

1677-199

07-18-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**July 18, 2007**

OPP Decision Number: 377406

Joy A. Salverda  
Registration and Compliance Manger  
Ecolab, Inc.  
370 N. Wabasha St.  
St. Paul, MN 55102

Subject: Application for Amended Registration  
Product Name: Quantum TB Disinfectant  
EPA Registration Number: 1677-199  
Application Date: March 23, 2007  
Receipt Date: March 27, 2007

The following amendment, submitted in connection with registration under section 3(c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comment(s).

**Proposed Amendment**

- Add claims for *Avian Influenza A*.

**Acceptable Data**

The submitted efficacy data (MRID #s470909-01 and 470909-02) supports the claim for *Avian Influenza A*.

**Labeling Comment**

Delete the language on page 2 of the proposed label that states "Quantum TB Disinfectant is affirmed as generally recognized as Safe (GRAS) under 21 CFR Part 184.1025." *This is an implied safety claim.*

Submit three copies (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. A Stamped copy of the label is enclosed for your record.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,



Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: {Stamped labeling & Efficacy review}

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# QUANTUM TB DISINFECTANT

Ready-to-Use

**"One-Step" Detergent-Disinfectant / Bactericide/Tuberculocide / Fungicide/  
Virucide\*/Deodorizer**

**Broad-Spectrum Disinfectant**

**Hospitals - Nursing Homes - Institutions – Schools – Daycare Centers  
Restaurants - Food Service - Beverage and Food Processing Plants  
Veterinary and Industrial Use**

**ACTIVE INGREDIENTS:**

Octanoic Acid ..... 0.138%

**OTHER INGREDIENTS:** ..... 99.862%

**TOTAL:**..... 100.000%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

**PRECAUTIONARY STATEMENTS:**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

**FIRST AID**

**If in Eyes:** Hold 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 eye. Call a poison control center or doctor for treatment advice.

**FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL 1-800-328-0026  
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL 1-651-222-5352 (IN THE USA)**

Have the product container or label with when calling a poison control center or doctor, or going for treatment.

**ENVIRONMENTAL HAZARDS (greater than 5 gallons):** 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 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.

**ACCEPTED  
with COMMENTS  
EPA Letter Dated:**

**JUL 18 2007**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended for the pesticide,  
registered under EPA Reg. No. **1677-199**

**QUANTUM TB DISINFECTANT** is a ready-to-use, "one-step" Detergent-Disinfectant, Bactericide, Tuberculocide, Fungicide and Virucide.

**QUANTUM TB DISINFECTANT** is recommended for disinfecting and cleaning floors, walls, and other hard non-porous environmental surfaces such as tables, chairs, countertops, changing tables, bathroom fixtures, sinks, shelves, racks, carts, exterior surfaces of refrigerators, non-food contact surfaces of coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (such as polyethylene, polypropylene, polyvinylchloride, and polycarbonate), metal, glass, and painted or varnished surfaces. **QUANTUM TB DISINFECTANT** will not harm finished floors.

**QUANTUM TB DISINFECTANT** is an effective product for blood-borne pathogen cleanup.

The active ingredient in **QUANTUM TB DISINFECTANT** is affirmed as Generally Recognized as Safe (GRAS) under 21 CFR Part 184.1025.

**QUANTUM TB DISINFECTANT** can be used to clean and disinfect hard, non-porous toys.

**Areas of Use:** hospitals, nursing homes, daycare centers, other health care-facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, dietary areas, beverage and food processing plants, restaurants, hotels, motels, office buildings, recreational facilities, retail and wholesale establishments.

**QUANTUM TB DISINFECTANT** 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. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

#### **DIRECTIONS FOR USE**

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

#### **DISINFECTION/CLEANING/DEODORIZING DIRECTIONS:**

For hospital disinfection, deodorizing and cleaning of hard non-porous surfaces according to the AOAC Use-Dilution Test, modified in the presence of 5% organic soil load. Apply **QUANTUM TB DISINFECTANT** with a coarse trigger sprayer, cloth, mop, brush, scrubber, or by soaking to thoroughly wet surface. Allow surface to remain wet for at least 10 minutes. Remove solution with a mop, cloth, sponge, or vacuum pickup or allow to air dry. For heavily soiled areas, a pre-cleaning step is required. Rinsing of non-food contact surfaces is not necessary. Rinse food contact surfaces with potable water prior to reuse. Do not use on glasses, dishes or utensils.

