

1043-60

01-15-1997

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1-15-97

Calgon Vestal Laboratories, Inc.
Subsidiary of Merck & Company
P.O. Box 147
St. Louis, MO 63166-0147

Attention: Michael Ebers

Subject: T.B.Q. Germicidal Detergent
EPA Registration Number 1043-60
Amendment Dated September 10, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended to update your label, is acceptable provided that you make the following labeling change before you release the product for shipment bearing the amended label.

The proposed label "TBQ" dated 9-16-96 must be revised to reflect the following instructions:

On the back panel and after "...the following viruses..." add "...on hard, nonporous inanimate surfaces..."

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final printed labels prior to release of this product for shipment.

If you have any questions concerning this letter, please contact Velma Noble at (703) 305-7441.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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T.B.Q.[®]

EPA Reg. No. 1043-60

- | | |
|------------------|-------------------|
| • Germicidal | • Pseudomonacidal |
| • Virucidal† | • Deodorizer |
| • Tuberculocidal | • Fungicidal |

0023

Active Ingredients:

Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl benzyl ammonium chloride8%

Inert Ingredients:92%

DANGER: KEEP OUT OF REACH OF CHILDREN

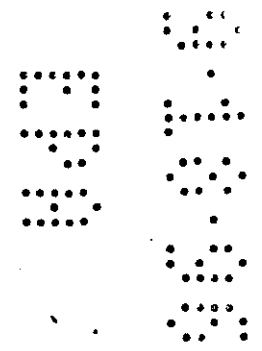
Read Side Panel For First Aid & Additional Precautions

Net Contents: One U.S. Gallon (3.78 Liters)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

1-15-97

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



Precautionary Statements

Hazard to Humans and Domestic Animals:

DANGER

Corrosive to tissues. This concentrate causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food. Do not use, pour, spill or store near heat or open flame.

FIRST AID: In case of contact, flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink large quantities of fluid—egg whites, gelatin solution or water; call a physician. Avoid alcohol. Do not induce vomiting. Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

DIRECTIONS FOR USE

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

Disinfection of Hard Surfaces—Dilute 1:128 (1 oz./gallon) with water and apply by normal methods with cloth, sponge or mop. Thoroughly wet all surfaces for a minimum of 10 minutes. Remove excess solution with a wringing-out applicator. Discard solution when it becomes dirty and replace with a fresh solution. For tuberculocidal activity dilute the product with deionized water and thoroughly preclean the surface to be treated.

Disinfection of Food Handling Surfaces—Dilute 1:128 with water and apply as directed in paragraph above. Protect or remove food during application. Rinse with potable water before reuse of surface.

General Care Areas, Dilutions with Hard Water, or Virucidal Activity—Dilute 1:64 (2 oz./gallon) and apply as directed above.

Always remove gross filth or heavy soil before applying the solutions of this product. Heavily soiled surfaces should be precleaned and rinsed before applying a T.B.Q. solution. This is a complete product. Do not add other chemicals. Use only as directed.

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 Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:64 use-solution (2 ounces per 1 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 other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

Prohibitions: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

Pesticide Disposal: This germicide, its solutions or rinsings from empty containers should be disposed of in a toilet or service sink served by a sewer, or in a landfill approved for pesticides.

Container Disposal: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.

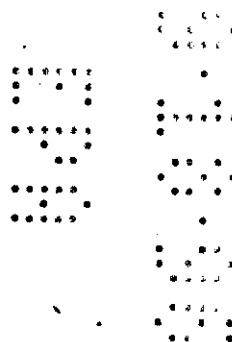
General: Consult Federal, State or Local disposal authorities for approved alternative procedures such as limited open burning. If frozen, thaw and remix before use.

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T.B.Q.

T.B.Q. is a detergent based germicide concentrate that is multi-purpose and phosphate-free. When diluted as directed, 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 environmental hard surfaces.

T.B.Q. is recommended for use on floors, walls, woodwork, bathroom fixtures, chrome, stainless steel, porcelain, glass, tile and other washable painted or varnished surfaces. It is intended for use only in institutions such as hospitals, nursing homes, schools, 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 or (2) contacts intact mucous membranes but which does not ordinarily penetrate the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

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 (1:64 dilution in 400 ppm hard water) Passes

Virucidal Test (Against the following viruses: *Vaccinia*, Type 5 Adenovirus, Herpes simplex, Influenza A₁), 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.

Primary skin irritation at 1:64 dilution Score* = 0.09

Eye irritation at 1:64 dilution Score* = 0.00

*Testing according to 16 CFR 1500.41 and 1500.42

Classified by Underwriter's Laboratories, Inc. as to electrical conductivity when used on conductive floors and spontaneous heating.

T.B.Q. Germicidal Detergent—For use with listed electrically conductive flooring of the vinyl type. 942 P.



Convatec

Division of E.R. Squibb & Sons, Inc.
St. Louis, MO 63110



EPA Est. No. 1043-MO-1

6345-061 (996)

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