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)



ANIOS IPA

Product type 2

Propan-2-ol

Case Number in R4BP: BC- QY025584-01

Evaluating Competent Authority: FR

Date: November 2018

Updated: May 2021

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**Note to the reader**

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

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

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

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | *BC-QY025584-01* | 18.12.2018 | Initial assessment |
|  | Post authorisation data assessment |

# CONCLUSION

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

The liquid products of the ANIOS IPA family (META SPC1) are an AL formulations. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a clear liquid. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 40°” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in bottle and can in HDPE (commercial packaging material). The long term storage stability study (24 months) is on-going and should be provided within 2 years.

After 3 months at 4°C, the appearance and technical characteristic have not significantly changed. The product is stable at 4°C. The study at 0°C has not been provided so the mention “protect from frost” should be added. Its technical characteristics are acceptable for an AL formulation. The product is flammable and classified cat. 2 H225. It has no explosive and no oxidizing properties.

* **Post authorisation assessment (2021)**

Long term storage stability study shows that after 3 years at ambient temperature in double bag HDPE spray, the product remains stable.

However as no minor change was submitted to request a change of shelf life, no modification of the SPC is performed and the 2 years shelf life already authorised is maintained.

The spray pattern is missing and should be provided at the renewal of the authorisation of the biocidal product.

The aerosol products of the ANIOS IPA family (Meta SPC2) are an AE formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

The appearance of the product is a clear liquid. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 40°” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium with epoxy-phenolic varnish can packaging material (commercial packaging material). The long term storage stability study (with spray pattern)(24 months) is on-going and should be provided into 2 years. After 3 months at 4°C, the appearance and technical characteristics have not significantly changed. The product is stable at 4°C. The study at 0°C has not been provided so the mention “protect from frost” should be added.

Its technical characteristics are acceptable for an AE formulation. The product is flammable and classified H222 and H229. It has no explosive and no oxidizing properties.

Method for detection and quantification of active substance in the product is considered in compliance with SANCO/3030/99 rev.4. According to EU, no residues are expected in soil and water. Analytical method for propan-2-ol residues in air is available in Assessment Report propan-2-ol, Product-type 02 (private area and public health area disinfectants and other biocidal products), January 2015. Please, refer to Letter of Access from Brenntag SA. As the active substance isopropanol is not classified Toxic or Very Toxic, an analytical method for the determination of isopropanol residue in human body fluids and tissues is unnecessary.

* **Post authorisation assessment (2021)**

Long term storage stability study shows that after 3 years at ambient temperature in aluminium aerosol bottle, the product remains stable.

However as no minor change was submitted to request a change of shelf life, no modification of the SPC is performed and the 2 years shelf life already authorised is maintained.

Weight loss of can after 5s spray is missing and should be provided at the renewal of authorisation of the biocidal product.

***Conclusion for Efficacy:***

French competent authorities (FR CA) assessed that the product family ANIOS IPA has shown a sufficient efficacy in accordance with the requirements of the transitional Guidance on Efficacy for product type PT1-5, Disinfectants (2016) and the EN 14885:2015 standard[[1]](#footnote-1), as:

* The liquid products of the ANIOS IPA family (META SPC1) is efficient against bacteria, yeasts, with a contact time of 5 minutes and against fungi with a contact time of 15 minutes, for hard surface disinfection (non porous) with or without mechanical action, at the temperature of 20 °C, in clean rooms (grades A to D) and in areas without controlled atmosphere, by spraying or by wiping (at 100 % v/v) by professional users.
* The aerosol products of the ANIOS IPA family (Meta SPC2) is efficient against bacteria, yeasts, with a contact time of 5 minutes and against fungi with a contact time of 15 minutes, for hard surface disinfection (non porous) with or without mechanical action, at the temperature of 20 °C, in clean rooms (grades A to D) and in areas without controlled atmosphere by spraying or by wiping (at 100 % v/v) by professional users.

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

***Conclusion for Human health:***

For both application, with a trigger spray or an aerosol, the risk is considered acceptable for professionals without PPE.

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

For an adult entering a room with freshly treated surfaces, the risk is considered acceptable.

***Conclusion for Environment:***

No unacceptable risk to sewer treatment plant, surface water, sediment and soil has been identified for the products included in the ANIOS IPA biocidal product family, when applied according to their intended uses. The predicted concentrations in groundwater are lower than the threshold value of 0.1 µg/L (Council Directive 98/83/EC).

# ASSESSMENT REPORT

## Summary of the product assessment

**Part I.- First information level**

### Administrative Information

#### Identifier of the product family

| **Identifier[[2]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| ANIOS IPA |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Laboratoires ANIOS |
| **Address** | Pavé du Moulin  59260 Lille-Hellemmes  France |
| **Authorisation number** | FR-2018-0114 | |
| **Date of the authorisation** | 18/12/2018 | |
| **Expiry date of the authorisation** | 17/12/2028 | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Laboratoires ANIOS |
| **Address of manufacturer** | Pavé du Moulin  59260 LILLE–HELLEMMES  FRANCE |
| **Location of manufacturing sites** | 3330 rue de Lille  59262 SAINGHIN EN MÉLANTOIS  FRANCE |

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

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

|  |  |
| --- | --- |
| **Active substance** | Propan-2‐ol |
| **Name of manufacturer** | Univar |
| **Address of manufacturer** | Univar, Steuber Drive, Manchester M44 5AL, UK  Univar Belgium, Rue de Sablieres 1, 7522 Biandain (Tournai) |
| **Location of manufacturing sites** | N/A – Supplied by Exxon, Shell or Sassol |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Brenntag |
| **Address of manufacturer** | Brenntag Ardennes, Route de Tournes, 08090 Cliron, France  Brenntag GmbH, Stinnes Platz 1, 45477 Mühlheim an der Ruhr |
| **Location of manufacturing sites** | N/A – Supplied by Exxon, Shell or Sassol |

|  |  |
| --- | --- |
| **Active substance** | Propan-2‐ol |
| **Name of manufacturer** | STEA SRL |
| **Address of manufacturer** | STEA SRL, 30174 Mestre, Italy |
| **Location of manufacturing sites** | N/A – Supplied by Exxon, Shell or Sassol |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Girelli Alcool SRL |
| **Address of manufacturer** | Girelli Alcool SRL, Via Riva die Trento 20139 Milano, Italy |
| **Location of manufacturing sites** | N/A – Supplied by Exxon, Shell or Sassol |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Sasol Solvents Germany GmbH |
| **Address of manufacturer** | Sasol Solvents Germany GmbH, Anckelmannsplatz, D‐ 20537 Hamburg |
| **Location of manufacturing sites** | Sasol Solvents Germany GmbH, Shamrockstrasse 88, D‐ 44623 Herne;  Sasol Solvents Germany GmbH, Römerstr. 733, D‐47443 Moers |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Shell Chemicals Europe B.V |

|  |  |
| --- | --- |
| **Address of manufacturer** | Shell Chemicals Europe B.V, Postbus 2334, 3000 CH Rotterdam |
| **Location of manufacturing sites** | Shell Nederland Chemie BV/Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam‐Pernis, Netherland |

|  |  |
| --- | --- |
| **Active substance** | Propan-2-ol |
| **Name of manufacturer** | Exxon Mobil |
| **Address of manufacturer** | ExxonMobil Chemical Europe, Hermeslaan 2, 1831 Machelen, Belgium |
| **Location of manufacturing sites** | Fawley Refinery and Petrochemical Plant, Fawley, Southampton, SO45 1TX, UK  Baton Rouge Chemical Plant (BRCP) 4999 Scenic Highway, Baton Rouge 70805, Louisiana, USA. |

### Family composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Propanol-2 |
| **IUPAC or EC name** | Propanol-2 |
| **EC number** | 200-661-7 |
| **CAS number** | 67-63-0 |
| **Index number in Annex VI of CLP** | 603-117-00-0 |
| **Minimum purity / content** | 99 % w/w |
| **Structural formula** |  |

#### Candidate(s) for substitution

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

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Propan-2-ol | Propan-2-ol | Active substance (pure)\* | 67-63-0 | 200-661-7 | 63% | 70% |

\* Based on the documents provided by the applicant, it was not clear whether propan-2-ol concentration was expressed as pure or technical Active Substance. The Human Health and Environment Risk Assessment have been performed based on 70% AS for which the applicant indicated lately it is pure active AS. Nevertheless, the purity of the AS is 99%. Hence, this very slight underestimation does not have any impact on the risk assessment.

#### Information on technical equivalence

Only sources considered as equivalent to the reference source at EU level can be used to formulate the product.

The decision on technical equivalence from ECHA published in March 2017 confirms that the alternative source of Propan-2-ol manufactured by Exxon Mobil is considered technically equivalent compared to the reference source from Brenntag GmbH.

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

Please see the confidential annex for further details.

#### Type of formulation

|  |
| --- |
| Any other liquid  Aerosol dispenser |

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

### Meta SPC 1 administrative information

#### Meta SPC identifier

| **Identifier** | Meta-SPC1 |
| --- | --- |

#### Suffix to the authorisation number

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

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  |  |

### Meta SPC 1 composition

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Propan-2-ol | Propan-2-ol | Active substance pure | 67-63-0 | 200-661-7 | 63% | 70% |

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

| **Formulation** |  |
| --- | --- |
| Any other liquid |  |

### Hazard and precautionary statements

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

**Meta SPC 1**

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  STOT SE 3  Flamable liquid Cat. 2. |
| Hazard statement | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H225 highly flammable liquid and vapour. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H225 highly flammable liquid and vapour. |
| Precautionary statements | P210; Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P235; Keep cool.  P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing  P337 + P313: If eye irritation persists get medical advice/attention  P403 + P233: Store in a well ventilated place and keep container tightly closed  P405: Store locked up  P501: Dispose of contents/container in accordance with local/regional/national/international regulation |
|  | |
| Note | EUH066: Repeated exposure may cause skin dryness or cracking |

### Authorised use(s) of the meta SPC 1

#### Use description

Table 1. Use # 1 – Surface disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in the pharmaceutical, medical equipment and cosmetic industries. |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time:   * 5 minutes for bactericidal and yeasticidal efficacy; * 15 minutes for fungicidal efficacy   Temperature: 20°C  Clean rooms (GMP EU in grade A and B). |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  • 5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

#### Use-specific instructions for use

|  |
| --- |
| * use in clean rooms only (GMP grades A to B) |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 2. Use # 2 – Surface disinfection in sterile conditions in laboratories and hospital pharmacies

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in laboratories and hospital pharmacies |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time :   * 5 minutes for bactericidal and yeasticidal efficacy; * 15 minutes for fungicidal efficacy   Temperature: 20°C  Clean rooms (GMP EU in grade A to B). |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  Secondary material (without contact with product), double bag:   * + - * Each 1L bottle is packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

#### Use-specific instructions for use

|  |
| --- |
| * use in clean rooms only (GMP grades A to B) |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 3. Use # 3 – Surface disinfection in non-sterile conditions in pharmaceutical, medical equipment and cosmetic industries

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades C and D) as well as without controlled atmosphere, in the pharmaceutical, medical (equipment) industries and in cosmetic industries |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time :   * 5 minutes for bactericidal and yeasticidal efficacy; * 15 minutes for fungicidal efficacy   Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  • 5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 4. Use # 4 – Surface disinfection in non-sterile conditions in laboratories and hospital pharmacies

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades C and D) as well as without controlled atmosphere in laboratories and hospital pharmacies |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time 5 minutes for bactericidal and yeasticidal efficacy; 15 minutes for fungicidal efficacy  Temperature: 20°C |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

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

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

#### Instructions for use

|  |
| --- |
| * Respect the indicated contact time for the required antimicrobial activity * Always read the label or leaflet before use and respect all the instructions provided. * Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and yeasticidal efficacy and for 15 minutes for fungicidal efficacy) * Clean carefully the surfaces before application * Let the surface dry * Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. The users should inform if the treatment is ineffective and report straightforward to the registration holder |

#### Risk mitigation measures

|  |
| --- |
| - Avoid direct or indirect contact with food and feed.  During **the spray application**, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:   * Minimisation of splashes and spills; * Minimise number of staff exposed; * Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; * Training for staff on good practice; * Good standard of personal hygiene.   PPE for the spraying phase are as following:   * Eye protection.   The product must only be applied for disinfection of small surfaces. |

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

|  |
| --- |
| * **Impaired consciousness:** do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately. * Keep the container or label available. * **Inhalation:** Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * **Mouth contact/Ingestion:** Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities. * **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur.   **Eye contact:** Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. |

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

|  |
| --- |
| * Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment. * Dispose of the product in accordance with local requirements. * Towels contaminated with the product / used wipes must be disposed in a closed container. |

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

|  |
| --- |
| * Shelf-life: 2 years. * Do not store at a temperature above 40°C. * Protect from frost. * Keep away from heat/sparks/open flames/hot surfaces. — No smoking. * Keep container tightly closed. * Use explosion-proof electrical/ventilating/lighting/…/equipment. * Use only non-sparking tools. * Take precautionary measures against static discharge. |

### Other information

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

**Part III.- Third information level – individual products in the meta SPC 1**

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

| **Trade name(s)** | **ANIOS ALCOOL ISOPROPYLIQUE 70% V/V IP STERILE**  **ANIOS ISOPROPYL ALCOHOL 70% V/V IP STERILE**  **ANIOS IPA 70% V/V IP STERILE** | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 63% |

| **Trade name(s)** | **ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE**  **ANIOS ISOPROPYL ALCOHOL 70% IP STERILE**  **ANIOS IPA 70% IP STERILE** | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 70% |

| **Trade name(s)** | **ANIOS ALCOOL ISOPROPYLIQUE 70% V/V**  **ANIOS ISOPROPYL ALCOHOL 70% V/V**  **ANIOS IPA 70% V/V** | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 63% |

| **Trade name(s)** | **ANIOS ALCOOL ISOPROPYLIQUE 70%**  **ANIOS ISOPROPYL ALCOHOL 70%**  **ANIOS IPA 70%** | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 70% |

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

### Meta SPC 2 administrative information

#### Meta SPC 2 identifier

| **Identifier** | Meta SPC2 |
| --- | --- |

#### Suffix to the authorisation number

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

#### Product type(s)

| **Product type(s)** | 2 |
| --- | --- |
|  |  |

### Meta SPC 2 composition

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 63% | 70% |

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

| **Formulation** |  |
| --- | --- |
| Aerosol dispenser |  |

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

**Meta SPC 2**

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit 2  STOT SE 3  Aerosol 1 |
| Hazard statement | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H222 Extremely flammable aerosol.  H229 Pressurised container: May burst if heated. |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H319: Causes serious eye irritation  H336: May cause drowsiness or dizziness  H222 Extremely flammable aerosol.  H229 Pressurised container: May burst if heated. |
| Precautionary statements | P210; Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  P410 + P412; Protect from sunlight. Do not expose to temperatures exceeding 50 ºC/122 ºF.  P211: Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use.  P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P264: Wash … thoroughly after handling  P271: Use only outdoors or in a well-ventilated area  P280: Wear protective gloves/protective clothing/eye protection/face protection  P312: Call a POISON CENTER/ doctor/…/if you feel unwell  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing  P337 + P313: If eye irritation persists get medical advice/attention  P403 + P233: Store in a well ventilated place and keep container tightly closed  P405: Store locked up  P501: Dispose of contents/container in accordance with local/regional/national/international regulation |
|  | |
| Note | EUH066: Repeated exposure may cause skin dryness or cracking |

