UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 10, 2016

Ms. Georgia Anastasiou
Agent for Halosil International, Inc.
Lewis & Harrison
122 C Street NW, Suite 505
Washington, DC 20001

Subject: Label Amendment – Adding organisms; adding marketing claims; revising post-application re-entry requirements
Product Name: HaloMist
EPA Registration Number: 84526-6
Application Date: September 8, 2015
Decision Number: 510494

Dear Ms. Anastasiou:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one 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 its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. 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. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

with FIFRA section 6. If you have any questions, please contact me by phone at (703) 308-8735, or via email at chao.julie@epa.gov.

Sincerely,

Julie Chao, Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted Label

HaloMist™

{Optional Claims}
For Use in Healthcare Facilities
For use as a Healthcare-Hospital Disinfectant
For use as a (Healthcare-Hospital) (Hospital-Healthcare) Disinfectant and (General Use) (Multiple Use) Disinfectant
HaloFogger:
Disinfectant Fogging Solution
Effective against *Clostridium difficile* Spores
Bactericide†
†Staphylococcus aureus (Staphylococcus) (Staph) (ATCC # 6538), Pseudomonas aeruginosa (Pseudomonas) (ATCC # 15442), and Clostridium difficile spores (C. diff) (ATCC # 43598))
Disinfects against Clostridium difficile spores (C. diff) (ATCC # 43598), Staphylococcus aureus (Staphylococcus) (Staph) (ATCC # 6538), and Pseudomonas aeruginosa (Pseudomonas) (ATCC # 15442)

Sprayer:
Bactericide*, Virucide** and Fungicide
{End Optional Claims}

Active Ingredients:	
Hydrogen Peroxide	5.00%
Silver	0.01%
Other Ingredients	94.99%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

See [back] [side] [right] [left] panel for additional precautionary statements.
Net Contents: (as indicated on container)

ACCEPTED
Jun 10, 2016
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84526-6

EPA Reg. No. 84526- 6
EPA Est. No. (as indicated on container)

[See bottom or side for Lot/Data code]
Questions? Comments? [symbol of telephone]
Call: (1-800-726-6765)
[or] Visit us at (www.halosil.com)
[Made in USA]
Distributed by: Halosil International Ltd, 91 Lukens Drive, New Castle, Delaware 19720 [or an authorized Halosil International distributor (insert name)]
HaloMist (and HaloFogger) are registered trademarks of Halosil International

Directions for Use
It is a violation of Federal law to use this product in a manner inconsistent with the label.

Halofogger:
For use as a microbial disinfectant fogging solution in environments for disinfection of dry, pre-cleaned, hard, non-porous, non-food contact surfaces in sealed spaces and rooms located in healthcare facilities and settings. Do not deviate from standard cleaning regimes when using HaloMist. Use product only with HaloFogger dispensing device following detailed instructions provided in the HaloFogger User Manual. Read and follow directions in user manual on room preparation, room set up and treatment protocol, and equipment operating procedures for the HaloFogger device.

Sprayer:
Prior to disinfection or sanitization, preclean surface. For use on hard, non porous, nonfood contact surfaces only. Hold (spray bottle) (container) (product) upright 6" to 8" from surface.
Spray 2 to 3 seconds until (thoroughly) (wet) (covered with mist)
To Disinfect: Let stand for ten (10) minutes (to air dry) (rinsing not required) (If desired) (wipe with paper towel) (clean dish towel) (or) (clean microfiber towel).
To Sanitize: Let stand for 5 (five) minutes (to air dry) (rinsing not required) (If desired) (wipe with paper towel) (clean dish towel) (or) (clean microfiber towel).
To Deodorize: Spray on surfaces as needed (let air dry). If desired wipe.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/ OBJECTS SOILED WITH BLOOD/BODY FLUIDS: In health care settings or other settings where there is an expected likelihood of soiling inanimate surfaces/ objects with blood or body fluids, and where the surfaces/ objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (AIDS Virus) the following special procedures must be used. PERSONAL PROTECTION: When handling items soiled with blood or other body fluids wear protective equipment, including disposable latex or rubber gloves, gowns, masks, and eye coverings. CLEANING PROCEDURE: Blood or other body fluids must be thoroughly cleaned from the soiled surfaces and objects before product can be applied. CONTACT TIME: To kill HIV-1 (AIDS Virus), a contact time of 10 minutes at room temperature. DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Special Label Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores
- Personal Protection: Refer to label PPE requirements.
- Cleaning Procedure: Pre-cleaning is to include removal of fecal matter/waste from surfaces/objects.
- Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Product effectively kills the following pathogens:
HaloFogger:
†Bacteria:
Clostridium difficile (spore form) (ATCC # 43598)
Pseudomonas aeruginosa (Pseudomonas) (ATCC # 15442)
Staphylococcus aureus (Staphylococcus) (Staph) (ATCC 6538)

