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)

Authorisation number: IE/BPA 70686

R4BP 3 asset reference number: IE-0020894-0002

Table Of Contents

Administrative information

1.1. Trade names of the product

Vaprox® 59 Hydrogen Peroxide Sterilant

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	IE/BPA 70686 1-2	

R4BP 3 asset reference number	IE-0020894-0002
Date of the authorisation	08/07/2019
Expiry date of the authorisation	14/04/2029

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	STERIS Corporation
Address of the manufacturer	6100 Heisley Road OH 44060 Mentor United States
Location of manufacturing sites	6100 Heisley Road OH 44060 Mentor 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/Afueras, s/n, La Zida 50784 Zararagoza Spain
Location of manufacturing sites	c/Afueras, s/n, La Zida 50784 Zarragoza Spain

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

2.2. Type of formulation

Ready to use (RTU) aqueous solution (AL)

3. Hazard and precautionary statements

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

Do not breathe vapours.

Avoid release to the environment.

Wear protective gloves.

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.

Wash contaminated clothing before reuse.

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

Dispose of contents to Comply with applicable local, national and international regulation.

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

Store locked up.

Wear protective clothing.

Wear eye protection.

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

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

Immediately call a POISON CENTER/doctor/….

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 - Disinfection of surfaces in industrial, commerical and institutional settings by vaporisation

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	Intentionally kept blank.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: All Scientific name: Fungi Common name: Fungi Development stage: All Scientific name: Bacterial spores Common name: Bacterial spores Development stage: All Scientific name: Viruses Common name: Viruses Development stage: All

	Scientific name: Yeast Common name: Yeast Development stage: All
Field(s) of use	Indoor Indoors Used for the disinfection of non-porous surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs, within sealed pre-cleaned enclosures in industrial, commercial and institutional settings.
Application method(s)	Vaporisation. All methods of application use a VHP machine to deliver hydrogen peroxide. - Disinfection by a Vaporized Hydrogen Peroxide (VHP) Unit. Vaporisation, applied using the VHP unit, using a machine to deliver hydrogen peroxide within sealed enclosures. Application to sealed, dry precleaned enclosures. When the target concentration of 300 ppm airborne H2O2 is achieved (sensors will be placed throughout the area in order to monitor the concentration of H2O2), initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores, viruses) or for 6 hours (against yeast and fungi). Number and timing of applications: Only one application is required, but the concentration must be maintained at 300 ppm for a certain period of time (for 3 hours against bacteria, bacterial spores, viruses and or for 6 hours against yeast and fungi).
Application rate(s) and frequencies	Only one application is required, but the concentration must be maintained at 300 ppm. - 0 % - Number and timing of applications: Only one application is required, but the concentration must be maintained at 300 ppm (v/v) for a certain period of time (for 3 hours against bacteria, bacterial spores and viruses or for 6 hours against yeast and fungi).
Category(ies) of users	Trained professional
Pack sizes and packaging material	HDPE Cartridge – for Vaprox® 59 Hydrogen Peroxide Sterilant (6 x 950 mL) HDPE Pail - for Vaprox® 59 Hydrogen Peroxide Sterilant (18.9 L) Polypropylene copolymer Plastic Cup - for Vaprox® 59 Hydrogen Peroxide Sterilant (3x113 mL (15 cycles)) Polypropylene copolymer Plastic Cup - for Vaprox® 59 Hydrogen Peroxide Sterilant (4 x 29 mL (4 cycles) Polypropylene copolymer Plastic Cup - for Vaprox® 59 Hydrogen Peroxide Sterilant (2 x 70 mL (1 cycle/cartridge)

4.1.1 Use-specific instructions for use

Prepare the treatment enclosure as described under 4.1.2
Directions for Use

For application to sealed, dry precleaned enclosures at 300 ppm H_2O_2 for 3 hours (against bacteria, bacterial spores and viruses and or for 6 hours (against yeast and fungi).

Use undiluted product.

Secure that the produced aerosol of hydrogen peroxide do not enter the ventilation system of the enclosure throughout the treatment.

