Vaporized Hydrogen Peroxide (VHP®)  
Gaseous Decontamination: 
'GREEN' Technology for the Highest Level of 
Microbial Control within a Pharmaceutical Facility

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ISPE Boston Area Chapter  
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Agenda – Part 1

- Overview of the VHP Process: efficacy, safety, regulatory landscape, environmental properties and material compatibility
- VHP Technology and Equipment
- VHP Biodecontamination Field Applications
- VHP Services and Project Planning
- Case Studies
Why Gaseous Decontamination?

- Contamination remediation
- Pre-occupancy new or renovated facility
- Preventative periodic bio-burden reduction
- Product/population change
- Equipment transfer
- Facility decommissioning
- Equipment maintenance, i.e. BSCs, HEPA housings, etc.

VHP: Background and History

- VHP process developed mid-1980s, utilizing patented closed-loop, low concentration "dry" process
- VHP process patent issued in early 1990s
- Over 1,200 VHP systems in use world-wide in pharma, med device, LAR, bio-containment fields
- 15+ years of validated use in pharmaceutical manufacturing
- Large scale VHP facility applications applied for remediation during 2001 anthrax attacks
- 2007 VHP contract service offering available to industry
VHP: the Process

Ambient Temperature Sterilization Process

35% Hydrogen Peroxide Liquid (Vaprox)

Vaporization

$2\text{H}_2\text{O}_2$ + $\text{O}_2$

Kills all Microbes at Low Concentrations (Sporicidal)

Non-Toxic Residues

“Typical” VHP Biodecontamination Cycle

VHP Concentration

More

Less

Cycle Phase

Dehumidification — target 30-50%

Condition

Decontamination

Aeration

Condensation Point

Rh start target: 30-50%

Gas Concentration: for room decon typically 150-400 ppm

100 %

Relative Humidity

0 %
Variables Affecting Efficacy

- Temperature and humidity affect how much hydrogen peroxide (HP) can be generated in the gas state, start RH typically 30-50%
- Concentration—typically 150-400 ppm room applications
  - (injection rate/ air flow) * wt. % of HP
- Saturation
  - Inject as much as possible but below dew-point
  - Humidity is good for microbial kill
- Distribution—may be facilitated with fans
- Materials which can reduce VHP concentration, cellulosic material (i.e. cardboard, paper), galvanized steel, standing water

Why H2O2 Vapor? Sporicidal at Low Concentrations

- Bacterial Spores - Most Resistant Organism to VHP
- Highly sporicidal even as low as 0.1 mg/l
- Broad kill spectrum
- 35% H2O2 Registered EPA sterilant
- As per EPA label short “contact” times, six log reduction: 30-90 minutes @ 250-400 ppm
Resistance to VHP for Biological Organism Classes

Most resistant

Bacillus stearothermophilus
Bacillus subtilis
Mycobacterium bovis
Pneumonic Plague
Variola (smallpox)

Bacterial Spores
Mycobacteria
Non-enveloped, Non-lipid viruses (hydrophilic)
Gram-negative vegetative bacteria
Fungi
Large non-enveloped viruses
Gram-positive bacteria
Enveloped, lipid viruses (lipophilic)

Molds
Aspergillus niger
Black Mold
Yeast
Candida parapsilosis
Rhodotorula glutinis

Enterococcus faecalis
Staphylococcus aureus (and MRSA)
Legionnaires Disease

Why H$_2$O$_2$ Vapor? Efficacy Testing and Monitoring

- Biological Indicators - Most VHP Resistant geobacillus stearothermophilus typically 4-6 log
- Chemical Indicators – Qualitative instant feedback
- Real-time monitoring with electro-chemical sensors
**VHP Kill Matrix**

*Geobacillus stearothermophilus* spores inoculated on Stainless Steel Coupons at 30°C

**Bacterial Spores Evaluated for Their Resistance to Hydrogen Peroxide Gas**

- *Bacillus anthracis*
- *Bacillus cereus*
- *Bacillus circulans*
- *Bacillus pumilus*
- *Geobacillus stearothermophilus*
- *Bacillus subtilis*
- *Clostridium botulinum*
- *Clostridium sporogenes*
- *Clostridium tetani*
- *Clostridium difficile*
Mycobacteria Evaluated for Their Resistance to Hydrogen Peroxide Gas

