

1839-93

07/19/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 19 2010

Mr. Thomas W. Isaac
Senior Regulatory specialist
Stephen Company
22 W. Frontage Rd.
Northfield, Illinois 60093

Subject: **Power Detergent/Disinfectant**
EPA Registration Number 1839-93
Notification Application Dated June 30, 2010
EPA Received Date July 1, 2010

Dear Mr. Isaac:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Revise the Personal Protection paragraph on page 3
- Revise the Disposal of Infectious Materials paragraph page 3

General Comments:

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

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Drusilla Copeland

for Velma Noble
Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

Please read instructions on reverse before completing form.

Form Approved. No. 2070-0080



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 1839-93	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Powder Detergent/Disinfectant	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Co. 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.)

On the Special Instructions for Cleaning and Decontamination HIV Section:

- Revise the PERSONAL PROTECTION: to read "...and eye coverings" to comply with PRN 2000-5 (see page 3 of master label).
- Revise the DISPOSAL of INFECTIOUS MATERIALS: to read "...must be autoclaved" to comply with PRN 2000-5 (see page 3 of master 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1, 1/8 oz	No. per container multiple	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 2 lbs. 13 ozs.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" 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 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 June 30, 2010	



June 30, 2010

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: Powder Detergent/Disinfectant
EPA Reg. No. 1839-93

Dear Ms. Noble:

This notification proposes the following label revisions:

On the Special Instructions for Cleaning and Decontamination HIV Section:

1. Revise the **Personal Protection** paragraph (see page 3) to read: "When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings."
2. Revise the **Disposal of Infectious Materials** paragraph (see page 3) to read: "Blood and body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal."

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:sf

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Stepan

pan Company

Northfield, Illinois 60093
Telephone 847 446 7500



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“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. Trace
Sr. Regulatory Specialist

Date: June 30, 2010

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POWDER DETERGENT/DISINFECTANT

CLEANER	DISINFECTANT
DETERGENT	DEODORIZER
FUNGICIDE (against pathogenic fungi)	* VIRUCIDE
MILDEWSTAT (on hard inanimate surfaces)	
Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)	

(For Commercial and Institutional Use Only)-Optional

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chlorides.....	7.95%
INERT INGREDIENTS	84.10%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

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.

See (side) (back) panel for additional precautionary statements.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

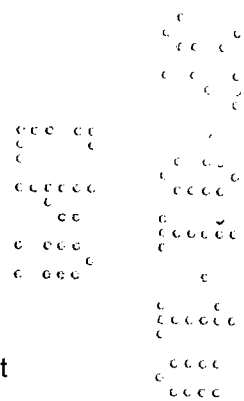
STEPAN COMPANY
22 West Frontage Rd.
Northfield, IL 60093

TOTAL NET CONTENTS 2 lb.13 oz.

90 Water Soluble Packets, Each containing 1/2 oz. of product
or

360 Water Soluble Packets, Each containing 1/8 oz. of product
or

221 Water Soluble Packets, Each containing 5.75 grams of product



DIRECTIONS FOR USE

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

Powder Detergent/Disinfectant is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, and other institutions where housekeeping is of prime importance in controlling the hazard of cross-contamination.

This product, when used as directed, is formulated to disinfect inanimate, hard non-porous surfaces such as walls, floors, sink tops, tables, and chairs. For larger areas such as operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfection.

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

PACKETS – *Tear open packet*—follow label dilution instructions and discard opened packet according to label disposal instructions.

Water soluble packet—follow label dilution instructions by dropping packet directly into water. Do not remove packets before use. Store in cool dry place. Do not handle packets with wet hands.

DISINFECTION - To disinfect inanimate, hard non-porous surfaces add one (1/8 oz., 5.75 gm or 1/2 oz.) pre-measured packet of product or measure powder at the following use dilutions:

Add this amount of product:	1/8 ounce (3.55 grams)	5.75 grams	1/2 ounce	1 ounce	1 1/2 ounces
in warm water to make:	One Quart	52 ounces	1 Gallon	2 Gallons	3 Gallons

Stir gently to form a uniform solution. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

BACTERICIDAL ACTIVITY - At the stated Disinfection dilution rate, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD-10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella* (*schottmuelleri*) *enterica*, *Salmonella* (*choleraesuis*) *enterica*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Staphylococcus aureus*, *Enterobacter aerogenes* and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces mix this product at the stated dilution rate for Disinfection. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears. At the disinfectant dilution rate, this product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

* **VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate, hard surfaces at the Disinfectant dilution rate, exhibits effective virucidal activity against HIV-1, Influenza A₂, Parainfluenza Type 1 (Sendai), Canine Distemper, Feline Pneumonitis, Vaccinia virus, Herpes Simplex Type 1, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV).

(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.

KILLS HIV-1, HBV and HCV 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, HBV and HCV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

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

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Powder Detergent/Disinfectant.

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

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

EFFICACY TESTS HAVE DEMONSTRATED THAT POWDER DETERGENT/DISINFECTANT IS AN EFFECTIVE BACTERICIDE AND FUNGICIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM.)

(Note: if the deodorizing use is listed on the label, the following paragraph must be included)

DEODORIZING and CLEANING - To deodorize and clean inanimate, hard, non-porous surfaces add one (1/8 oz., 5.75 gm or 1/2 oz.) pre-measured packet of product or measure powder as per the dilution chart in the DISINFECTION section.

Stir gently to form a uniform solution. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry. Prepare a fresh solution for each use.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

DANGER

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

(Note: If container size is of 5 gallons or greater, the following Environmental Hazards statement must be used.)

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F. Store in an area inaccessible to children.

(for products with industrial, institutional and commercial use sites)

CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container promptly after emptying.

(Containers 5 gallons or less)

Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Containers greater than 5 gallons):

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

PACKET DISPOSAL - Do not reuse packet. Discard packet in trash.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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Packet Label:

**POWDER
DETERGENT/DISINFECTANT**

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	7.95%
INERT INGREDIENTS	<u>84.10%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements and use directions.

Disposal - Do not reuse empty packet. Wrap packet and put in trash.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

Mix contents in **1 gallon** of water.
NET WEIGHT CONTENTS: **½ ounce**

or

Mix contents in **1 quart** of water.
NET WEIGHT CONTENTS: **1/8 ounce**

or

Mix contents in **52 ounces** of water.
NET WEIGHT CONTENTS: **5.75 grams**

Water Soluble Packet Label:

POWDER DETERGENT/DISINFECTANT

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chlorides	7.95%
INERT INGREDIENTS	84.10%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements
and use directions.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

Add one packet in **1 gallon** of water.
NET WEIGHT CONTENTS: **½ ounce**

or

Add one packet in **1 quart** of water.
NET WEIGHT CONTENTS: **1/8 ounce**

or

Mix contents in **52 ounces** of water.
NET WEIGHT CONTENTS: **5.75 grams**

**Alternate Water Soluble Packet Label:
(for small 1" x 1" packets)**

**POWDER
DETERGENT/DISINFECTANT**

Quaternary Ammonium Chlorides

KEEP OUT OF REACH OF CHILDREN

DANGER CORROSIVE

See outer container for
Precautions and Directions.

EPA REG. NO. 1839-93