Reorder Number: Net Contents: 
PB006US 950mL (32 fl. oz.) (1 qt.)

Active Ingredient:
Hydrogen Peroxide .......................................................... 35%
Inert Ingredients: .............................................................. 65%
Total: ............................................................................. 100%

EPA Reg. No. 58779-4  EPA Est. No. 58779-OH-003

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO
OXIDIZER CORROSIVE

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist.

See back panel for additional precautionary statements.

FIRST AID

If in eyes • Hold eye open and rinse slowly and gently with water for 15-20 minutes.
• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.
• Call a poison control center or doctor for treatment advice.

If swallowed • Call poison control center or doctor immediately for treatment advice.
• Have person sip a glass of water if able to swallow.
• Do not induce vomiting unless told to do so by the poison control center or doctor.
• Do not give anything by mouth to an unconscious person.

If on skin or clothing • Take off contaminated clothing.
• Rinse skin immediately with plenty of water for 15-20 minutes.
• Call a poison control center or doctor for treatment advice.

If inhaled • Move person to fresh air.
• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
• Call a poison control center or doctor for further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse.

Personal Protective Equipment PPE

Applicators and all other handlers must wear: long-sleeved shirt and long pants; socks and chemical resistant footwear; goggles or face shield; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton; a self
contained breathing apparatus if concentrations exceed 1 ppm during handling and/or application of Vaprox Hydrogen Peroxide Sterilant. Do not use oxidizable sorbants such as activated carbon.

**Physical or Chemical Hazards**

Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination, or contact with combustible materials. Clothing, shoes, or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. If allowed to dry in the materials, a fire may result. Discard shoes in a fireproof container.

IN CASE OF FIRE use water only.

CONTAIN SPILLS and dilute with 20 parts of water.

After diluting the spill, sodium metabisulfite or sodium sulfite (1.9 lbs. of SO₂ equivalent per 500 ml of peroxide) may be used to destroy the peroxide.

SEE EQUIPMENT MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.

**Environmental Hazards**

Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency.

**DIRECTIONS FOR USE**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

For use as a microbial sterilant in validated (up to 250,000 ft³) and non-validated (up to 4,000 ft³) applications for sterilization of sealed, dry pre-cleaned enclosures located in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing including clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles). Use only with STERIS VHP® application equipment. This product is for use in STERIS VHP application equipment only, and by trained personnel trained by STERIS Corporation. Read and follow package insert for complete directions on cleaning, sealing and use of Vaprox Hydrogen Peroxide Sterilant in validated and non-validated applications. See Equipment User Manual for operating procedures of the STERIS VHP application equipment. Do not use this product without development of an appropriate fumigation plan (see package insert). Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices. Not for residential use.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, feed by storage or disposal. Store containers upright. Do not freeze. Do not expose to cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials, or flammable vapors. Shade from radiant heat and direct sunlight. Stow away from powdered metals and permanganates.

**PESTICIDE DISPOSAL:** Rinse containers with 20 parts water and then empty into sink with running water. Hydrogen Peroxide is classified as a DOT oxidizer and a hazardous waste under U.S. EPA hazardous waste regulations and it is a violation of federal law to improperly dispose of pesticides.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

Product Made in U.S.A.

STERIS Corporation
5960 Heisley Road □ Mentor, OH 44060 □ U.S.A.
800-548-4873 □ www.steris.com

**LOT NUMBER:**

Not for sale or use after:
1. **VAPROX Application Process**

2. **User Safety Requirements**

3. **Efficacy and Use Applications**

4. **Fumigation Management Plan**

5. **Training and Certification of Applicators**

6. **Preparation of Enclosures**

7. **Application to Sealed Enclosures Requiring Validation of Conditions of Use**

   a. Validation of Alternate Use Conditions
   b. System Characterization
   c. Biological Indicator Selection and Distribution
   d. Process Characterization
   e. Aeration Monitoring and Re-entry
   f. Re-entry Instructions
   g. Releasing Treated Sealed Enclosures for Return to Service

8. **Application to Sealed Enclosures Up to 4,000 ft Not Requiring Validation of Use Conditions**

   a. Application to Sealed, Dry Premade Enclosures at 250 ppm VHP Sterilant Concentration
   b. Application to Sealed, Dry Premade Enclosures at 400 ppm VHP Sterilant Concentration
   c. Aeration Monitoring and Re-entry
   d. Re-entry Instructions

9. **Application to Sealed Enclosures Between 2 ft and 40 ft that require Validation**

10. **For use in Aseptic Food Processing Operations to achieve commercial sterility of food packaging equipment**

**General Information**

Restrictions:

VAPROX® Sterilant has been registered by STERIS in accordance with Federal Regulations for the specific uses described in this package insert. Use other than as specified and described is not permitted and may be ineffective in the sterilization of exposed surfaces in pre-cleaned sealed enclosures.

