



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 08 2010

Lewis & Harrison
Agent for Sanosil USA, LLC
122 C Street, NW Suite 700
Washington, DC, 20001

Attention: Eliot Harrison
Regulatory Manager

Subject: Sanosil S010
EPA Reg. No. 84526-1
Amendment Letter Date: August 11, 2009

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

- All references in the label that the product “kills or prevents” mold and mildew must be deleted. Efficacy data to support the product as a “mildewcide” were not submitted. Language that implies the product to have “mildewstatic” claims (i.e., controls mold or mildew) is acceptable. Please be aware that although data is not required to be submitted for mildewstatic claims, the Agency assumes that this information has been generated to support the registration. As such, EPA can require this data be submitted in the future if needed.
- On page 10, under the **Storage and Disposal** section, delete the language “unless the directions for use allow refilling empty container with this product”. In its place, insert the following: “except as described in the directions for use”. This language is consistent with language in PR Notice-2007-4 (Storage and Disposal).

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

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

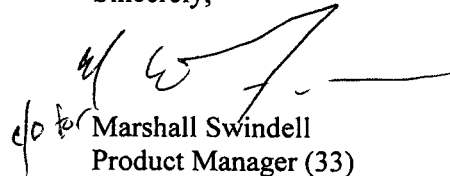
Additionally, the alternate Confidential Statement of Formula (CSF) submitted with respect to registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, meets

the requirements of PR 91-2 and 40 CFR 158.155 (Product Identity and Composition) and accurately reflects the Nominal Concentration for the active and inert ingredients.

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

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

Sincerely,



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

(Note: Bold, italicized text is information for the reader and is not part of the label).

Sanosil® S010
Bactericide and Virucide*
Effective against Mold and Mildew
Industrial/Animal Facility/Farm Use

Active Ingredients:
Hydrogen Peroxide.....5.00%
Silver..... 0.01%

Other Ingredients..... 94.99%
Total 100.00%

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84526-1

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. 84526-1
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.sanosilglobal.com)
[Made in Switzerland]
Distributed by: Sanosil USA, LLC, 100 Dean Drive, Newark, Delaware 19711
[or an authorized Sanosil USA distributor (insert name)]
Sanosil® is a licensed trademark of Sanosil Ltd. Switzerland

Optional Marketing Claims: (note that these claims may or may not appear on the commercial label; in addition, the claims may be used as bullet points or in a paragraph format)

Miscellaneous Claims

- Introductory
- New (*this claim will only be used for the first six months after commercial introduction*)
- (Fresh) (Neutral) (Lemon) (scent)
- (Unscented)
- Anytime (to-go)
- All-purpose
- Bleach (Chlorine) (Bleach and Chlorine) (Alcohol) free (formula) (technology) (disinfection) (disinfectant) (sanitization) (sanitizer)
- Dries quickly
- Dual Action (active) (system) (formula)
- Everyday formula
- Fast, Easy, Effective
- Frequent (regular) use formula
- Great for frequent use
- Leaves (household) surfaces sanitary (disinfected) (Scent free) (suitable for frequent use)
- Modern (Classic)
- On-the-go
- Ready to Use (formula) (no mixing required)
- The (disinfectant) (sanitizer) for the new era
- To-Go (anytime)
- Versatile Formula
- A technology that is enough to use around your family or pets (on the surfaces they touch the most)
- (Contains) no (lingering) (cleaning) chemicals
- Deodorizes sponges
- (Easy) (quick) (convenient) to use
- (Economy) (institutional) (value) (travel) (business) (size) (pack)
- Contains hydrogen peroxide, which breaks down into water and oxygen
- No (accidental whitening)
- Use throughout the (your) (home) (house)
- Makes your job easier
- No (mixing) (or) (dilution) (labor) required
- (Daily) sanitizing spray
- (Perfect) (ideal) for (business) (vacation) travel
- New Size
- Bonus Size
- Mini
- Pocket (size) (pack)
- Portable (size) (pack)
- Purse (size) (pack)
- Travel (size) (pack)
- Trial (size) (pack)
- Value (size) (pack)

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General Product Performance/Usage Claims

(Bactericidal) (Bactericide) (Disinfectant) (Disinfects) [Daily] [Multi-Action] (Multi-Purpose) (Multi-Room) (Multi-surface) (Disinfectant) (Sanitizer) (Virucidal*) (Virucide*) (Kills pathogenic bacteria and viruses*)

Sanosil S010 meets EPA standards for a (hospital) (home) (commercial) (institutional) (industrial) disinfectant.