- *Mycobacterium smegmatis*
- *Mycobacterium terrae*
- *Mycobacterium bovis*
- *Mycobacterium tuberculosis*
- *Nocardia lactamdurans*

Non-enveloped, Non-lipid Viruses Evaluated for Their Resistance to Hydrogen Peroxide Gas

- *Parvoviridae* (Feline and Canine parvovirus)
- *Picornaviridae* (Polio Type 1, Swine Vesicular, Rhinovirus 14)
- *Reoviridae* (Blue Tongue, Avian reovirus)
- *Caliciviridae* (Vesicular exanthema)
Gram-negative Vegetative Bacteria Evaluated for Their Resistance to Hydrogen Peroxide Gas

- *Burkholderia cepacia*
- *Pseudomonas aeruginosa*
- *Serratia marcescens*
- *Escherichia coli*
- *Proteus vulgaris*
- *Salmonella choleraesuis*

Fungi, Molds, and Yeasts Evaluated for Their Resistance to Hydrogen Peroxide Gas

- *Aspergillus niger*
- *Aspergillus terrus*
- *Candida parapsilosis*
- *Rhodotorula glutinis*
- *Fusarium oxysporum*
- *Penicillium chrysogenum*

- *Candida parapsilosis*
- *Saccharomyces cerevisiae*
- *Rhodotorula glutinis*
Large Non-enveloped Viruses Evaluated for Their Resistance to Hydrogen Peroxide Gas

- Adenovirus (Adenovirus 2)
- Poxviridae (Vaccinia)

Gram-positive Bacteria Evaluated for Their Resistance to Hydrogen Peroxide Gas

- Enterococcus faecium
- Enterococcus faecalis
- Staphylococcus aureus (MRSA)
- Lactobacillus casei
- Listeria monocytogenes
- Legionella pneumophila
Enveloped, Lipid Viruses Evaluated for Their Resistance to Hydrogen Peroxide Gas

- Orthomyxoviridae (Avian Influenza)
- Paramyxoviridae (New Castle)
- Herpesviridae (Pseudorabies, Herpes Simplex)
- Rhaboviridae (Vesicular stomatitis)
- Toga/Flaviviridae (Hog cholerae, BVD)

Why $\text{H}_2\text{O}_2$ Vapor? Safety Profile

<table>
<thead>
<tr>
<th>Hydrogen Peroxide</th>
<th>Chlorine Dioxide</th>
<th>Formaldehyde</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin/eye irritant</td>
<td>Severe irritant</td>
<td>Human carcinogen</td>
</tr>
<tr>
<td>PEL 1.0 ppm</td>
<td>PEL 0.1 ppm</td>
<td>PEL 0.75 ppm</td>
</tr>
<tr>
<td>IDLH 75 ppm</td>
<td>STEL 0.3 ppm</td>
<td>STEL 2 ppm</td>
</tr>
<tr>
<td></td>
<td>IDLH 5.0 ppm</td>
<td>IDLH 10 ppm</td>
</tr>
</tbody>
</table>

PEL - Permissible Exposure Limit (8 hours)
STEL - Short-term Exposure Limit (15 min.)
IDLH - Immediately Dangerous to Life or Health
Why H$_2$O$_2$ Vapor?
Safety Profile

Typical Decontamination Concentrations:
- VHP
  - Chlorine Dioxide: 500-1,500 ppm
  - Formaldehyde: 8,000-10,000 ppm

VHP Concentration

Average Reading: 214 ppm
Peak Reading: 357 ppm
4 Hours
Why $\text{H}_2\text{O}_2$ Vapor? Safety Profile

When considering VHP typical use concentrations, degradation and migratory properties and OSHA exposure limits, VHP offers less exposure risk to personnel and animals where small leaks occur.