Review the Vaperox Hydrogen Peroxide (VHP) User’s Equipment Manual for proper instructions on how to operate the JET-100 Sterilizer Generator prior to utilizing the equipment for sterilization. VAPROX Sterilant should be applied only by properly trained and certified personnel who are thoroughly trained in the use and operation of the VHP Generator.

**1. VAPROX Application Process**

Effective application of vaporized hydrogen peroxide requires adequate VHP concentration and exposure time. The VHP Generator is utilized to achieve the concentration and contact time of hydrogen peroxide in the enclosed area. The process parameters are controlled through the use of the control panel on the VHP Generator. See the VHP Generator Instruction Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

The VHP Generator is used as a carrier to deliver hydrogen peroxide vapor to exposed surfaces inside a sealed enclosure. This allows the process to take place at or near ambient atmosphere. Since the VHP process relies only on the contact of the VHP with the exposed surfaces, the transfer of heat and moisture required by steam or chemical processes is not necessary.

The VHP sterilant is continuously injected for the required exposure time to maintain the desired concentration of hydrogen peroxide vapor. Once the VHP sterilant leaves the enclosure, it is typically broken down into water vapor and oxygen.

The VHP process consists of four phases:

- **DEHUMIDIFICATION** – Dry air is circulated in the sealed treatment enclosure to reduce humidity to a predetermined level in the 10-70% relative humidity range. This permits the target VHP concentration to be maintained below condensation levels during the conditioning and sterilization phases. The time to reach the target dehumidification level increases with the volume of the enclosure, and is dependent on environmental conditions.

- **CONDITIONING** – The VHP sterilant is injected into the air stream. The conditioning phase facilitates reaching the desired VHP concentration in the sealed enclosure. Conditioning time is affected by VHP target concentration, injection rate, enclosure materials, environmental conditions, and enclosure volume.

- **STERILIZATION** – The VAPROX Sterilant is continuously injected at a selected rate to maintain the target VHP concentration over a pre-established period of time.

- **AERATION** – The VHP injection is stopped and the flow of dry air continues to reduce the VHP concentration within the enclosure to at or below one ppm level (≤1.0 ppm TWA 8 hr) prior to reentry into the enclosure by trained/applications. Treated enclosures may not be released for general public use until the level of hydrogen peroxide is at or below one ppm in the enclosure.

**2. User Safety Requirements:**

   1. Respirator Requirements – When a respirator is required for use with this product, the trained/applications or supervising the fumigation must make sure that:

      a. Respirators must be fit tested before use and changed to conform with OSHA’s requirements (described in 29 CFR Part 1910.134).

      b. Respirators must be tested in the actual environment using a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134).

      c. Respirator users must be evaluated by a qualified medical practitioner to ensure the physical ability to safely use the respiratory equipment to be used.

   2. Liquid hydrogen peroxide is corrosive and will cause irreversible eye damage or skin burns and may be fatal if inhaled at higher concentrations. It is also harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing, Do not breathe spray mist or vapor. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, or using the toilet. User should wash hands or shower before or after use. Do not handle clothing or absorbent material that has been heavily disinfected or contaminated with liquid hydrogen peroxide.

   3. Follow manufacturer’s instructions for cleaning/monitoring protective eyewear and respirators.

   4. User Safety Recommendation:

      a. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

      b. All users who use or work in the area should remove clothing, PPE immediately if hydrogen peroxide gets inside. Then wash thoroughly and put on the clean clothing.

      c. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As seen as practical, wash thoroughly and change into clean clothing.

**3. Efficacy:**

VAPROX Hydrogen Peroxide is effective as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide under the conditions on the label. VAPROX Hydrogen Peroxide is an INNOVATIVE IN CALIFORNIA FOR EFFICACY ON POROUS SURFACES and non-porous surfaces including floors, walls, furniture, equipment and other items in sealed enclosures in industrial, commercial and institutional settings (including production and pharmaceutical manufacturing, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, cruise ships, recreational facilities and emergency response vehicles) when used with STERIS VHP application equipment.

For 40 ft or smaller enclosures a Sterilization Cycle was developed for the VHP Generator and validated for both 2 ft and 40 ft pre-cleaned, sealed enclosures using an Association of Official Analytical Chemists (AOAC) sporicidal test protocol to validate sterilization when in use at 2.2 ppm of VAPROX Sterilant per minute for 30 minutes (should yield a theoretical value of 360 ppm).

- As a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide at a minimum of 250 ppm of VHP sterilant for 90 minutes in sealed enclosures up to 4,000 ft.

- As a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide at a minimum of 250 ppm of VHP sterilant for 30 minutes in sealed enclosures up to 4,000 ft.

- For larger than 40 ft enclosures as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide when used in a validated application in accordance with use instructions provided in Section 8.

