

1839-168

03/04/2003

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
 Washington, D.C. 20460

 OFFICE OF  
 PREVENTION, PESTICIDES  
 AND TOXIC SUBSTANCES

MAR - 4 2003

 Nancy S. Maitzen  
 Sr Regulatory Specialist  
 Stephan Company  
 22 Frontage Rd  
 Northfield, IL 60093

 Subject: Notification per PR Notice 98-10  
 BTC @ 885 Neutral Disinfectant Cleaner-32  
 EPA Reg. No. 1839 -168  
 Application Dated: February 13, 2003  
 Receipt Date: February 14, 2003

Dear Ms. Nancy S. Maitzen,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification**

- Addition of the word "immediately", to the IF ON SKIN OR CLOTHING in the First Aid section of the PRECAUTIONARY STATEMENTS, so the line reads:  
"Rinse skin immediately with plenty of water for 15-20 minutes"
- Addition of an alternate Terminal Sterilant/High level Disinfectant Statement to the Directions for use section. The sentence should read:  
"This product is not for use on medical device surfaces"

**General Comments**

Based on a review of the material submitted, the following comments apply:

This application for notification is acceptable. A copy has been inserted in the file for future reference. Should you have any questions or comments concerning this letter, please contact me at (703) 308-6233.

Sincerely,

Velma Noble

## CONCURRENCES

SYMBOL	7510(C)						
SURNAME	Albers						
DATE	3/11/03						

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



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number STEPAN COMPANY / 1839-168	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BTC885 Neutral Disinfectant Cleaner-32	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) STEPAN COMPANY 22 W. Frontage Rd. Northfield, IL 60093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION : 1) Addition of the word, Immediately, to the IF ON SKIN OR CLOTHING in the First Aid section of the PRECAUTIONARY STATEMENTS. It should read: "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."  
2) Addition of an alternate Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. This one sentence statement reads "This product is not for use on medical device surfaces."

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container qt., gal., 5 gal., 55 gal.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Nancy S. Maitzen		Title Sr. Regulatory Coordinator		Telephone No. (Include Area Code) 847/501-2278	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Nancy Maitzen</i>		3. Title Sr. Regulatory Coordinator			
4. Typed Name Nancy S. Maitzen		5. Date February 13, 2003			

# BTC<sup>®</sup> 885

## Neutral Disinfectant Cleaner-32

CLEANER  
DETERGENT  
DEODORIZER

DISINFECTANT  
FUNGICIDE (against pathogenic fungi)  
\* VIRUCIDE  
MILDEWSTAT (on hard, non-porous, inanimate surfaces)

### ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride.....	0.814%
Dioctyl dimethyl ammonium chloride .....	0.407%
Didecyl dimethyl ammonium chloride .....	0.407%
Alkyl (50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride .....	1.085%

INERT INGREDIENTS.....	<u>97.287%</u>
<b>Total</b>	<b>100.000%</b>

KEEP OUT OF REACH OF CHILDREN

## DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-168  
EPA EST. NO. 1839-IL-01

STEPAN COMPANY  
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

(center panel)

Notification 02/13/03

## 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-32 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; 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.

or

This product is not for use on medical device surfaces.

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 4 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 4 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 4 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 4 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 4 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.

**BACTERICIDAL ACTIVITY** - At the 4 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*, *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 4 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 ounce per gallon dilution, this product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's foot fungus) 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 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 A<sub>2</sub>/Hong Kong, Vaccinia, Rotavirus, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus, and Canine Distemper. Add 4 ounces of the product per gallon of water. For heavily soiled areas, a pre-cleaning step is required. Apply solution with 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 CaCO<sub>3</sub>) 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. 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 immediately 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.