### Authorised use(s) of the meta SPC 2

#### Use description

Table 5. Use # 1 – Surfaces disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in the pharmaceutical, medical equipment and cosmetic industries. |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time :   * 5 minutes for bactericidal and yeasticidal efficacy; * 15 minutes for fungicidal efficacy.   Temperature: 20°C.  Clean rooms (GMP EU in grade A and B). |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  • Aerosol can 400 mL in aluminium  Secondary material (without contact with product), double bag:  Each aerosol can is packaged in a primary bag, then in a second bag (double bag). Bag Material: LDPE |

#### Use-specific instructions for use

|  |
| --- |
| * Only use in clean rooms (GMP grades A to B) |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply more than 40 ml/m². |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 6. Use # 2 – Surfaces disinfection in sterile conditions in laboratories and hospital pharmacies

|  |  |
| --- | --- |
| **Product Type** | PT02 – Disinfectant |
| **Where relevant, an exact description of the authorised use** | The products ANIOS IPA family are used for the disinfection of equipment, material and non-porous surfaces in areas with controlled atmosphere (GMP grades A and B) in laboratories and hospital pharmacies. |
| **Target organism (including development stage)** | Bacteria  Yeast  Fungi |
| **Field of use** | Indoor use |
| **Application method(s)** | The ready to use product is sprayed on the previously cleaned surface or to a suitable wiping cloth. |
| **Application rate(s) and frequency** | Ready-to-use  Contact time :   * 5 minutes for bactericidal and yeasticidal efficacy; * 15 minutes for fungicidal efficacy.   Temperature: 20°C.  Clean rooms (GMP EU in grade A and B). |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Primary packaging:  • Aerosol can 400 mL in aluminum  Secondary material (without contact with product), double bag:  Each aerosol can is packaged in a primary bag, then in a second bag (double bag). Bag Material: LDPE |

#### Use-specific instructions for use

|  |
| --- |
| * Only use in clean rooms (GMP grades A to B) |

#### Use-specific risk mitigation measures

|  |
| --- |
| * Do not apply more than 40 ml/m². |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

#### Instructions for use

|  |
| --- |
| * Respect the indicated contact time for the required antimicrobial activity * Always read the label or leaflet before use and respect all the instructions provided. * Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal and yeasticidal efficacy and for 15 minutes for fungicidal efficacy) * Only use in clean rooms (grades A to B) * Let the surface dry * Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. The users should inform if the treatment is ineffective and report straightforward to the registration holder |

#### Risk mitigation measures

|  |
| --- |
| * Avoid direct or indirect contact with food and feed.   During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:   * Minimisation of splashes and spills; * Minimise number of staff exposed; * Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; * Training for staff on good practice; * Good standard of personal hygiene.   PPE for the spraying phase are as following:   * Eye protection. |

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

|  |
| --- |
| * **Impaired consciousness:** do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately. * Keep the container or label available. * **Inhalation:** Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * **Mouth contact/Ingestion:** Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities. * **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention if symptoms occur. * **Eye contact:** Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. |

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

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

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

|  |
| --- |
| * Shelf-life: 2 years. * Do not store at a temperature above 40°C. * Protect from frost. * Keep away from heat/sparks/open flames/hot surfaces. — No smoking. |

### Other information

|  |
| --- |
| * The authorization holder has to report any incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. * The long term storage stability study (24 months) should be provided within 2 years. |

**Part V.- Third information level: individual products in the meta SPC 2**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **ANIOS ALCOOL ISOPROPYLIQUE 70% V/V IP STERILE AEROSOL**  **ANIOS ISOPROPYL ALCOHOL 70% V/V IP STERILE AEROSOL**  **ANIOS IPA 70% V/V IP STERILE AEROSOL** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 63% |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **ANIOS IPA 70% IP STERILE AEROSOL**  **ANIOS ISOPROPYL ALCOHOL 70% IP STERILE AEROSOL**  **ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Propan-2-ol | Propanol-2 | Active substance pure | 67-63-0 | 200-661-7 | 70% |

### Packaging of the biocidal product

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Meta SPC 1 | Bottle | 1L | HDPE | Sprayer gun | Professional | Y |
| Can | 5L | HDPE | - | Professional | Y |
| Meta SPC 2 | Aerosol can | 400 mL | Aluminium gold epoxy-phenolic  The BP is in LDPE bag. | - | Professional | Y |

### Documentation

#### Data submitted in relation to product application

***Physico-chemistry:***

Physico-chemical properties studies and analytical methods on the family of biocidal product family ANIOS IPA were provided by Laboratoires ANIOS.

***Efficacy:***

The products of the ANIOS IPA family (70 % w/w propan-2-ol) has been tested following efficacy studies:

* For bacteria:
* Laboratory study according to EN1276 standard (phase 2, step 1)
* Laboratory study according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 13727 standard (phase 2 step 1)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For yeast:
* Laboratory study according to EN 1650 standard (phase 2, step 1)
* Laboratory study according to EN 13624 standard (phase2, step 1)
* 2 Laboratory studies according to EN 13697 standard (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)
* For fungi:
* Laboratory study according to EN 1650 standard (phase 2, step 1)
* Laboratory study according to EN 13624 standard (phase2, step 1)
* 2 Laboratory studies according to EN 13697standard (phase 2, step 2)
* Laboratory study according to EN 16615 standard (phase 2, step 2)

***Residue:***

By definition, PT2 biocidal product is for application on surfaces that are not used for direct contact with food or feeding stuffs. Therefore residues in food or feed are not expected. Considering the intended uses no data is required.

#### Access to documentation

Laboratories ANIOS has access to data on the active substance 2-propanol with a Letter of Access of Stockmeier Chemie, one applicant of the active substance 2-propanol.

## Assessment of the biocidal product family

### Intended use(s) as applied for by the applicant META SPC1

Table 2. Intended use # 1 –Surfaces disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries [[4]](#footnote-4)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non – porous surfaces for clean rooms (A and B grades) in pharmaceutical and cosmetics industries, medical device industries..  Ready to use solution. Remove the first wrapping before entering into the clean room. Remove the second wrapping when first use. Use without dilution on clean or  previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (+/- 30 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place |
| Application rate(s) and frequency | +/- 30 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in pharmaceutical, medical equipment and cosmetic industries. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  • 5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

Table 2. Intended use # 2 – Surfaces disinfection in sterile conditions in laboratories and hospital pharmacies [[5]](#footnote-5)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non–porous surfaces in areas with a controlled atmosphere (grades A and B) in laboratories and hospital pharmacies.  Ready to use solution. Remove the first wrapping before entering into the clean room. Remove the second wrapping when first use. Use without dilution on clean or  previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (+/- 30 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place. |
| Application rate(s) and frequency | +/- 30 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in laboratories and hospital pharmacies. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  Secondary material (without contact with product), double bag:   * + - * Each 1L bottle is packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

Table 3. Intended use # 3 – Surfaces disinfection in nonsterile conditions in pharmaceutical, medical equipment and cosmetic industries [[6]](#footnote-6)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non–porous surfaces in areas with a controlled atmosphere (grades C and D) as well as areas without a controlled atmosphere, in the pharmaceutical, medical equipment and cosmetic industries.  Ready to use solution. Use without dilution on clean or previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (+/- 30 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place |
| Application rate(s) and frequency | +/- 30 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in pharmaceutical, medical equipment and cosmetic industries |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  • 5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

Table 4. Intended use # 4 – Surfaces disinfection in nonsterile conditions in laboratories and hospital pharmacies[[7]](#footnote-7)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non – porous surfaces in areas with a controlled atmosphere (grades C and D) as well as areas without a controlled atmosphere, in laboratories and hospital pharmacies.  Ready to use solution. Use without dilution on clean or previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (+/- 30 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place |
| Application rate(s) and frequency | +/- 30 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in laboratories and hospital pharmacies |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging:  • 1L Bottle (HDPE) with sprayer gun (LDPE, HDPE, PP, PVC)  • 5L (HDPE) with cap (PP)  Secondary material (without contact with product), double bag:  Each 1L and 5L bottles are packaged in a primary bag, then in a second bag (double bag). bag Material: LDPE |

### Intended use(s) as applied for by the applicant META SPC2

Table 5. Intended use # 1 – Surfaces disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries [[8]](#footnote-8)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non–porous surfaces in areas with a controlled atmosphere (grades A and B) in the pharmaceutical, medical equipment and cosmetic industries.  Ready to use aerosol. Remove the first wrapping before entering into the clean room. Remove the second wrapping when first use. Use without dilution on clean or  previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (30 to 40 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20 cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place |
| Application rate(s) and frequency | 30 to 40 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20 cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in pharmaceutical, medical equipment and cosmetic industries |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging  Aerosol can of 400 mL in aluminium with internal epoxy phenolic varnish  Secondary packaging (without contact with product)  DOUBLE BAG:  Each aerosol can is packaged in a primary bag, then in a second bag (double bag) Material: LDPE. |

Table 6. Intended use # 2 – Surfaces disinfection in sterile conditions in laboratories and hospital pharmacies s[[9]](#footnote-9)

|  |  |
| --- | --- |
| Product Type(s) | PT 2 – Disinfectants and algaecides not intended for direct application to humans or animals |
| Where relevant, an exact description of the authorised use | - |
| Target organism (including development stage) | Bacteria, yeasts and fungi |
| Field of use | Indoor |
| Application method(s) | Manual application -  Disinfection of equipment, material and non–porous surfaces in areas with a controlled atmosphere (grades A and B) in laboratories, hospital pharmacies.  Ready to use aerosol. Remove the first wrapping before entering into the clean room. Remove the second wrapping when first use. Use without dilution on clean or  previously cleaned surfaces. Apply evenly and in sufficient quantity over the surface to be treated (30 to 40 ml/m²) or to a suitable wiping cloth (+/- 10 ml for a wipe of standard size 20 cm x 20cm). Respect the indicated contact time for the required antimicrobial activity. Make sure that the surfaces remain damp throughout the period of action. For the frequency of use and cleaning of the application equipment, refer to the hygiene plan in place. |
| Application rate(s) and frequency | 30 to 40 ml/m² or +/- 10 ml for a wipe of standard size 20 cm x 20cm  The application frequency follows the instructions given in the internal standard operating procedures for cleaning and disinfection established in laboratories and hospital pharmacies. |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Primary packaging  Aerosol can of 400 mL in aluminium with internal epoxy phenolic varnish  Secondary packaging (without contact with product)  DOUBLE BAG:  Each aerosol can is packaged in a primary bag, then in a second bag (double bag) Material: LDPE. |

**Identity**

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex.

### Physical, chemical and technical properties

The product does not contain PT6 preservative.

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

Formulation type: AL (all other liquids)

Hydrocarbon and H304 co-formulant content: 0%

#### Meta SPC 1

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | Batch l20150518R, l20150928R, l20151290R | Clear and colourless liquid | Sauty M., 2016  Study n° 16/001BPL |
| Colour at 20 °C and 101.3 kPa |  | 1%w/v | Clear and colourless liquid | Sauty M., 2016  Study n° 16/001BPL |
| Odour at 20 °C and 101.3 kPa |  | Batch l20150518R, l20150928R, l20151290R | Clear and colourless liquid | Sauty M., 2016  Study n° 16/001BPL |
| Acidity / alkalinity | CIPAC MT 75.3 | Batch l20150518R, l20150928R, l20151290R  1%w/v | 5.8 at 20°C at 1%w/v | Sauty M., 2016  Study n° 16/001BPL |
| Relative density / bulk density |  | Batch l20150518R, l20150928R, l20151290R  1%w/v | 0.862 | Sauty M., 2016  Study n° 16/001BPL |
| Storage stability test – **accelerated storage**  **(40°C)** | CIPAC MT 46.3  Method of quantification of AS is reported in section 2.2.4 | Batch l20150518R, l20150928R, l20151209R  I20160707R, I20160729R, U35411S  1%w/v | Bottle in HDPE of 750 mL and 1L with spray gun (material of the spray gun not precised in the study)   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T = 8 weeks | T = 3 months | | Aspect | Clear and colourless liquid | No change | No change | | AS content | 69.07 | 68.85% | 69.28% | | pH | 5.8 at 20°C | 5.76 at 20°C | 5.70 at 20°C | | Quantity delivered by spray | 0.554 g  0.642 mL | 0.551 g  0.639 mL | 0.568 g  0.658 mL | | Density | 0.863 at 20°C | 0.864 at 20°C | 0.863 at 20°C | | Refractive index | 1.3744 at 20°C | 1.3743 at 20°C | 1.3743 at 20°C |   Spray pattern before storage:    Spray pattern after storage:    The results show that Spray pattern and spray diameter are globally similar before and after storage.  The biocidal product is stable 3 months at 40°C. | Sauty M., 2016  Study n° 16/001BPL  Rodriguez N., 2016 Study n°: Mo5711” |
| Storage stability test – **long term storage at ambient temperature** | Method of quantification of AS is reported in section 2.2.4 | Batch l20150518R, l20150928R, l20151209R  I20160707R, I20160729R, U35411S  Code formule 316 PULVERISATEUR | |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T= 6 months | T= 12 months | | aspect | Clear and colourless liquid |  |  | | AS content | 69.48 | 68.19 | 69.54 | | Weight variation of packafing (%) | / | -0.078 | -0.14 | | pH | 5.8 at 20°C | 5.7 at 20.2°C | 5.72 at 20.5°C | | Density stability | 0.863 at 20°C | 0.865 at 20°C | 0.863 at 20°C | | Refractive index | 1.3746 at 20°C | 1.3743 at 20°C | 1.3743 at 20°C | | Quantity delivered by spray | 0.554 g  0.642 mL | 0.556 g  0.644 mL | 0.553 g  0.640 mL |   Bottle in HDPE of 750 mL and 1L with spray gun (material of the spray gun not precised in the study)  (material of the spray gun not precised in the study)  Spray pattern before storage:    The biocidal product is stable 1 year at ambient temperature. Nevertheless, Spray pattern after long term storage should be provided in post-authorization. | Sauty M., 2016  Study n° 16/001BPL  Rodriguez N., 2016 Study n°: Mo5711” |
| Storage stability test – **low temperature stability test for liquids**  **(4°C)** | Method of quantification of AS is reported in section 2.2.4 | Batch l20150518R, l20150928R, l20151290R  1%w/v  Batch l20160707R, l20160729R, U35411S | Bottle in HDPE of 1L with spray gun(material of the spray gun not precised in the study)   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T = 8 weeks | T = 3 months | | Aspect | Clear and colourless liquid | No change | No change | | AS content | 69.07% | 69.17% | 69.28% | | Weight variation of packaging(%) | / | -0.027 | -0.035 | | pH | 5.8 at 20°C | 5.56 at 20°C | 5.76 at 20°C | | Quantity delivered by spray | 0.554 g  0.642 mL | 0.540 g  0.625 mL | 0.552 g  0.639 mL | | density | 0.863 at 20°C | 0.864 at 20°C | 0.864 at 20°C | | Refractive index | 1.3744 at 20°C | 1.3743 at 20°C | 1.3743 at 20°C |   Spray pattern before storage:    Spray pattern after storage:    The results show that Spray pattern and spray diameter are globally similar before and after storage The biocidal product is stable 3 months at 4°C. However, the product should have been tested at 0°C during 7 days. As no storage stability study has been provided at 0°C, the mention “protect from frost” must be added to the label. | Sauty M., 2016  Study n° 16/001BPL  Rodriguez N. 2017 Study Mo5711 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Light has no effect on AS. Not required. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Temperature has been performed in storage stability studies.  Hydrolysis of active substance is not expected. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | Assessment of container material has been performed in storage stability studies. |  |
| Wettability |  |  | Not required because biocidal product is an AL. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required because biocidal product is an AL. |  |
| Wet sieve analysis and dry sieve test |  |  | Not required because biocidal product is an AL. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required because biocidal product is an AL. |  |
| Disintegration time |  |  | Not required because biocidal product is an AL. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required because biocidal product is an AL. |  |
| Persistent foaming |  |  | Not required because biocidal product is an AL. |  |
| Flowability/Pourability/Dustability |  |  | Not required because biocidal product is an AL. |  |
| Burning rate — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Burning completeness — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Composition of smoke — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Spraying pattern — aerosols |  | Batch l20160707R, l20160729R, U35411S | Spray pattern before storage: Acceptable | Rodriguez N. 2017 Study Mo5711 |
| Physical compatibility |  |  | Testing for physical and chemical compatibility with other products is not applicable to the Anios IPA biocidal product family. Products within the family are not intended to be used in combination with other products. |  |
| Chemical compatibility |  |  | Not required, the BP is a ready-to-use. |  |
| Degree of dissolution and dilution stability |  |  | Not required because biocidal product is an AL. |  |
| Surface tension | EC A5 method | PRODUCT CODE FORMULE 316  Batch: I20150928R | 22.7 mN/m at 20.3°C.  The biocidal product is surface-active. | Lefebvre A. 2016  N° 16-912013-003 |
| Viscosity | OECD 114 | PRODUCT CODE FORMULE 316  Batch: I20150928R | 3.68 mPa.s at 20°C  2.01 mPa.s at 40°C | Lefebvre A. 2016  N° 16-912013-003 |

