

100-95

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 19 1989

Mr. J. J. Kelly  
27 West Frontage Road  
Springfield, IL 62769

Attention: Leo A. Brink

Dear Sir:

Subject: RE 4.5 (D&F) Disinfectant  
EPA Registration No. 1639-95  
Your Application Date: April 5, 1989  
EPA Received Date: April 11, 1989

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Herbicide Act (FIFRA), is acceptable and is that you:

1. Make the following changes indicated below before you release the product for sale and use the amended label:
  - a. Correct the label to read: *Salmonella schottmayeri* to *Salmonella schottmayeri* and *Shigella dysenteriae* to *Shigella dysenteriae*.
  - b. Change Herpes simplex (causative agent of fever blisters and mononucleosis) to read Herpes simplex type 1 (causative agent of fever blisters).
  - c. On the side panel, expand the statement "KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS" to read "KILLS HIV 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.)"

54794:I:DeLaney:LL-11:KENCO:08/25/89:10/07/89:aw:SW:VO:DD

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely yours,

John H. Lee  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (H7505C)

Enclosure

## 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, deodorizing and disinfection specifically for hospitals, nursing homes, schools, food processing plants, food service establishments and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

NP 4.5 (D&F) Detergent/Disinfectant, when used as directed, is formulated to disinfect inanimate hard surfaces such as walls, floors, sink tops, toilet bowls, 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.

NP 4.5 (D&F) Detergent/Disinfectant 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.

**DISINFECTION** - To disinfect inanimate, hard surfaces add, 2 ounces NP 4.5 (D&F) Detergent/Disinfectant per gallon of water. Apply solution with a mop, cloth, sponge or mechanical sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove excess liquid.

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

To disinfect toilet bowls, flush toilet, add 2 ounces NP 4.5 (D&F) Detergent/Disinfectant 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.

**BACTERICIDAL ACTIVITY** - When diluted at the rate of 2 ounces per gallon of water, NP 4.5 (D&F) Detergent/Disinfectant exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schuttmuelleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes* and *Staphylococcus aureus* and meets all requirements for hospital use.

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 2 ounces of NP 4.5 (D&F) Detergent/Disinfectant 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 NP 4.5 (D&F) Detergent/Disinfectant is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

**EFFICACY TESTS HAVE DEMONSTRATED THAT NP 4.5 (D&F) DETERGENT/DISINFECTANT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE, IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).**

# Stepan S

Stepan Company  
Northfield, IL 60093

## NP 4.5 (D & F) Detergent/Disinfectant

CLEANER  
DETERGENT  
DEODORIZER  
MILDEWSTAT  
(on hard inanimate  
surfaces)

DISINFECTANT  
FUNGICIDE (against  
Pathogenic fungi)  
VIRUCIDE

### ACTIVE INGREDIENTS

n-Alkyl (60% C<sub>12</sub>, 30% C<sub>14</sub>, 5% C<sub>16</sub>,  
5% C<sub>18</sub>) dimethyl benzyl  
ammonium chlorides ..... 21.5%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>)  
dimethyl ethylbenzyl  
ammonium chlorides ..... 25%

INERT INGREDIENTS ..... 53.50%  
Total 100.00%

EPA REG NO 1839.95  
EPA EST NO 1839 IL-01

KEEP OUT OF REACH OF CHILDREN

## DANGER

ACCEPTED  
with COMMENTS  
in EPA Letter dated

see side panels for additional precautionary statements

SEP 19 1989

NET CONTENTS

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 1839-95

BEST AVAILABLE COPY

**VIRUCIDAL ACTIVITY** - Used on environmental surfaces, 1 gallon of water ex- A2/Japan (representative Type 1 (causative Adenovirus Type 2 and Vaccinia virus

**KILLS HUMAN IMMUNODEFICIENCY (AIDS) VIRUS ON SURFACES/OBJECTS BLOOD/BODY FLUIDS SPECIAL INSTRUCTIONS DECONTAMINATE SOILED WITH BLOOD PERSONAL PROTECTIVE EQUIPMENT** or body fluids use coverings. **CLEANING PROCEDURE** thoroughly clean with NP 4.5 (D&F) Detergent/Disinfectant. **CONTACT TIME** 10 minutes. **DISPOSAL OF INFECTED** fluids should be in accordance with regulations for infectious waste.

## PRECAUTIONS

**HAZARD TO HUMANS AND DOMESTIC ANIMALS** - Causes severe irritation of skin, eyes, nose, throat, and lungs. Avoid contact with skin, eyes, nose, throat, and lungs. Remove and wash thoroughly. **STORAGE** - In case of contact, flush with water for at least 15 minutes. Wash contaminated clothes, linens, and other items in hot water. Dispose of waste in accordance with local, state, and federal regulations.

**Precautionary measures** - Avoid contact with skin, eyes, nose, throat, and lungs. Remove and wash thoroughly.

## STORAGE

**DO NOT CONTAIN OR DISPOSE OF**

**STORAGE** - Store in a cool, dry place. Do not store in areas where the temperature is above 100°F or below 32°F.

**CONTAINER** - Empty container should be reconditioned or destroyed. Do not reuse containers for other products. Containers must be properly labeled.

**PESTICIDE** - Do not use for purposes other than those for which it is registered. Use according to label directions. Environmental representative.