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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Demson

Keller and Heckman LLP
1001 G Street NW,
Columbia City, IN 46725

OCT 2 0 2009

Attention: John Dubek
Agent for FMC Corporation

Subject: B-Cap 35 Antimicrobial Agent
EPA Reg. No. 72372-1
Amendment Letter Dated June 11, 2009

- The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

On the last page of the label delete the use direction for enclosures greater than 3500 cubic ft, (ie, enclosures up to 7000 cubic ft. There is no data to support this claim

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

B-Cap™ 35 Antimicrobial Agent

For Industrial Use Only –
Not for human consumption or household use

EPA Registration No. 72372-1
EPA Est. No. 65402-TX-001
60156-IL-001

B-Cap™ 35 Antimicrobial Agent is for use as a sterilant in conjunction with BIOQUELL Clarus™ hydrogen peroxide vapor generating equipment.

B-Cap™ 35 Antimicrobial Agent is for biofouling and slime control in:

- **Pulp and paper mill systems**
- **Recirculating and once through cooling water systems**
- **Pasteurizer cooling water systems**
- **Process Waters**
- **Biocidal control in packaging and storage vessels**

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

KEEP OUT OF REACH OF CHILDREN
DANGER

FMC and B-Cap™ are trademarks of FMC Corporation

FMC Corporation
Peroxygens Division
1735 Market Street
Philadelphia Pennsylvania 19103

Precautionary Statements
Hazards to Humans and Domestic Animals

DANGER
Corrosive, causes eye and skin damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection.

Physical or Chemical Hazards
Strong oxidizing agent. Mix only with water. B-Cap™ 35 Antimicrobial Agent is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

Environmental Hazards
This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

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

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 eye. • Call a poison control center or doctor for treatment advice.
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.
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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
Note to Physician:	Probable mucosal damage may contraindicate the use of gastric lavage.

Net Contents: 55 Gallons 500 pounds

72372-1

Storage and Disposal

Storage

NEVER RETURN B-CAP™ 35 ANTIMICROBIAL AGENT TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute **B-Cap™ 35 Antimicrobial Agent** with large volumes of water.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedure for Leak or Spill

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal

Pesticide Disposal

If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

B-Cap™ 35 Antimicrobial Agent, which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal

Empty drums are not returnable to FMC unless special arrangements have been made. Triple rinse drums with water. Dispose of drums in accordance with local, state, and Federal regulations. **DO NOT REUSE.**

Directions for Use

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

B-Cap™ 35 Antimicrobial Agent

A microbiocide for use in controlling slime and sulfate forming bacteria in process waters, air washing systems, recirculating and once through water cooling towers and systems, including pasteurizer cooling water systems and industrial closed recirculating process water systems, and packaging and storage vessels.

Air Washers and Recirculating and Once Through Cooling Water Systems, (cooling towers, evaporative condensers).

1. Severely fouled systems should be cleaned prior to treatment.
2. This product may be used in all types of cooling water systems that have mist-eliminating components. B-Cap™ 35 Antimicrobial Agent should be added at a point where uniform mixing can be achieved, for example the basin area. Addition may be intermittent or continuous. Hydrogen peroxide should not be mixed with other chemicals or additives without first checking for compatibility. Contamination with other chemicals could cause product decomposition.
   - Intermittent (Slug Dose) – For severely fouled systems add 3 to 163 fl oz of B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water in the system, (10 to 500 ppm). Repeat until control is achieved. When control is evident add 1 to 31 fl oz of B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water in system (3 to 100 ppm H_2O_2) as needed to maintain control.
   - Continuous Feed – Initial Dose: If the system is noticeably fouled, use slug dose procedure for the initial treatment. Once control is achieved, use a continuous feed of 0.3 to 16 fl oz B-Cap™ 35 Antimicrobial Agent per 1000 gallons of water per day in the system (1 to 50 ppm H_2O_2). Dosage rates should be increased or decreased depending on the extent of biofouling and control achieved.

Pasteurizer Cooling Water Systems

The product can be used at the same application rates and in the same manner as described above. The solution should be added to the closed recirculating system at a point where uniform mixing can be achieved, e.g., basin, sump, or collection areas.

Biofouling Control in Pulp and Paper Mill Systems

For use in the manufacture of paper and paperboard intended for non-food contact only. Not for use in the manufacture of paper and paperboard intended for food contact.

The product can be used to control bacterial, fungal and yeast growth in pulp, paper and papeboard mills.

1. Severely fouled systems should be cleaned prior to treatment with B-Cap™ 35 Antimicrobial Agent. Add B-Cap™ 35 Antimicrobial Agent directly to the system, don't mix with other chemicals or additives *without first testing for compatibility. Contamination with other* chemicals could result in product decomposition.
2. Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it can be mixed uniformly with the pulp, e.g., the beater, hydropulper, fan pump, broke pump, etc.
3. Apply 1 to 40 fl oz of B-Cap™ 35 Antimicrobial Agent per ton of (dry basis) pulp or paper produced, (10 to 500 ppm H_2O_2). Addition may be continuous or intermittent depending on the type of system and severity of the biofouling.

