

4972-43

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mark Alleman  
Protexall Products, Inc.  
73356 Hwy 41  
Pearl River, LA 70452

JUL -7 2014

SUBJECT: Sun Pac Mildewcide  
EPA Registration Number: 4972-43  
Application Dated: April 14, 2014  
Receipt Date: April 23, 2014

Dear Mr. Alleman:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- Minor revisions to label

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. A stamped copy of your labeling is enclosed for your records.

Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E).

In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

CONCURRENCES

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This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Eric Miederhoff at (703) 347-8028.

Sincerely,



Eric Miederhoff  
Acting Product Manager (33)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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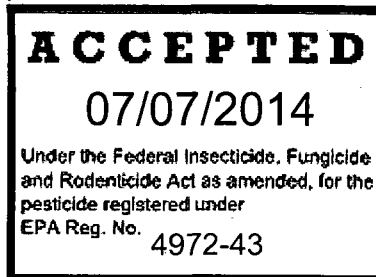
KEEP OUT OF REACH OF CHILDREN.  
DANGER POISON



For use as a Fumigant/Sterilant for  
Laboratories And Equipment - Leafcutting Bee Nesting Material

Active Ingredient:  
Paraformaldehyde .....91%  
Inert Ingredients .....9%  
Total: .....100%

E.P.A. Reg. No. 4972-43  
E.P.A. Est. No. 4972-LA-1



**Directions For Use:**

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

**For Use as a Fumigant - Sterilant**

For use in generating formaldehyde gas to fumigate and sterilize pre-cleaned (if feasible) hard, non-porous and porous surfaces in sealed enclosures located in government, industrial, commercial and institutional microbiological laboratory settings, including human and animal research facilities, laboratory equipment, biological safety cabinets, HEPA filters and their associated housings, airlocks and leafcutting bee nesting materials and leafcutting bee cells only.

Read and follow respective Product Manual for complete directions. Do not use without an approved fumigation plan (see Product Manual).

Laboratories Product Manual

([www.mold-kil/manual/labuse.pdf](http://www.mold-kil/manual/labuse.pdf))

Leafcutting Bee Product Manual

([www.mold-kil/manual/leafcutterbee.pdf](http://www.mold-kil/manual/leafcutterbee.pdf))

Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices.

First Aid	
<b>If in eyes</b>	- 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. - Call a poison control center or doctor for treatment advice.
<b>If on skin</b>	- 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.
<b>If swallowed</b>	- Call a 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 by a poison control center or doctor. - Do not give anything to an unconscious person.
<b>If inhaled</b>	- Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. - Call a poison control center or doctor for further treatment advice.

**Environmental Hazards:** This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the 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.

**Physical or Chemical Hazards:** Stable but may decompose if heated. Avoid contact with heat, sparks, open flame, and static discharge. Avoid dust generation. Do not mix with strong acids, strong bases or strong oxidizing agents. Paraformaldehyde decomposes to formaldehyde which can build up in a shipping container depending on time and temperature during transit. The level of formaldehyde exposure may be instantaneously high when the shipping container is opened.

**Storage and Disposal:**

Do not contaminate water, food, or feed by storage or disposal.

**Storage:** Keep away from sources of ignition. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep containers tightly closed. Paraformaldehyde decomposes to formaldehyde vapor. Use precautions against formaldehyde exposure when opening containers or entering a poorly ventilated storage area. In case of spill or leaking container: Clean up immediately. Place leaking containers in well-ventilated area. Eliminate ignition sources. To clean up spill, flush area sparingly with water or use an absorbent. Avoid runoff into storm sewers and ditches leading to natural waterways. Neutralize with ammonium hydroxide or sodium sulfite. Contact the manufacturer and your local Department of Agriculture in case of a spill, and for clean-up of spills. Lock the storage area, store product in the original container only, if a leaky container must be contained within another, mark the outer container to identify the contents. Separate products during storage to prevent cross-contamination with other pesticides, fertilizer, food and feed.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain. Dispose of in accordance with federal, state and local requirements.

**Pesticide Disposal:** Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**Precautionary Statements:**

Hazards to Humans and Domestic Animals.

**DANGER** Corrosive. Causes irreversible eye damage and skin irritation. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Do not get in eyes or on clothing. Avoid breathing dust or vapor. Wear protective eyewear and neoprene rubber, latex, vinyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FOR MAXIMUM EFFECTIVENESS - KEEP VAPORS CONFINED AS MUCH AS POSSIBLE.

