90150-1 12/30/2013 1/21

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

TOMI Environmental Solutions, Inc.
5712 Frederick Ave
Rockville, MD 20852
Attn: Jeffrey Citrin

DEC 30 2013

Subject: Changing Primary Brand Name
EPA Reg. No. 90150-1
Notification Letter Dated November 26, 2013

This letter acknowledges receipt of the Notification identified above submitted under the provisions of section 3(c)(9) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10. This Notification requests to change the primary brand name:

- BIT BINARY IONIZATION TECHNOLOGY

Based on a review of the submitted information, this notification is acceptable. This information has been made a part of your file.

Should you have any questions concerning this letter, please contact Seiichi Murasaki at murasaki.seiichi@epa.gov or (703) 347-0163.

Sincerely,

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

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
TOMI Environmental Solutions, Inc. / 90150-1	Marshall Swindell	[x] None [ ] Restricted
4. Company/Product (Name) Hydrogen Peroxide 7.5% Ready-To-Use	**PM#** 33	

5. Name and Address of Applicant *(Include ZIP Code)*

TOMI Environmental Solutions, Inc.
5712 Frederick Ave., Rockville, MD 20852

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Alternate Brand Name (ABN) -- BIT Binary Ionization Technology. Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1,5,55 gallons	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jeffrey Citrin	Chief Reg'y & Compl. Ofc.	301-686-8258

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
	Chief Regulatory & Compliance Officer	
4. Typed Name Jeffrey Citrin	**5. Date** November 26, 2013	

TOMI
ENVIRONMENTAL SOLUTIONS

USA East Coast Office
5712 Frederick Ave., Rockville, MD 20852
T 800-525-1698, F 301-468-6744
www.tomiesinc.com

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November 26, 2013

US Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Notification of Alternate Brand Name per PR Notice 98-10 (Reg. No. 90150-1)

Please accept this notification of change in Primary Brand Name for Reg. No. 90150-1, with the change from HYDROGEN PEROXIDE 7.5% READY-TO-USE to BIT BINARY IONIZATION TECHNOLOGY. Three (3) copies of the final product label and packet insert reflecting this change are attached.

Attached is EPA Form 8570-1 regarding this notification as required in PR Notice 1998-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,

Jeffrey Citrin
Chief Regulatory and Compliance Officer

TOMI™
ENVIRONMENTAL SOLUTIONS

BIT binary ionization technology®

For use in mold control and remediation

Active Ingredient:

Hydrogen peroxide	7.5%
Inert Ingredients:	92.5%
Total	100%

EPA Reg. No. 90150-1 EPA Est. No. 88692-AZ-001

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

OXIDIZER CORROSIVE

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

FIRST AID	
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 swallowed	• 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 do so by the poison control. • Do not give anything by mouth to an unconscious person.
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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

DANGER: Corrosive. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse.

Manufactured By: TOMI Environmental Solutions, 5712 Frederick Avenue, Rockville, MD 20852

NET CONTENTS: 4 liter, 5 gallon and 55 gallon.

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Personal Protective Equipment PPE
Applicators and all other handlers must wear: long-sleeved shirt and long pants; socks and chemical resistant footwear; goggles or face shield; chemical-resistant gloves such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or viton; a self-contained breathing apparatus if concentrations exceed 1 ppm during handling and/or application of BIT™ Binary Ionization Technology®. Do not use oxidizable sorbents such as activated carbon.

Physical or Chemical Hazards Liquid hydrogen peroxide is a strong oxidant and poses a FIRE EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination, or contact with combustible materials. Clothing, shoes, or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. If allowed to dry in the materials, a fire may result. Discard shoes in a fireproof container.

IN CASE OF FIRE, use water only. CONTAIN SPILLS and dilute with 20 parts of water. After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lbs. of SO_2 equivalent per 500 ml of peroxide) may be used to destroy the peroxide.
SEE EQUIPMENT MANUAL AND MATERIAL SAFETY DATA SHEET FOR ADDITIONAL INFORMATION.

Environmental Hazards Do not discharge effluent containing these products into lakes, streams, ponds, oceans, or public waters unless these products are specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage authority. For guidance contact your State Water Board or Regional Office U.S. Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. For use as a mold control and mold inhibitor during remediation of sealed, dry pre-cleaned enclosures located in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing including clean rooms, laboratories, animal research facilities, hotel rooms, offices, cruise ships, and recreational facilities). This product is not intended for use on or to control mold on textiles or hard porous surfaces. Use only with BIT™ Binary Ionization Technology® application equipment. This product is used to treat wood, wallboard, concrete, and masonry (cinder) block building materials which have been painted, coated or sealed. This product is intended to control and inhibit mold and mildew for aesthetic purposes only. Before applying this product, visible mold growth must be removed, and conditions favorable to mold growth must be identified and corrected. DO NOT use on food-contact surfaces, or on the interior of buildings engaged in food processing or food handling.

