

OCT - 7 1996

K962739

510(k) Summary

Trade Name: T.B.Q.

Common/Usual Name: General Purpose Disinfectant

Submitter/Manufacturer: ConvaTec, Division of E.R. Squibb and Sons, Inc.
5035 Manchester Avenue
St. Louis, MO 63110
Establishment Registration Number: 1940768

Contact: Mike Ebers, Manager Regulatory Affairs (314) 535-1390

Description: T.B.Q. is a liquid chemical germicide utilizing quaternary ammonium chloride compounds as active ingredients.

Intended Use: T.B.Q. is used to inactivate specific bacteria, fungi and viruses on hard inanimate surfaces including reusable non-critical medical devices and environmental surfaces in healthcare facilities.

Substantial Equivalence to: (1) Tor Germicidal Cleaner, Huntington Laboratories, (2) Quat-Syl 256, National Laboratories, (3) Futron 25, Hysan Corp.

Comparison to Listed Substantially Equivalent Products: Listed products are also liquid chemical germicides utilizing quaternary ammonium chloride compounds as active ingredients to inactivate specific bacteria, fungi, and viruses on hard inanimate surfaces.

Safety Data: Acute Oral LD₅₀ (Rats) = 1,900 mg/kg

Acute Inhalation LC₅₀ = >2.2 ml/ft³

Dermal Irritation (Rabbit) neat = Primary Irritation Index of 5.38 (Draize Scale), Moderate Irritation

Dermal Irritation (Rabbit) 1:64 aqueous dilution = Primary Irritation Index of 0.09 (Draize Scale), Barely Perceptible Irritation

Eye Irritation (Rabbit) neat = Corrosive

Eye Irritation (Rabbit) 1:64 aqueous dilution = No irritation

Dermal Sensitization (Guinea Pig) 2.5% w/w aqueous solution = Negative as sensitizer

Effectiveness Data: Germicidal: Passes AOAC Germicidal Use-Dilution Test in 400ppm hard water at a 1:64 dilution and in distilled water at a 1:128 dilution against *S. aureus*, *S. choleraesuis* and *Ps. aeruginosa*.

Tuberculocidal: Passes AOAC Tuberculocidal Test at a 1:128 dilution in distilled water.

Fungicidal: Passes AOAC Fungicidal Test in 400 ppm hard water at a 1:64 dilution and in distilled water at a 1:128 dilution against *T. mentagrophytes*.

Virucidal: Passes Virucidal Qualification Test in 400 ppm hard water at a 1:64 dilution against Influenza A₂, Herpes simplex, Vaccinia and Adenovirus Type 5

Passes EPA approved Dilution Method in 400 ppm hard water at a 1:64 dilution against the HIV-1 (AIDS) virus.