Process Water

B-Cap™ 35 Antimicrobial Agent may be used to aid in minimizing slime formation in process waters intended for use in precleaning hard non-porous surfaces, e.g., metals, glass or plastics prior to being painted, plated, or coated; cleaning pipes, equipment or other process equipment.

1. *Add B-Cap™ 35 Antimicrobial Agent at a point in the system where it* can be mixed uniformly. The quantity of product required will depend upon the severity of the fouling.
2. Apply 0.3 to 163 fl oz per 1000 gallons of water in the system (1 to 500 ppm). Once control is achieved, reduce application rate accordingly.

Control of Slime, Bacteria, Fungi, and Other Microorganisms in packaging and storage vessels such as railcars, trucks, ships, totes, IBCs tanks, etc. used to contain clays, calcium carbonate, titanium dioxide, barium sulfate, and other filler materials.

1. If treating the container or vessel in the field, place the vessel or container on an area with an impervious surface with controlled runoff. Ensure that the antimicrobial treatment solution will not be released to the environment.
2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
3. Prepare a dilute solution of the product by adding 1 to 4 volumes of B-Cap™ 35 Antimicrobial Agent to 11 volumes of potable water. This will provide solutions containing 3% to 10% hydrogen peroxide. Apply the diluted solution, at ambient or elevated temperatures, to the surface as a coarse spray, wipe/mop or flood to reduce bacterial and fungal contamination.
4. Allow antimicrobial agent to contact the surface for a period of time sufficient to ensure adequate cleaning. Depending on the microbial load, contact times can range from 5 to 30 minutes or longer.
5. Drain dry. Do not rinse.

B-Cap™ 35 Antimicrobial Agent is a sterilant for use in conjunction with BIOQUELL HPV generating equipment. The hydrogen peroxide vapor is intended for use as a sterilant in treating enclosures up to 3500 cubic feet *(validated) or greater (non-validated). Use this product for sterilization as* instructed in the BIOQUELL Use Manual. This product may not be used on food-contact surfaces unless followed by a potable water rinse.

For Enclosures up to 35 cubic feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator and add B-Cap® 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 3.1 g/minute for 55 minutes.
4. Allow vapor to remain for a minimum of 3 hours.

5. Aerate the chamber using the BIOQUELL HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

For Enclosures Greater than 35 Cubic Feet to a Maximum of 3500 Cubic Feet

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator and add B-Cap® 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent at an injection rate of 10 g/minute for 2.5 hours.
4. Allow vapor to remain for a minimum of 15 minutes.
5. Aerate the chamber using the BIOQUELL HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.

~~**For Enclosures Greater than 3500 Cubic Feet**~~

1. Ensure that all porous and non-porous surfaces are visibly clean and free from gross organic contamination.
2. Connect the BIOQUELL HPV generator(s) and add B-Cap® 35 Antimicrobial Agent according to the Use Manual instructions. Seal the enclosure to be sterilized.
3. Apply B-Cap® 35 Antimicrobial Agent as directed in the Use Manual for Non-Validated Enclosures. For a time cycle, apply at an injection rate of 10 g/minute and for a time period sufficient to generate 2.5 g/500 cubic feet in the enclosure. For example, a 7000 cubic feet enclosure, inject at 10 g/minute for 35 hours and 1 minute.
4. Allow vapor to remain for a minimum of 15 minutes.
5. Aerate the chamber using the BIOQUELL HPV generator until hydrogen peroxide vapor is at or below 1.0 ppm. See the BIOQUELL Use Manual for complete instructions for aeration and recommended methods of measuring hydrogen peroxide vapor.
6. Validate the cycle using appropriate biological indicators as per the Use Manual.

In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

EMERGENCY TELEPHONE NUMBERS (24 HOURS)
MEDICAL: COLLECT 303-595-9048
TRANSPORTATION: 800-424-9300
OTHER: 609-924-6677

For more information see Material Safety Data Sheet

Proper Shipping Name:
Hydrogen peroxide, aqueous solution with not less than 20 percent but not more than 40 percent hydrogen peroxide.

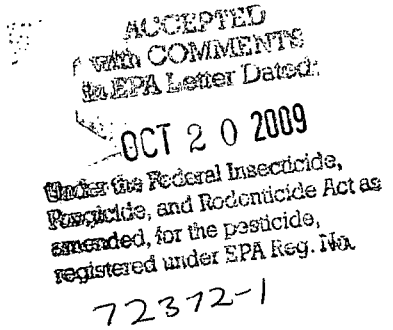
UN 2014

ACCEPTED
with COMMENTS
In EPA Letter Dated:
OCT 20 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
72372-1

BIOQUELL
Bio-decontamination solutions

5/20

Labeling Insert for FMC B-Cap 35 Hydrogen Peroxide Sterilant EPA Registration Number 72372-1



BIOQUELL
Bio-decontamination solutions

1 Overview

FMC B-Cap 35 Hydrogen Peroxide Sterilant has been registered by FMC in accordance with the Federal regulations for use in accordance with the instructions listed in this document. The contents may only be used with BIOQUELL products in line with their user manuals and must not be used for any purpose other than that described.

