

1561-11

8/5/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES



AUG - 5 2008

Mr. Robert Butz
Agent for Edwards Councilor Co, Inc.
Keller and Heckman, LLP
1001 G Street NW
Suite 500 West
Washington, DC 20001

Subject: Steramine 1-G Tablets
EPA Registration No.: 1561-11
Amendment Date: January 17, 2007
EPA Receipt Date: January 24, 2007

Dear Mr. Butz,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Increase maximum end use or use solution concentration of quaternary ammonium compound to 400 ppm per 40 CFR 180.940(a)

Conditions

Revise the label as follows:

- 1) On page 2, revise the second claim by deleting the term, "safely." Safety claims of a pesticide or its ingredients is considered false and misleading under FIFRA section 2(q)(1)(A).
- 2) On page 3, revise step 5 under the "Sanitizing Soft Serve-Frozen Dessert Machines and Equipment" by deleting the term, "tables" and state "tablets."

General Comments

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

Should you have any questions regarding this letter, please contact Jacqueline McFarlane

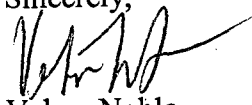
CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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STERAMINE™ 1-G Tablets

www.sanitize.com

The Multi-Purpose Sanitizer

FOR SANITIZING FOOD CONTACT SURFACES

USE ONE TO TWO TABLETS PER 1 GALLON OF WATER

Kills HIV-1 (AIDS Virus) when used as directed for sanitizing.

EPA REG. NO. 1561-11

Active Ingredient (Quaternary)	50%
Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate	
INERT INGREDIENTS	50%

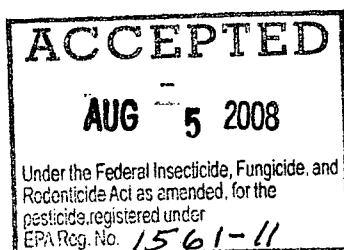
WARNING
KEEP OUT OF REACH OF CHILDREN

See left panel for additional precautionary statements.
For Institutional and Commercial use only.

150
Tablets

NET WEIGHT
8 OUNCES

Manufacturing Chemists
EDWARDS-COUNCILOR CO. INC., 1427 Baker Road, Virginia Beach, VA 23455



This product fulfills the sanitizing criteria of the US PUBLIC HEALTH SERVICE in waters up to 500 ppm of hardness calculated as CaCO₃ when tested by the AOAC Germicidal and Detergent Sanitizers – Official Method.

STERAMINE sanitizing solutions of 200 to 400 ppm concentration may be safely used on food processing equipment, utensils and other food contact articles and surfaces as specified under 40 CFR 180.940 of the U.S. Environmental Protection Agency.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS and DOMESTIC ANIMALS**

WARNING: Tablet dust causes substantial but temporary eye injury. Do not get dust in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Tablets may be harmful if swallowed.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advise.

IF ON SKIN: Rinse immediately with water for 15-20 minutes. If irritation persists, call poison control center or doctor for treatment advise.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advise. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center doctor. Do not give anything by mouth to an unconscious person. Have the product label or container with you when calling a poison control center or doctor, or going for treatment.

STORAGE and DISPOSAL: Store in original container in areas inaccessible to persons unfamiliar with its use. Do not reuse empty container. Wrap container and discard in trash.

DIRECTIONS

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Prepare sanitizing solutions with warm water. Allow several minutes for tablets to dissolve before using.

FOR SANITIZING DISHES, GLASSES, AND UTENSILS IN RESTAURANTS, TAVERNS, ETC.

1. Scrape and prewash utensils and glasses whenever possible.
2. Wash with a good detergent or compatible cleaner in first sink compartment.
3. Rinse with clean water in second sink compartment.
4. Sanitize in a solution of 1 to 2 TABLETS per 1 GALLON OF WATER (200 to 400 ppm) in third sink compartment. Immerse all utensils for at least one minute or for contact time specified by governing sanitary code.
5. Place sanitized utensils on a rack or drainboard to air dry.
6. A fresh sanitizing solution must be prepared at least daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR SPRAYING

FOR SANITIZING FOOD PROCESSING EQUIPMENT, DAIRY EQUIPMENT, SINKS, COUNTERTOPS, REFRIGERATED STORAGE AND DISPLAY EQUIPMENT and other hard nonporous food contact articles and surfaces.

1. Wash and rinse all articles and surfaces thoroughly.
2. Apply a solution (SPRAY ON WITH HAND TRIGGER SPRAYER OR WIPE ON) of 200 to 400 ppm concentration and allow surface to remain wet for at least one minute followed by adequate draining and air drying.

KILLS HIV-1 (AIDS Virus) when used as directed for sanitizing.

EPA EST. 1561-VA-1

FOR CLEANING AND SANITIZING SOFT SERVE – FROZEN DESSERT MACHINES AND EQUIPMENT

CLEANING INSTRUCTIONS

1. Drain all product from machine
2. Rinse machine thoroughly by adding 2 gallons of water and operating for 2 minutes, then drain all rinse water from machine
3. Wash machine thoroughly by adding 2 gallons of a suitable detergent solution and operating for 5 minutes, then drain detergent solution.
4. Rinse machine again by adding 2 gallons of water and operating for 2 minutes, then drain all rinse water from machine.

SANITIZING INSTRUCTIONS

5. Dissolve 2 to 4 tablets in 2 gallons of warm water to prepare 200 to 400 ppm sanitizing solution – allow several minutes for tablets to dissolve completely before using. Add this sanitizing solution to machine and operate for 5 minutes, then drain sanitizing solution from machine. Allow 5 minutes for machine dry.
6. Machine is now ready for refill.