

1839-96

PM 31

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JUN 19 1989

Stepan Company
22 West Frontage Road
Northfield, IL 60093

Attention: Leo J. Dringoli
Manager, Product Registration

Gentlemen:

Subject: NP 9.0 (D&F) Detergent/Disinfectant
EPA Registration No. 1839-96
Your Submission Dated March 27, 1989

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. Revise the 1st paragraph in the HIV section to read:

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings 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).

2. Include the reference asterisk next to the word Myrucide (two locations).

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CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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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 Valdis Goncarovs at (703) 557-3663.

Sincerely yours,

M. Sundell for,

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 9.0 (D&F) is a phosphate free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools, food processing plants and other institutions where housekeeping is of prime importance in controlling the hazard of cross contamination.

NP 9.0 (D&F), 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 9.0 (D&F) 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 1 ounce NP 9.0 (D&F) 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 pre-cleaning step is required. Prepare a fresh solution for each use.

To disinfect toilet bowls, flush toilet, add 1 ounce NP 9.0 (D&F) 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 1 ounce per gallon of water, NP 9.0 (D&F) exhibits effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD 10, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schultzei*, *Salmonella choleraesuis*, *Streptococcus salivarius*, *Brevibacterium ammoniagenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Enterobacter aerogenes*, *Staphylococcus aureus*, *Salmonella typhi*, and *Streptococcus pyogenes* and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces add 1 ounce of NP 9.0 (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 1 ounce per gallon dilution NP 9.0 (D&F) Detergent/Disinfectant is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

EFFICACY TESTS HAVE DEMONSTRATED THAT NP 9.0 (D&F) DETERGENT/DISINFECTANT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE, IN THE PRESENCE OF ORGANIC SOIL (5% LLOOD SERUM).

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Stepan Company
Northfield, IL 60093

NP 9.0 (D & F) Detergent/Disinfectant

CLEANER
DETERGENT
DEODORIZER
MILDEWSTAT
(on hard inanimate
surfaces)

DISINFECTANT
FUNGICIDE (against
Pathogenic fungi)
VIRUCIDE

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₂ , 30% C ₁₄ , 5% C ₁₆ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	4.50%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	4.50%
INERT INGREDIENTS	91.00%
Total	100.00%

EPA REG. NO. 1839-96
EPA EST. NO. 18J9-IL-01

VIRUCIDAL ACTIVITY - Effective virucidal activity against the common flu virus, fever blisters and measles agent of upper respiratory tract and the pox virus group.

KILLS HUMAN IMMUNODEFICIENCY VIRUS (HIV) ON PERSONAL PROTECTIVE SURFACES/OBJECTS.
SPECIAL INSTRUCTIONS:
DECONTAMINATION: Thoroughly cleaned floors, walls, and other surfaces soiled with blood or body fluids use disinfectant.
CLEANING PROCEDURE: Thoroughly cleaned floors, walls, and other surfaces soiled with blood or body fluids use disinfectant.
CONTACT TIME: At least 10 minutes.
DISPOSAL OF INFECTED FLUIDS: Infectious fluids should be autoclaved or incinerated according to regulations for infectious waste.

PRECAUTIONS

HAZARD TO HUMANS: DANGER. KEEP OUT OF REACH OF CHILDREN.
Causes severe eye irritation or on clothing. Wear protective gloves. Harmful if swallowed. Remove and wash immediately.

STATE: In case of contact, for at least 15 minutes wash contaminated areas with water. Whites, gelatin, soil, and other stains may require additional washing.

Probable mucosal irritation.

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements

NET CONTENTS

STORAGE

DO NOT CONTAMINATE OR DISPOSE OF

STORAGE: Store at or higher than 12°C.

CONTAINER DISPOSAL: Empty container, after conditioning or other procedures, may be recycled or disposed of as allowed by local regulations.

PESTICIDE DISPOSAL: Improper disposal is a violation of Federal law. Use according to Environmental Protection Agency representative at the time of purchase.

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FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE