

JUL - 2 2003

Mr. Thomas W. Isaac  
Sr. Regulatory Specialist  
Stepan Company  
22 West Frontage Rd.  
Northfield, Illinois 60093

Subject: NP 12.5 (D&F) Detergent/Disinfectant  
EPA Registration No. 1839-97  
Application Date: 4/2/03  
Receipt Date: 4/7/03

Dear Mr. Isaac:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable:

- Update First aid Statements
- Update Precautionary Statements
- Addition of expanded, specific environmental surfaces
- Addition of Terminal Sterilant Statement
- Revise Fungicidal Activity section
- Addition of food Processing Premises Disinfection Directions
- Addition of Food Service Establishment Food Contact Surface Disinfection Directions

**LABEL COMMENTS**

1. Under the "To disinfect food service establishment food contact surfaces" add the statement "Before using this product, food products and packaging materials must be removed from area or carefully protected".

**GENERAL COMMENTS**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES								
SYMBOL	1570C							
SURNAME	B. Jones							
DATE	7-1-03							

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

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble". The signature is fluid and cursive, with the first name "Velma" being more prominent than the last name "Noble".

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

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# NP 12.5 (D&F) Detergent/Disinfectant

CLEANER	DISINFECTANT
DETERGENT	* VIRUCIDE
DEODORIZER	
FUNGICIDE (against pathogenic fungi)	
MILDEWSTAT (on hard inanimate surfaces)	

## ACTIVE INGREDIENTS

n-Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> )	
dimethyl benzyl ammonium chloride .....	6.25%
n-Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl	
ethylbenzyl ammonium chloride .....	6.25%
INERT INGREDIENTS .....	87.50%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

## DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-97  
EPA EST. No. 1839-IL-01

STEPAN COMPANY  
22 West Frontage Road • Northfield, IL 60093

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUL 2 - 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1839-97

(Center Panel)

Amend 04/02/03

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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 12.5 (D&F) Detergent/Disinfectant has been designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments 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 environmental surfaces: walls, floors, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, sink tops, toilet bowls, cabinets, tables, chairs, telephones, and bed frames. For larger areas such as operating rooms, patient care facilities and restrooms, this product is designed to provide both general cleaning and disinfecting.

In addition, 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.

*(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 medical device surfaces.

**DISINFECTION** - To disinfect hard, inanimate, surfaces add 0.5 ounce 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 and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

**To disinfect toilet bowls**, flush toilet, add 0.5 ounce 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 0.5 ounce 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 0.5 ounce 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 0.5 ounce per gallon of water, this product exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, and *Enterobacter aerogenes* and meets all requirements for hospital use.

**FUNGICIDAL ACTIVITY** - At the 0.5 ounce 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.

**MILDEWSTAT** - To control mold and mildew and the odors they cause on pre-cleaned, hard, non-porous surfaces add 0.5 ounce 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.

**\* VIRUCIDAL ACTIVITY** - This product, when used on environmental inanimate hard surfaces at 0.5 ounce per gallon of water, exhibits effective virucidal activity against Influenza A2/Asian (representative of the common flu virus), Herpes simplex (causative agent of fever blisters), Adenovirus type 5 (causative agent of upper respiratory infections), Vaccinia virus (representative of the Pox virus group) and Human Immunodeficiency Virus (HIV-1).

**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 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 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. May be fatal if absorbed through skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

**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.

**(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.

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

**ENVIRONMENTAL HAZARDS**

This product 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.

**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.