

1043-60

12-10-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Michael G. Sarli  
STERIS Corporation  
PO Box 147  
St. Louis, MO 63166-0147

DEC 10 2009

Subject: T.B.Q.  
EPA Reg. No.: 1043-60  
Notification Date: November 12, 2009  
EPA Receipt Date: November 13, 2009

Dear Mr. Sarli,

This letter acknowledges receipt of your notification submitted in connection with registration under the provisions of PR Notice 98-10 and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

**Proposed Notification**  
Adding 2009 H1N1 Marketing Claims

**General Comments**

Based on a review of the submitted materials, your notification to add 2009 H1N1 Marketing Claims in accordance with the Agency guidance for testing labeling claims against Pandemic 2009 H1N1 Influenza A (Formerly called Swine Flu) is acceptable. A copy has been placed in our records for future reference.

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

Sincerely,

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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

EPA United States Environmental Protection Agency Washington, DC 20460		Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 1043-60		2. EPA Product Manager Velma Noble	3. Proposed Classification
4. Company/Product (Name) T.B.Q.		PM # 31	<input checked="" type="checkbox"/> None Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corp. P.O. Box 147 St. Louis, MO 63166-0647  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	
<b>Section - II</b>			
Amendment - Explain below.  Resubmission in response to Agency letter dated		Final printed labels in response to Agency letter dated "Me Too" Applicaton	
<input checked="" type="checkbox"/> Notification - Explain below.		Other - Explain below.	
<b>Explanation: Notification of label change per PR Notice 2007-4 and Notification of Additional Influenza A virus per PR Notice 95-2.</b> This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 95-2 and the requirements of EPA's regulations at 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156, 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.			
<b>Section - III</b>			
<b>1. Material This Product will be Packaged In:</b>			
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging Yes <input checked="" type="checkbox"/> No	<b>2. Type of Container</b> Metal <input checked="" type="checkbox"/> Plastic Glass Paper Other (Specify) <u>foil pouch</u>
*Certification must be submitted	If "Yes"                      No. per Unit Packaging wgt. container	If "Yes"                      No. per Package wgt                      container	
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label                      Container		<b>4. Size(s) Retail Container</b> 1 gal., 5 gal, and 55 gal.	<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label On Labeling accompanying product
<b>6. Manner in Which Label is Affixed to Product</b>		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled  Other	
<b>Section - IV</b>			
<b>1. Contact Point</b> (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
<b>Name</b> Michael G. Sarli		<b>Title</b> Lead Regulatory Specialist	<b>Telephone No. (Include Area Code)</b> 314-290-4704                      000000
<b>Certification</b> 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.			<b>6. Date Application Received</b>  (Stamped)  000000 000000 000000
<b>2. Signature</b> 		<b>3. Title</b> Lead Regulatory Specialist	
<b>4. Typed Name</b> Michael G. Sarli		<b>5. Date</b> 11/12/09	

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STERIS®



November 12, 2009

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
Regulatory Management Branch 1  
Antimicrobials Division (7510C)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
Attn: Velma Noble, PM #31

Re: Notification for T. B.Q. (EPA Reg. No. 1043-60)  
Revision of Container Disposal Language in Compliance with PR Notice 2007-4  
Addition of H1N1 Influenza Virus in Compliance with PR Notice 95-2

Dear Ms. Noble:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy) - Changes described with comments
- Labeling (1 copy) - "Clean" copy

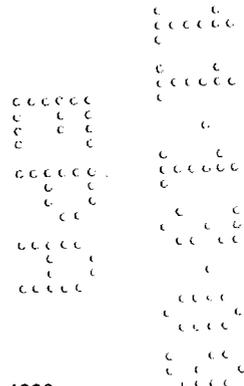
The Container Disposal statement has been revised in compliance with PR Notice 9007-4. The language related to the H1N1 Influenza A virus is drawn verbatim from the "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" EPA publication.

If you have any questions, I can be reached at 314-290-4704 or at [mike\\_sarli@steris.com](mailto:mike_sarli@steris.com).

Sincerely,

Michael G. Sarli  
Lead Regulatory Specialist  
STERIS Corporation

Enclosures





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# PRECAUTIONARY STATEMENTS

## Hazards to Humans and Domestic Animals

### DANGER

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear goggles, protective clothing and rubber gloves when handling. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

**CHEMICAL HAZARDS:** Do not use, pour, spill or store near heat or open flame.

**ENVIRONMENTAL HAZARD STATEMENT:** (For use on containers 5 gallons and larger) Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

**T.B.Q.** is a detergent based germicide concentrate that is multi-purpose and phosphate-free. When diluted at 1:128 in deionized/distilled water, it is biocidally effective against bacteria and fungi including *S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*, *M. tuberculosis*, and *T. mentagrophytes* in 10 minutes at 20°C on hard, non-porous environmental surfaces.