Place the hydrogen peroxide monitor in a location within the treatment enclosure which is most difficult for the vapor target concentration to reach. This is typically in a corner of the enclosure farthest away from the VHP generation unit. All drawers, closets & cabinet doors, etc. must be opened to permit exposure to hydrogen peroxide. Place chemical indicators throughout the enclosure to verify effective distribution of hydrogen peroxide. Place oscillating fans throughout the enclosure to facilitate effective distribution of the hydrogen peroxide.

Program the VHP Generator to initiate a DEHUMIDIFICATION phase to achieve 70% relative humidity. Ensure the ambient temperature is not less than 21˚ C or 70˚F initially and throughout the process. Once the DEHUMIDIFICATION phase is complete initiate a CONDITIONING phase to achieve a 300 ppm (v/v) hydrogen peroxide concentration in the sealed enclosure. When a 300 ppm (v/v) hydrogen peroxide concentration is achieved initiate the application phase and maintain this concentration for 3 hours (against bacteria, bacterial spores and viruses or for 6 hours (against yeast and fungi).

For room enclosures greater than 150 m3 it may be necessary to utilise multiple VHP units to achieve the target concentration

During the APPLICATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to ensure hydrogen peroxide levels do not exceed health and safety limits. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the APPLICATION phase, begin the AERATION phase to reduce the levels of hydrogen peroxide at or below the appropriate health and safety limits for hydrogen peroxide (1.25 mg/m3).

The disinfection process shall be biologically validated in a suitable "standard room" with the device to be used, after which a protocol for disinfection of similar rooms can be made and followed. The biological validation demonstrates which dosing and parameters for vaporisation (temperature, humidity, concentration in the air, and contact time during each phase: preparation, conditioning, disinfection, and terminal phase) should be used for optimal disinfection of the room in question, i.e. sufficient killing of organisms on all surfaces in the room. Biological validation is performed by monitoring efficacy against a challenging test organism (e.g. Geobacillus stearothermophilus spores) during the room disinfection process. Indicator strips are placed at places that are difficult to reach. After the disinfection the strips can be processed to verify the effectiveness of the process.

Detailed description of the equipment and its characteristics

Equipment name and model:
STERIS VHP Generator; models M1000-T4, M100, M100X, 1000ED, X10, M10, VICTORY

The STERIS VHP System uses an open/closed loop process utilising conditioned air as a carrier to deliver Vaprox® hydrogen peroxide Sterilant vapor to the exposed surfaces inside a pre-cleaned, dry, sealed Enclosure. This process allows the application process to take place at, or near, atmospheric pressure. The H_2O_2 vapor concentration depends on the temperature and humidity of the sealed Enclosure. Because application relies only on the contact of hydrogen peroxide with exposed surfaces, the transfer of heat and moisture required by steam processes is not necessary. Existing labeling for Vaprox clearly outlines that only STERIS VHP application equipment can be used with the product.

- diffusion principles (e.g. fogging, vapour, fumigation) and particles size distribution of aerosols or powder; Diffusion principle is vapour (vaporization of liquid to vapor and distributed using air movement). Particle size distribution is less than 1 micron.

- description of the diffusion performance of the equipment (e.g. volume to disinfect, diffusion speed); Liquid is flash vaporised in a vaporisation vessel and mixed and transported with incoming clean/dry air. Diffusion is accomplished with air velocity changes and additional air moving equipment to aid in complete diffusion and maintains a constant concentration during the decontamination cycle phase

- description of the ambient conditions (e.g. humidity, temperature) in which the process can be used; 70% or less on Relative humidity. Ensure temperature is not less than 21°C or 70°F initially and throughout the process.

- diffusion time for a specific volume; Diffusion times will vary based on the size or volume of the enclosed area to be treated. The diffusion time to reach the defined hydrogen peroxide vapour concentration is tied to the conditioning phase of the process cycle. As a result, only the conditioning phase will be variable. The defined contact time for the application or decontamination phase for hydrogen peroxide as defined in labelling will not change.

