

JUN 22 1989

Stepan Company
22 West Frontage Road
Northfield, IL 60093

Attention: Leo Dringoli

Gentlemen:

Subject: BTC 2125M 10% Solution
EPA Registration No. 1839-86
Your Application Dated January 20, 1988
EPA Received Date January 21, 1988

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

1. Efficacy Supported by the Data

- a. The submitted data developed for the product by the AOAC Use Dilution Method at a 1:256 (2.5 oz/5 gal) in the presence of 5 percent organic soil and distilled water against Listeria monocytogenes and Yersinia enterocolitica for a contact time of 10 minutes are satisfactory.

Effectiveness of the product for the recommended areas of use at the indicated dilution and indicated test conditions for specified, hard, nonporous, inanimate surfaces. The control survival studies as per DIS/TSS-2, item 6 are adequate in support of the product effectiveness as a disinfectant.

54762:I:Leavy:L-3:KENCO:6/16/89:7/28/89:KA:gj:ek:rw

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- b. As per item 7 of the DIS/TSS-16 virucidal data are not required, however, the submitted virucidal data are supportive of the claim against Avian influenza A, ATCC VR-798, strain A/Turkey/Wis./68 at 3.50 oz/gal in 400 parts per million of hard water and 5 percent serum equivalent (moderate amount of soil) in 10 minutes.

2. Labeling Revisions

- a. Under the use directions for sanitization as indicated on the right panel and after the wording "It is effective as a sanitizer against Yersinia enterocolitica," delete "Y" "enterocolitica."
- b. On the right hand panel and under virucidal use directions for the appropriate virus nomenclature, refer to the PM's letter dated January 5, 1989 and revise to reflect item 1(d).
- c. On the right hand panel and following "Mold and Mildewstat-BTC 2125 M prevents and controls . . ." delete the wording "prevents and."
- d. On the right hand panel, you should refer to the PM's letter of January 11, 1989 for the correct nomenclature concerning the proposed amendment for Avian influenza A."
- e. On the left hand panel and under the use directions for sanitization, remove the wording "Remove and let air dry" to read "Remove, drain the use solution from the surface and air dry."
- f. Delete the word "milk."
- g. Delete the statement "Measures against circulatory shock, respiratory depression and convulsion may be needed" from the "Note to Physician" section.
- h. Delete the statement "Only for Sale to Use and Storage by Service Persons."
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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.

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

If you have any questions concerning this letter, please contact Karen Leavy at (703) 557-3966.

Sincerely yours,



John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

DIRECTIONS FOR USE

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

BTC® 2125M 10% solution has been designed specifically for hospitals, food processing plants, dairies, restaurants, bars, and other institutions where disinfection and sanitization is of prime importance.

DISINFECTION-To disinfect previously cleaned hard inanimate surfaces (such as walls, floors, table tops), apply BTC® 2125M 10% solution with mop, cloth, or sponge or mechanical sprayer so as to wet thoroughly. Allow to remain wet for 10 minutes and then let air dry.

DILUTION RATES- General Disinfection - add 3 ounces per 5 gallons of water. Hospital Disinfection - add 3½ ounces per 5 gallons of water.

For disinfection of previously cleaned surgical instruments, barber tools and dental equipment, simply submerge instruments into solution containing 1½ ounces BTC® 2125M 10% per gallon of water for 10 minutes.

For disinfection, a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

DEODORIZER- To deodorize, apply BTC® 2125M solution as indicated under the heading "General Disinfection" above.

MILDEWSTAT- To control mold and mildew on pre-cleaned, hard non-porous surfaces (such as floors, walls, table tops), add 3 ounces BTC® 2125M 10% solution per gallon of water. Apply solution with a cloth, mop, or sponge 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 reappears.

