

1839-142

1-8-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN - 8 2004

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

Subject: BTC 2125M P-40 Sanitizer Concentrated
EPA Registration No. 1839-142
Application Date: 7/11/03
Receipt Date: 7/15/03

Dear Mr. Isaac:

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

- Reduction of the sanitizer hard water tolerance to 650 ppm
- Addition of Campylobacter, E. coli, Yersina enterocolitica and Listeria monocytogenes
- Addition of U.S. Public Health Service
- Addition of Wisconsin State Division of Health

EFFICACY

Please see the attachment

LABEL COMMENTS

1. Under Item #4 in the directions recommended by the U.S. Public Health Service (see page 3 of the proposed label), change "this product of product name" to "this product or product name".
2. The label indicates that the product may be used on chopping blocks (see page 2 of the proposed label). The Agency has indicated that chopping blocks are porous. You must revised the label by removing "chopping blocks" from the list of surfaces on which the product may be used because use of the product on chopping blocks is not appropriate.

GENERAL COMMENTS

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

CONCURRENCES

| | | | | | | | |
|---------|----------|--|--|--|--|--|--|
| SYMBOL | 1510C | | | | | | |
| SURNAME | J. Jones | | | | | | |
| DATE | 1-7-04 | | | | | | |

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



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

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BTC 2125[®] M-P40 SANITIZER CONCENTRATED POWDER

ACTIVE INGREDIENTS

| | |
|--|---------------|
| Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides | 20.00% |
| Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides | 20.00% |
| INERT INGREDIENTS | <u>60.00%</u> |
| Total | 100.00% |

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panels for additional precautionary statements.

EPA REG. NO. 1839-142
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road
Northfield, IL 60093

ACCEPTED
with **COMMENTS**
in EPA Letter Dated:
JAN 8 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1839-142

- NET CONTENTS:
- 0.0625 ounce per packet per tablet or
 - 0.125 ounce per packet per tablet or
 - 0.18755 ounce per packet per tablet or
 - 0.3125 ounce per packet per tablet or
 - 0.625 ounce per packet per tablet or
 - 1.25 ounce per packet per tablet

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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-P40 Sanitizer Concentrated Powder (product name) is designed specifically for use in restaurants, dairies, and bars where sanitization of food contact surfaces is of prime importance.

(This product or product name) will sanitize previously cleaned and rinsed non-porous food contact surfaces such as tanks, counter tops, drinking glasses and eating utensils. When used at the recommended concentration of 200 ppm no potable water rinse is required.

When used as directed, (this product or product name) is an effective sanitizer against Escherichia coli ATCC 11229, Staphylococcus aureus ATCC 6538, Campylobacter jejuni ATCC 29428, Escherichia coli 0157:H7 ATCC 43895, Listeria monocytogenes ATCC 35152, Yersinia enterocolitica ATCC 23715 when diluted in water up to 650 ppm hardness (CaCO₃).

SANITIZATION - 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 using the following dilution table:

| In order to make X gallons of Solution | Add Net Weight of Product | | | |
|--|---------------------------|-------------|---------------|---------------|
| | in Ounces | or in Grams | | |
| 1 | 0.0625 | 1.8 | or ONE Packet | or ONE Tablet |
| 2 | 0.125 | 3.5 | or ONE Packet | or ONE Tablet |
| 3 | 0.1875 | 5.3 | or ONE Packet | or ONE Tablet |
| 5 | 0.3125 | 8.9 | or ONE Packet | or ONE Tablet |
| 10 | 0.625 | 17.7 | or ONE Packet | or ONE Tablet |
| 20 | 1.25 | 35.4 | or ONE Packet | or ONE Tablet |

To sanitize immobile items such as tanks, chopping blocks and counter tops, apply sufficient use solution by low pressure coarse sprayer, hand pump trigger sprayer, mop, sponge or cloth to flood the area with a 200 ppm active quaternary solution for at least 60 seconds making sure to wet all surfaces completely. Drain the use solution from the surface and air dry. Prepare a fresh use 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 use 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 or product name) is an effective sanitizer when diluted in water up to 650 ppm hardness (CaCO₃).