Sprayer:
Effective disinfectant against the following (10 minute contact time):
*Bacteria:
Pseudomonas aeruginosa (Pseudomonas) (ATCC 15442)
Salmonella enterica (Salmonella) (ATCC 10708)
Staphylococcus aureus (Staphylococcus) (Staph) (ATCC 6538)
(Methicillin Resistant) Staphylococcus aureus (Staph) (MRSA) (ATCC 33592)
Escherichia coli (E coli) (ATCC 11229)
**Viruses:
Feline calicivirus (as surrogate for Norovirus) (ATCC VR-782)
Human Immunodeficiency Virus type 1 (HIV) (Stain HTLV-IIIB)
Influenza A strain Hong Kong (flu virus) (ATCC VR-544)
Influenza A (H5N1) (influenza) (flu virus) (Strain VNH5N1-PR8/CDC-RG CDC #2006719965)
Minute virus of Mice (MVM) (ATCC VR 1346)
Norovirus [Norwalk virus] (ATCC VR-782)
Rhinovirus type 37 (Rhinovirus)) (ATCC BR-1147, Strain 151-1)
Fungi:
Trichophyton mentagrophytes (ATCC 9533)
Aspergillus niger (ATCC 16404)

Effective sanitizer against the following (5 minute contact time):
*Bacteria:
Proteus mirabilis (ATCC 9240)
Staphylococcus aureus (Staphylococcus) (Staph) (ATCC 6538)
(Methicillin Resistant) Staphylococcus aureus (Staph) (MRSA) (ATCC 33592)
Enterobacter aerogenes (ATCC 13048)

Miscellaneous Claims:
Halofogger:
For use in the HaloFogger
For use in room fogging equipment [instrument[s] [device[s] [fogger[s] system[s]
Healthcare-grade [Hospital-grade] disinfectant
All-purpose
Ready-to-use [formula] [No mixing required]
Go [Goes] above, beyond, under and around disinfecting sprays and wipes
Advanced, Patented Formula
No Wipe, No rinse, Dry Mist
Whole [complete] Room Disinfection [Disinfecting] System
Bleach [Chlorine] [Bleach and Chlorine] [Alcohol] free formula [technology] [disinfection] [disinfecting] [disinfectant]
Fast, Easy, Effective
Frequent (daily) use formula
Great [suitable] for frequent (daily) use
Leaves [room] surfaces disinfected
Makes whole room disinfecting easier
No [mixing] [or] [dilution] [diluting] [labor] required
Room is safe to enter within minutes following aeration, once hydrogen peroxide is below 1 ppm
[Allows for] quick room turnover
Easily incorporated into (current) cleaning procedures
Lightweight, easy to transport, and capable of achieving reliable disinfection
Self-contained, allowing for reliable disinfection
Easy to transport and can be configured to treat multiple spaces simultaneously
Scalable technology - able to use multiple units/applicators
Economical, (non-corrosive), and easy to apply
Disinfection efficacy against bacteria
Disinfects hard to reach hard non-porous surfaces in treated room.
Disinfects high touch hard non-porous surfaces (in treated room)
Disinfects treated hard non-porous surfaces on high touch equipment
Disinfects hard non-porous high touch surfaces
Leaves no residues (no wiping necessary)
[Economical and] easy to apply
Whole (complete) Room Disinfection (Disinfecting) (Disinfectant) (System)
No (mixing) (or) (dilution) (diluting) required
When you re-enter the room, you can “smell the clean”
Room is safe to enter once hydrogen peroxide is below 0.2 ppm.
Effective whole (complete) room treatment for rooms up to (18’8” x 16’8”x 11’9”)/(3,663.7 ft3)/(104 m3)
Efficient whole (complete) room treatment for rooms up to (18’8” x 16’8”x 11’9”) (3,663.7 ft3) (104 m3))
Allows for quick room (disinfection) (and)(turnover)
Whole (complete) Room Disinfection (Disinfecting) (Disinfectant) (System)
Makes whole room disinfecting easier
(Whole) (Complete) room disinfection
[Note to reviewer: where room dimensions are stated, one of the three dimensions will be used]

General Performance Claims:
Halofogger:
Daily defense against [Clostridium difficile spores] [C. difficile spores] [C. diff spores]
Contains hydrogen peroxide
The smell of clean
Evaporates completely

Effectively eliminates [pathogens] [bacteria] from hard, nonporous surfaces.
Effective [alternative] broad-spectrum surface disinfectant
Intended for use in all medical, healthcare, semi-critical care, and long term care environments.
Gets everywhere, disinfects all [pre-cleaned, hard, non porous] room surfaces
Reaches into every nook, crevice and corner that disinfecting sprays and wipes can't
Reaches surfaces that regular disinfecting can't
Reduce[s] the risk of cross contamination associated with using a rag, wipe or sponge
Reduce[s] labor costs
[Disinfectant] [Disinfects] [Daily] [Multi-action] [Multi-purpose] [Multi-room] [Multi-surface] [Disinfectant]
Kills pathogenic bacteria
HaloMist meets EPA standards for healthcare [hospital] grade disinfectant
Controls odors caused by [bacteria] [inert bacteria]
Deodorizes by killing bacteria that causes odor[s]
Deodorizing by killing odor-causing [bacteria] at their source
Eliminates [removes] odors [caused by] [bacteria]
Gets rid of odors by killing the [bacteria] [that cause them]
Room fogger works to disinfect microorganisms† in even the most hard-to-reach areas
Disinfection efficacy against bacteria
Helps prevent the build-up of odors by killing odor-causing bacteria (on hard; pre-cleaned, non-porous surfaces)
For (hospital) (healthcare) (medical) (semi-critical care) (long term care) facilities as a disinfectant
Disinfects hard non-porous [non-food] contact surfaces in: [use sites]
For use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments as a disinfectant
For use on hard, non-porous surfaces located in: [use sites]
Great [suitable] for whole [complete] room [disinfecting] [disinfection]
Treats, does not cover up [no residue] [no need to rinse after use] as a disinfectant
Use on hard to reach areas [like nooks and crannies]
Use this product in [use sites]
Kills [eliminates] 99.9999% of [Clostridium difficile spores] [C-diff spores]
Kills [eliminates] 99.99% of Pseudomonas aeruginosa [Pseudomonas] bacteria
Kills [eliminates] 99.99% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria
Multiple [Multi-faceted] killing mechanism[s]
Multiple [Multi-faceted] mechanisms of killing action
Multiple modes of killing action
Does not require additional aeration (scrubbing) time or waiting time after H_2O_2 is below 0.2PPM
EPA registered equipment and solution combination for Hospital (Healthcare) disinfection