REMEDIAL TREATMENT This product must be used as part of a comprehensive mold remediation or water damage restoration program, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

For use in precleaned enclosures up to 3,663 ft³. The use rate to achieve a minimum 400 ppm hydrogen peroxide is approximately 0.4 ML of product per ft. of enclosure volume to achieve a dose of 400 PPM hydrogen peroxide of enclosure, which should be maintained for a 20 minute contact time. The product is to be used as packaged and is not to be diluted in any way. Use an appropriate volume of the product in the fogger to ensure that the hydrogen peroxide concentration in the room remains at 400 ppm for at least 20 minutes. The quantity of product required to achieve 400 PPM hydrogen peroxide may vary according to the enclosure being treated. Prior to use of the product for a particular enclosure, test the fogger and product to determine the volume of product needed to maintain the atmospheric hydrogen peroxide concentration of 400 ppm at the current room temperature and humidity. Appropriate dose application can be verified using exposure time and PPM hydrogen peroxide. Chemical Indicators (CIs) may also be used as an adjunct to exposure time and ppm. See package insert for details on dose application verification. Shade from radiant heat and direct sunlight. Stow away from powdered metals and permanganates. This product is for use in BIT™ Binary Ionization Technology® application equipment only, and by trained personnel trained by TOMI Environmental Solutions, Inc. Read and follow package insert for complete directions on cleaning, sealing and use of BIT™ Binary Ionization Technology® in monitored and non-monitored applications. See Equipment User Manual for operating procedures of the BIT™ Binary Ionization Technology® application equipment. Do not use this product without development of an appropriate fumigation plan (see package insert). Not for use as a terminal sterilant or high-level disinfectant for reprocessing of critical or semi-critical medical devices.

STORAGE AND DISPOSAL Store containers upright at or below 77° F. Do not freeze. Do not expose to cyanide, hexavalent chromium compounds, other oxidizers, reducers, combustible materials, or flammable vapors.

PESTICIDE DISPOSAL Rinse containers with 20 parts water and then empty into sink with running water. Hydrogen peroxide is classified as a DOT oxidizer and a hazardous waste under U.S. EPA hazardous waste regulations and it is a violation of federal law to improperly dispose of pesticides.

CONTAINER DISPOSAL Rinse container with running water and dispose of with normal non-incinerated waste.

Product No. BIT-400 Lot #

Product Made in U.S.A.

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TOMI™ ENVIRONMENTAL SOLUTIONS

BIT Binary Ionization technology®

Package Insert for Binary Ionization Technology® (BIT™) Hydrogen Peroxide 7.5% Ready-To-Use EPA Reg. No: 90150-1

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1. GENERAL INFORMATION AND RESTRICTIONS

BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is for use in mold control and remediation, and is not intended for use on or to control mold on textiles or hard porous surfaces. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is for use in enclosures that do not exceed 3,663 ft^3. This product has been registered by TOMI Environmental Solutions, Inc. in accordance with Federal Regulations for the specific uses described in this package insert. Uses other than as specified and described are not permitted and may not be effective in remediating exposed surfaces in pre-cleaned sealed enclosures.

This product is used to treat wood, wallboard, concrete, and masonry (cinder) block building materials which have been painted, coated or sealed. This product is intended to control and inhibit mold and mildew for aesthetic purposes only, when the materials are subjected to moist or wet environments. Before applying this product, visible mold growth must be removed, and conditions favorable to mold growth must be identified and corrected.

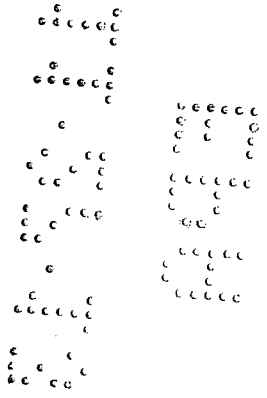
DO NOT use on food-contact surfaces, or on the interior of buildings engaged in food processing or food handling.

REMEDIAL TREATMENT
This product must be used as part of a comprehensive mold remediation or water damage restoration program, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

Review the Binary Ionization Technology® (BIT™) Equipment User's Manual for proper instructions on how to operate the BIT™ Fogger prior to utilizing the equipment for treating contaminated areas. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use should be applied only by properly trained and certified personnel who are thoroughly trained in the use and operation of the BIT™ Fogger and BIT™ Hydrogen Peroxide 7.5% Ready-To-Use Application Process.