Why $\text{H}_2\text{O}_2$ Vapor? A Green Solution

Non-toxic byproducts
No post-decon wipe down

EPA: “no risks to the environment are expected from use of pesticide products containing hydrogen peroxide because 1) the substance readily decomposes to water and oxygen gas, leaving no residue; 2) it is effective at low concentrations where no toxic effects are expected” www.epa.gov
# Material Compatibility*

<table>
<thead>
<tr>
<th>Metals</th>
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<tbody>
<tr>
<td>Aluminum</td>
<td>Excellent</td>
</tr>
<tr>
<td>Anodized Aluminum</td>
<td>Good</td>
</tr>
<tr>
<td>Brass</td>
<td>Good</td>
</tr>
<tr>
<td>Copper</td>
<td>Good</td>
</tr>
<tr>
<td>Stainless Steel – all grades</td>
<td>Excellent</td>
</tr>
<tr>
<td>Steel</td>
<td>Good</td>
</tr>
<tr>
<td>Titanium</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Plastics</th>
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<tbody>
<tr>
<td>ABS</td>
<td>Excellent</td>
</tr>
<tr>
<td>Aflas</td>
<td>Excellent</td>
</tr>
<tr>
<td>CPVC (chlorinated polyvinylchloride)</td>
<td>Excellent</td>
</tr>
<tr>
<td>Kel – F</td>
<td>Excellent</td>
</tr>
<tr>
<td>Nylon</td>
<td>Fair</td>
</tr>
<tr>
<td>PMMA</td>
<td>Excellent</td>
</tr>
<tr>
<td>Polymethylpentene (PES)</td>
<td>Excellent</td>
</tr>
<tr>
<td>Polyetherketone (PEEK)</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Elastomers</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Buna N</td>
<td>Fair</td>
</tr>
<tr>
<td>Butyl Rubber</td>
<td>Good</td>
</tr>
<tr>
<td>Chem Raz</td>
<td>Good</td>
</tr>
<tr>
<td>EPDM</td>
<td>Fair</td>
</tr>
<tr>
<td>Viton</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

*Compatibility is defined as the materials ability to undergo exposure to VHP with no significant changes in physical, or chemical properties (i.e. no changes in strength, flexibility, chemical composition, color etc.).

## Why H₂O₂ Vapor?

### Material and Component Compatibility Pharma Project

### Pilot Field Test

- Laptop computer (turned on)
- LCD monitor (turned off)
- Telephone (on)
- Electronic scales (on)
- Various electronic sensors
- Stainless steel clamps, fittings, and connectors
- Rubber grommets and washers
- Rubber hoses
- Plastic funnel and containers
Why H\textsubscript{2}O\textsubscript{2} Vapor? EPA-registered, FIFRA compliant

In compliance with Federal Insecticide, Fungicide and Rodenticide Act, all anti-microbial agents must be EPA registered. 35% hydrogen peroxide EPA reg. no. 58779-4

Why VHP? A Summary of Advantages

- Rapid decontamination at ambient temperatures and low concentrations
- Strong history of use and efficacy data, easily validated with BIs
- Strong comparative safety profile—detectable well below IDLH, no “trapped gases”
- Non-toxic by-products—a “green” solution
- No lengthy aeration
- No residue
- Strong material and component compatibility profile
- EPA Registered—FIFRA compliant
VHP Pharmaceutical Facility Applications

Rapidly Increasing in Popularity, Common Applications Include:

- Aseptic Manufacturing Rooms and Pilot Production Rooms: pre-occupancy new or renovated facility, remediation of known contaminant, periodic preventative
- Tissue Culture Rooms, Cold Rooms, Warm Rooms
- Lab Animal Research Procedure, Cage Change and Equipment Transfer Rooms
- Biological Safety Laboratories Level 3 (BSL-3)
- Biological Safety Cabinets, Incubators, Enclosures

VHP Generation Technology

- Mobile VHP
- Installed VHP
- Facility integrated VHP
- EPA-registered 35% HP
- For Room Applications with ARD use, for 3,500 ft³ room, typically 1 machine will achieve six-log kill in 2 hours or 7,000 ft³ in 4 hours
Methods of VHP Injection

- External via integrated ports
- External via installed Plexiglas panels
- In room, solo or daisy-chained
- Via AHUs (can include ductwork decontamination)

VHP Room Decontamination
Typical Room Application
VHP Service Project Planning

- Fumigation management plan (FMP) project document
- Define purpose and scope of decontamination
- Identify the team players including stakeholders and support personnel (area managers and PIs, EH &S, facilities engineering, security, etc.) and assign responsibilities
- Review site schematics, perform site visit, evaluate HVAC and electrical capabilities
- Review personnel/authority notification, site control and security, site signage
VHP Project Planning contd.