**For use as a Household Mildewcide**  
LASTS FOR MONTHS  
PACKAGED SUNSHINE FOR  
YOUR STORAGE NEEDS  
KILLS MILDEW & RIDS MUSTY ODORS  
PROTECTS  
CLOTHING - LEATHER - PAPER - WOOD

**Household Mildewcide:**

Use only in unoccupied structure that can be ventilated (6) hours prior to re-occupancy. AVOID DIRECT CONTACT WITH COLORED MATERIALS ONLY. EASY TO USE. For clothing and linen storage bins, cupboards, bathroom and kitchen cabinets not containing any food, dresser drawers, trunks, suitcases, lockers, golf bags, trailers. Hang cloth bag in closet or lay on shelf or in drawer. Contents of this bag will treat up to 700 cu. ft. Sun Pac fumes are heavier than air. For best results place bag at highest point in area to be protected. Sun Pac

quickly and effectively rids all areas of mildew, musty odor. Occasional inspection to replenish supply if continued effectiveness is desired. Do not store photographic film in same area.

When closing home for vacation or season, place one bag Sun Pac for each 700 Cu. ft. of space. Home will be sunshine fresh, no mildew or musty odor.

For musty odors in bedding, place one bag Sun Pac along with mattress, quilts, blankets, sheets in a sealed closet space no larger than 100 cu. ft. Leave articles 24 hours. Bedding will be clean, sweet and fresh.

PROTEXALL PRODUCTS, INC. 1-800-458-2699 www.mold-kil.com

**Container Specifications:**

For Laboratory and Leafcutting Bee Nesting Area Use:  
Gallon Plastic Jug with Child resistant Cap - Net Weight 112 Ounce

For Household Use:  
Child resistant Plastic or Foil Bag - Net Weight 3 Ounce and 4 Ounce

**Storage:** Always store pesticides in the original container. If a leaky container must be contained within another, mark the outer container to identify the contents. Storage areas must be locked and secure from vandalism, with precautionary signs posted. The storage area must be dry, well-lit, and well-ventilated. Keep pesticide storage areas clean. Clean up any spills promptly. Store pesticides away from food, pet food, feed, seed, fertilizers, and veterinary supplies. Protect pesticide containers from extreme heat and cold.

**Pesticide Disposal:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**Container Handling** Nonrefillable container. Do not reuse or refill this container. **If empty:** Wrap in newspaper and discard in trash.

# Product Manual for SunPac Mildewcide



Danger - Poison

This Product Manual is for fumigation of leafcutting bee nest material and leafcutting bee cells only.

EPA Reg. No. 4972-43  
EPA Est. No. 4972-XX-00000

Protexall Products, Inc.  
73356 Hwy 41  
Pearl River LA 70452  
1-800-458-2699

**PRECAUTIONARY STATEMENTS: Hazards to Humans and Domestic Animals.**

DANGER Corrosive. Causes irreversible eye damage and skin irritation. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Do not get in eyes or on clothing. Avoid breathing dust or vapor. Wear protective eyewear and neoprene rubber, latex, vinyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

<b>First Aid</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>- 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.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin</b>	<ul style="list-style-type: none"> <li>- Take off contaminated clothing.</li> <li>- Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>- Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>- Call a poison control center or doctor immediately for treatment advice.</li> <li>- Have person sip a glass of water if able to swallow.</li> <li>- Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>- Do not give anything to an unconscious person.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>- Move person to fresh air.</li> <li>- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>- Call a poison control center or doctor for further treatment advice.</li> </ul>

**DIRECTIONS FOR USE:**

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

Carefully read and follow the label and this product manual. Inform owner or person in charge of the treated structure and/or space of the plans for fumigation. Be familiar and comply with all applicable state and local laws.

Place nest material or bee cells in well-sealed fumigation chamber. Because problems may occur with persistence of formaldehyde vapor under certain conditions, treatment of nest material or bee cells must only be undertaken in a chamber designed specifically for paraformaldehyde fumigation and not used for any other purpose. Review MSDS prior to use and ensure access to MSDS during treatments. Prior to fumigation, condition nest material or bee cells in the chamber for 48 hours at 20-25°C (68°-77° F) with a relative humidity of 60-70%. Fumigate with paraformaldehyde at a rate of 1.1 lb. /1000 cubic ft. (5 g/cubic ft.) of fumigation chamber by placing product in heat generation unit (electric frying pan) attached to electric timer. Set timer to heat product for 4 hours at a heat setting of at least 400° (but no more than 475° F) in the sealed and locked chamber. After 24 hours, the formaldehyde gas must be neutralized by heating ammonium carbonate or bicarbonate to generate ammonia

