

1839-85

5/20/2009

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

Stepan Company
22 West Frontage road
Northfield, IL 60093

MAY 20 2009

Attention: Thomas W. Isaac
Senior Regulatory Specialist

Subject: Aerosol Surface Disinfectant
EPA Registration No. 1839-85
Notification Dated April 20, 2009

This will acknowledge receipt of your notification to add additional label language at the request of California DPR, submitted under the provisions of FIFRA Section 3(c)(9). 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 added to your file.

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

Sincerely

A handwritten signature in cursive script that reads 'Marshall Swindell'.

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

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<p>United States Environmental Protection Agency Washington, DC 20460</p>	<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 1839-85	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aerosol Surface Disinfectant	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Road 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: 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 text addition through PR Notice 98-10. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.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 98-10 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. Please contact David Swain at 260-244-6273 (fax) with any questions.

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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* 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
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input 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 David Swain	Title Agent for Stepan Company	Telephone No. (include Area Code) 260-244-6270
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<p style="text-align: center;">Certification</p> <p>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.</p>	6. Date Application Received (Stamped)	
2. Signature 	3. Title Agent for Stepan Company	
4. Typed Name David Swain	5. Date April 20, 2009	

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SRC

Scientific & Regulatory

Consultants, Inc.

April 20, 2009

Mr. Marshall Swindell, PM -33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

SUBJECT: Notification of minor label change per PR Notice 98-10
Aerosol Surface Disinfectant
EPA Reg. No. 1839-85

Dear Marshall:

On behalf of Stepan Company (Stepan), for this action on EPA Reg. No. 1839-85 only, enclosed is a notification to add additional label language for Aerosol Surface Disinfectant (EPA Reg. No. 1839-85). An e-mail from Stepan regulatory official Tom Isaac granting permission to Scientific & Regulatory Consultants, Inc. to make this submission is enclosed.

The new text is being added at the request of California DPR. The proposed changes are:

- Add dispenser description language for automatic dispenser unit to include locked housing, 2 motion sensors and power indicator light.

The additions to the label are highlighted on the enclosed label.

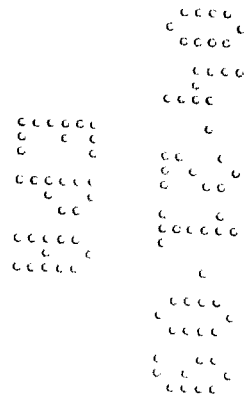
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 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.

Thank you for your assistance in this matter. If you have any questions regarding this notification contact me at (260) 244-6270.

Sincerely,



David Swain
Agent for Stepan Company



AEROSOL SURFACE DISINFECTANT

DISINFECTANT

MILDEWSTAT (on hard non-porous inanimate surfaces)

DEODORANT

AIR REFRESHENER

Kills 99.9% of Bacteria (*Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*)

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.1%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.1%
Isopropanol.....	53.0%
INERT INGREDIENTS	46.8%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panels for additional precautionary statements.

EPA REG. NO. 1839-85
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NET CONTENTS

(Center Panel)

Amend 2/10/09

DIRECTIONS FOR USE

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

Aerosol Surface Disinfectant is designed for use in hospitals, nursing homes, hotels, schools, and homes, where disinfection and deodorization is of prime importance. When used as directed, this product 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 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 can also be used as a room air deodorizer and refreshener.

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 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 precleaning step is required.

(Aerosol Spray Can Label:) FOR USE IN (AN) AUTOMATIC DISPENSER UNITS (UNIT TRADE NAME) FOR (DOOR PUSH PLATE(S), (DOOR KNOB(S)), (and) (DOOR LEVER (S)) SURFACE DISINFECTION - Remove cap and install in automatic aerosol dispensing unit (unit trade name). Dispenser unit (unit trade name) should be mounted 6"-12" above (bathroom) (door push plate) (door knob) (door lever) (and) (door surface) (high touch) surface. The unit (unit trade name) will provide a controlled spray that will wet accessible parts of the (door knob or lever) (and) (door push plate) surface. Allow to remain wet for 10 minutes for disinfection. Use only in a well ventilated area. Avoid inhaling spray mist or vapor. Avoid contact of spray mist or vapor with skin. The unit (unit trade name) will dispense every 15, 30 or 60 minutes. Each can (can trade name) will continue to release disinfectant for 7 to 30 days depending on the interval setting.