This product is not to be used as a terminal high level disinfectant or sterilant for reprocessing of any medical/semi-critical medical device in a healthcare setting. Not for use in residential applications.

**4. Fumigation Management Plan**

The STERIS Corporation trained/applications are responsible for working with the owners and/or responsible managers of the site to be sterilized to develop a site specific Fumigation Management Plan (FMP) for each site that will be treated with VHP. The aseptic sterility is responsible for all tasks of the fumigation process except otherwise noted in the FMP and must be on site for the entire fumigation process. The FMP must describe characteristics of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

- Inspect the structure and/or area to determine its suitability for fumigation.

- Sampling and reporting: sampling is required for any specific regulations for each change to the structure, seal, leak, and monitor any occupied adjacent rooms and/or buildings to ensure safety.

- Prior to each fumigation, review any existing fumigation, MSDS, equipment Manual and other relevant safety procedures with all personnel and employees.

- Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be and in and around the area during application and fumigation.

- Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during fumigation and fumigation. The plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowed limits.

- Consult with owners and/or responsible managers of the site who will be responsible for the installation of procedures for long-term housing of nearby residents in the event of an emergency.

- Perform the placement of placards to secure entrance into any area under fumigation.

- Confirm the required safety equipment is in place and the necessary manpower, and order all facilities correctly. If the applicator has any questions about the development of an
FMP, contact STERIS Corporation for further assistance. An FMP must be developed for each treated area. In the event of an emergency application, a generic FMP which can be updated may be used and updated after fumigation. The STERIS Corporation trained applicator must sign the plan and an indication that it was followed. The signed FMP and related documentation, including monitoring records, must be maintained by the applicator for a minimum of 2 years and a copy provided to the owner of the treated area.

1. GUIDANCE FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN
   A Fumigation Management Plan (FMP) is required to ensure the required steps involved to help ensure a legal and effective fumigation will also assist you and others in complying with pesticide product label requirements. The guidance that follows is designed to help you in anticipating all the necessary factors involved in preparing for and fumigating a structure and/or area. This guidance is intended to help you plan any fumigation that you might perform PRIOR TO ACTUAL TREATMENT. It is meant to be somewhat prescriptive, yet flexible enough to allow the experience and expertise of the fumigator to make changes based on circumstances that may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, an effective fumigation can be performed. Before any fumigation begins, carefully read and review the label and the Equipment Manual. This information must be given to the appropriate company officials (supervisor, foreman, safety officer, etc.) in charge of the structure and/or area. Preparation is the key to any successful fumigation. If the type of fumigation that you are to perform is not listed in this section, contact your local pest management professional for assistance.

2. A CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN
   This checklist is provided to help you take into account factors that must be addressed prior to performing any fumigation. It emphasizes safety steps to protect people and property. The checklist is general in nature and cannot be expected to apply to all types of fumigation situations. It is to be used as a guide to prepare the required plan. Each item must be considered, however, so the method by which each fumigation is different and not all items will be necessary for each fumigation structure and/or area.

A. PLANNING AND PREPARATION
   1. Determine the purpose of the fumigation.
   2. Stabilization of roaches, cockroaches, fleas, and bedbugs.

B. STABILIZATION OF FUMIGATING VEHICLES
   1. Determine the type of fumigation, for example:
      a. Pharmaceutical Operations
      b. Laboratories, animal research facilities
      c. Patient rooms, hospital rooms, offices, recreational facilities
      d. Cruise ship rooms
      e. In addition to the Equipment Manual, read the US Coast Guard Regulations 46CFR 147A

C. EVALUATE THE STRUCTURE OR AREA TO BE FUMIGATED, AND DEVELOP A SITE-SPECIFIC PLAN THAT INCLUDES THE FOLLOWING POINTS, AS APPLICABLE:
   a. The general structure, layout, construction (material, design, age, maintenance, etc.), of the structure, to have or not have hazards, conditions, structures, and excess moisture and/or water, and/or overgrown vegetation and or water, and other unique hazards or structure characteristics, meet with the owner/operator to discuss this information. Determine if there is a drainage system or other drainage structures.
   b. The need for buffer zones in rooms adjacent to the treated enclosure to limit access to only trained applicators. This would include adjacent rooms that could be occupied when using VHP in areas such as hotel rooms, patient rooms or offices. Additional consideration should also be given to adjacent rooms above or below the enclosure if the structure does not consist of solid construction (i.e., floors/walls adjacent to the enclosure) that would preclude exposure if the treated enclosure was not properly sealed.
   c. The number and identification of persons who routinely enter the area to be fumigated (i.e., employees, visitors, contractors, etc.).
   d. Accessibility of utility service connections.
   e. Access to areas above or below the structure or adjacent to the treated enclosure.
   f. Emergency shut-off stations for electricity and gas. Mark the location of these items on the drawings.
   g. Current emergency numbers of local authorities (Fire, Police, Hospital) and respond to emergencies.
   h. Name and phone number of the designated personnel.
   i. Review and prepare the points of fumigation application.
   k. Exposure time considerations:
      a. Fumigant to be used.
      b. Minimum fumigation period, as defined and described by the label use directions.
      c. Down time required to be available.
      d. Avail time considerations.
   l. Determination of dosage:
      a. Cubic footage or other appropriate space/locating calculations.
      b. Structure sealing capability and methods.
      c. Label directions.
      d. Pest history of fumigation of structure.
      e. Exposure time.

