



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

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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](mailto: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%
<u>Other Ingredients.....</u>	<u>94.99%</u>
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)

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]

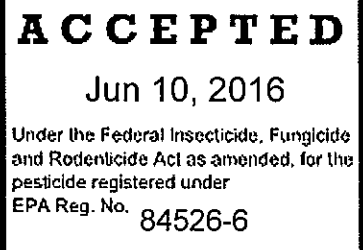
Call: (1-800-726-6765)

[or] Visit us at ([www.halosil.com](http://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) (Strain HTLV-III<sub>B</sub>)

Influenza A strain Hong Kong (flu virus) (ATCC VR-544)

Influenza A (H5N1) (influenza) (flu virus) (Strain VN H5N1-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 H2O2 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.