

1839-173

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6/17/2003

1/7

JUN 17 2003

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

Subject: 7.5% BTC 885 Disinfectant/Sanitizer  
EPA Registration No. 1839-173  
Application Date: 3/21/03  
Receipt Date: 3/24/03

Dear Mr. Isaac:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided you make the following changes to the label listed under "**GENERAL COMMENTS**".

- . Update First Aid Statements
- . Update Precautionary Statements
- . Expanded Sanitizer Use Dilution Table
- . Addition of Sanitizer Use Directions for multiple use site/applications
- . Addition of Use Directions for Cleaning of Body Surfaces and Orifices of Human Remains
- . Addition of Use Directions for the control of mold & mildew on large, inflatable plastic & rubber structures
- . Addition of Use Directions for Bag-in-Box containers
- . Addition of U.S. Public Health Service
- . Addition of Wisconsin State Division of Health

**GENERAL COMMENTS**

1. On the left panel-1: Revise the "Disinfection of Poultry Equipment, Animal Quarters and Kennels" directions by adding the statement, "Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure". This statement must appear immediately after the contact time.

CONCURRENCES							
SYMBOL	The statement, "thoroughly wash surfaces with detergent or compatible cleaner, then rinse thoroughly with potable water" must be added to the following directions:						
SURNAME							
DATE	6-11-03						

A. Sanitizing food processing equipment (Ice Machines) and other hard surfaces in food contact locations.

B. Directions for Food Processing Equipment and Diaries

C. Beverage Dispensing Equipment Sanitizer Directions

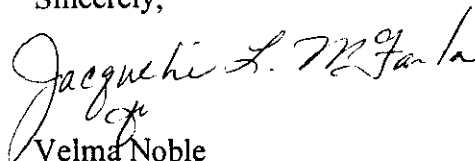
D. Storage Tank Sanitizer Directions

3. Under the "Directions for Food Processing Equipment and Diaries" add the following text: "Surfaces must remain thoroughly wet for at least 60 seconds by immersion or with a cloth, mop, sponge or sprayer. Allow equipment and utensils to drain thoroughly and air dry before reuse".

4. On the left panel-3 of the label, insert the word "not" between may and be. Whenever "automated systems" are on the label, you may "not reused for sanitizing".

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

Sincerely,



Velma Noble

Product Manager 31

Regulatory Management Branch 1

Antimicrobial Division (7510C)

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ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JUN 17 2003  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1839-173

# 7.5% BTC<sup>®</sup> 885 Disinfectant/Sanitizer

DISINFECTANT                      \* VIRUCIDE  
SANITIZER                         DEODORIZER  
MILDEWSTAT (on hard, inanimate surfaces)  
FUNGICIDE (against pathogenic fungi)

## ACTIVE INGREDIENTS

Octyl decyl dimethyl ammonium chloride ..... 2.250%  
Dioctyl dimethyl ammonium chloride ..... 1.125%  
Didecyl dimethyl ammonium chloride ..... 1.125%  
Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>16</sub>) dimethyl  
benzyl ammonium chloride ..... 3.000%

INERT INGREDIENTS ..... 92.500%  
TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN

## DANGER

See right panel for additional precautionary statements.

EPA REG. NO. 1839-173  
EPA EST. NO. 1839-IL-01

STEPAN COMPANY  
22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

(center panel)

Amend 03/21/03

## DIRECTIONS FOR USE

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

7.5% BTC® 885 Disinfectant/Sanitizer is designed for use in hospitals, nursing homes, hotels, schools, homes, food processing plants, dairies, restaurants, bars, animal quarters, kennels, farm use, and institutions where disinfection, sanitization and deodorization is of prime importance. This product can be used in federally inspected meat and poultry processing plants. When used as directed, this product is formulated to disinfectant hard, non-porous, inanimate, environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs, countertops, appliances and telephones.

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, pet areas and any other areas which are prone to odors caused by microorganisms.

In addition, this product can also be used for sanitization of shell eggs intended for food in shell egg and egg product processing plants.

*(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 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.

OR

This product is not for use on medical device surfaces.

**DISINFECTION** - To disinfect inanimate, hard, non-porous surfaces apply this product with mop, cloth, sponge, low pressure coarse spray or hand-pump trigger sprayer so as to wet all surfaces thoroughly. Allow treated surfaces 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.

**GENERAL DISINFECTION** - Add 2 ounces of this product per 4.5 gallons (0.44 ounce per gallon) of water for disinfection against *Staphylococcus aureus* and *Salmonella choleraesuis*.

