

1561-12

10/20/2010

1 of 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Robert G. Butz
Edwards-Councilor Co., Inc.
1427 Baker Road
Airport Industrial Park
Virginia Beach, VA 23455

OCT 20 2010

SUBJECT: Steramine™ 6-Q Tablets
EPA Registration Number: 1561-12
Application Dated: October 1, 2010
Receipt Date: October 31, 2010

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.

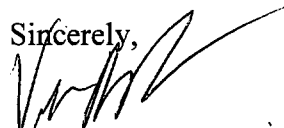
- Propose the alternate brand name: QUAT-TABS QUATERNARY SANITIZING TABLETS.

Based on a review of the submitted information, this notification is acceptable. Your proposed alternative brand name 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) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,



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

CONCURRENCES							
SYMBOL	7510P						
SURNAME	E. Oiguenblik						
DATE	Oct. 19, 2010						

2014

Please read instructions on reverse before completing form

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



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1561-12	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Steramine 6-Q Tablets	PM # 31	
5. Name and Address of Applicant (Include ZIP Code) Edwards-Councilor Co., Inc. 1427 Baker Road Airport Industrial Park 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 an alternate brand name (ABN) per PR Notice 98-10.
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 point: Robert G. Butz, phone 202-623-5710, email butz@clm.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 8 ounces, 13.3 ounces and 16 ounces		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 type="checkbox"/> Lithograph	<input type="checkbox"/> Other _____	
			<input checked="" type="checkbox"/> Paper glued		
			<input type="checkbox"/> Stenciled		

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 Staff Scientist Carter, Ledyard & Milburn LLP Authorized Agent	Telephone No. (Include Area Code) 202-623-5710
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 Staff Scientist Carter, Ledyard & Milburn LLP Authorized Agent	
4. Typed Name Robert G. Butz	5. Date October 1, 2010	

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CARTER LEDYARD & MILBURN LLP

Counselors at Law

Robert G. Butz Ph.D.
Staff Scientist

Direct Dial: 202-623-5710
E-mail: butz@clm.com

701 8th Street, N.W., Suite 410
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Tel (202) 898-1515
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2 Wall Street
New York, NY 10005-2072
(212) 732-3200

570 Lexington Avenue
New York, NY 10022-6856
(212) 371-2720

October 1, 2010

VIA COURIER

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

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

Attention: Ms. Velma Noble, Product Manager 31

Re: Steramine™ 6-Q Tablets, EPA Reg. No. 1561-12: Submission of Notification for Alternate Brand Name

Dear Velma:

On behalf of Edwards-Councilor Co. Inc., I am submitting a notification to add an alternate brand name for the Steramine 6-Q Tablets label. The alternate brand name is "QUAT-TABS QUATERNARY SANITIZING TABLETS".

Enclosed please find:

- Application Form (EPA Form 8570-1) with Notification Statement set forth in PR Notice 98-10
- One copy of the label showing the alternate brand name and a copy of the currently approved Steramine™ 6-Q Tablets label.

Please do not hesitate to contact me immediately at 202-623-5710 if there are any questions.

Sincerely,

Robert G. Butz

Enclosures

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.

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 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 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.

STORAGE and DISPOSAL: Store in original container in areas inaccessible to persons unfamiliar with its use. Do not reuse empty container. Wrap container and discard in trash.

S12-0305-106

STERAMINE

www.sanitize.com

6-Q Tablets
The Multi-Purpose Sanitizer

FOR SANITIZING FOOD CONTACT SURFACES

USE ONE TABLET PER 1 1/2 GALLONS OF WATER

Kills HIV-1 (AIDS Virus) when used as directed for sanitizing.

EPA REG. NO. 1561-12

Active ingredient (Quaternary)	50%
Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate	50%
INERT INGREDIENTS	50%
TOTAL	100%

WARNING
KEEP OUT OF REACH OF CHILDREN

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

NET WEIGHT 8 OUNCES

100 Tablets

Manufacturing Chemists
 EDWARDS-COUNCILOR CO. INC., 1427 Baker Road, Virginia Beach, VA 23455

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.

- Scrape and prewash utensils and glasses whenever possible.
- Wash with a good detergent or compatible cleaner in first sink compartment.
- Rinse with clean water in second sink compartment.
- Sanitize in a solution of 1 TABLET per 1 1/2 GALLONS OF WATER (200 ppm) in third sink compartment. Immerse all utensils for at least one minute or for contact time specified by governing sanitary code.
- Place sanitized utensils on a rack or drainboard to air dry.
- 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 non-porous food contact articles and surfaces.

- Wash and rinse all articles and surfaces thoroughly.
- Apply a solution (SPRAY ON WITH HAND TRIGGER SPRAYER OR WIPE ON) of 200 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) when used as directed for sanitizing.

EPA Est. 1561-VA-1

7 56720 00012 6

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.

PRECAUTIONARY STATEMENTS
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STORAGE and DISPOSAL: Store in original container in areas inaccessible to persons unfamiliar with its use. Do not reuse empty container. Wrap container and discard in trash.

SUPC 8826986

QUATERNARY SANITIZING TABLETS

FOR SANITIZING FOOD CONTACT SERVICES

USE 1 TABLET PER 1 1/2 GALLONS OF WATER

KILLS HIV-1 (AIDS Virus) when used as directed for sanitizing.

ACTIVE INGREDIENT (Quaternary)	50%
Alkyl (C14 95%, C12 3%, C16 2%) dimethyl benzyl ammonium chloride dihydrate	50%
OTHER INGREDIENTS	50%
TOTAL	100%

KEEP OUT OF THE REACH OF CHILDREN
WARNING

See left panel for additional precautionary statements.

EPA REG. NO. 1561-12 EPA EST. NO. 1561-VA-1
 For Institutional and Commercial use only.

100 tablets NET WT. 8 ounces

Manufacturing Chemists
 EDWARDS-COUNCILOR CO. INC., 1427 Baker Road, Virginia Beach, VA 23455
 www.quattabs.com

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.

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KILLS HIV-1 (AIDS Virus) when used as directed for sanitizing.

QT810