gas. For an application rate of 5 grams per cubic foot of paraformaldehyde, the amount of ammonium carbonate needed is calculated by multiplying the cubic feet of the unit (length X width X height in feet) by 20 grams per cubic foot. For ammonium bicarbonate at this application rate, the ratio is 27 grams per cubic foot. Place the correct total amount of neutralizer in one or more electric heating devices during setup. When the formaldehyde exposure time has been completed, turn on the electric heating device until decomposition is complete (from 30 minutes to 3 hours). After neutralization is complete, begin continuous ventilation of chamber by exhausting from the top of the chamber to the outside and ensuring an adequate incoming flow of fresh air. Then test the air with a device or method capable of measuring 0.1 ppm formaldehyde (e.g., a Draeger detection tube used with a formaldehyde activation tube) to ensure that the formaldehyde concentration is below this level before allowing unprotected reentry. If formaldehyde is still detectable above 0.1 ppm, ventilate for an additional 24-48 hours. Re-enter chamber without respiratory protection only after the air concentration of formaldehyde is less than 0.1 ppm. Following fumigation, deploy nest material directly in the field. Bee cells should be placed in the incubator following adequate ventilation.

Check the adjacent space for any leakage during the application, neutralization and aeration periods using a device capable of measuring 0.1 ppm formaldehyde. Document the test methods used as well as the times and data collected. Record where the data was collected.

Applicators must minimize impacts to migratory birds, particularly nesting and developing young that are more vulnerable to toxicity. Since releases to the environment are largely confined to vents at fumigation facilities, facility designation procedures and designs should take into account the location of occupied nesting habitat and potential nesting habitat in an effort to avoid direct exposure to birds. Facilities must be sited away from nesting bird habitats, or the timing of fumigations be altered to avoid periods of increased bird use in the surrounding area.

**PROTECTIVE CLOTHING AND RESPIRATORY PROTECTION:**

If reentering the fumigation chamber before neutralization has occurred, use self-contained breathing apparatus (SCBA). If reentering after neutralization, wear a powered air purifying or full face negative pressure respirator with cartridges or an industrial canister approved by NIOSH/MSHA for use with formaldehyde. The respirator must be fit tested and fit checked using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134). The respirator user must be trained using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134). The respirator user must be cleared by a qualified medical practitioner as being able to safely wear the style of respirator to be worn. The respirator must be maintained according to a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134). Persons weighing/preparing and application of the paraformaldehyde must wear neoprene rubber, latex, vinyl or nitrile gloves and protective eyewear. Persons engaged in setup, application and monitoring must wear Saranex coated coveralls or equivalent. Wash thoroughly with soap and water after handling.

**PLACARDING/SIGNAGE:**

The applicator in charge of the fumigation must placard all entrances to the fumigated areas or spaces with signs bearing:

- Skull and crossbones symbol
- DANGER/PELIGRO
- Areas or spaces under fumigation. DO NOT ENTER/NO ENTRE.
- Date and time of fumigation
- Name, address and telephone number of the applicator
- Do not enter or allow entry by unprotected persons into the fumigated areas or spaces until the signs are removed. Signs must not be removed before the air concentration level of formaldehyde is measured as less than 0.1 ppm.

**ENVIRONMENTAL HAZARDS:**

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the 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.

**IN CASE OF FIRE:**

Use CO<sub>2</sub> or dry chemical for small fires, alcohol-type aqueous film-forming foam or water spray for large fires. Use water spray to cool fire-exposed vessels or structures. Wear self-contained breathing apparatus (SCBA) and complete personal protective equipment when potential for exposure to vapor or products of combustion exists.

**IN CASE OF SPILL:**

Clean up immediately. Place leaking containers in well-ventilated area. Eliminate ignition sources. To clean up spill, flush area sparingly with water or use an absorbent. Avoid runoff into storm sewers and ditches leading to natural waterways. Neutralize with ammonium hydroxide or sodium sulfite. Contact the manufacturer and your local Department of Agriculture in case of a spill, and for clean-up of spills.

**STORAGE AND DISPOSAL:**

Do not contaminate water, food, or feed by storage or disposal.

