

JUL 14 2003

Ms. Nancy S. Maitzen
Sr. Regulatory Coordinator
Stepan company
22 West Frontage Rd.
Northfield, Illinois 60093

Subject: NP 4.5 Detergent/Disinfectant
EPA Registration No. 1839-79
Application Date: 6/18/03
Receipt Date: 6/18/03

Dear Ms. Maitzen:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

PROPOSED NOTIFICATION

- Removal of the word "pre-cleaned" from the first line of the Disinfection use directions.
- Addition of an alternate Terminal Sterilant Level Disinfectant Statement to the Directions for use section.
- Removal of the Wisconsin State Division of Health instructions in the directions for use - Sanitization section.
- Addition of the word, immediately to the If On Skin Or Clothing in the First Aid section . . . of the Precautionary Statements.
- Addition of the word, Pesticide to Storage in the Storage and Disposal section.

GENERAL COMMENTS


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

The notification application is acceptable and a copy has been inserted in your file for future reference.

CONCURRENCES							
SYMBOL	175100						
SURNAME	J. Jones						
DATE	7-11-03						

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble

Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

April 14, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Antimicrobials Division (7510C)
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTN: Ms. Velma Noble
PM 31
Regulatory Management Branch I

RE: NP 4.5 Detergent/Disinfectant
EPA Reg. No. 1839-79

Dear Ms. Noble:

This Notification proposes the following:

- 1) Removal of the word "pre-cleaned" from the first line of the **DISINFECTION** use directions. This line should read:

"To disinfect inanimate, hard, non-porous surfaces, apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly."

This registration's efficacy data demonstrated bactericidal and fungicidal activity in the presence of organic load (5% blood serum) and supports the removal of the pre-cleaning step. The word "pre-cleaned" was not on the original approved label, however, it has been inadvertently added with subsequent label amendments.
- 2) Addition of an alternate Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. This one sentence statement reads "This product is not for use on medical device surfaces."
- 3) Removal of the Wisconsin State Division of Health instructions in the Directions for Use - Sanitization section. Since Wisconsin requires a 500 ppm water hardness, this would not apply because it is effective in water up to 250 ppm hardness (as CaCO₃).
- 4) Addition of the word, immediately, to the IF ON SKIN OR CLOTHING in the First Aid section of the PRECAUTIONARY STATEMENTS. It should read:

"If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice."
- 5) Addition of the word, **PESTICIDE**, to **STORAGE** in the Storage and Disposal Section. It should read:
PESTICIDE STORAGE.

Five (5) copies of the proposed label are enclosed for Agency review.

Should you have any questions concerning this notification, please contact me at 847/501-2278.

Sincerely,
STEPAN COMPANY



Nancy S. Maitzen
Sr. Regulatory Coordinator

NSM:sif

Enclosures

cc: Tom Isaac

052-03-run-USEPA-79-N.doc





Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number STEPAN COMPANY / 1839-79	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) NP 4.5 Detergent/Disinfectant	PMS 31	
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: 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.)

See attached sheet.

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Notification 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 qt. gal., 5 gal., 55 gal.,	5. Location of Label Directions <input checked="" type="checkbox"/>
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 Nancy S. Maitzen	Title Sr. Regulatory Coordinator	Telephone No. (Include Area Code) 847/501-2278
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 <i>Nancy S. Maitzen</i>	3. Title Sr. Regulatory Coordinator	
4. Typed Name Nancy S. Maitzen	5. Date April 14, 2003	

April 14, 2003

Stepan Company
NP 4.5 Detergent/Disinfectant
EPA Reg. No. 1839-79

Section II – Explanation

This notification proposes the following:

- 1) Removal of the word "pre-cleaned" from the first line of the **DISINFECTION** use directions.
This line should read:
"To disinfect inanimate, hard, non-porous surfaces, apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly."
This registration's efficacy data demonstrated bactericidal and fungicidal activity in the presence of organic load (5% blood serum) and supports the removal of the pre-cleaning step. The word "pre-cleaned" was not on the original approved label, however, it has been inadvertently added with subsequent label amendments.
- 2) Addition of an alternate Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. This one sentence statement reads "This product is not for use on medical device surfaces."
- 3) Removal of the Wisconsin State Division of Health instructions in the Directions for Use - Sanitization section. Since Wisconsin requires a 500 ppm water hardness, this would not apply because it is effective in water up to 250 ppm hardness (as CaCO₃).
- 4) Addition of the word, immediately, to the **IF ON SKIN OR CLOTHING** in the First Aid section of the **PRECAUTIONARY STATEMENTS**. It should read:
"If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice."
- 5) Addition of the word, **PESTICIDE**, to **STORAGE** in the Storage and Disposal Section. It should read: **PESTICIDE STORAGE**.