- Review area preparation: pre-cleaning, material/equipment transfer, HVAC control/support, smoke detector disengagement responsibilities, sealing of space
- Establish safety buffer zone, project safety plan and external monitoring plan
- Review post decontamination area clearance and equipment/material retrieval procedures
- Define acceptance criteria, establish BI quantity/mapping where applicable
- Establish the final project schedule, task sequencing and responsibilities

VHP Project Execution

- Upon arrival to job site equipment, material and personnel transfer commences in accordance with site requirements (gowning, equipment transfer protocols)
- Target area is prepared for decontamination: BI, CI, VHP generator, fan, emergency signage placement
- Smoke detectors disengaged/ HVAC isolated
- Final pre-go walk-thru/assessment with client to confirm area readiness
- Upon client authorization/clearance VHP injection commences
- Real-time internal and external monitoring of VHP
- Following injection commensurate with project requirements, aeration commences to bring VHP levels in area to below PEL 1.0 ppm
- Following area clearance, equipment, and BI/CI retrieval
- Upon completion of independent third-party BI analysis, report issued
Case Study 1: Pharmaceutical Manufacturing Facility

- Project scope: 240,000 ft$^3$ manufacturing space including bioreactor rooms
- Issue: bacterial remediation emergency
- Remote (AHU) and terminal ceiling HEPA filtration
- AHU and local VHP injection

VHP Case Study 1 continued

- 65 rooms, 48 hours
- 56 liters of Vaprox 35%
- 165 biological indicator locations
- 95 Chemical Indicators
- VHP injection 12 g/min
- VHP average concentration 242 ppm
VHP Case Study 1: Results

- All CIs changed color
- 96% BIs > 6 log kill, with remaining > 5 log kill
- External monitoring VHP concentration < 1.0 ppm throughout safety perimeter
Case Study 2: Pharmaceutical Manufacturing Facility

- Project Scope: 84,000 ft³ pilot production facility
- Issue: Preventative during shutdown
- Remote (AHU) and terminal ceiling HEPA filtration
- Local VHP injection

VHP Case Study 2 continued

- 28 rooms, 24 hours
- 22 liters of Vaprox 35%
- 65 biological indicator locations
- 28 Chemical Indicators
- VHP injection 12 g/min
- VHP average concentration 282 ppm
VHP Case Study 2 continued

- All CIs changed color
- Six-log kill all 65 BIs
- External monitoring
  - VHP concentration < 1.0 ppm throughout safety perimeter
Questions and Project Discussion

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Nick Flynn nick.flynn@bandvtesting.com,
800-851-9081
www.bandvtesting.com
www.steris.com

Agenda – Part 2

• H₂O₂ - Vapor vs. Condensate
• Portable or Modular?
• Installation of Modular VHP Systems
• Modular VHP Case Studies
• Final Thoughts
Vapor or Condensate?

Boiling Points:
- H₂O: 100°C
- H₂O₂: 150°C

...if you can see it, it's not a vapor

Vapor (300ppm) vs. Condensate (700,000ppm)

Effect of improper application

Weight Percent of Hydrogen Peroxide

GAS (VHP)

GAS + LIQUID

LIQUID

35% 77.8%
**VHP Flexibility**

- Maximum flexibility – multiple enclosure types
- Rooms, product or package handling equipment
- Integrations with Chambers, Washers and Autoclaves

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**Which VHP System?**

**Portable**
- Spaces not yet defined
- Uses in different buildings
- Typically less than 10,000 ft³
- Cycle time not a constraint
- Use of fans not an issue
- Less frequent use

**Modular**
- Large and small spaces up to ~80,000 ft³
- Same enclosures repeatedly
- Frequent use (chamber)
- Short cycle times
- Automated sequenced decontamination of multiple rooms
Why Modular?