Effective application of BIT™ Hydrogen Peroxide 7.5% Ready-To-Use requires adequate hydrogen peroxide concentration and exposure time. The BIT™ Fogger is utilized to achieve the desired concentration and contact time of hydrogen peroxide in the enclosed area. The process parameters are controlled through the use of appropriate monitoring instruments. See the BIT™ Fogger Equipment User's Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.



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The BIT™ Fogger uses air as a carrier to deliver hydrogen peroxide aerosol to exposed surfaces inside a sealed enclosure. This allows the process to take place at atmospheric pressure. Since the BIT™ process relies only on the contact of the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use solution with exposed surfaces, the transfer of heat and moisture required by steam or chemical processes is not necessary.

The BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is injected for the required time to maintain the desired concentration of hydrogen peroxide. Once the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use leaves the enclosure, it is typically broken down into water vapor and oxygen.

The BIT™ process consists of three phases:

- EXPOSURE - The BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is injected into the air stream. The EXPOSURE phase facilitates reaching the desired hydrogen peroxide concentration in the sealed enclosure. EXPOSURE time is affected by hydrogen peroxide target concentration, injection rate, enclosure materials, environmental conditions and enclosure volume.

- DWELL - The PPM of hydrogen peroxide is monitored. Usually, a sufficient EXPOSURE time will provide adequate hydrogen peroxide levels during DWELL without adding more BIT™ Hydrogen Peroxide 7.5% Ready-To-Use. In some instances additional injections of BIT™ Hydrogen Peroxide 7.5% Ready-To-Use may be required to maintain the target hydrogen peroxide concentration in the sealed enclosure required to achieve the required level of remediation.

- AERATION - The BIT™ Hydrogen Peroxide 7.5% Ready-To-Use injection is stopped and the enclosure is aerated and/or scrubbed to reduce the hydrogen peroxide concentration within the enclosure to a 1 PPM level (≤1.0 PPM TWA 8 hr.) prior to reentry into the enclosure by trained applicators. Treated enclosures may not be released for general public use until 1 hour after a 1 PPM level of hydrogen peroxide is achieved in the enclosure.

2. USER SAFETY REQUIREMENTS

a) RESPIRATOR REQUIREMENTS - When a respirator is required for use with this product, the trained applicator supervising the fumigation must make sure that:

   i. Respirators must be fit tested and fit checked using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134).

   ii. Respirator users must be trained using a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134).

   iii. Respirator users must be examined by a qualified medical practitioner to ensure the physical ability to safely wear the style of respirator to be worn.

   iv. Respirators must be maintained according to a program that conforms with OSHA's requirements (described in 29 CFR Part 1910.134).

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b) CONTACT PRECAUTIONS - Liquid hydrogen peroxide is corrosive and will cause irreversible eye damage or skin burns and may be fatal if inhaled at higher concentrations. It is also harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist or vapor. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse. Discard clothing and/or absorbent material that has been heavily drenched or contaminated with liquid hydrogen peroxide.

c) CLEANING PROTECTIVE EQUIPMENT - Follow manufacturer's instructions for cleaning/maintaining protective eyewear and respirators.

d) USER SAFETY RECOMMENDATIONS

i. Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ii. Users should remove clothing/PPE immediately if hydrogen peroxide gets inside. Then wash thoroughly and put on clean clothing.

iii. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as practical, wash thoroughly and change into clean clothing.

3. USE OF PRODUCT

BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is effective in controlling and inhibiting mold as remediation on exposed, pre-cleaned, dry, non-porous surfaces in sealed enclosures in industrial, commercial and institutional settings (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, laboratories, animal research facilities, hotel rooms, offices, cruise ships, and recreational facilities) when used with BIT™ application equipment. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is for use in mold control and remediation, and is not intended for use on or to control mold on textiles or hard porous surfaces. See Section 7 for instructions on developing parameters for application.

BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is for use in enclosures that do not exceed 3,663 ft^3. The dose application for the enclosure being treated can be verified using exposure time and PPM hydrogen peroxide. Optional confirmation of applied dose can be verified using exposure Chemical Indicators (CIs) as an adjunct to exposure time and PPM. See Section 8 for instructions on verifying dose application with CIs.

This product is not to be used as a terminal high level disinfectant or sterilant for reprocessing of any critical/semi-critical medical device in a healthcare setting.

