

1839-86

3-14-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 14 2003

Mr. Thomas Isaac
 The Stepan Company
 22 West Frontage Road
 Northfield, IL 60093

Subject: BTC 2125 M 10% Solution
 EPA Registration No. 1839-86
 Amendment Date: May 15, 2002
 EPA Receipt Date: May 22, 2002

Dear Mr. Isaac,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the conditions listed below.

- Addition of Hepatitis C Virus and Citrus Canker
- Addition of use sites and claims

Conditions

Revise the label as follows:

1. Under "Food service establishment" disinfection directions, add the statement, "Do not use on utensils, dishes, glasses, or cookware."
2. Under "Poultry Equipment, Animal Quarters, Kennels" directions, add 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."
3. You must clearly separate or place the The "Interior Surfaces of Water Softners/ Reverse Osmosis Units and Ice Machines/ Water Coolers/ Water Holding Tanks/ Pressure Tanks" directions must either be clearly separated or placed in a different type set to distinguish them from the Wisconsin State Division of Health sanitization directions
4. Revise the heading, "Interior Surfaces of Water Softners/ Reverse Osmosis Units and Ice Machines/ Water Coolers/ Water Holding Tanks/ Pressure Tanks" headings to state "Interior *Hard, Nonporous* Surfaces"

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

5. Under "Interior Surfaces of Water Softners/ Reverse Osmosis Units and Ice Machines/ Water Coolers/ Water Holding Tanks/ Pressure Tanks" sanitizing directions, you must state that the "units/tanks must be washed with a compatible detergent and rinsed with potable water before sanitizing." It should appear as step 2.
6. Step 4 for the "Interior Surfaces of Water Softners/ Reverse Osmosis Units and Ice Machines/ Water Coolers/ Water Holding Tanks/ Pressure Tanks" directions are inappropriate for a formulation that is cleared as food contact sanitizer and must be deleted. Food contact surfaces that are sanitized are not to be rinsed with potable water; this step would be appropriate for disinfection claim. If you want to rinse with potable water, you must submit a justification to the Agency as to why a potable water rinse is needed for food contact sanitization or revise the directions so they are appropriate for a disinfection claim.
7. Under "Reverse Osmosis Units" add the statement, "Do not use this product to sanitize the membrane element; it must be sterilized." This statement must appear as the last sentence in step 1.

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Effectiveness Using Bovine Viral Diarrhea Virus	Submitted study, MRID 456841-01	Acceptable
Confirmatory Virucidal Effectiveness Using Bovine Viral Diarrhea Virus	Submitted study, MRID456841-02	Acceptable

The aforementioned data is accepted conditionally. The following information must be provided:

- a) Request information on the specific virus strain and specific cell culture line identification used in the two studies (only the source was identified).
- b) Obtain a more detailed description of the challenge BVDV strain, concerning its virus stock preparation and titration.
- c) Obtain a full description of the host cell line (MDBK) including its preparation, susceptibility to BVDV, and the rationale for its selection over other candidate cell lines.
- d) Obtain an explanation why only 0.5 mL of the virus-disinfectant mixture is neutralized when using a column instead of the full 2.0 mL recovered from the plate.
- e) Obtain a complete description of the infectivity assay using immunofluorescence.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised

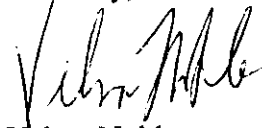
labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above 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 bearing the amended labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

BTC 2125[®]M

10% Solution

DISINFECTANT
DEODORIZER

SANITIZER
* VIRUCIDE

MILDEWSTAT (on hard nonporous, inanimate surfaces)

CITRUS CANCER CONTROL

Not for Use in California

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂,

5% C₁₈) dimethyl benzyl

ammonium chlorides..... 5.0%

Alkyl (68% C₁₂, 32% C₁₄)

dimethyl ethylbenzyl

ammonium chlorides..... 5.0%

INERT INGREDIENTS..... 90.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-88
EPA EST. NO. 1839-IL-01

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 14 2003

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1839-86

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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 2125[®]M 10% Solution is designed for use in hospitals, nursing homes, hotels, schools, homes, athletic/recreational facilities/tanning spas, dairies, food processing plants, food service establishments, restaurants, bars, animal quarters and kennels where disinfection, sanitization and deodorization is of prime importance. When used as directed, this product is formulated to disinfect hard nonporous, inanimate environmental surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs, tanning beds 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.