#### **BACTERICIDAL:**

*Quantum TB Disinfectant* is effective against the following pathogenic bacteria at a contact time of 10 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

*Pseudomonas aeruginosa* – ATCC 15442

*Staphylococcus aureus* – ATCC 6538

*Salmonella choleraesuis* – ATCC 10708

*Staphylococcus aureus* (MRSA) – ATCC 33592

*Staphylococcus aureus* (VISA) – ATCC 5836

*Enterococcus faecalis* (VRE) – ATCC 51299

*Klebsiella pneumoniae* – ATCC 4352

*Proteus vulgaris* – ATCC 9920

*Enterobacter aerogenes* – ATCC 13048

*Serratia marcescens* – ATCC 14756

*Escherichia coli* – ATCC 11229

*Escherichia coli* O157:H7 – ATCC 35150

*Salmonella typhi* – ATCC 6539

*Shigella flexneri* – ATCC 9380

**TUBERCULOCIDAL:**

*Quantum TB Disinfectant* is effective against *Mycobacterium bovis* – BCG at a contact time of 5 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

**FUNGICIDAL:**

*Quantum TB Disinfectant* is effective against *Trichophyton mentagrophytes* (the athlete's foot fungus) - ATCC 9533 at a contact time of 10 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

**VIRUCIDAL\*:**

*Quantum TB Disinfectant* is effective against the following viruses at a contact time of 10 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection/Cleaning/Deodorizing directions for use.

HIV-1 (AIDS virus)\*

Herpes simplex Virus Type 1 – VTCC VR-733\*

Herpes simplex Virus Type 2 – ATCC VR-734\*

Hepatitis B Virus (HBV)\*

Human Corona Virus – ATCC VR-740\*

Respiratory syncytial virus (ATCC VR-26)\*

Vaccinia Virus – ATCC VR-119\*

Rhinovirus Type 37 – ATCC VR-1147\*

Influenza A Virus – ATCC VR-544\*

Avian Influenza Virus – ATCC VR-2072\*

**\*KILLS HIV-1 (AIDS VIRUS) and HBV 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 can be associated with the potential for the transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS) or Hepatitis B virus (HBV).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) AND HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** Disposable latex or vinyl gloves, gowns faces masks, or eye coverings must be worn during all cleaning of body fluids, blood, and decontamination procedures.

**CLEANING PROCEDURES:** Blood/body fluids must be thoroughly cleaned from surfaces and objects before application of *Quantum TB Disinfectant*. This cleaning may be accomplished with any cleaning solution, including this product.

**CONTACT TIME:** 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

**DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNS, KENNELS, CAGES, HUTCHES, ETC):** Remove animals and feed from facilities. Remove litter, waste matter, and gross soils. Empty all troughs, rack and other feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Disinfect surfaces as described under **Disinfection/Deodorizing Directions**. Ventilate buildings and other closed spaces. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. Allow to air dry before reintroducing animals.

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Containers 1 gallon or less:

**STORAGE & DISPOSAL**

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use. Do not reuse container. Wrap container and discard in the trash.

(1 gal. bladder in box) Remove empty bladder from outer corrugated box. Do not reuse bladder. Wrap bladder and box and put in trash.

Containers greater than 1 gallon:

**STORAGE & DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store this product in a cool, dry area, away from direct sunlight and heat.

**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:**

(greater than 1 gallon): Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(2.5 gal. bladder in box): Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling or dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Reg. No. 1677-199

EPA Est.: 303-IN-1 (L), 1677-MN-1 (P), 1677-CA-2 (R), 1677-CA-1 (S), 1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 1677-PR-1 (B), 1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code

Ecolab Inc.  
370 North Wabasha Street  
St. Paul, MN 55102-1390

Net Contents:

- 1 U.S. quart (946 ml)
- 1 U.S. gallon (3.78 L)
- 2.5 U.S. gallons (9.45 L)
- 5 U.S. gallons (18.9 L)
- 55 U.S. gallons (208.8 L)

U.S. Patent No. 5,234,719