Specific Disinfecting Claims

Halofogger:
Sporicidal
Kills [eliminates] bacteria [Clostridium difficile spores] [C-diff spores]
Kills [eliminates] 99.9999% of [Clostridium difficile spores] [C-diff spores]
Kills [eliminates] Pseudomonas aeruginosa [Pseudomonas] bacteria
Kills [eliminates] 99.99% Pseudomonas aeruginosa [Pseudomonas] bacteria
Kills [eliminates] Staphylococcus aureus [Staphylococcus] [Staph] bacteria
Kills [eliminates] 99.99% of Staphylococcus aureus [Staphylococcus] [Staph] bacteria
First disinfectant [disinfecting] fogging [solution] [formula] [product] proven to kill [eliminate] bacteria [Clostridium difficile spores] [C-diff spores]
First EPA registered disinfectant [disinfecting] fogging [solution] [formula] [product] for whole [complete] room surface disinfection [disinfecting]
An effective disinfectant [solution] [formula] [product] for use in healthcare facilities
An effective disinfectant [solution] [formula] [product] for use in healthcare facilities for whole [complete] room surface disinfection [disinfecting]
An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments
An effective disinfectant [solution] [formula] [product] for use in [hospital[s] [healthcare] [medical] [semi-critical care] [long term care] environments for whole [complete] room surface disinfection [disinfecting]
Effective against bacteria
Disinfection of all hard non-porous surfaces in a hospital (patient) room
(Disinfectant) (Disinfecting) fogging (formula) (product) for (whole) (complete) room surface (disinfection) (disinfecting)
(This product) kills the bacteria† that cause (bad) odors
(This product) kills bacteria† on hard non porous, nonfood contact surfaces in public places
(This product) kills bacteria† on commonly touched on hard non-porous, non-food contact surfaces (in non-residential public places) (in hotel rooms) (in medical facilities)Kills [eliminates] [destroys] [bacteria] on hard, non-porous surfaces
Kills [eliminates] bacteria [odors] and deodorizes
On hard, non-porous, non-food contact surfaces this product kills [eliminates] bacteria
Surface Disinfectant
Whole [Complete] Room Surface Disinfectant
This product reduces the risk of cross contamination of bacteria on treated hard, non-porous surfaces
This product [helps] aids] in the reduction of cross contamination of bacteria on treated hard, non-porous surfaces
This product helps fight the spread of bacteria on treated hard, non-porous surfaces
[You can] [Use] this product in places that are difficult to [disinfect] [sanitize] [reach] such as nooks and crannies

Sprayer:
Kills (99.99% of) (bacteria*) (the bacteria specified on the product label)
(Salmonella) (Staph) (MRSA) (Enterobacter Aerogenes) control
Effective against (bacteria*) (the bacteria specified on the product label)
Fights (and) (kills) odors
Kills (Destroys) (Eliminates) (99.99%) (of) (the) (bacteria*) (the bacteria specified on the product label) on hard non porous surfaces
Kills antibiotic resistant bacteria* (Methicillin Resistant) (Staphylococcus aureus) (MRSA)

Kills (99.99% of) (bacteria*) (eliminates odors) (and) (deodorizes)
Kills (99.99% of) (bacteria*) on hard non porous, nonfood contact surfaces
On hard, non-porous, non-food contact surfaces this product kills (99.99% of) the bacteria specified on the product label.

Healthcare Use Sites:
This product [or product name] is designed specifically as a healthcare-grade [ready-to-use] disinfectant [disinfecting] fogging [solution] [formula] [product] for use in:

Including but not limited to:
Ambulatory Surgical Centers (ASC)
Anesthesia Rooms or Areas
[Assisted Living or Full Care] Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms or Areas
Critical Care Units or CCUs
Dental operatories
Dentist office
Elevators
Examination room[s]
Dialysis Clinics [Facilities]
Donation Centers [blood] [plasma] [semen] [milk] [apheresis]
Emergency Rooms or ERs
Emergency Vehicles
Eye Surgical Centers
Health Care Settings or Facilities
[Hospital] Kitchens (non-food contact surfaces)
Hospices
Intensive Care Units ICU[s] [areas]
Isolation Areas
Laundry Rooms
Laboratories
Long Term Care Facilities
Medical Facilities
Newborn or Neonatal [Nurseries] [Intensive Care] Units [NICU]
Nursing or Nursing Stations
Operating Rooms or ORs
Ophthalmic Offices
Orthopedics
Out Patient [Surgical Centers (OPSC)] [Clinics] [Facilities]
Patient Areas
Patient Restrooms
[Pediatric] Examination Rooms or Areas
Pediatric Intensive Care Units [PICU]
Pharmacies
Physical Therapy Rooms or Areas