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4. FUMIGATION MANAGEMENT PLAN

The TOMI Environmental Solutions, Inc. trained applicator is responsible for working with the owners and/or the responsible employees of the site to be fumigated to develop a site-specific Fumigation Management Plan (FMP) for each site that will be treated with BIT™ Hydrogen Peroxide 7.5% Ready-To-Use. The applicator is responsible for all tasks of the fumigation process unless otherwise noted in the FMP and must be on site for the entire fumigation treatment process. The FMP must address characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

a) Inspect the structure and/or area to determine its suitability for fumigation.

b) When sealing is required, consult previous records for any changes to the structure, seal leaks, and monitor any occupied adjacent rooms and/or buildings to ensure safety.

c) Prior to each fumigation, review any existing FMP, MSDS/SDS, Equipment User's Manual and other relevant safety procedures with company officials and appropriate employees.

d) Consult with company officials in the development of procedures and appropriate safety measures for nearby workers who will be in and around the area during application and aeration.

e) Consult with company officials to develop an appropriate monitoring plan that will confirm that nearby workers and bystanders are not exposed to levels above the allowed limits during application, fumigation and aeration. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.

f) Consult with owners and or responsible employees at the site who will be responsible for development of procedures for local authorities to notify nearby residents in the event of an emergency.

g) Confirm the placement of placards to secure entrance into any area under fumigation.

h) Confirm the required safety equipment is in place and the necessary manpower is available to complete fumigation.

These factors must be considered in putting a FMP together. It is important to note that some plans will be more comprehensive than others. All plans should reflect the experience and expertise of the applicator and circumstances at and around the structure and/or area.

In addition to the plan, the applicator must read the entire label and Equipment User's Manual and follow all directions carefully. If the applicator has any questions about the development of an FMP, contact TOMI Environmental Solutions, Inc. for further assistance. An FMP must be developed for each treated site. In the event of an emergency application, a generic FMP which can be updated may be used and updated after fumigation. The TOMI Environmental Solutions, Inc. trained applicator must sign the plan indicating it was followed. The signed FMP and related

documentation, including monitoring records, must be maintained by the applicator for a minimum of 2 years and a copy provided to the owner of the treated site.

- GUIDANCE FOR PREPARATION OF A FUMIGATION MANAGEMENT PLAN

A Fumigation Management Plan (FMP) is an organized, written description of the required steps involved to help ensure a legal and effective fumigation. It will also assist you and others in complying with pesticide product label requirements. The guidance that follows is designed to assist you in addressing all the necessary factors involved in preparing for and fumigating a structure and/or area.

This guidance is intended to help you plan any fumigation that you might perform PRIOR TO ACTUAL TREATMENT. It is meant to be somewhat prescriptive, yet flexible enough to allow the experience and expertise of the fumigator to make changes based on circumstances that may exist in the field. By following a step-by-step procedure, yet allowing for flexibility, an effective fumigation can be performed.

Before any fumigation begins, carefully read and review the label and the Equipment User's Manual. This information must also be given to the appropriate company officials (supervisors, foreman, safety officer, etc.) in charge of the structure and/or area. Preparation is the key to any successful fumigation. If the type of fumigation that you are to perform is not listed in this Guidance Document you will want to construct a similar set of procedures. Finally, before any fumigation begins you must be familiar with and comply with all applicable state and local laws. The success of the fumigation is not only dependent on your ability to do your job but also upon carefully following all rules, regulations, and procedures required by governmental agencies.

See Section 9 for a checklist guide for a Fumigation Management Plan.

5. TRAINING AND CERTIFICATION OF APPLICATORS

Prior to use, applicators must be adequately trained and certified by TOMI Environmental Solutions, Inc. on hazards and label directions for BIT™ Hydrogen Peroxide 7.5% Ready-To-Use, on the use and operation of the BIT™ application equipment, hydrogen peroxide monitoring procedures and when appropriate, process monitoring procedures.

6. PREPARATION OF ENCLOSURES

a) Cleaning: Remove gross filth and visible soil prior to application. Wash soiled surfaces with a compatible detergent using a cloth, sponge or appropriate cleaning device to ensure visible soils are removed. Rinse with potable water and allow to air dry. All the surfaces in the treatment area must be completely dry prior to BIT™ Hydrogen Peroxide 7.5% Ready-To-Use application.