This product can also be used for sanitization of shell eggs intended for food in shell egg and egg product processing plants when used as directed.

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.

DISINFECTION - To disinfect pre-cleaned, inanimate, hard nonporous 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 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 3 ounces of this product per 5 gallons of water for disinfection against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, and *Yersinia enterocolitica*.

HOSPITAL DISINFECTION - Add 3 1/2 ounces of this product per 5 gallons of water for disinfection against *Pseudomonas aeruginosa* and Vancomycin Intermediate resistant *Staphylococcus aureus* (VISA), as well as the organisms listed under the GENERAL DISINFECTION section.

To disinfect food processing premises: floors, walls, and storage areas, add 3 ounces of this product per 5 gallons 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 food service establishment or restaurant food contact surfaces: countertops, outside of appliances, tables, add 3 ounces of this product per 5 gallons 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.

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 3 1/2 ounces of this product per 5 gallons 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.

ACCEPTED
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in EPA Letter Dated:

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Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-86

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
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registered under EPA Reg. No. 1839-86 Amend 10/16/02

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DISINFECTING POTATO STORAGE AREA AND EQUIPMENT - Remove all potatoes prior to disinfection of potato storage area or equipment. Preclean hard surfaces by removing heavy soil or gross filth. Follow general disinfection (3 oz. per 5 gal.) procedure described above. All treated surfaces must be thoroughly rinsed with potable water prior to reuse.

CITRUS CANCER CONTROL - For prevention of Citrus Canker Disease through treatment of equipment. This product, when used at a 1:48 dilution (2000 ppm active quaternary) or 2.87 ounces (79 ml) per gallon of water up to 200 ppm hardness (as CaCO_3), is effective against *Xanthomonas axonopodis* pathovar *citri* (Citrus Canker). Treat all trucks, vehicles, and equipment thoroughly at the 1:108 dilution. Treatment can be applied to outer clothing, shoes, trucks, attached trailers, field harvesting equipment; including cargo area, wheels, tires, under carriage, hood, roof, fenders and any other part of transportation equipment that can be taken into infested areas. To prevent the spread of Citrus Canker by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing, using the maximum rate of 2000 ppm quaternary. After use, all surfaces which come in contact with food or crop must be rinsed with potable water. Clothing should be either thoroughly rinsed or laundered before reuse. Footwear should be rinse before reuse. **NOTE: Not for Use in California.**

***VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate, hard nonporous surfaces at 3 1/2 ounces per 5 gallons of water exhibits effective virucidal activity against Influenza A₂/Japan (representative of the common flu virus), Herpes Simplex Type 1 (causative agent of fever blisters), Adenovirus Type 5 (causative agent of upper respiratory infections), Vaccinia virus (representative of the pox virus group), and Avian Influenza A/Turkey/Wisconsin (causative agent of an acute avian lower respiratory tract infection), HIV-1 (Human Immunodeficiency Virus Type 1), Newcastle disease virus, Laryngotracheitis Virus, Hepatitis B virus (HBV) and Hepatitis C virus (HCV).

KILLS HIV-1, 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 (HIV-1) (associated with AIDS), Hepatitis B virus (HBV) and Hepatitis C virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, 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.

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

MILDEWSTAT: To control mold and mildew on pre-cleaned, hard, nonporous 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.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

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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*, *Escherichia coli* 0157:H7, *Staphylococcus aureus*, *Yersinia enterocolitica*, and *Listeria monocytogenes*.

