

1839-50

2-13-2002

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

FEB 13 2002

Subject: Notification per PR Notice 98-10
CD 1.6 Detergent/Disinfectant
EPA Reg. No. 1839-50
Application Dated: October 12, 2001

Dear: Thomas W. Isaac,

This letter acknowledges receipt of your notification to add the " Note to Physician" statement to the label. Per FIFRA 3(c)9, 40 CFR 152.46, PR Notice 98-10 & 2001-1 and based on a review of submitted materials, the application is acceptable as a notification.

This notification has been made a part of the records for this file. If you have any questions concerning this letter, please contact Velma Noble at 703-308-6233.

Sincerely,



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

CONCURRENCES

SYMBOL	7510(c)							
SURNAME	A Peters							
DATE	2/12/02							

CD 1.6 Detergent/Disinfectant

CLEANER
DETERGENT
MILDEWSTAT (on hard inanimate
surfaces)
SANITIZER

DISINFECTANT
FUNGICIDE (against
Pathogenic fungi)
*VIRUCIDE
CANINE PARVOCIDAL

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.80%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	0.80%
INERT INGREDIENTS	<u>98.40%</u>
TOTAL	100.00%

EPA REG. NO. 1839-50
EPA EST. NO. 1839-IL-01

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

(Middle Panel)

Notification 10/12/01

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

CD 1.6 Detergent/Disinfectant is designed to provide effective cleaning, deodorizing, sanitization and disinfection specifically for hospitals, nursing homes, schools, animal quarters, kennels, 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 to control 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, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs (non-upholstered surfaces), and telephones. For larger areas: 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 hard, inanimate, 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 and then let air dry.

GENERAL DISINFECTION - Add 4.5 ounces of this product per gallon of water.

HOSPITAL DISINFECTION - Add 6 ounces of this product per gallon of water.

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

To disinfect toilet bowls: Remove gross filth or soils from surfaces with bowl brush. Add 4.5 ounces of this product directly to the bowl water. Brush or 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 4.5 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 4.5 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.

SANITIZATION - Recommended for use in restaurants, dairies, food processing plants, and bars. When used as directed this product is an effective sanitizer against Escherichia coli and Staphylococcus aureus.

Remove all gross food particles and soil from areas which are to be sanitized with a good detergent, pre-flush, pre-soak or pre-scrape treatment. Rinse with a potable water rinse. To sanitize pre-cleaned and potable water-rinsed, non-porous, food contact surfaces, prepare a 200 ppm active quaternary solution by adding 8 ounces of this product to 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 for at least 60 seconds making sure to wet all surfaces completely. Remove excess, drain the use solution from the surface and air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

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. Remove items, drain the use solution from the surface and air dry. 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 the active quaternary to 200 ppm. **NO POTABLE WATER RINSE IS REQUIRED.** This product is an effective sanitizer when diluted in water up to 500 ppm hardness (CaCO₃).

BACTERICIDAL ACTIVITY - When diluted at the rate of 4.5 ounces per gallon of water, this product exhibits disinfectant activity against the organisms: Salmonella choleraesuis, Staphylococcus aureus and Escherichia coli.

When diluted at the rate of 6 ounces per gallon of water, this product exhibits effective disinfectant activity against Pseudomonas aeruginosa in addition to the above microorganisms and meets all requirements for hospital use.

***VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate, hard, non-porous surfaces at a dilution of 18 ounces per gallon of water exhibits effective virucidal activity against Canine Parvovirus.

FOR DISINFECTION AGAINST CANINE PARVOVIRUS - Add 18 ounces of this product per gallon of water.

DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS - For disinfection of pre-cleaned poultry equipment (brooders, watering founts, feeding equipment), animal quarters and kennels, apply a solution of 6 ounces of this product per gallon of water. Remove all poultry, animals, and feed from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry or animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate the surfaces with the disinfecting solution for a period of 10 minutes. Ventilate building, coops, and other closed spaces. Do not house poultry or animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

MILDEWSTAT - To control mold and mildew (such as Aspergillus niger ATCC 6275) and the odors they cause on pre-cleaned, hard, non-porous inanimate surfaces add 4.5 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 4.5 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, VIRUCIDE, 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 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 a poison control center or doctor for treatment advice.

If swallowed: Call a 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

This pesticide is toxic to fish. 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 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.