

1839-152

8-7-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 7 2003

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

Subject: BTC @ 1010
EPA Registration No. 1839-152
Amendment dated: May 13, 2003
EPA Received date: May 13, 2003

Dear: Mr. Thomas W. Isaac,

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

Proposed Amendment

- Update the First Aid Statement consistent with PR Notice 2001-1
- Update precautionary Statements consistent with the Label Review Manuel
- Addition of expanded, specific environmental surfaces: stainless steel, metal and plastic surfaces
- Addition of Environmental Hazards Statement
- Addition of TERMINAL STERILANT STATEMENT consistent with PR Notice 94-4 and optional line statement
- Replace "mechanical sprayer" mode of delivery with "hand pump trigger sprayer" and "low pressure coarse spray".
- Addition of directions for disinfection of food service establishment or restaurant food contact surfaces and disinfection of food-processing premises.
- Expanded Fungicidal Activity section with specific environmental surfaces.
- Change the trade name to **BTC @1010 7.5% Solution**

		CONCURRENCES					
SYMBOL	751010						
SURNAME	A. Peters						
DATE	8/7/03						

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Conditions

• Revise the label as follows:

- 1. Qualify the phrase hard surfaces as hard *non-porous* surfaces which appears in the second paragraph and Disinfection directions on page two.
- 2. Add the following statement to the **To disinfect food service establishment or restaurant food contact surfaces**

Do not use on glasses, dishes and utensils

- 3. Revise the Disinfection of Poultry Equipment, Animal Quarters and Kennels per DIS/TSS 19

For disinfection of precleaned poultry equipment (Brooders, watering founts, and feeding equipment) and other animal quarters (such as stalls and kennel areas) apply a solution of 2 ounces of this product per 4 gallons of water with a mop cloth or brush. Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

- 4. Add the following statement to the FUNGICIDAL ACTIVITY directions for use

Follow disinfection directions

- 5. On page 2 of the proposed label Sanitization directions modify the last paragraph as follows:

Udders, flanks, and Teats of Dairy Cows: sanitize by washing with a solution of 1 ounce of this product per 4 gallons of warm water.....

General Comments

A stamped label is enclosed for your records. Please submit three copies (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above condition is not compiled with, the registration will be subject to cancellation in accordance with FIFRA section (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of the condition. Should you have any questions concerning this letter please contact me at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (7510c)

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 7 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-152

BTC® 1010 7.5% SOLUTION

DISINFECTANT
FUNGICIDE (against pathogenic fungi)

SANITIZER
DEODORIZER

ACTIVE INGREDIENTS

Didecyl dimethyl ammonium chloride.....7.5%

INERT INGREDIENTS.....92.5%

Total 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements.

EPA REG. NO. 1839-152

EPA EST. NO. 1839-IL-01

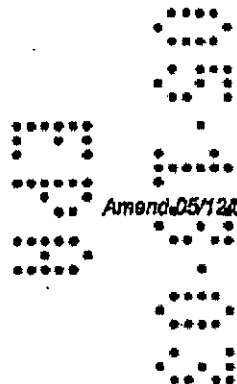
STEPAN COMPANY

22 West Frontage Road

Northfield, IL 60093

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Amend 05/12/03

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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® 1010 7.5% Solution is designed specifically for hospitals, nursing homes, and other health care institutions, schools, food processing plants, dairies, restaurants, bars, animal quarters, poultry equipment, kennels and institutions where disinfection, sanitization and deodorization is of prime importance.

non-porous

When used as directed, this product is formulated to disinfect pre-cleaned inanimate, hard surfaces: walls, floors, sink tops, tables, countertops, bathing areas, lavatories, bed frames, chairs, garbage pails, stainless steel surfaces, plastic surfaces, metal surfaces 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 other areas which are prone to odors caused by microorganisms.

In addition, this product will sanitize previously cleaned and rinsed non-porous food contact surfaces such as food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, and refrigerated storage and display equipment. This product can also be used to sanitize the udders, flanks, and teats of dairy cows.