**T.B.Q.** is recommended for use on floors, walls, finished woodwork, bathroom fixtures, chrome, stainless steel, glazed porcelain, glass, glazed tile and other washable painted or varnished surfaces. It is intended for use only in institutions such as hospitals, nursing homes, restaurants, industrial plants, food preparation and service facilities, and medical and dental offices. Use-dilutions made as directed are not harmful to fabrics, resilient flooring, tile, painted or varnished surfaces.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Germicidal Qualification: A.O.A.C. use-dilution confirmation, 10 minutes at 20°C when diluted 1:128 in distilled water; (1:64 in 400 ppm hard water) (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) ..... Passes  
A.O.A.C. Tuberculocidal Test, 1:128 dilution in distilled water .... Passes

A.O.A.C. Fungicidal Test (*T. mentagrophytes*) 1:128 dilution in distilled water (1:64 dilution in 400 ppm hard water).....Passes

\*Virucidal Test (Against the following viruses on hard, non-porous inanimate surfaces: Vaccinia, Type 5 Adenovirus, Herpes Simplex, Influenza A<sub>2</sub>), 1:64 dilution.....Passes

**When tested by a Dilution Method, the HIV-1 (AIDS virus), with added 5% organic soil (serum), was completely inactivated by a 1:64 (2-ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 10 minutes at 20-25°C.**

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

or

Kills Pandemic 2009 H1N1 influenza A virus formerly called swine flu.

### DIRECTIONS FOR USE

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

**Disinfection of Hard, Non-porous Surfaces with Deionized (Distilled) Water** – Preclean surfaces before disinfection. Dilute 1:128 (1 oz./gallon with deionized or distilled water) and apply with cloth, sponge or mop by thoroughly wetting all hard, non-porous surfaces for a minimum of 10 minutes. Remove excess solution. Allow surfaces to air dry. At this use dilution, 1:128 in deionized or distilled water, this product is effective against *S. aureus*, *S. choleraesuis*, *P. aeruginosa*, *T. mentagrophytes* and *M. tuberculosis*. A properly prepared solution with deionized or distilled water of T.B.Q. intended for use as a hard surface disinfectant has a shelf life of 7 days (use life) when stored in a closed container such as a spray bottle.

**Disinfection of Hard, Non-porous Food Handling Surfaces with Deionized (Distilled) Water**- Dilute 1:128 with deionized or distilled water and apply as directed in paragraph above. Carefully protect or remove food products and packaging materials before application. Do not use on utensils, glasses, dishes, or cookware. Rinse with potable water before reuse of surface.

**Disinfection of Hard, Non-porous Surfaces with Hard Water** – Heavily soiled surfaces should be precleaned and rinsed before disinfection. Dilute 1:64 [2 oz./gallon of hard water (up to 400 ppm) ] and apply with cloth, sponge, or mop by thoroughly wetting al hard, non-porous surfaces for a minimum of 10 minutes. Remove excess solutions. Allow surfaces to air dry. At this use dilution, 1:64 in hard water, this product is effective against *S. aureus*, *S. choleraesuis*, *P. aeruginosa*, *T. mentagrophytes*, *Vaccinia*, Type 5 Adenovirus, Herpes Simplex, Influenza A2, and HIV-1. T.B.Q. is effective against *T. mentagrophytes* (the cause of Athlete’s foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, and shower/bath areas.

**Cleaning/Deodorizing:** Dilute 1:128 (1 oz/gallon) of water and apply to hard, non-porous surfaces by thoroughly wetting surfaces with cloth, mop, or sponge. Allow surfaces to air dry.

**KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

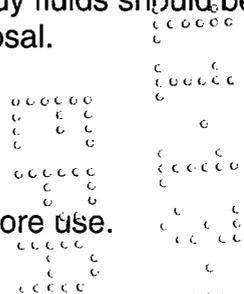
**Cleaning Procedures:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:64 use-solution (2 ounces per gallon). Prepare and apply solution as directed in paragraph above. **Contact Time:** Use a 10-minute contact time for disinfection of all organisms on this label. **Infectious Materials Disposal:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

### STORAGE AND DISPOSAL

(For containers greater than 1 gallon):

Do not contaminate food, feed, or water by storage or disposal.

**Storage:** Do not store near heat or open flame. If frozen, thaw and remix before use.



**Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Disposal:** Do not reuse empty container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**Container Disposal:** (For ≤5 gal.) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(For containers 1 gallon and smaller):

Store in original container in areas inaccessible to children. If frozen, thaw and remix before use. Do not reuse empty container. Rinse thoroughly before discarding in trash.