

1677-199

9/17/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 17 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Rhonda K. Schulz
Associate Director, Product Registration & Compliance
Ecolab Inc.
370 B, Wabasha Street
St. Paul, MN 55102

Subject: Quantum TB Disinfectant
EPA Registration No. 1677-199
Application Date: June 23, 2009
Receipt Date: June 25, 2009

Dear Ms. Schulz:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comment.

Proposed Amendment:

Revised Labeling per PR Notice 2007-4

General Comments:

On page three (3) of the label under the Special Instructions for Cleaning and Decontamination... Fluids, after face masks change the word "or" to "and".

Other Comments:

Thank you for submitting this amendment as an electronic application. Please continue to submit your application(s) electronically. Refer to the following website for guidance on electronic submissions and label: <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>. If you have questions concerning electronic labeling, a list of contacts is available at the above website.

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Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: carlisle.shaRon@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA Stamped Label

3066

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
in EPA Letter Dated:

SEP 17 2009

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.

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.

- | | |
|--|--|
| <i>Pseudomonas aeruginosa</i> – ATCC 15442 | <i>Proteus vulgaris</i> – ATCC 9920 |
| <i>Staphylococcus aureus</i> – ATCC 6538 | <i>Enterobacter aerogenes</i> – ATCC 13048 |
| <i>Salmonella choleraesuis</i> – ATCC 10708 | <i>Serratia marcescens</i> – ATCC 14756 |
| <i>Staphylococcus aureus</i> (MRSA) – ATCC 33592 | <i>Escherichia coli</i> – ATCC 11229 |
| <i>Staphylococcus aureus</i> (VISA) – ATCC 5836 | <i>Escherichia coli</i> O157:H7 – ATCC 35150 |
| <i>Enterococcus faecalis</i> (VRE) – ATCC 51299 | <i>Salmonella typhi</i> – ATCC 6539 |
| <i>Klebsiella pneumoniae</i> – ATCC 4352 | <i>Shigella flexneri</i> – ATCC 9380 |

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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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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

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SEP 17 2003**

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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