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a solution of warm water at 200 ppm quat (see Dilution Table above). The use solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this use solution 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 use solution should not be reused for sanitizing eggs.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 8 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, this pesticide,
registered under EPA Reg. No.

1839-142

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PACKETS: (If using packets, use either the tear open or water soluble instructions)

(Tear open packet) Follow label dilution instructions and discard opened packet according to label disposal instructions.

(Water soluble packet) Follow label instructions by dropping packet directly into water. Do not remove packets before use.

TABLETS: Follow label dilution instructions by dropping tablet directly into water. Do not remove tablets from container before use.

DIRECTIONS FOR SANITIZING FOOD PROCESSING EQUIPMENT, UTENSILS, AND FOOD CONTACT ARTICLES REGULATED BY 21CFR sec 178.1010.

1. Scrape, flush or pre-soak articles (whether mobile or stationary) to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize articles using a solution of 0.3125 ounce of (this product or product name) per 5 gallons of water (or equivalent dilution) (200 ppm active quaternary). Articles that can be immersed in use solution should remain in solution for 60 seconds. Articles too large for immersion should be thoroughly wetted by rinsing, spraying or swabbing.
5. Remove immersed items from use solution to drain and then air dry. Non-immersed items should also be allowed to air dry.

U.S. PUBLIC HEALTH SERVICE - FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped, and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in a hot detergent solution. Rinse utensils and equipment thoroughly with potable water.
2. Sanitize equipment and utensils by immersing in 0.3125 ounce of this product per 5 gallons (or equivalent dilution) of water (200 ppm active quaternary) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine.
3. Allow sanitized surfaces to drain and air dry. Do not rinse.
4. For equipment and utensils too large to sanitize by immersion, apply 0.3125 ounce of (this product or product name) per 5 gallons of water (or equivalent dilution) (200 ppm active quaternary) by rinsing, spraying or swabbing. Allow the items to remain thoroughly wet for at least 60 seconds, then let air dry. Do not rinse.

(This statement is required for marketing food contact sanitizers in Wisconsin.)

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 potable water.
4. Sanitize in a solution of 0.3125 ounce of (this product or product name) per 5 gallons of water (or equivalent dilution) (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.
6. Fresh sanitizing solution should be prepared at least daily or when visibly soiled or diluted.

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

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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. May be fatal 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 immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

If swallowed: Call 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 product supplied in containers 50 lbs. or greater.)

This pesticide 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.

(Water Soluble Packet) Store in a cool dry place. Do not handle packets with wet hands.

(Tablets) Store in a cool dry place. Do not handle tablets with wet hands.

CONTAINER DISPOSAL - Do not reuse empty container. Triple rinse empty container with water. 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.

PACKET DISPOSAL *(for tear open packets only)* - Do not reuse packet. Discard packet 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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Tear Open Packet Label:

BTC 2125[®]M-P40 SANITIZER CONCENTRATED POWDER

ACTIVE INGREDIENTS

| | |
|---|--------------|
| Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides | 20.0% |
| Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides | 20.0% |
| INERT INGREDIENTS | 60.0% |
| Total | 100.00% |

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See master label for additional precautionary statements and use directions.

Disposal - Do not reuse empty packet. Wrap packet and put in trash.

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EPA EST. NO. 1839-IL-01

STEPAN COMPANY
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Mix contents of one packet into X gallons of water.

NET CONTENTS:

- 0.0625 ounce per packet per tablet or
- 0.125 ounce per packet per tablet or
- 0.1875 ounce per packet per tablet or
- 0.3125 ounce per packet per tablet or
- 0.625 ounce per packet per tablet or
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1839-142

Amend 07/11/03

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Water Soluble Packet Label:

**BTC 2125[®]M-P40
SANITIZER CONCENTRATED
POWDER**

ACTIVE INGREDIENTS

| | |
|---|--------------|
| Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides | 20.0% |
| Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides | 20.0% |
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Add one packet to X gallons of water.

NET CONTENTS: 0.0625 ounce per packet per tablet or
 0.125 ounce per packet per tablet or
 0.1875 ounce per packet per tablet or
 0.3125 ounce per packet per tablet or
 0.625 ounce per packet per tablet or
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