

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1185****of 8 July 2022****granting a Union authorisation for the biocidal product family ‘Contec Hydrogen Peroxide Biocidal Product Family’****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular the Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 3 December 2020, Contec Europe submitted an application, in accordance with Article 43(1) of Regulation (EU) No 528/2012, for authorisation of a biocidal product family named ‘Contec Hydrogen Peroxide Biocidal Product Family’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Slovenia had agreed to evaluate the application. The application was recorded under case number BC-PP063133-29 in the Register for Biocidal Products.
- (2) ‘Contec Hydrogen Peroxide Biocidal Product Family’ contains hydrogen peroxide as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 26 May 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 15 December 2021, the Agency submitted to the Commission an opinion <sup>(2)</sup>, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘Contec Hydrogen Peroxide Biocidal Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘Contec Hydrogen Peroxide Biocidal Product Family’ is a ‘biocidal product family’ within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 19 January 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘Contec Hydrogen Peroxide Biocidal Product Family’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on biocidal products,

<sup>(1)</sup> OJL 167, 27.6.2012, p. 1.

<sup>(2)</sup> ECHA opinion of 29 November 2021 on the Union authorisation of ‘Contec Hydrogen Peroxide Biocidal Product Family’ (ECHA/BPC/298/2021), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

HAS ADOPTED THIS REGULATION:

*Article 1*

A Union authorisation with authorisation number EU-0027735-0000 is granted to Contec Europe for the making available on the market and use of the biocidal product family 'Contec Hydrogen Peroxide Biocidal Product Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union Authorisation is valid from 31 July 2022 to 30 June 2032.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 July 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

**Summary of product characteristics for a biocidal product family**

## Contec Hydrogen Peroxide Biocidal Product Family

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals  
(Disinfectants)

Authorisation number: EU-0027735-0000

R4BP asset number: EU-0027735-0000

## PART I

**FIRST INFORMATION LEVEL****1. ADMINISTRATIVE INFORMATION****1.1. Family name**

|      |  |
|------|--|
| Name | Contec Hydrogen Peroxide Biocidal Product Family |
|------|--|

**1.2. Product type(s)**

|                 |  |
|-----------------|--|
| Product type(s) | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) |
|-----------------|--|

**1.3. Authorisation holder**

|  |                 |   |
|--|-----------------|---|
| Name and address of the authorisation holder | Name            | Contec Europe                                       |
|  | Address         | ZI Du Prat Avenue Paul Duplaix, 56000 Vannes France |
| Authorisation number                         | EU-0027735-0000 |   |
| R4BP asset number                            | EU-0027735-0000 |   |
| Date of the authorisation                    | 31 July 2022    |   |
| Expiry date of the authorisation             | 30 June 2032    |   |

**1.4. Manufacturer(s) of the biocidal products**

|                                 |  |
|---------------------------------|--|
| Name of manufacturer            | Contec Inc.,   |
| Address of manufacturer         | 525 Locust Grove., 29303 Spartanburg, United States                                  |
| Location of manufacturing sites | Unit 6A, Wansbeck Business Park, Rotary Parkway,, NE63 8QW Ashington, United Kingdom |

1.5. **Manufacturer(s) of the active substance(s)**

|                                 |   |
|---------------------------------|---|
| Active substance                | Hydrogen peroxide   |
| Name of manufacturer            | Solvay Chemicals International  |
| Address of manufacturer         | Rue Ransbeek 310,, 1120 Brussels, Belgium   |
| Location of manufacturing sites | Rue Solvay 39,, B-5190 Jemeppe-sur-Sambre, Belgium<br>Via Piave 6, Rosignano Solvay,, I-57013 Livorno, Italy<br>Köthensche Strasse 1-3,, D06406 Bernburg, Germany<br>Baronet Road,, WA4 6HA Warrington, United Kingdom<br>Yrjönojantie 2,, 45910 Voikkaa, Finland<br>Rua Eng. Clement Dumoulin,, P-2625-106 Povoá de Santa Iria, Portugal |

