

Summary of product characteristics for a biocidal product family

Family name: Vaprox biocidal product family

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

Authorisation number: UST201905-105

R4BP 3 asset reference number: IS-0021037-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Vaprox biocidal product family

1.2. Product type(s)

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

1.3. 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

UST201905-105

R4BP 3 asset reference number

IS-0021037-0000

Date of the authorisation

18/07/2019

Expiry date of the authorisation

14/04/2029

1.4. 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

Name of the manufacturer	Cantel Medical (Italy) S.r.l
Address of the manufacturer	Via Laurentina, 169 00071 Pomezia (RM) Italy
Location of manufacturing sites	Via Laurentina, 169 00071 Pomezia (RM) Italy

1.5. 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 Zaida 50784 Zarragoza Spain
Location of manufacturing sites	c/Afueras, s/n, La Zaida 50784 Zarragoza Spain

2. Product family composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	34,8 - 59,4

2.2. Type(s) of formulation

Ready to use (RTU) aqueous solution (AL)
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Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1 - Vaprox 35%

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	34,8 - 35,8

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

Ready to use (RTU) aqueous solution (AL)

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful if swallowed.
Causes skin irritation.
Causes serious eye damage.
May cause respiratory irritation.

Precautionary statements

Harmful to aquatic life with long lasting effects. May intensify fire; oxidiser
Avoid breathing vapours. Avoid release to the environment. Wear eye protection. Wear protective gloves. Wear protective clothing. IF ON SKIN:Wash with plenty of 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. Store in a well-ventilated place.Keep container tightly closed. Dispose of contents to comply with applicable, local, national and international regulation.. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep away from clothing and other combustible materials. Immediately call a POISON CENTER/doctor.

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type

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

Method: Vaporisation. All methods of application use a VHP machine to deliver hydrogen peroxide.
Detailed description:
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

Application Rate: Only one application is required, but the concentration must be maintained at 300 ppm (v/v).
Dilution (%): 0
Number and timing of application:
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® Hydrogen Peroxide Sterilant (6 x 950 mL)
HDPE Pail - for Vaprox® Hydrogen Peroxide Sterilant (18.9 L)
Polyethylene Drum - for Vaprox® Hydrogen Peroxide Sterilant (200.6 L)
Polypropylene copolymer Plastic Cup - for Vaprox® Hydrogen Peroxide Sterilant (8 x 141 mL)

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 H₂O₂ 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 Biodecontamination Systems.

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 H₂O₂ 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 EITRUNARMÍÐSTÖÐ, Landspítala, 101 Reykjavík for further advice (543 2222 or eitur@landspitali.is). 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 incompatible materials.

5. General directions for use of the meta SPC

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.

The hazard and precautionary statements shall be in Icelandic on the product label:

The hazard statements in Icelandic:

- H302 Hættulegt við inntöku.
- H315 Veldur húðertingu.
- H318 Veldur alvarlegum augnskaða.
- H335 Getur valdið ertingu í öndunarferum.
- H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.
- H272 Getur aukið bruna, eldmyndandi (oxandi).

The precautionary statements in Icelandic:

- P261 Gætið þess að anda ekki inn gufu.
- P273 Forðist losun út í umhverfi.
- P280 Notið augnhlífur.
- P280 Notið hlífðarhanska.
- P280 Notið hlífðarfatnað.
- P302 + P352 BERIST EFNID Á HÚÐ: Þvoið með miklu vatni.
- P304 + P340 EFTIR INNÖNDUN: Flytjið viðkomandi í ferskt loft og látið hann hvílast í stellingu sem léttir öndun.
- P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.
- P403 + P233 Geymist á vel loftræstum stað. Ílát skal vera vel lukt.
- P501 Fargið innihaldi í samræmi við staðbundnar/landsbundnar/alþjóðlegar reglur.
- P210 Haldið frá hitagjöfum, heitum flötum, neistagjöfum, opnum eldi og öðrum íkveikivöldum. Reykingar bannaðar.
- P220 Efnid má ekki koma nálægt fatnaði og öðrum brennanlegum efnum.
- P310 Hringið umsvifalaust í EITRUNARMÍÐSTÖÐ / lækni (s. 543 2222 / 112)

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7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Vaprox® Hydrogen Peroxide Sterilant	Market area: IS
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IS-0021037-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	35

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2 - Vaprox 59%

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

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

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	58,4 - 59,4

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

Ready to use (RTU) aqueous solution (AL)

3. Hazard and precautionary statements of the meta SPC

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 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..

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 eye protection.

Wear protective clothing.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Disinfection of surfaces in industrial, commercial and institutional settings by vapourisation

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

Application method(s)

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.

Method: Vaporisation. All methods of application use a VHP machine to deliver hydrogen peroxide.
Detailed description:
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

Application Rate: Only one application is required, but the concentration must be maintained at 300 ppm.
Dilution (%): 0
Number and timing of application:
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 H₂O₂ 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 Biodecontamination Systems.

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 H₂O₂ 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 EITRUNARMÍÐSTÖÐ, Landspítala, 101 Reykjavík for further advice (543 2222 or eitur@landspitali.is). 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 of the meta SPC

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.

The hazard and precautionary statements shall be in Icelandic on the product label:

The hazard statements in Icelandic:

H302 Hættulegt við inntöku.

H314 Veldur alvarlegum bruna á húð og augnskaða.

H332 Hættulegt við innöndun.

H335 Getur valdið ertingu í öndunarfærum.

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

H272 Getur aukið bruna, eldmyndandi (oxandi).

The precautionary statements in Icelandic:

P260 Andið ekki að ykkur gufu.

P273 Forðist losun út í umhverfi.

P280 Notið augnhlífur.

P280 Notið hlífðarhanska.

P280 Notið hlífðarfatnað.

P304 + P340 EFTIR INNÖNDUN: Flytjið viðkomandi í ferskt loft og látið hann hvílast í stellingu sem léttir öndun.

P305 + P351 + P338 BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægjið snertilinsur ef það er auðvelt. Skolið áfram.

P403 + P233 Geymist á vel loftræstum stað. Ílát skal vera vel lukt.

P501 Fargið innihaldi í samræmi við staðbundnar/landsbundnar/alþjóðlegar reglur.

P210 Haldið frá hitagjöfum, heitum flötum, neistagjöfum, opnum eldi og öðrum íkveikivöldum. Reykingar bannaðar.

P220 Efnið má ekki koma nálægt fatnaði og öðrum brennanlegum efnum.

P310 Hringið umsvifalaust í EITRUNARMÍÐSTÖÐ / lækni (s. 543 2222 / 112)

P363 Þvoið fót, sem óhreinast af efninu, fyrir næstu notkun.

P321 Sérstök meðferð (sjá á þessum merkimiða).

P405 Geymist á læstum stað.

P303 + P361 + P353 BERIST EFNIÐ A HUÐ (eða í hár): Farið strax úr fötum sem óhreinkast af efninu. Skolið húðina með vatni.
P301 + P330 + P331 EFTIR INNTÖKU: Skolið munninn. EKKI framkalla uppköst.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Vaprox® 59 Hydrogen Peroxide Sterilant	Market area: IS
Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small>	IS-0021037-0002 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	59
