

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Meta SPC 1 product

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

Authorisation number: NL-0032412-0000 1-1

R4BP asset number: NL-0032412-0001

<i>R4BP asset number</i>	NL-0032412-0001
Date of the authorisation	08/05/2024
Expiry date of the authorisation	08/05/2034

1.3. Manufacturer(s) of the product

Name of manufacturer	STERIS Corporation
Address of manufacturer	7501 Page Avenue MO 63133 St. Louis United States (the)
Location of manufacturing sites	STERIS Corporation site 1 Medivators Inc., 14605 28th Avenue North MN55447 Minneapolis United States (the)

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

Active substance	Peracetic acid
Name of manufacturer	PeroxyChem
Address of manufacturer	One Commerce Square, 2005 Market Street, Suite 3200 PA19103 Philadelphia United States (the)
Location of manufacturing sites	PeroxyChem site 1 35 Sawyer Avenue NY 14150 Tonawanda United States (the)

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		active substance	79-21-0	201-186-8	0,08
Hydrogen peroxide	Hydrogen Peroxide	Non-active substance	7722-84-1	231-765-0	1
Glacial Acetic Acid	Acetic acid	Non-active substance	64-19-7	200-580-7	5

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H318: Causes serious eye damage. H412: Harmful to aquatic life with long lasting effects. H290: May be corrosive to metals.
Precautionary statements	P280: Wear eye/face protection. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P234: Keep only in original packaging. P390: Absorb spillage to prevent material damage. P310: Immediately call a POISON CENTER. P310: Immediately call a doctor. P273: Avoid release to the environment. P501: Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.. P501: Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 1 - Disinfectant of small equipment in pharmaceutical manufacturing and clean room environments or areas with air ventilations of ≥ 10 air exchanges per hour - Immersion

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Bacterial spores Development stage: no data
Field(s) of use	indoor use Disinfectant of hard non-porous surfaces, materials and small equipment (stainless steel, plastic items and glass) which are not used for direct contact with food or feeding stuffs. For industrial and institutional use only not for use in healthcare and other areas with similar hygienic requirements (Pharmaceutical manufacturing, clean rooms or areas with air ventilations of ≥ 10 air exchanges per hour).
Application method(s)	Method: open system: immersion Detailed description: The product is ready-to-use.
Application rate(s) and frequency	Application rate: The product can be used daily. Dilution (%): - Number and timing of application: Contact time: 5 min.
Category(ies) of users	professional
Pack sizes and packaging material	HDPE Bottle 850 mL HDPE Bottle 3 .2 L HDPE Bottle 5 L HDPE Drum 189.25 L HDPE Bottle 946 mL The ETO product is sold with a separately packed sprayer with the following characteristics: 28/400 sprayer made of high density polyethylene with a polypropylene dip tube.

4.1.1. Use-specific instructions

Use only on equipment or items with hard, non-porous surfaces. Thoroughly clean and rinse the surfaces of the item before disinfection; remove any obvious debris or organic material from the surface or item to be disinfected.

Application method

Immersion: Fill a small container with the ready-to-use product. Completely immerse the item to be disinfected in the disinfection solution for at least five minutes.

Rinse with purified water (e.g. deionized) or water of drinking water quality. Allow to dry. The bath can only be used once, do not re-use the liquid.

Some materials may be incompatible with the disinfection product. Test material prior to use. Do not allow product to mix with alkaline substances such as bleach (Sodium Hypochlorite) or other oxidizing agents.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. Use description

Table 2. Use # 2 - Disinfectant of hard non-porous surfaces in pharmaceutical manufacturing and clean room environments or areas with air ventilations of ≥ 10 air exchanges per hour - Wiping, Trigger spraying and Mopping