Psychiatric Facilities
Public [Care] Areas
Radiology or X Ray Rooms or Areas
Recovery Rooms
Rehabilitation Centers
Respiratory Therapy Rooms or Areas
Restrooms
Surgery Rooms or Operating Rooms or ORs
Waiting Rooms or Areas

Other Use Sites
Animal Industry, Bio-Safety labs, Biotech Industry, Commercial, Education, Entertainment, Government, Historic Buildings, Homeland Defense, Hospitality, Industrial, Institutional, Multifamily housing, Military, Pharmaceutical, Recreational, Entertainment and Residential Settings and Assets, Senior Living, Tissue banks, Transportation (public and private), Worship Facilities.

Specific Areas of use include; Airplane, Ambulance‡, Automobile‡, Barrier isolator, Biological Decontamination Chamber, Biological Safety Cabinet, Blood Bank, Boat, Bowling Alley, Brothel, Bus, Cargo Planes, Campground Facility, Church (Temple) (Mosque) (House of worship), Clean Room (Electronic) (Pharmaceutical) (Tissue Bank), Clinic (Medical), College or University Facility, Commercial Building, Correctional Facility, Cruise Ship, Day Care Center, Dorm, Factory, Gymnasium, Health Club (Spa), Home, Hospital, Hotel, Industrial Facility, Infirmary, Institutional Facility, Laundromat (Institutional), Locker Room, Manufacturing Plant (non-food), Massage Therapy Facility, Military (Installation) (Vessel) (Aircraft) (Vehicle) (Asset), Mobile Home, Motel, Nursing Home, Office (Medical, Dental, Physician's, Commercial, Correctional, Sheriff), Pharmaceutical Test and Manufacturing Facility, Pharmacy, Indoor Playground, Police Department, Public Facilities, Public Restroom, Recreational Center, Rental Facility, Residential Facility, Retail Facility, Recreational Vehicle, School Bus, Schools, Shelter, Sports Arena, Submarine, Theaters, Tissue Bank, Train, Veterinary Clinic, Vivarium, and Warehouse. ‡ Only for application with [product name] sprayer [unit].

Food Handling Use Sites (includes Storage, Preparation, Processing, and Serving):
Food Manufacturing Plant, Food Handling Establishments, Food warehouses, Cafeteria, Farmer’s Market, Food Service Establishment (Restaurant) (Fast food), Supermarket or Grocery Store

FOOD AREAS: In establishments where food and food products are held, prepared, processed and served, application may be made only when the facility is not in operation provided exposed food is covered or removed from the area being treated prior to application. Food contact surfaces must be rinsed with potable water after use of the product. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible waste storage, enclosed processing systems (mills, dairies, edible oils, syrups), serving areas (where prepared foods are served, such as dining rooms).

NON-FOOD AREAS: This product may be used to treat nonfood areas in food handling use

sites. Nonfood areas include garbage rooms, lavatories, entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling)

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

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 on Skin:** Rinse skin immediately with plenty of water for 15-20 minutes. The affected skin can turn white and itchy. These symptoms will disappear within a few minutes.

STORAGE AND DISPOSAL Do not contaminate water, food, or feed by storage and disposal. Keep out of direct sunlight and away from heat. Do not freeze. Store in original container in areas inaccessible to small children and pets. Non-refillable container. Do not reuse or refill this container. Recycle, if available, or discard in trash. If product leaking or spills should occur, please dilute with water and dry with absorbent material, or dilute with water as it is flushed into waste water drain.

Questions? Comments, or in case of an emergency, call toll free (1-877-726-6745). Have the product container or label with you when calling a Poison Control Center, or doctor, or going for treatment.

HaloMist Use Instructions

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1. General Information

1.1 HALOMIST

HALOMIST has been registered by Halosil International 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 the disinfection of exposed surfaces in pre-cleaned, sealed rooms.

2. HALOMIST Disinfectant Application Process

HALOMIST should be should only be dispensed using the HaloFogger. Effective application of HALOMIST requires adequate product concentration and exposure time. The HaloFogger is designed to achieve the correct concentration and contact time of HALOMIST within a defined area.
Select the standard HaloFogger or extended nozzle HaloFogger version depending on space and access. Read the HaloFogger User's Manual prior to initiating the application process to determine the appropriate steps to take in development and application of the process.

The HaloFogger uses air as a carrier to deliver a dry mist (suspension of small liquid droplets in the air) of HALOMIST to exposed surfaces inside a sealed room for a time based on the size of the room. Read the HALOMIST SDS prior to fogging. The HALOMIST disinfectant is continuously fogged for the required dispensing time to maintain the desired concentration of the product mist. The HaloFogger will automatically stop fogging at the selected time. HALOMIST decomposes into water and oxygen.

The HALOMIST process can consist of 1, 2 or 3 phases depending upon application:

1. Dehumidification - The Dehumidification phase is required only if the room to be disinfected is above 50% relative humidity. In rooms with higher humidity levels the dispensing of product can be affected by increased condensation levels, which can decrease the efficacy of the product. Room air is first circulated in the sealed treatment room by the dehumidifier to reduce humidity to a predetermined level in the 30-50% relative humidity (RH) range. This permits the target Dry Mist Hydrogen Peroxide (DMHP) concentration to be maintained below condensation levels during the disinfection phase. The time to reach the targeted dehumidification level increases with the volume of the room, and is dependent on environmental conditions.