B. PERSONNEL
   1. Confirm with writing that all personnel in and around the area to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initials indicating they have been notified.
   2. Instruct all fumigation personnel about the hazards that may be encountered and about the selection of personal protection devices, including detection equipment.
   3. Confirm that all personnel are aware of and know how to proceed in case of an emergency illness.
   4. Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a hospital number for emergency reporting.
   5. Instruct all personnel to report to proper authorities any theft of treated and/or equipment related to fumigation.

C. MONITORING
   1. Perimeter Safety
      a. Monitoring of hydrogen peroxide concentrations must be conducted immediately adjacent to the fumigated space to prevent excessive exposure and to determine where exposure may occur. Document where monitoring will occur.
      b. Keep a log or manual of all readings at each fumigation site. This log must at a minimum contain the time, number of readings taken and level of concentrations found in each location.
      c. When monitoring for leaks, document there is no hydrogen peroxide present above the one ppm level. Subsequent tests monitoring is not required. However, spot checks must be made, especially if conditions significantly change.

D. NOTIFICATION
   1. Confirm that all appropriate local authorities (fire departments, police departments, etc.) have been notified as per label instructions, local ordinances if applicable, or instructions of the customer.
   2. Prepare written procedure ("Emergency Response Plan") which contains explicit instructions, names, and telephone numbers so as to be able to notify local authorities if hydrogen peroxide levels are exceeded in an area that could be dangerous to bystanders and/or domestic animals.
   3. In the event of a breach or leak of the enclosure where levels of hydrogen peroxide are above one ppm adjacent to the area to be fumigated, about the application process and initiate the evacuation process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded one ppm are occupied by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring to determine hydrogen peroxide exposure in the sealed area. The treated area and adjacent areas must remain unoccupied until hydrogen peroxide exposure is below one ppm. Early reentry into the sealed treated enclosure at use concentration levels in the case of an emergency requires utilizing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide respirator, self-contained breathing apparatus, gloves and boots to prevent from inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues.

E. SEALING PROCEDURES
   1. Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials will remain intact until the fumigation is complete. Verify effectiveness of the sealing process by conducting a smoke test to ensure there are no leaks where openings have been sealed in the enclosure.
   2. The structure and/or area has been fumigated before, review the previous FMP for previous sealing information.
   3. Make sure that construction/remodeling has not changed the building in a manner that will affect the fumigation.

F. APPLICATION PROCEDURES & FUMIGATION PERIOD
   1. Plan carefully and apply all fumigants in accordance with the label requirements.
   2. When entering the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.
   3. Apply fumigant from outside the fumigation space.
   4. Provide watchmen when a fumigation site cannot otherwise be made secure from entry by unauthorized persons.
   5. When entering structures always follow OSHA rules for confined spaces.
   6. The applicator should verify compatibility of items surfaces to be treated prior to the application process.

G. TIME APPLICATION OPERATIONS
   1. Provide watchmen when you cannot secure the fumigation site from entry by unauthorized persons during the fumigation or time.
   2. Use a VHP detector before reentry to determine fumigant concentrations.
   3. Keep written records of monitoring to document completion of aeration.
   4. Consider temperature when aeration.
   5. Ensure aeration is complete before moving vehicles into public roads.
   6. Remove warning placards when aeration is complete.
   7. Inform business/owners that employees/other persons may return to work or otherwise be allowed to enter the treated area.

H. CRITERIA FOR SUCCESSFUL FUMIGATION
   1. All VHP fumigation process conditions (concentration, temperature, relative humidity) are achieved through the fumigation cycle.
   2. All fumigants that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.
   3. All Bis that are properly recovered (no beach of asceptic technique) are negative for growth.
   4. Positive control Bis demonstrates growth following incubation.
   5. Negative control Bis exhibit no growth following incubation.
   6. Not applicable to areas not requiring validation

I. TRAINING AND CERTIFICATION OF APPLICATORS
   1. Prior to use, applicators must be adequately trained and certified by STERIS Corporation on the hazards and label directions for VAPROX Hydrogen Peroxide on the use and operation of the application equipment, hydrogen peroxide monitoring procedures and when appropriate, valid for the procedures.