Before using FMC B-Cap 35 Hydrogen Peroxide Sterilant the operator should ensure that he / she has undergone appropriate training on the specific BIOQUELL HPV generator and has been certified as such. If unsure, refresher training should be arranged before using the unit to run a bio-decontamination cycle.

2 HPV Bio-decontamination

When bio-decontaminating an enclosure (the "Enclosure") using hydrogen peroxide vapor ("HPV"), the operator uses the BIOQUELL HPV generator to inject HPV into the atmosphere of the Enclosure resulting, once saturation conditions have been reached, with the formation of a very thin layer of 'micro-condensation' onto every exposed surface within the Enclosure. It is the formation of this microscopic layer of hydrogen peroxide condensate that provides the rapid efficacy of the bio-decontamination process and thus the success of the bio-decontamination cycle itself.

BIOQUELL's unique HPV generation technology does not pressurize the Enclosure and thus (with adequate area sealing and monitoring) can be safely deployed across a range of different chambers, rooms or enclosures including those facilities that have not been purpose built and designed for use with gaseous sterilants.

Upon completion of the active phase of the bio-decontamination cycle the HPV is catalytically converted into oxygen and water vapor (humidity), thus negating the need for post injection extraction of the vapor via the ventilation system.

A typical hydrogen peroxide vapor bio-decontamination cycle is made up of 4 distinct phases, each of which is described below.

2.1 Conditioning

The conditioning phase is made up of internal system tests within the unit along with the heating of the vaporizer in preparation for the start of the gassing cycle.

2.2 Gassing

During the gassing phase the BIOQUELL HPV generator flash evaporates the FMC B-Cap 35 Hydrogen Peroxide Sterilant to generate HPV which is then injected into an air-stream at a specified rate. The active distribution system injects the HPV into the sealed target enclosure resulting in an increase in the concentration of HPV and, at saturation, producing micro-condensation deposition onto surfaces.

2.3 Dwell

Following the completion of the gassing phase, a pre-established, timed dwell phase results in the HPV circulating throughout the Enclosure ensuring that the HPV sterilant has sufficient contact time with the biological agents to ensure a successful bio-decontamination.

2.4 Aeration

The aeration phase results in the removal of the HPV from the target area, reducing the vapor concentration to < 1PPM, the OSHA PEL (Permitted Exposure Limit) in the United States. This is typically achieved by the catalytic conversion of the HPV into water vapor and oxygen.

The aeration phase can be accelerated using proprietary BIOQUELL equipment, designed and tested for this purpose and application. The process can be further accelerated, where appropriate, using the ventilation system serving the Enclosure. However, use of the ventilation to purge any gaseous sterilant must only be conducted by trained personnel. The restricted access status of the Enclosure may only be revoked upon completion of the aeration phase when the vapor concentration has been verified throughout as < 1PPM or local equivalent exposure level.

3 User Safety Requirements

3.1 Respirator use

In the event of a respirator being required for use with this product, the trained operator conducting the bio-decontamination shall ensure that:

- All respirators are fit for purpose and are fitted with suitable NIOSH approved filters suitable for the perceived breathing hazards.
- All respirator users have undergone appropriate respirator training and have been checked to ensure that they are medically able to wear, and work in the respirator safely and comfortably.

3.2 Handling FMC B-Cap 35 Hydrogen Peroxide Sterilant

FMC B-Cap 35 Hydrogen Peroxide Sterilant contains the active ingredient hydrogen peroxide. Liquid hydrogen peroxide is classified as corrosive and must be handled with the utmost care and whilst wearing appropriate personnel protection equipment, ("PPE"). After handling, users should remove all PPE immediately and wash their hands before eating, drinking, or using the bathroom. Hydrogen peroxide vapor is also harmful in high concentrations and as such liquid hydrogen peroxide should only be handled in open areas or those that have adequate ventilation.

A summary of the health and safety information concerning liquid hydrogen peroxide is shown below, and any PPE used when handling liquid hydrogen peroxide that is not disposable must be maintained in accordance with manufacturers' recommendations.