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. **Qualitative and quantitative information on the composition of the family**

| Common name       | IUPAC name | Function         | CAS number | EC number | Content (%) |      |
|-------------------|------------|------------------|------------|-----------|-------------|------|
|                   |            |                  |            |           | Min         | Max  |
| Hydrogen peroxide |            | Active Substance | 7722-84-1  | 231-765-0 | 6,67        | 6,67 |

2.2. **Type(s) of formulation**

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL - Any other liquid |
|----------------|-----------------------|

## PART II

## SECOND INFORMATION LEVEL - META SPC(S)

## META SPC 1

1. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

|            |            |
|------------|------------|
| Identifier | meta SPC 1 |
|------------|------------|

1.2. **Suffix to the authorisation number**

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

1.3. **Product type(s)**

|                 |  |
|-----------------|--|
| Product type(s) | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) |
|-----------------|--|

2. **META SPC 1 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

| Common name       | IUPAC name | Function         | CAS number | EC number | Content (%) |      |
|-------------------|------------|------------------|------------|-----------|-------------|------|
|                   |            |                  |            |           | Min         | Max  |
| Hydrogen peroxide |            | Active Substance | 7722-84-1  | 231-765-0 | 6,67        | 6,67 |

2.2. **Type(s) of formulation of the meta SPC 1**

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL - Any other liquid |
|----------------|-----------------------|

3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1**

|                          |   |
|--------------------------|---|
| Hazard statements        | Causes serious eye irritation.  |
| Precautionary statements | Wash hands thoroughly after handling.<br>Wear eye protection/face protection.<br>IF IN EYES: Rinse cautiously with water for several minutes.<br>Remove contact lenses, if present and easy to do. Continue rinsing.<br>If eye irritation persists: Get medical attention.<br>If eye irritation persists: Get medical advice. |

4. **AUTHORISED USE(S) OF THE META SPC 1**4.1. **Use description**

**Table 1. Use # 1 – Use #1 - Application by trigger spray onto a suitable cleanroom wipe to distribute onto the inner surface of isolators and Restricted Access Barrier Systems ('RABS')**

|  |  |
|--|--|
| Product type   | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)                             |
| Where relevant, an exact description of the authorised use | /  |
| Target organism(s) (including development stage)           | Scientific name: /<br>Common name: Bacteria<br>Development stage: /<br>Scientific name: /<br>Common name: Yeasts<br>Development stage: / |

|                                   |  |
|-----------------------------------|--|
|                                   | Scientific name: /<br>Common name: Fungi<br>Development stage: /   |
| Field(s) of use                   | Indoor<br>In isolators and RABS positioned in cleanrooms: disinfection of hard/non-porous surfaces. Not for use in healthcare.   |
| Application method(s)             | Method: Spraying the product onto a suitable cleanroom wipe used to distribute the product on the surface.<br><br>Detailed description:<br>/   |
| Application rate(s) and frequency | Application Rate: /<br><br>Dilution (%): No dilution - product is ready to use ('RTU')<br><br>Number and timing of application:<br>Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C).<br><br>Application frequency is specific to the user's site and requirements. |
| Category(ies) of users            | Professional   |
| Pack sizes and packaging material | 1L adjustable trigger spray high density polyethylene ('HDPE') bottle sealed with a polyethylene outer bag.  |

#### 4.1.1. Use-specific instructions for use

Spray the product onto a cleanroom wipe inside the isolator or RABS and use to apply the product to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 ml product/m<sup>2</sup>. Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

#### 4.1.2. Use-specific risk mitigation measures

Avoid hand to eye contact.

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

See section General directions for use.

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

See section General directions for use.

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

See section General directions for use.

