

1839-167

2-11-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 11 2004

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

Subject: BTC 885 Neutral Disinfectant Cleaner-256
EPA Registration No. 1839-167
Application Date: 11/11/03
Receipt Date: 11/13/03

Dear Mr. Isaac:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions:

Reduction in the Fungicidal water hardness to 200 ppm (as CaCO₃) from
400 ppm (as CaCO₃)

CONDITIONS

1. Revise the label as follows: Under the Citrus Canker, you must either delete the clothes and shoes from the list of sites for application or submit specific directions on how to apply product to clothing. Please refer to Agency letter dated December 3, 2003.

GENERAL COMMENTS

The Confidential Statement of Formula (CSF) November 5, 2003 is acceptable. It is in compliance with PR Notice 91-2 and in agreement with the label.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

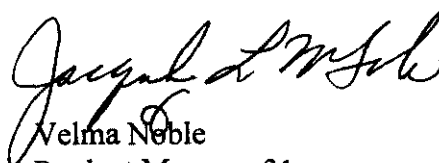
CONCURRENCES							
SYMBOL	17510C						
SURNAME	J. Jones						
DATE	2-10-04						

OFFICIAL FILE COPY

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Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,

A handwritten signature in cursive script, appearing to read "Jacqueline L. Noble".

Velma Noble

Product Manager 31

Regulatory Management Branch 1

Antimicrobial Division (7510C)

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BTC[®] 885

Neutral Disinfectant Cleaner-256

CLEANER
DETERGENT
DEODORIZER

DISINFECTANT
FUNGICIDE (against pathogenic fungi)
* VIRUCIDE

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

CITRUS CANKER CONTROL MUSHROOM FARM SANITATION

Not for Use in California

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride.....	6.510%
Dioctyl dimethyl ammonium chloride.....	3.255%
Didecyl dimethyl ammonium chloride.....	3.255%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	8.680%
INERT INGREDIENTS.....	78.300%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-167
EPA EST. NO. 1839-IL-01

ACCEPTED
With COMMENTS
in EPA Letter Dated:

FEB 11 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-167

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

NET CONTENTS

(OPTIONAL) NET CONTENTS: XX ounces per packet

(center panel)

Amend 11/11/03

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-256 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 business, and athletic/recreational facilities where housekeeping is of prime importance in controlling the hazard of cross-contamination. For use in federally inspected meat and poultry processing plants.

This product, when used as directed, is formulated to disinfect 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: 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 formulated to a neutral pH and will not dull high-gloss floor finishes with repeated use.

(For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)

This product is not 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 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 not for use on medical device surfaces.

GENERAL CLEANING – Apply product to soiled area with a mop, cloth, sponge, or hand pump trigger sprayer. Product can be diluted at $\frac{1}{2}$ ounce 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 – To disinfect inanimate, hard, non-porous surfaces add $\frac{1}{2}$ ounce 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.

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

PACKETS - *Pre-measured tear open packets* – (Simply) open and pour contents into XX gallons of water (for a 1:256 dilution). Keep packets in box until ready to use. (Pour contents of packet into XX gallons of water for a 1:256 dilution).

TO DISINFECT FOOD PROCESSING PREMISES: floors, walls, and storage areas, add $\frac{1}{2}$ 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. All surfaces which may come in contact with food must be rinsed with potable water.

TO DISINFECT FOOD SERVICE ESTABLISHMENT FOOD CONTACT SURFACES: countertops, appliances, tables, add $\frac{1}{2}$ 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. This product cannot be used to clean the following food contact surfaces: utensils, glassware and dishes.

TO DISINFECT TOILET BOWLS – Prior to disinfection, remove gross filth or soils from surfaces with bowl brush. Add $\frac{1}{2}$ ounce 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.

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

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 $\frac{1}{2}$ 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.

BACTERICIDAL ACTIVITY – At the ½ 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. *rhannosus*, *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*, Methicillin resistant *Staphylococcus 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* (ATCC 51575), and Vancomycin intermediate resistant *Staphylococcus aureus* (VISA).

