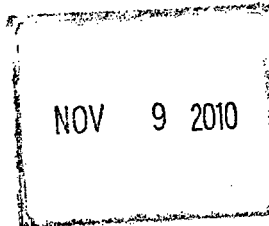


1561-11

11/9/2010

1 of 6

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: August 11, 2010
EPA Receipt Date: August 12, 2010

Dear Mr. Butz,

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

Proposed Amendment

- Label revisions

Conditions

Revise the label as follows:

- 1) Your label includes claims for HIV-1. As such you must include appropriate directions for this use. Revise the note on page 3 to read exactly as follows:
"Note to reviewer: The following special instructions in brackets will *appear if any HIV claim is present on this label.*"
- 2) Revise the second claim near 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.

CONCURRENCES

SYMBOL	7510P						
SURNAME	R. Butz						
DATE	11/8/10						

2016

3) Should you wish to retain a reference to the company's website on your label, then please be aware that such a reference transforms the website into labeling under the Federal Insecticide Fungicide and Rodenticide Act sec 2 (p) (2) and then the website is subject to review by the Agency. If the website content is false or misleading, the product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Although EPA has not yet determined the extent to which it will routinely review company websites, if the Agency finds or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

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. 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
 7510P:T.Lantz:11/8/2010:1561-11 label amendment

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

3096

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV - 9 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 CaCO₃, 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 CaCO₃, 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 (F100 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. ~~With the exception of page one, page two and above are on the 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.

Contact Time: One minute.

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

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.