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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Meta SPC 2 product

Product type(s)

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

Authorisation number: NL-0032412-0000 1-2

R4BP asset number: NL-0032412-0002

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes Spor-Klenz Ready-To-Use Sporicide Wipes
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	STERIS Ireland Limited
	Address	IDA Business and Technology Park Tullamore R35 X865 County Offaly Ireland
Authorisation number	NL-0032412-0000 1-2	
<i>R4BP asset number</i>	NL-0032412-0002	
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

XX - RTU Wipes

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. P310: Immediately call a POISON CENTER or doctor/physician. P234: Keep only in original packaging. P390: Absorb spillage to prevent material damage. P310: Immediately call a POISON CENTER. P310: Immediately call a doctor. 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.. P273: Avoid release to the environment.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use # 3 - 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

Product type	PT02: Disinfectants and algacides 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: Tuberculosis bacilli 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 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).
Application method(s)	Method: Wiping Detailed description: The product is ready-to-use.
Application rate(s) and frequency	Application rate: The application rate is 4 wipes (wipe size 22.9x22.9 cm) per m ² . Dilution (%): - Number and timing of application: The product can be used daily. Contact time: 5 min.
Category(ies) of users	professional
Pack sizes and packaging material	15 clean room wipes per package-48 packages per cardboard case. The wipes are made of 100% polyester interlock Knit. Inner pouch is made of CPA20 (nylon)/PE/PE/PE (coextruded peel-able). The outer pouch is composed of Polyester/

Polyethylene Film. The peel and reseal label is formed by Polyolefin.

4.1.1. Use-specific instructions

Use only on hard, non-porous surfaces. Thoroughly clean and rinse surfaces 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:

Saturation of the dry wipes contained in the package is required at point of use.

Wiping:

- 1) Ensure package opening is facing up. Use two hands to roll one end of the pouch and apply pressure until you feel the inner packet release the disinfectant solution.
- 2) Invert pouch until wipes are fully saturated.
- 3) Using the resealable cover, remove wipes. Reseal once desired number of wipes have been removed.
- 4) Use 4 wipes per m² to thoroughly wet the surface. Make sure to only use wet wipes and cover the surface completely. Allow to take effect for at least 5 minutes.
- 5) Let air dry or rinse with purified water (e.g. deionized) or water of drinking water quality.
- 6) Any unused wipes must be discarded one day after saturation.

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.

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;

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.

When using, do not eat, drink or smoke.

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 2:

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.