

84526-2

10/15/2009

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

84526-2

Date of Issuance:

OCT 15 2009

Term of Issuance:

Conditional

Name of Pesticide Product:

Sanosil HWP

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Sanosil USA, LLC
100 Dean Drive
Newark, Delaware 19711

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec: 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Revise the "EPA Registration Number to read, "EPA Reg. No. 84526-2".

Signature of Approving Official:

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

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b. Revise the following statement to the Precautionary section to read:

"Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet".

c. The statement "After product is diluted in accordance with the directions for use, protective eyewear and protective clothing is not required" must be removed from the precautionary section since the Agency has not received any data or other information substantiating this claim.

d. On page 2 of 9, delete "All purpose", "Versatile Formula" and "Sanosil HWP meets EPA standards for a (hospital)(commercial)(institution) (industrial) (farm Use) (animal facility use) disinfectant.

e. On page 3 of 9, remove the parenthesis () from the word "(non-food).

f. On page 3 of 9, change "Simply spray (this product) on surfaces that you and your family and pets come in contact with everyday (including): (inset use surfaces) to Simply spray (this product) on hard nonporous surfaces that you and your family and pets come in contact with everyday (including): (inset use surfaces).

g. On page 3 of 9, delete the phrase "(No residue)" from the statement beginning with "(This product) (disinfects) (and) (sanitizes) (in) (the following areas.....".

h. On page 3 of 9, under "Specific Sanitizing Claims", change the last sentence to "Kills 99.9% of (household) (kitchen) bacteria on hard, non-porous on-food contact surfaces.

h. On page 8 of 9, under the heading "Fogging" change "....can be use for disinfecting hard, nonporous surfaces....directions" to "....can be use for treating hard, nonporous surfacesdirections."

3. Submit two (2) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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EPA Registration No. 84526-2

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

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this Notice of Registration, please contact Martha Terry at (703) 308-6217.

Sincerely,



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

Enclosure: (Stamped Label)

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

Sanosil® HWP
Bactericide-Fungicide-Virucide*
For Hospital/Institutional/
Industrial/Animal Facility/Farm Use
General Disinfectant Concentrate

Active Ingredients:	
Hydrogen Peroxide.....	50.0%
Silver.....	0.1%
<u>Other Ingredients</u>	<u>49.9%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See [back] [side] [right] [left] panel for additional precautionary statements.

Net Contents: (as indicated on container)

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

[See bottom or side for Lot/Data code]

Questions? Comments? [symbol of telephone]
Call: (1-877-726-6745)
[or] Visit us at (www.sanosilusa.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

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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)

(Unscented)

(Scent free)

All-purpose

Bleach (Chlorine) (Bleach and Chlorine) (Alcohol) free (formula) (technology) (disinfection) (disinfectant) (sanitization) (sanitizer)

Contains no phosphorous (compounds)

Dries quickly

Dual Action (active) (system) (formula)

Everyday formula

Fast, Easy, Effective

Modern (Classic)

On-the-go

The (disinfectant) (sanitizer) for the new era.

~~Versatile Formula~~

Deodorizes sponges

Contains hydrogen peroxide, which breaks down into water and oxygen.

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 HWP meets EPA standards for a (hospital) (commercial) (institutional) (industrial) (farm use) (animal facility use) disinfectant.~~

Sanosil HWP 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)

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General Product Performance/Usage Claims - continued

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 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)

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) (surfaces).

Kills 99.9% of antibiotic-resistant bacteria (methicillin-resistant *Staphylococcus aureus*) (MRSA)

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

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Specific Disinfecting Claims

(Controls)(Kills) odor-causing (bacteria)
 Disinfection Control (Formula)
 Disinfects (sanitizes) and deodorizes by killing bacteria and controlling their odors.
 (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) (whenever) you need it
 Kills (household) (kitchen) (bacteria) on hard non porous, nonfood contact surfaces
 On hard, non-porous, non-food contact surfaces this product kills bacteria
 (This product) (controls) (kills) the (bacteria) that cause unpleasant odors (at the source),
 (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.

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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.

Preparation of Use Solution: Dilute 1 part of Sanosil HWP with 9 parts water (1:9)

Prior to disinfection or sanitization, preclean the target surface. Apply the use-solution to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge or sprayer. For sprayer applications, spray 6-8 inches from the surface.

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.

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

The Sanosil HWP use-solution 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)

Viruses

- Human Immunodeficiency Virus type 1 (HIV) (Strain 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 (ATCC 9533)

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 Stretchers, (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

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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, Recreational Vehicle (RV)
Closets, Kitchen, Playroom

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
Hospitals

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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. Prepare a disinfecting use solution by adding 1 oz of Sanosil HWP to 9 ounces of water.
6. Make sure area is well-ventilated prior to initiating treatment.
7. To disinfect, saturate surfaces with a disinfecting solution for at least 10 minutes.
8. Prior to reuse, thoroughly scrub treated feed equipment (e.g, feed racks, troughs, fountains, etc.) with a detergent and rinse with water.
9. 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. Prepare a disinfecting solution by adding 1 oz. of Sanosil HWP to 9 oz. of water.
4. Make sure area is well-ventilated prior to initiating treatment.
5. Apply disinfecting solution via wiping, mopping, or spraying (use a coarse spray device onto the surface to be treated. Let the use-solution soak in on the treated surface for at least 10 minutes and then allow to air dry.
6. Reintroduce eggs and chicks after all surfaces have dried.

Fogging

Fogging of Sanosil HWP can be used for ^{fogging} ~~disinfecting~~ hard, nonporous surfaces in rooms as an adjunct following regular manual cleaning and disinfecting of room surfaces. Sanosil HWP 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.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Danger. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. If fogged, avoid breathing spray mists. Wear protective eyewear such as goggles, face shield or safety glasses and protective clothing (long-sleeved shirt and long pants, socks, rubber gloves and chemical resistant footwear). *After product is diluted in accordance with directions for use, protective eyewear and protective clothing is not required.* Wash thoroughly with soap and water after handling and before eating, drinking, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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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: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment.

If swallowed: call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person. *If product diluted in accordance with the directions for use, gets on skin, medical attention is not required.*

NOTE TO PHYSICIAN: Probably mucosal damage may contraindicate the use of gastric lavage.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

(If container size is 5 gallons or larger, use the following Environmental Hazards statement).

Environmental Hazards

Do not discharge effluent containing this product into lakes, streams, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination system (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your state water board or Regional Office of the EPA.

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PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with oxidizing and reducing agents.

STORAGE AND DISPOSAL

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

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Pesticide Storage: Keep out of direct sunlight and away from heat. Do not freeze. Store in original container in areas inaccessible to small children and pets.

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

Container Disposal:

Plastic (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. (Contains no phosphorous.)