Prevents the growth of mold and mildew

Mold and mildew buster

█████ mold

█████ mold and mildew, bacteria and ^{kill}viruses*

Mold and mildew ██████████

Sanosil S010 is a ready-to-use mold control agent

Sanosil S010 is effective against mold

Sanosil S010 helps ██████████ the re-occurrence of mold

Sanosil S010 ██████████ and inhibits mold and eliminates musty odors

Sanosil S010 can be used on bathroom and shower surfaces, walls, floors, tile, fiberglass, grout and plastic.

Controls kitchen odors caused by (insert bacteria) (bacteria)

Controls pet odors caused by (bacteria)

(This product) Deodorizes by killing (many) (bacteria) that cause odors.

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)

Gets to the heart of odors

Helps prevent the build-up of odors by killing odor-causing bacteria (on hard non-porous non-food contact surfaces)

Odor fighter

Perfect for eliminating your toughest odors at their source

(This product) Eliminates odors at their source

(This product) prevents odors at their source caused by (bacteria)

To eliminate odors use (this product) around (insert use sites) (insert use surfaces){insert use sites)

Disinfects hard non-porous (non-food) contact surfaces (such as) (insert use sites)

Disinfects (insert use sites) (and) (insert use surfaces)

For Hospital Use (graphics)

(For use in) hospitals (and homes) (as a) (disinfectant)

For use (on) (in) (insert use sites)(insert use surfaces)

For use in institutional, (animal care) (restaurants) (food-handling establishments) (and industrial) (facilities)

For use on hard, non-porous surfaces located in: (insert use sites)

Great for spot disinfection (target performance)

Simply spray (this product) on surfaces that you and your family and pets come in contact with everyday (including): (insert use surfaces)

(This product) (disinfects) (and) (sanitizes) (deodorizes) (the following surfaces) (insert use surface)

(This product) (disinfects) (and) (sanitizes) (in) (the following areas) (insert use sites)

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General Product Performance/Usage Claims (continued)

Treats, does not cover up (No residue) (No need to rinse after use) as a sanitizer and disinfectant
Use on hard to reach areas (like nooks and crannies)
Use this product (in) (under) (around) (on) (insert use site)
Ready to use
Use this product (on) (insert use surfaces)

Specific Sanitizing Claims

An effective sanitizer for non-food contact surfaces (for use in (insert use sites)
(Sanitizer)

Great for use as a non-food contact surface sanitizer in (insert use sites).

Kills (Destroys) (Eliminates) 99.9% of bacteria

Kills (Destroys) (Eliminates) 99.9% of bacteria on hard, non-porous surfaces

Kills (Destroys) (Eliminates) 99.9% of bacteria on hard, non-porous
(kitchen)(bathroom)(household) surfaces

Kills (99.9%) (of) (household) bacteria

Leaves (household) surfaces (sanitized) (and) (or) (disinfected)

Sanitizes (kitchen) (household) (bathroom) (restroom) (non-food contact) surfaces

Sanitizes (Kitchen) (household) (bathroom) (hard non-porous) (surfaces)

Sanitizer (Sanitizes)

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Specific Disinfecting Claims

An effective disinfectant for use in the kitchen, bathroom, bedroom and other household areas
(Controls)(Kills) odor-causing (bacteria)

Disinfection Control (Formula)

Disinfects (sanitizes) and deodorizes by killing (bacteria and viruses) and controlling their odors.

Dries, kills (bacteria)

(Salmonella) (Staph) (MRSA) (Enterobacter Aerogenes) control

Effective against bacteria

Eliminates bacteria (viruses) (and) (odors) on hard non porous surfaces that you (and) (your family) (your children) come into contact with everyday

Fights (and) (kills) odors

(Bacteria) (Virus) (killer) (destroyer)(eliminator)

Kills the viruses associated with the flu and the common cold.

Kills the (flu) (common cold) virus

Kills antibiotic resistant bacteria (MRSA)

Kills (Destroys) (Eliminates) (of) (bacteria) on hard non porous surfaces

Kills antibiotic resistant bacteria (Methicillin Resistant) (Staphylococcus aureus) (MRSA)

Kills (bacteria) (eliminates odors) (and) (deodorizes)

Kills (bacteria) helps (leaves) your house (home) smell (smelling) clean (and) (fresh)

Kills (bacteria) (whenever) you need it

Kills (household) (kitchen) (bacteria) on hard non porous, nonfood contact surfaces

Kills (kitchen)(household)(bathroom)

Kills (most) Household (bacteria)

On hard, non-porous, non-food contact surfaces this product kills bacteria

Surface Disinfectant

(This product) (controls) (kills) the (bacteria) that cause unpleasant odors (at the source),

(This product) (also) eliminates odor causing (bacteria) (at their source) (to leave your home smelling fresh and clean).

