

1561-11

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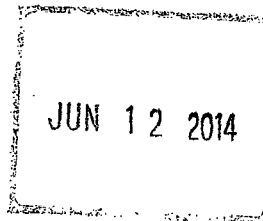
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Robert G. Butz
Agent for Edwards-Councilor Co., Inc
Sullivan & Worcester, LLP
1666 K Street, NW
Washington, DC 20006



SUBJECT: Steramine 1-G Tablets
EPA Registration Number: 1561-11
Application Dated: March 14, 2014
Receipt Date: March 14, 2014

Dear Mr. Butz:

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

- Minor revisions to label

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data. A stamped copy of your labeling is enclosed for your records.

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.

CONCURRENCES

SYMBOL	SURNAME	DATE					

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Tracy Lantz

for

Velma Noble
Team Leader (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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

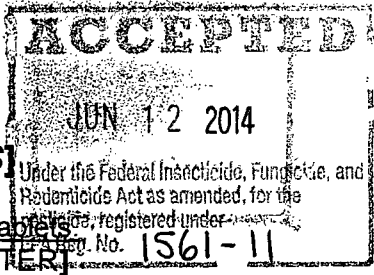
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www.sanitize.com

STERAMINE™ 1-G Tablets
[Alternate Brand Names:
STERAMINE™ 1-QT Tablets or
SANI-SPRAY Tablets or
SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS or
STERAMINE™ 6-Q Tablets or
QUAT-TABS Quaternary Sanitizing Tablets

[The Multi-Purpose Sanitizer]

[FOR SANITIZING FOOD CONTACT SURFACES]



Note to reviewer: The following statement is only applicable to Steramine 1-G Tablets
[USE ONE (1.5g) TO TWO TABLETS PER 1 GALLON OF WATER]

Note to reviewer: [The following statement is only applicable to Steramine 6-Q Tablets or
QUAT-TABS Quaternary Sanitizing Tablets.

[USE ONE TO TWO TABLETS PER 1½ GALLONS 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, 200 or 250 or 300] Tablets

NET WEIGHT [NET WT.]
[2, 3, 4, 8 or 13.3 or 16] OUNCES [OZ.]

EPA REG. NO. 1561-11

EPA EST. 1561-VA-1

[Batch No./Lot 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 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*.**]

[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 or SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS :] [Used as directed at 300 ppm concentration (one 0.56g tablet 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*.**]

[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.

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.]

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

Note to reviewer: Add special instructions in brackets if HIV claim appears on 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.

Do not use more tablets than indicated on this label. 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 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.

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

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[OR]

[Directions for Use For Steramine™ 1-QT Tablets or SANI-SPRAY Tablets or SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS, Below]

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.

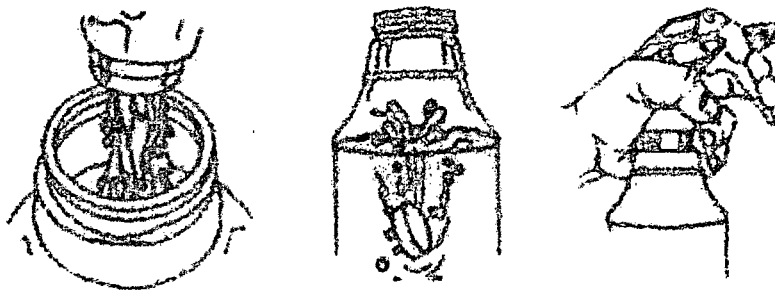
[DIRECTIONS FOR SANITIZING WITH HAND TRIGGER SPRAY BOTTLE]

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 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.

[The graphic shown below will only be used on the label for alternate brand names:

STERAMINE™ 1-QT Tablets or SANI-SPRAY Tablets or SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS.



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

[OR]

**[Directions for Use For Steramine™ 6-Q Tablets or
QUAT-TABS Quaternary Sanitizing Tablets]**

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 to 2 TABLETS per 1½ GALLONS 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.**

3. Wash and rinse all articles and surfaces thoroughly.
4. Apply a solution of 200 to 400 ppm concentration by combining 1 or 2 tablets per 1½ gallons 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

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

SANITIZING INSTRUCTIONS

11. Dissolve 2 to 4 tablets in 3 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.
12. Machine is now ready for refill.]

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

[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.]

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