

04/28/2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/10

1839-155



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 28 2003

Nancy S. Maitzen
Sr Regulatory Specialist
Stephan Company
22 Frontage Rd
Northfield, IL 60093

Subject: Notification per PR Notice 98-10
BTC 2125M@ 20% Solution
EPA Reg. No. 1839 -155
Application Dated: March 27, 2003
Receipt Date: March 31, 2003

Dear Ms. Nancy S. Maitzen,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification

- Addition of the word "immediately", to the IF ON SKIN OR CLOTHING in the First Aid section of the Precautionary Statements
- Removal of the word "pre-cleaned" from the first line of the Disinfection Section,
- Replace the sentence "For disinfection, a pre-cleaning step is required with
"For heavily soiled areas, a pre-cleaned step is required"
- Addition of a an alternate Terminal Sterilant/High level Disinfectant statement to the Directions for Use section. "This product is not for use on medical device surfaces"

General Comments

Based on a review of the material submitted, the following comments apply:

This application for notification is acceptable. A copy has been inserted in the file for future reference. Should you have any questions or comments concerning this letter, please contact me at (703) 308-6233.

Sincerely,

Velma Noble
Product Manager (31)

CONCURRENCES							
MBOL							
RNAME							
TE							



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-155	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BTC 2125@M 20% Solution	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) STEPAN COMPANY 22 W. Frontage Rd. Northfield, IL 60093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See enclosed sheet.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	* Certification must be submitted	<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Other (Specify) _____
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt		<input checked="" type="checkbox"/> Plastic	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container gal., 5 gal., 55 gal.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph	<input type="checkbox"/> Other _____	
			<input checked="" type="checkbox"/> Paper glued		
			<input checked="" type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy S. Maitzen	Title Sr. Regulatory Coordinator	Telephone No. (include Area Code) 847/501-2278
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy S. Maitzen</i>	3. Title Sr. Regulatory Coordinator	
4. Typed Name Nancy S. Maitzen	5. Date March 27, 2003	

March 27, 2002

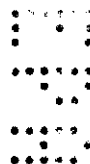
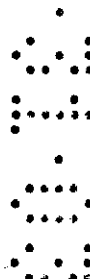
BTC 2125[®]M 20% Solution
EPA Reg. NO. 1839-155

SECTION II - Explanation:

- 1) Addition of the word, **immediately**, to the **IF ON SKIN OR CLOTHING** in the First Aid section of the **PRECAUTIONARY STATEMENTS**. It should read:
“If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.”
- 2) Removal of the word “pre-cleaned” from the Directions for Use section. This line should read:
“When used as directed, this product is formulated to disinfect inanimate, hard surfaces such as walls, floors, sink tops, tables, chairs and telephones.”
 This registration’s efficacy data demonstrated bactericidal and fungicidal activity in the presence of organic load (5% blood serum) and supports the removal of the pre-cleaning step.
- 3) Replace the sentence “For disinfection, a pre-cleaning step is required.” with
“For heavily soiled areas, a pre-cleaning step is required.”
- 4) Addition of an alternate Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. This one sentence statement reads **“This product is not for use on medical device surfaces.”**

Signature: *Nancy J. Matzger*

Title: Sr. Regulatory Coordinator





March 27, 2003

Document Processing Desk (NOTIF)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Antimicrobials Division (7510C)
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTN: Ms. Velma Noble
PM 31
Regulatory Management Branch I

RE: BTC 2125[®]M 20% Solution
EPA Reg. No. 1839-155

Dear Ms. Noble:

This Notification proposes the following:

- 1) Addition of the word, **immediately**, to the IF ON SKIN OR CLOTHING in the First Aid section of the PRECAUTIONARY STATEMENTS. It should read:

"If on skin or clothing: Take off contaminated clothing. Rinse skin **immediately** with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice."
- 2) Removal of the word "pre-cleaned" from the Directions for Use section. This line should read:

"When used as directed, this product is formulated to disinfect inanimate, hard surfaces such as walls, floors, sink tops, tables, chairs and telephones."

This registration's efficacy data demonstrated bactericidal and fungicidal activity in the presence of organic load (5% blood serum) and supports the removal of the pre-cleaning step.
- 3) Replace the sentence "For disinfection, a pre-cleaning step is required." with

"For heavily soiled areas, a pre-cleaning step is required."
- 4) Addition of an alternate Terminal Sterilant/High Level Disinfectant Statement to the Directions for Use section. This one sentence statement reads "This product is not for use on medical device surfaces."