* **Post authorisation assessment (2021)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Guideline and method | Purity of the test substance | Results | Reference | Comment |
| Technical monograph N°.17  Method of quantification of AS is reported in section 2.2.4 | Code formule 316  PULVERISATEUR | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | months | T0 | T6 | T9 | T12 | T18 | T24 | T36 | | Appearance of test item | Clear and colorless liquid | | | | | | | | Appearance of the packaging | Double bagged white HDPE spray  (The material of the spray gun was not precised in the study) | | | | | | | | Weight loss % | - | -0.078 | -0.11 | -0.14 | -0.2 | -0.64 | -0.36 | | Quantity delivered by spray | 0.554g  0.642 mL | 0.556g  0.644 mL | 0.559g  0.648mL | 0.533g  0.640mL | 0.561g  0.648mL | 0.559g  0.647mL | 0.557g  0.645mL | | pH (at 19.9-20.9°C) | 5.9 | 5.8 | 6.2 | 5.9 | 6.1 | 5.5 | 5.8 | | Density (at 20.0°C) | 0.863 | 0.865 | 0.864 | 0.863 | 0.865 | 0.864 | 0.863 | | Refractive index (at 20°C) | 1.3744 | 1.3743 | 1.3743 | 1.3743 | 1.3742 | 1.3743 | 1.3744 | | AS content (%w/w) | 69.07 | 68.19 | 69.22 | 69.54 | 68.73 | 69.58 | 70.86 | | Variation of AS content | - | -1.3% | +0.2% | +0.7% | -0.5% | +0.7% | 2.6% | | Sauty, M. 2020  Study report N°: 16/001BPL | Acceptable.  The product is stable for 36 months in double bagged HDPE spray.  However the spray pattern is missing after long term storage. No more data are requested as the spray pattern after 1 year was stable and the quantity delivered by spray is stable after 3 years. |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The meta SPC 1 of the biocidal product family ANIOS IPA is an AL formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the products of the meta SPC 1 is a clear liquid. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 40°C” should be added.  The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in bottle and can in HDPE (commercial packaging material). The long term (24 months) storage stability study (with spray pattern) is on-going and should be provided within 2 years in post-authorization.  After 3 months at 4°C, the appearance and technical characteristic have not significantly changed. The product is stable at 4°C.  The study at 0°C has not been provided so the mention “protect from frost” should be added.  Technical characteristics are acceptable for an AL formulation.  Implication concerning labelling: -Do not store at a temperature above 40°C.  -Protect from frost.   * **Post authorisation assessment (2021)**   Long term storage stability study shows that after 3 years at ambient temperature in double bag HDPE spray, the product remains stable.  However as no minor change was submitted to request a change of shelf life, no modification of the SPC is foreseen and the 2 years shelf life already authorised is maintained.  The spray pattern is missing and should be provided at the renewal of the authorisation of the biocidal product. |

#### Meta SPC 2:

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | Batch: A568, A569 and A570 | Clear and colourless liquid | Sauty M., 2016  Study n° 16/002BPL |
| Colour at 20 °C and 101.3 kPa |  | Batch: I20150928R | Clear and colourless liquid | Sauty M., 2016  Study n° 16/002BPL |
| Odour at 20 °C and 101.3 kPa |  | Batch: A568, A569 and A570 | Clear and colourless liquid | Sauty M., 2016  Study n° 16/002BPL |
| Acidity / alkalinity | CIPAC MT 75.3 | Batch: A568, A569 and A570 | 5.8 at 20°C at 1%w/v | Sauty M., 2016  Study n° 16/002BPL |
| Relative density / bulk density |  | PRODUCT CODE FORMULE 316  Batch: A568, A569 and A570 | 0.862 | Sauty M., 2016  Study n° 16/002BPL |
| Storage stability test – **accelerated storage**  **(40°C)** | CIPAC MT 46.3  Method of quantification of AS is reported in section 2.2.4 | Batch: A568, A569 and A570 | Aerosol Bottle in aluminium with internal varnish gold epoxy-phenolic 400 mL   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T = 8 weeks | T = 3 months | | Aspect | Clear and colourless liquid | No change | No change | | AS content | 69.48 | 69.92% | 70.35% | | Weight variation of packaging (%) | / | -0.027 | +0.111 | | pH | 5.88 at 20°C | 5.76 at 20°C | 5.60 at 20°C | | Quantity delivered by spray | 0.554 g  0.642 mL | 0.551 g  0.639 mL | 0.568 g  0.658 mL | | Density | 0.861 at 20°C | 0.861 at 20°C | 0.861 at 20°C | | Refractive index | 1.3746 at 20°C | 1.3746 at 20°C | 1.3746 at 20°C |   The biocidal product is stable 3 months at 40°C. | Sauty M., 2016  Study n° 16/002BPL |
| Storage stability test – **long term storage at ambient temperature** | Method of quantification of AS is reported in section 2.2.4 | Batch A568, A569, A570  Code formule 316 AEROSOL | Testing packaging: 400 mL aerosol bottle in aluminium with internal varnish gold epoxy-phenolic.   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T= 6 months | T= 12 months | | aspect | Clear and colourless liquid |  |  | | AS content | 69.48 | 69.70 | 69.76 | | Weight variation of packaging (%) | / | -0.009 | -0.023 | | pH | 5.8 at 20°C | 5.8 at 20°C | 5.8 at 20.5°C | | Density stability | 0.861 at 20°C | 0.861 at 20°C | 0.861 at 20°C | | Refractive index | 1.3746 at 20°C | 1.3746 at 20°C | 1.3746 at 20°C | | Quantity delivered by spray | On-going | On-going | On-going |   The biocidal product is stable 12 months at ambient temperature.  Spray pattern after long term storage should be provided in post-authorization. | Sauty M., 2016  Study n° 16/002BPL |
| Storage stability test – **low temperature stability test for liquids**  **(4°C)** | Method of quantification of AS is reported in section 2.2.4 | Batch A568, A569, A570  1%w/v | 400 mL aerosol bottle in aluminium with internal varnish gold epoxy-phenolic   |  |  |  |  | | --- | --- | --- | --- | |  | T0 | T = 8 weeks | T = 3 months | | Aspect | Clear and colourless liquid | No change | No change | | AS content | 69.48% | 69.9% | 70.93% | | Weight variation of packaging (%) | / | -0.006 | -0.003 | | pH | 5.8 at 20°C | 5.74 at 20°C | 5.54 at 20°C | | Quantity delivered by spray | 0.554 g  0.642 mL | 0.540 g  0.625 mL | 0.552 g  0.639 mL | | density | 0.861 at 20°C | 0.861 at 20°C | 0.861 at 20°C | | Refractive index | 1.3746 at 20°C | 1.3746 at 20°C | 1.3746 at 20°C |   The biocidal product is stable 3 months at 4°C. However, the product should have been tested at 0°C during 7 days. As no storage stability study has been provided at 0°C, the mention “protect from freeze” must be added to the label | Sauty M., 2016  Study n° 16/001BPL |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Light has no effect on AS. Not required. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Temperature has been performed in storage stability studies.  Hydrolysis of active substance is not expected. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | Assessment of container material has been performed in storage stability studies. |  |
| Wettability |  |  | Not required because biocidal product is an AL. |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required because biocidal product is an AL. |  |
| Wet sieve analysis and dry sieve test |  |  | Not required because biocidal product is an AL. |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required because biocidal product is an AL. |  |
| Disintegration time |  |  | Not required because biocidal product is an AL. |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required because biocidal product is an AL. |  |
| Persistent foaming |  |  | Not required because biocidal product is an AL. |  |
| Flowability/Pourability/Dustability |  |  | Not required because biocidal product is an AL. |  |
| Burning rate — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Burning completeness — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Composition of smoke — smoke generators |  |  | Not required because biocidal product is an AL. |  |
| Spraying pattern — aerosols |  | Batch PRODUCT CODE FORMULE 316  Batch: Batch A568, A569, A570 | Acceptable | Rodriguez N., 2016  Study n°: Mo5505 |
| Physical compatibility |  |  | Testing for physical and chemical compatibility with other products is not applicable to the Anios IPA biocidal product family. Products within the family are not intended to use in combination with other products. |  |
| Chemical compatibility |  |  | Not required, the BP is a ready-to-use. |  |
| Degree of dissolution and dilution stability |  |  | Not required because biocidal product is an AL. |  |
| Surface tension | EC A5 method | PRODUCT CODE FORMULE 316  Batch: I20150928R | 22.7 mN/m at 20.3°C.  The biocidal product is surface-active. | Lefebvre A. 2016  N° 16-912013-003 |
| Viscosity | OECD 114 | PRODUCT CODE FORMULE 316  Batch: I20150928R | 3.68 mPa.s at 20°C  2.01 mPa.s at 40°C | Lefebvre A. 2016  N° 16-912013-003 |

* **Post authorisation assessment (2021)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Guideline and method | Purity of the test substance | Results | Reference | Comment |
| Technical monograph N°.17  Method of quantification of AS is reported in section 2.2.4 | Batch A568, A569, A570  Code formule 316 Aerosol  Propan-2-ol 70% (w/w) | Storage at 25 °C ±2°C  Testing packaging: 400 mL aerosol bottle in aluminium   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | months | T0 | T6 | T9 | T12 | T18 | T24 | T36 | | Appearance of test item | Clear and colourless liquid | | | | | | | | Appearance of the packaging | 400 mL aerosol | | | | | | | | Weight loss % | - | -0.009 | -0.01 | -0.023 | -0.03 | -0.046 | -0.076 | | pH (at 19.1-21.6°C) | 5.97 | 6.1 | 5.85 | 5.83 | 5.85 | 5.61 | 5.75 | | Density (at 20.0°C) | 0.861 | 0.861 | 0.861 | 0.861 | 0.861 | 0.860 | 0.860 | | Refractive index (at 20°C) | 1.3746 | 1.3746 | 1.3746 | 1.3746 | 1.3746 | 1.3746 | 1.3746 | | AS content (%w/w) | 69.48 | 69.7 | 70.37 | 69.76 | 69.73 | 69.62 | 71.33 | | Variation of AS content | - | +0.32 | +1.29 | +0.4 | +0.36 | +0.21 | +2.66 | | Mathieu SAUTY , 2021  Study number: 16/002BPL | Acceptable.  The product is stable for 36 months in aluminium aerosol bottle.  However, weight loss of can after 5s spray is missing.  No more data is requested at this stage as the quantity delivered by spray was stable after accelerated storage.  Weight loss of can after 5s spray should be provided at the renewal of the authorisation of the biocidal product. |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The meta SPC 2 of the BPF ANIOS IPA is an AE formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the products of the meta SPC 2 is a clear liquid. There is no effect of high temperature on the stability of the formulation, since after 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The mention “do not store at temperatures above 40°C” should be added. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in aluminium can packaging material (commercial packaging material). The long term storage stability study (with spray pattern) (24 months) is on-going and should be provided within 2 years in post-authorization.    After 3 months at 4°C, the appearance and technical characteristic have not significantly changed. The product is stable at 4°C. The study at 0°C has not been provided so the mention “protect from frost” should be added.  Technical characteristics are acceptable for an AE formulation.  Implication concerning labelling: -Do not store at a temperature above 40°C.  -Protect from frost.   * **Post authorisation assessment (2021)**   Long term storage stability study shows that after 3 years at ambient temperature in aluminium aerosol bottle, the product remains stable.  However as no minor change was submitted to request a change of shelf life, no modification of the SPC is foreseen and the 2 years shelf life already authorised is maintained.  Weight loss of can after 5s spray is missing and should be provided at the renewal of authorisation of the biocidal product. |

### Physical hazards and respective characteristics

#### Meta SPC 1

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | statement |  | Based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p. 92, Screening procedures and waiving of testing), a substance or mixture is not classified as explosive:  - when there are no chemical groups associated with explosive properties present in the molecule;  - when the substance or mixture contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.  When considering the products within the Anios IPA biocidal products family, none of the components of the mixtures contain any of the chemical groups associated with explosive properties listed in Tables A6.1 (Examples of chemical groups indicating explosive properties in organic chemicals) in Appendix 6 of the UN RTDG, Manual of Tests and Criteria. In addition, the oxygen contained in propan-2-ol is not bound in energetic functional groups, it is bound in CO groups which do not exhibit explosive behaviour. The oxygen balance is less than -200 and no explosive properties to be expected. Consequently, no explosive properties are expected for the Anios IPA products and classification as an explosive mixture can be safely excluded without further testing.  eCA agrees with applicant assessment. |  |
| Flammable gases |  |  | Not required BP is a liquid. |  |
| Flammable aerosols |  |  | Not required BP is a liquid. |  |
| Oxidising gases |  |  | Not required BP is a liquid. |  |
| Gases under pressure |  |  | Not required BP is a liquid. |  |
| Flash point | EC A9 method | PRODUCT CODE FORMULE 316  Batch: l20150928R | Flash point: 20.5°C  Due to the flash point and boiling point the meta SPC 1 is classified cat.2 H225 | Lefebvre A. 2016  N° 16-912012-003 |
| Boiling point | EC A 2  OECD 103 | Batch: l20160707R | 80.1°C  Due to the flash point and boiling point the meta SPC 1 is classified cat.2 H225 | Winkler S., 2017  Report PS20170070-1 |
| Flammable solids |  |  | Not required BP is a liquid. |  |
| Self-reactive substances and mixtures | Statement of Applicant |  | Based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p158, Classification criteria), mixtures must be considered for classification in the hazard class self-reactive substance or mixture:  - unless the mixture is already classified for certain other hazards (explosive, oxidizing or organic peroxides), or  - unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties.  In the case of the products within the Anios IPA biocidal product family, none of the above cited classifications (explosive, oxidizing, organic peroxides) apply. The components of the products do not contain any of the chemical groups associated with explosive or self-reactive properties listed in Tables A6.1 (Examples of chemical groups indicating explosive properties in organic chemicals) and A6.2 (Examples of chemical groups indicating self-reactive properties in organic chemicals) in Appendix 6 of the UN RTDG, Manual of Tests and Criteria. In addition, the oxygen contained in propan-2-ol is not bound in energetic functional groups, it is bound in CO groups which do not exhibit explosive or self-reactive behaviour. The oxygen balance is less than -200 and no explosive / self-reactive properties are to be expected. Consequently, no self-reactive properties are expected and classification as self-reactive mixture can safely be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Pyrophoric liquids | Statement of Applicant |  | Experience in manufacturing and handling shows that for products within the Anios IPA biocidal product family, the liquid does not ignite spontaneously on coming into contact with air at normal temperatures. Based on the guidance on the application of the CLP criteria (Guidance on Regulation (EC) No 1272/2008, 2015, version 4.1, p170, Screening procedures and waiving of testing), this classification can be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Pyrophoric solids |  |  | Not required BP is a liquid. |  |
| Self-heating substances and mixtures |  |  | not relevant |  |
| Substances and mixtures which in contact with water emit flammable gases | Statement of Applicant |  | Experience in handling and use shows that products within the Anios IPA biocidal products family do not react with water. Moreover, the formulations contain at least 30% water. Thus based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p194, Screening procedures and waiving of testing), this classification can be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Oxidising liquids | Statement of Applicant |  | Based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p204, Screening procedures and waiving of testing), before submitting a mixture to the full test procedure, an evaluation of its chemical structure may be very useful to prevent unnecessary testing. The following text provides a guideline for the theoretical evaluation of potential oxidising properties: "For organic substances or mixtures, the classification procedure for this hazard class need not be applied if:  - the substance or mixture does not contain oxygen, fluorine or chlorine; or  - the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen". [...]  Any substance or mixture that complies with the above waiving criteria can be safely regarded to have no oxidising properties and, hence, needs not to be tested and needs not to be regarded as an oxidising liquid". In the case of the products within the Anios IPA biocidal product family, the product ingredients only contain oxygen as a highly electronegative atom. In all components, oxygen is chemically bonded only to carbon or hydrogen. Consequently, no oxidizing properties are expected and classification as oxidizing liquid can safely be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Oxidising solids |  |  | Not required BP is a liquid. |  |
| Organic peroxides | Statement of Applicant |  | Products within the Anios IPA biocidal product family do not contain any organic peroxides. This classification can thus be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Corrosive to metals | Statement of Applicant |  | Products within the Anios IPA biocidal product family do not contain any components that are classified as Met. Corr. 1 (H290). Moreover, handling experience with the products indicate no corrosion of metals. It can therefore be concluded that products within the family are not corrosive to metals.  eCA agrees with applicant assessment. |  |
| Auto-ignition temperatures of products (liquids and gases) | Statement of Applicant |  | No test is required to determine the auto-ignition temperature of products within the Anios IPA biocidal product family. The auto-ignition temperature of the pure propane-2-ol is estimated between 399°C and 455.6°C (ECHA, Brief substance profile). The dilution of the active substance in the water will increase the value of the auto-ignition temperature. Therefore, the auto-ignition temperature of a product containing 63% w/w or 70% w/w propan-2-ol in water is higher than 400°C. Storage recommendations for these formulations are between +5°C and +25°C. The maximum recommended storage temperature is 16 times less important than the lowest estimated value of the auto-ignition temperature.  eCA agrees with applicant assessment. |  |
| Relative self-ignition temperature for solids |  |  | Not required BP is a liquid. |  |
| Dust explosion hazard |  |  | Not required BP is a liquid. |  |

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| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| Products of the meta SPC 1 of the BPF ANIOS IPA are flammable and classified cat. 2 H225. They have no explosive and no oxidizing properties. |

2.2.4.2 Meta SPC 2

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Statement of Applicant |  | No study is required for products within the Anios IPA biocidal products family. Based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p. 92, Screening procedures and waiving of testing), a substance or mixture is not classified as explosive: - when there are no chemical groups associated with explosive properties present in the molecule; or  - when the substance or mixture contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.  When considering the products within the Anios IPA biocidal products family, none of the components of the mixtures contain any of the chemical groups associated with explosive properties listed in Tables A6.1 (Examples of chemical groups indicating explosive properties in organic chemicals) in Appendix 6 of the UN RTDG, Manual of Tests and Criteria. In addition, the oxygen contained in propan-2-ol is not bound in energetic functional groups, it is bound in CO groups which do not exhibit explosive behaviour. The oxygen balance is less than -200 and no explosive properties to be expected. Consequently, no explosive properties are expected for the Anios IPA products and classification as an explosive mixture can be safely excluded without further testing.  eCA agrees with applicant assessment. |  |
| Flammable gases |  |  | Not required BP is an aerosol. |  |
| Flash point | EC A9 method | PRODUCT CODE FORMULE 316  Batch: I20150928R | Flash point: 20.5°C  The meta SPC 2 is classified cat.1 H229  cat1. H222 by default because the boiling has not been provided. | Lefebvre A. 2016  N° 16-912013-003 |
| Flammable aerosols | Statement of Applicant |  | No studies were carried out on products within the Meta SPC2 of the Anios IPA biocidal product family. Products within the Meta SPC2 are contained in an aerosol packaging. As the liquid formula is classified as Flam liq. 2 (cfr. flash point study carried out on the liquid formulation of the Meta SPC1), based on CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p123, Classification criteria), the meta SPC contains > 1% of flammable components and the ignition distance test is not performed so the product is classified as Aerosol Cat. 1 H222 and H229 by default.  eCA agrees with applicant assessment. |  |
| Oxidising gases |  |  | Not required BP is an aerosol. |  |
| Gases under pressure |  |  | Azote is under pressure but it is not in contact with BP. |  |
| Flammable liquids |  |  | Not required BP is an aerosol. |  |
| Flammable solids |  |  | Not required BP is an aerosol. |  |
| Self-reactive substances and mixtures | Statement of Applicant |  | Based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p158, Classification criteria), mixtures must be considered for classification in the hazard class self-reactive substance or mixture:  - unless the mixture is already classified for certain other hazards (explosive, oxidizing or organic peroxides), or  - unless there are no chemical groups present in the molecule associated with explosive or self-reactive properties.  In the case of the products within the Anios IPA biocidal product family, none of the above cited classifications (explosive, oxidizing, organic peroxides) apply. The components of the products do not contain any of the chemical groups associated with explosive or self-reactive properties listed in Tables A6.1 (Examples of chemical groups indicating explosive properties in organic chemicals) and A6.2 (Examples of chemical groups indicating self-reactive properties in organic chemicals) in Appendix 6 of the UN RTDG, Manual of Tests and Criteria. In addition, the oxygen contained in propan-2-ol is not bound in energetic functional groups, it is bound in CO groups which do not exhibit explosive or self-reactive behaviour. The oxygen balance is less than -200 and no explosive / self-reactive properties are to be expected. Consequently, no self-reactive properties are expected and classification as self-reactive mixture can safely be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Pyrophoric liquids |  |  | Not required BP is an aerosol. |  |
| Pyrophoric solids |  |  | Not required BP is an aerosol. |  |
| Self-heating substances and mixtures |  |  | not relevant |  |
| Substances and mixtures which in contact with water emit flammable gases | Statement of Applicant |  | Experience in handling and use shows that products within the Anios IPA biocidal products family do not react with water. Moreover, the formulations contain at least 30% water. Thus based on the guidance on the application of the CLP criteria (Guidance to Regulation (EC) No 1272/2008, 2015, version 4.1, p194, Screening procedures and waiving of testing), this classification can be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Oxidising liquids |  |  | Not required BP is an aerosol. |  |
| Oxidising solids |  |  | Not required BP is an aerosol. |  |
| Organic peroxides | Statement of Applicant |  | Products within the Anios IPA biocidal product family do not contain any organic peroxides. This classification can thus be excluded without further testing.  eCA agrees with applicant assessment. |  |
| Corrosive to metals | Statement of Applicant |  | Products within the Anios IPA biocidal product family do not contain any components that are classified as Met. Corr. 1 (H290). Moreover, handling experience with the products indicate no corrosion of metals. It can therefore be concluded that products within the family are not corrosive to metals.  eCA agrees with applicant assessment. |  |
| Auto-ignition temperatures of products (liquids and gases) | Statement of Applicant |  | No test is required to determine the auto-ignition temperature of products within the Anios IPA biocidal product family. The auto-ignition temperature of the pure propane-2-ol is estimated between 399°C and 455.6°C (ECHA, Brief substance profile). The dilution of the active substance in the water will increase the value of the auto-ignition temperature. Therefore, the auto-ignition temperature of a product containing 63% w/w or 70% w/w propan-2-ol in water is higher than 400°C. Storage recommendations for these formulations are between +5°C and +25°C. The maximum recommended storage temperature is 16 times less important than the lowest estimated value of the auto-ignition temperature.  eCA agrees with applicant assessment. |  |
| Relative self-ignition temperature for solids |  |  | Not required BP is an aerosol. |  |
| Dust explosion hazard |  |  | Not required. |  |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Products within meta SPC 2 of BPF ANIOS IPA are flammable and classified H222 and H229. They have no explosive and no oxidizing properties. |

### Methods for detection and identification

Report: Sauty M. 2016

Report no 15/003BPL

Test facilities:

Laboratoire ANIOS-Laboratoire de chimie analytique

3330 route de Lille

59262 Sainghin en Melantois

Principle of the method:

Determination of propan-2-ol by gas chromatogram equipped with flame ionization detector, using external standard calibration following standard operating procedure MON23 in use.

Validation data:

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * blank Formulation * Test item of the product   No interference was found: no peak appears in the blank formulation.  All chromatograms were available. | |
| Linearity | Linearity was studied by carrying out five concentrations of 5 independent series between 0.1% to 0.5%w/w.  Calibration curve has been provided with a R2 higher than 0.999. | |
| Compound | Linearity % |
| Propan-2-ol | 0.1% to 0.5%w/w Y = 2408.4X + 3.7853 R2 = 1  n=5 |
| Precision | Repeatability was evaluated by analyzing 5 reconstituted samples 5 days ago at 3 concentrations. | |
| Compound | Repeatability (RSD) |
| Propan-2-ol | RSD = 0.90-1.12% |
| Accuracy | Accuracy was determined by analysis of 5 reconstituted samples two days ago. The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 86% w/w | 87.01;87.41;85.62;86.11;87.87;88.09;86.31;86.34;85.15;86.76 | 86.69 | 1.11 | 10 | | 55% w/w | 55.26;55.67;54.94;54.92;55.74;55.78;56.2;55.94;54.89;55.15 | 55.09 | 0.90 | 10 | | 70% w/w | 69.9;70.43;70.23;70.56;69.73;69.48;69.61;68.66;71.22;70.87 | 70.07 | 1.12 | 10 | | |

The analytical method is fully validated for the determination of the active substance propan-2-ol in the products.

In storage stability studies specifity and linearity have been performed.

### Analytical method for residues.

Following the indications of the BPC opinion for propan-2-ol PT2 (June 2014):

- Soil, water, food and feeding stuffs: Analytical methods for the determination of residues of propan-2-ol in soil, water (drinking water, surface water) and food and feeding stuffs are not deemed necessary, because residues are not expected.

- Body tissues or body fluids: Analytical methods for the determination of residues of propan-2-ol in body tissues or body fluids are not deemed necessary because propan-2-ol is not classified as toxic or very toxic.

- Air: An acceptable primary method for the determination of propan-2-ol in air is available in the active substance dossier. Please refer to LoA delivered by the active substance notifier for this section. Analytical methods were provided at EU level for the determination of propan-2-ol residue in air with LOQ =0.109 mg/m3.

The applicant Laboratoires Anios has a Letter of Access from Stockmeier Chemie GmbH & Co for these data.

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

### Efficacy against target organisms

#### Function and field of use

Main Group 01: Disinfectants

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

The products of the ANIOS IPA family are ready to use products used for surfaces disinfection in pharmaceutical and cosmetic industries, medical devices industries, and in laboratories and hospital pharmacies, in clean rooms in sterile conditions (GMP EU in grade A to B), and in areas in non-sterile conditions (GMP EU in grade C to D) as well as areas without controlled atmosphere.

The family was separated in two META-SPC:

* + META-SPC1: the product (ready to use liquid) is intended to be used for non-porous hard surface disinfection by spraying or wiping by professional users.
  + META-SPC2: the product (ready to use aerosol) is intended to be used for non-porous hard surface disinfection by spraying or wiping by professional users.

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

The products ANIOS IPA family are used to disinfect non-porous surfaces. They irreversibly inactivate vegetative bacteria, yeasts and fungi.

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

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

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

#### Mode of action, including time delay

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

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

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

#### Efficacy data

For both META SPCs, the laboratory studies were conducted with the product ANIOS ALCOOL ISOPROPYLIQUE 70 % IP STERILE (70 % w/w propan-2-ol) (development code: Formula 0316) and with wipes impregnated with the product ANIOS ALCOOL ISOPROPYLIQUE 70 % IP STERILE (development code: Formula 0316), according to the Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, May 2016) and EN 14885:2015 standard.