Skin 	Contact with the skin causes irritation and possible burns. May also cause discoloration, swelling and the formation of blisters. Prolonged or repeated contact may cause dermatitis. Drench the skin thoroughly with water (and wash with soap if available). If spilled on clothing, remove immediately and wash before reuse. Skin contact may cause discoloration (whiteness) of the skin, but this is only temporary and the skin will quickly recover its normal color, usually within one hour. **If symptoms persist, seek medical advice.**
Eyes 	Contact is potentially very serious. Eye contact is corrosive and may cause severe burns, corneal damage and blindness. Do NOT allow victim to rub or keep eyes closed. Irrigate with an eye wash kit or water for at least 10 minutes whilst holding the eyelids open. **Seek immediate medical advice.**
Mouth / Ingestion 	Corrosive and irritating to the mouth, throat, and abdomen. Large doses may cause symptoms of abdominal pain, vomiting, and diarrhea as well as blistering or tissue destruction. Stomach distensions (due to rapid liberation of oxygen), and risk of stomach perforation, convulsions, fluid on the lungs or brain, coma, and death are possible. Do NOT induce vomiting. Rinse mouth thoroughly with water and give the casualty plenty of water to drink. **Seek immediate medical advice.**
Vapor 	Hydrogen peroxide vapor can cause irritation to the eyes, nose, throat, lungs and skin. Acute damage to the respiratory tract may also occur at high concentrations. More serious consequences include insomnia, nervous tremors with numb extremities, chemical pneumonia, unconsciousness and death. Remove casualty immediately to fresh air, rest and keep warm. **Seek immediate medical advice.**
Fire 	During a fire, highly toxic gasses may be generated by thermal decomposition. Do not attempt to tackle a hydrogen peroxide fire. **Call the fire department and ask for chemical emergency team.** (Water **only** should be used on a hydrogen peroxide fire).

10/20

4 Efficacy

FMC B-Cap 35 Hydrogen Peroxide Sterilant is only to be used with BIOQUELL HPV generators and when used correctly is a highly effective sterilant, active against spores, bacteria, viruses, and fungi on exposed, pre-cleaned dry porous and non-porous surfaces in sealed enclosures. FMC B-Cap 35 solution can be used in healthcare, pharmaceutical, defense, university and life sciences sectors including hospitals, office blocks, outdoor sheds, aircraft, retail facilities, restaurants, power stations, schools, factories, laboratories, marine craft, army vehicles, bars, sewage works, nursing homes, pharmaceutical buildings, warehouse/storage facilities, governmental buildings. Mobile medical facilities, domestic residences, water treatment plants.

When FMC B-Cap 35 solution is used in conjunction with BIOQUELL HPV generators, the following validated cycles shall apply:

For use as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures up to 35ft³, inject 3.1g/min for 55 minutes, followed by a 1820 minute dwell, followed by aeration.

For use as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures up to 3,500ft³, inject 10g/min for 150 minutes, followed by a 15 minute dwell, followed by aeration.

For use as a sporicide, fungicide, bactericide, and virucide in sealed enclosures greater than 3,500ft³ in accordance with instructions in part 6.

This product is designed to be used in BIOQUELL HPV generation equipment and may not be used with any other equipment other than for which it was designed. Use of this product in any manner other than for which it was designed is strictly prohibited and may not produce the desired results. This product is not to be used as a terminal disinfectant or sterilant for the processing of critical or semi-critical medical devices.

5 Bio-decontamination Cycle Protocol, (BCP)

Prior to commencing a bio-decontamination cycle of any target enclosure the individual responsible for decontaminating the Enclosure (the "Cycle Manager") must ensure that he / she has adequate and current training and in liaison with the appropriate parties (e.g. the building manager, or supervisor of the proposed Enclosure) a bio-decontamination protocol has been established. This should cover all aspects of the bio-decontamination cycle and may include, but not be limited to:

- Health and safety considerations;
  - monitoring points and frequency,
  - an evacuation plan,
  - any impact on existing evacuation plans (i.e. will isolation of the target enclosure impact on an active fire escape),
  - target area signage,
  - emergency procedures,
  - PPE required for pre-cycle entry,
  - PPE required for post cycle entry.

- Practical considerations;
  - ventilation configuration within the target area,
  - power requirements,
  - access to the target area,
  - biological indicator regime, if any, and location plan,
  - equipment location plan,
  - sealing of the target area,
  - any changes to the fabric of the building or ventilation system since the previous bio-decontamination cycle was performed.

The BCP should be comprehensive and may ultimately take the format of a checklist to ensure that every necessary task has been completed by the Cycle Manager. The BCP should relate to the Enclosure and be appropriately detailed, although the contents of the BCP will by necessity vary with the relative complexity of the Enclosure and the frequency of the bio-decontamination. The aim of the BCP is to ensure that each bio-decontamination cycle is run in a safe, considered and efficient manner - and may also form part of a validation process where consistency and repeatability are important.

As standard procedure, prior to undertaking a bio-decontamination cycle the Cycle Manager and any other operators should re-acquaint themselves with this packaging material, the user manual and any additional training materials supplied with the BIOQUELL HPV generator. These should be read in context with any existing BCPs that have been established for use within the Enclosure, and any applicable local or state laws.

For facilities that are undergoing HPV bio-decontamination for the first time a new BCP should be produced. Subsequent bio-decontaminations of the same facility may be conducted using an existing BCP. The following sections provide a template that a typical BCP may follow although it must be noted that each bio-decontamination and target facility are inherently different and, as such, this list is not exhaustive and each prospective cycle must be considered individually and will present its own points to address.

