

1839-95

11-7-2002

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV - 7 2002

Subject: NP 4.5 (D&F) Detergent/Disinfectant  
EPA Registration No. 1839-95  
Application Date: 5/03/02  
Receipt Date: 5/14/02

Dear Mr. Isaac:

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

- . Addition of Hepatitis C Virus (HCV) claim to label
- . Addition of household & automotive garages use sites

## GENERAL COMMENTS

The proposed label claims identifying the product, NP 4.5 (D&F) Detergent/Disinfectant, as having virucidal activity against Hepatitis C Virus on hard, non-porous surfaces in the presence of organic soil (5% serum) are acceptable, as supported by MRID Nos. 456764-01 and -02 using Bovine Viral Diarrhea virus as a surrogate. Although the product demonstrated complete inactivation of the virus at all dilutions tested, a few minor modifications regarding specific procedural details must be submitted to the Agency:

- i. A more detailed description of the challenge BVDV strain, concerning the virus stock preparation and titration should be provided.
- ii. A full description of the host cell line (MDBK) including its preparation and susceptibility to BVDV should be provided. Are there other cell lines that are also susceptible to this virus and appropriate for use in the assay?
- iii. Please explain why only 0.5 ml of the virus-disinfectant mixture is neutralized when using column instead of the full 2.0 ml recovered from the plate.
- iv. A complete description of the infectivity assay using immunofluorescence should be provided.

## CONCURRENCES

SYMBOL	7510C						
SURNAME	J. S. Jones						
DATE	11-8-02						

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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. Please see attachment for corrections to be added to the labeling before it is returned as a final printed label.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble".

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

# NP 4.5 (D&F)

## Detergent/Disinfectant

CLEANER  
 DETERGENT  
 DEODORIZER  
 MILDEWSTAT (on hard inanimate  
 surfaces)

DISINFECTANT  
 FUNGICIDE (against  
 Pathogenic fungi)  
 \*VIRUCIDE

### ACTIVE INGREDIENTS

Alkyl (60% C <sub>14</sub> , 30% C <sub>16</sub> , 5% C <sub>12</sub> , 5% C <sub>18</sub> ) dimethyl benzyl ammonium chlorides .....	2.25%
Alkyl (68% C <sub>12</sub> , 32% C <sub>14</sub> ) dimethyl ethylbenzyl ammonium chlorides .....	2.25%

<b>INERT INGREDIENTS</b> .....	<b>95.50%</b>
<b>Total</b>	<b>100.00%</b>

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

NET CONTENTS

ACCEPTED  
 with COMMENTS  
 in EPA Letter Dated:  
 NOV 7 2002  
 Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No.  
 1839-95

(Center Panel)

Amend 05/03/02

## 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 mal odors.

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.

**DISINFECTION** - To disinfect pre-cleaned, 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 can not 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.

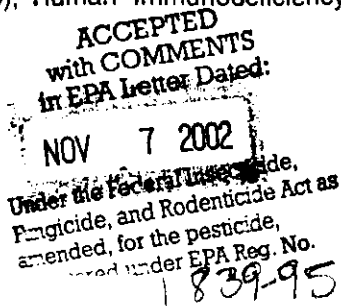
**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces, add 2 ounces of this product per gallon of water. Apply solution with a cloth, mop or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly 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).

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

(Left Panel)



Amend 05/03/02

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•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, 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.

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Accepted with COMMENTS  
in EPA Letter Dated:  
NOV 7 2002  
Under the Federal Insecticide,  
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