

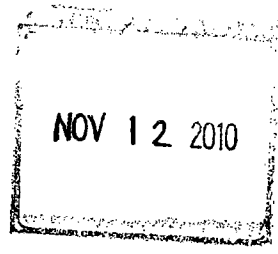
1043-60

11/12/2010

1 of 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Michael G. Sarli
Regulatory Affairs Manager
STERIS, Corp.
P.O. Box 147
St. Louis, MO 63166-0647



Subject: T.B.Q. Germicidal Detergent
EPA Registration No.: 1043-60
Amendments Dated: August 13, 2010
EPA Receipt Date: August 16, 2010

Dear Mr. Sarli,

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

Conditions

- 1) Revise the label to provide clarity by deleting the word "only" such that the text on page 1 reads: "For Industrial and Institutional Use".
- 2) Revise the Precautionary statements to include the following language: "... Wash thoroughly with soap and water after handling *and before eating, drinking, chewing gum, using tobacco or using toilet.*
- 3) Revise the Environmental Hazards statement to include: "*This pesticide is toxic to fish. Do not discharge...*"
- 4) List the complete names (genus and species) of the organisms against which this product is effective as follows: *Staphylococcus aureus, Salmonella enterica (formerly Salmonella choleraesuis), Pseudomonas aeruginosa, Mycobacterium tuberculosis and Trichophyton mentagrophytes.*
- 5) Revise the directions for Disinfection of Hard, Non-Porous Food Handling Surfaces with Deionized (Distilled) Water: to include the following statement: "*Pre-clean surfaces before disinfection.*"

6) Revise the HIV instructions to include the following: "Wear appropriate barrier protection such as latex gloves, ~~CONCURRENTERS~~ and eye coverings"

SYMBOL	7510P						
SURNAME	J. J. [Signature]						
DATE	11/12/10						

7) Your proposed Storage and Disposal language is not appropriate for a product with public health claims.

Revise the container disposal statement (≤ 5 gallons) to read as follows: "...Triple rinse as follows. Empty the remaining contents *and dispose of as pesticide waste*. Drain for 10 seconds after the flow...Shake for 10 seconds. *Dispose of rinsate as pesticide waste*. Drain for 10 seconds..."

Revise the container disposal statement (≥ 5 gallons) to read as follows: "...Triple rinse as follows. Empty the remaining contents *and dispose of as pesticide waste*. Fill container $\frac{1}{4}$ full with water...and tip it back and forth several times. *Dispose of rinsate as pesticide waste*. Repeat this procedure..."

8) Revise the Container Disposal section to include the following information for all sizes of containers: "*Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.*"

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,

Tracy Lantz

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

Enclosure: Stamped Label
7510P:T.Lantz:11/12/10:1043-60 accept label amend

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CAUTIONARY 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 1:64 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.

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 – Preclean surfaces before disinfection. Dilute 1:64 (2 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, 1:64 in deionized or distilled water, this product is effective against *S. aureus*, *S. choleraesuis*, *P. aeruginosa*, *T. mentagrophytes*, *M. tuberculosis*, Vaccinia, Type 5 Adenovirus, Herpes Simplex, Influenza A2, and HIV-1.. 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.

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.

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Disinfection of Hard, Non-porous Food Handling Surfaces with Deionized (Distilled) Water- Dilute 1:64 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.

Cleaning/Deodorizing: Dilute 1:64 (2 oz/gallon) of deionized or distilled 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 of deionized or distilled water). 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

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: (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. ~~Four 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.