Specific Disinfecting Claims- (continued)

(This product) (helps) reduce cross contamination of (antibiotic resistant bacteria) (on hard, non-porous surfaces)

(This product) (helps) (aids) in the reduction of cross contamination of (antibiotic resistant bacteria) (on hard, non-porous surfaces)

(This product) (helps) (fight the spread of) (antibiotic resistant bacteria) (on hard, nonporous surfaces)

(This product) kills the (bacteria) that cause (bad) odors

(This product) kills bacteria on hard non porous, nonfood contact surfaces in your home and in public places.

You can also use (this product) in places that are difficult to (disinfect) (sanitize) (reach) such as nooks and crannies

Your family comes in contact with bacteria everyday (both in the home and in public (places)

(this product) kills bacteria on commonly touched on hard non porous, nonfood contact surfaces (in your home) (in public places) (in hotel rooms)

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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read the entire label before using the product.

Prior to disinfection or sanitization, pre-clean surface. For use on 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) (or) (clean dish towel).

To Sanitize: Let stand for 5 (five) minutes (to air dry) (rinsing not required) (If desired) (wipe with paper towel) (or) (clean dish towel).

To Deodorize: Spray on surfaces as needed (let air dry)

Do not use on polished wood, painted surfaces, leather, rayon fabrics, or acrylic plastics.

To control mold and mildew:

- 1) Spray mold and mildew contaminated surfaces with Sanosil S010. Be sure to cover the entire area with spray.
- 2) Let air dry for at least 10 minutes.
- 3) Thoroughly wash, scrub and brush off visible residue with a synthetic brush and hot, soapy water.
- 4) Rinse with a wet cloth and let dry.
- 5) In approximately 2-3 hours, or when surface has dried, apply a second layer of Sanosil S010 following the instructions in Step 1. Let dry.

Depending on the extent of contamination, the treatment can be repeated every 2-3 days. Allow the surface to dry completely between each application.

Refilling or Spray Bottles

To refill (spray bottles):

1. (Remove) Remove trigger sprayer (or) cap from empty bottle
2. (Pour) Unscrew cap on refill and pour contents directly into empty bottle.
3. (Use) Replace trigger sprayer and use as you normally would (or) unscrew cap and transfer your trigger to this bottle.

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Organisms

Studies conducted with Sanosil S010 have demonstrated that the product kills the following bacteria and viruses:

Bacteria:

- Pseudomonas aeruginosa (Pseudomonas) (ATCC # 15442)
- Staphylococcus aureus (Staphylococcus) (Staph) (ATCC 6538)
- Salmonella enterica (Salmonella) (ATCC 10708)
- (Methicillin Resistant) Staphylococcus aureus (Staph) (MRSA) (ATCC 33592)
- Enterobacter aerogenes (ATCC 13048)
- Escherichia coli (E coli) (ATCC 11229)
- [Sulfate Reducing Bacteria]

Viruses

- Human Immunodeficiency Virus type 1 (HIV) (Stain HTLV-III_B)
- Influenza A strain Hong Kong (flu virus) (ATCC VR-544)
- Influenza A (H5N1) (influenza) (flu virus) (Strain VNH5N1-PR8/CDC-RG CDC #2006719965)
- Rhinovirus type 37 (Rhinovirus) (common cold virus) (ATCC BR-1147, Strain 151-1)

Fungi

- Trichophyton mentagrophytes

Fogging

Fogging of Sanosil S010 can be used for disinfecting hard, nonporous surfaces in rooms as an adjunct following regular manual cleaning and disinfecting of room surfaces. Sanosil S010 ready to use product is recommended for use in fogging operations as a supplemental measure either before or after regular cleaning and disinfecting procedures. Fog until the area is moist using foggers according to manufacturing's use directions.

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SURFACES (- Graphic — depicting surface)

Hard Non-porous Surfaces

Enamel, Sealed Granite, Brass, Glass, Chrome, Glazed ceramic tile, Copper, Glazed Porcelain, Stainless Steel, Linoleum, cultured marble, Vinyl (tile), synthetic marble. Do not use on glasses, dishes and utensils or other food contact surfaces.