## 4.2. Use description

**Table 2. Use # 2 – Use #2 - Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the inner surface of isolators and RABS**

|  |  |
|--|--|
| Product type   | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)   |
| Where relevant, an exact description of the authorised use | /  |
| Target organism(s) (including development stage)           | <p>Scientific name: /<br/> Common name: Bacteria<br/> Development stage: /</p> <p>Scientific name: /<br/> Common name: Yeasts<br/> Development stage: /</p> <p>Scientific name: /<br/> Common name: Fungi<br/> Development stage: /</p>  |
| Field(s) of use  | <p>Indoor</p> <p>In isolators and RABS positioned in cleanrooms: disinfection of hard/non-porous surfaces.</p> <p>Not for use in healthcare.</p>   |
| Application method(s)                                      | <p>Method: Pouring the product into a suitable container and then distributing it on the surface with a suitable cleanroom wipe or mop.</p> <p>Detailed description:<br/>/</p>   |
| Application rate(s) and frequency                          | <p>Application Rate: /</p> <p>Dilution (%): No dilution - product is RTU.</p> <p>Number and timing of application:<br/> Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements.</p> |
| Category(ies) of users                                     | Professional   |
| Pack sizes and packaging material                          | 0.5L, 1 L and 5L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.  |

## 4.2.1. Use-specific instructions for use

Pour the product into a suitable container inside the isolator or RABS and use a cleanroom wipe or mop to apply the product to the surface to be disinfected. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 ml product/m<sup>2</sup>. Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

4.2.2. *Use-specific risk mitigation measures*

Avoid hand to eye contact.

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

See section General directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section General directions for use.

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

See section General directions for use.

4.3. **Use description**

**Table 3. Use # 3 – Use #3 - Application by trigger spray onto a suitable cleanroom wipe to distribute onto the surface of cleanrooms**

|  |   |
|--|---|
| Product type   | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)  |
| Where relevant, an exact description of the authorised use | /   |
| Target organism(s) (including development stage)           | Scientific name: /<br>Common name: Bacteria<br>Development stage: /<br>Scientific name: /<br>Common name: Yeasts<br>Development stage: /<br>Scientific name: /<br>Common name: Fungi<br>Development stage: /  |
| Field(s) of use  | Indoor<br>Disinfection of hard, non-porous surfaces in cleanrooms.<br>Not for use in healthcare.  |
| Application method(s)                                      | Method: Spray the product onto a suitable cleanroom wipe used to distribute the product on the surface.<br>Detailed description:<br>/   |
| Application rate(s) and frequency                          | Application Rate: /<br>Dilution (%): No dilution - product is RTU.<br>Number and timing of application:<br>Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements. |



|                                   |   |
|-----------------------------------|---|
| Category(ies) of users            | Professional  |
| Pack sizes and packaging material | 1L adjustable trigger spray HDPE bottle sealed with a polyethylene outer bag. |

#### 4.3.1. Use-specific instructions for use

Spray the product onto a cleanroom wipe and use to apply the product to the surface to be disinfected in the cleanroom. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 ml product/m<sup>2</sup>. Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

#### 4.3.2. Use-specific risk mitigation measures

The product must only be applied for disinfection of small surfaces.

The use of eye protection during handling of the product is mandatory.

For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory (e.g. room ventilation or Local Exhaust Ventilation ('LEV')). A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.

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

See section General directions for use.

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

See section General directions for use.

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

See section General directions for use.

### 4.4. Use description

**Table 4. Use # 4 – Use #4 - Application by pouring into a container and using a suitable cleanroom wipe or mop to distribute onto the surface of cleanrooms**

|  |   |
|--|---|
| Product type   | PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)  |
| Where relevant, an exact description of the authorised use | /   |
| Target organism(s) (including development stage)           | <p>Scientific name: /<br/>Common name: Bacteria<br/>Development stage: /</p> <p>Scientific name: /<br/>Common name: Yeasts<br/>Development stage: /</p> <p>Scientific name: /<br/>Common name: Fungi<br/>Development stage: /</p> |
| Field(s) of use  | Indoor<br>Disinfection of hard, non-porous surfaces in cleanrooms.<br>Not for use in healthcare.  |