(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.

non porous

DISINFECTION - To disinfect pre-cleaned, inanimate, hard surfaces, apply this product with a cloth, mop, hand pump trigger sprayer or low pressure coarse spray device so as to wet all surfaces thoroughly. Allow treated surfaces to remain wet for 10 minutes. Prepare a fresh solution for each use or when the use solution becomes visibly dirty.

GENERAL DISINFECTION - Add 2 ounces of this product per 4 gallons of water for effective disinfection against *Staphylococcus aureus* and *Salmonella choleraesuis*.

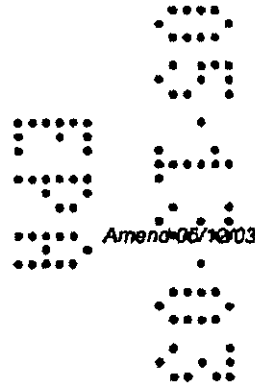
HOSPITAL DISINFECTION - Add 3.5 ounces of this product per 4 gallons of water for effective disinfection against *Pseudomonas aeruginosa*.

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 gallons (0.88 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 ounces to 4.5 gallons of water (0.88 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.

Stepan Company
Northfield, IL 60093
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Amend-06/10/03

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DISINFECTION OF POULTRY EQUIPMENT, ANIMAL QUARTERS AND KENNELS - For disinfection of pre-cleaned poultry equipment (brooders, watering founts, and feeding equipment) and other animal quarters (such as stalls and kennel areas) apply a solution of 2 ounces of this product per 4 gallons of water with a mop, cloth or brush. Small utensils should be immersed in this solution. Prior to disinfection, all poultry, other animals and their feeds must be removed from the premises. This includes emptying all troughs, racks, and other feeding and watering appliances. Remove all litter and droppings from floors, walls, and other surfaces occupied or traversed by poultry or other animals. After disinfection, ventilate building, coops, and other closed spaces. Do not house poultry or other animals nor 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 USE.

FUNGICIDAL ACTIVITY - At 2 ounces per gallon 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.

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*.

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 ppm active quaternary solution by adding 1 ounce of this product per 4 gallons of water. Surfaces should remain wet for at least 1 minute followed by adequate draining and air drying. Fresh solution should be prepared daily or when the solution becomes visibly dirty. For mechanical application, use solution may not be reused for sanitizing applications.

To sanitize immobile items such as tanks, chopping blocks, counter tops, sink tops, refrigerated storage and display equipment, flood the area with a 150 ppm active quaternary solution for at least 60 seconds making sure to wet all surfaces completely, followed by adequate draining and air drying.

To sanitize mobile items such as drinking glasses, eating and cooking utensils, and other similarly sized food processing equipment, immerse in a 150 ppm active quaternary solution for at least 60 seconds, making sure to immerse completely, followed by removing from use dilution, adequate draining, and air drying.

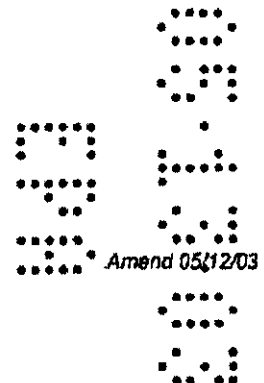
When used for sanitization of previously cleaned food equipment or food contact items, limit the active quaternary to 150 ppm. **NO POTABLE WATER RINSE IS REQUIRED.**

This product is an effective sanitizer when diluted in water up to 1000 ppm hardness (as CaCO_3).

The udders, flanks, and teats of dairy cows can be sanitized by washing with a solution of 1 ounce of this product per 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 a fresh solution.

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**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.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F.

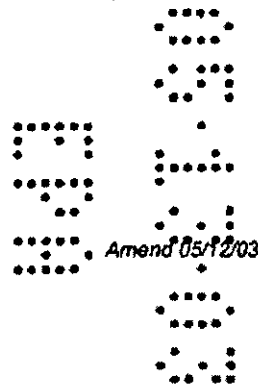
CONTAINER DISPOSAL - Do not reuse empty container. Triple rinse empty container with water. Return metal drum then offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities. Plastic containers may be disposed of in a sanitary 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 you State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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Amend 05/2/03