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.

In eyes:
• Hold palpebral and inferior conjunctiva, and gently wash with water for 15-30 minutes.
• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.

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.
• Wash skin immediately with plenty of water for 15-30 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 ventilation, preferably by mouth-to-mouth if possible.
• Call a poison control center or doctor for further treatment advice.

FIRST AID

DIRECTIONS FOR USE
For use in 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 container 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. Store away from powdered metals and peroxodisulfur.

PESTICIDE DISPOSAL: Rinse containers with 20 parts water and then empty into sink with running water. Hydrogen Peroxide is classified as a KD1 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.

Lot Number: Not for sale or use after:

PMS 3425 GREEN COLOR BAND
PMS 279 BLUE HEXAWAVE
REST BLACK
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 a control panel on the VHP Generator. See the VHP Generator Equipment User’s Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

The VHP Generator uses a carrier to deliver hydrogen peroxide vapor to exposed surfaces inside a sealed enclosure. This allows the process to take place at or near atmospheric pressure. Since the VHP process relies only on the contact of the VHP sterilant with 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 targeted dehumidification level is dependent on 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 VHP sterilant is continuously injected at a selected rate to maintain the target VHP concentration over a pre-established period of time.

2. User Safety Requirements:

- Respirator Requirements – When a respirator is required for use with this product, the trained applicator supervising the fumigation must make sure that:
  - a. Respirators must be fit tested and fit checked using a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134).
  - b. Respirators must be maintained and cleaned using a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134).
  - c. Respirator users must be trained and periodically re-trained on safe work practices.
  - d. Respirators must be maintained according to a program that conforms with OSHA’s requirements (described in 29 CFR Part 1910.134).

- Aeration is a phase of the VHP application process. Aeration time is determined by VHP sterilant concentration and enclosure volume.

- For VHP sterilant concentrations of 250 ppm, aeration shall be carried out for 90 minutes in sealed enclosures up to 4,000 ft

- For VHP sterilant concentrations of 400 ppm, aeration shall be carried out for 30 minutes in sealed enclosures up to 4,000 ft.

- Aeration shall be carried out for 10 minutes in sealed enclosures greater than 4,000 ft.

3. Efficacy:

VAPROX Hydrogen Peroxide Vapor is effective as a Sterilant, Sporicide, Bactericide, Virucide, and Fungicide under the following conditions on exposed, pre-cleaned, dry, porous, non-sterile surfaces including environmental and non-environmental surfaces including food, floors, furniture, equipment and other items in sealed enclosures in industrial, commercial and institutional settings, and non-sterile areas including public, recreational areas, and recreational facilities.

- For 400 ppm or smaller enclosures a sterilization cycle was developed for the VHP Generator and validated for both 250 ppm and 400 ppm sterilant concentrations. Pre-cleaned, dry, porous, non-sterile surfaces including food, floors, furniture, equipment and other items in sealed enclosures in industrial, commercial and institutional settings, and non-sterile areas including public, recreational areas, and recreational facilities.

- For 250 ppm or smaller enclosures a sterilization cycle was developed for the VHP Generator and validated for both 250 ppm and 400 ppm sterilant concentrations. Pre-cleaned, dry, porous, non-sterile surfaces including food, floors, furniture, equipment and other items in sealed enclosures in industrial, commercial and institutional settings, and non-sterile areas including public, recreational areas, and recreational facilities.

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4. Fumigation Management Plan

- The STERIS Corporation trained applicator is responsible for working with the owners and/or responsible employees of the site to be fumigated to develop a site specific Fumigation Management Plan (FMP) for each site that will be treated with VHP. The applicator is responsible for all aspects of the fumigation process unless otherwise noted in the FMP and must be on site for the entire fumigation treatment process. The FMP must address characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

  - a. Inspect the structure and or area to determine its suitability for fumigation.
  - b. When sealing is required, consult with appropriate organizations to determine the type of the structure, seal, leaks, and monitor any occupied adjacent rooms and/or buildings to ensure safety.
  - c. Prior to each fumigation, review any existing VHP, MOU, Equipment User Manual and other relevant safety procedures with company officials and appropriate employees.
  - d. Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.
  - e. 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 application, fumigation, and aeration. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
  - f. Consult with owners and/or responsible employees at the site who will be responsible for development of procedures for local authorities to notify nearby residents in the event of an emergency.
  - g. Confirm the placement of placards to secure entrance into any area under fumigation.
  - h. Confirm the required safety equipment is in place and the necessary manpower is available to complete fumigation.

