

1839-169

8/29/2002
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Nancy S. Maitzen
Senior Regulatory Coordinator
Stepan Company
22 W. Frontage Road
Northfield, IL 60093

AUG 29 2002

Subject: Amendment per FIFRA
BTC 885 Neutral Disinfectant Cleaner - 64
EPA Registration No. 1839-169
Application Dated: May 22, 2002
EPA Received Date: May 31, 2002

Dear Ms. Maitzen:

The following amendment, submitted in connection with registration under 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Proposed Amendment

- Addition of Methicillin resistant *Staphylococcus aureus* (MRSA)
- Addition of Vancomycin intermediate resistant *Staphylococcus aureus* (VISA)
- Addition of Hepatitis B Virus (HBV) claim
- Addition of Rotavirus claim
- Expanded specific use sites and environmental surfaces
- Update First Aid Statements per PR Notice 2001-1
- Update Precautionary Statements to conform to the Label Review Manual

Label Comments

1. Revise the "Fungicidal Activity" directions to include the organism *Trichophyton mentagrophytes* per this product's last stamped label dated July 13, 1998.
2. Revise the "Contact Time" section of the HIV-1, HIV-2, and HBV directions to include the contact time for HBV.
3. Revise the "If on skin or clothing" section of the First Aid Statements to read:
If on skin or clothing: Take off contaminated clothing. Rinse skin *immediately* with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

CONCURRENCES

SYMBOL	7510c						
SURNAME	Shay						
DATE	8-28-02						

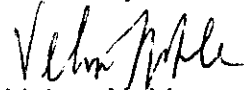
4. Delete the virus "HCV (Heptitis C Virus)" from your label. It is not an acceptable organism according to current Agency guidelines.

General Comments

A stamped copy of the label is enclosed for your records. Please submit two (2) copies of the final printed label before distributing or selling the product bearing the revised language.

Should you have any questions regarding this letter, please contact me at 703-308-6233.

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510 C)

BTC[®] 885

Neutral Disinfectant Cleaner-64

CLEANER
DETERGENT
DEODORIZER

MILDEWSTAT (on hard, non-porous, inanimate surfaces)

DISINFECTANT
FUNGICIDE (against pathogenic fungi)
* VIRUCIDE

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride 1.627%
 Dioctyl dimethyl ammonium chloride 0.814%
 Didecyl dimethyl ammonium chloride 0.814%
 Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl
 benzyl ammonium chloride 2.170%

INERT INGREDIENTS 94.575%
Total 100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-169
 EPA EST. NO. 1839-IL-01

STEPAN COMPANY
 22 West Frontage Road • Northfield, IL 60093

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
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(center panel)

Amend 5/22/02

DIRECTIONS FOR USE

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

BTC® 885 Neutral Disinfectant Cleaner-64 is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection for hospitals, nursing homes, hotels, schools, restaurants, and food processing plants, where housekeeping is of prime importance in controlling cross contamination from treated surfaces.

This product, when used as directed, is formulated to disinfect the following hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, vanity tops, shower stalls, bathtubs, and cabinets. For larger areas such as operating rooms and patient care facilities, 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.

(Note: The terminal sterilant paragraph below is required when labels contain a hospital claim.)

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.

This product is formulated to a neutral pH and will not dull high-gloss floor finishes with repeated use.

GENERAL CLEANING – Apply product to soiled area with a mop, cloth, sponge, or hand-pump trigger sprayer. Product can be diluted at 2 ounces per gallon or applied at full strength. Thoroughly wet soiled surface and scrub as necessary. Rinse surface with potable water and wipe dry with a dry paper towel or lint-free cloth.

DISINFECTION - For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use. To disinfect inanimate, hard, non-porous surfaces 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.

TO DISINFECT TOILET BOWLS - Remove gross filth or soils from surfaces with bowl brush. Add 2 ounces of product 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 2 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 restaurant food contact surfaces: countertops, appliances, and tables, add 2 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 cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

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

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BACTERICIDAL ACTIVITY - At the 2 ounce per gallon dilution, this product demonstrates effective disinfectant activity against the organisms: *Pseudomonas aeruginosa* PRD-10, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Staphylococcus aureus* (clinical isolate), *Bordetella bronchiseptica*, *Corynebacterium ammoniagenes*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Enterobacter cloacae* (clinical isolate), *Enterococcus faecalis*, *Enterococcus faecalis* (clinical isolate), *Escherichia coli*, *Escherichia coli* (clinical isolate), *Fusobacterium necrophorum*, *Klebsiella pneumoniae* subsp. *pneumoniae*, *Lactobacillus casei* subsp. *rharnosus*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus vulgaris*, *Proteus mirabilis* ATCC 9921, *Proteus mirabilis* ATCC 25933, *Salmonella choleraesuis* subsp. *choleraesuis* serotype paratyphi B, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhi, *Salmonella choleraesuis* subsp. *choleraesuis* serotype typhimurium, *Salmonella choleraesuis* subsp. *choleraesuis* serotype pullorum, *Serratia marcescens*, *Shigella sonnei*, *Shigella flexneri* Type 2b, *Shigella dysenteriae*, *Staphylococcus aureus* subsp. *aureus*, *Staphylococcus epidermidis*, *Staphylococcus epidermidis* (clinical isolate), *Streptococcus pyogenes* (Clinical - Flesh Eating Strain BIRD M3), *Streptococcus pyogenes* Group A, *Xanthomonas maltophilia* (clinical isolate), Vancomycin resistant *Enterococcus faecalis* (VRE), Methicillin resistant *Staphylococcus aureus* (MRSA), and Vancomycin intermediate resistant *Staphylococcus aureus* (VISA).

MILDEWSTAT - To control mold and mildew (such as *Aspergillus niger*) and the odors they cause on pre-cleaned, hard, non-porous inanimate 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 ounce per gallon dilution, this product is fungicidal against the pathogenic fungus, *Candida albicans*. 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.

*** VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate, hard, non-porous surfaces exhibits effective virucidal activity against HIV-1, HIV-2, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital), Influenza A₂/Hong Kong, Vaccinia, Rotavirus, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus, and Canine Distemper. Add 2 ounces of the product per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with a cloth, mop, 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.

KILLS HIV-1, HIV-2, HBV, AND HCV 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 or Type 2 (HIV-1 or HIV-2) (associated with AIDS), Hepatitis B virus (HBV), and Hepatitis C virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HIV-2, HBV, AND HCV 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, VIRUCIDE AND FUNGICIDE AGAINST THE LISTED ORGANISMS IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

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(left panel - 2)

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Amend 5/22/02

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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. May be fatal if absorbed through the skin. Harmful if swallowed. Wear goggles or face shield, rubber gloves, and protective clothing. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

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.

(Note: If container size is of 5 gallons or greater, the following Environmental Hazards statement must be used.)

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.

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. Offer empty metal or plastic containers for recycling if available. Return metal drums 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. Wrap in newspaper and discard 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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