5.1 Preparation of the BCP - Step 1: Pre-cycle planning

5.1.1 Target Area Dossier

In the cycle planning phase the potential target facility must be inspected and a meeting with any appropriate parties arranged in advance of the cycle. Appropriate people to liaise with may include (but are not limited to):

- The responsible person for the target enclosure (e.g. building manager, unit manager, ward sister, matron etc)
- Site security.
- Safety officer.
- Fire officer.
- Quality Control.

The outcome of the Enclosure inspection should allow compilation of a dossier containing such information as.

- Contact details for both the Cycle Manager and any other responsible persons.
- Target area dimensions, layout, and floor plans.
- A list of any areas not within the target enclosure to be designated as restricted access for the duration of the bio-decontamination cycle, e.g. adjacent plant rooms or technical areas.
- A description of the normal purpose of the prospective target area
- Reason for the bio-decontamination and information concerning the nature of any potential contamination present in the area and subsequent PPE requirements.
- Access and security clearance protocols.
- Details of any on-site inductions / training required
- Photographs of the target facility where appropriate.
- Access information for transfer of equipment into (pre-cycle) and out of (post cycle) the target enclosure. This is particularly pertinent in aseptic/GMP or containment applications.
- A description, and where possible/appropriate drawings of the ventilation system serving the target facility, and the status of the system throughout each stage of the cycle. In certain configurations heating, ventilation and air-conditioning, (HVAC), systems have the potential to reduce cycle times by accelerating the aeration phase, but more importantly represent a severe risk of vapor leakage to other areas and, as such, **MUST** be clearly understood before proceeding with any aspect of the bio-decontamination. The following points should be considered:
    - Regardless of the configuration of the HVAC system, it **must** be isolated for the duration of the 'gassing', and 'dwell' phases of the bio-decontamination cycle, either by shutting the system down or by appropriately sealing the inlet and outlet ducts.
    - If the target facility has been designed with gaseous fumigation in mind **and** an appropriate HVAC fumigation protocol is in place then the HVAC system may be re-instated during the aeration phase. Reinstating the HVAC system serves to purge the HPV from the target enclosure and thus accelerate the aeration phase, and ultimately reduce the total cycle time.
    - If the HVAC system serving the target area is common to other areas outside the target area, or if the HVAC system cannot be shutdown within the enclosure then both inlet and outlet ducts must be sealed and remain sealed for the duration of the cycle. The sealing material may only be removed once the cycle has been completed, i.e. the HPV concentration within the target area is <1PPM and safe for personnel re-entry.
    - If the cycle manager is in any doubt as the configuration of the HVAC system then both inlet and extract ducts must be sealed for the duration of the cycle.
- A marked floor plan of the area showing possible vapor leakage paths, areas to be sealed and where signage is to be displayed. Signage must be in the appropriate languages (e.g. English and Spanish) and should display the emergency contact information of the cycle manager and remain in place for the duration of bio-decontamination cycle. Potential leakage paths to be illustrated on the plan and sealed include, but are not limited to:
    - Doors and all access points to the facility (windows, pass through hatches, inspection ports, ill fitting pipe-work).

ACCEPTED
With Comments
In Letter Dated
OCT 20 2009
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 72372-1

BIOQUELL
Bio-decontamination solutions

  - All potential access points to any floors above and below the target facility including chutes, electrical risers, chimneys, hatches, damaged/loose flooring, pipe-fittings.
  - Damaged, missing, or worn sections of false ceilings within the facility.
  - Any potentially damaged areas of the fabric of the target area itself.
- A global plan/sketch of the area surrounding the target enclosure showing evacuation routes and the location of emergency equipment (e.g. fire extinguishers, fire alarm 'break-glass' points, emergency shower/eye-wash stations, telephones).
- An evacuation plan in the event of an emergency listing muster points and a list of appropriate emergency contact telephone numbers including:
  - Cycle manager.
  - Target area responsible person (e.g. Unit Manager / supervisor).
  - On-site emergency personnel (if applicable).
  - Local emergency services (Fire, ambulance, police, hospitals).

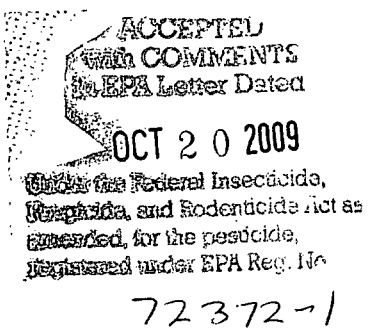
Whilst it is essential that all areas are independently assessed for suitability, if there are a number of identical enclosures, or enclosures which are representative of each other, it is not essential that a new or full BCP is completed for every decontamination. However, the Cycle Manager must ensure that all processes and procedures are carried out in accordance with a generic dossier, with any enclosure specific alterations adhered to.