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b) Prepare the BIT™ Application Equipment: Position or connect the BIT™ application equipment for optimum BIT™ Hydrogen Peroxide 7.5% Ready-To-Use distribution into the treatment enclosure. See Equipment User's Manual for proper equipment preparation and set-up.

c) Sealing: Seal the treatment enclosure adequately to assure that hydrogen peroxide levels outside the enclosure are kept at acceptable levels (≤ 1 PPM time weighted average for 8 hours [TWA]) and ensure sufficient concentration of BIT™ Hydrogen Peroxide 7.5% Ready-To-Use in the treatment enclosure.

   i. Close and seal windows and doors. Sealing techniques can vary, but most often include polyethylene sheeting and adhesive tape. Verify effectiveness of the sealing process by conducting an air draft potential analysis using a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.

   ii. Turn off all ventilation systems including HVAC and seal any supply or return vents/ductwork.

   iii. Monitor areas immediately adjacent to the fumigated space to ensure levels are below TWA for hydrogen peroxide.

d) Securing Enclosure:

   i. Assure all personnel have vacated the treatment enclosure prior to BIT™ Hydrogen Peroxide 7.5% Ready-To-Use application. Remove all plants, animals, beverages and food.

   ii. Applicators must not re-enter the treated enclosure until exposure levels of hydrogen peroxide are at or below 1 PPM. Do not release the treated enclosure to the general public until 1 hour after a level of 1 PPM hydrogen peroxide is achieved in the enclosure.

e) Placarding of Treatment Enclosure: The applicator must placard or post all entrances to the treatment enclosure and designated buffer zones with signs in English bearing:

   i. The signal word "DANGER/ PELIGRO" in red.

   ii. "Area under treatment, "DO NOT ENTER/ NO ENTER."

   iii. The statement "This sign may only be removed 1 hour after the treatment enclosure has been aerated to hydrogen peroxide levels less than or equal to 1 PPM."

   iv. Identification of hydrogen peroxide as a hazard associated with the treatment process.

   v. Contact information for the applicator.

All entrances to the treatment enclosure must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated enclosure. Placards are removed 1 hour after the treatment enclosure contains concentrations of hydrogen peroxide at

or below 1 PPM.

7. DEVELOPING THE BIT™ HYDROGEN PEROXIDE 7.5% READY-TO-USE APPLICATION CYCLE

BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is for use in mold control and remediation, and is not intended for use on or to control mold on textiles or hard porous surfaces. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use has been registered by TOMI Environmental Solutions, Inc. in accordance with Federal Regulations for the specific uses described in this package insert. Uses other than as specified and described are not permitted. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use may not be effective in remediation of molds without careful, thorough development and monitoring. In addition, the ability of the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use to decontaminate obstructed or covered surfaces is limited. The instructions that follow explain how to define appropriate use conditions and validate these conditions for use in a dry, pre-cleaned sealed enclosure of a fixed size, location and materials of composition. This includes sealed enclosures in industrial, commercial and institutional setting (including production operations in pharmaceutical manufacturing, manufacturing clean rooms, laboratories, animal research facilities, hotel rooms, offices, cruise ships and recreational facilities). Process conditions must be properly developed prior to use to achieve applied dose to the treated enclosure. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is only for use in applications where the enclosure does not exceed 3,663 ft^3. See instructions for use in applying BIT™ Hydrogen Peroxide 7.5% Ready-To-Use at a prescribed concentration and contact time using a pre-developed cycle. For additional guidance, in-service, and training on how to develop and monitor custom cycles, contact TOMI Environmental Solutions, Inc.

USE OF PRE-DEVELOPED CYCLES

BIT™ Hydrogen Peroxide 7.5% Ready-To-Use may be used in pre-developed cycles for treatment of pre-cleaned, dry sealed enclosures when the enclosure to be treated is of a fixed volume configuration and contains materials of composition that remain consistent in comparison to a BIT™ Hydrogen Peroxide 7.5% Ready-To-Use development run. The cycle developed for the treatment enclosure must be capable of consistently achieving the desired applied dose requirements as specified by the use of the enclosure. Several factors need to be considered when developing the cycle. The volumetric size, materials of construction, the physical nature of the contents and the temperature range of the treatment enclosure will affect application time and concentration. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is not to be diluted in any way and is to be used as packaged. In general, 0.4 ML BIT™ Hydrogen Peroxide 7.5% Ready-To-Use per ft^3 of enclosure will achieve a dose of 400 PPM hydrogen peroxide. Large enclosures will take longer to reach the target hydrogen peroxide concentration due to a longer exposure phase. Absorptive materials present in the construction of an enclosure or in the contents will also increase the exposure time and the time required for aeration of the enclosure. BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is a surface mold control treatment, therefore the enclosure and its contents should be prepared to maximize BIT™ Hydrogen Peroxide 7.5% Ready-To-Use exposure. Working temperature ranges must be established to ensure that the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use does not excessively condense on exposed surfaces in the treated enclosure. Excessive condensation can result in damage to enclosure surfaces and result in reduced cycle effectiveness. Placement of fans or other devices to assist hydrogen peroxide distribution must be documented. Standard Operating Procedures (SOPs) must be written to

describe the physical preparation of an enclosure and its contents required to achieve reproducible results.