J. PREPARATION OF ENCLOSURES
   a. Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces
with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed. Rinse with potable water and allow to air dry. All the surfaces in the treatment area must be completely dry to the touch or visibly dry prior to VHP application.

b. The VHP Application Equipment: Position or connect the VHP application equipment for optimum VHP distribution into the treatment enclosure. See Equipment User’s Manual for proper equipment preparation and set-up.

c. Sealing: Seal the treatment enclosure adequately to ensure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels (≤1 ppm) time weighted average for eight hours (TWA) and ensure sufficient concentration of VHP sterilant in the treatment enclosure.

1. Close and seal windows and doors. Sealing techniques can vary, but most often includes utilizing a sealant and adhering it to a single sheet of plastic to maintain the integrity of the sealing process by conducting an air leak potential analysis using a smoke stick test to ensure proper sealing. There are also aerosol sprays that have been used to seal this enclosure.

2. Turn off all ventilation systems including HVAC and seal any supply or return vents/ductwork.

3. Monitor areas immediately adjacent to the fumigated space to ensure levels are below TWA for hydrogen peroxide.

d. Securing Enclosure: 1. Assure all personnel have vacated the treatment enclosure prior to VHP application.

2. Remove all plants, animals, beverages and food.

3. Applications must not reenter the treated enclosure until exposure levels of hydrogen peroxide are below one ppm or below.

4. Placing of Treatment Enclosure: The applicator must place or post all entrances to the treatment enclosure and designated buffer areas with signs in English bearing:

   “The area on and around the green pipe or hose assembly is being treated with gas sterilant. Stay out of the area and do not enter.”

   “DO NOT ENTER. NO CIVILIAN UNLESS DIRECTED BY LICENSED STERISIS HOSPITAL STERILIZATION TECHNICIANS”

   “All personnel in the treatment area must be removed prior to the application of gas sterilant. No personnel are allowed in the treatment area during the application of gas sterilant. No personnel are allowed in the treatment area until the concentration is reduced to the level specified by the manufacturer.”

   “All personnel in the treatment area must be removed prior to the application of gas sterilant. No personnel are allowed in the treatment area during the application of gas sterilant. No personnel are allowed in the treatment area until the concentration is reduced to the level specified by the manufacturer.”

5. Applications to Sealed Enclosures Requiring Validation of Use Conditions:

   VAPROX Hydrogen Peroxide has been registered by STERIS in accordance with Federal Regulations for the specific uses described in this product insert. VAPROX Sterilant is used with enclosures that have been pre-cleaned of visible soils and any gross contamination. Use other than as specified and described are not permitted. VAPROX Sterilant may not be effective in sterilization without careful, thorough development and validation. In addition, the ability of the VHP sterilant to disinfect or decontaminate covered or concealed surfaces is limited. The instructions that follow explain how to utilize appropriate use conditions and validate these conditions for use in a dry, pre-cleaned sealed enclosure of a fixed size, location and materials of composition. This includes sealed enclosures in industrial, commercial, institutional settings (excluding production operations in pharmaceutical manufacturing, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, on-site hospitals, recreational facilities and emergency response vehicles). Process conditions must be properly validated prior to use to achieve sterilization of the treatment enclosure. For use in applications where the enclosure configuration, size, materials of composition and construction will vary, please see instructions for use in applying VHP sterilant at a pre-determined concentration and contact time (See Section 9 “Sites Not Requiring Use Validation”). For additional guidance, in-service, and training on how to develop and validate custom cycles, contact STERIS’ Corporation.

Validation of Alternate Use Conditions:

VAPROX Sterilant may be used in validated custom cycles for treatment of pre-cleaned, dry sealed enclosures when the enclosure to be treated is of a fixed volume configuration and contains materials of composition that remain constant in comparison to the VHP validation run. The custom cycle developed for the treatment enclosure must be capable of consistently achieving the desired log reduction in the number of Geobacillus stearothermophilus ATCC 7953 spores inoculated on biological indicator substrates.

System Characterization:

Several factors need to be considered when validating an application. The volumetric size, materials of construction, the physical nature of the contents and the temperature range of the treatment enclosure will affect application time and concentration. In general, large enclosures will take longer to reach the target VHP concentration due to a longer conditioning phase. Absorptive materials present in the construction of an enclosure or in the contents will also increase the conditioning time. In some cases, the time required to aerate of the enclosures. Vapors of hydrogen peroxide is a surface sterilant, therefore the enclosure and its contents should be prepared to maximize VHP exposure.

Working temperature and humidity ranges must be established to ensure that the VHP sterilant does not condense on exposed surfaces in the treatment enclosure. The chosen enclosure temperature and humidity conditions must not reach the expected dew point. Condensation can result in damage to enclosure surfaces and result in reduced cycle effectiveness. Placement of fans or other devices to assist VHP distribution must be documented. Standard Operating Procedures (SOPs) must be written to describe the physical preparation of an enclosure and its contents required to achieve reproducible results.