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

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Bactericide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | EN1276:2010 Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1). | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested: 10%, 20% 40% and 80% v/v  Criteria: at least a 5 log reduction | Bactericidal  concentration: 40% v/v | *C.Pluchart and G. Rauwel*  *2015*  *A15 102 1276*  *33176*  *IC 1*  *6.7\_01* |
| Fungicide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Candida albicans*  *Aspergilus brasiliensis* | EN1650+A1:2013  Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas — Test method and requirements (phase 2, step 1). | Contact time: 15 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested: 5%, 20 % 50% and 80% v/v  Criteria: at least a 4 log reduction | Yeasticidal concentration:  50% v/v  Fungicidal concentration  80 % v/v | *C.Pluchart and G. Rauwel*  *2016*  *A15 104 1650*  *33197*  *IC1*  *6.7\_02* |
| Yeasticide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Candida albicans* | EN1650+A1:2013  (phase 2, step 1). | Contact time: 5 minutes  Temperature: 20°C ± 1°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested: 5%, 20 % 50% and 80% v/v  Criteria: at least a 4 log reduction | Yeasticidal concentration:  50% v/v | *C.Pluchart and G. Rauwel*  *2015*  *A15 106 1650*  *33199*  *IC1*  *6.7\_03* |
| Fungicide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Candida albicans*  *Aspergilus brasiliensis* | EN 13697:2015  Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2, step 2) | Contact time: 15 minutes  Temperature: 18°C – 25°C  Soiling: clean condition (0.3 g /L BSA  Concentration tested: 20% , 40%, 50% and 100 % v/v  Criteria: at least a 3 log reduction | Yeasticidal concentration:  40% v/v  Fungicidal concentration  50 % v/v | *K. Pegeot and G. Rauwel*  *A15 105 13697*  *33198*  *IC1*  *6.7\_04* |
| Bactericide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Staphylococcus aureus*  *Enterococcus hirae* | EN 13727 + A2:2015 Quantitative suspension test for the evaluation of bactericidal activity in medical area – Test method and requirement (Phase 2, step 1) | Contact time: 5 minutes  Temperature: 20 °C  Soiling: clean condition (0.3 g /L BSA  Concentration tested: 5% , 20%, 50% and 80 % v/v  Criteria: at least a 5 log reduction | Bactericidal  concentration: 50% v/v | *C.Pluchart and G. Rauwel*  *2016*  *A16 65 13727*  *34025*  *IC1*  *6.7\_05* |
| Bactericide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Pseudomonas aeruginosa*  *Escherichia coli*  *Staphylococcus aureus*  *Enterococcus hirae* | EN 13697:2015  Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas — Test method and requirements without mechanical action (phase 2, step 2) | Contact time: 5 minutes  Temperature: 18°C – 25°C  Soiling: clean condition (0.3 g /L BSA  Concentration tested: 10% , 20%, 50% and 80 % v/v  Criteria: at least a 4 log reduction | Bactericidal  concentration: 50% v/v | *C.Pluchart and G. Rauwel*  *2016*  *A16 63 13697*  *34026*  *IC1*  *6.7\_06* |
| Yeasticide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Candida albicans* | EN 13624:2013  Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirement (Phase 2, step 1) | Contact time: 5 minutes  Temperature: 20 °C ± 1 °C  Soiling: clean condition (0.3g /L BSA  Concentration tested: 5% , 20%, 50% and 80 % v/v  Criteria: at least a 4 log reduction | Yeasticidal concentration:  50% v/v | *C.Pluchart and G. Rauwel*  *2016*  *A16 66 13624*  *34027*  *IC1*  *6.7\_07* |
| Yeasticide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Candida albicans* | EN 13697:2015  (phase 2, step 2) | Contact time: 5 minutes  Temperature: 18°C – 25°C  Soiling: clean conditions 0.3 g/L BSA  Concentration tested: 20%, 40 % 50% and 80% v/v  Criteria: at least a 4 log reduction | Yeasticidal concentration:  40% v/v | *C.Pluchart and G. Rauwel*  *2016*  *A13 64 13697*  *34031*  *IC1*  *6.7\_08* |
| Fungicide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Aspergilus brasiliensis* | EN 13624:2013  (Phase 2, step 1) | Contact time: 15 minutes  Temperature: 20 °C ± 1 °C  Soiling: clean condition (0.3g /L BSA  Concentration tested: 5% , 20%, 50% and 80 % and 97 % v/v  Criteria: at least a 4 log reduction | activity against *Aspergilus brasiliensis*  97% v/v | *C.Pluchart and G. Rauwel*  *2016*  *A16 80 13624*  *34087*  *IC2*  *6.7\_09* |
| Fungicide | disinfection of clean surfaces | Formula 0316 (propan-2-ol 70 % w/w) | *Aspergilus brasiliensis* | EN 13697:2015 (phase 2, step 2)  37.6 µL on germ carrier of 4 cm in diameter equivalent to 30 mL/m² | Contact time: 15 minutes  Temperature: 18°C – 25°C  Soiling: clean condition (0.3g /L BSA  *A. brasiliensis*  Concentration tested: 100% (v/v)  Criteria: at least a 3 log reduction | **activity against *Aspergilus brasiliensis***  **100% v/v** | *C.Pluchart and G. Rauwel*  *2016*  *34096*  *IC1* |
| Bactericide  Yeasticide | disinfection of clean surfaces | wipes impregnated of the formula 0316 (propan-2-ol 70 % w/w)  (12 mL/wipes) | *Pseudomonas aeruginosa*  *Staphylococcus aureus*  *Enterococcus hirae*  *Candida albicans* | EN16615 :2015  chemical Quantitative test method for the evaluation of bactericidal and yeasticidal action employing wipes in the medical area (4-field test) (phase 2, step 2) | Contact time 5 minutes  Temperature:  20 °C ± 1 °C  concentration tested: 90 % v/v  soiling  clean conditions (0.3 g/L BSA) | R (logarithmic reduction of the viable cells number , efficacy threshold R>5 for bacteria and R>4 for yeast and average accumulation on fields 2 to 4 lower than 50 cfu/25 cm²  *P. aeruginosa* : >5.4  *S. aureus* : 5.1  E. hirae: >5.7  C. albicans: >4.9  average accumulation (2-4)  *P. aeruginosa*: 18  *S. aureus :* 34  *E. hirae*: 30  *C. albicans*: 5  **bactericidal and yeasticidal concentration:**  **90% v/v with a contact time of 5 minutes at** | *C.Pluchart and K. Pegeot*  *2017*  *35559*  *IC1* |
| Fungicide | disinfection of clean surfaces | wipes impregnated of the formula 0316 (propan-2-ol 70 % w/w)  (12 mL/wipes) | *Aspergilus brasiliensis* | EN16615 :2015  (phase 2, step 2) | Contact time 15 minutes  Temperature:  20 °C ± 1 °C  concentration tested: 90 % v/v  soiling  clean conditions (0.3 g/L BSA) | R (logarithmic reduction of the viable cells number , efficacy threshold R>4 for fungi and average accumulation on fields 2 to 4 lower than 50 cfu/25 cm²  *A. brasiliensis* : 4.1  average accumulation (2-4)  *A. brasiliensis:* 295  **Activity against *A. brasiliensis* with a contact time of 15 minutes at 90 % v/v** | *C.Pluchart and K. Pegeot*  *2017*  *35561*  *IC1* |

The product Formula 0316 (propan-2-ol 70 % w/w) has been tested in conditions representative of the uses with clean conditions:

* Bactericidal activity is demonstrated in phase 2 step 1 test according to the EN 1276 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in use concentration of 40 % v/v.
* Bactericidal activity is demonstrated in phase 2 step 1 test according to the EN 13727 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in use concentration of 50 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 2 test according to the EN 13697 standard, at the temperature of 20 °C, for a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 50 % v/v.
* Bactericidal activity is demonstrated in phase 2, step 2 test according to the EN 16615 standard, at the temperature of 20 °C, for a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, bactericidal activity is shown at the in-use concentration of 90 % v/v, with 12 ml/wipe.
* Yeasticidal activity is demonstrated in phase 2, step 1 test according to the EN 1650 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in use concentration of 50 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test according to the EN 1650 standard, at the temperature of 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, the yeasticidal activity is shown at the in use concentration of 50 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 1 test according to the EN 13624 standard, at the temperature of 20 °C, with a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, the yeasticidal activity is shown at the in use concentration of 50 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 2 test according to the EN 13697 standard, at the temperature of 20 °C, for a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 40 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 2 test according to the EN 13697 standard, at the temperature of 20 °C, for a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 40 % v/v.
* Yeasticidal activity is demonstrated in phase 2, step 2 test according to the EN 16615 standard, at the temperature of 20 °C, for a contact time of 5 minutes, in clean conditions (0.3 g/L BSA). In these conditions, yeasticidal activity is shown at the in-use concentration of 90 % v/v, with 12 ml/wipe.
* Fungicidal activity is demonstrated in phase 2, step 1 test according to the EN 1650 standard, at the temperature of 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, the fungicidal activity is shown at the in use concentration of 80 % v/v.
* Fungicidal activity is demonstrated in phase 2, step 2 test according to the EN 13697 standard, at the temperature of 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, fungicidal activity is shown at the in-use concentration of 50 % v/v.
* Activity against *A. brasiliensis* is demonstrated in phase 2, step 1 test according to the methodology of EN 13624 standard, at the temperature of 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, an activity against *A. brasiliensis* is shown at the in use concentration of 97 % v/v.
* Activity against *A. brasiliensis* is demonstrated in phase 2, step 2 test according to the EN 16615 standard, at the temperature of 20 °C, for a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, an activity against *A. brasiliensis* is shown at the in-use concentration of 90 % v/v, with 12 mL/wipe

One additional efficacy study according to the methodology of EN 13697 was also provided. In this study, the volume of the product deposit on the carrier germ has been adapted to reproduce the usual recommendation i.e. 30 mL/m² (instead of a volume of 0,1 mL on a surface of 2 cm diameter) in order to show that the product, despite its volatility properties, is able to provide a sufficient effect within 15 minutes :

* Activity against *A. brasiliensis* is demonstrated in phase 2, step 2 test according to the methodology of EN 13697 standard, at the temperature of 20 °C, with a contact time of 15 minutes, in clean conditions (0.3 g/L BSA). In these conditions, activity against *A. brasiliensis* is shown at the in-use concentration of 100 % v/v.

The product Formula 0316 (propan-2-ol 70 % w/w) passed all the standards with 5 minutes of contact time for bacteria and yeasts and with 15 minutes of contact time for fungi at the temperature of 20 °C, in clean conditions.

The BPF ANIOS IPA also contains products with 63 % w/w propan-2-ol (equivalent to 70 % v/v propan-2-ol). These products are only for “industrial settings[[10]](#footnote-10)”.

* For industrial areas, the data generated with the product Formula 0316 (propan-2-ol 70 % w/w) are extrapolated to the products containing 63 % w/w propan-2-ol (equivalent to 70 % v/v propan-2-ol) since all the dilutions tested in the efficacy studies demonstrated efficacy at product dilutions of 90 % v/v and lower, therefore proven the efficacy of the products containing 63 % w/w.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the biocidal product family ANIOS IPA has shown a sufficient efficacy in accordance with the requirements of the transitional Guidance on Efficacy for product type PT1-5, Disinfectants (2016) and the EN 14885:2015 standard[[11]](#footnote-11), as:   * The liquid products of the ANIOS IPA family (META SPC1) are efficient against bacteria, yeasts, with a contact time of 5 minutes and against fungi with a contact time of 15 minutes, for non-porous hard surface disinfection with or without mechanical action, at the temperature of 20 °C, in clean rooms (grades A to B and grade C and D), ( and in areas without controlled atmosphere, by spraying or by wiping (at 100 % v/v) by professional users * The aerosol products of the ANIOS IPA family (Meta SPC2) are efficient against bacteria, yeasts, with a contact time of 5 minutes and against fungi with a contact time of 15 minutes, for non-porous hard surface disinfection with or without mechanical action, at the temperature of 20 °C, in clean rooms (grades A to B and grades C and D), and areas without controlled atmosphere by spraying or by wiping at 100 % v/v by professional users |

#### Occurrence of resistance and resistance management

Due to the unspecific mode of action of propan-2-ol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where propan-2-ol is ineffective at any concentration. No specific data has been found in the literature regarding occurrence of resistance to propan-2-ol when used in industrial clean rooms.

Strategies such as alternate with other disinfectant active substances and avoidance of over frequent use are efficient standard practices and should be applied also to biocide uses of propan-2-ol, in order to combat any potential for the onset of resistance.

#### Known limitations

None

#### Evaluation of the label claims

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

* By spraying or by wiping (at 100 % v/v) for the disinfection of equipment, material and surfaces in areas with controlled atmosphere (grades A and B) in the pharmaceutical, medical equipment and cosmetic industries, on clean surfaces in clean room (grade A and B), at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;
* By spraying, or by wiping (at 100 % v/v) for the disinfection in sterile conditions in laboratories and hospital pharmacies, on clean surfaces in clean room (grade A and B), at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;
* By spraying or by wiping (at 100 % v/v) for the surface disinfection in non-sterile conditions in pharmaceutical, medical equipment and cosmetic industries, on clean surfaces in clean room (grade C and D) as well as without controlled atmosphere, at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;
* By spraying or by wiping (at 100 % v/v) for the surface disinfection in non-sterile conditions in laboratories and hospital pharmacies, on clean surfaces in clean room (grade C and D) as well as without controlled atmosphere, at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;
* By spraying or by wiping (at 100 % v/v) for Surfaces disinfection in sterile conditions in pharmaceutical, medical equipment and cosmetic industries with controlled atmosphere (grades A and B) in the pharmaceutical, medical equipment and cosmetic industries, on clean surfaces in clean room (grade A and B), at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;
* By spraying or by wiping (at 100 % v/v) for the surface disinfection in sterile conditions in laboratories and hospital pharmacies, on clean surfaces in clean room (grade A and B), at the temperature of 20 °C, against bacteria, yeasts, with a contact time of 5 minutes and fungi with a contact time of 15 minutes;

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

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

The products of the family ANIOS IPA are not intended to be used with other biocidal products.

### Risk assessment for human health

The ANIOS IPA biocidal products family contains a series of PT 2 products with a concentration of active substance, propan-2-ol, ranging from 63 to 70% w/w.

The products are intended for use as surface disinfectants (non-porous) in the pharmaceutical industry, medical equipment industry, cosmetic industry, laboratories and hospital pharmacies. Surfaces to be disinfected are small scale and include workstations, cleaning material, window panes and gloves.

The family is divided into 2 Meta SPCs depending on the mode of application: trigger spray or aerosol.

All the formulations are applied by spraying directly on the surface to be treated or a on a suitable tissue. The surfaces to be treated might be wiped afterwards.

The formulations are intended for professioanl use only.

#### Assessment of effects on Human Health

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

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

***Skin corrosion and irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin corrosion and irritation |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin irritation. |

***Eye irritation***

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

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

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation. |

***Skin sensitization***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin sensitization. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for oral acute toxicity. |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity. |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | No study has been performed on any products of the ANIOS IPA family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

Furthermore, the content of a.s classified STOT SE 3 - H336 being higher than 10%, a classification H336 is also required for the products.

***Information on dermal absorption***

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

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

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

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

Not applicable.

***Other***

Not applicable.

