1839-85

07/16/2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON D.C., 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Stepan Company 22 W. Frontage Rd. Northfield, IL 60093

JUL 1 6 2009

Attention: Thomas W. Issac **Regulatory** Mananger

Subject:

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Aerosol Surface Disinfectant EPA Reg. No. 1839-85 _

Amendment Dated June 17, 2009

This will acknowledge receipt of your notification regarding the use of an alternate brand name submitted under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

"Proposal for new Container Disposal language consistent with PR Notice 2007-

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 Demson Fuller at (703) 308-8062.

Sincerely,

Marshall Swindel

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

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Please read instructions on r	everse before completin	g form.		Form Approve	d. OMB No.	2070-0060	Print Form
\$EPA	United States Environmental Protection Ager Washington, DC 20460				Regist		OPP Identifier Number
	A	pplication fo	r Pestici	de - Sectio	n l		
1. Company/Product Number 1839-85			2. EPA Product Manager 3. Proposed Classificati Marshall Swindell				
4. Company/Product (Name) AEROSOL SURFACE DISINFECTANT			PM# 33				
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Rd. Northfield, IL 60093			 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 				
			ection -	ict Name			
Amendment - Explain Resubmission in resp Notification - Explain Explanation: Use eddition This notification proposes Mr. Demson Fuller.	onse to Agency letter d below. al page(s) if necessary.	(For section and		Final printed la Agency letter "Me Too" App Other - Explain e consistent w	dated lication. below.		d per discussions with
1. Material This Product Will	Ro Daokanad In:	Se	ection -	10	-		
Child-Resistant Packaging	Unit Packaging	We	ter Soluble I	Packaning	2 7.50	of Container	
Yes* X No * Certification must	Yes No	No. per If *	Yes No Yes"	No. per	2. Type of Container Metal Plastic Glass Paper		
be submitted 3. Location of Net Contents I		container Pac . Size(s) Retail Con , 16, 32 ozs.	kage wgt	container	Location of L X On La	Other (S	
Kabel C 6. Manner in Which Label is .		X Lithograph X Paper glued Stenciled	<u> </u>	Other	On La	beling accom	panying product
			ction - I	v			
1. Contact Point <i>(Complete</i>	items directly below for				ecessery. to	process this	application.)
Name		Title	<u>.</u>				No. (Include Area Code)
Thomas W. Isaac		Sr. Re	gulatory S	pecialist			1-2309-255
I acknowledge that an both under applicable I	nents I have made on th y knowingly false or mis ew	leading statement	may be pur	•			6. Date Application Received ((Stamped)
Signature 1 homas W. Asaan			3. Title Constraints Constraints				
4. Typed Name Thomas W. Isaac	.	5. Dat	• 17, 2009				
EPA Form 8570-1 (Rev. 8-94)	Previous editions are o	bsolete.		White	EPA File Co	py (original)	Yellow - Applicant Co

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Stepan 'Company

Northfield, Illinois 6009' Telephone 847 446 756

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June 17, 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: Ms. Marshall Swindell PM-33 Regulatory Management Branch I

RE: Aerosol Surface Disinfectant EPA Reg. No. 1839-85

Dear Mr. Swindell:

This notification proposes the addition of new Container Disposal language consistent with PR Notice 2007-4 and per discussions with Mr. Demson Fuller.

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.

Five (5) copies of the proposed label are enclosed. One copy 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

W.

Thomas W. Isaac Sr. Regulatory Specialist

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

051-09-TI-EPA-1839-85

"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."

Thomas W. Anna Sr. Regulatory Specialist

Date: 06-17-09

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	
Isopropanol	
	<u>46.8%</u>
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)

NOTIF 06/17/09

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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.

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.

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 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.

Stepan Company Northfield, IL 60093 EPA Reg. No. 1839-85 **BACTERICIDAL ACTIVITY** - When used as directed, this product exhibits effective disinfectant activity against the organisms: Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Pseudomonas aeruginosa (ATCC 15442) and Methicillin Resistant Staphylococcus aureus (ATCC 33591) (MRSA) and meets all requirements for hospital use. This product kills 99.9% of bacteria on hard, non-porous inanimate surfaces.

VIRUCIDAL ACTIVITY – When used as directed, this product exhibits effective virucidal activity against the organisms: Rhinovirus (ATCC VR-284), Influenza A₂ (Japan/305/57)(H2N2), Norovirus (Norwalk Virus) and Feline Calicivirus.

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, VIRUCIDE AND FUNGICIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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 – 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.

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

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

(Right Panel)

NOTIF 06/17/09

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.

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

(Right Panel)

Dispenser Description:

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

- <u>Locked Housing</u> which requires a key to open for replacement of the disinfectant spray or batteries.
- <u>2 Motion sensors</u> 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.
- <u>Power Indicator Light</u> 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)