FUNGICIDAL ACTIVITY – At the ½ ounce per gallon dilution, this product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* and *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 at ½ ounce per gallon of water exhibits effective virucidal activity against Human Immunodeficiency Virus Type 1 (HIV-1), Human Immunodeficiency Virus Type 2 (HIV-2), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital disease), Influenza A₂/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus, Canine Distemper and Rotavirus.

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.

MUSHROOM FARM SANITATION – This product disinfects, cleans, and deodorizes in one step. Recommended for use in mushroom farm sanitation. Apply to surfaces which do not come in contact with the crop, compost or casing. Remove gross filth and heavy soil deposits using a shovel, broom or vacuum depending on the area to be disinfected. For heavily soiled areas, a pre-cleaning step is required. Apply this product at ½ ounce per gallon of water dilution (1:256), thoroughly wetting the surfaces with a mop, sponge, cloth, spraying or soaking. Treated surfaces should remain wet for 10 minutes and let air dry. The recommended use solution is prepared fresh for each use, then discarded. If greater detergency is required, dilute this product at 1 to 2 ounces per gallon of water. **DO NOT APPLY TO MUSHROOM CROP, COMPOST OR CASING.**

FOR FOOT DIP OF WATERPROOF FOOTWEAR – Use this product at ½ ounce per gallon of water in foot dip tray. Shoe baths must contain at least 1 inch of freshly made solution and should be placed at the entrances to buildings. Scrape shoes and place in diluted solution for 60 seconds before entering building. Change solution in bath daily or sooner if solution appears dirty.

BACTERICIDAL ACTIVITY – When diluted at ½ ounce per gallon, this product demonstrates effective disinfectant activity against the following mushroom pathogens: *Pseudomonas tolaasii* (Blotch Disease) and *Pseudomonas* sp. (Mummy Disease).

FUNGICIDAL ACTIVITY – When diluted at ½ ounce per gallon, this product demonstrates effective fungicidal activity against the following mushroom pathogens: *Verticillium fungicola* (Verticillium Disease, dry bubble, brown spot or fungus spot), *Mycogone perniciosa* (Mycogone Disease or wet bubble), *Tricoderma viride*, *Dactylium dendroides* (Hypomyces Disease, cobweb or soft decay), and *Tricoderma harzianum*. **NOTE: Not for Use in California.**

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CITRUS CANCKER CONTROL – For prevention of Citrus Canker Disease through treatment of equipment. This product, when used at a 1:108 dilution (2000 ppm active quaternary) or 1.18 ounces (35 ml) per gallon of water, is effective against *Xanthomonas axonopodis* pathovar *citri* (Citrus Canker). Treat all trucks, vehicles, and equipment thoroughly at the 1:108 dilution. Treatment can be applied to outer clothing, shoes, trucks, attached trailers, field harvesting equipment; including cargo area, wheels, tires, under carriage, hood, roof, fenders and any other part of transportation equipment that can be taken into infested areas. To prevent the spread of Citrus Canker by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing, using the maximum rate of 2000 ppm quaternary. After use, all surfaces which come in contact with food or crop must be rinsed with potable water. Clothing should be either thoroughly rinsed or laundered before reuse. Footwear should be rinsed before reuse. **NOTE: Not for Use in California.**

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND *VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM). THIS PRODUCT IS AN EFFECTIVE FUNGICIDE AGAINST THE LISTED FUNGI IN WATER UP TO 200 PPM HARDNESS (AS CaCO₃) 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. May be fatal if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles or face shield), clothing, and gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.

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 immediately 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.

HOT LINE NUMBER (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.

(Required for containers 5 gallons or greater)

ENVIRONMENTAL HAZARDS

This product 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. 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. Wrap in newspaper and discard in trash.

PACKET DISPOSAL – Do not reuse, discard empty 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.

Packet Label:

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BTC[®] 885 Neutral Disinfectant Cleaner-256

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride	6.510%
Dioctyl dimethyl ammonium chloride	3.255%
Didecyl dimethyl ammonium chloride	3.255%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	8.680%
INERT INGREDIENTS	<u>78.300%</u>
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements and use directions

Disposal – Do not reuse empty packet and put in trash.

EPA REG. NO. 1839-167
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

(OPTIONAL) Pour contents of packet into XX gallons of water for a 1:256 dilution.

NET CONTENTS: XX ounces per packet