Biological Indicator Selection and Distribution:

The VHP sterilant effectiveness for applications must be validated using Biological Indicators (BIs) employing Geobacillus stearothermophilus spores. This organism has been deemed as the most VHP-resistant organism. Additionally, biological indicators consisting of other organisms of interest may be used to verify product performance. Use BIs with spore populations of ≥105 when using an aseptic feeding and application method. It is important that BIs that are suitable for evaluating VHP sterilant. STERIS Corporation supplies BIs designed for these applications and should be consulted regarding proper use and selection of BIs for validation of the VHP process.

Numerous BIs locations are used when validating a new application. Biological indicators are often geometrically distributed, but should also be placed in areas considered to be most difficult for the VHP sterilant to reach. Additional BIs may be placed in areas considered to be critical such as a product contact point in an aseptic area. Location and justification of BI placement should be documented. In addition to BIs, Chemical Indicators (CIs) must be used during validation to provide qualitative information about VHP resistant spore. The number of BIs and CIs used during validation varies, depending on the size and complexity of the application. The number of biological indicators used to validate the process must at a minimum be based on the following:

- Number of BIs = 1 per 100 ft² of floor space in the enclosure.

Process Development:

Typically the initial step in validating the VHP process is to determine the effectiveness of the process against Geobacillus stearothermophilus BIs of a known population. This is achieved by application of the sterilant at varying contact times and concentrations while keeping constant other VHP cycle parameters in order to determine the level of spore inactivation occurring on the BI at each exposure time. One approach to establishing effective kill times is the application of a "D-value" which is the number of minutes or time required for a one log reduction of the target organism. The information can be utilized to extrapolate cycle parameters to achieve the desired level of BI kill.

The following steps are required in developing a validated application process:

- **DEHUMIDIFICATION** – Reduce humidity to a predetermined level in the enclosure. A typical range for relative humidity is 10-20%. This permits the necessary VHP concentration to be maintained below condensation levels during the CONDIDING and STERILIZATION phases. The time to reach the targeted dew point levels increases with the volume of the enclosure, and is dependent on environmental conditions such as temperature and humidity in the sealed enclosure. The chosen enclosure temperature and humidity conditions must not reach the enclosure dew point. This may result in condensation on enclosure surfaces. Condensation can result in damage to enclosure surfaces and reduced cycle effectiveness.

- **CONDITIONING** – The VHP sterilant is injected into the sealed enclosure. The injection rate is typically pre-determined and controlled based on guidelines established for the VHP equipment (refer to VHP Generator Equipment User’s Manual for more details). This determines the concentration of hydrogen peroxide in the sealed enclosure. CONDITIONING time is affected by VHP sterilant concentration, injection rate, enclosure materials, environmental conditions and enclosure volume.

- **STERILIZATION** – A constant flow of VHP sterilant is maintained at a selected VAPROX injection rate to maintain the target VHP concentration in the sealed enclosure required to achieve a 10 log level of kill over a pre-established period of time.

- **AERATION** – The VHP injection is stopped and the flow of air is continued to reduce the VHP concentration within the enclosure to an acceptable level (≤1 ppm TWA 8 hr) prior to reentry into the enclosure by trained applicators. Trained applicators may not be released for general public use until the level of hydrogen peroxide is at or below one ppm in the enclosure.

Once acceptable cycle parameters have been determined, three VHP cycle replicates must be conducted to verify the performance of the process. After successful validation of the process, the applicator must use the validated cycle conditions and contact time for VHP application.

Significant changes to the enclosure such as major modifications to room dimensions and materials of composition will require additional validation or modification of application parameters.

Monitoring of H₂O₂ Concentrations in the Sealed Enclosure and Reentry Instructions Following Aeration:

VHP Monitoring: Giger tubes or other VHP monitoring devices are utilized by means of a mininal invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After the VHP concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of one ppm, the enclosure may be released to normal operations and general public use.

Criteria for Successful Fumigation:

1. All VHP fumigation processes complete (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.

2. All BIs that are properly recovered and evaluated exhibit a noticeable color change following exposure to VHP.

3. All BIs that are properly recovered (no breach of aseptic technique) are negative for growth.

4. Positive control BIs demonstrate growth following inoculation.

5. Negative control BIs exhibit no growth following inoculation.

(Not applicable to areas not requiring validation.)

Reentry Instructions:

1. Early reentry in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in the pressure mode. Full body suits, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to fabrics. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

2. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a certified breathing apparatus at VHP concentrations up to 5 ppm to allow for windows to be opened and to diminish this concentration to non-irritant levels. The number of BIs and CIs used during validation varies, depending on the size and complexity of the application. The number of biological indicators used to validate the process must at a minimum be based on the following:

- Number of BIs = 1 per 100 ft² of floor space in the enclosure.