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**STORAGE:**

Keep away from sources of ignition. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep containers tightly closed. Paraformaldehyde decomposes to formaldehyde vapor. Use precautions against formaldehyde exposure when opening containers or entering a poorly ventilated storage area. In case of spill or leaking container: Clean up immediately. Place leaking containers in well-ventilated area. Eliminate ignition sources. To clean up spill, flush area sparingly with water or use an absorbent. Avoid runoff into storm sewers and ditches leading to natural waterways. Neutralize with ammonium hydroxide or sodium sulfite. Contact the manufacturer your local Department of Agriculture in case of a spill, and for clean-up of spills. Do not contaminate food or feed.

**PESTICIDE DISPOSAL:**

Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

**CONTAINER HANDLING:**

Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain. Dispose of in accordance with federal, state and local requirements.

**NOTICE TO BUYER:**

Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product and accepts the product on that condition.



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# Laboratories Product Manual for SunPac



## Danger - Poison

SunPac has been registered by Protexall Products, Inc. for use in fumigating/sterilizing/decontaminating pre-cleaned, porous and non-porous surfaces in the sealed enclosures listed under EFFICACY below. Uses other than those specified in this Product Manual are not permitted and may not be effective.

Review and follow all SunPac Product Manual instructions and precautions on how to properly apply this product. This product may be applied only by persons who are trained in the application procedures and use of the safety equipment specified in this Product Manual. All personnel involved in the application must be familiar with the guidance pertaining to use of paraformaldehyde/formaldehyde for laboratory and laboratory equipment decontamination in "Biosafety in Microbiological and Biomedical Laboratories, 5<sup>th</sup> Edition" (U.S. DHHS, PHS, CDC, NIH, December 2009) and in "NSF/ANSI Standard 49, Annex F" (2011).

### PRODUCT MANUAL

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Protexall Products, Inc  
73356 Hwy 41  
Pearl River, LA 70452

EPA Reg. No 4972-43 EPA Est. No. 4972-LA-1

**OVERVIEW OF THE FUMIGATION/STERILIZATION/DECONTAMINATION PROCESS**

Effective application of this product requires generating and maintaining an adequate concentration of formaldehyde gas in a sealed enclosure for a specified exposure time, temperature and relative humidity, as described in APPLICATION TO THE SEALED ENCLOSURES below. The fumigation/sterilization/decontamination process consists of several phases:

**Establishing Conditions** – The enclosure must be pre-cleaned and sealed where feasible (see PREPARATION OF ENCLOSURES below), and then the temperature and humidity of the enclosed space must be adjusted to be within the operational parameters described in APPLICATION TO THE SEALED ENCLOSURES below. Pre-cleaning sealed HEPA filters and associated housings and similar enclosures prior to fumigation may not be feasible as it may pose a risk of exposure to applicators and/or a release of contaminating agents to the environment.

**Fumigation/Sterilization/Decontamination**– Place the appropriate amount of paraformaldehyde in an electric heating device or generator and heated until depolymerized to produce formaldehyde gas. The enclosure must be kept sealed for at least 10 hours to allow for all exposed surfaces to be sterilized/decontaminated.

**Confirmation of Efficacy with Biological Indicators (BIs)** – Place BI's containing at least 6 logs of *Bacillus subtilis*, *Bacillus atrophaeus*, or *Geobacillus stearothermophilus* spores in the area or space to be treated. One BI per 1000 cubic feet of internal volume plus one untreated BI as a positive control for each two BIs used (same lot number) is recommended. In small, standardized spaces such as Biological Safety Cabinets (BSC), two BIs are recommended to validate that repeated fumigations will be effective. After neutralization or aeration, retrieve exposed BIs and incubate and analyze them per manufacturer instructions. One or more positive BIs may indicate failure of the treatment process and requires an evaluation by qualified personnel to determine if the sterilization/decontamination process should be repeated after any necessary corrective steps identified from evaluation findings are taken.

**Neutralization**– After the specified contact time (at least 10 hours) has been met, heat a measured amount of ammonium carbonate or ammonium bicarbonate to convert it to a gaseous form which neutralizes the formaldehyde.

**Aeration**- After neutralization is completed, proceed with aeration typically to the outside and test the air with a device capable of measuring 0.1 ppm formaldehyde (e.g., a Draeger detection tube used with a formaldehyde activation tube) to ensure that the formaldehyde concentration is below this level before allowing unprotected reentry.

**USER SAFETY REQUIREMENTS**

**Personal Protective Equipment (PPE):**

**Respirator requirements:** If reentering a treated space prior to neutralization, wear a Self-Contained Breathing Apparatus (SCBA). If reentering after neutralization, wear a powered air purifying or full face negative pressure respirator with cartridges or an industrial canister approved by NIOSH/MSHA for use with formaldehyde. No respirator is required after the measured level of formaldehyde in air is less than 0.1 ppm.