The initial step in developing the BIT™ fumigation cycle is to determine the EXPOSURE time and DWELL parameters required to achieve a minimum average applied dose of 400 PPM hydrogen peroxide over a dwell time of 20 minutes. Additionally, an AERATION method, time and monitoring SOP must be established before entry is allowed.

In addition to the exposure time and PPM hydrogen peroxide, Chemical Indicators (CIs) can be used during monitoring to provide qualitative information about hydrogen peroxide exposure. See Section 8 for more information on the use of CIs.

The fumigation cycle is developed by application of the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use at varying EXPOSURE times and concentrations while keeping constant other BIT™ cycle parameters in order to determine the level PPM hydrogen peroxide retained during the DWELL period. One approach to establishing effective applied dose is the characterization of the PPM hydrogen peroxide decay during the DWELL period. This information can be utilized to extrapolate cycle parameters to achieve the desired level of applied dose.

The fumigation cycle should be considered effective if the applied dose meets the criteria of an average minimum exposure of 400 PPM hydrogen peroxide left to dwell for 20 minutes. Additionally, if CIs are used they should exhibit consistent exposure colorimetric characteristics.

The following steps are required in developing a BIT™ fumigation cycle:

- EXPOSURE - The BIT™ Hydrogen Peroxide 7.5% Ready-To-Use is injected into the sealed enclosure. The injection rate is adjusted and controlled based on guidelines established for the BIT™ equipment (refer to BIT™ Fogger Equipment User's Manual). The EXPOSURE phase facilitates reaching the desired hydrogen peroxide concentration in the sealed enclosure. EXPOSURE time is affected by hydrogen peroxide target concentration, injection rate, enclosure materials, environmental conditions and enclosure volume.

- DWELL - The PPM of hydrogen peroxide is monitored. Usually, a sufficient EXPOSURE time will provide adequate hydrogen peroxide levels during DWELL without adding more BIT™ Hydrogen Peroxide 7.5% Ready-To-Use. In some instances additional injections of BIT™ Hydrogen Peroxide 7.5% Ready-To-Use may be required to maintain the target hydrogen peroxide concentration in the sealed enclosure required to receive level of remediation.

- AERATION - The BIT™ Hydrogen Peroxide 7.5% Ready-To-Use injection is stopped and the enclosure is aerated and/or scrubbed to reduce the hydrogen peroxide concentration within the enclosure to a 1 PPM level (≤1.0 PPM TWA 8 hr.) prior to reentry into the enclosure by trained applicators. Treated enclosures may not be released for general public use until 1 hour after a 1 PPM level of hydrogen peroxide is achieved in the enclosure.

In all cases, prepare the treatment enclosure as defined above (in Section 6. Preparation of Enclosures) including pre-cleaning and preparation of BIT™ Fogger (refer to the BIT™ Fogger

Equipment User's Manual), sealing the enclosure and placarding of the enclosure to be treated. Place the hydrogen peroxide monitor in the treatment enclosure in a location most difficult for hydrogen peroxide target concentration to be reached. This is typically in a corner of the enclosure farthest away from the BIT™ Fogging unit. All drawers, closets & cabinet doors, etc. must be opened to permit exposure to BIT™ Hydrogen Peroxide 7.5% Ready-To-Use. Oscillating fans may be placed throughout the enclosure to facilitate effective distribution of the BIT™ Hydrogen Peroxide 7.5% Ready-To-Use. Activate the BIT™ Fogger to initiate an EXPOSURE phase until the desired hydrogen peroxide concentration is achieved in the sealed enclosure. When the desired hydrogen peroxide concentration is achieved initiate the DWELL phase and maintain this concentration for the desired time. During the DWELL phase, monitor areas adjacent to the sealed enclosure with devices such as Dräger tubes to assure hydrogen peroxide levels do not exceed 1 PPM. If this level is exceeded outside the treatment enclosure, the applicator should immediately abort the treatment process and ensure the enclosure is properly sealed. Upon completion of the remediation phase, begin the AERATION phase to reduce levels of hydrogen peroxide to at or below 1 PPM (TWA).

After successful development of the fumigation cycle, the applicator must monitor cycle conditions and contact time for each BIT™ Hydrogen Peroxide 7.5% Ready-To-Use application to insure that they correspond to the pre-developed fumigation cycle conditions. Significant changes to the enclosure such as major modifications to room dimensions and materials of composition will require additional development or modification of application parameters.