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 200 ppm active quaternary solution by adding 1 ounce of this product to 4 gallons of water, 2 1/2 ounces to 10 gallons of water, or 5 ounces to 20 gallons of water.

To sanitize immobile items such as tanks, chopping blocks and counter tops, flood the area with a 200 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 200 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 to 200 ppm. **NO POTABLE WATER RINSE IS REQUIRED.** This product is an effective sanitizer when diluted in water up to 750 ppm hardness (CaCO₃).

To sanitize previously cleaned food-grade eggs in shell egg and egg product-processing plants, spray with a solution of 1 ounce of this product in 4 gallons of warm water (200 ppm quat). The solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are broken immediately for use in the manufacture of egg products. Eggs should be reasonably dry before casing or breaking. The solution should not be reused for sanitizing eggs.

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 cleaner.
3. Rinse with clean water.
4. Sanitize in a solution of 1oz/4 gallons of this product (200 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.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HSS 196.13 of the Wisconsin Administrative Code.

Sanitization of Interior Surfaces of Water Softeners and Reverse Osmosis (RO) Units

Water Softeners - Sanitization should occur after initial installation, after the system is serviced and periodically during its use.

1. Backwash the softener and add 2 ounces of sanitizer per 8 gallons of water (200 ppm active quaternary) to the brine tank well. (NOTE: standard system capacity is 48 gallons). (The brine tank should have water in it to permit the solution to be carried into the softener).
2. Proceed with the normal regeneration or interrupt the cycle after the brining step and let the softener soak for a minimum of 60 seconds.
3. Backwash the softener with potable water to make sure all sanitizing solution is thoroughly rinsed from the unit before returning it to service.

Reverse Osmosis (RO) Units - Sanitization should occur after initial installation, after the system is serviced and periodically during its use.

1. Turn off RO system, drain storage tank and remove membrane element and pre-filters. Put membrane element in a plastic bag so it remains wet.
2. Fill empty pre-filter housing with 2 ounces of sanitizer per 8 gallons of water (200 ppm active sanitizer) and turn on raw water. (NOTE: standard system capacity is 1-2 gallons).
3. After holding tank is full, let system stand idle for a minimum of 60 seconds. Turn off water. Drain holding tank.
4. Before the system is put back into service, flush system with potable water to assure sanitizing solution is rinsed thoroughly from system. Follow the manufacturer's directions for re-installation of new pre-filters, membrane element and post filter.

Sanitization of Interior Surfaces of Ice Machines, Water Coolers, Water Holding Tanks and Pressure Tanks

Ice Machines - Sanitization should occur after initial installation, after the machine is serviced and periodically during its use.

1. Shut off incoming water line to machine.
2. Prepare a solution of 2 ounces of sanitizer per 8 gallons of water (200 ppm active quaternary).
3. Circulate solution through machine making sure to wet all surfaces and allow a minimum contact of 60 seconds.
4. Drain and completely flush machine twice with potable water.
5. Return machine to normal operation.

Water Coolers, Water Holding Tanks and Pressure Tanks - Sanitization should occur after initial installation, after the system is serviced and periodically during its use.

1. Shut off incoming water line.
2. Prepare a solution of 2 ounces of sanitizer per 8 gallons of water (200 ppm active quaternary).
3. Apply or circulate (if possible) to wet all surfaces and allow a minimum contact of 60 seconds.
4. Drain and completely flush system twice with potable water.
5. Return to service by opening incoming water lines.

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-86

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(Left Panel-3) Under the Federal Insecticide,
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Amend 10/16/02

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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. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, rubber gloves, and protective clothing. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

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 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.

ENVIRONMENTAL HAZARDS

(Required for products supplied in containers 5 gallons or greater)

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.

Contains no phosphorus.

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 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 (bottle, can, bucket). Wrap container and put 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Stepan Company
Northfield, IL 60093
EPA Reg. No. 1839-88

MAR 14 2003

(Right Panel)

Amend 10/16/02

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