These factors must be considered in putting a FMP together. It is important to note that some plans may be more comprehensive than others. All parties should reflect the knowledge and expertise of the applicator and circumstances at and around the structure and or area. In addition to the plan, the applicator must read the entire label and equipment manual and follow all directions carefully. 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 site. In the event of an emergency application, a generic FMP which can be updated may be used provided after fumigation. The STERIS Corporation trained applicator must sign the plan indicating it was followed. The signed FMP and related documentation, including monitoring records, must be retained by the applicator for a minimum of 2 years and a copy provided to the owner of the treated site.

1. GUIDANCE FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN
   A Fumigation Management Plan (FMP) is an organized, written description of the steps involved to help ensure a legal and effective fumigation. It will also assist you and others in complying with pesticide product label requirements. The guidance that follows is designed to help you fulfill 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 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 will also be given to the applicable company officials (supervisors, 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 Guidance Document you will want to construct a similar set of procedures. Finally, before any fumigation begins, you must be familiar with and comply with all applicable state and local laws. The success of the fumigation is not only dependent on your ability to do your job but upon carefully following all rules, regulations, and procedures required by governmental agencies.

A. PLANNING AND PREPARATION
   1. Determine the purpose of the fumigation.
      a. Sterilization of entire structure.
      b. Sterilization of emergency vehicles.
      c. Sterilization of hydrogen peroxide residues.
   2. Determine the type of fumigation. For example:
      a. Pharmaceutical Operations, clean rooms, medical device sterilization manufacturing
      b. Laboratories, animal research facilities.
      c. Patient rooms, hotel rooms, offices, recreational facilities.
      d. Create an electronic file in addition to the Equipment Manual, read the US Coast Guard Regulations, 46CFR 147A.
   3. 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 (materials, design, age, maintenance, of the structure, fire or combustibility hazard, etc.) and space usage (e.g., area used for employee storage, etc.)
      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 staff rooms, patient rooms or offices. Additional considerations should also be given to adjacent rooms above or below the enclosure if the structure does not have an approved ventilation system (i.e. negative pressures 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 (e.g., employees, visitors, customers, etc.).
      d. Responsibility of utility service connections.
      e. Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.
      f. Emergence of valley stations for electricity water and gas. Mark the location of these items on the drawing/sketch.
      g. Corporate telephone numbers of local Health, Fire, Police, Hospital and Physician responders.
      h. Name and phone number (both day and night) of appropriate company officials.
      i. Checkmark and prepare the points of fumigation application.
      k. Exposure time considerations.
      l. Determination of dosage.
         1. Cubic footage or other appropriate space/location calculations.
         2. Structure sealing capability and methods.
         3. Label directions.
         4. Past history of fumigation of structure.
         5. Exposure time.
   B. PERSONNEL
   1. Confirm in writing that all personnel in and around the area to be fumigated have been notified in compliance with all applicable state and local laws. The success of the fumigation is not only dependent on your ability to do your job but upon carefully following all rules, regulations, and procedures required by governmental agencies.
   2. Confirm that all personnel know how to proceed in case of an emergency situation.
   3. Confirm that all personnel on how to report any accident and/or incident related to fumigation exposure. Provide a telephone number for emergency response reporting.
   4. Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to Fumigation.
   5. Establish a meeting area for all personnel in case of emergency for all personnel in case of emergency.
   6. Confirm that all applicators have been trained in the use of VAPROX Hydrogen Peroxide Sterilant and are in good standing including the required refresher training.
   7. Develop a written health and safety plan by OSHA for all applicators. The owner/operators of the facility being treated should have a written Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

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 monitoring records for each fumigation site. This log must at a minimum contain the timing, 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 levels. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.
      d. Monitoring must be conducted during aeration and corrective action taken if gas levels exceed the allowed levels in an area where bystanders and/or nearby residents may be exposed.
   2. Efficacy
      a. Hydrogen peroxide readings should be taken from within the fumigated structure to ensure proper vapor concentrations. This can be safely achieved outside the structure through the use of a remote sensor reading.
      b. All reading of hydrogen peroxide concentration, temperature and relative humidity must be documented.

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 owner.
   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 in adjacent areas to the enclosure, about the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded one ppm are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below one ppm hydrogen peroxide. The treated enclosure and adjacent areas must remain unoccupied until hydrogen peroxide levels are at or below one ppm. Early entry into the sealed treated enclosure at use concentration levels in the event of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, gloves and boots to protect from the 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 monitoring a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.
   2. If 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.
   4. Warning placards must be placed on every possible entrance to the fumigation site.

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 the outside of the fumigated area.
   4. Provide watches when a fumigation site cannot otherwise be made secure from entry by unauthorized personnel.
   5. When entering structures always follow OSHA rules for confined spaces.
   6. The applicator should verify compatibility of item surfaces to be treated prior to the application process.
   7. POST-APPLICATION OPERATIONS
      1. Provide watches when you cannot secure the fumigation site from entry by unauthorized persons during the aeration process.
      2. Ventilate and aerate in accordance with structural limitations.
      3. Turn on ventilating or aeration fans where appropriate.
      4. Use a suitable VHP detector before reentry to determine fumigant concentration.
      5. Keep written records of monitoring to document completion of aeration.
      6. Consider temperature when aeration.
      7. Ensure aeration is complete before moving vehicle into public roads.
      8. Remove warning placards when aeration is complete.
      9. Inform business/land that employees/other persons may return to work or otherwise be allowed to reenter the sealed structure.