#### Exposure assessment

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

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

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| **1.** | Mixing and loading | **Primary exposure – Dermal and inhalation exposure**  For product of Meta SPC 1, the bottle of 1L with trigger spray can be refilled from a 5L can leading to dermal and inhalation exposure during mixing and loading. | Professionals |
| **2.** | Spraying application (Trigger spray and Aerosol) | **Primary exposure – Dermal and inhalation exposure**  Products of Meta SPC 1 and 2 are sprayed on small surfaces or tissues using a trigger spray or an aerosol leading to dermal and inhalation exposure during application. | Professionals |
| **3.** | Wiping the treated surface | **Primary exposure – Dermal exposure**  After application of the product (Meta SPC 1 and 2), the treated surfaces can be wipped with a tissue leading to dermal exposure. | Professionals |
| **4.** | Exposure to volatilized residues during application | **Primary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs during the application of the product (spraying + wipping) | Professionals |
| **5.** | Exposure to volatilized residues after application | **Secondary exposure – Inhalation (evaporation) exposure**  Due to the high volatility of the active substance, exposure to volatilized residues occurs if persons enter rooms after the used of the product. | Bystanders |

***Industrial exposure***

Not applicable.

***Professional exposure***

*Scenario [1] Mixing and loading*

| **Description of Scenario [1]** | | | | |
| --- | --- | --- | --- | --- |
| The product of Meta SPC 1 is refilled from a container of 5L to a spray bottle of 1L with a trigger spray when the bottle is empty. This application takes place indoors.  TNsG Mxing and Loading Model 4 has been used to predict dermal exposure.  ConsExpo exposure to vapour (evaporation from constant surface) has been used to predict inhalation exposure.  Taking into account a density of 0.862 for the product, the amount of product contained in a 5L bottle is 4.31 kg. | | | | |
|  | **Parameters** | **Value** | **Source** |
| **Dermal exposure**  **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Density of the product | 0.862 | Applicant’s data |
| Indicative value from the exposure model (mL product/operation) | 0.2 | M&L model 4 |
| Body weight (kg) | 60 | HEADHoc recommendation 14 |
| Dermal flux rate (mg/cm2) | 0.85 | CAR on a.s |
| **Dermal exposure**  **Tier 2** | Gloves penetration factor | 10% | HEEG Opinion 9 |
| **Inhalation exposureTier 1** | Exposure Duration (min) | 0.75 | Cleaning Products Fact sheet |
| Product Amount (mg)  (*Half of the product amount in a 5L bottle*) | 2155 | Cleaning Products Fact sheet |
| Room volume (m3)  (*user breathing zone*) | 1 | Cleaning Products Fact sheet |
| Ventilation rate (nbr/h)  (*default value for* *unspecified room*) | 0.5 | General Fact Sheet |
| Release area (cm2)  (*circular opening of 5 cm diameter for a 5L container)* | 20 | Cleaning Products Fact sheet |
| Application duration (min) | 0.3 | Cleaning Products Fact sheet |
| Mass Transfer Rate (m/h) | 10 | Thibodeaux model (maximum value) |
| Molecular Weight Matrix (g/mol) | 18 | Value for water |
| Vapour Pressure (Pa) | 5780 | CAR on a.s |
|  |  |  |  |

**Calculations for Scenario [1]**

Dermal exposure

The indicative dermal contamination value from TNsG Mixing and Loading Model 4 is 0.2 ml/operation for unspecified design (worst-case consideration). This would result in a total amount of 0.12 g propan-2-ol (considering a density value of 0.862 and 70% of a.s in the product). Assuming that one mixing/loading operation is performed in a day and the surface area of both hands is available for dermal exposure (820 cm2), following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

*t = mRTK/Mβ*pA

|  |  |
| --- | --- |
| *t* | = time [s] |
| *m* | = mass of propan-2-ol on surface [mg] (120 mg) |
| *R* | = gas constant [J K-1 mol-1] (8.314 J K-1 mol-1) |
| *T* | = skin/surface temperature [K] (303.15 K) |
| *K* | = conversion factor (36000) |
| *M* | = molar mass [g mol-1] (60.1 g mol-1) |
| β | = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1) |
| *p* | = vapour pressure of the pure substance [Pa] (7600 Pa (30°C)) |
| *A* | = surface area [cm2] (820 cm2) |

According to this equation the evaporation time is 3.34 secs.

Therefore for a worst-case scenario, it is assumed that the total amount evaporates at once after this time interval.

The absorption/dermal flux rate for propan-2-ol is 0.85 mg/cm2/h (EU-agreed value (LoEP January 2015)). During a time interval of 3.34 secs on the skin surface of both hands 820 cm2, this result in a total absorbed amount of 0.66 mg per day. This is equivalent to 0.011 mg/kg bw/d without PPE or 0.0011 mg/kg bw/d with PPE gloves for a body weight of 60 kg.

It should be noted that although the amount of product used per day varies depending on the situation of use, the predicted dermal exposure is considerably low such that an unrealistic number of mixing/loading operations would have to occur in order for a professional user to exceed the AEL.

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [1] | Tier 1/no PPE | 3.0 x 10-3 | 0.011 | - | 0.014 |
| Scenario [1] | Tier 2/ PPE (gloves) | 3.0 x 10-3 | 0.0011 | - | 0.0041 |

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

None

*Scenario [2] Spraying application (Trigger spray and Aerosol)*

| **Description of Scenario [2]** | | | |
| --- | --- | --- | --- |
| The products are applied by indoors spraying to a small surface to disinfect it using a trigger spray (Meta SPC 1) or an aerosol (Meta SPC 2).  To assess the exposure to generated aerosols during the spray application with a trigger spray, the ”Consumer Spraying and Dusting model 2 (hand held trigger spray)” from the TNsG 2008 has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure values from the model are as follows:   * 36.1 mg/min (hands/forearms); * 9.7 mg/min (feet/legs/face); * 10.5 mg/m3 (inhalation).   For the spray application using an aerosol, the ”Consumer Spraying and Dusting model 2 (aerosol spray can)” from the TNsG 2008 has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure values from the model are as follows:   * 64.7 mg/min (hands/forearms); * 45.2 mg/min (feet/legs/face); * 35.9 mg/m3 (inhalation). | | | |
|  | **Parameters** | **Value** | **Source** | |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data | |
| Task duration (min) | 30 | Recommendation 6 of HEAd Hoc | |
| Gloves penetration factor | 100% | HEEG Opinion 9 | |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 | |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 | |
| Dermal absorption (mg/cm2) | 0.85 | CAR of active substance | |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 | |

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

**Calculations for Scenario [2]**

Dermal exposure

The indicative dermal contamination value from TNsG ”Consumer Spraying and Dusting model 2 (hand held trigger spray)” is 45.8 mg pb/min for trigger spray application and 109.9 mg/min for aerosol application.

This would result in a total amount of 961.8 mg propan-2-ol for trigger spray and 2307.9 mg propan-2-ol for aerosol can (considering a task duration of 30 min and 70% of a.s in the product).

Assuming that the surface area of both hands is available for dermal exposure (820 cm2) (representing a very worst-case), following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

*t = mRTK/Mβ*pA

|  |  |
| --- | --- |
| *t* | = time [s] |
| *m* | = mass of propan-2-ol on surface [mg] (961.8 mg for trigger spray and 2307.9 g for aerosol can) |
| *R* | = gas constant [J K-1 mol-1] (8.314 J K-1 mol-1) |
| *T* | = skin/surface temperature [K] (303.15 K) |
| *K* | = conversion factor (36000) |
| *M* | = molar mass [g mol-1] (60.1 g mol-1) |
| β | = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1) |
| *p* | = vapour pressure of the pure substance [Pa] (7600 Pa (30°C)) |
| *A* | = surface area [cm2] (820 cm2) |

According to this equation the evaporation time is:

* 26.8 secs for trigger spray application;
* 64.3 sec for aerosol can application.

Considering:

* that it is assumed that the total amount evaporates at once after this time interval (worst-case scenario);
* the absorption/dermal flux rate for propan-2-ol is 0.85 mg/cm2/h (EU-agreed value (LoEP January 2015));
* a skin surface of both hands 820 cm2;
* a body weight of 60 kg (adult)

During these times of interval, the total amount of a.s absorbed is as follows:

|  |  |  |
| --- | --- | --- |
|  | **Total absorbed amount (mg/kg bw/d)** | |
|  | **Tier 1 (no PPE)** | **Tier 2 (gloves)** |
| **Trigger spray** | 0.086 | 0.0251 |
| **Aerosol can** | 0.207 | 0.975 |

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (aerosols) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Trigger spray (Meta SPC 1)** | | | | | |
| Scenario [2] | Tier 1/no PPE | 7.66 x 10-2 | 0.086 | - | 0.163 |
| Scenario [2] | Tier 2/ PPE (gloves) | 7.66 x 10-2 | 0.0251 | - | 0.10 |
| **Aerosol (Meta SPC 2)** | | | | | |
| Scenario [2] | Tier 1/no PPE | 2.62 x 10-1 | 0.207 | - | 0.469 |
| Scenario [2] | Tier 2/ PPE (gloves) | 2.62 x 10-1 | 0.975 | - | 0.36 |

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

None

*Scenario [3] Wiping the treated surface*

| **Description of Scenario [3]** | | | |
| --- | --- | --- | --- |
| The products are also applied by wiping the product previously sprayed on a small surface or by wiping the product sprayed on a tissue directly on a small surface to disinfect it in order of keeping this surface sterile.  To assess dermal exposure, the model of application by wiping from the BEAT data base has been used according to the Recommendation 6 of HEAd Hoc.  The indicative exposure value from the model is 214 µL/min (hands) with 10 wiping/events and 1 min/events. | | | |
|  | **Parameters1** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 10 | HEAd Hoc Recommendation 6  UA discussions (June 2017) |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption (mg/cm2) | 0.85 | CAR on propan-2-ol |
| **Tier 22** | Gloves penetration factor | 10% | HEEG Opinion 9 |

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

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

**Calculations for Scenario [3]**

Dermal exposure

The indicative dermal contamination value from BEAT is 214µL/min (75th percentile). This would result in a total amount of 0.13 g propan-2-ol/min(considering a density value of 0.862 and 70% of a.s in the product).

Assuming 10 wiping events/day and 1 min/event and the surface area of one palm hand that is available for dermal exposure (205 cm2), following the approach in the propan-2-ol Assessment Report, the time of evaporation is calculated as follows:

*t = mRTK/Mβ*pA

|  |  |
| --- | --- |
| *t* | = time [s] |
| *m* | = mass of propan-2-ol on surface [mg] (120 mg) |
| *R* | = gas constant [J K-1 mol-1] (8.314 J K-1 mol-1) |
| *T* | = skin/surface temperature [K] (303.15 K) |
| *K* | = conversion factor (36000) |
| *M* | = molar mass [g mol-1] (60.1 g mol-1) |
| β | = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1) |
| *p* | = vapour pressure of the pure substance [Pa] (7600 Pa (30°C)) |
| *A* | = surface area [cm2] (205 cm2) |

According to this equation the evaporation time is 143.8 secs.

Therefore for a worst-case scenario, it is assumed that the total amount evaporates at once after this time interval.

The absorption/dermal flux rate for propan-2-ol is 0.85 mg/cm2/h (EU-agreed value (LoEP January 2015)).

During a time interval of 143.8 secs on the skin surface of one palm hand 205 cm2, this result in a total absorbed amount of 6.96 mg per day. This is equivalent to 0.12 mg/kg bw/d without PPE or 0.012 mg/kg bw/d with PPE gloves for a body weight of 60 kg.

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| Scenario [3] | Tier 1/no PPE | - | 0.116 | - | 0.116 |
| Scenario [3] | Tier 2/ PPE (gloves) | - | 0.0116 | - | 0.0116 |

**Further information and considerations on scenario [3]**

None

*Scenario [4] Exposure to volatilized residues during application*

| **Description of Scenario [4]** | | | |
| --- | --- | --- | --- |
| Due to the high volatility of the active substance, the exposure to vapor during spraying and wiping has been assessed using ConsExpo web and the model for disinfectant.  The maximum application rates claimed by the applicant for application with a trigger spray or an aerosol are 30 mL and 40 mL/m2 respectively.  Considering a density of 0.785 and a treated surface of **5m2**, the amount of product deposited on the treated surface is of **129.3g** (30 mL/m2 x 0.862 x 5 m2 = 129.3g) for trigger spray and **172.4g** (40 mL/m2 x 0.862 x 5 m2 = 172.4g) for aerosol.  An exposure duration of **40 min** is considered in order to take into account the time duration of the spraying and the wiping, 30 min and 10 min respectively.  For the other parameters, ConsExpo default values have been kept. | | | |
|  | **Parameters** | **Value** | **Source** |
| **Tier 1** | Concentration of a.s in the product | 70% | Applicant’s data |
| Task duration (min) | 40 | Spraying + wiping |
| Release area (m2) | 5 | CAR on propan-2-ol  UA discussions |
| Room volume (m3) | 25 | ConsExpo default value |
| Vapor pressure (Pa) | 5780 | Substance data |
| Emission duration (h) | 24 | ConsExpo default value |
| Ventilation rate | 8/h |  |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Inhalation rate (m3/h) | 1.25 | HEAD Hoc recommendation 14 |

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

**Calculations for Scenario [4]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation (evaporation) uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Trigger spray (30 mL/m2)** | | | | | |
| Scenario [4] | Tier 1/no PPE | 9.2 | - | - | 9.2 |
| **Aerosol (40 mL/m2)** | | | | | |
| Scenario [4] | Tier 2/ no PPE | 12 | - | - | 12 |

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

None

*Combined scenarios*

| **Summary table: combined systemic exposure from professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Application using a trigger spray** | | | | |
| Scenarios [1,2,3,4]  Tier 1 | 9.28 | 0.21 | - | 9.49 |
| Scenarios [1,2,3,4]  Tier 2 | 9.28 | 0.04 | - | 9.32 |
| **Application using an aerosol** | | | | |
| Scenarios [2,3,4]  Tier 1 | 12.26 | 0.32 | - | 12.59 |
| Scenarios [2,3,4]  Tier 2 | 12.26 | 0.11 | - | 12.37 |

\* Please include the Tier where relevant

*[Add and delete lines as needed. Output tables from exposure assessment tools can be included in Annex 3.2 to complement the table].*

***Non-professional exposure***

Not applicable.

***Secondary exposure***

*Scenario [5]*

| **Description of Scenario [5]** |
| --- |
| Inhalation of volatilized residues after indoor application is possible. .It can be considered that this exposure is equal or lower than the direct exposure of the professional applying the product.  Furthermore, the dermal exposure is considered negligible because of the high volatility of the a.s containing in the product.  Therefore, the same parameters used in scenario 4 have been applied leading to similar exposure to volatilized residues for an adult entering a room with freshly treated surfaces;  For details please refer to the scenario 4. |

**Calculations for Scenario [5]**

| **Summary table: estimated exposure from professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/d)** | **Estimated dermal uptake**  **(mg/kg bw/d)** | **Estimated oral uptake** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **Trigger spray (30 mL/m2)** | | | | | |
| Scenario [5] | Tier 1/no PPE | 9.2 | - | - | 9.2 |
| **Aerosol (40 mL/m2)** | | | | | |
| Scenario [5] | Tier 2/ no PPE | 12.0 | - | - | 12.0 |

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

None

***Monitoring data***

None.