5.1.2 Pre-cycle Planning File

On completion of the target area dossier it should be compiled along with all other pertinent documentation to form a single file. Documents that should be compiled include the following (where applicable).

- A HVAC system bio-decontamination protocol (if applicable).
- Bio-decontamination cycle protocol, BCP, documents from previous cycles within the target area.
- The training records of the cycle manager and all other operators of the BIOQUELL HPV equipment.
- User manuals and calibration records for the BIOQUELL HPV generators and pertinent ancillary equipment to be used during the fumigation (e.g. Handheld HPV sensors).

Each facility will have its own protocols and procedures which govern actions on site. The list presented here is a guide and should be used as the basis of the planning file.



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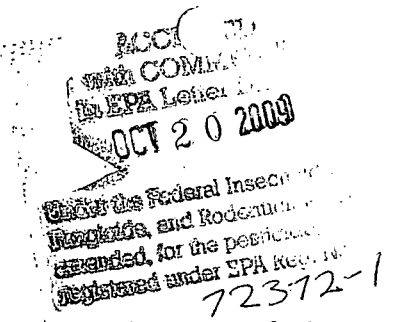
Bio-decontamination solutions



5.2 Step 2: Notification

5.2.1 Personnel Briefing

Prior to commencing any HPV bio-decontamination cycle it is of the utmost importance that all personnel who may have access to the target facility are made aware of the process. All staff/personnel should be briefed in-terms of the logistical factors (cycle timings, areas designated out-of-bounds, restricted access areas, monitoring points) and how their normal working practices may be impacted for the cycle duration and, of course, the health and safety aspects of HPV bio-decontamination.

If appropriate a briefing session should be arranged with key personnel that may routinely have access to the target area and they should be made aware of relevant aspects of the bio-decontamination to be performed including:

- Proposed cycle timings and timescales.
- Target enclosure boundaries.
- Other areas that are to be designated restricted access zones.
- Monitoring points during the cycle (e.g. is access required to patient areas adjacent to the target enclosure?).
- Emergency procedures and evacuation routes.
- Any impact on existing emergency procedures (i.e. does the target area obscure an active fire escape route if so alternative arrangements must be made prior to the cycle start).
- A background of HPV and the bio-decontamination process.

When performing a bio-decontamination cycle within a public building where access protocols and restrictions are more difficult to enforce the briefing should be given to relevant facility staff and additional personnel drafted in as appropriate to 'police' doors and access points to the target/restricted areas for the duration of the cycle.

5.2.2 Cycle Operator Briefing

Prior to the cycle start the cycle operators should have a separate briefing in which all aspects of the BCP are discussed in order to ensure that all cycle personnel are familiar with the detail of the proposed bio-decontamination schedule.

5.2.3 Signage

Each access point to the target enclosure must display adequate signage to ensure that no person may gain unauthorized access to the target enclosure. Signs should always adhere to local legislation and requirements.

5.3 Step 3: Target Enclosure Sealing

All possible leakage paths that were identified within the target area dossier must be adequately sealed to prevent leakage of HPV from the target enclosure but also to prevent the ingress of fresh air into the target enclosure that can dilute the HPV and impinge on the efficacy of the cycle. A number of sealing methods may be used including non-marking adhesive tape, dedicated blanking sheets, or if sealing

ventilation ducts then mechanical gas-tight dampers may be used as appropriate. Alternative methods to those listed are available.

When sealing potential leakage paths, they should be sealed using a secure method that will ensure the seal will be maintained for the duration of the bio-decontamination cycle, this is especially pertinent when sealing inlet ventilation grills where pressure can occasionally build up.

5.4 Step 4: Target Enclosure Preparation

Prior to commencing any bio-decontamination cycle the target enclosure should be optimized in order to maximize the efficacy and achieve a rapid and consistent bio-decontamination. There are a number of steps to be taken and these are listed and discussed below.

5.4.1 Cleaning

Hydrogen peroxide vapor has limited penetrating power into dirt and other gross contamination and thus prior to commencing the bio-decontamination cycle the target area must be subject to a minimum level of cleaning to ensure that the target area is *visibly clean* - i.e. free from all gross contamination including dust, dirt, blood, faeces, animal feed. If large levels of dust or dirt are present upon commencing the cycle then viable micro-organisms may well be present below the gross contamination and could possibly survive the bio-decontamination process.

5.4.2 Absorbent Materials

Whilst absorbent materials can safely remain within the target area and be exposed to the bio-decontamination cycle (although subsequent desorption will extend the aeration process) in many situations it is favorable for these to be removed if appropriate.

Consumables (gloves, paper towels etc) can remain within the target area although the risk of surface area occlusion becomes an issue if large amounts of consumables are present within a small area.

5.4.3 Occluded Surfaces

HPV is not freely penetrating through many materials; as such it is vitally important that the occurrence of occluded (i.e. covered) surfaces is minimized. This is achieved by opening all cupboards and drawers to expose the internal surfaces (and contents) along with any other equipment within the area that can be opened or configured such to ensure the maximum surface area is exposed.