When a respirator is required for use with this product:

- The respirator must be fit tested and fit checked using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134). The respirator user must be trained using a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134)
- The respirator user must be cleared by a qualified medical practitioner as being able to safely wear the style of respirator to be worn.
- The respirator must be maintained according to a program that conforms with OSHA's requirements (see 29 CFR Part 1910.134)

**OSHA Monitoring Program:** The user must be enrolled in a formaldehyde monitoring program, as per 29 CFR 1910.1048.

**Other Protective Clothing:** Persons weighing/preparing the paraformaldehyde, or retrieving spore strips (or other biological indicators), must wear neoprene rubber, latex, vinyl or nitrile gloves, and protective eyewear. Persons that may be exposed to free paraformaldehyde gas should wear appropriate PPE, including respiratory protection and protective clothing that prevents or significantly reduces dermal and/or mucosal exposure. Such PPE could include Tyvek or Tychem, other Saranex-coated protective clothing, or their equivalent. PPE must be chosen based on an adequate assessment of the risk to personnel given the local conditions and exposure potential (including expected or measured concentration of gas), and personnel must be trained to prevent contact exposure during donning and doffing of the PPE.

**Precautionary Statements:** DANGER Corrosive. Causes irreversible eye damage and skin irritation. May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Do not get in eyes or on clothing. Avoid breathing dust or vapor. Wear protective eyewear and neoprene rubber, latex, vinyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

**User Safety Recommendations:**

- Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Users should remove clothing/PPE immediately if eyes or skin come in contact with the fumigant. Wash affected area thoroughly.
- Users should remove all PPE immediately after handling this product. Wash the outside of gloves before removing, or turn gloves inside out when removing. As soon as possible, wash hands thoroughly with soap and water."
- Users should have available to them, and be familiar with, all Material Safety Data Sheets regarding formaldehyde and the neutralizing agent.

**EFFICACY**

**Approved Uses:** SunPac is registered for use in generating formaldehyde gas to fumigate/sterilize/decontaminate pre-cleaned (where feasible), non-porous and porous surfaces in sealed enclosures located in government, industrial, commercial and institutional microbiological laboratory settings, including human and animal research facilities and areas, animal isolation rooms, animal cages, necropsy suites, ancillary equipment, biological safety cabinets, supply and exhaust filter systems including associated pre and HEPA filters, chambers, and airlocks.

**Use Restrictions:** This product may not be used as a terminal high level disinfectant or sterilant for reprocessing of any critical or semi-critical medical device in a healthcare setting. Do not use in food handling areas or food and beverage consumption areas.

**FUMIGATION MANAGEMENT PLAN (FMP) or STANDARD OPERATING PROCEDURE (SOP)**

**Purpose and Development of FMP or SOP.** A site-specific Fumigant Management Plan (FMP) or Standard Operating Procedure (SOP) must be developed and approved by an appropriate authority in advance of the use of this fumigant product. The FMP or SOP must specify procedures protective of the safety of the fumigators, other persons on-site, the surrounding community, and the environment. It must also be designed to achieve effective sterilization/decontamination in conformance with label requirements. The FMP or SOP must be up-to-date and accurately reflect the site and current circumstances for treatment before it takes place, and the application must be conform to the FMP or SOP. The FMP or SOP must be consistent with the product labeling and take into account site-specific information such as the size, contents and condition of the treated structure. See Appendix for a sample outline of an FMP or SOP. For emergency applications that must be performed with limited advance notice on sites with no existing FMP or SOP, users may rely on generic plans or SOPs. The FMP or SOP must be compliant with the requirements of the OSHA Formaldehyde Standard (29 CFR 1910.1048).

Carefully read, review and follow the label, this Product Manual, the FMP/SOP and the product manual of any application equipment being used. Give this information to the appropriate officials in charge of the treated structure and/or space. Finally, be familiar and comply with all applicable state and local laws.

**PREPARATION OF ENCLOSURES**

**Pre-Cleaning:** If gross filth or visible soil is present in feasibly accessible sealed enclosures, wash soiled surfaces with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed. After washing, rinse with potable water and allow surfaces to air dry. All the surfaces in the treated structure or space must be clean and dry prior to application. Where pre-cleaning is impractical and where gross filth or visible soil is not anticipated to be present, such as in a sealed HEPA enclosure and associated housing, decontamination may be initiated without opening the contaminated enclosure and causing exposure to the surrounding area and/or personnel.

