

1839-168

12/20/2001

1087

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Bruce Greene  
Senior Regulatory Chemist  
Stephan Company  
22 W. Frontage Road  
Northfield, IL 60093

DEC 20 2001

Subject: Notification per PR Notice 98-10  
BTC 885 Neutral Disinfectant Cleaner-32  
EPA Reg. No. 1839-168  
Application Dated: November 20, 2001

Dear: Mr. Bruce Greene

This letter acknowledges receipt of your notification for the addition of the terminal sterilant paragraph minus the last sentence. Per FIFRA 3(c)9, 40 CFR 152.46, PR Notice 98 -10, PR Notice 94 - 4 and based on a review of submitted materials, the application is acceptable and the notification has been made a part of the records for this file.

Should 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	12/19/01							

2097



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95

	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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### Application for Pesticide - Section I

1. Company/Product Number 1839-168	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BTC 885 Neutral Disinfectant Cleaner-32	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Road 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 checked="" type="checkbox"/> Amendment - Explain below.  <input type="checkbox"/> Resubmission in response to Agency letter dated _____  <input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application.  <input type="checkbox"/> Other - Explain below.
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**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
 Addition of the terminal sterilant paragraph minus last sentence.

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  <i>* Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes" Unit Packaging wgt.    No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes" Package wgt.    No. per container	2. Type of Container <input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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 gallon plastic	5. Location of Label Directions <input checked="" type="checkbox"/> On label
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Bruce L. Greene	Title Sr. Regulatory Chemist	Telephone No. (Include Area Code) 847-501-2320	
Certification 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.			8. Date Application Received (Stamped)  <div style="text-align: center;"> <div style="display: flex; justify-content: space-around;"> <div>.....</div> <div>.....</div> </div> <div style="display: flex; justify-content: space-around;"> <div>.....</div> <div>.....</div> </div> <div style="display: flex; justify-content: space-around;"> <div>.....</div> <div>.....</div> </div> <div style="display: flex; justify-content: space-around;"> <div>.....</div> <div>.....</div> </div> </div>
2. Signature 	3. Title Sr. Regulatory Chemist		
4. Typed Name Bruce L. Greene	5. Date 11/20/2001		

**Stepan**

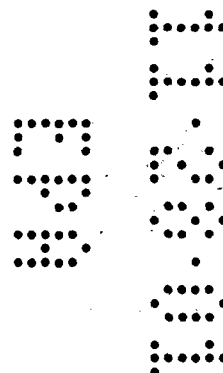
Stepan Company

Northfield, Illinois 60093  
Telephone 847 446 7500



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This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 FR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



31 **Stepan**

Stepan Company

Northfield, Illinois 60093  
Telephone 847 446 7500



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November 20, 2001

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, DC 20460-0001  
Attn: PM 31—Velma Noble

Re: **Label Update via Notification:**  
BTC 885 Neutral Disinfectant Cleaner-32  
EPA Reg. No. 1839-168

Dear Ms. Noble:

Stepan Company is proposing to add the terminal sterilant statement (minus the last sentence) to the subject product label.

Please note that I have highlighted in yellow the proposed label change.

Thank you for your attention on this matter. If you should have any questions, please do not hesitate to contact me at Stepan Company at 847-501-2329 (my direct number).

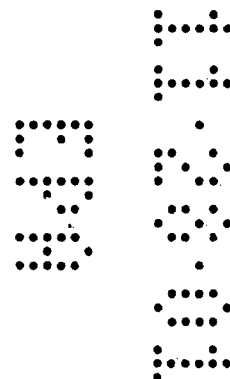
Sincerely,  
STEPAN COMPANY

Bruce L. Greene  
Sr. Regulatory Chemist

BG/slf

Attachments

BG-01-616



Printed on Recycled Paper

# BTC<sup>®</sup> 885

## Neutral Disinfectant Cleaner-32

CLEANER  
DETERGENT  
DEODORIZER

DISINFECTANT  
FUNGICIDE (against pathogenic fungi)  
\* VIRUCIDE

MILDEWSTAT (on hard, nonporous, 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 .....	97.287%
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Total	100.000%
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KEEP OUT OF REACH OF CHILDREN

## DANGER

See side panels for additional precautionary statements.

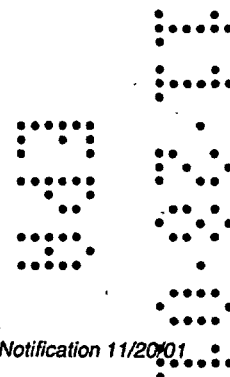
EPA REG. NO. 1839-168  
EPA EST. NO. 1839-IL-01

STEPAN COMPANY  
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

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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.

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 other institutions where housekeeping is of prime importance in controlling cross-contamination from treated surfaces. Authorized by USDA 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 such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, 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.

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

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 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 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.

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 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.

**EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO<sub>3</sub>) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).**

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

**BACTERICIDAL ACTIVITY** - At the 4 ounces 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), and Vancomycin resistant *Enterococcus faecalis* (ATCC 51575).

**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 ounces per gallon dilution, this product demonstrates effective fungicidal activity against the pathogenic fungi *Trichophyton mentagrophytes* and *Candida albicans*.

Stepan Company  
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\* **VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard non porous surfaces at 4 ounces per gallon of water exhibits effective virucidal activity against Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital disease), Influenza A/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus, and Canine Distemper.

**KILLS HIV-1 and HIV-2 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).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 and HIV-2 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.

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**

**DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE:** Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

**STATEMENT OF PRACTICAL TREATMENT**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician.

If swallowed, drink large quantities of water. Avoid alcohol. Call a physician immediately.

**NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage.

**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.**

**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 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. Rinse thoroughly before discarding 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.