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

FOR USE IN (AN) AUTOMATIC DISPENSER UNITS (UNIT) FOR (DEODORIZING) (REFRESHING) (AIR) - Remove protective cap and install in 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 disperse 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 disperse 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 exhibits effective disinfectant activity against the organisms: Staphylococcus aureus (ATCC 6538), 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.

FUNGICIDAL ACTIVITY - This product 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 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.

CONTAINER DISPOSAL - Replace cap and dispose of container in trash. Do not incinerate or puncture.

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

The following installation information will be provided with the Automatic Dispenser Unit(s) for Surface Disinfection only: (Parentheses identify optional language)

Suggested Places for Use (Installation of Automatic Dispenser Unit)(Unit Trade Name): *(Any of the following may be listed)* Public Restroom (Exit Doors), Public Restroom Toilet Stall (Doors), Hospital Patient Room (Doors), School Classroom (Doors), Hotel Room (Doors), Dormitory (Dormitories)(Doors), Spa (Doors), Theater (Doors), Kitchen (Doors), Doors, Daycare facility (Doors)

Optimal Installation (Tips):

(The user will) Install the Automatic Dispenser Unit (Unit Trade Name) 6-12 inches above a (high touch) surface (door knob) (push plate). To properly disinfect, the Automatic Dispenser Unit (Unit Trade Name) should be centered such the (high touch) surface (door knob) (door lever) (push plate) is thoroughly wetted by the released disinfectant aerosol. (After 10 minutes,) Only the wet area contacted by the disinfectant aerosol will be disinfected (after 10 minutes.)

The Automatic Dispenser Unit (Unit Trade Name) can be manually set to spray at intervals of either 15, 30, or 60 minutes. The interval time is determined by the traffic in the location where the Automatic Dispenser Unit (Unit Trade Name) is installed. Depending on the surface (style of the door handle/knob/lever), place the Automatic Dispenser Unit (Unit Trade Name) in a position where the handle will receive the maximum amount of wetness. The spray is released in a conical pattern and the Automatic Dispenser Unit (Unit Trade Name) must be positioned correctly to achieve the most coverage. Once the position has been determined, affix the dispenser to the door with either the mounting tape or screws provided. See Installation Positioning (diagrams).

Additional Installation Instructions:

(Simply) Install the Automatic Dispenser Unit (Unit Trade Name) 6-12 inches above the (high touch) surface (e.g. door knob, door handle, door lever, push plate) and choose the interval time of 15, 30, 60 minutes between sprays. The unit will spray a light mist of an EPA registered disinfecting formula that will cover the (high touch) accessible area of the surface (handle)(knob)(lever)(plate). The quick drying formula will disinfect the wetted surface in 10 minutes. Each aerosol can (Spray Can Trade Name) will continue to release disinfectant for 7-30 days depending on the interval setting.

Additional Claims:

(Spray Can Trade Name) is a hospital disinfectant registered with the US EPA. The disinfectant has been shown to be effective against the following bacteria: Staphylococcus aureus, a common bacterial inhabitant of human skin, Salmonella enterica, a bacterium associated with foodborne illnesses, and Pseudomonas aeruginosa, a bacterial organism found in water, soil and food.

(Spray Can Trade Name) has been shown to kill 99.9% of these important bacteria:

Staphylococcus aureus
Salmonella enterica
Pseudomonas aeruginosa

Dispenser Description:

(Spray Can Trade Name) dispensing units are equipped with:

- Locked Housing which requires a key to open for replacement of the disinfectant spray or batteries.
- 2 Motion sensors which detect motion up to 1 meter in front of the housing and below the housing. If motion is detected, the unit does not dispense. The detection range cannot be manipulated.
- Power Indicator Light which indicates the status of battery power. This light also flashes when the disinfectant is being dispensed. When the battery no longer has charge, the unit shuts down and the disinfectant will not spray.

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-85

(Right Panel)

Amend 3/5/08