**Preparing the area:** Leave all doors, compartments and lids on containers within the sealed area open where practical. Remove any items which should not be fumigated.

**Sealing:** Seal the enclosure adequately to assure that formaldehyde levels outside the enclosure are kept below 0.1 ppm and ensure sufficient concentration of formaldehyde in the treatment enclosure. Alternatively, users must ensure that personnel and/or critical assets (e.g. experimental animals) are not exposed to concentrations of PFA greater than 0.1ppm through required offsets and environmental monitoring. In this case, personnel monitoring (e.g. personal dosimetry) must be performed if monitoring is completed manually. In any established, regulated area where the concentration of airborne formaldehyde exceeds (or is expected to exceed) either

the time-weighted average (TWA) or the short term exposure limit (STEL) of free PFA, all entrances and access ways must be posted with signs that indicate: DANGER FORMALDEHYDE IRRITANT AND POTENTIAL CANCER HAZARD - AUTHORIZED PERSONNEL ONLY (or similar). The warning signs cannot be removed until building formaldehyde levels are below the OSHA permissible exposure levels (PEL) and/or EPA exemption levels (if applicable).

--Turn off all ventilation systems including HVAC and seal any supply or return vents or Ductwork.

--Fill all drains and traps with water, mineral oil and/or disinfectant.

--Close and seal windows and doors. Sealing with polyethylene sheeting and duct tape, or equivalent, is acceptable. Verify effectiveness of the sealing process by conducting an air draft potential analysis where openings have been sealed in the enclosure.

**Setting up Equipment:** Position or connect the application equipment for optimum distribution of formaldehyde gas into the treatment enclosure. Verify the electrical outlets and circuit breakers to ensure there is adequate power to run the equipment. Position fans if necessary to ensure adequate distribution of gas.

**Securing Enclosure:**

--Assure all personnel have vacated the treatment enclosure prior to application. Remove all plants, animals, beverages and food from the treatment area.

--Applicators must not reenter the treated enclosure without protective equipment and clothing until the concentration of formaldehyde is at or below 0.1 ppm is achieved in the enclosure.

**Placarding/Signage:** The applicator in charge of the fumigation must placard all entrances to the fumigated areas or spaces with signs bearing:

--Skull and crossbones symbol

--DANGER/PELIGRO

--Areas or spaces under fumigation. DO NOT ENTER/NO ENTRE. Toxic gas in use

--Date and time of fumigation

--Name, address and telephone number of the applicator

--Do not enter or allow entry by unprotected persons into the fumigated areas or spaces until the signs are removed. Such signs must not be removed before the air concentration level of formaldehyde is measured as less than 0.1 ppm.

**APPLICATION TO SEALED ENCLOSURES**

**Application Rates:** The rate of application is 0.3 – 0.6 grams of paraformaldehyde per cubic foot of the space to be treated, depending on the concentration required. The total amount of product needed is calculated by multiplying the interior volume of the enclosure to be treated (length X width X height in feet) by the application rate (0.3 – 0.6 grams per cubic foot) and then dividing the answer by the average percentage of paraformaldehyde (91%) in the registered product.

**Exposure Time:** The treated surfaces in the sealed area must remain in contact with the formaldehyde gas for at least 10 hours at the target concentration.

**Temperature and Relative Humidity:** Apply only between a temperature of 60° and 90° F and a relative humidity (RH) between 60% and 90%. If product must be used outside these ranges, measure and account for local conditions through a combination of environmental modification equipment (e.g. humidifiers, dehumidifiers) and/or product application changes (e.g. use more

product to account for cold conditions). Increased efficacy monitoring (e.g. more biological indicators placed in remote areas of the decontamination space) should be used to verify the protocol modifications.

**Gas Generation Methods:** Heat paraformaldehyde prills or flakes to at least 400° (but no more than 475° F) via heat to depolymerize the material to produce formaldehyde gas. The method of heating may be on an electric heating device or via a formaldehyde generator. The formaldehyde gas permeates the entire room or chamber, including any air handling ducts and other areas inaccessible to liquid disinfectants.

