

1839-103

3-24-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Stepan Company
22 West Frontage Road
Northfield, IL 60093

MAR 24 2000

ATTENTION: Nancy Maitzen

SUBJECT: CD 3.2 (D & F) Detergent/Disinfectant
EPA Registration Number: 1839-103
Your Amendment Dated: December 21, 1999
EPA Received Date: December 29, 1999

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. As per DIS/TSS 15 your label must include specific directions for use as a cleaner. Revise your label to include the following cleaning instructions: "**Cleaning:** Add 2 ounces of this product per gallon of water. Apply solution with a cloth, sponge, or hand trigger sprayer so as to wet all surfaces thoroughly. Then remove excess liquid."

B. As per our phone conversations on 3/20 and 3/23 revise the first paragraph in the "Directions for Use" section of the label by deleting the terms "commercial, institutional and industrial" and replacing with the following: "*transportation terminals and manufacturing facilities*".

C. Revise the order of your directions for use in food processing areas and add further directions as follows to provide clarity for the user and comply with DIS/TSS-15. Also delete the word "equipment" which is too broad: "To disinfect food processing premise: Floors, walls, and storage areas, add 2 ounces of this product per gallon of water. *Before using this product, food products and packaging materials must be removed from the area or carefully protected. Preclean surfaces then apply solution with a mop...*" In addition, Revise the last statement of this section: "After use, all surfaces in the area must be thoroughly rinsed with potable water." to read as follows: "*All surfaces which may come in contact with food must be rinsed with potable water.*"

D. Revise the "Precautionary Statements" such that the signal word "**DANGER**" appears

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on a separate line and in bold text directly below the phrase "Hazards to Humans and Domestic Animals."

E. Revise the "Environmental Hazards" statement by deleting the phrase "and aquatic invertebrates."

F. Revise the "Pesticide Storage" statement to include the following information:
"Store in tightly closed container in a secure area inaccessible to children."

G. Revise the "Container Disposal" statement as follows: "...Plastic containers may be offered for recycling or reconditioning, or punctured and disposed of in a sanitary landfill..."

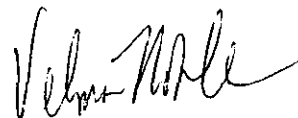
2. Submit two (2) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

The following is provided for informational purposes only.

Based on our discussions with you it is our understanding that you would like to add the sites office buildings, lodging establishments, retail businesses, and athletic/recreational facilities to the label for this product. The addition of these commercial sites are considered new uses for this product. These sites differ significantly from those which were previously accepted on this label. These new uses require the Agency to review the available data base on these active ingredients to determine if the new uses cause any increase in risk. Thus in order to support these sites you must include in your next amendment to the Agency a complete Data Matrix (generic and product specific) as well as a Certification With Respect to Citation of Data form in support of these new use sites. Please refer to PR Notice 98-5 for the revised Agency and Public File Copies of the Data Matrix. Alternatively you may decide to use the "Cite-all" method of support in which case only the Certification With Respect to Citation of Data form would be required, but it is recommended that the product specific matrix be submitted as well. As we discussed it is also acceptable for you to use the selective method with "cite-all" option.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C).

Enclosure: Stamped Label

7510C.T. Lantz 3/20/00.1839-103a

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CD 3.2 (D&F) Detergent/Disinfectant

CLEANER
DETERGENT
DEODORIZER
MILDEWSTAT (on hard inanimate
surfaces)

DISINFECTANT
FUNGICIDE (against
pathogenic fungi)

ACTIVE INGREDIENTS

n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂,
5% C₁₈) dimethyl benzyl
ammonium chlorides 1.60%
n-Alkyl (68% C₁₂, 32% C₁₄)
dimethyl ethylbenzyl
ammonium chlorides 1.60%

INERT INGREDIENTS 96.80%
Total 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-103
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
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ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-103

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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.

CD 3.2 (D&F) Detergent/Disinfectant has been designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, schools, food service establishments, food processing plants, [REDACTED] premises where housekeeping is of prime importance in controlling the hazard of cross contamination.

This product, when used as directed, is formulated to disinfectant hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, 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.

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 pre-cleaned, inanimate, hard, non-porous surfaces, 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.

GENERAL DISINFECTION - Add 2 ounces of this product per gallon of water.

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 service establishment contact surfaces: countertops, appliances, tables, add 2 ounces of this product per gallon of water. 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.

To disinfect food processing premises: floors, walls, storage areas and [REDACTED] 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. 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.

HOSPITAL DISINFECTION - Add 3 ounces of this product per gallon of water.

BACTERICIDAL ACTIVITY - When diluted at the rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: Salmonella choleraesuis and Staphylococcus aureus.

When diluted at the rate of 3 ounces per gallon of water, this product exhibits effective disinfectant activity against Pseudomonas aeruginosa in addition to the above mentioned organisms 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 fungicidal against the pathogenic fungi, Trichophyton mentagrophytes (Athlete's Foot Fungus). Apply solution with a cloth, sponge or hand pump trigger sprayer to hard, non-porous surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard non-porous surfaces commonly contacted by bare feet. Allow the surface to remain wet for 10 minutes, then remove excess liquid. Diluted product should be applied daily or more frequently with heavy facility use.

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DEODORIZATION - To deodorize, apply this product as indicated under the heading, GENERAL DISINFECTION.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND FUNGICIDE 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 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.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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.

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.

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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