

1839-84

02/29/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

FEB 29 2008

Thomas Isaac
Senior Regulatory Specialist
Stepan Company
22 W. Frontage Rd.
Northfield, IL 60093

Subject: Aerosol Detergent/Disinfectant
EPA Reg. No. 1839-84
Application Dated: February 18, 2008
Receipt Date: February 19, 2008

Dear Mr. Isaac,

The following notification submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c) 9 and the provisions of PR Notice 98-10, is acceptable.

Proposed Notification

· Addition of the qualifier "KILLS 99.9% of BACTERIA"

Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to add the qualifier is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch 1
Antimicrobial Division (7510P)

CONCURRENCES							
IBOL	7510P						
NAME							
DATE	2/28/08						

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 1839-84	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aerosol Detergent/Disinfectant	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage rd. Meadowdale, IL 60057 <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 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.)

Notification to add a qualifier to "Kills 99.9% of Bacteria" claim.

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 <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4,8,12,16,32 oz		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 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 as both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Thomas W. Isaac</i>	3. Title Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac	5. Date February 18, 2008	



February 18, 2008

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. Velma Noble
PM-31
Regulatory Management Branch I

RE: Aerosol Detergent/Disinfectant
EPA Reg. No. 1839-84

Dear Ms. Noble:

This Notification proposes the following label addition:

1. Addition of a qualifier, designated by a double asterisk ** for the marketing statement "KILLS 99.9% of BACTERIA" (see page 1 of label).

This notification should be coded as a FAST-TRACK; no data review required.

Five (5) copies of the proposed label are enclosed are for Agency review. One copy is highlighted to illustrate the proposed label additions.

Should you have any questions concerning this submission, please contact me at (847) 501-2309 or via email: tisaac@stepan.com.

Sincerely,
STEPAN COMPANY

Thomas W. Isaac
Sr. Regulatory Specialist

Enclosures: 1839-84 label (5 copies)
TWI:sif

011-08-TI-EPA-1839-84





“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. Hoar
Sr. Regulatory Specialist

Date: Feb. 18, 2008



AEROSOL DETERGENT/DISINFECTANT

CLEANER
DEODORIZER
FUNGICIDE (against pathogenic fungi)
MILDEWSTAT (on hard, inanimate surfaces)
DISINFECTANT
*VIRUCIDE
FRESH SCENT
LEMON SCENT
PINE SCENT
KILLS 99.9% of BACTERIA **

(** If this claim is made, organisms must be listed as follows:)

** Staphylococcus aureus (Staph), Salmonella enterica (Salmonella), Pseudomonas aeruginosa

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	0.1%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	0.1%
INERT INGREDIENTS	<u>99.8%</u>
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator. See side panel for additional precautionary statements.

EPA REG. NO. 1839-84
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 W. Frontage Rd.
Northfield, IL 60093

NET CONTENTS

(Center Panel)

Notification 02/18/08

DIRECTIONS FOR USE

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

Aerosol Detergent/Disinfectant is designed for cleaning, deodorizing, and disinfecting for hospitals, nursing homes, schools, hotels, homes, and food processing establishments. This product is effective where housekeeping is of prime importance in controlling cross-contamination from treated surfaces.

This product when used as directed is formulated to disinfect inanimate hard non-porous surfaces: walls, floors, sink tops, toilet bowls, toilet seats, chairs, tables, telephones, restrooms, shower stalls, bathtubs, hampers, cabinets, hospital beds, traction devices, MRI, CAT, examining tables, scales, paddles and wheelchairs.

(For labels that list medical premises and/or stainless steel surfaces, one of the following statements must be used:)

This product is not 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 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.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, toilet bowls, and other areas which are prone to odors caused by microorganisms.

Cooling Coils Disinfectant Cleaner. (This product or product name) is a disinfectant cleaner for small air conditioner cooling coils and refrigeration equipment, refrigerator, or freezer evaporative coils. When using (this product or product name) to disinfect and clean cooling coils or evaporative coils, disconnect power to the unit before applying product. Follow the directions under the **DISINFECTION, DEODORIZATION AND CLEANING** section.

DISINFECTION, DEODORIZATION AND CLEANING - Shake can before using. Hold container six to eight inches from surface to be treated. Spray area until it is covered with white foam. Allow foam to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. This product will not leave grit or soap scum.

For heavily soiled areas, a pre-cleaning step is required before treatment.

When used in food processing establishments, cover or remove all food and packaging materials, remove all gross soils, saturate all surfaces with the spray product, scrub to loosen all soils, allow to soak for 10 minutes, thoroughly rinse all wetted and cleaned surfaces with potable water.

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, Salmonella enterica and Pseudomonas aeruginosa and meets AOAC Germicidal Spray Products Test requirements for hospital disinfectants.

FUNGICIDAL ACTIVITY - This product is fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus) (a cause of ringworm) (a cause of ringworm of the foot), 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.

***VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard non-porous surfaces exhibits effective virucidal activity against HIV-1 (associated with AIDS).

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING

KEEP OUT OF REACH OF CHILDREN. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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 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 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 advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(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.

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.