**HOSPITAL DISINFECTION** - Add 3.5 ounces of this product per 4.5 gallons (0.78 ounce per gallon) of water for disinfection against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*.

**DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS** - For disinfection of pre-cleaned poultry equipment (brooders, watering founts, feeding equipment), animal quarters and kennels, apply a solution of 2 ounces of this product per 4.5 gallons (0.44 ounce per gallon) of water. Remove all poultry, animals, and feed from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry or animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate the surfaces with the disinfecting solution for a period of 10 minutes. Ventilate building, coops, and other closed spaces. Do not house poultry or animals or employ equipment until treatment has been absorbed, set or dried. All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

**To disinfect food service establishment or restaurant food contact surfaces:** countertops, outside of appliances and tables, add 3.5 ounces of this product per 4.5 gallons (0.78 ounce 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. For sprayer application use a coarse spray. Before using this product, food products and packaging materials must be removed from the area or carefully protected.

**To disinfect food-processing premises:** floors, walls and storage areas, add 3.5 ounces to 4.5 gallons of water (0.78 ounce per gallon). 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. For sprayer application use a coarse spray. Allow to remain wet for 10 minutes, then remove excess liquid. Before using this product, food products and packaging materials must be removed from area or carefully protected. After use, all surfaces must be thoroughly rinsed with potable water.

**\*VIRUCIDAL ACTIVITY** - This product, when used on environmental inanimate hard surfaces at 3.5 ounces per 4.5 gallons of water exhibits effective virucidal activity against Influenza A<sub>2</sub>/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Herpes Simplex Type 2 (genital disease), Vaccinia virus (representative of the pox virus group), and Avian Influenza A/Turkey/Wisconsin (causative agent of an acute avian lower respiratory tract infection). Treated surfaces must remain wet for 10 minutes.

**FUNGICIDAL ACTIVITY** - At 1 ounce per 4.5 gallons of water, this product is fungicidal against the pathogenic fungi, *Trichophyton mentagrophytes* (Athlete's Foot Fungus), when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, non-porous, hard surfaces commonly contacted by bare feet.

**MILDEWSTAT** - To control mold and mildew on pre-cleaned, hard, non-porous surfaces, add 3 ounces of this product per 5 gallons of water. Apply solution with a cloth, mop, sponge, or hand pump trigger sprayer 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.

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

**SANITIZATION** - Recommended for use in restaurants, dairies, food processing plants, and bars. When used as directed this product is an effective sanitizer against *Escherichia coli* and *Staphylococcus aureus*. Tests show that this product is an effective sanitizer at the 150 ppm level. However, if you wish an extra margin of performance, this product may be used up to the 400 ppm level.

Remove all gross food particles and soil from areas which are to be sanitized with a good detergent, pre-flush, pre-soak or pre-scrape treatment. Rinse with a potable water rinse. To sanitize pre-cleaned and potable water rinsed, non-porous, food contact surfaces, prepare a 150, 200, 300 or 400 ppm active quaternary solution by using the following dilution table:

Active Quat Solution	1 Gallon	4 Gallons	10 Gallons	20 Gallons
150 ppm	0.25 ounce	1 ounce	2.5 ounces	5 ounces
200 ppm	0.34 ounce	1.36 ounces	3.4 ounces	6.8 ounces
300 ppm	0.5 ounce	2 ounces	5 ounces	10 ounces
400 ppm	0.67 ounce	2.67 ounces	6.67 ounces	13.34 ounces

To sanitize immobile items such as tanks, chopping blocks, counter tops, refrigerated storage and display equipment, and food processing equipment, flood the area with a 150, 200, 300 or 400 ppm active quaternary solution for at least 60 seconds making sure to wet all surfaces completely. Remove excess, drain the use solution from the surface and air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

To sanitize mobile items such as drinking glasses and eating utensils, immerse in a 150, 200, 300 or 400 ppm active quaternary solution for at least 60 seconds making sure to immerse completely. Remove items, drain the use solution from the surface and air dry. Prepare a fresh solution daily or more frequently as soil is apparent.

When used for sanitization of previously cleaned food equipment or food contact items, limit the active quaternary from 150 ppm to 400 ppm. NO POTABLE WATER RINSE IS REQUIRED. This product is an effective sanitizer when diluted in water up to 800 ppm hardness (CaCO<sub>3</sub>).

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants when used as directed (wet shells with a 150 ppm active quaternary solution for at least 60 seconds, drain, then let air dry).

The udders, flanks and teats of dairy cows can be sanitized by washing with a solution of 1 ounce of this product in 4 gallons of warm water. No potable water rinse is required. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip used towel back into sanitizing solution. When solution becomes visibly dirty, discard and provide fresh solution.

**DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY 21CFR sec 178.1010: b(22), c(17).**

1. Scrape, flush or pre-soak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles using a solution of 0.25 to 0.67 ounce of this product per gallon of water (150-400 ppm active quaternary). Articles that can be immersed in solution should remain in solution for 60 seconds. Articles too large for immersion should be thoroughly wetted by rinsing, spraying or swabbing.
5. Remove immersed items from solution to drain and then air dry. Non-immersed items should also be allowed to air dry.

**U.S. PUBLIC HEALTH SERVICE - FOOD SERVICE SANITIZATION RECOMMENDATIONS**

**CLEANING AND SANITIZING:** Equipment and utensils shall be thoroughly pre-flushed or pre-scraped, and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution. Rinse utensils and equipment thoroughly with potable water.
2. Sanitize equipment and utensils by immersing in 1 to 2.67 ounces of this product per 4 gallons of water (150-400 ppm active quaternary) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
3. For equipment and utensils too large to sanitize by immersion, apply 2 ounces of this product per 4 gallons of water (300 ppm active quaternary) by rinsing, spraying or swabbing. Allow the items to remain thoroughly wet for at least 60 seconds, then let air dry.

**WISCONSIN STATE DIVISION OF HEALTH - DIRECTIONS FOR EATING ESTABLISHMENTS:**

1. Scrape and pre-wash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleanser.
3. Rinse with potable water.
4. Sanitize in a solution of 1.36 to 2.67 ounces per 4 gallons of this product (200-400 ppm active quaternary). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drain board to air-dry.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

**NOTE:** A clean potable water rinse following sanitization is not permitted under Section HSS 196.33 of the Wisconsin Administrative Code.

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**For Continuous Treatment of Meat . Poultry or Fruit and Vegetable Conveyors** move gross food particles and excess soil by a pre-flush or pre-scrape, wash with a good detergent or compatible cleaner, rinse equipment thoroughly with potable water, then rinse equipment with sanitizing solution. To sanitize the belt, apply this product at a 150-400 ppm quaternary level (1 to 2.67 ounce(s) per 4 gallons of water) (or equivalent use dilution) to conveyors with suitable feeding equipment. Do not allow this solution to be sprayed directly on food. Controlled volumes of sanitizer are applied to the return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of the belt. During interruptions in operation, coarse spray the equipment, peelers, collators, slicers and saws with this product at a dilution of 150-400 ppm active quaternary. Conveyor equipment should be free of product when applying this coarse spray.

**For Sanitizing In Fisheries, Milk, Citrus, Potato and Ice Cream Processing Plants.** For use as a sanitizer on conveyor belts and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes. Follow directions for sanitizing food contact surfaces.

**Cleansing of Body Surfaces and Body Orifices of Human Remains.** To cleanse away skin secretions and accompanying malodor, to insure the removal of all soil and bloodstains, and to remove and reduce surface contamination, apply 3.5 ounces of this product to 4.5 gallons of water (0.78 ounce per gallon of water) (450 ppm active quaternary) (or equivalent dilution) to the surfaces and body openings, natural or artificial. Allow 10 minute contact time for optimal results. Bathe the entire body using sponge or washcloth. A soft brush may be employed on surfaces other than the face. Prepare a fresh solution for application to each remains.

**To Control Mold and Mildew on Large, Inflatable, Non-Porous Plastic and Rubber Structures (animals, promotional items, moonwalk, slides, obstacle course play equipment, exercise equipment, and wrestling mats).** Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use solution of 3.5 ounces per 4.5 gallons of water (0.78 ounce per gallon of water) (450 ppm active quaternary) (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not use equipment until treatment has been absorbed, set or dried.

*(Alternative language for bag in the box dispensing equipment)*

#### **Directions For Bag-In Box Containers.**

**HOW TO USE THIS PACKAGE:** This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on the box.

**TRIGGER SPRAYERS:** Fill bottle from dispenser. Apply to surfaces according to directions above.

**MOP BUCKETS:** Fill bucket from dispenser. Set up "Wet Floor" signs. Mop floor surfaces as specified in directions above.

**EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, VIRUCIDE AND FUNGICIDE 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 skin. Harmful if swallowed. Harmful if inhaled. Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, rubber gloves and protective clothing when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash 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 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 a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a 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 mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**(OPTIONAL):** You may contact XXX/XXX-XXX for emergency medical treatment information.

#### **NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage.

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

### **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.**

**PESTIFIDE 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. 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.

Stepan Company

Northfield, IL 60093

EPA Reg. No. 1839-173

(right panel)

Amend 03/21/03