

DEC 19 1996

Stepan Company
22 West Frontage Road
Northfield, IL 60093

Attention: Leo Dringoli
Manager, Product Registration

Subject: BTC 885 Neutral Disinfectant Cleaner - 128
EPA Registration No. 1839-166
Amendment Dated June 20, 1996

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to add claims against the organisms Streptococcus pyogenes, Enterococcus faecalis, Aspergillus niger, Candida albicans, and Trichophyton mentagrophytes are acceptable provided that you comply with the items listed below.

1. Submit/cite all data required for registration/-reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Change the "If Swallowed" instructions of your "Statement of Practical Treatments" section to read "If swallowed, drink large quantities of water. Avoid alcohol. Call a physician immediately." Submit five (5) copies of your final printed labeling before you release the product for shipment.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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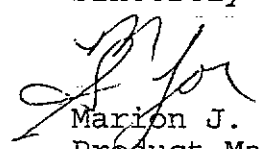
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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Marshall Swindell (703) 305-6908.

Sincerely yours,



Marion J. Johnson
Product Manager 31
Antimicrobial Programs Branch
Registration Division (7505C)

3045

BTC[®] 885

Neutral Disinfectant Cleaner-128

CLEANER
DETERGENT
DEODORIZER

DISINFECTANT
FUNGICIDE (against pathogenic fungi)
* VIRUCIDE

ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride.....	3.255%
Dioctyl dimethyl ammonium chloride.....	1.628%
Didecyl dimethyl ammonium chloride.....	1.628%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride.....	4.339%
INERT INGREDIENTS.....	89.150%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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EPA REG. NO. 1839-166
EPA EST. NO. 1839-IL-01

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* **VIRUCIDAL ACTIVITY** - This product when used on environmental, inanimate hard non porous surfaces at 1 ounce 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 A₂/Hong Kong, Vaccinia, Pseudorabies, Bovine Rhinotracheitis, Feline Leukemia, Feline Picornavirus, and Canine Distemper.

KILLS HIV-1 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 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 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 egg whites or gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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.

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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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-128 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.

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.

DISINFECTION - To disinfect inanimate, hard non porous surfaces add 1 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.

TO DISINFECT TOILET BOWLS: Remove gross filth or soils from surfaces with bowl brush. Add 1 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN WATER UP TO 400 PPM HARDNESS (AS CaCO_3) 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 1 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), and Vancomycin resistant *Enterococcus faecalis* (ATCC 51575).

Fungicidal Activity - At the 1 ounce per gallon dilution, this product demonstrates effective fungicidal activity against the pathogenic fungi *Microbotryomycetozoa*, *Phytophthora*, *Candida albicans*, and *Aspergillus niger*.

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