

EPA United States Environmental Protection Agency Washington, DC 20460	Registration Amendment X Other	OPP Identifier Number
Application for Pesticide - Section I		
1. Company/Product Number 1043-60	2. EPA Product Manager Velma Noble	3. Proposed Classification
4. Company/Product (Name) T.B.Q.	PM # 31	X None Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147 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		
<p>Explanation: "Notification of minor label revision 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 and false statement to EPA. I further understand that if this statement 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."</p>		
Section - III		
1. Material This Product will be Packaged In:		
Child-Resistant Packaging Yes* X No	Unit Packaging Yes No X If "Yes" Unit Packaging wgt.	Water Soluble Packaging Yes No X If "Yes" Package wgt
*Certification must be submitted	No. per container	No. per container
2. Type of Container Metal Plastic X Glass Paper Other (Specify)		
3. Location of Net Contents Information Label X Container	4. Size(s) Retail Container 1 gallon, 5 gallon and 55 gallon	5. Location of Label Directions On Label X On Labeling accompanying product X
6. Manner in Which Label is Affixed to Product Lithograph X Paper glued X Stenciled		
Section - IV		
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Michael G. Sarli	Title Regulatory Specialist	Telephone No. (Include Area Code) 314-535-2198
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 Lead Regulatory Specialist	
4. Typed Name Michael G. Sarli	5. Date 3/24/06	

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STERIS®



File in jacket

March 24, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
Attn: Velma Noble, PM #31
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Notice of Minor Label Revision for T.B.Q., (EPA Reg. No. 1043-60)
And Submission of Final Printed Labeling

Dear Ms. Noble:

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

- Application for Pesticide (EPA Form 8570-1)
- Final Labeling (3 copies).

The labeling has been modified by adding the tag line "Hard Surface Disinfectant" and the phrase "For Industrial and Institutional Use Only."

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

Enclosures

e Disinfectant

Net Contents:
18.93 Liters (5 Gal.)

**acidal
erculocidal**

8%
92%
100%

CHILDREN

ONAL USE ONLY

Precautions

FIRST AID	
If in eyes	<ul style="list-style-type: none"> Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> Call 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

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 stentant/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 A₂*), 1:64 dilution..... Passes
When tested by an Dilution Method, the HIV-1 (AIDS virus), with added 5% organic soil (serum), was completely inactivated by a 1:64 (2 oz./gallon) solution in 400 ppm A.O.A.C. hard water in 10 minutes at 20-25°C.

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: 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.

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: Pre-clean 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*, *Ps. 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 s...
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 prior to application. Do not use on utensils, glasses, dishes or cookware. Rinse with water before reuse of surface.

DISINFECTION OF HARD, NON-POROUS SURFACES WITH HARD WATER: Surfaces should be pre-cleaned and rinsed before disinfection. Dilute 1:64 (2 oz./gallon water (up to 400 ppm)) and apply with cloth, sponge, or mop by thoroughly wetting all non-porous surfaces for a minimum of 10 minutes. Remove excess solution. Allow surfaces to air dry. At this use-dilution, 1:64 in hard water, this product is effective against *S. choleraesuis*, *Ps. 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) 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 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. Surfaces/objects likely to be soiled with blood or body fluids can be soiled with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex glove or eye coverings.
Cleaning Procedures: Blood and other body fluids must be thoroughly cleared and objects before application of a 1:64 use-solution (2 oz./gallon). Prepare as directed in paragraph above.
Contact Time: Use a 10-minute contact time for disinfection of all organism.
Infectious Materials Disposal: Blood and other body fluids should be autoclaved or according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

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 solid or liquid wastes is a violation of Federal Law. If these wastes cannot be disposed of according to label instructions, contact your state Pesticide or Environmental Protection Agency for more information.
Hazardous Waste representative at the nearest EPA Regional Office for guidance.
Container Disposal: Do not reuse empty container. Triple rinse (or equivalent) and recycle where allowed. Do not puncture. Do not burn. Do not dispose of in a sanitary land fill or by incineration, unless allowed by state and local authorities, by burning. If burned, stay out of smoke.

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