Keep Equipment Outside Space
Save space within room / Pass Through
Avoid cross contamination
Keep maintenance activities outside

No Set Up
Decon at the Press of a Button
Run Sequential Decons via BMS*
Reduced Handling of Peroxide Excellent Distribution

Cost
Less expensive than multiple portables
Save on labor
The easier to use – the more frequent the use -the cleaner the space

* BMS = Building Management System

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VHP Modular Integration Schematic

Single Pass

VHP Supply to Room

VHP Exhaust from Room
VHP Emissions

- No EPA Limit
- Uniform Fire Code
  - ½ IDLH emergency conditions for “toxic” gases
  - Local regulations? Check.

Exhaust is rarely if ever an issue.

Why?
- Dilution
- Break down (galvanized ductwork)
- Easy to install catalyst

There are 2 options for integration...

<table>
<thead>
<tr>
<th>Airflow</th>
<th>Single Pass</th>
<th>Recirculating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typical Applications</td>
<td>BSL, Lab Animal</td>
<td>Clean Room, RABS</td>
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<tr>
<td>Dehumidification</td>
<td>HVAC</td>
<td>HVAC</td>
</tr>
<tr>
<td>VHP Supply</td>
<td>Dedicated each room</td>
<td>HVAC</td>
</tr>
<tr>
<td>Pressure control</td>
<td>Dedicated blower</td>
<td>HVAC</td>
</tr>
<tr>
<td>Aeration</td>
<td>HVAC</td>
<td>HVAC</td>
</tr>
</tbody>
</table>
Single Pass System

- **VHP Pipes**
  - Made of CPVC or PP
  - Insulated (supply only) but not traced

- **Cycle Phases**
  - Dehumidification via HVAC
  - Decontamination phase
    - HVAC is stopped
    - Leaktight dampers are closed
    - Gas flows into and from the rooms at specified rates via pre-set butterfly valves

- **Aeration Phase**
  - HVAC restarted (VHP - exhausted to outside)

- **Pressure Control (Positive or Negative)**
  - Possible during decontamination cycles
  - On small and/or leaktight rooms
  - By variable speed exhaust fan
Recirculating System (Clean Room)

- VHP Pipework
  - Made of CPVC or PP.
  - Section to central supply insulated but not traced

- Ductwork / HEPAs
  - Must be air-tight
  - Materials - PVC coated, galvanized, Aluminum, Stainless Steel but no bare copper
  - VHP will penetrate and decontaminate HEPAs

- Cycle Phases:
  - Dehumidification/ Injection Phase
    - Runs closed loop only, with no fresh air.
    - Recirculation allows an even distribution of the gas concentration in all the rooms.
    - Cooling and heating of the HVAC will be stopped.
  - Aeration: the maximum of fresh air is admitted during the Aeration Phase
Large Room Biopharmaceutical Fermentation Suite

Volume: 32,000ft³ (900m³)
Ceiling height: 28ft (8.5m)
Single pass, No fans
6-log reduction
Cycle time 6 hours
New construction

<table>
<thead>
<tr>
<th>Cycle Phase</th>
<th>Time</th>
<th>Airflow</th>
<th>Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>min.</td>
<td>g/min</td>
<td></td>
</tr>
<tr>
<td>Dehumidification</td>
<td>30</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Condition</td>
<td>30</td>
<td>120</td>
<td>96</td>
</tr>
<tr>
<td>Decontamination</td>
<td>90</td>
<td>120</td>
<td>60</td>
</tr>
<tr>
<td>Aeration</td>
<td>210</td>
<td>40 A.E./h</td>
<td></td>
</tr>
</tbody>
</table>

RABS – (Restricted Access Barrier Systems)

Modular VHP systems can rapidly decontaminate both Active & Passive RABS and the surrounding rooms.

