

Summary of product characteristics for a biocidal product

Product name: Hydrogen Peroxide Solution

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

Authorisation number: FR-2019-0090

R4BP 3 asset reference number: FR-0016933-0000

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Administrative information

1.1. Trade names of the product

Hydrogen Peroxide Solution

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Advanced Sterilization Products, a division of Cilag GmbH International
	Address	Gubelstrasse 34 6300 Zug Switzerland
Authorisation number	FR-2019-0090	
R4BP 3 asset reference number	FR-0016933-0000	
Date of the authorisation	19/07/2019	
Expiry date of the authorisation	18/07/2029	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Advanced Sterilization Products (ASP), Division of Cilag GmbH International
Address of the manufacturer	Gubelstrasse 34 CH-6300 Zug Zurich Switzerland
Location of manufacturing sites	33 Technology Drive, Irvine CA 92618 California United States

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

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	PeroxyChem Spain, S.L.U
Address of the manufacturer	C/Afuera s/no, La Zaida 5078 Zaragoza Spain
Location of manufacturing sites	PeroxyChem Bayport Plant - 12000 Bay Area Blvd, TX 77507 Pasadena United States

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	59,8

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	<p>May intensify fire; oxidiser</p> <p>Harmful if swallowed.</p> <p>Fatal if inhaled.</p> <p>Causes severe skin burns and eye damage.</p> <p>Harmful to aquatic life with long lasting effects.</p> <p>Corrosive to the respiratory tract.</p>
Precautionary statements	<p>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.</p> <p>Keep away from clothing and other combustible materials.</p>

Do not breathe vapours.

Wash ... thoroughly after handling.

Do no eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Wear protective gloves.

[In case of inadequate ventilation] wear respiratory protection.

IF SWALLOWED:Call a POISON CENTER/doctor if you feel unwell.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

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

Immediately call a POISON CENTER/doctor/....

Specific treatment is urgent (see ... on this label).

Specific treatment (see ... on this label).

Rinse mouth.

Wash contaminated clothing before reuse.

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

Store locked up.

Dispose of contents to in accordance with local/regional/national/international regulation.

In case of fire:Use ... to extinguish.

4. Authorised use(s)

4.1 Use description

Use 1 - Professional user only in STERRAD® 200 GMP Systems

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

The hydrogen peroxide solution will be used within the Sterrad® 200 GMP System for the disinfection of instruments and materials in manufacturing and other industrial sectors.

Target organism(s) (including development stage)

Scientific name: - other
Common name: Bacteria
Development stage: -

Scientific name: - other
Common name: bacterial spores
Development stage: -

Scientific name: - other
Common name: Viruses
Development stage: -

Scientific name: - other
Common name: Fungi/yeasts
Development stage: -

Field(s) of use

Indoor

Indoor

Application method(s)

Closed system -

Closed System

To be applied only with the STERRAD® 200 GMP system.

Application rate(s) and frequencies

Injection volume per injection stage: 5 mL of product HYDROGEN PEROXIDE SOLUTION - Chamber concentration: 13.47 mg H₂O₂ /L. -

Injection volume per injection stage: 5 mL of product HYDROGEN PEROXIDE SOLUTION

Chamber concentration: 13.47 mg H₂O₂ /L.

A disinfection cycle will have a minimum of 2 injection stages.

The minimum volume of hydrogen peroxide used per cycle is 10 mL.

Category(ies) of users

Professional

Pack sizes and packaging material

Bottle volume/material: 500 mL HDPE

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

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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

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

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

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5. General directions for use

5.1. Instructions for use

- Always read the label or leaflet before use and follow all the instructions provided.
- Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.)
- Clean and dry carefully all items before placing them in the STERRAD 200 GMP system.
- Some materials and instruments are not compatible with hydrogen peroxide disinfection. Please refer to the STERRAD system Operator's Manual for more information.
- Inform the registration holder if the treatment is ineffective

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), during product handling phase.
 - The user has to handle a hydrogen peroxide gas detector. If the threshold of 1.25 mg / m³ is exceeded, the room has to be evacuated
- Use only in a well-ventilated area
- In case of inadequate ventilation, wear respiratory protection
- It is recommended to open packaging over a sink to ensure safety.
 - Before opening the outer packaging, check the product packaging for excessive damage during shipping. Check the tilt indicator on the side of the pail. Presence of blue beads inside the arrow indicates that the pail may have been mishandled or tipped. In either case, the inner contents may still be usable. Exercise caution when opening pail. Remove the cable tie that secures the cover to the pail.
 - To remove the cover, push back the top of the red lever with thumb while turning the cover counterclockwise. Carefully remove each bagged bottle from the pail and inspect to determine if any hydrogen peroxide has spilled into the yellow absorbent material.
 - Remove the cable tie wrapped around the outer bag. Keeping the package in an upright orientation, carefully remove the bottle and absorbent material from the bags. Remove the bottle from the absorbent material and inspect for any damage.
 - Remove the red protective cap from the bottle and inspect the white membrane inside the cap for damage.
- Note: The membrane is meant to vent vapour. Some condensation may be present but does not constitute a defect.
- The white bottle cap is not intended to be removed. If contents are not damaged, replace the red protective cap and store the bottle in the original packaging if not for immediate use. If inner contents have spilled, refer to instructions for disposal and call local ASP Representative.
- Use only in the STERRAD System without tubes or pipes connecting to sewage systems.

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

- 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.
 - Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist 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 warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
 - Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
 - Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

- Protect from frost.
- Do not store at temperature above 30°C.
- Shelf life: 1 year

6. Other information

- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA)
- the use for the disinfection of instruments and materials which is covered by the medical devices Regulation is not concerned by this authorisation