MONITORING OF HYDROGEN PEROXIDE CONCENTRATIONS IN THE SEALED ENCLOSURE AND REENTRY INSTRUCTIONS FOLLOWING AERATION

Dräger tubes or other hydrogen peroxide monitoring devices are utilized as means of a minimally invasive technique for hydrogen peroxide sampling to determine the hydrogen peroxide concentration in the sealed enclosure during and after the aeration phase. One hour after the hydrogen peroxide concentration within the treated enclosure is at or below the OSHA Permissible Exposure Limit (PEL) of 1 PPM, the enclosure may be released to normal operations and general public use.

Early reentry in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues. When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

Reentry to the sealed enclosure by a trained and certified applicator is allowed with a SCBA at hydrogen peroxide concentrations up to 5 PPM to allow for windows to be opened and to augment the aeration process if deemed appropriate at the specific location by the trained and certified applicator. Otherwise, do not reenter the treated enclosure until exposure levels of hydrogen peroxide are at or below 1 PPM.

Once hydrogen peroxide levels are determined to be at or below 1 PPM, applicators may reenter the treated enclosure and remove any sealing materials and disconnect/remove the BIT™ Fogger from the treated sealed enclosure. The applicator may also turn on ventilation systems including the HVAC system. One hour after the levels of hydrogen peroxide are determined to be at or below 1 PPM the applicator should remove placards and release the treated enclosure for normal

operation and use.

The criteria for successful fumigation is that all BIT™ fumigation process conditions established during the fumigation cycle development (e.g., vapor concentration, exposure and dwell time and temperature) are achieved throughout the fumigation cycle. If Chemical Indicators (CIs) are used they are properly recovered and exhibit a visible color change following exposure to BIT™ Hydrogen Peroxide 7.5% Ready-To-Use.

8. OPTIONAL USE OF CHEMICAL INDICATORS (CIs) FOR CONFIRMING APPLIED DOSE

Hydrogen peroxide Chemical Indicators (CIs) may be used as a secondary confirmation of hydrogen peroxide exposure. Typically, CIs are potassium iodide- and starch-based filter paper strips that change color upon exposure to hydrogen peroxide. The color change is usually from white to a dark purple.

If CIs are used during the fumigation cycle a minimum of one (1) CI per 100 ft^2 of floor space should be equally spaced within the enclosure. The number of CIs used during cycle development can vary depending on the size, material construction and complexity of the application. For more information regarding CI sources and applications contact TOMI Environmental Solutions, Inc.

9. A CHECKLIST GUIDE FOR A FUMIGATION MANAGEMENT PLAN

This checklist is provided to help you take into account factors that must be addressed prior to performing all fumigations. It emphasizes safety steps to protect people and property. The checklist is general in nature and cannot be expected to apply to all types of fumigation situations. It is to be used as a guide to prepare the required plan. Each item must be considered, however, it is understood that each fumigation is different and not all items will be necessary for each fumigation structure and/or area.

A. PLANNING AND PREPARATION

1) Determine the purpose of the fumigation:

   a) Remediation of molds and fungi in room enclosures.

   b) Remediation of molds and fungi in emergency vehicles.

2) Determine the type of fumigation, for example:

   a) Pharmaceutical operations, clean rooms, medical device manufacturing,

   b) Laboratories, animal research facilities,

   c) Patient rooms, hotel rooms, offices, recreational facilities, and

d) Cruise ship rooms (in addition to the Equipment User's Manual, read the US Coast Guard Regulations 46CFR 147A).

3) Evaluate the structure or area to be fumigated, and develop a site-specific plan that includes the following points, as applicable:

a) 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 structure to be fumigated, delineating features, hazards, and other structural issues.

b) The need for buffer zones in rooms adjacent to the treated enclosure to limit access to only trained applicators. This would include adjacent rooms that could be occupied when using BIT™ Hydrogen Peroxide 7.5% Ready-To-Use in areas such as hotel rooms, patient rooms or offices. 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 if the treated enclosure was not properly sealed.

c) The number and identification of persons who routinely enter the area to be fumigated (i.e., employees, visitors, customers, etc.).

d) Accessibility of utility service connections.

e) Nearest telephone or other means of communication, and mark the location of these items on the drawing/sketch.

f) Emergency shut-off stations for electricity water and gas. Mark the location of these items on the drawing/sketch.

g) Current emergency telephone numbers of local health, Fire, Police, Hospital and Physician responders.

h) Name and phone number (both day and night) of appropriate company officials.

i) Checkmark and prepare the points of fumigation application.

j) Review labeling and Equipment User's Manual.

k) Exposure time considerations:

i. Fumigant to be used.

ii. Minimum fumigation period, as defined and described by the label use

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directions.

iii. Down time required to be available.

iv. Aeration requirements.

