

84526-1

11/10/2009

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



Office of Pesticide Programs

Sanosil USA, LLC
100 Dean Drive
Newark, Delaware 19711

NOV 10 2009

AGENT: Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, D. C. 20001

Attention: Georgia Anastasiou

Subject: Sanosil S010
EPA Registration No. 84526-1
Notification Dated October 26, 2009

This will acknowledge receipt of your notification to add additional Influenza A virus per PR Notice 95-2 (Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)) to the product label, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification dated October 26, 2009 is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

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

Sincerely

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

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other:	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 84526-1	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sanosil S010	PM# Team 33	
5. Name and Address of Applicant (Include ZIP Code) Sanosil USA, LLC 300 Creek View Rd, Suite 101 Newark, DE 19711 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below

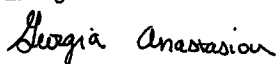
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of Additional Influenza A Virus per PR Notice 95-2

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted					
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Georgia Anastasiou Lewis & Harrison, 122 C Street NW, Suite 740, Washington DC 2001	Title Agent for Sanosil USA	Telephone No. (Include Area Code) 202-393-3903 x19
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Sanosil USA	
4. Typed Name Georgia Anastasiou	5. Date October 26, 2009	

LEWIS & HARRISON

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

Consultants in Government Affairs

October 26, 2009

HAND DELIVERED

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTENTION: Marshall Swindell
Product Manager, Team 33

SUBJECT: Sanosil USA, LLC
Sanosil S010 (EPA Reg. No. 84526-1)
Notification of Additional Influenza A Virus per PR Notice 95-2

Dear Mr. Swindell:

As agent for Sanosil USA, LLC, I am submitting a notification to add H1N1 claims for the product, **Sanosil S010 (EPA Reg. No. 84526-1)**. Please note Sanosil S010 is a broad-spectrum hard surface disinfectant. Efficacy data has been reviewed and accepted by the Agency to show that this product is effective against influenza A virus.

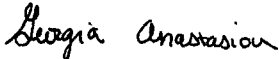
This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Enclosed please find the following documents to support this submission:

- a) Application for Pesticide Registration;
- b) One (1) copy of label with changes highlighted; and,
- c) Two (2) copies of the label.

If you have any questions and/or comments about the enclosed submission, please contact me by telephone at 202-393-3903 ext. 19 or by e-mail at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Sanosil USA

cc: Chris Ungermann (Sanosil)

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

Sanosil® S010

Active Ingredients:

Hydrogen Peroxide.....5.00%
Silver..... 0.01%

Other Ingredients(*) 94.99%
Total100.00%

(*Individual Inert Ingredients will be listed)

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)

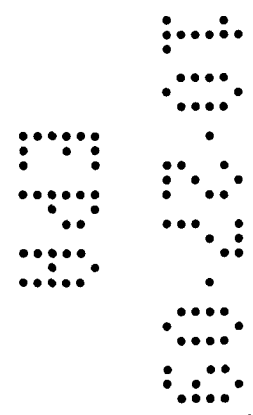
[or] Visit us at (www.sanosilglobal.com)

[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)

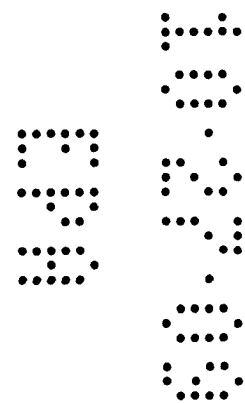
Portable (size) (pack)

Purse (size) (pack)

Travel (size) (pack)

Trial (size) (pack)

Value (size) (pack)



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.

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)

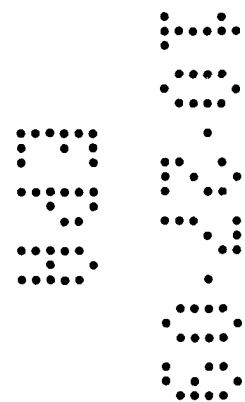
Treats, does not cover up (No residue) (No need to rinse after use) as a sanitizer and disinfectant

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 Disinfecting Claims- (continued)

(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)

H1N1 Claims:

-Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.

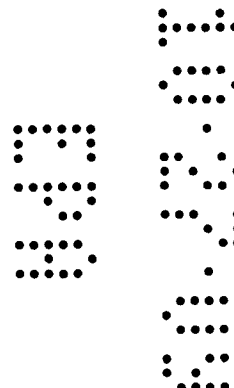
[Sanosil S010] [this product] is a broad-spectrum hard surface disinfectant that has been shown to be effective against influenza A virus (H5N1) (influenza) (flu virus) (Strain VNH5N1-PR8/CDC-RG CDC #2006719965) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

-[Sanosil S010] [This product] has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

-[Sanosil S010] [This product] has demonstrated effectiveness against influenza A virus (H5N1) (influenza) (flu virus) (Strain VNH5N1-PR8/CDC-RG CDC #2006719965) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

-Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)."

-Kills Pandemic 2009 H1N1 influenza A virus.



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, preclean 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).

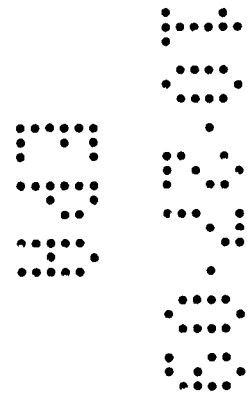
To Deodorize: Spray on surfaces as needed (let air dry)

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

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.



Organisms

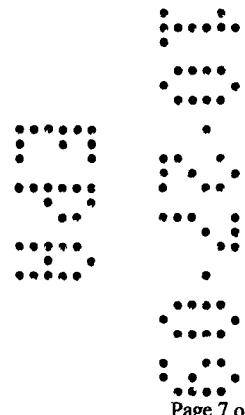
Studies conducted with Sanosil S010 have demonstrated that the product kills the following bacteria and viruses*:

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)

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)



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,

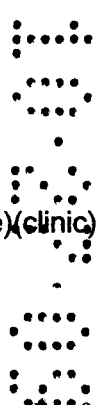
Nonfood contact (Counters) and (tables), Linen carts, Plastic Toilet (Seats) (areas), Diaper Pails, Plastic (baby) (Children)Toys, (Toilet) (Urinal), Litter boxes, Plastic Laundry Basket (Hamper), Under sinks Dish Racks, Plastic mattress covers, Door Knob (handle), Washable Wall Paper, Dressing carts, 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

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



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. Do not reuse this container (or) Refill only with this product (Replace cap and) (Recycle 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 Discard in Trash. (Contains no phosphorous)

