

# Decontamination of enclosed areas with VHP<sup>®</sup>

## Decontaminating pharmacy workstations, safety cabinets, isolators and rooms

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### References

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**C**ritical enclosed environments including workstations, safety cabinets, isolators and rooms require periodic decontamination. Traditionally, wipe down techniques with a variety of liquid antimicrobials have been used. In general, these methods are very time consuming, labour intensive and difficult to validate. Fumigation with formaldehyde has been used to treat larger areas, but is difficult to control, slow acting and, more importantly, has significant safety and health concerns. Over the last 15 years, alternative systems based on Vaporized Hydrogen Peroxide (VHP<sup>®</sup>) have replaced these traditional methods. VHP systems are now widely used for the routine decontamination of isolators, biological safety cabinets, rooms, duct work and filters for pharmaceutical production, manufacturing, and research laboratory facilities.

A variety of VHP systems are available for decontamination. These systems, including modular or mobile generators, can be routinely connected to any enclosed environment. The VHP100 series are designed for smaller enclosed areas (up to 2m<sup>3</sup>/70ft<sup>3</sup>). VHP1000 systems have been used for areas up to 231m<sup>3</sup> (8000ft<sup>3</sup>) and, more recently, higher capacity systems have been used for remediation of larger areas (eg, 15,000m<sup>3</sup>/500,000ft<sup>3</sup>). These automated systems control the whole VHP process, including cycle documentation.

The cycle consists of four phases: dehumidification, conditioning, sterilisation and aeration, which are controlled and monitored by the system. A given area is generally dehumidified below 40% relative humidity and then VHP introduced to rapidly achieve sporicidal conditions (conditioning). VHP is produced by flash heating (vaporisation) of 35% liquid hydrogen peroxide. During the sterilisation phase of the cycle, hydrogen peroxide is maintained at a constant concentration in a dry vapour form to maximise efficacy. VHP decontamination is referred to as a 'dry' process, as the concentration is maintained below the critical condensation point of the vapour. This should not be mistaken for alternative condensation or fogging ('wet') methods that force concentrated hydrogen peroxide to condense on a surface; these methods are distinct and are not considered further in this report. It is recommended that condensation should be avoided to prevent surface damage and inefficient decontamination. Finally, during aeration, VHP is no longer introduced and

is rapidly removed to a safe level (<1ppm). Cycle times are generally less than 3 hours and will vary depending on the area size, desired level of decontamination, and area contents.

Although the exact antimicrobial mode of action of VHP is unknown, the agent itself and breakdown intermediates (including hydroxyl radicals) are known to react and breakdown protein, lipids and nucleic acids which cause inactivation.<sup>1</sup>

VHP is rapidly bactericidal, virucidal, fungicidal and even sporicidal at low concentrations (>0.1mg/L) in comparison to liquid hydrogen peroxide. VHP is a registered sterilant with well-established broad-spectrum antimicrobial activity.<sup>2</sup> Recent reports have confirmed its efficacy against multidrug-resistant bacteria, food-borne pathogens, *Legionella*<sup>3</sup> parvoviruses<sup>4</sup> and parasitic eggs.<sup>5</sup> Like any biocidal process, VHP is more effective on visually clean surfaces, but has recently been tested under worst-case conditions.<sup>6</sup> These tests included the identification of the most resistant organism (*Bacillus* spores), most resistant surface material (paper, as it breaks down VHP) and in the presence of 50% whole blood. Despite these test conditions, when tested in two isolator/workstation designs, a greater than 6 log reduction was observed in 40 minutes contact, for a total cycle time of 2.5 hours.

As an essentially dry process, VHP demonstrates the most extensive compatibility with a wide range of materials, including electronics, plastics, metals, and elastomers. Minor cosmetic changes have been observed with a limited number of materials.

For room decontamination, VHP has probably the best safety and environmental profile. A limit of 1ppm for an 8-hour time weighted average for worker exposure has been established, with a short-term danger level is 75ppm for 30 minutes. To reduce the risk of leakage, enclosures are sealed, and the process is operated at ambient pressure, to prevent flow of gases either into or out of the enclosure. In general, personnel can safely work in adjacent, monitored areas while a room is being decontaminated. No additional clean-up or conditioning is required following the process, leaving the area ready for immediate use.

VHP processes offer safe, effective and efficient alternatives for area decontamination to traditional formaldehyde or liquid-based methods.