

1839-81

1/12/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Stepan Company
22 W. Frontage Rd.
Northfield, IL 60093

JAN 12 2001

Subject: NP 9.0 Detergent/Disinfectant
EPA Registration No. 1839-81
Amendment Dated November 1, 2999

Attn: Thomas W. Isaac
Sr. Regulatory Specialist

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable for the addition of the two organisms (Strep Pyogenes (Flesh Eating) & Vancomycin Intermediate resistant Staph aureus (VISA) to the label with the revisions to the label language and updating of the First Aid statements.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment.

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

Sincerely,



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

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Z. Jones						
DATE	1-9-01						

NP 9.0

Detergent/Disinfectant

CLEANER
 DETERGENT
 DEODORIZER
 MILDEWSTAT (on hard
 inanimate surfaces)

DISINFECTANT
 FUNGICIDE (against
 Pathogenic fungi)
 SANITIZER
 * VIRUCIDE

ACTIVE INGREDIENTS

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	4.5%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	4.5%
INERT INGREDIENTS	91.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-81
 EPA EST. NO. 1839-IL-01

Stepan Company
 22 W. Frontage Road
 Northfield, IL 60093

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

JAN 12 2001

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 1839-81

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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 9.0 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, transportation terminals, office buildings, manufacturing facilities, lodging establishments, retail businesses and athletic/recreational facilities 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, non-porous surfaces: floors, sink tops, toilet bowls, tables, chairs, and telephones. For larger areas such as operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfecting.

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.

In addition, this product sanitizes previously cleaned and rinsed non-porous food contact surfaces such as tanks, chopping blocks, counter tops, drinking glasses, and eating utensils.

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.

DISINFECTION - To disinfect inanimate, hard, non-porous surfaces add 1 ounce of this product 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.

disinfect toilet bowls: flush toilet, add 1 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 1 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 1 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.

SANITIZATION - To sanitize previously cleaned and rinsed non-porous food contact surfaces prepare a 200 ppm active quaternary solution by adding 1 ounce of this product to 3.5 gallons of water.

To sanitize immobile items such as tanks, chopping blocks, and counter tops, flood the area with a 200 ppm active quaternary solution or apply with a cloth or sponge making sure to wet all surfaces completely for at least 60 seconds. Let air dry. Prepare a fresh solution for each use.

To sanitize mobile items such as drinking glasses and eating utensils, immerse in a 200 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Let air dry. Prepare a fresh solution for each use. Prepare a fresh solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit active quaternaries to 200 ppm. NO POTABLE WATER RINSE IS REQUIRED. This product is an effective sanitizer when diluted in water up to 250 ppm hardness (as CaCO_3).

BACTERICIDAL ACTIVITY - When diluted at the rate of 1 ounce 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*, *Streptococcus pyogenes* (Clinical-Flesh Eating Strain BIRD M3), 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 1 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.

At the 1 ounce per gallon dilution this product is also fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes*.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

with COMMENTS
in EPA Letter Dated:

JAN 12 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-81

Amend 11/01/00

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-81

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*** VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard surfaces at 1 ounce 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), and Vaccinia virus (representative of the pox virus group).

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.

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 and rubber gloves and protective clothing. Harmful if swallowed. Remove and wash contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

FIRST AID

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) Have the product container or label with you when calling a poison control center or doctor, or going for treatment. 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

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.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

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.

ACCEPTED
RECOMMENDATIONS
in EPA Letter Dated:

JAN 12 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1839-81

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Northfield, IL 60093
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(Right Panel)