured value available, default value based on screening test |
| DT50 for biodegradation in surface water | 15 | d | No measured value available, default value based on screening test |
| DT50 for hydrolysis in surface water | - | - | No hydrolysis |
| DT50 for photolysis in surface water | Not relevant (absorbance < 290 nm) | - | - |
| DT50 for degradation in soil | 30 | d | No measured value available, default value based on screening test |
| DT50 for degradation in air | 2.8 | d | Half-life in the troposphere |
| BFCfish | 0.33 | L/kgwet fish | Calculated from log Kow |
| BFCworm | 0.86 | L/kgwet earthworm | Calculated from log Kow |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment – *Propan-2-ol*** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Molecular weight | 60.09 | g/mol | - |
| Melting point | -89.50 | °C | - |
| Boiling point | 82.50 | °C | - |
| Vapour pressure (at 25°C) | 5.78x103 | Pa |  |
| Water solubility (at 25°C) | 1x105 | mg/L | Completely miscible in water, set to maximum value in EUSES |
| Log Octanol/water partition coefficient | 0.05 | Log 10 | - |
| Organic carbon/water partition coefficient (Koc) | 3.30 | L/kg | - |
| Henry’s Law Constant (at 25°C) | 0.80 | Pa/m3/mol | - |
| Biodegradability | Readily biodegradable | - | - |
| Rate constant for STP | 1 | h-1 | No measured value available, default value based on screening test |
| DT50 for biodegradation in surface water | 15 | d | No measured value available, default value based on screening test |
| DT50 for hydrolysis in surface water | - | - | No hydrolysis |
| DT50 for photolysis in surface water | Not relevant (absorbance < 290 nm) | - | - |
| DT50 for degradation in soil | 30 | d | No measured value available, default value based on screening test |
| DT50 for degradation in air | 3.1 | d | Half-life in the troposphere |
| BFCfish | 0.22 | L/kgwet fish | Calculated from log Kow |
| BFCworm | 0.85 | L/kgwet earthworm | Calculated from log Kow |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP *(SIMPLE TREAT 4.0)*** | | |
| Compartment | Percentage [%] | |
| Propan-1-ol | Propan-2-ol |
| Air | 0.2597 | 0.273 |
| Water | 7.958 | 7.956 |
| Sludge | 0.0357 | 0.0298 |
| Surplus sludge | 0.0012 | 0.0010 |
| Degraded in STP | 91.74 | 91.74 |

***Calculated PEC values***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for Propan-1-ol** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/L] | [mg/l] | [mg/kgdwt] | [mg/kgdwt] | [μg/l] |
| Scenario 1 | 3.38x10-1 | 3.38x10-2 | 1.35x10-1 | 8.54x10-3 | 13.52 |
| Scenario 3 | 5.91x10-2 | 5.91x10-3 | 2.36x10-2 | 1.43x10-3 | 2.37 |
| Scenario 4 (On-site) | 5.49x10-1 | 3.43x10-3 | 1,37x10-2 | 6.23x10-5 | 0.099 |
| Scenario 4 (Off-site) | 2.46x10-3 | 2.46x10-4 | 9.84x10-4 |
| Scenario 5 | 3.38 | 3.38x10-1 | 1.35 | 8.54x10-2 | 135.25 |
| Scenario 6 | 5.86 | 5.86x10-1 | 2.34 | 1.15x10-1 | 78.95 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values for Propan-2-ol** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/L] | [mg/l] | [mg/kgdwt] | [mg/kgdwt] | [μg/l] |
| Scenario 1 | 1.34x10-1 | 1.34x10-2 | 5.28x10-2 | 2.94x10-3 | 5.27 |
| Scenario 3 | 1.41x10-2 | 1.41x10-3 | 5.55x10-3 | 3.09x10-4 | 0.55 |
| Scenario 4 (On-site) | 5.49x10-1 | 3.43x10-3 | 1.35x10-2 | 5.38x10-5 | 0.097 |
| Scenario 4 (Off-site) | 2.46x10-3 | 2.46x10-4 | 9.68x10-4 |
| Scenario 5 | 1.34 | 1.34x10-1 | 5.28x10-1 | 2.94x10-2 | 52.74 |
| Scenario 6 | 2.33 | 2.33x10-1 | 9.16x10-1 | 3.82x10-2 | 27.19 |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not expected to occur during normal use of the products. Primary poisoning is therefore considered to be not relevant.

Secondary poisoning

According to the CAR of Propan-1-ol and Propan-2-ol, the substances are not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

Therefore, no PEC or PNEC calculation is needed.

#### Risk characterisation

***Atmosphere***

According to the propan-1-ol and propan-2-ol CAR the substance has a potential for long range environmental transport, however effects on stratospheric ozone and acidification are not expected as propan-2-ol does not contain halogens, nitrogen or sulphur and is not listed as an ozone depleting substance. Inhalation studies with mammals also indicate that adverse effects are not expected to occur to terrestrial mammals.

Conclusion: No unacceptable risk to the atmosphere is expected.

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNECSTP values** | | |
|  | **Propan-1-ol** | **Propan-2-ol** |
| Scenario 1 | 3.38x10-2 | 1.34x10-2 |
| Scenario 3 | 5.91x10-3 | 1.41x10-3 |
| Scenario 4 (On-site) | 5.49x10-2 | 5.49x10-2 |
| Scenario 4 (Off-site) | 2.46x10-4 | 2.46x10-4 |
| Scenario 5 | 3.38x10-1 | 1.34x10-1 |
| Scenario 6 | 5.86x10-1 | 2.33x10-1 |

Conclusion: No unacceptable effect to the aquatic micro-organisms of the STP is expected.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNECwater & sed1 values** | | |
|  | **Propan-1-ol** | **Propan-2-ol** |
| Scenario 1 | 1.47x10-2 | 4.77x10-3 |
| Scenario 3 | 2.57x10-3 | 5.01x10-4 |
| Scenario 4 (On-site) | 1.49x10-3 | 1.22x10-3 |
| Scenario 4 (Off-site) | 1.07x10-4 | 8.73x10-5 |
| Scenario 5 | 1.47x10-1 | 4.77x10-2 |
| Scenario 6 | 2.55x10-1 | 8.27x10-2 |
| 1 PNECsed for Propan-1-ol and Propan-2-ol are calculated with the EPM method, therefore, PEC/PNEC ratios are identical for water and sediment | | |

Conclusion: No unacceptable effect to the organisms of the aquatic compartment is expected.

***Terrestrial compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNECsoil values** | | |
|  | **Propan-1-ol** | **Propan-2-ol** |
| Scenario 1 | 1.75x10-2 | 5.23x10-3 |
| Scenario 3 | 3.06x10-3 | 5.49x10-4 |
| Scenario 4 | 1.27x10-4 | 9.57x10-5 |
| Scenario 5 | 1.75x10-1 | 5.23x10-2 |
| Scenario 6 | 2.35x10-1 | 6.79x10-2 |

Conclusion: No unacceptable effect to the organisms of the terrestrial compartment is expected.

***Groundwater***

According to the CAR of both the Active Substances 10% is emitted to the water and 90% is emitted to the air. This was applied for all emission calculations (except for the dipping scenario). Therefore, the PECgw was derived taking into account both the sludge application (resulting from the substance released via STP) and the aerial deposition (resulting from the releases to the air).

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PECGW values [μg/l]** | | |
|  | **Propan-1-ol** | **Propan-2-ol** |
| Scenario 1 | 13.52 | 5.27 |
| Scenario 3 | 2.37 | 0.55 |
| Scenario 4 | 0.099 | 0.097 |
| Scenario 5 | 135.25 | 52.74 |
| Scenario 6 | 78.95 | 27.19 |

The calculated results of PECGW for scenarii 1,3,5 and 6 are above the maximum permissible concentration in groundwater of 0.1 µg/L for biocides (Council Directives 98/83/EC). However, according to the TAB entry 188 : *“For products containing very volatile substances (according to the VOC directive) used in general, i.e. it is not distinguished between professionals and non-professionals, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air”*. Based on this and on the following elements, no unacceptable risk for the groundwater compartment is expected :

* The approach to calculate the PECGW is considered as overly conservative : the groundwater exposure is due to wet and dry aerial deposition on soil. The estimated concentration in the groundwater is defined by the concentration of active substance in pore water of agricultural soils (Guidance BPR IV ENV B, 2015). Degradation in soil, transformation and dilution in deeper soil layers are not taken into account.According to the OPS model, the whole fraction released to outdoor air is emitted within 1000m vicinity of the emission source. The environmental risk assessment according to the guidance BPR IV Part B + C assumes that the active substance is emitted only to agricultural soils (FOCUS-scenarios). However, particularly for biocides/disinfection products most of the emission will take place in urban areas with sealed soil.The assumption that the whole fraction released to air is deposited on agricultural soils only within a radius of 1000m from the emitter is considered as unrealistic.
* FOCUS PEARL is unlikely to provide realistic refinement. FOCUS PEARL can take volatilization into account when active substance specific diffusion coefficients to air and water are available. These parameters are not part of the core data set required for active substances under evaluated under the BPR. Consequently, these parameters are not available. Therefore, the current model outcome may overestimate the concentration of the active substance in the porewater. In addition, the unlimited applicability of the model for the very diverse field of biocidal applications is questionable. In the present case, where the products are used in urban areas where a direct exposure to the urban environment is assumed, the model assumptions of FOCUS PEARL may not be accurate. The same applies, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, for which the model might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.

