

Summary of product characteristics for a biocidal product

Product name: Product

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

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Authorisation number: EU-0027735-0000

R4BP 3 asset reference number: EU-0027735-0001

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	2
3. Hazard and precautionary statements	2
4. Authorised use(s)	3
5. General directions for use	9
5.1. Instructions for use	9
5.2. Risk mitigation measures	9
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	9
5.4. Instructions for safe disposal of the product and its packaging	10
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	10
6. Other information	10

Administrative information

1.1. Trade names of the product

Contec HydroPure
Contec Sterile HydroPure

1.2. 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 1-1	

R4BP 3 asset reference number

EU-0027735-0001

Date of the authorisation

31/07/2022

Expiry date of the authorisation

30/06/2032

1.3. Manufacturer(s) of the biocidal products

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

1.4. Manufacturer(s) of the active substance(s)

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	Solvay Chemicals International
Address of the manufacturer	Rue Ransbeek 310, 1120 Brussels, Belgium
Location of manufacturing sites	Rue Solvay 39, B-5190 Jemeppe-sur-Sambre, Belgium
	Via Piave 6, Rosignano Solvay, I-57013 Livorno, Italy
	Köthensche Strasse 1-3, D06406 Bernburg, Germany
	Baronet Road, WA4 6HA Warrington, United Kingdom
	Yrjönojentie 2, 45910 Voikkaa, Finland
	Rua Eng. Clement Dumoulin, P-2625-106 Povia de Santa Iria, Portugal

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

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

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Causes serious eye irritation.
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Precautionary statements

Wash hands thoroughly after handling.

Wear eye protection/face protection.

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

If eye irritation persists: Get medical attention.

If eye irritation persists: Get medical advice.

4. Authorised use(s)

4.1 Use description

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 algacides 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: /
Common name: Bacteria
Development stage: /

Scientific name: /
Common name: Yeasts
Development stage: /

Scientific name: /
Common name: Fungi
Development stage: /

Field(s) of use

Indoor

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.
Detailed description:
/

Application rate(s) and frequencies

Application Rate: /
Dilution (%): No dilution - product is ready to use ('RTU')
Number and timing of application:
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

Pack sizes and packaging material

Professional

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/m². 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

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 algacides 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: /
Common name: Bacteria
Development stage: /

Scientific name: /
Common name: Yeasts
Development stage: /

Scientific name: /
Common name: Fungi
Development stage: /

Field(s) of use

Indoor

In isolators and RABS positioned in cleanrooms: disinfection of hard/non-porous surfaces.
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.
Detailed description:
/

Application rate(s) and frequencies

Application Rate: /
Dilution (%): No dilution - product is RTU.
Number and timing of application:
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, 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/m². 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

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: /
Common name: Bacteria
Development stage: /

Scientific name: /
Common name: Yeasts
Development stage: /

Scientific name: /
Common name: Fungi
Development stage: /

Field(s) of use

Indoor

Disinfection of hard, non-porous surfaces in cleanrooms.
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.

Detailed description:
/

Application rate(s) and frequencies

Application Rate: /
Dilution (%): No dilution - product is RTU.
Number and timing of application:
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/m². 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

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 algacides 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: / Common name: Bacteria Development stage: /</p> <p>Scientific name: / Common name: Yeasts Development stage: /</p> <p>Scientific name: / Common name: Fungi Development stage: /</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of hard, non-porous surfaces in cleanrooms. 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 Detailed description: /</p>
Application rate(s) and frequencies	<p>Application Rate: / Dilution (%): No dilution - product is RTU. Number and timing of application: 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, 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/m². 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/m³) 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

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.