5.4.4 Extremes of Temperature

The hydrogen peroxide vapor bio-decontamination process relies on saturation of the atmosphere of the sealed target area with vapor in order to form a layer of micro-condensation of hydrogen peroxide that in turn affects the bio-decontamination; as such any factors that can effect the formation of the condensate layer must be controlled. Temperature gradients within the target area should be avoided as cooler surfaces will see the formation of micro-condensation sooner and more plentifully than warmer areas and as such areas within the same

room may not be exposed to the same cycle. Failure to do so may potentially lead to reduced efficacy of the bio-decontamination cycle due to uneven vapor distribution throughout the target enclosure.

In order to prevent the formation of temperature gradients all equipment that operates outside ambient room temperature should be shutdown in advance of the cycle and allowed to return to ambient temperature prior to the commencement of the bio-decontamination cycle. Such equipment includes hot rooms, autoclaves, incubators, refrigerators, freezers, cold rooms, ovens etc.

5.4.5 Active Air-paths

As with all gaseous sterilants airflows present within the target area can impinge on vapor distribution and thus the cycle itself. Any equipment that re-circulates air flow solely within the target area can be left running throughout the cycle although if there is any internal filtration within the equipment itself the cycle parameters should be changed as appropriate to counteract the absorption within the filters. E.g. recirculatory safety hoods within the target area may be left running although the cycle should be elongated to counteract absorption into the filters. Equipment such as computers and laptops should be left running to draw HPV through the unit itself, thus bio-decontaminating the internals of the machine.

5.5 Step 5: Cycle Start

Before commencing the bio-decontamination cycle the Cycle Manager should go through the BCP as a checklist acknowledging that all necessary steps have been completed ensuring the safety of the cycle.

The facility manager should also confirm that all personnel who work within the target facility and any personnel who may have cause to access the area (e.g. cleaning or security staff) have been notified about the cycle and all evacuation and emergency procedures.

Upon completion of the acknowledgement procedures the Cycle Manager may then begin the bio-decontamination cycle.

5.6 Step 6: Monitoring

Monitoring the bio-decontamination cycle takes two distinct phases, monitoring the perimeter of the target enclosure for vapor leakage, and monitoring the vapor concentration within the target enclosure to monitor the cycle progress, and ultimately to confirm the end of the cycle.

5.6.1 Leak Monitoring

The cycle operators should use a hand held hydrogen peroxide sensor in order to verify that there is no escape of vapor from the target enclosure, by monitoring the perimeter of the target area along with any areas that are served by a common ventilation system. Leak monitoring should continue through the gassing and dwell phases of the bio-decontamination cycle.

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5.6.2 Cycle Monitoring

The progress of the bio-decontamination cycle itself should (where applicable) be monitored using remote sensory equipment placed within the target area. The sensors should be configured such that they provide real-time data of the cycle parameters within the target enclosure. This data should then be logged at regular intervals throughout the cycle to record the cycle progress. On completion of the gassing and dwell phases, as the cycle moves into aeration the sensors allow verification of the vapor concentration for post-cycle re-entry.

5.7 Step 7: Cycle Completion

5.7.1 Cycle Finish Verification

A bio-decontamination cycle is completed once the cycle is in the aeration phase and the vapor concentration is below the applicable local exposure limit for personnel re-entry without the need for any respiratory apparatus, (<1PPM). The vapor concentration should first be verified using the remote sensors (where applicable) and if they read < 1PPM (or other appropriate local exposure limit) then personnel may re-enter the target enclosure with a high-resolution hand held hydrogen peroxide monitor to perform an enclosure concentration measurement. If the concentration throughout the facility is measured at less than 1PPM the bio-decontamination cycle has been completed.

5.7.2 Post-cycle Re-entry

Prior to re-entering the target enclosure personnel must first ensure that the measured vapor concentration is <1PPM (or appropriate local limit). The Cycle Manager should liaise with the facility or unit manager prior to re-entry to take into account any gowning/PPE protocols that may be in place within the area. This is especially pertinent when performing bio-decontamination cycles within aseptic or containment scenarios.

Upon verification that the vapor concentration is safe for re-entry and removal of all bio-decontamination and sampling equipment from within the target enclosure, all signage should be removed, all sealing materials removed and the area 'released' for normal operation.

5.7.3 Cycle Success Criteria

A bio-decontamination cycle may be declared successful if the validation standards defined in the BCP have been satisfied, and the aeration phase has been completed with the vapor concentration within the target enclosure confirmed as < 1PPM.

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6 Validated and Non-Validated Use

6.1 Validated Use in Enclosures up to 3,500ft³

Validated bio-decontamination cycles utilizing FMC B-Cap 35 solution and BIOQUELL HPV generators have been developed for use as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures up to 35ft³, and 3,500ft³.