Five (5) copies of the proposed label are enclosed for Agency review.

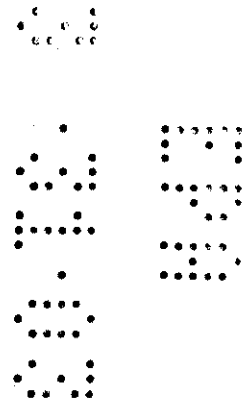
Should you have any questions concerning this notification, please contact me at (847) 501-2278.

Sincerely,
STEPAN COMPANY

Nancy S. Maitzen
Sr. Regulatory Coordinator

Enclosures

cc: Tom Isaac
NSM:slf
040-03-nm-USEPA-155-N.doc



"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Nancy Matyzen

March 27, 2003



BTC 2125[®] M

20% Solution

DISINFECTANT
 DEODORIZER
 MILDEWSTAT (on hard inanimate surfaces)
 LAUNDRY BACTERIOSTAT

SANITIZER
 *VIRUCIDE

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	10.0%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	10.0%
INERT INGREDIENTS	<u>80.0%</u>
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements.

EPA Reg. No. 1839-155
 EPA Est. No. 1839-IL-01

STEPAN COMPANY
 22 West Frontage Road • Northfield, IL 60093

NET CONTENTS

DIRECTIONS FOR USE

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

BTC 2125[®]M 20% Solution is designed specifically for hospitals, food processing plants, dairies, restaurants, bars, animal quarters, poultry and turkey farms, kennels and institutions where disinfection, sanitization, and deodorization is of prime importance.

When used as directed, this product is formulated to disinfect inanimate, hard surfaces such as walls, floors, sink tops, tables, chairs, and telephones.

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

In addition, this product will sanitize previously cleaned and rinsed non-porous food contact surfaces such as tanks, chopping blocks, counter tops, drinking glasses and eating utensils. This product can also be used to sanitize previously cleaned food grade eggs 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 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.

DILUTION RATES:

GENERAL DISINFECTION - Add 1.5 ounces of this product per 5 gallons of water for disinfection against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Listeria monocytogenes*, and *Yersinia enterocolitica*.

HOSPITAL DISINFECTION - Add 1.75 ounces of this product per 5 gallons of water for disinfection against *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 1.75 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.

KILLS HIV-1 ON LAUNDRY IN COMMERCIAL, INDUSTRIAL, AND INSTITUTIONAL APPLICATIONS. This product provides virucidal activity against HIV-1 on fabrics when added to the final rinse at a rate of 3.0 ounces per 100 pounds of dry laundry.

This product, when added to the final rinse, will provide virucidal activity against HIV-1 at a dosage rate of 1 ounce (1/8 cup) per load in small capacity top-loading and front-loading commercial, industrial and non-medical institutional laundering machines.

LAUNDRY BACTERIOSTAT FOR COMMERCIAL, INDUSTRIAL, AND NON-MEDICAL INSTITUTIONAL LAUNDRY APPLICATIONS: This product provides the fabric with residual bacteriostatic activity against odor causing gram-negative and gram-positive bacteria when this product is added to the final rinse at a rate of 4.8 ounces per 100 lbs. of dry laundry.

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 that 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 0.5 ounce of this product to 4 gallons of water, 1.25 ounces to 10 gallons of water, or 2.5 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, 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, 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 0.5 ounce of this product in 4 gallons of warm water (200 ppm active quaternary solution). 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 **POTABLE WATER RINSE ONLY IF THEY ARE BROKEN IMMEDIATELY** for use in the manufacture of egg products. Eggs should be dry before casing or breaking. The solution should not be reused for sanitizing eggs.

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 1 ounce 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 1 ounce 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 1 ounce 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 1 ounce 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.

* **VIRUCIDAL ACTIVITY** - This product, when used on environmental, inanimate hard surfaces at 1.75 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), Avian Influenza A/Turkey/Wisconsin (causative agent of an acute avian lower respiratory tract infection), Newcastle disease virus, Laryngotracheitis Virus, and HIV-1 (Human Immunodeficiency Virus Type 1).

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, non-porous surfaces add 1.5 ounces of this product per 5 gallons 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 appears.

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE AND VIRUCIDE 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. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. May be fatal if swallowed or absorbed through skin. 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 a 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 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.

(Required for product supplied in containers 5 gallons or greater.)

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.

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 (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.