|                                   |   |
|-----------------------------------|---|
| Application method(s)             | Method: Pouring the product into a suitable container and then distributing it on the surface with a suitable cleanroom wipe or mop<br><br>Detailed description:<br>/   |
| Application rate(s) and frequency | Application Rate: /<br><br>Dilution (%): No dilution - product is RTU.<br><br>Number and timing of application:<br>Ready-to-use product active against bacteria in 15 min and against yeasts and fungi in 30 min contact time at room temperature (~ 20 °C). Application frequency is specific to the user's site and requirements. |
| Category(ies) of users            | Professional  |
| Pack sizes and packaging material | 0.5L, 1L and 5L tamper evident cap HDPE bottle sealed with a polyethylene outer bag.  |

#### 4.4.1. Use-specific instructions for use

Pour the product into a suitable container and use a cleanroom wipe or mop to apply the product to the surface to be disinfected in the cleanroom. Ensure the entire surface is visibly wet for the contact time: 15 minutes for bacteria and 30 minutes for yeasts and fungi. Do not use more than 50 ml product/m<sup>2</sup>. Uniform distribution of the biocidal product should be ensured. For visibly soiled surfaces, cleaning prior to the disinfection is required.

#### 4.4.2. Use-specific risk mitigation measures

Pouring of product shall be done in ventilated rooms only (with min. 3 air change/h).

The use of eye protection during handling of the product is mandatory.

For use in cleanrooms, adequate technical/engineering controls to remove airborne residues is mandatory (e.g. room ventilation or LEV. A minimum ventilation rate of 360/hr is mandatory for cleanrooms where the product is applied.

If the product is applied by wiping, the disinfection must be limited to small area.

When using the product with a mop to disinfect floors or other large surfaces in cleanrooms, additional risk mitigation measures must be considered:

- Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory for the professional user and all other personnel within the room. At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) to be specified by the authorisation holder within the product information).
- All personnel must leave the room after mopping.
- Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before professionals are permitted to enter into treated areas after large surface disinfection. Monitor the air concentration and ensure that the limit value (1.25 mg/m<sup>3</sup>) is not exceeded when professionals re-enter the area.

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

See section General directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section General directions for use.

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

See section General directions for use.

## 5. **GENERAL DIRECTIONS FOR USE <sup>(1)</sup> OF THE META SPC 1**

### 5.1. **Instructions for use**

See Use-specific instructions for use.

### 5.2. **Risk mitigation measures**

Used wipes must be disposed in a closed container.

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

#### DIRECT/INDIRECT EFFECTS

Causes serious eye irritation. No other health injuries are known or expected under normal use.

#### FIRST AID INSTRUCTIONS

IF INHALED: If symptoms occur, call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. If symptoms occur, call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

#### EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Avoid release to the environment.

### 5.4. **Instructions for safe disposal of the product and its packaging**

Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

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

Store in a dry well ventilated area and protect from damage and direct sunlight.

Store in properly designed bulk storage tanks or in original vented container.

Keep container tightly closed.

Do not freeze.

Do not store at temperature above 30°C.

The shelf-life: 24 months.

## 6. **OTHER INFORMATION**

Not relevant.

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<sup>(1)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**7.1. **Trade name(s), authorisation number and specific composition of each individual product**

|                      |                          |                  |                 |           |             |
|----------------------|--------------------------|------------------|-----------------|-----------|-------------|
| Trade name(s)        | Contec HydroPure         |                  | Market area: EU |           |             |
|                      | Contec Sterile HydroPure |                  | Market area: EU |           |             |
| Authorisation number | EU-0027735-0001 1-1      |                  |                 |           |             |
| Common name          | IUPAC name               | Function         | CAS number      | EC number | Content (%) |
| Hydrogen peroxide    |                          | Active Substance | 7722-84-1       | 231-765-0 | 6,67        |