***Dietary exposure***

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

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

Residue definitions

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

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

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

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

Not relevant.

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

Not relevant.

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

Not relevant.

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

Not applicable.

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake**  **(mg/kg bw/d)** |
| **1,2,3,4**  **Trigger spray application** | Professionals | Tier 1/no PPE | 9.49 |
| **1,2,3,4 Trigger spray application** | Professionals | Tier 2/PPE (gloves) | 9.32 |
| **2,3,4 Aerosol can Application** | Professionals | Tier 1/no PPE | 12.59 |
| **2,3,4**  **Aerosol can Application** | Professionals | Tier 2/PPE (gloves) | 12.37 |
| **5** | Bystanders | Tier 1/no PPE – trigger spray | 9.2 |
| **5** | Bystanders | Tier 1/no PPE – aerosol | 12 |

#### Risk characterisation for human health

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

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

1 Please explain background and reason for assessment factor.

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

**Maximum residue limits or equivalent**

Not relevant

***Risk for industrial users***

Not applicable.

***Risk for professional users***

**Systemic effects – Application with a Trigger Spray**

| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- | --- | --- |
| **Scenario [1]**  **Mixing and loading** | Tier 1/no PPE | 17.9 | 1.38 x 10-2 | 0.08 | yes |
| **Scenario [1]**  **Mixing and loading** | Tier 2/PPE (gloves) | 17.9 | 4.08 x 10-3 | 0.02 | yes |
| **Scenario [2]**  **Spray application** | Tier 1/no PPE | 17.9 | 0.163 | 0.91 | yes |
| **Scenario [2]**  **Spray application** | Tier 2/PPE (gloves) | 17.9 | 0.1 | 0.57 | yes |
| **Scenario [3]**  **Wiping** | Tier 1/no PPE | 17.9 | 0.116 | 0.65 | yes |
| **Scenario [3]**  **Wiping** | Tier 2/PPE (gloves) | 17.9 | 0.012 | 0.06 | yes |
| **Scenario [4]**  **Inhalation of volatilized residues** | Tier 1/no PPE | 17.9 | 9.2 | 51.4 | yes |

**Systemic effects – Application with an Aerosol**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Scenario [2]**  **Spray application** | Tier 1/no PPE | 17.9 | 0.47 | 2.62 | yes |
| **Scenario [2]**  **Spray application** | Tier 2/PPE (gloves) | 17.9 | 0.098 | 2.01 | yes |
| **Scenario [3]**  **Wiping** | Tier 1/no PPE | 17.9 | 0.12 | 0.65 | yes |
| **Scenario [3]**  **Wiping** | Tier 2/PPE (gloves) | 17.9 | 0.012 | 0.06 | yes |
| **Scenario [4]**  **Inhalation of volatilized residues** | Tier 1/no PPE | 17.9 | 12 | 67 | yes |

**Combined scenarios**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Application with a trigger spray** | | | | | |
| **[1,2,3,4]** | Tier1/no PPE | 17.9 | 9.49 | 53.03 | yes |
| Tier 2/PPE (gloves) | 17.9 | 9.32 | 52.05 | yes |
| **Application with an aerosol** | | | | | |
| **[2,3,4]** | Tier1/no PPE | 17.9 | 12.59 | 70.3 | yes |
| Tier 2/PPE (gloves) | 17.9 | 12.37 | 69.1 | yes |

**Local effects**

As the product is irritant for eyes (Eye Irrit 2 – H319), a local risk assessment according to the guidance on the BPR: Volume III HH part B is performed.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hazard | | | Exposure | | | | | | | Risk |
| Hazard Category | Effects in terms of C&L | Additional relevant hazard information | PT | Who is exposed? | Tasks, uses, processes | Potential exposure route | Frequency and duration of potential exposure | Potential degree of exposure | Relevant RMM & PPE | Conclusion on risk |
| Low | Eye Irri 2 | - | 2 | Professional | Spraying downard on small surfaces (desk, equipment materials...) in area with or without controlled atmosphere | ocular | Few minutes per day | Low | **RMM Technics:** - Minimisation of splashes and spills;  **RMM Organisation:** - Minimise number of staff exposed; -Management /supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene  **PPE**  - Eye protection | The spray aplication should be downward in order to avoid any facial exposure.  Considering that these recommendations can be followed during this task, ,the risk is acceptable according to RMM and PPE |

**Conclusion**

For both applications, with a trigger spray or an aerosol, the risk is considered acceptable for professionals without PPE.

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

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

Not applicable.

***Risk for secondary exposure***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| **Application with a trigger spray** | | | | | |
| Scenario [5]  Inhalation of volatilized residues | Tier 1 | 17.9 | 9.2 | 51.4 | yes |
| **Application with an aerosol** | | | | | |
| Scenario [5]  Inhalation of volatilized residues | Tier 1 | 17.9 | 12 | 67.0 | yes |

**Local effects**

Not applicable.

**Conclusion**

For an adult entering a room with freshly treated surfaces, the risk is considered acceptable.

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

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

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

Not relevant.

### Risk assessment for animal health

Not applicable.

### Risk assessment for the environment

|  |
| --- |
| **Box 1- FR CA position :**    Please notice that the environmental exposure assessment (section 2.8.4) is reported as provided by the applicant. The FR CA position is presented **in green evaluation boxes at the end of each part of the environmental risk assessment section.** |

The ANIOS IPA biocidal products family contains a series of PT 2 products, intended for use as surface disinfectants in the pharmaceutical industry, medical equipment industry, cosmetic industry, laboratories and hospital pharmacies. Surfaces to be disinfected are small scale and include workstations, cleaning material, window panes and gloves.

The products are divided into two Meta SPCs, based on their use under the form of an aerosol or non-aerosol product. The products within the family have the same ingredients and the same uses. These uses are covered in the propan-2-ol assessment report (AR) and the product ingredients are identical to that of the representative product assessed in the propan-2-ol AR. No SOCs are present in the product composition and no metabolites are formed in the environment as indicated in the propan-2-ol AR.

Three products within the ANIOS IPA biocidal products family do however have a slightly higher concentration in propan-2-ol than the representative product referenced in the AR (70 % w/w or 76.87 % v/v for the three ANIOS products versus 70 % v/v for the dummy product in the AR), therefore requiring a new risk assessment to be carried out for these products. The three products are the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE and the ANIOS ALCOOL ISOPROPYLIQUE 70% from the Meta SPC 1 and the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL from the Meta SPC 2.

Amongst these three products, it is possible to identify a worst case product, for which this risk assessment will be carried out. All three products have an identical composition and the overall same uses. The main differences that could impact environmental emissions are the dose of product applied and the aerosol characteristic of products within the Meta SPC 2, as indicated in the following table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Worst case selection : product comparison** | | | |
| Meta SPC | **META SPC 1** | | **META SPC 2** |
| Biocidal product | **ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE** | **ANIOS ALCOOL ISOPROPYLIQUE 70%** | **ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL** |
| Active substance concentration | 70 % w/w | 70 % w/w | 70 % w/w |
| Product dose | 30 ml/m² | 30 ml/m² | 30-40 ml/m² |
| Use frequency and treated surface | Default value for small scale application of ready-to-use products in industrial areas is set at 100 m² treated daily. | | |

The way propan-2-ol fractions between the air and surface on which it is applied could vary between the aerosol and non-aerosol products. The Emissions Scenario Document for Product Type 18 indicates that particles whithin the aerosol size range will fall to the ground within 24 hours and the default fraction of product emitted to air is set to 2%. Following the hypothesis laid down in the propan-2-ol AR, it is assumed that propan-2-ol will fraction to air and surfaces at 90% and 10% respectively, due to propan-2-ol’s high volatility. As a 90% fraction to air is a worst case value compared to the default 2% fraction to air, it can be assumed that selecting a 90% fraction to air would be a worst case for both the aerosol and non-aerosol products. The distinction between aerosol and non-aerosol products therefore doesn’t impact the selection of a worst case product. All else being equal, the product dose is highest in the Meta SPC 2 and the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL can therefore be considered as the worst case product in this risk assessment.

No new environmental studies have been carried out with the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL. All data pertaining to the active substance is therefore derived from the propan-2-ol assessment report.

#### Effects assessment on the environment

PNEC values were derived from the endpoints generated in the propan-2-ol AR. Ecotoxicological studies on the active substance were carried out for STP and aquatic organisms and are summarized in the following table :

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table of ecotoxicological studies from the propan-2-ol assessment report** | | | |
| **Species** | **Time-scale** | **Endpoint** | **Toxicity** |
| **Fish** | | | |
| *Pimephales promelas* | 96 h | Mortality, LC50 | *8692 mg a.s./L* |
| **Invertebrates** | | | |
| *Daphnia magna* | 48 h | Immobility, EC50 | *2285 mg a.s./L* |
| *Daphnia magna* | 16 d | Growth (length), NOEC | *141 mg a.s./L* |
| **Algae** | | | |
| *Pseudokirchneriella subspicata* | 48 h | Growth rate, ErC50 | *10500 mg a.s./L* |
| **Microorganisms** | | | |
| Activated sewage sludge (municipal sewage treatment plant) | 3 hours (static) | Respiration inhibition, EC50 | > 1000 mg a.s./l |

Corresponding PNEC values were calculated with EUSES 2.1.2. and are listed in the following table:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on PNEC values** | | | | | | | |
| **PNECSTP** | **PNECwater** | **PNECsed** | **PNECseawater** | **PNECseased** | **PNECsoil** | **Trigger value GW** | **PNECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/ kgwwt] | [g/l] | [mg/m3] |
| 10 | 2.82 | 2.41 | 0.141 | 0.12 | 0.496 | 0.1 | - |

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

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 2 |
| Assessed scenarios | Surface disinfection in industrial areas |
| ESD(s) used | Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (Scenario p. 11 : Release of disinfectants used in industrial areas), 2011 |
| Approach | Average consumption |
| Distribution in the environment | Estimated according to :   * Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), April 2015. * Assessment report: Propan-2-ol, PT2 – Private area and public health area disinfectants and other biocidal products, January 2015. |
| Groundwater simulation | No |
| Confidential Annexes | No |
| Life cycle steps assessed | Product use |
| Remarks | - |

***Emission estimation***

The ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL is intended for use as a surface disinfectant in the pharmaceutical industry, medical equipment industry, cosmetic industry, laboratories and hospital pharmacies. Surfaces to be disinfected are small scale and include workstations, cleaning material, window panes and gloves.

The scenario “Release of disinfectants used in industrial areas” (ESD for Product Type 2: Private and public health area disinfectants and other biocidal products, 2011, p.11) is most adapted to this product use as it covers “industrial premises dealing with packaging materials, biotechnology i.e. laboratories (yeast, proteins, enzymes), production of pharmaceutics, cosmetics and toiletries and production of computers” and covered surfaces are “the rooms themselves (floors, walls, ceilings) or smaller surfaces (furniture, equipment, working places, isolator benches, etc.)”.

In the case of the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL, all the different treated surfaces can be considered as a single “surface disinfection” and the total amount of product applied is considered to be subsequently released to air and waste water. This is a worst case approach as the treated gloves are discarded to solid waste and a lesser amount of product will in fact be released to waste water. As indicated in the Technical Agreements for Biocides (TAB, Sept. 2015, p.13), default surface areas treated with ready-to-use products for small scale applications in the industrial area are considered to be 10% of the default surface area provided in the existing scenario (1000 m²). The default value for the total daily surface disinfection with ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL is therefore set as 100 m².

The following input paramaters were also used for estimating propan-2-ol release to the environment :

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | | |
| **Input** | | **Value** | **Unit** | **Remarks** |
| Scenario: Surface disinfection in an industrial setting | | | | |
| *Vform* | Application rate of biocidal product | 0.04 | l/m² | The product is applied at a rate of 30-40 ml/m². Worst-case value is selected. |
| *Cform* | Concentration of active substance in the product | 603 | g/l | The product contains 70 %w/w active substance and has a density of 0.862, giving it a concentration in active substance of 603 g/l. |
| *AREAsurface* | Surface area to be disinfected | 100 | m² | Daily covered surfaces do not exceed 100 m² for small scale applications in industrial areas for ready-to-use products (Technical Agreements for Biocides, Sept. 2015, p.13). |
| *Nappl* | Number of applications per day | 1 | d-1 |
| *Fdis* | Fraction of substance disintegrated during or after application (before release to the environment) | 0 | - | Default value, worst case (ESD, 2011) |
| *Fenv* | Fraction released to the environment | 1 | - | Default value, worst case (ESD, 2011) |

The amount of propan-2-ol locally emitted in a day can be estimated using the following equation (ESD, 2011, p.11) :

*Elocal [kg/d] = Vform* • *Cform* • *AREAsurface* • *Nappl* • *(1 - Fdis)* • *Fwater / 1000*

= 0.04 \* 603 \* 100 \* 1 \* 1 \* 1 / 1000

= 2.412 kg/d

Due to propan-2-ol’s high volatility, a large fraction of the emitted active substance will evaporate to the air compartment while the remainder is released to waste water via rinse-off and cleaning of the treated surfaces. The propan-2-ol AR suggests as a worst case that 90% of the emitted active substance fractions to the air compartment and the remainding 10% is released to waste water. As the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL has an almost identical composition to the dummy product represented in the propan-2-ol AR (same two ingredients, in almost identical proportions) and is used in a similar manner as the dummy product, it can be assumed that the 90%-10% fractioning to air and waste water can apply to the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL as well.

In this case, local emissions to air and waste water are the following:

*Elocalair* = 2.412 \* 0.9 = 2.1708 kg/d

*Elocalwater* = 2.412 \* 0.1 = 0.2412 kg/d

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| Air | 2.1708 | - |
| STP | 0.2412 | - |

|  |
| --- |
| **Box 3- FR CA position :**  We agree with the emission calculations carried out by the applicant and the proposed Elocal for wastewater and air regarding small scale applications of RTU products.  It is worth noting that the proposed treated surface of 100 m2 is a worst case value compared to the TAB entry ENV 38 where a treated surface of 25 m2 is considered for PT02 small scale applications in institutional areas. Moreover, the highest dose rate (0.04 L/m2) normally restricted to the clean rooms in controlled atmosphere has been used. |

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

At product use, direct emission of the active substance will occur to waste water following rinse-off and cleaning of treated areas. Direct emissions will also occur to indoor air, due the high vapour pressure of the active substance. Indoor air is then considered to be emitted to the local air outdoors. Primary receiving compartments are therefore waste water and air. Indirect emissions can occur from the STP to surface water and sediment. Indirect releases can also occur to the terrestrial compartment following application of sewage sludge to agricultural soil and deposition of propan-2-ol from the atmosphere.