1) Determination of dosage:

i. Cubic footage or other appropriate space/location calculations.

ii. Structure sealing capability and methods.

iii. Label directions.

iv. Past history of fumigation of structure.

v. Exposure time.

B. PERSONNEL

1) Confirm in writing that all personnel in and around the area to be fumigated have been notified prior to application of the fumigant. Consider using a checklist that each employee initials indicating they have been notified.

2) Instruct all fumigation personnel about the hazards that may be encountered, and about the selection of personal protection devices, including detection equipment.

3) Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.

4) Instruct all personnel on how to report any accident and/or incidents related to fumigant exposure. Provide a telephone number for emergency response reporting.

5) Instruct all personnel to report to proper authorities any theft of fumigant and/or equipment related to fumigation.

6) Establish a meeting area for all personnel in case of emergency.

7) Confirm that all applicators have been trained in the use of BIT™ Hydrogen Peroxide 7.5% Ready-To-Use and are in good standing including the required refresher training.

8) Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner/operators of the facility being treated should have a Worker Health and Safety Plan as required by OSHA developed for their employees located within close proximity of the application process.

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C. MONITORING

1) Perimeter Safety

a) Monitoring of hydrogen peroxide 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.

b) Keep a log or manual of monitoring records for each fumigation site. This log must at a minimum contain the timing, number of readings taken and level of concentrations found in each location.

c) When monitoring for leaks, document there is no hydrogen peroxide present above the 1 PPM levels. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.

d) Monitoring must be conducted during aeration and corrective action taken if gas levels exceed the allowed levels in an area where bystanders and/or nearby residents may be exposed.

2) Efficacy

a) Hydrogen peroxide readings should be taken from within the fumigated structure to ensure proper vapor concentrations. This can be safely achieved outside the structure through the use of a remote sensor reading.

b) All reading of hydrogen peroxide concentration and temperature must be documented.

D. NOTIFICATION

1) Confirm that all appropriate local authorities (fire departments, police departments, etc.) have been notified as per label instructions, local ordinances if applicable, or instructions of the client.

2) Prepare written procedure ("Emergency Response Plan") which contains explicit instructions, names, and telephone numbers so as to be able to notify local authorities if hydrogen peroxide levels are exceeded in an area that could be dangerous to bystanders and/or domestic animals.

3) In the event of a breach or leak of the enclosure where levels of hydrogen peroxide are above 1 PPM in areas adjacent to the enclosure, abort the application process and initiate the aeration process in the sealed enclosure. Ensure that the adjacent areas where levels have exceeded 1 PPM are evacuated by general personnel and that proper respiratory protection is utilized by applicators that enter the area. Continue monitoring the area until levels are below 1 PPM hydrogen peroxide. The treated enclosure and adjacent areas must remain unoccupied until one hour after hydrogen

peroxide levels are at or below 1 PPM. Early re-entry into the sealed treated enclosure at use concentration levels in the case of an emergency requires wearing a Self Contained Breathing Apparatus (SCBA) operated in pressure-demand mode, full hydrogen peroxide resistant body suit, gloves and boots to protect from the inhalation hazard as well as the corrosive action of hydrogen peroxide to tissues.

E. SEALING PROCEDURES

1) Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials will remain intact until the fumigation is complete. Verify effectiveness of the sealing process by conducting a smoke stick test to ensure there are no leaks where openings have been sealed in the enclosure.

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

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

4) Warning placards must be placed on every possible entrance to the fumigation site.

F. APPLICATION PROCEDURES & FUMIGATION PERIOD

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

2) When entering into the area under fumigation always work with two or more people under the direct supervision of a trained applicator wearing appropriate respirators.

3) Apply fumigant from outside the fumigation space.

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

5) When entering structures always follow OSHA rules for confined spaces.

G. POST-APPLICATION OPERATIONS

1) Provide watchmen when you cannot secure the fumigation site from entry by unauthorized persons during the aeration process.

2) Ventilate and aerate in accordance with structural limitations.

3) Turn on ventilating or aerating fans where appropriate.

4) Use a suitable hydrogen peroxide detector before reentry to determine fumigant concentration.

5) Keep written records of monitoring to document completion of aeration.

6) Consider temperature when aerating.

7) Ensure aeration is complete before moving vehicle into public roads.

8) Remove warning placards when aeration is complete.

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

H. CRITERIA FOR SUCCESSFUL FUMIGATION

The criteria for successful fumigation is that all BIT™ fumigation process conditions established during the fumigation cycle development (e.g., vapor concentration, exposure and dwell time and temperature) are achieved throughout the fumigation cycle.