**Biological Indicators (BI):** Prior to treatment, place an appropriate number of BIs containing at least 6 logs of *Bacillus subtilis*, *Bacillus atrophaeus* or *Geobacillus stearothermophilus* spores in the area or space to be treated. In a sealed and inaccessible enclosure, place the BIs in the off-gassing pathway or downstream of the HEPA filters within the decontamination system. At least one spore strip must be placed in the treated enclosure per 1000 cubic feet of internal volume. For every two BIs used in the treated enclosure, use one untreated BI (same lot number) as a positive control. In small, standardized spaces such as Biological Safety Cabinets (BSC), two BIs are recommended to validate that the initial and subsequent fumigations are effective. Exposed biological indicators must be incubated and analyzed per manufacturer instructions. One or more positive BIs indicates failure of the treatment and requires that the sterilization/decontamination process be repeated after any necessary corrective steps are taken. The treatment may be deemed successful if no microbial growth is found on any BI.

**Neutralization:** At the end of the exposure period, the formaldehyde gas must be neutralized by heating ammonium carbonate or bicarbonate to generate ammonia gas. For an application rate of 0.3 grams per cubic foot of paraformaldehyde, the amount of ammonium carbonate needed is calculated by multiplying the total amount of paraformaldehyde (grams) used by a factor of 1.2. For ammonium bicarbonate at this application rate, the total amount of paraformaldehyde (grams) used is multiplied by a factor of 1.6. For an application rate of 0.6 grams per cubic foot of paraformaldehyde, the amount of ammonium carbonate or bicarbonate needs to be doubled (i.e., multiply the total amount of paraformaldehyde (grams) by 2.4 and 3.2, respectively). Place the correct amount of neutralizer in one or more electric heating devices during setup. When the formaldehyde exposure time has been completed, turn on the electric heating device until decomposition is complete (from 30 minutes to 3 hours). In the case of a formaldehyde generator application, the unit will advance automatically to the neutralization phase.

**Aeration:** After neutralization is completed, proceed with aeration typically to the outside and then test the air with a device or method capable of measuring 0.1 ppm formaldehyde (e.g., a Draeger detection tube used with a formaldehyde activation tube) to ensure that the formaldehyde concentration is below this level before allowing unprotected reentry to retrieve the BIs.

**Monitoring:** Check the adjacent space for any leakage during the application, neutralization and aeration periods using a device capable of measuring 0.1 ppm formaldehyde. Document the test methods used as well as the times and data collected. Record where the data was collected.

**Post-Application Steps:** After the air in the treated area has been tested and determined to be below 0.1 ppm formaldehyde, the placards may be removed and reentry authorized. A water wash of treated surfaces may be required to remove all traces of formaldehyde and neutralized byproducts. Note that any water that may have condensed on chilled surfaces (e.g., windows, exterior doors, etc.) will have absorbed formaldehyde, and should therefore be removed and properly disposed.

**APPENDIX - Outline of Fumigation Management Plan (FMP) or Standard Operating Procedure (SOP)**

The following elements should be included in an FMP or SOP as applicable to each site. The FMP or SOP is not required to follow this particular outline, but must address each of the substantive issues presented. In addition, the FMP or SOP must not specify any requirement that is less restrictive than or conflicts with the label.

**PLANNING AND PREPARATION**

- Determine the purpose(s) of the fumigation, for example:
  - Decontamination or sterilization in enclosed rooms/spaces
- Determine the location of fumigation, for example:
  - Laboratories, animal research facilities
  - Animal quarters
- Evaluate the structure or area or space to be fumigated and develop a site-specific plan that includes the following points, as applicable:
  - The general structure layout, construction (materials, design, age, maintenance of the structure), fire or combustibility hazards, connecting structures and escape routes, above and below ground, and other unique hazards or structure characteristics. Meet with the owner/operator/person in charge. Draw or have a drawing or sketch of the structure to be fumigated, delineating features, hazards and other structural issues.
  - The need for buffer zones in rooms adjacent to the treated enclosure and to limit access only to applicators. This includes adjacent rooms that could be occupied when using paraformaldehyde. Additional consideration should also be given to adjacent rooms above or below the enclosure, if the structure does not consist of solid construction (i.e., floors/walls adjacent to the enclosure) that would preclude exposure from an improperly sealed enclosure.
  - The number and type of persons who routinely enter the area or space to be fumigated (i.e., employees, visitors, customers, etc.) and steps for keeping them out.
  - Accessibility of utility service connections.
  - Nearest telephone or other means of communication, marking their locations on the drawing/sketch.
  - Emergency shut-off stations for electricity, water and gas, marking their locations on the drawing/sketch.
  - Current emergency telephone numbers of responsible Health, Fire, Police, Hospital and Physician responders.
  - Name and telephone numbers (both day and night) of appropriate company officials.
  - Identify the points of fumigation application.
  - Review labeling and equipment manual.
  - Exposure time:
    - Fumigant to be used
    - Minimum fumigation period
  - Determination of dosage:
    - Cubic footage or other appropriate space/location calculations
    - Structure sealing capability and methods
    - Label directions
    - Past history of fumigation of structure
    - Exposure time
    - Neutralization