Environmental compartments exposed during the use of ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL are resumed in the following table:

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

*++ : directly exposed + : indirectly exposed - : not exposed*

The fate and distribution of propan-2-ol in the environment were calculated via EUSES 2.1.2. The following endpoints were taken from the propan-2-ol AR (2015) and were used as input for the model:

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| **Input** | **Unit** | **Value** | **Remarks** |
| Molecular weight | g/mol | 60.09 | Propan-2-ol AR endpoints (2015) |
| Melting point | °C | -89.5 |
| Boiling point | °C | 82.5 |
| Vapour pressure (at 25°C) | Pa | 5780 |
| Water solubility | mg/l | 1 x 105 |
| Partition coefficient n-octanol/water (log Kow or Pow) | log 10 | 0.05 |
| Partition coefficient organic carbon/water (Koc) | l/kg | 3.3 |
| BCF earthworm | l/kg | 0.85 |
| BCF fish | l/kg | 0.22 |
| Henry’s law constant (25°C) | Pa. m³/mol | 0.8 |
| Biodegradability | - | Readily biodegradable |
| Air: degradation | days | DT50 = 3.1 days |

After entering the STP, the propan-2-ol fractions in the following manner:

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP** | | |
| Compartment | Percentage [%] | Remarks |
| Air | 0.165 | Calculated via EUSES 2.1.2 |
| Water | 12.6 |
| Sludge | 0.0312 |
| Degraded in STP | 87.2 |

***Calculated PEC values***

Resulting PEC values are summarized in the following table:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | |
| **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/ kgwwt] | [mg/l] | [mg/m3] |
| 0.0152 | 1.52 x 10-3 | 1.3 x 10-3 | 1.21 x 10-3 | 1.03 x 10-3 | 7.48 x 10-5 | 9.38 x 10-5 | 1.65 x 10-6 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 4- FR CA position :**  Concerning the applications in clean rooms in controlled atmosphere areas, no risk assessment for the environment is considered needed as no wet cleaning or other releases are expected.  For the other intended application areas, the proposed emission scenario was conducted by the applicant for small scale applications with RTU products using a worst case treated surface of 100 m2 at the highest dose rate (0.04 L/m2) normally restricted to the clean rooms in controlled atmosphere.  **Regarding the release to the STP:**  FR CA agrees with the environmental risk assessment as described above by the applicant for the STP, surface water and sediment. Nevertheless, no emission to soil (and groundwater) via the STP sludge application is foreseen according to the CAR as the release fractions to the STP sludge was set to 0%.  Therefore, concerning the releases via the STP, the PEC values for the relevant environmental compartments are:   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Elocalwater** | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [kg.d-1] | [mg.L-1] | [mg.L-1] | [mg.kg-1wwt] | [mg.kg-1wwt] | [µg.L-1] | | 0.2412 | 1.52E-02 | 1.52E-03 | 1.30E-03 | 0 | 0 |   **Regarding the deposition to soil *via* the atmosphere:**  No emission scenario for the releases via the emission to atmosphere was proposed by the applicant. From the Elocal air of 2.1708 kg/d, the annual average total deposition flux DEPtotalann and the resulting PEClocalsoil and PEClocalgroundwater were calculated according to the ECHA Guidance on the Biocidal Products Regulation Vol IV part B, using the characteristics of the substance, as described in the CAR of Propan-2-ol. A rate constant for removal from agricultural top soil of 0.0476 was applied (i.e sum of kbio = 0.0231, kvolat = 0.0165 and kleach = 8.02E-03).   |  |  |  |  | | --- | --- | --- | --- | | **Elocalair** | **DEPtotalann** | **PECsoil** | **PECgroundwater** | | [kg.d-1] | [µg.m-2.d-1] | [µg.kg-1wwt] | [µg.L-1] | | 2.1708 | 0.87 | 5.37E-02 | 3.05E-01 |   As the first Tier assessment for groundwater led to an unacceptable level of the substance in this compartment (> 0.1 µg/L), a refinement using FOCUS Pearl 4.4.4 was applied, with the same method than used in the CAR with the following input parameters:   |  |  |  | | --- | --- | --- | | **Parameters** | **Unit** | **Propan-2-ol** | | Molar mass | g·mol-1 | 60.09 | | Saturated vapour pressure measured at 25°C | Pa | 5780 | | Solubility in water measured at 25°C | mg·L-1 | 1000000 | | Half-life in soil measured at 12°C | d | 30 | | Kom (coef. for sorption on organic matter) at 20°C | L·kg-1 | 1.92 | | Freundlich exponent | - | 0.9 | | Plant uptake factor | - | 0.0 | | Aerial Deposition on Arable land and Grassland | | | | Application type | - | To soil surface | | Crops | - | Maize and Alfalfa | | Target depth | m | 1 | | Annual incorporation | - | 12 applications per year at the beginning of each month | | Incorporation depth | m | 0.0 |   The application rate (Apprate) relevant for FOCUS modeling was calculated as follows:  Apprate (kg.ha-1.application-1) = DEPtotalann (µg.m-2.d-1) x 365 (d) x 1E-05 / 12 = 2.64E-04  The results of refined PECgroundwater by FOCUS PEARL 4.4.4 are summarized below:   |  |  |  | | --- | --- | --- | | **Location** | **Arable land (µg.L-1)** | **Grassland (µg.L-1)** | | CHATEAUDUN | 0.027201 | 0.030690 | | HAMBURG | 0.099920 | **0.101265** | | JOKIOINEN | -\* | **0.144017** | | KREMSMUENSTER | 0.041009 | 0.037590 | | OKEHAMPTON | 0.066142 | 0.060345 | | PIACENZA | 0.044333 | 0.042639 | | PORTO | 0.037874 | 0.038799 | | SEVILLA | 0.014508 | 0.019744 | | THIVA | 0.012600 | 0.016119 |   \* currently no FOCUS scenario defined  The refinement of the concentrations in groundwater with the FOCUS Pearl model leads to acceptable level of propan-2-ol (< 0.1 µg/L). Only two values are close to the trigger value (Hamburg scenario and Jokioinen scenario for grassland). Considering that a very worst assumption concerning the area of treated surfaces has been considered (100 m2 compared to the TAB value of 25 m2) has been made for this calculation, the predicted concentrations in groundwater are lower than 0.1 µg/L.  Considering that the Freundlich exponent has been recently revised and should be set now at 1, the modelling has been conducted again with this value on the realistic surface area of 25 m2 for small scale applications.  The results of refined PECgroundwater by FOCUS PEARL 4.4.4 with **a Freundlich exponent of 1** are summarized below and confirm acceptable risks for groundwater:   |  |  |  | | --- | --- | --- | | **Location** | **Arable land (µg.L-1)** | **Grassland (µg.L-1)** | | CHATEAUDUN | 0.009718 | 0.010517 | | HAMBURG | 0.036129 | 0.036353 | | JOKIOINEN | - | 0.061574 | | KREMSMUENSTER | 0.0141 | 0.013282 | | OKEHAMPTON | 0.021689 | 0.020141 | | PIACENZA | 0.014365 | 0.013848 | | PORTO | 0.011472 | 0.011706 | | SEVILLA | 0.005249 | 0.006583 | | THIVA | 0.004569 | 0.005527 | |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning is not likely to occur as the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL is intented for an indoor use.

Secondary poisoning

The risk of secondary poisoning is considered negligible. Propan-2-ol has a low Kow (log Kow = 0.05) as well as low BCF falues for fish and worms (BCFfish = 0.22 l/kgwwt and BCFworm = 0.85 l/kgwwt), indicating a low potential for bioaccumulation. The propan-2-ol AR also states that no other indicators point to a potential for bioconcentration and propan-2-ol is not expected to accumulate in the environment.

|  |
| --- |
| **Box 5- FR CA position :**  FR CA agrees with the applicant, according to the assessment report of propan-2-ol, no risk assessment for poisoning is needed. |

#### Risk characterisation

PEC/PNEC ratios were calculated for the different compartments and are summarized in the following table:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on PEC/PNEC ratios for the relevant exposed compartments** | | | | | | | |
| **PEC/PNEC STP** | **PEC/PNEC water** | **PEC/PNEC sediment** | **PEC/PNEC seawater** | **PEC/PNEC**  **sea sediment** | **PEC/PNEC**  **soil** | **PEC GW** | **PEC air** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/ kgwwt] | [mg/l] | [mg/m3] |
| 1.52 x 10-3 | 5.39 x 10-4 | 5.39 x 10-4 | 8.55 x 10-3 | 8.55 x 10-3 | 1.51 x 10-4 | 9.38 x 10-5 | 1.65 x 10-6 |

PEC/PNEC ratios for the STP, aquatic and soil compartments are all under the trigger value of 1. No unacceptable risk is identified for these compartments.

No unacceptable risk is identified for the groundwater compartment either as the calculated PECGW is below the EU trigger value of 0.1 g/l. Furthermore, this PECGW is an extreme worst case as calculations at a first tier level are based on active substance concentration in soil porewater. No DT50 for soil is available in the propan-2-ol AR and the default values applied in EUSES for readily biodegradable substances will also overestimate soil persistence of propan-2-ol.

No PNEC value is available for the air compartment. However, the propan-2-ol AR indicates that a biotic risk is not expected for the air compartment. Comparison of the calculated PECair to short-term and long-term inhalation endpoints of the propan-2-ol AR does not give indications of any unacceptable biotic effects to the air compartment. No abiotic effects are expected for the air compartment either. As stated in the propan-2-ol AR, no acidifaction or impact on the stratospheric and tropospheric ozone is expected. Finally, the risk for the air compartment is reduced as the ANIOS ALCOOL ISOPROPYLIQUE 70% IP STERILE AEROSOL is emitted to indoor air. Propan-2-ol could be indirectly emitted to outdoor air by evaporation from the STP. However the fraction of propan-2-ol emitted to air from the STP is calculated by EUSES to be 0.165% of the amount of active substance first entering the STP, which is negligible considering the total amount of propan-2-ol emitted. Residues in air are not expected to persist due to degradation (propan-2-ol degrades in air with a half-life of 3.1 days) and dilution.

As stated previously, primary poisoning is unlikely due to the intended product use, and a risk for secondary poisoning is considered negligible in view of propan-2-ol’s biochemical properties.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 6- FR CA position :**  PEC/PNEC ratios for STP, surface water, sediment and soil are all under the trigger value of 1. The concentrations in groundwater calculated with FOCUS Pearl are considered below the trigger value of 0.1 µg/L.  No unacceptable risks are therefore identified for the environment.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Summary table on PEC/PNEC ratios for the relevant exposed compartments | | | | | | PEC/PNEC | PEC/PNEC | PEC/PNEC | PEC/PNEC | PEC | | **STP** | **Surface water** | **sediment** | **Soil** | **GW** | | [mg.L-1] | [mg.L-1] | [mg.kg-1wwt] | [mg.kg-1wwt] | [µg.L-1] | | 1.52E-03 | 5.39E-04 | 5.39E-04 | 1.08E-04 | < 0.1 | |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| Based on this risk assessment and on available data, no unacceptable risk to the environment has been identified for the products included in the ANIOS IPA biocidal products family, when applied according to their intended use. |

|  |  |  |
| --- | --- | --- |
| **Box 7- FR CA position :**   |  | | --- | | **Overall conclusion on the risk assessment for the environment of the product** | | No unacceptable risk to STP, surface water, sediment and soil has been identified for the products included in the ANIOS IPA biocidal product family, when applied according to their intended uses. The predicted concentrations in groundwater are lower than the threshold value of 0.1 µg/L (Council Directive 98/83/EC). | |

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

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

### Assessment of a combination of biocidal products

Not relevant.

# Annexes

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Chrystèle Pluchart, Gaétan Rauwel | 2015 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the bactericidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF EN 1276 (March 2010).  Laboratoires Anios A 15 102 1276  33176 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2016 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the bacte ricidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF EN 13727 + A2 (December 2015).  Laboratoires Anios A 16 65 13727  34025 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2016 | Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of bactericidal activity of the formula 0316. Test method without mechanical action and requirements (phase 2 –step 2) according to the NF EN 13697 (June 2015).  Laboratoires Anios A 16 63 13697  34026 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2015 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the yeasticidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF EN 1650 + A1 (July 2013).  Laboratoires Anios A 15 106 1650  33199 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2016 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the yeasticidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF EN 13624 (November 2013). Laboratoires Anios  A 16 66 13624  34027 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2016 | Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of yeasticidal activity of the formula 0316. Test method without mechanical action and requirements (phase 2 -step 2) according to the NF EN 13697 (June 2015).  Laboratoires Anios A 16 64 13697  34031 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2015 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the fungicidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF EN 1650 + A1 (July 2013).  Laboratoires Anios A 15 104 1650  33197 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel | 2016 | Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of the fungi  cidal activity of the formula 0316. Test method and prescriptions (phase 2 - step 1) according to NF  EN 13624 (November 2013). Laboratoires Anios  A 16 80 13624  34087 | Yes | Laboratoires ANIOS |  |
| Katharina Pegeot, Chrystèle Pluchart |  | Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of fungicidal activity of the formula 0316. Test method without mechanical action and requirements (phase 2 -step 2) according to the NF EN 13697 (June 2015).  Laboratoires Anios A 15 105 13697  33198 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Gaétan Rauwel |  | Antiseptics and chemical disinfectants. Quantitative carrier test for the evaluation of fungicidal activity of the formula 0316. Test method without mechanical action and requirements (phase 2-step 2) according to an adaptation of the EN13697 (June 2015)  Laboratoires Anios  34096 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Katharina Pegeot |  | Chemical antiseptics and disinfectants. Quantitative test method for the evaluation of the bactericidal and yeasticidal activity on non- porous surfaces with mechanical action employing wipes in the medical area (4 fields test) of the formula 316. Test method and prescriptions (phase 2 - step 2) according to NF EN 16615 (May 2015).  Laboratoires Anios A 17 48 16615  35559 | Yes | Laboratoires ANIOS |  |
| Chrystèle Pluchart, Katharina Pegeot |  | Chemical antiseptics and disinfectants. Quantitative test method for the evaluation of the fungicidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4 fields test) of the formula 316. Test method and prescriptions (phase 2 - step 2) according to NF EN 16615 (May 2015).  Laboratoires Anios 35561 | Yes | Laboratoires ANIOS |  |

* **Post authorisation assessment (2021)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Mathieu SAUTY | 2020 | Stability study of the product CODE FORMULE 316 PULVERISATEUR Product Code: 316  Study number: 16/001BPL | Yes | Laboratoires ANIOS | December 2020 |
| Mathieu SAUTY | 2021 | Stability study of the product CODE FORMULE 316 AEROSOL Product Code: 316  Study number: 16/002BPL | Yes | Laboratoires ANIOS | March 2021 |

## Output tables from exposure assessment tools

None.



## New information on the active substance

None.

## Residue behaviour

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

## Summaries of the efficacy studies (B.5.10.1-xx)[[12]](#footnote-12)

Not relevant (IUCLID file available).

## Confidential annex

Please refer to the Confidential annex file.

## Other

None.

1. Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antispetics [↑](#footnote-ref-1)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
3. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-3)
4. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-4)
5. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-5)
6. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-6)
7. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-7)
8. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-8)
9. Copy this section as many times as necessary (one table per use). [↑](#footnote-ref-9)
10. Including the pharmaceutical industry, the cosmetic industry and the medical equipment industry. [↑](#footnote-ref-10)
11. Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antispetics [↑](#footnote-ref-11)
12. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-12)