Reloading Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may re-enter the treated enclosure and remove any remaining materials and disconnect/remove VHP generator from the treated sealed enclosure.

b. Turn on ventilation systems including HVAC.

c. Remove plaques and vigilant indicators for normal operation and use after the levels of hydrogen peroxide are determined to be at or below one ppm.

d. Release the treated enclosure for general use after hydrogen peroxide levels are determined to be at or below one ppm.
8. Application to Sealed Enclosures of Up to 4,000 ft² Not Requiring Validation of Use Conditions:

VAPROX sterilant may be also be applied to dry, sealed pre-cleaned enclosures without prior validation when the area is treated on a non-routine basis or enclosures being treated vary in configuration, materials of construction and areas enclosed. To be treated in the treated enclosure. The use of the VHP process in these conditions requires the application to apply a fixed VHP concentration over the set contact time. In addition, the enclosure must be dehumidified and conditioned as part of the application process prior to aeration after sterilization. VAPROX sterilant may be applied at a set concentration and contact time to sealed enclosures of up to 4,000 ft² in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing facilities, manufacturing clean rooms, medical device sterilization as part of a manufacturing process, laboratories, animal research facilities, patient rooms, hotel rooms, offices, retail shops, transportation facilities and amusement parks) with these applications, the VAPROX concentration should be monitored using a hydrogen-peroxide sensor to ensure an adequate concentration level is maintained during the STERILIZATION phase of the process. Additional, hydrogen-peroxide sensor must be placed throughout the enclosed enclosure to be treated to verify distribution of hydrogen peroxide throughout the enclosure. If more than one room of a consistent dimension is being treated, the operator may use the same VHP cycle settings as established in the initial room without considering the concentration of the treatment cycle. These operations should be carried out by STERIS trained and certified applicators familiar with the set up and operation of VHP application equipment.

Sterilization of Sealed, Dry PreCleaned Enclosures at 250 ppm VAPROX Sterilant for 90 minutes:

Prepare the treatment enclosure as described above (Preparation of Enclosures Section) including pre-cleaning, drying and preparation of VHP Generator (refer to User's Manual for VHP Generator Unit), sealing the enclosure and placarding of the enclosure to be treated. Place VHP monitor in a location most difficult for VHP target concentration to be reached in the treatment enclosure. This is typically a corner in the enclosure farthest away from the VHP generator unit. All drawers, closets and cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Place chemical indicators throughout the enclosure to verify effective distribution of VHP sterilant. The number of indicators placed throughout the enclosure should be based on the formula of one chemical indicator per 100 ft². The chemical indicators must be placed in room corners in areas difficult for the VHP sterilant to access such as closets, dressers, cabinets, or other partially occluded areas. Place oscillating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase for at least 20% dehumidification and prevent the ambient temperature is not less than 21°C or 70°F initially and throughout the fumigation process. Once the DEHUMIDIFICATION phase is complete initiate a STERILIZATION phase for 90 minutes (250 ppm VHP sterilant concentration in the sealed enclosure) and aeration phase. When a 250 ppm VHP sterilant concentration is achieved initiate the STERILIZATION phase and maintain this concentration for 90 minutes. During the STERILIZATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to assure hydrogen peroxide levels do not exceed one ppm. If this level is exceeded outside the treatment enclosure, the operator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the STERILIZATION phase, begin the AERATION phase to reduce levels of hydrogen peroxide at or below one ppm (TWA).

Sterilization of Sealed, Dry PreCleaned Enclosures at 400 ppm VAPROX Sterilant for 30 minutes:

Prepare the treatment enclosure as described above (Preparation of Enclosures Section) including pre-cleaning, drying and preparation of VHP Generator (refer to User's Manual for VHP Generator Unit), sealing the enclosure and placarding of the enclosure to be treated. Place VHP monitor in a location most difficult for VHP target concentration to be reached in the treatment enclosure. This is typically a corner in the enclosure farthest away from the VHP generator unit. All drawers, closets and cabinet doors, etc. must be opened to permit exposure to VHP sterilant. Place chemical indicators throughout the enclosure to verify effective distribution of VHP sterilant. The number of indicators placed throughout the enclosure must be based on the formula of one chemical indicator per 100 ft². The chemical indicators must be placed in room corners and in areas difficult for the VHP sterilant to access such as closets, dressers, cabinets, or other partially occluded areas. Place oscillating fans throughout the enclosure to facilitate effective distribution of the VHP sterilant. Program the VHP Generator to initiate a DEHUMIDIFICATION phase for at least 20% dehumidification and prevent the ambient temperature is not less than 21°C or 70°F initially and throughout the fumigation process. Once the DEHUMIDIFICATION phase is complete initiate a STERILIZATION phase for 30 minutes (400 ppm VHP sterilant concentration in the sealed enclosure). When a 400 ppm VHP sterilant concentration is achieved initiate the STERILIZATION phase and maintain this concentration for 30 minutes. During the STERILIZATION phase, monitor areas adjacent to the sealed enclosure with devices such as Drager tubes to assure hydrogen peroxide levels do not exceed one ppm. If this level is exceeded outside the treatment enclosure, the operator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the STERILIZATION phase, begin the AERATION phase to reduce levels of hydrogen peroxide at or below one ppm (TWA).