2. Disinfection –For all disinfecting applications, HALOMIST is continuously fogged for a selected time to obtain the target DMHP concentration over a pre-established period of time for the volume of the enclosed area. It is recommended the room temperature be in the range of 20º C +/- 2º C (68º F +/- 4º F). Whenever possible, delay room re-entry and allow treated room to remain unoccupied overnight for safety and maximum efficacy.

3. **Post Treatment Aeration** - When accelerated room re-entry is necessary, the dehumidifier will speed the reduction of the DMHP concentration in the room to a 0.2 ppm level, allowing earlier reentry into the room by trained applicators. Treated rooms may not be released for general public use until after a 0.2 ppm level of DMHP is achieved in the room.

3. User Safety Requirements

Refer to the product label for user safety requirements and PPE.

4. Disinfection Management Plan

4.1 GENERAL

Employees of the site to be disinfected should develop a site specific Disinfection Management Plan (DMP) for each room to be fogged with HALOMIST. The user is responsible for all tasks of the disinfection process unless noted in the DMP and must be on site for the entire disinfection treatment process. The DMP must address a full characterization of the site, and include appropriate monitoring and notification requirements, consistent with, but not limited to, the following:

1. Inspect the structure and or area to determine its suitability for disinfection (size, non-porous surfaces, pre-cleaned).
2. Seal the room to be treated adequately to ensure that DMHP levels outside the room are kept at acceptable levels and that there is adequate coverage of product within the room. Periodically monitor any occupied adjacent rooms and/or buildings to ensure safety.
3. Prior to each disinfection, review any existing DMP, SDS, Equipment Manuals and other relevant safety procedures with appropriate employees.
4. 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.
5. 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. This plan must also demonstrate that nearby residents will not be exposed to concentrations above the allowable limits.
6. Confirm the placement of placards to secure entrance into any area under disinfection.
7. Confirm the required safety equipment is in place and the necessary manpower is available to complete disinfection.

These factors must be considered in putting a DMP 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 user must read the entire label and equipment manuals and follow all directions carefully. If the user has any questions about the development of a DMP, contact Halosil International or authorized distributor for further assistance.

4.2. PERSONNEL

1. Training and Certification of Applicators
Prior to use, applicators must be adequately trained and certified by Halosil International or its authorized distributor or reseller on the hazards and label directions for HALOMIST, on the use and operation of the DMHP application equipment, HALOMIST monitoring procedures and, when appropriate, disinfection validation procedures.

2. Confirm in writing that all personnel in and around the area to be fogged have been notified prior to application of the disinfectant. Consider using a checklist that each employee initials indicating that they have been notified.
3. Instruct all disinfection personnel about the hazards that may be encountered, about the selection of PPE, and the use of any hydrogen peroxide detection equipment.
4. Confirm that all personnel are aware of and know how to proceed in case of an emergency situation.
5. Instruct all personnel on how to report any accident or incidents related to disinfectant exposure.
6. Establish a meeting area for all personnel in case of emergency.
7. Confirm that all applicators have been trained in the use of HALOMIST and are in good standing including any required refresher training.
8. Develop a Worker Health and Safety Plan as required by OSHA for applicators. The owner and 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.

4.3. MONITORING

A. Perimeter safety
1. Monitoring of HALOMIST concentrations must be conducted immediately adjacent to the fogged space to prevent excessive exposure and to determine where exposure may occur. Document where monitoring will occur.
2. Keep a log or manual of monitoring records for each disinfection site. This log must at a minimum contain the timing, number of readings taken and level of concentrations found in each location.
3. When monitoring for leaks, document that there is no DMHP present above the 0.2 ppm level. Subsequent leak monitoring is not routinely required. However spot checks must be made, especially if conditions significantly change.
4. Monitoring must be conducted during aeration and corrective action taken if H_2O_2 levels exceed the allowed levels in an area where bystanders or nearby residents may be exposed.

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 0.2 ppm DMHP. The treated room and adjacent areas must remain unoccupied until DMHP levels are at or below 1ppm.

B. Efficacy
1. Chemical Indicators (CIs) may be used in all areas of the room to assure consistent delivery.
2. Document HaloFogger run times, temperature, room humidity and CI color change.

4.4. SEALING PROCEDURES

1. Sealing must be adequate to prevent any leaks. Care should be taken to ensure that sealing materials remain intact until the disinfection is complete.
2. If the structure and/or area has been fogged before, review the previous DMP information.
3. Make sure that construction or remodeling has not changed the building in a manner that will affect the disinfection process.
4. Warning placards must be placed on every possible entrance to the disinfection site.

4.5. APPLICATION PROCEDURES AND DISINFECTION PERIOD

1. Plan carefully and apply disinfectant in accordance with the label requirements.
2. When entering into the area under disinfection always work under the direct supervision of a trained applicator wearing appropriate PPE.
3. Provide watchmen when a disinfection site cannot otherwise be made secure from entry by unauthorized persons.
4. Follow Use Instructions (See Section 5.)

