

PM 31

1839-86
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

7-15-99

1046

JUL 15 1999

Stepan Company
22 W. Frontage Road
Northfield, IL 60093

Subject: BTC 2125M 10% Solution
EPA Registration No. 1839-86
Amendment Dated January 28, 1999

Attn: Bruce L. Greene
Regulatory Chemist

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. You requested this Agency to add to this product a use for 80% solution of the product to the previously registered uses of the 50% product. The submission is in order. The revised Confidential Statements of Formula (CSF) dated January 8, 1999 are approved. The products have been approved for use as sanitizers by 21 CFR, Part 178.1010, and by the FDA. The revised label ingredient claims statement is in conformity with the CSF, meets the requirements of PR Notice 91-2.

The submitted microbiological data developed by the Official Methods of the AOAC Use Dilution Test Method 15th edition are supportive of the product effectiveness against Staphylococcus (Vancomycin Resistant-HP 3836) at a dilution of 3.50 ounces/5 gallons in the presence of 5% organic soil (fetal bovine serum) for a 10 minute contact time. The proposed label does not contain any adverse labeling comments. A stamped copy is enclosed for your records.

Submit one (1) copy of the finished label before the product is released for shipment. If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

CONCURRENCES

SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	7-14-99						

EPA Form 1320-1A (1/90)

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Sincerely,

A handwritten signature in cursive script, appearing to read "Velma Noble".

Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

BTC 2125[®]M

10% Solution

DISINFECTANT
 DEODORIZER
 MILDEWSTAT (on hard nonporous, inanimate surfaces)

SANITIZER
 * VIRUCIDE

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	5.0%
Alkyl (68% C ₁₂ , 32% C ₁₄) 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.

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
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 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
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 1839-86

EPA REG. NO. 1839-86
 EPA EST. NO. 1839-IL-01

STEPAN COMPANY
 22 West Frontage Road • Northfield, IL 60093

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Amend 1/12/99

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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, dairies, restaurants, bars, animal quarters, kennels and institutions where disinfection, sanitization and deodorization is of prime importance. This product is authorized by USDA for use in Federally inspected meat and poultry processing plants. When used as directed, this product is formulated to disinfectant hard nonporous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, cabinets, tables, chairs, 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.

DISINFECTION - To disinfect pre-cleaned, inanimate, hard nonporous surfaces apply this product with 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.

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 resistant *Staphylococcus aureus*, as well as the organisms listed under the GENERAL DISINFECTION section.

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.

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.

***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), and HIV-1 (Human Immunodeficiency Virus Type 1).

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

(Left Panel-1)

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In EPA Letter Dated:

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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 (CaCO_3).

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.

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.

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).

Stapan Company
Northfield, IL 60093
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(Left Panel-2)

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes severe 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, promptly drink large quantities of water. Do not induce vomiting. 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.

Contains no phosphorus.

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 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.

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