H. CRITERIA FOR SUCCESSFUL FUMIGATION:
   1. All VHP fumigation process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.
   2. All DIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.
   3. All DIs that are properly recovered (no breach of aseptic technique) are negative for growth.*
   4. Positive control DIs demonstrate growth following incubation.*
   5. Negative control DIs exhibit no growth following incubation.*

   [not applicable to areas not requiring validation]

   5. Negative control DIs exhibit no growth following incubation.*

   [not applicable to areas not requiring validation]

   5. Prepare written procedure and approved for use by OSHA developed for their employees located within close proximity of the application process.

   6. Preparation of Enclosures
      a. Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces
Steris Corp.
Steris-PB006-IN C Vaprox Insert, cp
For Sale 7-26ip6 Lead 7.4ip
Vaprox/US/Insert/Design/PB006-IN. 3/13/12

DO NOT PRINT SPOT RED TEMPLATE

ALL BLACK
3/13/12
1:12 pm

11"x8-1/2"

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 touch or visibly dry prior to 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 sterilant exposure. The number of BIs and CIs used during validation varies, depending on the size and complexity of the application. The number of BIs and CIs should be determined by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until after the level of hydrogen peroxide is at or below one ppm in the enclosure.

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. All BIs that are properly recovered (no breach of aseptic technique) are negative for growth. Positive control BIs demonstrate growth following incubation*.

3. Monitoring of the treated enclosure and equipment preparation and set-up.

4. Conditioning – The VHP sterilant is injected into the treated enclosure. The injection rate is adjusted and controlled based on guidelines established for the VHP equipment (refer to VHP Generator Equipment User’s Manual). 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.

5. 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 10⁴ level of kill of a pre-established period of time.

Vaprox Monitoring: Dräger tubes or other VHP monitoring devices are utilized by means of a monitor, invasive technique for VHP sampling to determine the VHP concentration in the sealed enclosure during and after the treatment cycle. 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 process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the fumigation cycle.
2. All OIs that are properly recovered and evaluated exhibit a visible 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 incubation*.
5. Negative control BIs exhibit no growth following incubation*.

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 gloves, boots and masks 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 as determined by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until after the level of hydrogen peroxide is at or below one ppm.

Additionally, biological indicators consisting of other organisms of interest to the user may be utilized to verify product performance. Use BIs with spore populations of V. P. when validating enclosure configuration and specific use conditions. It is important to utilize 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.

Biological Indicator Selection and Distribution:

The VHP sterilant effectiveness for applications must be validated using Biological Indicators (BIs) containing Geobacillus stearothermophilus spores. This organism has been shown to be the most VHP resistant organism. Additionally, biological indicators consisting of other organisms of interest to the user may be utilized to verify product performance. Use BIs with spore populations of V. P. when validating enclosure configuration and specific use conditions. It is important to utilize 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 BI 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
8. Application to Sealed Enclosures of Up to 4,000 ft²

VAPROX Sterilant may also be applied to dry, sealed pre-cleaned enclosures without prior validation of the sterility assurance level. Aseptic processing equipment surfaces. Use techniques such as, but not limited to, immersion, coarse.

9. Application to Sealed Enclosures Between 2 ft³ and 40 ft³

VAPROX Sterilant may be used in validated custom cycles for treatment of pre-cleaned, dry sealed enclosures when the enclosure is treated by a fixed volume configuration and contains materials of composition that remain consistent 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 recovered spores/CFU. Each spore species inoculated in biological indicator substrates. See Section 7.3 for specific instructions regarding development of validated 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 to normal operations and use.

Criteria for Successful Sterilization:

a. All VHP sterilization process conditions (vapor concentration, temperature, relative humidity) are achieved throughout the sterilization cycle.

b. All UVIs that are properly recovered and evaluated exhibit a visible color change following exposure to VHP.

c. For validated processes, negative control BIs exhibit no growth following incubation*. For validated processes, positive control BIs demonstrate growth following incubation*.

d. For validated processes, positive control BIs demonstrate growth following incubation*. (Not applicable to chambers requiring validation)

Reentry Instructions:

a. Early reentry 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, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues. When entering the area under fumigation always work with multiple people to provide adequate aeration.

b. 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 reentry to be conducted. Do not enter the treated enclosure until exposure levels of hydrogen peroxide are at or below one ppm.