4.6. POST-APPLICATION OPERATIONS

1. Ventilate and aerate in accordance with structural limitations.
2. Turn on ventilating or aerating fans where appropriate.
3. Use a suitable DMHP detector before reentry to determine disinfectant concentration. (example: Draeger or ATS PortaSens II)
4. Keep written records of monitoring to document completion of aeration.
5. Remove warning placards when aeration is complete.
6. Inform business clients that employees or other persons may return to work or otherwise be allowed to re-enter the aerated structure.

4.7. CRITERIA FOR SUCCESSFUL DISINFECTION:

1. All CIs that are properly recovered and evaluated exhibit a visible color change following exposure to DMHP.

5. USE INSTRUCTIONS

5.1 ROOM PREPARATION

CAUTION – Before proceeding, ensure that personnel who operate the HaloFogger have received appropriate training, including:
- Review HaloFogger User Manual and HALOMIST Labeling
- Review HALOMIST Safety Data Sheet

Cleaning: Remove gross filth and visible soil. Wash soiled surfaces with a generic cleaning agent (i.e. soap and water, a multi-purpose cleaner, etc.) using a cloth, sponge, wipe or appropriate cleaning device to ensure visible soils are removed All the surfaces within the treatment area must be completely dry to the touch prior to initiating DMHP application.

IMPORTANT – The HaloFogger does not replace the requirement for manual room cleaning. You must follow facility's cleaning procedure before using the HaloFogger.

5.2. ROOM SET UP

1. It is recommended that all ventilation systems, including HVAC, be turned off for the duration of the fogging process. Seal any supply or return vents and duct work to prevent of distribution of HALOMIST through the ductwork. Cover any smoke detectors. Sealing techniques can vary, but most often includes either the use of HaloShield Vent and Smoke Detector covers or polyethylene sheeting and adhesive tape.

2. Seal the room to be treated to ensure that DMHP levels outside the room are kept at acceptable levels and that there is adequate coverage of product within the room

3. Open internal doors, cupboards, and drawers of room furniture unless specifically directed to leave them closed (as in the operating room).

4. Remove mattresses from beds and tilt them on their sides.

5. Monitor areas immediately adjacent to the fogged space to ensure levels are below TWA for DMHP.

6. If possible, modify ambient conditions in the room to meet the following recommended parameters: Temperature: 20º C +/- 2º C (68º F +/- 4º F); Relative Humidity: between 30% - 50%.

7. Assure all personnel have vacated the treatment room prior to DMHP application. Remove all plants, animals, beverages and food.

8. Close all windows and seal door(s) from outside of room being treated.

9. Applicators must not re-enter the treated room until exposure levels of DMHP are at or below one ppm.

10. Placarding of Treatment Room: The applicator must placard or post all entrances to the designated buffer zones with signs in English bearing:

1. The signal word "CAUTION/PRECAUCION" in red.
2. "Area under treatment, DO NOT ENTER.”
3. The statement "This sign may only be removed after the treatment of enclosed area, after DMHP levels are less than or equal to one ppm".
4. Identification of HALOMIST disinfectant mist as hazard associated with the treatment process
5. Contact information for the applicator.

All entrances to the treatment room must be placarded. Placards must be placed in advance of the treatment in order to keep unauthorized persons from entering the treated room. Placards can be removed after the treatment room contains concentrations of DMHP at or below 1 ppm.

5.3 TREATMENT PROCEDURE PROTOCOL

1. Position the HaloFogger in a corner of the room approximately one foot away from the wall, pointing the nozzle towards the center of the room. Choose a corner farthest away from vents, ductwork and door. IMPORTANT - Dispensing airflow path from the HaloFogger must remain unobstructed during entire treatment procedure.

2. Measure the length, width and height of the room. Round up to the nearest cubic foot or cubic meter. These measurements will determine the final room size and recommended run-time of the HaloFogger.

3. Plug the HaloFogger into a standard, grounded electrical wall outlet. When the power connection has been made, the green status indicator light on top of the device will illuminate.

4. The HaloFogger run time is calculated based on a dose concentration of 0.011 oz/ft3.

5. Turn the timer dial on the top of the HaloFogger to the number of minutes specified for your room size. ***Do not*** *set the timer for longer than the suggested time. Excessive fogging can cause condensation, which may reduce effectiveness.*

6. Check the fluid level indicator lights to see level of HALOMIST in the HaloFogger It is recommended the unit reservoir be topped off before proceeding with the treatment process. Refer to the Setup and Filling, Section 8.1.

7. Press and hold the HaloFogger Start button for 2 seconds. The green status indicator light will begin to flash red, indicating that you have 30 seconds to leave the room before the HaloFogger device begins to operate.

8. Close the door to the room after you have exited. Post a sign on the door indicating that the room should not be entered during treatment process. Note time treatment process was started on room sign.

9. After at least 30 seconds, the status indicator light will turn solid red and the HaloFogger will begin to dispense HALOMIST into the room. It is likely that you can hear the HaloFogger running.

10. When the HaloFogger has finished dispensing the room will be full of atomized HaloMist disinfectant. The status indicator will remain illuminated red. DO NOT ENTER ROOM at this time.