The cycle parameters are,

For use as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures up to 35ft³, inject 3.1g/min for 55 minutes, followed by a 1820 minute dwell, followed by aeration.

For use as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures up to 3,500ft³, inject 10g/min for 150 minutes, followed by a 15 minute dwell, followed by aeration.

6.2 Non-Validated Use in Enclosures greater than 3,500ft³

FMC B-Cap 35 hydrogen peroxide solution may also be used as a sterilant, sporicide, fungicide, bactericide, and virucide in sealed enclosures of various volumes (including enclosures greater than 3,500ft³) with the development of a customized validated bio-decontamination cycle.

The set-up and cycle management phases of customized cycles are identical to those for a validated cycle with regard to the preparation of the bio-decontamination cycle protocol, ("BCP"), and target area set-up and sealing procedures.

In order for a customized cycle to be effective it is vital that the Cycle Manager gives due consideration to global vapor distribution throughout the target facility in order to ensure uniform formation of micro-condensation. As such, due consideration must be given to the number and location of BIOQUELL HPV generators deployed during the cycle, and the appropriate use of oscillating distribution fans or other appropriate equipment to ensure good vapor distribution. In accordance with the procedures described above the positions of all equipment used within the bio-decontamination cycle should be recorded on a facility plan within the BCP.

When performing customized validated cycles the cycle must be capable of attaining the required bio-burden reduction (as specified in the BCP), and have appropriate use of pre-determined indicators to ensure that the specified level is reached throughout the target facility.

On completion of the target area set-up and sealing procedures (including indicator placement) (sections 5.1 to 5.4), the Cycle Manager can begin the cycle; the cycle itself will have the same structure as a validated cycle with discrete conditioning, gassing, dwell and aeration phases.

Upon successful completion of the 'conditioning' phase (including system test) the cycle moves into the 'gassing' phase with HPV injected into the enclosure. The Cycle Manager should monitor the cycle environmental data from within the target enclosure recorded via the on-board sensory equipment in order to recognize the

point of onset of micro-condensation, the dew-point. Once micro-condensation has been achieved within the enclosure the cycle then moves into the 'dwell' phase in which the vapor is allowed to circulate within the target enclosure and ensure adequate contact time is allowed between the sterilant and the biological agents to affect a successful bio-decontamination.

Upon completion of the dwell phase the cycle moves in the aeration phase removing the HPV from the target area, reducing the vapor concentration to < 1PPM, the OSHA PEL (Permitted Exposure Limit). Once the vapor concentration has been confirmed as <1PPM, the restricted access status of the target facility may be revoked and the facility 'released' back into normal operation.

Should a cycle fail to meet the pre-determined target challenge then the cycle has not been successful and the cycle should be repeated with the gassing and/or dwell periods increased, and the validation process repeated.

When conducting any bio-decontamination cycle validated or non-validated all user safety procedures listed in section 3 and operational procedures in section 5 (including monitoring and post cycle re-entry) must be adhered to and overseen by the Cycle Manager.

6.2.1 Biological Indicators, BIs

In order to assess the success of bio-decontamination cycles a standard challenge is used to ensure that the cycle has been effective. Whilst various validation methods can be used biological indicators, (BIs), are the industry standard method for validation of hydrogen peroxide bio-decontamination cycles as they present the most consistent, and repeatable challenge.

A number of organisms may be used although the accepted organism is *Geobacillus stearothermophilus;* Bacillus endospores are the most resistant class of organisms to deactivation and thus provide suitable challenge organisms. *Geobacillus stearothermophilus* also has inherent practical operational advantages in that it is thermophilic with an optimum incubation temperature of 57°C, limiting the possibility of false positives due to the high incubation temperature. It is also a category 1 organism so is not harmful to humans and thus may be easily and safely handled.

The industrially accepted biological indicator challenge is a 6-log (i.e. > 1,000,000 spores per indicator) inoculum of *Geobacillus stearothermophilus* although lower challenge BIs (i.e. 4-log - 10,000 spores) are also commercially available. Experience has shown that the most consistent BIs are those that are inoculated onto a stainless steel substrate; other inoculum substrates including paper are available but experience has shown them to be less consistent and repeatable.

BIs should be placed throughout the target enclosure typically placed in the corners of rooms where a 'dead spot' in terms of vapor distribution is formed at the point where three walls meet. The number of indicators used is at the discretion of the cycle manager but typically 1 BIs per 15m³, and each location should be recorded on a floor plan of the target enclosure and should be kept with the bio-decontamination plan.

Upon completion of the bio-decontamination cycle the BIs should be retrieved and incubated as per the organism protocols and the results available after the defined incubation period.

6.2.2 Chemical Indicators, CIs

Chemical indicators, (CIs) that change color in the presence of hydrogen peroxide vapor are also commercially available. CIs offer no quantitative insight as to the dosage of HPV received only providing a crude assessment of the vapor distribution by visually comparing the degree of color change. It is BIOQUELL best practice that CIs are not used as a method of cycle validation.