

1839-188

12-16-2009

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



Office of Pesticide Programs

Stepan Company
22 West Frontage road
Northfield, IL 60093

DEC 16 2009

Attention: Thomas W. Isaac
Senior Regulatory Specialist

Subject: Aerosol SDAS
EPA Registration No. 1839-188
Notification Dated November 17, 2009

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- To Add H1N1 Claims
- Addition of approved environmental surfaces omitted from previous stamped label

General Comment

Based on a review of the submitted material, the following comments apply:

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of 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)

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-188	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) AEROSOL SDAS	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Rd. Northfield, IL 60093 <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: <input checked="" type="checkbox"/> 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.)

- Addition of Labeling Claims Against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09.
- Addition of previously approved environmental surfaces that were inadvertently omitted from previous stamped label. The surfaces were approved on the April 28, 2009 stamped label.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input type="checkbox"/> Plastic	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 16, 32 ozs.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas W. Isaac	Title Sr. Regulatory Specialist	Telephone No. (Include Area Code) (847)501-2309
Certification 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 Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac	5. Date November 6, 2009	



November 6, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Antimicrobials Division
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Mr. Marshall Swindell
PM-33
Regulatory Management Branch I

RE: AEROSOL SDAS
EPA Reg. No. 1839-188

Dear Mr. Swindell:

This Notification proposes the following label addition:

- Addition of Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus per EPA's Guidance Document dated 10/21/09.
- Addition of previously approved environmental surfaces that were inadvertently omitted from previous stamped label. The surfaces were approved on the April 28, 2009 stamped label.

LABELS:

Five (5) draft labels are enclosed. One label is highlighted for Agency review.

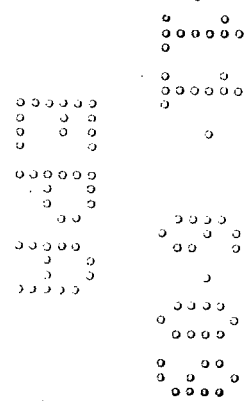
Should the Agency need additional information in order to process this notification, please feel free to contact me immediately at (847) 501-2309 or via email: tisaac@stepan.com.

Sincerely,
STEPAN COMPANY

Thomas W. Isaac
Sr. Regulatory Specialist

Enclosures: Notification administrative package, labels (5 copies)
TWI:slf

102-09-TI-EPA-1839-188



DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

(This product or product name) is designed for use in hospitals, nursing homes, veterinary clinics, animal life science laboratories, kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, hotels, schools, and homes, where disinfection and deodorization is of prime importance. When used as directed, (this product or product name) is formulated to disinfect clean, inanimate, non-porous, hard surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs, bed springs, door knobs, linen carts, hampers, wheel chairs, garbage pails, and telephones.

(This product or product name) deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, pet areas and any other areas which are prone to odors caused by microorganisms.

(This product or product name) can also be used as a room air deodorizer and refreshener.

(This product or product name) helps to temporarily reduce the number of airborne bacteria in a room. (This product or product name) eliminates tough odors from pets, smoke, bathrooms, garbage and mildew.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

or

This product is not for use on critical and semi-critical medical device surfaces.

SURFACE DISINFECTION AND DEODORIZATION – For one-step disinfection, hold container six (6) inches from surface and spray area until completely wet, allowing the surface to remain wet for 10 minutes. For heavily soiled surfaces a pre-cleaning step is required.

Veterinary Practice/Animal Care Animal Laboratory/Zoos/Pet Shop/Kennels Disinfection Directions: For cleaning and disinfecting the following hard non-porous surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, doors, cages, kennels, stables, catteries and animal transport vehicles. **Do not use on animal feeding or watering equipment.** Remove all animals and feed from the premises or transport vehicles. Remove all litter, droppings and manure from floors, walls and surfaces occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Thoroughly saturate the surface to be disinfected by holding the container six (6) inches from the surface and spray until completely wet. Allow the surface to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until the surfaces have completely dried.

AIR SANITIZER, AIR DEODORIZER AND AIR REFRESHENER - Spray upwards to center of room for three (3) seconds.

FOR USE IN (AN) AUTOMATIC AEROSOL DISPENSER UNITS (UNIT) FOR (SANITIZING) (DEODORIZING) (REFRESHING) AIR- Remove protective cap and install in an automatic aerosol dispensing unit (unit trade name). Dispenser should be mounted 7 ft. from the floor and away from exposed foods. Position so that the concentrated spray will not come into direct contact with people, animals, food, animal feed, food processing surfaces, and/or solvent-sensitive surfaces (polished or varnished surfaces). Use only in a well ventilated area. Avoid inhaling spray mist or vapor. When the dispensing unit (unit trade name) is set for 24 hour operation and to dispense every 15 minutes, this can (container) contains 3900 controlled sprays that will last for approximately 30 days. When the dispensing unit (unit trade name) is set for 12 hour operation and to dispense every 15 minutes, this can (container) contains 3900 controlled sprays that will last for approximately 60 days.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces spray surface to be treated making sure to wet completely. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

BACTERICIDAL ACTIVITY - When used as directed, (this product or product name) exhibits effective disinfectant activity against the organisms: Staphylococcus aureus (ATCC 6538), Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33591), Salmonella enterica (ATCC 10708) and Pseudomonas aeruginosa (ATCC 15442) and meets all requirements for hospital use. This product kills 99.9% of bacteria on hard, non-porous inanimate surfaces.

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(Left Panel)

Amend 11/06/09

VIRUCIDAL ACTIVITY- (This product or product name) is virucidal against the organisms: Norovirus (Norwalk Virus), Rhinovirus Type 14 (ATCC VR-284), Influenza A₂/Japan (H2N2) and Feline Calicivirus (FCV) when used as directed on hard, non-porous surface. Allow treated surfaces to remain wet for 10 minutes and let air dry.

optional statements to appear anywhere on the label)

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product (Product Name) has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product (Product Name) has demonstrated effectiveness against (Influenza A virus tested and listed on the label) 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.

FUNGICIDAL ACTIVITY – (This product or product name) is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) (ATCC 9533), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, or other clean, non-porous, hard surfaces commonly contacted by bare feet.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, VIRUCIDE AND FUNGICIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

KEEP OUT OF REACH OF CHILDREN. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
IF IN EYES: Hold eye open and rinse slowly with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment.

(Optional) You may contact xxx/xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS

Flammable! Contents under pressure. Do not use near fire, sparks, or flame. Do not puncture or incinerate container. Exposure to temperatures above 120°F may cause bursting.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

(for industrial, institutional and commercial products)

CONTAINER DISPOSAL – Do not puncture or incinerate! Nonrefillable container. Do not reuse or refill this container. If empty: place in trash or offer for recycling, if available. If partially filled: Call your local solid waste agency for disposal instructions.

(for household use products only)

CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-188

(Right Panel)

Amend 11/06/09