Conclusion : Based on expert judgement no exceedance of the groundwater trigger value is expected, thus no unacceptable risk to the groundwater is expected.

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not expected to occur during normal use of the products. Primary poisoning is therefore considered to be not relevant.

Secondary poisoning

According to the CAR of Propan-1-ol and Propan-2-ol, the substances are not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

Conclusion: No unacceptable risk of primary or secondary poisoning for terrestrial or aquatic animals is expected.

***Mixture toxicity***

**PEC/PNEC summation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | STP | Water and sediment1 | Soil | Groundwater |
| Scenario 1 | 4.72x10-2 | 1.95x10-2 | 2.27x10-2 | See section section 2.2.8.3 risk characterisation - Groundwater |
| Scenario 3 | 7.32x10-3 | 3.07x10-3 | 3.61x10-3 |
| Scenario 4 (On-site) | 1.10x10-1 | 2.71x10-3 | 2.23x10-4 |
| Scenario 4 (Off-site) | 4.93x10-4 | 1.94x10-4 |
| Scenario 5 | 4.72x10-1 | 1.95x10-1 | 2.72x10-1 |
| Scenario 6 | 8.19x10-1 | 3.37x10-1 | 3.03x10-1 |
| 1 PNECsed for Propan-1-ol and Propan-2-ol are calculated with the EPM method, therefore, PEC/PNEC ratios are identical for water and sediment | | | | |

Conclusion: The ∑PEC/PNEC are below 1 for all the compartments meaning no unacceptable risk.

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



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

The CAR of Propan-1-ol indicates that : *“The amount of propan-1-ol that is used annually for biocidal purposes accounts for less than 5 % of the total production and import volume in the EU in 2007 (trigger value is below 10 % of the total production and import volume in the EU). The intended uses (hand and skin disinfection (leave-on-product), disinfection of small surfaces in the sanitary sector and small surfaces in food industry (e.g. slaughterhouses) are widely dispersive and do not represent a specific emission pattern . Hence, according to the decision tree it has been concluded that no aggregated exposure assessment for a.s. propan-1-ol has to be performed.”*

The CAR of Propan-2-ol indicates that : *“According to the “Decision tree on the need for estimation of aggregated exposure” the requirement for aggregated exposure estimations*

*was checked for propan-2-ol. In summary, it has been concluded that no aggregated*

*exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-*

*2-ol is less than 10 % of the total tonnage produced and no specific biocidal emission patterns are identified.”*

Conclusion: no aggregated exposure assessment is necessary.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| No unacceptable effect to the environment is expected for the Christeyns’ Propan-1/2-ol BPF, neither for the STP, the aquatic compartment nor for the terrestrial compartment. No unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected. The threshold value was exceeded for groundwater, nevertheless, no unacceptable risk to the groundwater is expected based on expert judgement. |

### Assessment of endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Christeyns’ Propan-1/2-ol BPF :

1. Assessment of the ED properties of the active substances in Christeyns’ Propan-1/2-ol BPF:

According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorisation procedures. As Propan-1-ol and Propan-2-ol are not part of the list[[16]](#footnote-17) of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

Therefore, BE eCA considers that there are no concerns regarding ED properties of Propan-1-ol and Propan-2-ol.

1. Assessment of the ED properties of non-active substances (co-formulants) in Christeyns’ Propan-1/2-ol BPF:

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex - ED assessment), none of the co-formulants has been identified as having ED properties or are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, BE eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product/family regarding ED properties:

Based on the existing knowledge and the data provided by the applicant, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product (family) Christeyns’ Propan-1/2-ol BPF.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product/family authorisation will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

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

Measures to protect man:

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P261 - Avoid breathing mist, spray, vapour

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor/physician

P403+P233 - Store in a well-ventilated place. Keep container tightly closed.

Measures to protect animals: not relevant

Measures to protect the environment:

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

### Assessment of a combination of biocidal products

Not applicable: the biocidal product is not intended to be authorised for use together with other biocidal products.