Monitoring of H₂O₂ Concentrations in the Sealed Enclosure and Reentry Instructions Following Aeration.

VHP Monitoring: Drager tubes or other VHP monitoring devices are utilized by means of a minimally invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After the VHP concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of one ppm, the enclosure may be released for normal operations and general public use.

Criteria for Successful Sterilization:

- All VHP sterilization process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the cycle.
- All OIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP sterilant.
- For validated processes, all OIs that are properly recovered (no breach of aseptic technique) are negative for growth.*
- For validated processes, positive control OIs demonstrate growth following inoculation.*
- For validated processes, negative control OIs exhibit no growth following inoculation.*

*Not applicable to chambers not requiring validation.

Reentry Instructions:

1. Early reentry in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, face cap, eye protection, head boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

2. Reentry to the sealed enclosure by a trained and certified applicator is allowed with a self-contained breathing apparatus at VHP concentrations up to 5 ppm to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until exposure levels of hydrogen peroxide are at or below one ppm.

Releasing Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may re-enter the treated enclosure and remove any sealings materials and disconnect/remove VHP Generator from the treated sealed enclosure.

b. Turn on ventilation systems including HVAC.

c. Remove placards and release the treated enclosure for normal operation and use after the exposure levels of hydrogen peroxide are determined to be at or below one ppm.

d. Release the treated enclosure for general public use after hydrogen peroxide levels are determined to be at or below one ppm.

9. Application to Sealed Enclosures Between 2 ft³ and 40 ft³ that require Validation:

Use of VHP in sealed enclosures of this size, such as isolation chambers where reentry by applicators or other individuals is not possible does not require a sterilization management plan (RMP). All other applicable calculations for use of hydrogen peroxide should be adhered to when applying VHP in these chambers.

Applications Not Requiring Validation of Use Conditions:

VAPROX Sterilant may be used at 250 ppm for 90 minutes or 400 ppm for 30 minutes using a hydrogen-peroxide sensor and chemical indicators to verify these use conditions are met. See Section 8 above for specific instructions regarding use under these conditions.

Validation of Alternate Use Conditions:

VAPROX Sterilant may be used in validated custom cycles for treatment of pre-cleaned, dry sealed enclosures when the enclosure is to be treated for a fixed volume configuration and contains materials of composition that remain constant in comparison to the VHP validation run. The specific cycle or validated cycle must be capable of consistently achieving the desired log reduction in the number of spore forming units selected on biological indicator substrates. See Section 7 above for specific instructions regarding development of valid cycle conditions for alternate use conditions.

Monitoring of H₂O₂ Concentrations in the Sealed Enclosure and Instructions Following Aeration.

VHP Monitoring: Drager tubes or other VHP monitoring devices are utilized by means of a minimally invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the aeration phase. After the VHP concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of one ppm, the enclosure may be released for normal operations.

Criteria for Successful Sterilization:

- All VHP sterilization process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the cycle.
- All OIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP sterilant.
- For validated processes, all OIs that are properly recovered (no breach of aseptic technique) are negative for growth.*
- For validated processes, positive control OIs exhibit growth following inoculation.*
- For validated processes, negative control OIs exhibit no growth following inoculation.*

*Not applicable to chambers not requiring validation.

Reentry Instructions:

1. Early reentry or opening of the chamber in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, face cap, eye protection, head boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues.

Releasing Treated Sealed Enclosure for Return to Service:

a. Once VHP levels are determined to be at or below one ppm, applicators may open the isolation/chamber and remove any sealing materials and disconnect/remove VHP Generator from the treated sealed enclosure.

b. Remove placards and release the treated enclosure for normal operation.

10. Aseptic Food Processing Operations:

VAPROX Sterilant is a ready to use solution. It may be used to achieve commercial sterility of food packaging materials and food processing equipment. Apply VAPROX Sterilant on the exterior and interior of food containers and closure systems (cans, seals, etc.) or appropriate food processing equipment surfaces. Use techniques such as, but not limited to, immersion, circular spray, or circulation to sterilize the equipment. Apply VAPROX Sterilant at a minimum temperature of 25°C. This product must remain in contact with the packaging surface for a minimum of 28 seconds. Use an aseptic food processing operation moisture testing required for the release validation. Food subject to these FDA regulations may not be sold in a treated package until after the scheduled process for the food processing operation has been accepted by the FDA.

Manufactured by:
STERIS Corporation
5960 Halsey Road
Mentor, OH 44060 • USA
800-548-4873
www.steris.com

62263
PB06-1NC(0312)
10001451 Rev. D