Signature:

Nancy Maitzer

Title: Sr. Regulatory Coordinator



JUN. 18. 2003 8:14AM

STEPAN PS&C
Stepan Company

Northfield, Illinois 60093
Telephone 847 446 7500

NO. 429 P. 5

Stepan

S.

6/9

"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."

Nancy Maize
April 14, 2003



Printed on Recycled Paper

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NP 4.5

Detergent/Disinfectant

CLEANER
DETERGENT
MILDEWSTAT (on hard inanimate surfaces)
FUNGICIDE (against pathogenic fungi)

DISINFECTANT
SANITIZER
* VIRUCIDE
DEODORIZER

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	2.25%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl	
ethylbenzyl ammonium chlorides	2.25%
INERT INGREDIENTS	<u>95.50%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-79
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NET CONTENTS

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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.

NP 4.5 Detergent/Disinfectant is a phosphate free formulation designed to provide effective cleaning, deodorization, sanitization, and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments, transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses and athletic/recreational facilities 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 surfaces such as walls, floors, sink tops, toilet bowls, tables, chairs, and telephones. For larger areas such operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfecting.

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.

In addition, this product sanitizes previously cleaned and rinsed non-porous food contact surfaces such as tanks, chopping blocks, counter tops, drinking glasses, and eating utensils.

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

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.

DISINFECTION - To disinfect inanimate, hard surfaces add 2 ounces of this product per gallon of water. 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, then remove excess liquid.

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

To disinfect toilet bowls: flush toilet, add 2 ounces of this product directly to the bowl water. Swab the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

To disinfect food processing premises: floors, walls, and storage areas, add 2 ounces of this product per gallon of water. For heavily soiled areas, a pre-cleaning step is required. 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, then remove excess liquid. Before using this product, food products and packaging materials must be removed from the area or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable water.

To disinfect food service establishment food contact surfaces: countertops, appliances, tables, add 2 ounces of this product per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow the surface to remain wet for 10 minutes, then remove excess liquid and rinse the surface with potable water.

SANITIZATION - Remove all gross food particles and soil from areas, which are to be sanitized, with a good detergent, pre-flush, pre-soak or pre-scrape treatment. Rinse with potable water. To sanitize previously cleaned and rinsed non-porous food contact surfaces prepare a 200 ppm active quaternary solution by adding 2 ounces of this product to 3.5 gallons of water.

To sanitize immobile items such as tanks, chopping blocks, and counter tops, flood the area with a 200 ppm active quaternary solution or apply with a cloth or sponge making sure to wet all surfaces completely for at least 60 seconds. Let air dry. Prepare a fresh solution each use.

sanitize mobile items such as drinking glasses and eating utensils, immerse in a 200 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit active quaternaries to 200 ppm. At this level **NO POTABLE WATER RINSE IS REQUIRED**. This product is an effective sanitizer when diluted in water up to 250 ppm hardness (as CaCO₃).

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Staphylococcus aureus*, Methicillin resistant *Staphylococcus aureus* (MRSA), and Vancomycin intermediate resistant *Staphylococcus aureus* (VISA) and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge 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.

FUNGICIDAL ACTIVITY - At the 2 ounces per gallon dilution, this product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet.

*** VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard surfaces at 2 ounces per gallon of water exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 2 (causative agent of upper respiratory infections), Vaccinia virus (representative of the pox virus group), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

*** 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), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV).

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, 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 NP 4.5 DETERGENT/DISINFECTANT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

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. Harmful if swallowed. 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 poison control center or doctor for treatment advice.

If swallowed: Call 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.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

HOTLINE NUMBER (OPTIONAL)

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

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic invertebrates. 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.

Contains no phosphorous.

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.

CONTAINER DISPOSAL - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary landfill, incinerated, or if allowed by local authorities, by burning. If burned, stay out of smoke.

For containers 1 gallon or less: Do not reuse empty container (bottle, can, bucket). Wrap container and put 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.