### Comparative assessment

Not relevant: propan-1-ol and propan-2-ol are not candidates for substitution.

# Annexes

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



## Output tables from exposure assessment tools

**For human health:**

The exposure calculations and risk assessment for all room types are presented in the embedded excel file.











**Calculations for scenario 5.1 – Adulty bystander present during disinfection**

| **Description of Scenario [5.1] – re-entry** | | | |
| --- | --- | --- | --- |
| The concentration of the active substances in the air should not exceed AEC (52.6 mg/m3) for propan-2-ol and the acceptable air concentration derived from the AEL (55.2 mg/m3) for propan-1-ol for the re-entry of professional users in the treated room.  Consexpo web was used to model this re-entry period following these parameters:   * Amount of active substance: mean event concentration (mg/m3) × room volume (m3)   To model the air concentration in the treated room, the Consexpo model Exposure to vapour – instantenous release was selected.  Consexpo web was used to model this re-entry period following these parameters. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Model | Exposure to vapour | Expert judgment |
| Mode of release | Instantaneous release | Expert judgement |
| Exposure duration (min) | 480 | 8-hour working day |
| Molecular weight matrix (g/mol) | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol | Product specific data |
| Mean event concentration propan-1-ol (mg/m3)  Mean event concentration propan-2-ol (mg/m3) | Depends on the room type (see table below) | See below |
| Room volume (m3) | Depends on the room type (see table below) | Expert judgement eCA |
| Ventilation rate (volume/hour) | Depends on the room type (see table below) | Expert judgement eCA |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Ventilation rate (h-1)** | **Room size (m3)** | **Trigger spraying** | | **Low pressure spraying** | | **Dipping** | | **Wiping** | |
|  | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** |
| **Cleanrooms** | 8 | 55 | 19 | 7.6 | **1900** | **1200** | / | / | 2.8 | 1.1 |
| **Pharmaceutical and cosmetics manufacturing facilities** | 8 | 80 | 27 | 15 | **1400** | **870** | / | / | 7.0 | 2.9 |
| **Laboratories and biotechnology** | 8 | 25 | 42 | 17 | **3800** | **2500** | / | / | 6.1 | 2.4 |
| **Unspecified rooms** | 0.6 | 20 | **850** | **350** | **6600** | **4500** | **98** | **82** | **130** | **53** |
| **Kitchen and canteens** | 15 | 25 | 42 | 17 | / | / | 55 | 46 | 6.1 | 2.4 |
| **Food processing machinery** | 20 | 300 | 12 | 4.8 | / | / | 4.1 | 3.4 | 1.7 | 0.7 |
| **Institutional kitchens and canteens** | 15 | 25 | / | / | **2600** | **1700** | / | / | / | / |
| **Industrial kitchen** | 15 | 2400 | / | / | 12 | 4.6 | / | / | / | / |
| **Industrial production room** | 20 | 300 | / | / | **130** | **55** | / | / | / | / |
| **Small rooms** | 0.6 | 10 | **850** | **350** | **6600** | **4500** | **200** | **160** | **130** | **53** |

Based on the graphs from Consexpo (see below) the re-entry time was determined for the room types, requiring PPE during application and where the air concentration exceeded the acceptable limits (indicated in bold).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Propan-1-ol** | **Propan-2-ol** | | |
| **Unspecified rooms – trigger spraying** | |  |  | | |
| **Cleanrooms – low pressure spraying** | |  |  | | |
| **Pharmaceutical and cosmetics manufacturing facilities – low pressure spraying** | |  |  | | |
| **Laboratories and biotechnology – low pressure spraying** | |  |  | | |
| **Unspecified rooms – low pressure spraying** | |  |  | | |
| **Institutional kitchens and canteens – low pressure spraying** | |  |  | | |
| **Industrial production room – low pressure spraying** | |  |  | | |
| **Unspecified rooms - dipping** | |  |  | | |
| **Unspecified rooms - wiping** | |  |  | | |
| **Small rooms – trigger spraying** |  | | |  |
| **Small rooms – low pressure spraying** |  | | |  |
| **Small rooms - dipping** |  | | |  |
| **Small rooms - wiping** |  | | |  |