SANITIZATION - Recommended for use in restaurants, dairies, food processing plants, bars etc. Remove all gross food particles and soil from areas which are to be sanitized with a good detergent by a pre-flush, pre-soak or pre-scrape treatment. Rinse with a potable water rinse. To sanitize previously cleaned and rinsed non-porous food contact surfaces, prepare a 200ppm active quaternary solution by adding 1 oz. 10% BTC 2125M to 4 gal. of water, or 2½ oz. to 10 gal. or 5 oz. to 20 gal. of water. To sanitize immobile items (such as tanks, chopping blocks, counter tops), flood the area with 200ppm 10% BTC 2125M solution for at least 60 seconds making sure to wet all surfaces completely. Remove and let air dry. Prepare a fresh solution daily or more frequently as soil is apparent. To sanitize mobile items (drinking glasses, eating utensils etc.), immerse in 200ppm 10% BTC 2125M solution for at least 60 seconds making sure to immerse completely. Remove and let air dry. Prepare a fresh solution daily, more frequently when needed.

To Sanitize shell-grade eggs, see attached brochure.

PRECAUTIONARY STATEMENTS

Hazard to Human and Domestic Animals
DANGER

Keep Out Of Reach Of Children. Causes severe eye and skin damage. Do not get in eyes, skin or on clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink egg whites, gelatin solution or if these are not available, drink large quantities of water. Call a physician.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
COMMENTS
EPA Letter Date:

JUN 22 1989

1839-86

BTC® 2125M 10% SOLUTION

DISINFECTANT
DEODORIZER

SANITIZER
VIRUCIDE*

ACTIVE INGREDIENTS:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	5.0%
dimethyl benzyl ammonium chlorides	5.0%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides	90.0%
INERT INGREDIENTS:	TOTAL 100.0%

EPA REG. NO 1839-85

KEEP OUT OF REACH OF CHILDREN

DANGER

see side panels for additional precautionary and practical treatment statements

STEPAN COMPANY

22 WEST FRONTAGE ROAD • NORTHFIELD, ILL. 60093

EPA Est. No. 1839-IL-01

NET CONTENTS

BEST AVAILABLE COPY.

10% BTC 2125M solution product and deodorizing in Hospitals, Dairies, Restaurants, Bars, used as directed, it is effective against *Escherichia coli*, *Yersinia enterocolitica*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Yersinia enterocolitica*, and *BTC 2125M* is authorized under the Federal Food, Drug, and Cosmetic Act as a sanitizing solution at 200 ppm.

DISINFECTION- At 2.5 oz./5 gal. dilution, effective disinfectant against *Listeria monocytogenes* and *Escherichia coli*.

At 3 oz./5 gal. dilution, infectant activity against *Choleraesuis* and *Staphylococcus aureus*.

At 3.5 oz./5 gal. dilution, hospital disinfectant and activity against *Pseudomonas* and *Staphylococcus aureus*.

VIRUCIDAL ACTIVITY*

environmental, inanimate surfaces. 10% solution of water is effective against the flu virus, Herpes simplex virus, and mononucleosis. Adenovirus (upper respiratory infection of the pox virus group).

EFFICACY TESTS HAVE

2125M IS AN EFFECTIVE

THE PRESENCE OF ORG

DEODORIZATION- BTC

generally are hard to kill. storage areas, empty garages, other areas which are prone to odors.

MOLD & MILDEWSTAT- mold and mildew on the inanimate surfaces.

SANITIZATION- When cleaned food equipment, quaternaries to 200ppm. RINSE is required.

BTC® 2125M is an effective 750 ppm hardness (CaCO₃).

STORAGE

DO NOT CONTAMINATE WATER. (DISPOSAL)

STORAGE- Store in a dry place or higher than 120°F.

CONTAINER DISPOSAL-

rinse empty container with water. Do not puncture or burn. Do not use for other purposes.

Plastic containers may be used if allowed by local authorities.

PESTICIDE DISPOSAL- Improper disposal of pesticides is a violation of Federal Law. If use according to label instructions.

Environmental Control Agency at the nearest EPA office.