11. The treated room must remain unoccupied until the minimum room re-entry wait time has expired and hydrogen peroxide concentration level (ppm) has been checked. When possible, it may be easier to delay re-entry and allow treated room to remain unoccupied overnight for safety and maximum efficacy. Hydrogen peroxide concentration levels must be at or below one ppm for safe room re-entry. Once safe levels are determined to be at or below one ppm, it is recommended that all doors and HVAC vents be opened and HVAC system be restarted to allow increased ventilation and airflow circulation in the room. Uncover smoke detectors.
Upon expiration of room re-entry wait time, to assure occupational health levels are not exceeded, verify safe hydrogen peroxide concentration level is at or below one ppm, using a handheld hydrogen peroxide detector (example: Draeger or ATS PortaSens II), If level is not at or below one ppm, wait an additional 10-minutes and re-check. Continue to check until safe health exposure level is at or below one ppm. Treated room can be re-occupied after hydrogen peroxide concentration level is determined to be at or below 0.2ppm.

12. When treatment is complete, unplug the HaloFogger from the power source.

13. Store HaloFogger upright, in a safe, dry location. It is not necessary to drain HaloFogger of disinfectant.

Disinfecting for High Humidity Environments and Applications Requiring Accelerated Room Re-Entry – Special Instructions

A. Prepare the room as outlined in Sections 5.1, Room Preparation and 5.2 Room Set Up – then,

1. Room humidity level of 50% or less is recommended before starting the treatment process. *Some rooms may have a higher humidity level which can extend the room re-entry time.* Position the dehumidifier next to HaloFogger. Verify that the dehumidifier's reservoir is empty or empty reservoir prior to use.

2. Plug dehumidifier into the correct location on the Power Module, and then plug the power module into a standard, grounded electrical wall outlet.

3. Turn on dehumidifier; set fan to highest speed setting. Check humidity level with humidity sensor; if humidity level is above 50%, let dehumidifier run until the humidity level is reduced to recommended level.

4. Plug the HaloFogger into the correct location on the Power Module. When the power connection has been made, the green status indicator light on top of the device will illuminate.

5. Continue following steps section 5.3 – Treatment Procedure Protocol

5.4. SPECIAL ROOM RE-ENTRY INSTRUCTIONS

WARNING – During the treatment process, HALOMIST mist is dispensed. Personal protection equipment including the use of an appropriate air respirator is required for hydrogen peroxide concentration levels exceeding 0.2ppm.

5.4.1 Early Room Re-Entry

In case of an emergency and/or unknown levels of Hydrogen peroxide mist that may exceed applicable exposure limits within the treated room requires an a Self-Contained Breathing Apparatus (SCBA) or an airline respirator. When entering into an area with the HaloFogger running, always work under the direct supervision of a trained applicator wearing appropriate PPE.

5.4.2 Re-Entry to Sealed Room

Re-entry to a sealed room by a trained applicator is allowed under the following circumstances:

a. Only enter the room to perform a planned task, e.g. to retrieve equipment, open windows, augment aeration process etc. and leave the room in the shortest time possible.

b. Always wear wrap around style goggles to protect against irritation of eyes.

c. Determine Hydrogen peroxide levels prior to room entry using a handheld hydrogen peroxide detector (example: Draeger or ATS PortaSens II).

d. Hydrogen Peroxide levels between 1 and 10 ppm requires at least half-face piece respirator (and appropriate eye protection) with either 3M 6003 or 6006 (organic vapor/acid gas or multi-gas) cartridge in combination with particulate filter (i.e. 5N11 or 5P71).*

e. Using a full-face piece respirator (when quantitatively fit tested) with either cartridge mentioned in 5.4.2.c gives an Assigned Protection factor of 50 for use up to 50ppm of Hydrogen Peroxide.*

*3M Technical Bulletin #185 and Solvay Chemicals Technical Communication TDS No. HOOH-PAA-RESP

Otherwise, do not re-enter the treated room until exposure levels are at or below one ppm.

5.5. RELEASING TREATED SEALED ROOM FOR RETURN TO SERVICE

1. The treated room can be released for general public use after DMHP levels are determined to be at or below one ppm.

2. Once DMHP levels are determined to be at or below one ppm, applicators may re-enter the treated room and remove any sealing materials including any covered fire alarms and disconnect or remove the HaloFogger from the treated sealed room.

3. Turn on ventilation systems including HVAC.

4. Remove placards and release the treated room for normal operation.

5.6 EMERGENCY VEHICLE DECONTAMINATION PROTOCOL

1) Vehicle should be parked in an open bay near an accessible electrical outlet. Wearing proper PPE, pre-clean all ambulance surfaces of gross filth with an appropriate cleaner or cleaner/disinfectant. All surfaces must be dry prior to treatment.

2) If the ambulance has been in the cold for an extended period of time, pre-warm the cab and patient compartment of vehicle. Keep heat on prior to fogging so patient compartment is at or above 70 degrees F. In very humid conditions use of the vehicle's air conditioning system may be required to adjust humidity level so patient compartment is below 50% relative humidity prior to fogging. If the ambulance bay has a fume exhaust system, turn it on. Make sure the fogging solution is not below 65 degrees F prior to use.

3) Notify others working in the building that a disinfection procedure is taking place and post signage accordingly.

4) Inside patient compartment, remove, close or bag in plastic, any porous materials. Remove and bag any sheets or blankets on the stretcher pad and place the stretcher pad on its side to

expose all areas of the stretcher. Open fully any drawers or cabinets that require disinfection. Close all that don't require treatment. Close and seal all vents in compartment and door to driver's cab (optional), with painters tape. Seal exhaust vents on exterior of vehicle with painters tape.

5) Position fogger in a back corner of the vehicle patient compartment with the nozzle pointing towards center of compartment.

