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1043-116

12/19/97

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510W)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

1043-116

DEC 19 1997

Term of Issuance: Conditional

Name of Pesticide Product:

T.B.Q. RTU

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Steris Corporation
P.O.Box 147
St. Louis, MO 63166-0147

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 1043-116".
 - b. Revise the ingredients statement to include "Total Ingredients.....100%".
 - c. Revise the Statement of Practical Treatment to read :

"IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting."

-OR-

Signature of Approving Official:

Date:

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"IF SWALLOWED: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available by administering syrup of ipecac. If person is unconscious, do not give anything by mouth and do not induce vomiting."

3. Submit two copies of the revised final printed label for the record.
4. The Acute Toxicity Profile for this product is as follows:

Acute Oral Toxicity	III
Acute Dermal Toxicity	IV
Acute Inhalation Toxicity	IV
Primary Eye Irritation	III
Primary Dermal Irritation	III
Dermal Sensitization	Non-sensitizer

5. Submit two copies of the revised final printed label for the record.

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

A stamped copy of the label is enclosed for your records.

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(Center Panel)

RECD EPA/OPP/DPD1

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T.B.Q.[®] RTU

EPA Reg. No. 1043-XXX

- Germicidal
- Virucidal
- Tuberculocidal
- Deodorizer
- Fungicidal

Active Ingredients:

Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl benzyl ammonium chloride0.125%

Inert Ingredients: 99.875%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Statement of Practical Treatment

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

See Side Panel For Additional Precautionary Statements

Net Contents:

ACCEPTED
with COMMENTS
in EPA Letter Dated:

12-19-97

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the purpose of
registered under FIFRA, 7 U.S.C. § 136

1043-116

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

12-19-97

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

1043-116

TBQ RTU (Left Panel)

Precautionary Statements

Hazard to Humans and Domestic Animals:

CAUTION

Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

DIRECTIONS FOR USE

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

Use only as directed. This is a complete product. Do not add other chemicals

Disinfection of Hard Surfaces-- floors, walls, bathroom fixtures, chrome, stainless steel and other washable painted or varnished surfaces. Hold container six to eight inches from surface to be treated and spray area until it is covered with solution. Allow the surface to remain wet for 10 minutes.

Disinfection of Food Handling Surfaces: Protect or remove food during application. Rinse with potable water before reuse of surface.

Always remove heavy soil before applying the solution of this product. Heavily soiled surfaces should be precleaned and rinsed before applying TBQ.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care 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, and in which the surfaces/objects to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV -1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFIENCY 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 TBQ RTU. **Contact Time:** Use a 10-minute contact time for 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 water, food, or feed by storage or disposal.

Container Disposal- Do not reuse container. Rinse thoroughly before discarding in trash.

Storage- Store in a cool, dry place.

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T.B.Q. RTU (Right Panel)

TBQ RTU is a phosphate free, detergent based , ready to use hospital grade germicide . It is effective against bacteria, fungi and viruses including S. Aureus, S. Choleraesuis, Ps. Aeruginosa, M. Tuberculosis, T. Mentagrophytes, HIV-1 (AIDS Virus), Vaccinia, Type 5 Adenovirus, and Herpes simplex, in 10 minutes at 20°C on environmental hard surfaces.

TBQ RTU 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 and ambulance services. It is not harmful to fabrics, resilient flooring, tile, painted or varnished surfaces.

This product is not to be used as a terminal sterilant/high level 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.

EPA Est. No. 1043-MO-1

ConvaTec

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

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