

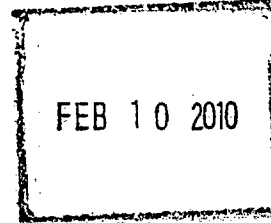
1561-11

02/10/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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: September 25, 2009  
EPA Receipt Date: September 25, 2009

Dear Mr. Butz,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the conditions below.

**Proposed Amendment**

- Addition of microorganisms and marketing claims

**Conditions**

Revise the label as follows:

- 1) Your label includes a claim for HIV-1. As such you must include appropriate directions for this use. Add the following text to the Directions for Use section of this label:

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**“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.

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.”

2) Revise the claim at the top of page two which begins as follows: “Used as directed at 200 to 400 ppm concentration, this product fulfills the sanitizing criteria...” by deleting the reference to “HIV-1 (AIDS Virus)” from this section. Your product was not tested against the HIV-1 virus using a sanitizing test method.

3) Revise the Directions for Spraying to include complete information by revising #2 to read as follows: “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 surfaces to remain wet for at least one minute followed by adequate draining and air drying.”

4) Make the following revision to the final statement of the Container Disposal statement: “...If not available, *puncture and dispose of* in a sanitary landfill.”

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Efficacy Data

The following data may be used to support this product. The review of this data is attached.

Data Requirement	Means of Support	Status
Germicidal and Detergent Sanitizing Rinse: <i>Escherichia coli</i> O157:H7	Submitted study, MRID 478694-01	Acceptable, pre-cleaned food contact surfaces, 500 ppm hard water, contact time of 60 seconds
Germicidal and Detergent Sanitizing Rinse: Community Associated Methicillin Resistant <i>Staphylococcus aureus</i> (Genotype USA 300)	Submitted study, MRID 478694-02	Acceptable, pre-cleaned food contact surfaces, 500 ppm hard water, contact time of 60 seconds
Germicidal and Detergent Sanitizing Rinse: <i>Listeria monocytogenes</i>	Submitted study, 478694-03	Acceptable, pre-cleaned food contact surfaces, 500 ppm hard water, contact time of 60 seconds
Germicidal and Detergent Sanitizing Rinse: <i>Yersinia enterocolitica</i>	Submitted study, 478694-04	Acceptable, pre-cleaned food contact surfaces, 500 ppm hard water, contact time of 60 seconds
Germicidal and Detergent Sanitizing Rinse: <i>Shigella dysenteriae</i>	Submitted study, 478694-05	Acceptable, pre-cleaned food contact surfaces, 500 ppm hard water, contact time of 60 seconds

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

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4/7

If the above 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 bearing the amended labeling constitutes acceptance of these conditions. 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)

Enclosure: Stamped Label, DER D370682  
7510P:T.Lantz:2/10/2010:1561-11 relying on new data

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5/7

# 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) 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  
Tablets

NET WEIGHT  
8 OUNCES

EPA REG. NO. 1561-11

EPA EST. 1561-VA-1

[Batch No. will appear on label]

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
FEB 10 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1561-11

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, 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 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.

**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, 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.

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

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

## [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.]

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

**Pesticide Storage:** Store in original container in areas inaccessible to persons unfamiliar with its use.

**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying by triple rinsing as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, dispose in a sanitary landfill.

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