

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

STERI-PEROX® 6% WIPE

Product type(s)

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

Authorisation number: 1-1

R4BP asset number: EU-0031643-0001

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	STERI-PEROX® 6% WIPE
---------------	----------------------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Veltek Associates Inc. Europe
	Address	Rozengaard 1940 8212DT Lelystad Netherlands
Authorisation number	1-1	
<i>R4BP asset number</i>	EU-0031643-0001	
Date of the authorisation	10/07/2024	
Expiry date of the authorisation	30/06/2034	

1.3. Manufacturer(s) of the product

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

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US))
Address of manufacturer	One Commerce Square 2005 Market Street Suite 3200 PA 19103 Philadelphia United States (the)
Location of manufacturing sites	Evonik Operations GmbH (Acting for Evonik Active Oxygens, LLC (US)) site 1 PeroxyChem Bayport Plant, 12000 Bay Area Blvd TX 77507 Pasadena 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 (%)
Hydrogen peroxide		active substance	7722-84-1	231-765-0	6,4

2.2. Type(s) of formulation

Ready to Use Wipe

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H319: Causes serious eye irritation.
Precautionary statements	P264: Wash face and hands thoroughly after handling. P280: Wear eye protection/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. P337+P313: If eye irritation persists: Get medical advice.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. 1.1 – Industrial use – Wipe - Indoors - Meta SPC 1

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: Yeasts Development stage: no data
Field(s) of use	indoor use Disinfectant of hard non-porous inanimate surfaces, materials and equipment which are not used for direct contact with food or feeding stuffs. Not for use in medical areas. Disinfectant for use in manufacturing facilities including the clean room areas found in the pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities.
Application method(s)	Method: Wiping Detailed description: -
Application rate(s) and frequency	Application rate: 30,5 cm x 30,5 cm wipe – 32,5 ml per wipe. 7,5 ml is freely available per wipe. 1 wipe = 7,5 ml per m ² Dilution (%): The product is ready to use. Number and timing of application: Frequency: 3 applications per day. Contact time: 10 minutes Use temperature: room temperature
Category(ies) of users	industrial
Pack sizes and packaging material	Wipe is composed of 100% continuous filament polyester fibre. Pack sizes are detailed below: Sterile (gamma irradiated) or non-sterile Wipes: 12 x 12 inches (30,5 cm x 30,5 cm). 20 wipes per pack. 10 packs per case. Reclosable (peel and seal) low density polyethylene (opaque) bags. 12 x 12 inches (30,5 cm x 30,5 cm). Individual wipe. 100 packs per case. Low density polyethylene (opaque) bags.

4.1.1. Use-specific instructions

See general directions for use

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

Apply away from eyes and face. Pre-clean surface before application.

Only use wet wipes. Remove one or two wipes at a time. Wipe article thoroughly to ensure it is visibly wet.

Allow surface to remain wet for 10 minutes (bactericidal and yeasticidal uses). Discard wipe after use. Close the package after opening.

5.2. Risk mitigation measures

During application only the user of the product can be present in the room.

During application and for re-entry, the airborne hydrogen peroxide levels may not exceed the AEC inhalation limit of 1.25 mg/m³ (or a lower relevant national reference value). A calibrated sensor shall be used to establish that the airborne hydrogen peroxide levels are not exceeded.

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

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.

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

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

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

Waste disposal recommendation: Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials: Avoid release to the environment.

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Reseal package between uses to retain moisture.

Store in original container. Protect from frost. Do not store at temperatures high than 40°C.

Shelf-life = 2 years

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

6. OTHER INFORMATION