**Calculations for scenario 5.2 – Re-entry of infants to treated rooms**

| **Description of Scenario [5.2] – Re-entry of infants to treated rooms** | | | |
| --- | --- | --- | --- |
| After disinfection of certain room types, namely unspecified rooms and small rooms by trigger spraying, low-pressure spraying and wiping, it is expected that infants enter those premises and be exposed to the product.  Consexpo Web was used to model this re-entry period based on the air concentration present after the application. The model used was Exposure to vapour – instantaneous release using the air concentration of propan-1-ol and propan-2-ol present in the treated room after application. This concentration was compared with the acceptable air concentrations:   * **Propan-1-ol: 10.95 mg/m3** (based on the AEL of 9.2 mg/kg bw/day, a body weight of 8kg, inhalation rate of 0.84m3/h and an exposure duration of 8h) * **Propan-2-ol: 52.6 mg/m3** (based on the AEC)   If the air concentration after application exceeds the acceptable air concentration, a re-entry time needs to be defined. The re-entry time per application per room type is listed in the tables below. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Model | Exposure to vapour | Expert judgment |
| Mode of release | Instantaneous release | Expert judgement |
| Exposure duration (min) | 1440 | One day |
| Molecular weight matrix (g/mol) | Propan-1-ol:  24,58 g/mol  Propan-2-ol:  31,38 g/mol | Product specific data |
| Mean event concentration propan-1-ol (mg/m3)  Mean event concentration propan-2-ol (mg/m3) | Depends on the room type (see table below) | See below |
| Room volume (m3) | Depends on the room type (see table below) | Expert judgement eCA |
| Ventilation rate (volume/hour) | Depends on the room type (see table below) | Expert judgement eCA |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Ventilation rate (h-1)** | **Room size (m3)** | **Trigger spraying** | | **Low pressure spraying** | | **Wiping** | |
|  | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** | **Mean event conc. propan-1-ol (mg/m3)** | **Mean event conc. propan-2-ol (mg/m3)** |
| **Unspecified rooms** | 0.6 | 20 | **850** | **350** | **6600** | **4500** | **130** | **53** |
| **Small rooms** | 0.6 | 10 | **850** | **350** | **6600** | **4500** | **130** | **53** |

Based on the graphs from Consexpo (see below) the re-entry time was determined for the room types where entering an infant is expected.

|  |  |  |
| --- | --- | --- |
|  | **Propan-1-ol** | **Propan-2-ol** |
| **Unspecified rooms – trigger spraying** |  |  |
| **Unspecified rooms – low pressure spraying** |  |  |
| **Small rooms – trigger spraying** |  |  |
| **Small rooms – low pressure spraying** |  |  |
| **Unspecified rooms - wiping** |  |  |
| **Small rooms – Wiping** |  |  |

**For environment:**

SimpleTreat :

 

## New information on the active substance

There is currently no new information presented on the active substances.

## Residue behaviour

From a residue test with Mida San 311 KZ, no residues below the detection limit of 10 mg/l were found. Taking into account the high vapour pressure. most of the active substances will evaporate quickly to the air compartment. In case residues in the environment would occur. the active substances are readily biodegradable. There is therefore no concern about residues of the products in food or feeding stuffs or in the environment.

## Summaries of the efficacy studies

Please refer to the IUCLID file.

## Confidential annex

The confidential annex is provided as a separate document.

## Other

1. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work). [↑](#footnote-ref-2)
2. Germany, 2017 p. 49 [↑](#footnote-ref-3)
3. Germany, 2015 p. 46 [↑](#footnote-ref-4)
4. Germany, 2017 p. 49 [↑](#footnote-ref-5)
5. Germany, 2015 p. 46 [↑](#footnote-ref-6)
6. Germany, 2017 p. 49 [↑](#footnote-ref-7)
7. Germany, 2015 p. 46 [↑](#footnote-ref-8)
8. Certificate of analysis No. 01/2020 Christeyns. Renolab study code 2020-85 NC. Madeddu, 2020. [↑](#footnote-ref-9)
9. Germany, 2017 p. 49 [↑](#footnote-ref-10)
10. Germany, 2015 p. 46 [↑](#footnote-ref-11)
11. Germany, 2017 p. 49 [↑](#footnote-ref-12)
12. Germany, 2015 p. 46 [↑](#footnote-ref-13)
13. <https://www.icis.com/explore/resources/news/2007/11/05/9076020/isopropanol-ipa-uses-and-market-data/> [↑](#footnote-ref-14)
14. <https://pubchem.ncbi.nlm.nih.gov/compound/1-propanol#section=Industry-Uses> [↑](#footnote-ref-15)
15. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0872&from=EN> [↑](#footnote-ref-16)
16. Please refer to CA-September18.Doc.7.5.a-final . [↑](#footnote-ref-17)