6) Set the timer dial on top of the HaloFogger according to dimensions. *Do not set timer for longer that the suggested time. Excessive fogging can cause condensation, which may reduce effectiveness.*

7) Plug the fogger's power cord into a grounded extension cord. Pass the cord under and through the juncture of the back door seal outer corner and plug into a building wall outlet. Seal the vehicle's rear doors tightly with painters tape. Plug the extension cord into a standard, grounded wall outlet. When the power connection is made the green status indicator light on top of the fogger will illuminate.

8) Check the fluid level indicator lights to see the level of HaloMist Disinfectant in the fogger. Refer to the Set Up and Filling instructions in the HaloFogger manual.

9) Press and hold the Start button on the HaloFogger for 2 seconds. The green status indicator light will begin to flash red indicating you have 30 seconds to vacate the vehicle before the HaloFogger begins to operate.

10) Upon exiting vehicle through side door, seal all side door seams with painters tape.

11) When the HaloFogger has finished dispensing the vehicle will be full of aerosolized HaloMist disinfectant. DO NOT ENTER VEHICLE at this time.

12) The treated vehicle must remain unoccupied until the hydrogen peroxide concentration is at or below one ppm for safe vehicle re-entry. Once safe levels are determined to be at or below 1 ppm, it is recommended that all vehicle doors and be opened to allow increased ventilation and airflow circulation in the room.

Upon expiration of vehicle re-entry wait time, to assure occupational health levels are not exceeded, using a handheld hydrogen peroxide detector, verify safe hydrogen peroxide concentration level is at or below 0.2 ppm. Vehicle can be re-occupied after hydrogen peroxide concentration level is determined to be at or below 0.2 ppm.

13) When treatment is complete, unplug the Halosil HaloFogger from the power source.

14) Store Halosil HaloFogger upright, in a safe, dry location. It is not necessary to drain Sanosil HaloFogger of disinfectant.

15) Exterior ambulance compartments like the outside door handles including cab and exterior stretcher compartment, for example, may be sprayed with HaloSpray disinfectant according to label directions.

6. PRECAUTIONS

6.1 CAUTION STATEMENTS

A caution statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately, could lead to serious injury or death.

1. **KEEP OUT OF REACH OF CHILDREN.**
2. Carefully read all instructions, warnings, cautions and first aid statements prior to use.
3. Do not enter room while the HaloFogger is in use. Keep door and windows closed.
4. Use only as directed.
5. Allow Room Re-entry Wait Time to expire before re-occupying the room. Re-entry before wait time has expired could result in sensory irritation and should only be done while using proper personal protection equipment (PPE) including, at a minimum, wrap-around style goggles, N-95 respirator mask and gloves.
6. Avoid inhalation of vapors or skin and eye contact with HALOMIST fog.
7. The HaloFogger is designed for ease-of-use. However, only properly trained individuals should use this device.
8. Electric shock hazard. Do not plug in if electrical plug or parts are wet.
9. There are no user-serviceable parts inside the HaloFogger other than the nozzle. An operator may only perform maintenance procedures specifically described in this manual. The manufacturer should make all other repairs.
10. While in use, the body of the HaloFogger may become warm to the touch. Use caution when handling.
11. Use personal protection equipment (PPE) including wrap-around style goggles and gloves when pouring disinfectant fluid into the device. Avoid splashing or overfilling which could harm the user and/or the device.
12. Specific warning and caution statements are included for HALOMIST (see Section 6.3).
13. Halosil International is not responsible for any injury or damage caused by using this device outside of the specific parameters detailed in this manual.

6.2 OPERATION WARNINGS

These warnings pertain to the actual use of the HaloFogger unit.

1. To ensure effectiveness and safety, use ***only*** with HALOMIST. Using any other manufacturer's disinfecting or cleaning product ***will*** result in serious injury, exposure and environmental damage.
2. Position the device on a secure surface to prevent rolling or moving while in use.
3. Use only an OEM supplied electrical cord.
4. Always unplug the power cord from the outlet before moving the device.
5. Clean debris from the device nozzle and funnel on a regular basis according to the instructions in this manual (see Section 9, Maintenance).
6. Regularly check disinfectant fluid level to ensure sufficient volume is present to treat each particular room size.
7. Do not set the timer for longer than the suggested fogging time. Excessive fogging can create

condensation, which may activate fire alarm systems.

8. Protect this device from severe impact or shock.
9. Take care to prevent water or other fluid from entering the device. Should this occur, allow to completely dry before use. Check the accuracy of all operating functions.
10. Do not tip the HaloFogger on its side at any time unless completely empty and dry.
11. Store HaloFogger in an upright position, in a safe, dry location. Do not place anything on top of the device.
12. Additional warning and caution statements are included for HALOMIST.

7. ROUTINE SYSTEM MAINTENANCE AND TROUBLESHOOTING

Refer to the HaloFogger User Manual for instructions regarding routine system and troubleshooting guidance.

8. STORAGE AND DISPOSAL

Storage: Store in a safe, dry location. Do not place anything on top of the device. Store in an upright position. Keep the refill door closed.
Do not allow HALOMIST to be stored in the HaloFogger for longer than one year.
Disposal: Electrical and electronic devices may not be disposed of with domestic waste. This product is in accordance with the law “waste electrical and electronic equipment” (WEEE).

Please contact your local representative for more information.