Source: Pharmaceutical International
## Pass-Through Chambers / Transfer Hatches / Material Air Locks

Shown above

<table>
<thead>
<tr>
<th>Enclosure v Volume ft³</th>
<th>Enclosure surface material</th>
<th>Injection rate Condition gm/min.</th>
<th>Injection rate Decon gm/min.</th>
<th>Decon time Min &amp; log</th>
<th>Decon airflow ft³/min</th>
<th>PPM</th>
<th>Aeration airflow ft³/min</th>
<th>Total Cycle Time min</th>
</tr>
</thead>
<tbody>
<tr>
<td>460 (6x8x9.5'L)</td>
<td>Stainless</td>
<td>32</td>
<td>23</td>
<td>12</td>
<td>120</td>
<td>1000</td>
<td>765</td>
<td>45</td>
</tr>
<tr>
<td>175 (4x6x7'L)</td>
<td>Epoxy paint</td>
<td>12</td>
<td>9</td>
<td>8</td>
<td>40</td>
<td>950</td>
<td>1750</td>
<td>30</td>
</tr>
</tbody>
</table>

## HEPA Filter Decontamination

Exhaust

Inlet
BSL Lab & BSC Decon
Single Pass

Simultaneous Decon
of Primary Containment

A2 type biosafety cabinets can be decontaminated together with the room
- Exhaust dampers above cabinets are closed
- Cabinet blowers left on

Automated Sequential Zone
BSL-3 Lab Decontamination
Single Pass
### Task List

<table>
<thead>
<tr>
<th>Vendor</th>
<th>General Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Parts</td>
<td></td>
</tr>
<tr>
<td>✓ VHP Generator</td>
<td></td>
</tr>
<tr>
<td>✓ Dehumidifier (Munters)</td>
<td></td>
</tr>
<tr>
<td>✓ Bulk Fill apparatus</td>
<td></td>
</tr>
<tr>
<td>✓ Extra Controllers (remote)</td>
<td></td>
</tr>
<tr>
<td>✓ Sensors/ Monitors</td>
<td></td>
</tr>
<tr>
<td>✓ Consulting / Labor</td>
<td></td>
</tr>
<tr>
<td>✓ System Selection / Layout</td>
<td></td>
</tr>
<tr>
<td>✓ VHP Air Supply Balance</td>
<td></td>
</tr>
<tr>
<td>✓ Cycle Development</td>
<td></td>
</tr>
<tr>
<td>✓ Interface with BMS</td>
<td></td>
</tr>
<tr>
<td>✓ IQ/OQ and commissioning</td>
<td></td>
</tr>
<tr>
<td>✓ VHP Unit Installation</td>
<td></td>
</tr>
<tr>
<td>✓ Parts</td>
<td></td>
</tr>
<tr>
<td>✓ Ductwork (piping)</td>
<td></td>
</tr>
<tr>
<td>✓ Dampers (airtight)</td>
<td></td>
</tr>
<tr>
<td>✓ Booster Fan (if needed)</td>
<td></td>
</tr>
<tr>
<td>✓ Labor</td>
<td></td>
</tr>
<tr>
<td>✓ BMS Integration</td>
<td></td>
</tr>
<tr>
<td>✓ Ductwork Installation</td>
<td></td>
</tr>
</tbody>
</table>

### Selected Installations

**Pharma / Animal Health**
- GSK
- Intervet
- Fresenius
- Sanofi
- Merial
- Alcon
- Pfizer
- Fort Dodge

**Public Health Labs**
- Indiana
- New Jersey
- West Virginia

**Others**
- Tripler- US Army
- Univ. Nebraska
- Lawrence Livermore National Labs
- INRS
Why VHP?

- **Environmentally Safe**
  - Excellent Material Compatibility, Even with Sensitive Electronics, and Low Toxicity

- **Residue-Free**
  - Quickly Breaks Down into Water Vapor and Oxygen.

- **Ideal for Cleanrooms**
  - Integrated as a user-friendly Utility

- **Use Registered with EPA**

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Why VHP?

- **Consistency & Distribution**
  - Wet surfaces / minimal contact times - not an issue
  - Passes through HEPA filters
  - Decontaminates biosafety cabinets and HEPAs during room decon
  - Rapidly kills airborne and surface microbes

- **Labor**
  - Minimal labor required
  - Hundreds of validation applications
Acknowledgements

Claire Fritz and John Klosterymer
STERIS Corporation

Thank you!

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