

1043-60

12/5/2001

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Michael Sarli,  
Regulatory Specialist  
Steris Corporation  
P.O. Box 147  
St. Louis, MO 63166-0147

DEC 05 2001

Subject: T.B.Q.  
EPA Registration No. 1043-60  
Your Amendment Date: September 5, 2001  
EPA Receipt Date: September 7, 2001

Dear Mr. Sarli:

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

- Revised product label addressing comments in Agency letter dated August 29, 2001

#### Conditions

You will need to put the "Chemical Hazards" heading in bold type.

#### General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

*Velma Noble*  
Velma Noble

Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

#### CONCURRENCES

SYMBOL	7510C						
SURNAME	McFarlane						
DATE	12/05/01						

**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.

**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*, *P. aeruginosa*, *T. meningophytes* and *M. tuberculosis*.

**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. Protect or remove food during application. Do not use on utensils, glasses, or dishes. Rinse with potable water before reuse of surface.

**Disinfection of Hard, Non-porous Surfaces with Hard Water** - Heavily soiled surfaces should be pre-cleaned 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 all 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. meningophytes*, *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):

**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 other means. Do not burn. Stay out of smoke.

(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.

DEC 5 2001

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No. 1043-60

**T.B.Q.®**

•Germicidal  
 •Virucidal†  
 •Tuberculocidal

•Pseudomonacidal  
 •Deodorizer  
 •Fungicidal

**Active Ingredients:**

Alkyl (50% C<sub>14</sub>, 40% C<sub>12</sub>, 10% C<sub>10</sub>)  
 dimethyl benzyl ammonium chloride ..... 8%

Inert Ingredients: ..... 92%

**KEEP OUT OF REACH OF CHILDREN**

**DANGER**

**Read Side Panel For Additional Precautions**

FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
HOTLINE 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.®**

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 an EPA-approved 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.**

**(Logo) STERIS Corporation**

5035 Manchester Avenue  
 St. Louis, MO 63110 U.S.A.

EPA Reg. No. 1043-60

EPA Est. No. 1043-MO-1

Net Contents:

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