

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 30 2004

Mr. Michael Sarli
Steris Corporation
P.O. Box 147
St. Louis, MO 63166

Subject: T.B.Q Germicidal Detergent
EPA Registration No. 1043-60
Amendment Date: August 4, 2003
EPA Receipt Date: August 5, 2003

Dear Mr. Sarli,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with the following conditions

- Addition of 7 day holding period claim
- Updated Basic Formulation

Conditions

Revise the label as follows:

1. The "First Aid" statements must be organized so that the most sever routes of exposure, as demonstrated by the toxicity classification, are listed first. Therefore, reorganized the "First Aid" statements so that the are listed as follows: " If in eyes, If on skin or clothing, If swallowed, and If inhaled."
2. The Headings, "Precautionary Statements" and "Chemical Hazards" must appear in all capital letters so that they mirror the other heading on the label.
3. Under "Disinfection of hard, nonporous food handling surfaces," add the statement, "Do not use on utensils, glasses, dishes, or cookware."
4. Revise the right panel HIV claim by deleting the phrase "EPA approved."

CONCURRENCES

| | | | | | | | | |
|----------------|--|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | | |
| SURNAME | | | | | | | | |
| DATE | | | | | | | | |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Acceptable Data

| Data Requirement | Means of Support | Status |
|---|---------------------------------|------------|
| 7-Day Stability of TBQ End Use Dilution at Room Temperature w/ Addendum | Submitted study, MRID 457875-01 | Acceptable |
| AOAC Use Dilution Method | Submitted study, MRID 457695-01 | Acceptable |

General Comments

The Confidential Statement of Formula dated 8/1/03 is acceptable. It is in compliance with PR Notice 91-2 and in agreement with the label.

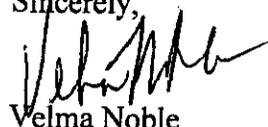
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely,



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

CONCURRENCES

| SYMBOL | | | | | | | |
|---------|--|--|--|--|--|--|--|
| SURNAME | | | | | | | |
| DATE | | | | | | | |

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 - 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, or dishes 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 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. 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 residue 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.

(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.

T.B.Q.®

- Germicidal
- Virucidal
- Tuberculocidal
- Pseudomonacidal
- Deodorizer
- Fungicidal

Active Ingredients:

Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₀) 8%
 dimethyl benzyl ammonium chloride 8%
Inert Ingredients: 92%
Total: 100%

KEEP OUT OF REACH OF CHILDREN
DANGER
 Read Side Panel For Additional Precautions

| FIRST AID | |
|--|--|
| If inhaled | •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. |
| If on skin or clothing | •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 in eyes | •How 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 swallowed | •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. |
| 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. | |

Net Contents:

ACCEPTED
 With COMMENTS
 in EPA Letter Dated:

JAN 30 2014

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

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 20EC 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 20EC 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 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 20-25EC.

STERIS Corporation
 St. Louis, MO 63133 U.S.A.

EPA Reg. No. 1043-60

EPA Est. No. 1043-MO-002
 EPA Est. No. 6658-MO-001

3/3