

1561-11

07/06/2011

1/8

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL - 6 2011

Mr. Robert G. Butz  
Edwards-Councilor Co., Inc.  
1427 Baker Road  
Airport Industrial Park  
Virginia Beach, VA 23455

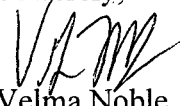
Subject: Steramine™ 1-G Tablets  
EPA Registration No. 1561-11  
Amendment Date: June 9, 2011  
EPA Receipt Date: June 10, 2011

Dear Mr. Butz,

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and per PR Notice 98-10.

- Revise label statements per Agency letter of 11/9/10 and e-mail correspondence of 11/29/10

Based on a review of the submitted information this notification is acceptable. This notification will be made part of the record for this file. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415 or Velma Noble at (703) 308-6233.

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

7510P:T.Lantz:7/6/11:1561 notification

CONCURRENCES							
SYMBOL	7510P						
SURNAME	T. Lantz						
DATE	7/6/11						







NOTE: Bracketed information is optional wording/text for product specific labels

# 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 Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) when used as directed for sanitizing.]**

or

**[Kills HIV-1 (AIDS Virus) and Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) when used as directed for sanitizing.]**

**ACTIVE INGREDIENT:**

(Quaternary) Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate ..... 50%

**OTHER INGREDIENTS:** ..... 50%

**TOTAL**..... 100%

**KEEP OUT OF REACH OF CHILDREN  
WARNING**

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

[150 or 250 or 300]  
Tablets

NET WEIGHT  
[8 or 13.3 or 16] OUNCES

EPA REG. NO. 1561-11

EPA EST. 1561-VA-1

[Batch No. \_\_\_\_]

Manufactured by:  
EDWARDS-COUNCILOR CO. INC., 1427 Baker Road, Virginia Beach, VA 23455

NOTE: Bracketed information is optional wording/text for product specific labels

[Used as directed at 200 to 400 ppm concentration, this product fulfills the sanitizing criteria of the US PUBLIC HEALTH SERVICE in waters up to 500 ppm of hardness calculated as CaCO<sub>3</sub>, when tested by the AOAC Germicidal and Detergent Sanitizers Official Method by killing 99.999% of the following pathogenic organisms in 60 seconds: Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA), *Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Staphylococcus aureus*, *Shigella dysenteriae*, and *Yersinia enterocolitica*.]

or

[Used as directed at 200 to 400 ppm concentration, ~~this product fulfills the sanitizing criteria of the US PUBLIC HEALTH SERVICE in waters up to 500 ppm of hardness calculated as CaCO<sub>3</sub>, when tested by the AOAC Germicidal and Detergent Sanitizers Official Method by killing 99.999%~~ this product is effective against the following pathogenic organisms in 60 seconds: Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA), *Escherichia coli*, *Escherichia coli* O157:H7, HIV-1 (AIDS Virus), *Listeria monocytogenes*, *Staphylococcus aureus*, *Shigella dysenteriae*, and *Yersinia enterocolitica*.]

[STERAMINE sanitizing solutions of 200 to 400 ppm concentration may be 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, using tobacco or using the toilet. 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.

**DIRECTIONS FOR USE**

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, AND OTHER PUBLIC EATING PLACES.**

- 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.

NOTE: Bracketed information is optional wording/text for product specific labels

- 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 of 200 to 400 ppm concentration by combining 1 or 2 tablets per gallon of water, allowing several minutes for tablets to dissolve completely before using. Spray with hand trigger sprayer or wipe on and allow surface to remain wet for at least one minute followed by adequate draining and air drying. ]

**[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 to dry.
- 6. Machine is now ready for refill. ]

**[Kills Community Associated Methicillin Resistant *Staphylococcus aureus* (CA-MRSA) when used as directed for sanitizing.]**

or

**[Kills HIV-1 (AIDS Virus) and Community Associated Methicillin Resistant *Staphylococcus aureus* [CA-MRSA] when used as directed for sanitizing.]**

*Note to reviewer: The following special instructions in brackets will ~~only appear on product labeling if the any~~ HIV claim ~~is on page one, page two and above~~ present are on the is label.*

**[SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

Personal Protection: The specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

NOTE: Bracketed information is optional wording/text for product specific labels

Contact Time: One minute.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to local regulation for infectious waste disposal.]

**[To control ODOR CAUSING and slime FORMING BACTERIAL / ALGAE GROWTH in all manually filled EVAPORATIVE CONSOLE and PAPER FILTER TYPE HUMIDIFIERS. Not for use in Heat Vaporizing, Atomizing or Ultrasonic type Humidifiers.**

Start with a clean humidifier tank and filter.

Initially add 1 tablet per every 4 gallons of water in humidifier tank. Thereafter add 1 tablet per every 8 gallons of refill water added to tank. Tablets are effervescent and will dissolve completely.

For best results, avoid using more tablets than required. Rinse residual deposits from tank periodically. Clean your humidifier thoroughly every 4 weeks.

Do not use the product in heat vaporizing, atomizing or ultrasonic humidifiers. ]

**[To control the growth of odor causing and slime forming Bacteria / Algae in waterbed mattresses.**

DOSAGE: To control the growth of odor causing and slime forming Bacteria / Algae in waterbed mattresses.

Add one (1) tablet for every 20 gallons of waterbed mattress capacity.

In a twin size waterbed mattress of 90 to 100 gallons capacity, use 5 tablets.

In a waterbed mattress of 180 to 200 gallons capacity, use 10 tablets.

Repeat this application of tablets at 4 to 6 month intervals to maintain the control of Bacterial and Slime Growth in waterbed mattresses. ]

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage and disposal. Store in original container in areas inaccessible to persons unfamiliar with its use. Nonrefillable container. Do not reuse or refill this container. Triple rinse promptly after emptying. Offer empty container for recycling if available or discard in trash. **[PESTICIDE AND RINSATE DISPOSAL:]** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.