Bathroom surfaces, Exterior surfaces of (Microwave [oven], Oven, Refrigerators), Bathtub (Tub), Examination tables, Mirror, Remote controls, Telephones, Bed Frame Fixtures, No wax floors, (Resilient)(ceramic)Floor, Bed Springs, Floors, non-wood baby furniture, Salad Bar Sneeze Guards, Bidet Faucets (non-wood), Cabinets, garbage (cans) (pails), (non-wood) chairs, Shower (Stall) (Area), Cat litter boxes, (non-wood) crib, Shower (curtain)(plastic)(liner)(and glass-topped), Furniture (non-wood), Highchair (non-wood), Sinks (basin), Clean-up carts, Sports equipment, Nonfood contact Counter (Countertop), Crystal, (Non-wood) Outdoor Stretches, (Household) tools (patio), Nonfood contact table (tabletops), Desk Laminate (surfaces), Parquet Tin (Diaper) changing tables, Lamps, Patient Chairs,

Nonfood contact (Counters) and (tables), Linen carts, Plastic Toilet (Seats) (areas), Diaper Pails, Plastic (baby) (Children)Toys, (Toilet) (Urinal), Litter boxes, Plastic Laundry Basket (Hamper), Under sinks Dish Racks, Plastic mattress covers, Door Knob (handle), Washable Wall Paper, Dressing carts, Wheelchairs, Metal Portable Toilets, Whirlpool interiors, Metal Blinds, Recycling bins, Windows (windowsills), (Electronic) remote controls

HOUSEHOLD USE SITES (- Graphic — depicting surface)

Attic (damp), Storage Area Rooms, Laundry Room, Public eating places
Automobile, Den, Study, Litter boxes, Public places
Basement, Dining Room, Living Room, (Public) restrooms
Bathroom, Dorm lockers, Sunroom
Bedroom, Family Room ,Mobile Home, Supermarket (grocery store)
Boat, Garage, Mud Room, Tool Shed
Camper Home, House, Nursery, Vacation home
Car, (Home) Workshop, Pet areas, Vehicles
Closets, Kitchen, Playroom

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PROFESSIONAL USE SITES (Graphic — depicting surface)

Airplane, Factory, Kitchen, Public places
Air conditioning and/or heating vents
Ambulance, Gymnasium (gym), Laboratory, (Public) restrooms
Blood Bank, Health Care Facility, Manufacturing Plant, Public telephones (booth)
Boat, Health Club, (Medical) Clinic, Recreational Center
Bowling Alley, Hospital, Military Installation, Restaurant
Business, Hotel, Motel, Nursery, Child Care, School
Cafeteria, Infirmary, Nursing Home, School Bus
Campground (facility), Industrial, Building Office (Buildings), Shelters
Clinics, Institutional, Patient Rooms, Sick rooms
College (Institutional), Bathroom, Pharmacy, Toll Booth
Commercial Building, (Institutional) kitchen, Physicians Office, Train Interiors
Convenience stores (Institutional), Laundromat, Playground (facility), Veterinary (office)(clinic)
Day Care Centers, (Institutional) Restroom, Public eating places, Waiting Rooms
Dental Office, Kennel, Public facility, Warehouse, Club
Doctors Office

Sanosil S010 (EPA Reg. No. 84526-1)
EPA Draft Label 12/09/09

Disinfection and Deodorizing Animal Housing Facilities and Buildings, Farm Equipment, Poultry Premises, Coops, Trucks and Crates

1. Remove all animals/poultry from the facilities, items/areas to be disinfected.
2. Remove gross soils, litters, droppings, etc with a warm water flush or by sweeping.
3. Empty all troughs, racks, and other feeding and watering equipment.
4. Thoroughly clean all surfaces with detergent or cleaning solution and rinse with water.
5. Make sure area is well-ventilated prior to initiating treatment.
6. To disinfect, saturate surfaces with a disinfecting solution for at least 10 minutes.
7. Prior to reuse, thoroughly scrub treated feed equipment (e.g, feed racks, troughs, fountains, etc.) with a detergent and rinse with water.
8. Keep animals/poultry out of treatment areas and/or do not use treated equipment until solution has been completely absorbed and air dried.

Poultry Hatchery Disinfection

1. Remove any eggs, chicks, poultry and feeds along with all gross soils and other hatching-related debris.
2. Thoroughly clean all surfaces with an appropriate detergent or cleaning solution; then rinse with water.
3. Make sure area is well-ventilated prior to initiating treatment.
4. Apply disinfecting solution via wiping, mopping, spraying, or fogging. Let the use-solution soak in on the treated surface for at least 10 minutes and then allow to air dry.
5. Reintroduce eggs and chicks after all surfaces have dried.

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84526-1

12
12

PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with oxidizing and reducing agents.

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.

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

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.

(Note to Reviewer: One of the following statements will be used)

Nonrefillable container. Do not reuse or refill this container ~~unless the directions for use allow to refill empty container with this product.~~

-or-

Nonrefillable container. Do not reuse or refill this container.

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. Offer for recycling, if available or (replace cap and) discard in trash.

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