- precautions for over and under-dosing. Dosing is controlled by two variables; time and injection rate of the liquid into the

vaporiser. Instruments within the injection system provide feedback of the performance of the system and automatically control changes within the system to keep dosing at the predetermined concentration. If an error occurs in the system or the process and dosing goes out of range the unit will have an aborting alarm which will immediately go into the aeration phase and breakdown the present peroxide to safe levels for human occupancy. At this point the cycle must be restarted from the beginning. The cycle must successfully complete all 4 phases consecutively for the cycle to complete.

4.1.2 Use-specific risk mitigation measures

Preparation of Enclosures:
1. Cleaning:
All the surfaces in the treatment area must be clean and dry prior to Vaprox application.
2. VHP Application Equipment:
Position or connect the VHP application equipment for optimum vapour distribution into the treatment enclosure. See Equipment User's Manual for proper equipment preparation and set-up.
3. Sealing:
Seal the treatment enclosure adequately to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable health and safety levels
4. Securing the Enclosure:
Ensure all personnel have vacated the treatment enclosure prior to Vaprox application. Remove all plants, animals, beverages and food. Applicators must not re-enter the treated enclosure until exposure levels of hydrogen peroxide are at/or below required health and safety limits. In case of emergency when the hydrogen peroxide concentration is still above 1.25 mg/m3 entering in the room is only allowed by wearing appropriate PPE including SCBA (Self Contained Breathing Apparatus).
5. Placarding of Treatment Enclosure
The applicator must placard or post all entrances to the treatment enclosure with signs bearing:
1. The signal word "DANGER" in red. "Area under treatment, "DO NOT ENTER/NO ENTRY."
2. The statement "This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1.25 mg/m3".
3. Identification of hydrogen peroxide as a hazard associated with the treatment process.
4. Contact information for the applicator.

During the APPLICATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to ensure hydrogen peroxide levels do not exceed health and safety limits. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed.

Wear protective chemical resistant gloves, a protective coverall and eye protection during product handling phase (glove material to be specified by the authorisation holder within the product information). Suitable respiratory mask should be worn as specified by the authorisation holder within the product information.

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

First-aid measures general:
Never give anything by mouth to an unconscious person. In all cases of doubt, or when symptoms persist, seek medical attention. If medical advice is need, have product container or label at hand.

First-aid measures after inhalation:
Remove to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Immediately get medical attention.

First-aid measures after skin contact:
Remove contaminated clothing immediately. Immediately flush skin with plenty of water for at least 15 minutes. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

First-aid measures after eye contact:
In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Immediately get medical attention.. Remove contact lenses, if present and easy to do. Continue rinsing..

First-aid measures after ingestion:
Give water if the person is fully conscious. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.
Medical professionals should contact The National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166), for further advice. Environmental precautions and accidental release measures:
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

Methods for cleaning up:
Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Do not absorb in sawdust, paper, cloth or other combustible absorbents. Comply with applicable local, national and international regulation. Collect spillage. Store away from other materials.

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

Waste disposal recommendations:
Do not re-use empty containers. Containers remain hazardous when empty.
Consult the appropriate authorities about waste disposal. Dispose in a safe manner in accordance with local/national regulations.

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

Storage conditions:
Keep only in the original container in a cool, dry, well-ventilated place.
Keep container tightly closed.
Shelf-life – 24-months.

Prohibitions on mixed storage:
Do not store near reducing or oxidizing agents.
Keep away from clothing and other combustible materials.

5. General directions for use

5.1. Instructions for use

See Authorised uses.

5.2. Risk mitigation measures

General measures:
Ensure adequate ventilation. Do not breathe fumes, vapors. Avoid contact with skin, eyes and clothes. Stop leak if safe to do so.

Protective equipment:
Wear protective gloves and eye/face protection. Exposure-controls/personal protection.
A protective coverall (at least type 6, EN 13034) shall be worn.

Emergency procedures:
Stop leak if safe to do so. Evacuate unnecessary personnel.

Environmental precautions:
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

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

See Authorised uses.

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

See Authorised uses.

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

See Authorised uses.

6. Other information

The active substance contains a number of stabilisers (Confidential to the active substance manufacturer) to prevent the active substance breaking down when it is stored. An ED assessment has been carried out on the stabilisers (Confidential PAR). Post authorisation requirement has been set – see Confidential PAR for further details.