

1677-199

12-29-2009

1/7



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

DEC 29 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Theodore D. Head, Product Registration Manager  
Ecolab, Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102

Subject: Quantum TB Disinfectant  
EPA Registration Number: 1677-199  
Application Date: November 20, 2009  
Receipt Date: November 30, 2009

Dear Mr. Head:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3(c) 9.

**Proposed Notification:**

Optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1.

**General Comments:**

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me by telephone at 703-308-6416 or by email at [mcfarlane.jacqueline@epa.gov](mailto:mcfarlane.jacqueline@epa.gov) or Killian Swift by telephone at 703-308-6346 or by email at [swift.killian@epa.gov](mailto:swift.killian@epa.gov). When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline McFarlane".

Jacqueline McFarlane  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier  
 Number

2  
7

**Application for Pesticide - Section I**

1. Company/Product Number 1677-199	2. EPA Product Manager Sharon Carisle	3. Proposed Classification
4. Company/Product (Name) Quantum TB Disinfectant	PM# 34	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

Amendment – Explain below.  Final printed labels in response to Agency letter  
 Resubmission in response to Agency letter dated  "Me Too" Application.  
 Notification – Explain below.  Other – Explain below.

**Explanation:** Use additional Page(s) if necessary. (For section I and Section II)

Deleting the term "or" and adding the term "and" under "Special Instructions for Cleaning and Decontamination" per comments on EPA letter dated 9/17/09, and adding optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-199 (Quantum TB Disinfectant).

**Section - III**

**1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* <b>Certification must be submitted</b>		If "Yes" Unit Packaging wgt.   No. per Container	If "Yes" Unit Package wgt.   No. Per Container

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 quart, 1 gal., 2.5 gal., 5 gal., 55 gal.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input type="checkbox"/> Stenciled		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)

Name Theodore D. Head	Title Product Registration Manager	Telephone No. (Include Area Code) (651) 293-2866
--------------------------	---------------------------------------	---

**Certification**  
 I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Product Registration Manager	6. Date Application Received (Stamped)
4. Typed Name Theodore D. Head	5. Date November 20, 2009	



3  
7

THEODORE HEAD  
Manager, Product Registration  
Regulatory Affairs  
T 651.293.2848  
F 651.225.3122  
ted.head@ecolab.com

November 20, 2009

Document Processing Desk (E-SUB)  
Office of Pesticide Programs (7502P)  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive  
Arlington, VA 22202

**ATTN: Sharon Carisle, PM-34**

**Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-199 (Quantum TB Disinfectant)**

Dear Sharon:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1.

Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8750-1.
- Certification with Respect to Label Integrity.
- Proposed Labeling (5 copies)
- Label CD

If you have any questions please contact me at the above phone, fax or email address.

Sincerely,

Theodore D. Head  
Product Registration Manager  
Regulatory Affairs  
Ecolab Inc.

# 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.

NOTIFICATION  
Date Reviewed: 12/29/02  
Reviewed By: K. Smith

5  
2

**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.

**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)*                        | Respiratory syncytial virus (ATCC VR-26)* |
| Herpes simplex Virus Type 1 – VTCC VR-733* | Vaccinia Virus – ATCC VR-119*             |
| Herpes simplex Virus Type 2 – ATCC VR-734* | Rhinovirus Type 37 – ATCC VR-1147*        |
| Hepatitis B Virus (HBV)*                   | Influenza A Virus – ATCC VR-544*          |
| Human Corona Virus – ATCC VR-740*          | 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, facemasks, and 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.

**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:**

(≤55-gallon rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available, or discard in trash.

(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.

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

**Optional Marketing Language:**

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- 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.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.