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data

	<p>Scientific name: no data Common name: Tuberculosis bacilli Development stage: no data</p> <p>Scientific name: no data Common name: Bacterial spores Development stage: no data</p>
Field(s) of use	<p>indoor use</p> <p>Disinfectant of hard non-porous surfaces, materials and equipment (stainless steel, plastic items and glass) which are not used for direct contact with food or feeding stuffs. For industrial and institutional use only. (Pharmaceutical manufacturing, clean rooms or areas with air ventilations of ≥ 10 air exchanges per hour).</p>
Application method(s)	<p>Method: Wiping, trigger spraying and mopping</p> <p>Detailed description: The product is ready-to-use.</p>
Application rate(s) and frequency	<p>Application rate: The application rate is 50 ml/m².</p> <p>Dilution (%): -</p> <p>Number and timing of application: The product can be used daily. Contact time: 5 min.</p>
Category(ies) of users	professional
Pack sizes and packaging material	<p>HDPE Bottle 850 mL HDPE Bottle 3.2 L HDPE Bottle 5 L HDPE Drum 189.25 L HDPE Bottle 946 mL</p> <p>The ETO product is sold with a separately packed sprayer with the following characteristics: 28/400 sprayer made of high density polyethylene with a polypropylene dip tube.</p>

4.2.1. Use-specific instructions

Use only on hard, non-porous surfaces. Thoroughly clean and rinse the surface before disinfection; remove any obvious debris or organic material from the surface to be disinfected. Remove excess water from the surface before disinfection, if appropriate.

Application method:

Spraying: Pour the ready-to-use product into the reservoir of a trigger spray (3.2 L and 5 L pack sizes). Make sure to wet the surface completely by spraying the product onto the surface to be disinfected.

Wiping: Pour the ready-to-use product onto the surface and then wipe the surface to equally distribute the product on the surface to be disinfected. Make sure that the surface is completely wet after the wiping step.

Mopping: Soak the mop with the ready-to-use product until completely soaked and mop the surface to be disinfected. Make sure that the surface is completely wet after the mopping step.

Allow to take effect for at least five minutes. Let air dry or rinse with purified water (e.g. deionized) or water of drinking water quality.

Some materials may be incompatible with the disinfection product. Test material prior to use. Do not allow product to mix with alkaline substances such as bleach (Sodium Hypochlorite) or other oxidizing agents.

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See 'Use-specific instructions for use'.

5.2. Risk mitigation measures

Appropriate engineering controls: Emergency eye wash and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation.

Personal protective equipment: Avoid all unnecessary exposures. Personal protective equipment should be selected based upon the conditions under which this product is handled or used. The minimum requirements for personal protective equipment are;

The use of eye protection when pouring, applying the product by trigger sprayer or using an immersion bath is mandatory.

For application by wiping:

Avoid contact with eyes.

Wash hands thoroughly after handling.

Respiratory protection: Work in areas with ventilations of ≥ 10 air exchanges per hour.

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

Particulars of likely direct or indirect effects:

Symptoms/injuries: Causes serious eye damage.

Symptom/injuries after inhalation: May cause minor irritation to the respiratory tract and to other mucous membranes. The following symptoms may occur: runny nose, sore throat, coughing, sneezing.

Symptoms/injuries after skin contact: Effects of skin contact may include: irritation and burning feeling

Symptoms/injuries after eye contact: Causes serious eye damage. Direct contact may cause severe irritation, pain and burns, possibly severe, and permanent damage including blindness.

Symptoms/injuries after ingestion: May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract. May cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Bleeding of the gastrointestinal tract.

First aid instructions:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a Doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals ($\text{pH} > 11$), amines and acids like acetic acid, formic acid or propionic acid

Emergency measures to protect the environment:

Avoid direct release of product to the environment.

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

Biocide Disposal: Wastes resulting from the use of this product may be disposed of on-site in a sanitary sewer or at an approved waste disposal facility. Biocide wastes are acutely hazardous. Disposal of unused product should be done in accordance with local regulations.

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

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

Meta SPC 1:

Do not contaminate water, food or feed by storage or disposal.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

Do not expose to direct sunlight. Protect from frost. Avoid contact with combustible materials. Store in original closed container. Store at temperatures not exceeding 40°C. Shelf-life 2 years.

6. OTHER INFORMATION

When using, do not eat, drink or smoke.