

Facility Decontamination of Anthrax Spores Utilizing Vaporized Hydrogen Peroxide (VHP®).

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Introduction

STERIS Corporation's patented Vaporized Hydrogen Peroxide technology (VHP®) is used widely in the pharmaceutical industry for the microbial decontamination of aseptic processing environments, equipment and clean rooms etc. VHP offers broad spectrum antimicrobial efficacy and material compatibility.

Until recently VHP was applied to volumes of up to 15,000 cubic feet. After the anthrax attacks of October 2001, STERIS's large scale VHP generator was deployed for the decontamination of a contaminated building.

This poster provides an overview of the VHP system and describes a case study and the treatment of a contaminated building.

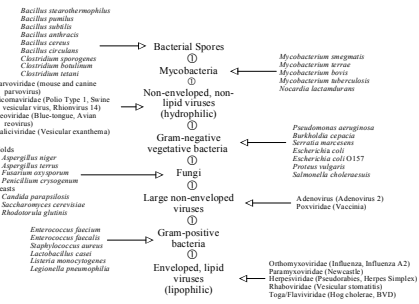


Figure 3 Listing of Organisms tested. Classes of organisms are listed in descending order of resistance to VHP

Antimicrobial Efficacy

The efficacy of VHP has been tested against a broad range of microorganisms. Figure 3 shows a representative listing of organisms tested, the classes of organisms are shown in descending order of resistance to VHP. *Bacillus stearothermophilus* has been shown to be the most resistant organism. Figure 4 shows the relationship between VHP concentration and the D value for *B. stearo.* at ambient temperatures.

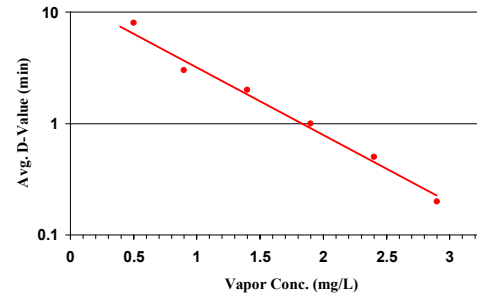


Figure 4 Plot of Decimal reduction value (D-value) for *Bacillus stearothermophilus* as a function of hydrogen peroxide vapor concentration.

Building Decontamination

Building Description:

A GSA building in Washington, DC., with a floor area of approximately 60,000 square feet. The volume of the building is approximately 1,400,000 cubic feet.

Contamination:

Anthrax spores entered the building via cross contamination of mail that passed through the Brentwood Postal Facility. The level of spores found within the building were not excessive, but spores were found in locations around the building. Rather than rely on limited surface decontamination the decision was made to fumigate the entire building to ensure all spores within the building were inactivated.

Building Preparation:

Partitions were constructed to divide the building into zones of between 150,000 to 250,000 cubic feet.

The VHP generator was located outside the building and ducting was used to deliver the VHP to the zones during fumigation

Fumigation Process:

HVAC Systems:

In the warehouse area the HVAC ducting system crossed multiple partitions. Therefore the HVAC system was treated first. The VHP system was connected to the air return of each of the HVAC units in turn and VHP was forced through the HVAC unit and into the ducting. BIs (10^6 *Bacillus subtilis* on stainless steel coupons) were hung in the registers at the extremities of the ducting system to confirm that VHP had been delivered throughout the system. VHP was injected for a total of six hours to treat the ducts. After fumigation the registers were sealed to prevent recontamination.

Zones:

Before fumigation BIs and CIs were hung in each zone. Large capacity oscillating floor fans were placed around the zone to facilitate vapor distribution. The VHP was delivered to the zones from the VHP generator outside the building using ducting. The VHP feed and return ducts were located at opposite ends of the rectangular zones to ensure that the vapor was forced to migrate across the entire length of the area. Depending on the volume of the zone VHP was injected for between 6 and 12 hours. After aeration the BIs were collected and incubated for seven days.

Results:

Over 1000 BIs were placed during the course of the fumigation process. All showed complete inactivation of the indicator organism. The VHP process has also been used to decontaminate the external surfaces of packaged contaminated materials prior to transportation for ethylene oxide treatment.

VHP Process

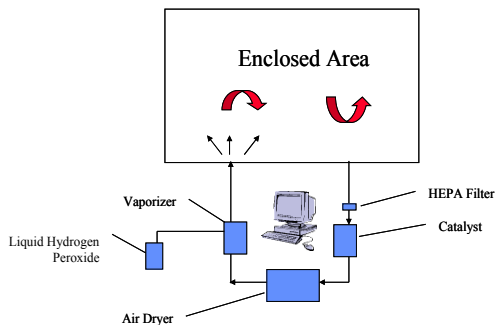


Figure 1 Schematic representation of the VHP generation system

The VHP processing cycle is divided into four parts:

- i) **Dehumidification:** Moisture within the enclosure is removed. Lowering the humidity permits a higher concentration of hydrogen peroxide vapor to be supported.
- ii) **Conditioning:** VHP is injected rapidly to quickly elevate the hydrogen peroxide concentration to the desired set point level.
- iii) **Decontamination:** VHP injection rate is set to maintain a steady state concentration of hydrogen peroxide vapor for the duration of the phase - decontamination time is determined by the desired level of microbial inactivation, which is in turn determined by the concentration of hydrogen peroxide that is maintained.
- iv) **Aeration:** Injection is terminated and air is cycled through the VHP unit to remove the hydrogen peroxide vapor. Aeration continues until hydrogen peroxide levels are considered acceptable (see Figure 2).

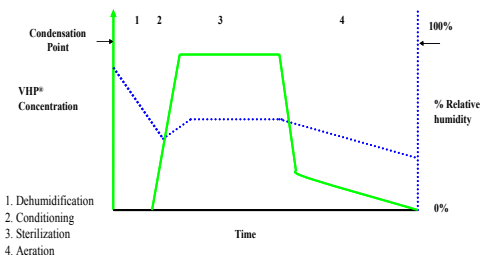


Figure 2 Plot showing concentrations of hydrogen peroxide and water vapor over the course of the VHP processing cycle

VHP is typically employed as a closed loop process, where air is removed from the enclosure to be decontaminated. The air stream passes through a HEPA filter (to ensure that the system does not become contaminated), and then a catalyst bed to convert hydrogen peroxide to water and oxygen. The air is then dried in a desiccant bed before passing through a vaporizer where 35% hydrogen peroxide solution is vaporized. The dried air stream, with the entrained hydrogen peroxide vapor is then reintroduced to the enclosure. (See Figure 1)

The VHP process is controlled so that the vapor produced is dry (i.e. the concentrations of water and hydrogen peroxide vapor are kept below the point at which condensation can occur). The use of dry vapor facilitates even distribution throughout the enclosure, and provides excellent materials compatibility.

Case Study

To demonstrate the efficacy of the large capacity VHP system a storage warehouse containing office furniture and cubicle partitions was fumigated. The warehouse had a volume of ~ 33,000 cubic feet. Twenty biological indicators (BIs, 10^6 *Bacillus stearothermophilus* on stainless steel coupons) were placed around the room, in locations that presented a barrier to vapor distribution. VHP was injected for six hours, followed by aeration for an additional six hours before the BIs were aseptically recovered. All the Biological indicators showed no growth after seven days incubation.



Figure 5 Photographs of the warehouse storage area showing cubicle partitions and office furniture.