

1561-11

01/11/2013

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Robert G. Butz
Sullivan & Worcester LLP
1666 K Street NW
Washington DC 20006

JAN 11 2013

SUBJECT: Steramine 1-G Tablets
EPA Registration Number: 1561-11
Application Date: December 14, 2012
Receipt Date: December 14, 2012

Dear Mr. Butz:

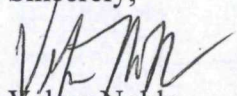
This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Addition of a new container size.
- Additional of optional marketing graphic.
- Addition of an alternate name "SANI-SPRAY MULTIPURPOSE SANITIZING TABLETS"
- Editing one marketing statement to improve grammar.

Based on a review of the submitted information, this notification is acceptable. Your proposed change will be made part of the record for this file.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,


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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Please read instructions on reverse before completing form

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98

	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

Application for Pesticide – Section I

1. Company/Product Number 1561-11	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Steramine 1-G Tablets	PM # 31	
5. Name and Address of Applicant (Include ZIP Code) Edwards-Councilor Co., Inc. 1427 Baker Road Virginia Beach, VA 23455 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg No. Product Name	

Section – II

<input type="checkbox"/> Amendment – Explain below	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification – Explain below	<input type="checkbox"/> Other – Explain below

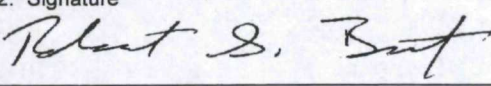
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
 Notification to add container size, add marketing graphic, add alternate brand name "SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS" and edit one marketing statement to improve grammar.
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.
Contact: Robert Butz at 202-775-1211 or butz@sandw.com

Section III

1. Material This Product Will be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 3, 4, 8.0, 13.3 or 16 oz		5. Location of label directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Robert G. Butz	Title Authorized Agent, Staff Scientist Sullivan & Worcester LLP	Telephone No. (Include Area Code) 202-775-1211

Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law		6. Date Application Received (Stamped)
2. Signature 	3. Title Authorized Agent, Staff Scientist Sullivan & Worcester LLP	
4. Typed Name Robert G. Butz	5. Date December 14, 2012	

Phone: 202 775 1211
Email: rbutz@sandw.com

December 14, 2012

VIA COURIER

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Velma Noble (PM 31)

Re: Notification for Steramine 1-G Tablets, EPA Reg. No. 1561-11

Dear Velma:

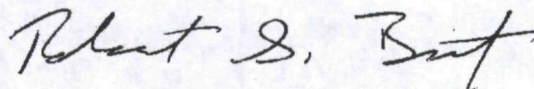
On behalf of Edwards-Councilor Co. Inc., I am submitting a notification for Steramine 1-G Tablets, EPA Reg. No. 1561-11. The following changes to the label have been made:

- Addition of a new container size
- Addition of optional marketing graphic,
- Addition of an alternate brand name "SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS", and
- Edit one marketing statement to improve grammar.

Attached please find Application Form (EPA Form 8570-1); two copies of proposed label; and one copy of proposed label with changes marked in yellow highlight. I have also attached the actual draft final printed label for the SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS product to demonstrate how this new sub label with new graphic will appear.

Please call or email me if you have any questions about this action.

Sincerely,



Robert G. Butz, Ph.D.
Staff Scientist

Attachments

{W0247523; 1}

4/10

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

STERAMINE™ 1-G Tablets

www.sanitize.com

[Alternate Brand Names:

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

[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**

NOTIFICATION
Date Reviewed: 1/19/13
Reviewed By: ED

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

[100, 150, 200, 250 or 300] Tablets

NET WEIGHT [NET WT.]
[2, 3, 4, 8, 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

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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.

NOTIFICATION
Date Reviewed: 4/11/13
Reviewed By: [Signature]

6/10

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.]

NOTIFICATION
Date Reviewed: 4/11/13
Reviewed By: [Signature]

7/10

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 Bacteria 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.

9/10

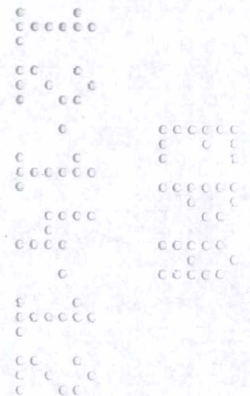
NOTE: Bracketed information is optional wording/text for product specific labels

[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.



1



NOTIFICATION
 Date Reviewed: 1/11/13
 Reviewed By: [Signature]

10/10

Draft Final Printed Label for EPA Reg. No. 1561-11, for SANI-SPRAY MULTI-PURPOSE SANITIZING TABLETS product

USED AS DIRECTED, EACH 0.56g TABLET PRODUCES ONE QUART OF 10 RINSE FOOD CONTACT SURFACE SANITIZER SPRAY SOLUTION

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

ACTIVE INGREDIENT: Quaternary Amyl 92%, C12.2%, C16.2%

OTHER INGREDIENTS: Dimethyl beryl ammonium chloride hydroxide 50%

TOTAL: 100%

KEEP OUT OF THE REACH OF CHILDREN

WARNING

See left panel for additional precautionary statements. For Institutional and Commercial Use only.


EPA REG. NO. 1561-11 EPA EST. NO. 1061-3A-1

Manufactured by
EDWARDS-COINCOLOR CO., INC.
1427 Baker Road, Virginia Beach, VA 23465

NET WT 4.0Z

200 TABLETS

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*.

SANI-SPRAY sanitizing solutions 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 US 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, 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 advice.

IF ON SKIN: Rinse immediately with water for 15-20 minutes. If irritation persists, call poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by poison control center or 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.

ESL060652012

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. 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, SNIS, COUNTERTOPS, TABLES, REFRIGERATED STORAGE AND DISPLAY EQUIPMENT AND OTHER HARD NON-POROUS 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 (2 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.

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 regulations for infectious waste disposal.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage and disposal. Spray in original container in areas inaccessible to persons unfamiliar with its use. Non-flammable. Do not reuse or refill the container. This use is for emergency use only. Other empty container for recycling is available or discard in trash. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

56720 00013



NOTIFICATION
Date Reviewed: 11/13
Reviewed By: EF