**PERSONNEL**

- Confirm in writing that all personnel in and around the area or space to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initials indicating that he/she has been notified.
- Instruct all fumigation personnel about the hazards that may be encountered and about the selection of personal protection devices, including detection equipment.
- Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
- Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a telephone number for emergency response reporting.
- Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to fumigation.
- Establish a meeting area or space for all personnel in case of emergency.
- Confirm that all applicators have been trained in the use of SunPac.

**MONITORING**

**Perimeter Safety**

- Monitoring of formaldehyde 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.
- Keep a log or manual of monitoring records for each fumigation site. This log must at a minimum contain the timing, number or readings taken and the level of concentrations found in each location.
- When monitoring for leaks, document that no formaldehyde is present above 0.1 ppm. Subsequent leak monitoring is not routinely required. However, spot checks must be made, especially if conditions significantly change.
- Monitoring must be conducted during aeration and corrective action taken if gas/vapor levels exceed the allowed levels in an area or space where bystanders and/or nearby residents may be exposed.

**NOTIFICATION**

- Confirm that all appropriate local authorities (Fire Departments, Police Departments, etc.) have been notified as per label instructions, local ordinances, or instructions of the client.
- Prepare written procedure ("Emergency Response Plan") which contains explicit instructions, names and telephone numbers so as to be able to notify local authorities if formaldehyde levels are exceeded in an area or space that could be dangerous to bystanders and/or domestic animals.
- In the event of a breach or leak of the enclosure where the level of formaldehyde is above 0.1 ppm in adjacent area or spaces to the enclosure, stop the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent area or spaces where levels have exceeded 0.1 ppm are evacuated by general personnel and that proper respiratory protection is used by applicators that enter the area or space. Continue monitoring the area or space until levels are below 0.1 ppm formaldehyde. The treated enclosure and adjacent area or spaces must remain unoccupied until the formaldehyde level is at or below 0.1 ppm. Early reentry into the sealed, treated enclosure at use concentration levels in the case of an emergency requires wearing (insert same respirator requirements as listed in the Product Manual).

**SEALING PROCEDURES**

- Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials will remain intact until the fumigations to complete. Verify effectiveness of the sealing process to ensure there are no leaks where openings have been sealed in the enclosure.



If the structure and/or area or space has been fumigated before, review the previous for previous sealing information.

Make sure that construction or remodeling has not changed the building in a manner that will affect the fumigation.

Warning placards or signs must be placed on every possible entrance to the fumigation site.

#### **APPLICATION PROCEDURES & FUMIGATION PERIOD**

Plan carefully and apply all fumigants in accordance with the label requirements.

When entering into an area or space under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate protective clothing and respirators.

Provide watchpersons when a fumigation site cannot otherwise be made secure from entry by unauthorized persons.

#### **POST-APPLICATION OPERATIONS**

Provide watchpersons when a fumigation site cannot otherwise be made secure from entry by unauthorized persons during the neutralization and aeration process.

Heat a measured amount of ammonium carbonate or ammonium bicarbonate to neutralize the formaldehyde gas.

Ventilate and aerate in accordance with structural limitations

Turn on ventilating or aerating fans where appropriate.

Use a suitable formaldehyde detector before reentry to determine fumigant concentration.

Keep written records of monitoring to document completion of aeration.

Consider temperature when aerating.

For fumigated vehicles, ensure aeration is complete before moving vehicle into public roads.

Remove warning placards/signs when aeration is complete.

Inform business/client that employees and other persons may return to work or otherwise be allowed to reenter the aerated structure.

#### **CRITERIA FOR SUCCESSFUL FUMIGATION**

The criterion for successful fumigation is that all fumigation process conditions established on the label (e.g., gas/vapor concentration, exposure time, temperature and relative humidity) are achieved throughout the fumigation cycle.

The biological indicators (BI) placed in the treated areas or spaces must be incubated and analyzed according to the manufacturer's requirements. One or more positive BIs may indicate failure of the treatment process and requires an evaluation by qualified personnel to determine if the sterilization/decontamination process should be repeated after any necessary corrective steps identified from evaluation findings are taken.