

1839-95

12-2-2002
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/6

DEC 2 2002

Thomas W. Isaac
Sr. Regulatory Specialist
Stephan Company
22 W. Frontage Road
Northfield, IL 60093

Subject: Notification per PR Notice 98-10
NP 4.5 (D & F) Detergent Disinfectant
EPA Reg. No. 1839-95
Application dated: November 15, 2002
Receipt Date: November 21, 2002

Dear Mr. Thomas W. Isaac,

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. This line should read: "To disinfect inanimate, hard, non-porous surfaces add 2 ozs. of this product per gallon of water"
- Addition of terminal Sterilant/High Level Disinfectant statement to the Directions for use section. Also included alternate one sentence statement to read "This product is not for use on medical device surfaces."

General Comments

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

This notification application is acceptable and a copy has been made a part of the records for this file. Should you have any questions or comments concerning this letter, please contact me at (703) 308-6233.

Sincerely,

Valma Noble
Valma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobial Division (75100)

CONCURRENCES							
SYMBOL	75100						
SURNAME	A. Peters						
DATE	12/2/02						



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

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United States
Environmental Protection Agency
Washington, DC 20460☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-95	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(D&F) Detergent Disinfectant	PM# 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.)

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 add 2 ozs. of this product per gallon of water."

Addition of Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. Also included alternate one sentence statement to read "This product is not for use on medical device surfaces."

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 type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container	<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container qt., gal, 5 & 55 gals.		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
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 _____	

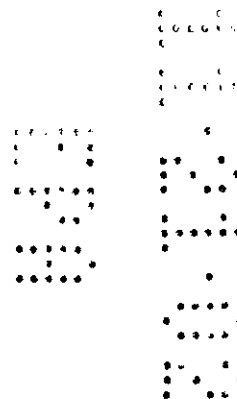
Section - IV

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 or both under applicable law.			
2. Signature Thomas W. Isaac		3. Title Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac		5. Date November 15, 2002	
		6. Date Application Received (Stamped)	

"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. Isaac
Sr. Regulatory Specialist

November 15, 2002



4/6

NP 4.5 (D&F) Detergent/Disinfectant

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

DISINFECTANT
DEODORIZER
*VIRUCIDE

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chlorides2.25%
Alkyl (68% C₁₂, 32% C₁₄)
dimethyl ethylbenzyl ammonium chlorides2.25%

INERT INGREDIENTS.....95.50%
Total100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-95
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NOTIFICATION

Date Reviewed: 12/2/02
Reviewed By: A. K. [Signature]

NET CONTENTS

(Center Panel)

Notificatiön, 11/15/02

DIRECTIONS FOR USE

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

NP 4.5 (D&F) Detergent/Disinfectant is a phosphate free formulation designed to provide effective cleaning, deodorization, and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments, transportation terminals, automotive garages, office buildings, manufacturing facilities, lodging establishments, retail businesses, athletic/recreational facilities and households where housekeeping is of prime importance in controlling the hazard of cross contamination.

When used as directed, this product is formulated to disinfect hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, fiberglass, plastic surfaces, vinyl, chrome, bathrooms, shower stalls, shower doors, shower curtains, bathtubs, toilets, bathroom fixtures, kitchens, countertops, sinks, exteriors of microwaves, refrigerators, stoves, and other kitchen appliances, stovetops, automobile interiors, cabinets, tables, chairs, desks, dining room surfaces, doorknobs, garbage cans 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, toilet bowls, behind and under sinks and other areas where bacterial growth can cause malodors.

This product cleans, deodorizes and disinfects all hard non-porous household surfaces. It inhibits the growth of mold and mildew, leaving bathrooms and kitchens clean and fresh smelling.

This product is a non-abrasive (non-scratch) cleaner for showers, tubs, shower doors, shower curtains, fixtures and toilet bowls.

This product is an economical concentrate that can be used with a mop and bucket, hand pump trigger sprayer or sponge.

(For labels that list medical premises and metal 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, non-porous 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.

For 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. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

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.

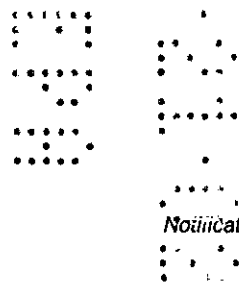
***VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate, hard, non-porous surfaces at 2 ounces per gallon of water, exhibits effective virucidal activity against Influenza A2/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters),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

NOTIFICATION

Date Reviewed: 12/2/02
Reviewed By: J. R. Lutz

Stapan Company
Northfield, IL 60093
EPA Reg. No. 1839-95

(Left Panel)



Notification 11/15/02

6/6

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) and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV AND HCV 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

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 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.

(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.

ENVIRONMENTAL HAZARDS

(Required for products supplied in containers 5 gallons or greater.)

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 or 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.

(Reusable Container Statement) Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser (specific equipment such as "Dynamix dispenser" can be named to replace "dilution dispenser"). Dispenser will automatically dilute a disinfectant solution. Remove concentration label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

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.

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-95

(Right Panel)

NOTIFICATION
Date Reviewed: 12/2/02
Reviewed By: [Signature]

Notification 11/15/02