

1561-11

9/5/2012

page 186

SEP -5 2012

Mr. Robert G. Butz
Carter Ledyard & Milburn LLP
701 8th Street, N.W., Suite 410
Washington, D.C. 20001-3893

Subject: **Steramine 1-G Tablets**
EPA Registration Number 1561-11
Application Dated June 7, 2012
EPA Received Date June 8, 2012

Dear Mr. Butz:

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

Proposed Amendment:

- Add and edit Direction for Use
- Add Container sizes, add tablet size, add marketing statements, and add alternate brand names "Steramine 1 QT Tablets" and "Sani-Spray Tablets"

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



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

CONCURRENCES

SYMBOL	Enclosure: Stamped Label						
SURNAME							
DATE							

286

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

Formatted: Not Highlight

STERAMINE™ 1-G Tablets

www.sanitize.com

Formatted: Font: 18 pt

[Alternate Brand Names:

Formatted: Font: 18 pt

**STERAMINE™ 1-QT Tablets or
SANI-SPRAY Tablets]**

Formatted: Font: 14 pt

Formatted: Font: 14 pt

Formatted: Font: 14 pt

[The Multi-Purpose Sanitizer]

[FOR SANITIZING FOOD CONTACT SURFACES]

[USE ONE (1.5g) TO TWO TABLETS PER 1 GALLON OF WATER]

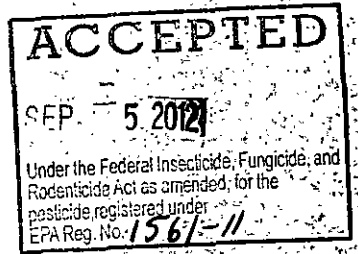
[The No Rinse Food Contact Surface Sanitizer Spray]

[Used as directed, each- 0.56g tablet- produces one quart of No Rinse Food Contact Surface Sanitizer Spray Solution]

[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.]

[100, 150 or 250 or 300] Tablets

NET WEIGHT [NET WT.]

[2, 3, 8 or 13.3 or 16] OUNCES [OZ.]

EPA REG. NO. 1561-11

EPA EST. 1561-VA-1

[Batch No./Lot No. _____]

Formatted: Left

Formatted: Left

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

376

Formatted: Not Highlight

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, in waters up to 500 ppm of hardness calculated as CaCO₃, 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*.**]

Formatted: Font: Bold

[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.]

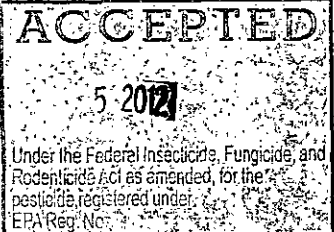
[or]

[for Steramine 1-Qt Tablets or SANI-SPRAY Tablets:] [Used as directed at 300 ppm concentration (one tablet (0.56g) dissolved in one quart of warm water), in waters up to 500 ppm of hardness calculated as CaCO₃, 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*.**]

Formatted: Font color: Red

Formatted: Font color: Red

[Steramine] [SANI-SPRAY] sanitizing solution of 300 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.

486

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

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 thoroughly 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.
4. Sanitize in a solution of 1 (1.5g) 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, TABLES, 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 (1.5g) or 2 tablets, per gallon of warm 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. Do not rinse or wipe.]

[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.

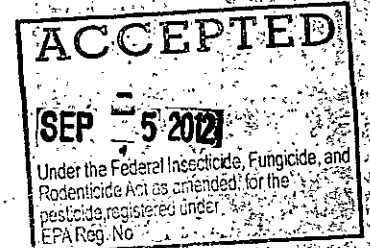
SANITIZING INSTRUCTIONS

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.]



576

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

Note to reviewer: The following special instructions in brackets will appear if any HIV claim is present on this 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.

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 (1.5g) 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 (1.5g) for every 20 gallons of waterbed mattress capacity.

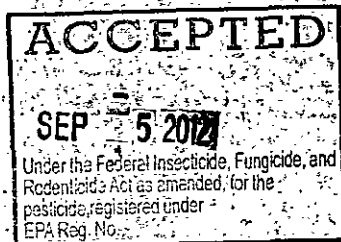
In a twin size waterbed mattress of 90 to 100 gallons capacity, use 5 tablets.

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



686

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

Formatted: Not Highlight

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.

Formatted: Centered

[OR]

Formatted: Font: (Default) Arial, 12 pt, Bold

[Directions for Use For Steramine™ 1-QT Tablets or SANI-SPRAY Tablets Below]

Formatted: Font: (Default) Arial, 12 pt, Bold

Formatted: Font: 14 pt

Formatted: Font: 14 pt

Formatted: Font: 14 pt

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[Steramine 1-QT] [SANI-SPRAY] Tablets is a no-rinse food contact surface sanitizer.

[DIRECTIONS FOR SANITIZING WITH HAND TRIGGER SPRAY BOTTLE]

Formatted: Centered

Formatted: Font: Bold

FOR SANITIZING FOOD PROCESSING EQUIPMENT, DAIRY EQUIPMENT, SINKS, COUNTERTOPS, TABLES, REFRIGERATED STORAGE AND DISPLAY EQUIPMENT AND OTHER HARD NONPOROUS FOOD CONTACT ARTICLES AND SURFACES.

Formatted: Not Highlight

Formatted: Font: Bold

1. Wash and rinse all articles and surfaces thoroughly.
2. Apply a solution of 300 ppm concentration by dissolving one tablet (0.56g) in a clean one-quart size (32 oz.) hand trigger spray bottle filled with warm water, allowing several minutes for tablet to dissolve thoroughly before using. Spray surfaces to be sanitized with hand trigger spray bottle and allow surfaces to remain wet for at least one minute followed by adequate draining and air drying. Do not rinse or wipe.

Formatted: All caps

Formatted: Numbered + Level: 1 + Numbering Style: 1, 2, 3, ... + Start at: 1 + Alignment: Left + Aligned at: 0" + Tab after: 0.25" + Indent at: 0.25"

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

Formatted: Font: Bold

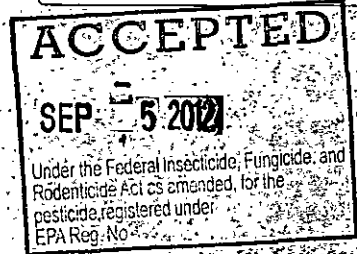
Formatted: Centered

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.]



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.

Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers

Formatted: Font: (Default) Arial, Bold

Formatted: Default, Adjust space between Latin and Asian text, Adjust space between Asian text and numbers