

42964-17

3-25-2008

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 25, 2008

James M. Duffy
Manager, Product Registration & Compliance -- Canada
Regulatory Affairs
Ecolab Inc.
370 Wabasha Street North - EUC 9
St. Paul, MN 55102-1390

Subject: **Asepticare**
EPA Registration No. 42964-17
Application Dated: November 20, 2007
Receipt Date: November 28, 2007

Dear Mr. Duffy:

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

Proposed Amendment:

- Updated NAFTA labeling

Other comments:

A stamped copy of the accepted labeling is enclosed.

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@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,



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

cc: Ian Chisholm/Therapeutic Products Directorate (TPD)

Enclosure: EPA stamped approved labeling

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ASEPTICARE

AEROSOL-DISINFECTANT VIRUCIDE*

DIN 00801828
EPA Reg. No. 42964-17

Active Ingredients:

n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
Dimethyl Benzyl Ammonium Chlorides	0.15%
n-Alkyl (68% C12, 32% C14)	
Dimethyl Ethylbenzyl Ammonium Chlorides.....	0.15%
Ethanol.....	62.74%
Inert Ingredients:	36.96%
Total:	100.00%

(Includes Essential Oil Odor Control Agents)

KEEP OUT OF REACH OF CHILDREN

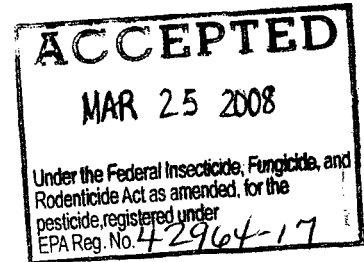
WARNING



FLAMMABLE/INFLAMMABLE



CONTAINER MAY EXPLODE IF HEATED
CE CONTENANT PEUT EXPLOSER S'IL EST CHAUFFÉ



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial, but temporary eye injury or skin irritation. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield (safety glasses). Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

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

PHYSICAL AND CHEMICAL HAZARDS: Flammable. Contents under pressure. Do not use in the presence of open flame or spark. Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat. Do not puncture or incinerate container or store in temperatures over 50°C (130°C).

KILLS THE FOLLOWING GERMS –ON HARD NON-POROUS SURFACES:

Bacteria:

Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Mycobacterium tuberculosis

Fungi: Trichophyton mentagrophytes (the cause of athlete's foot fungus)

Viruses: Feline Calicivirus, **Norovirus**, Human Corona Virus, Polio Virus, Sabin Strain Type 1, Influenza A2 (Aichi), Respiratory Syncytial (RSV), Rhinovirus Type 37, Adenovirus Type 2, Herpes Simplex Type 1 & 2, HIV (Human Immunodeficiency Virus), Parainfluenza I (Sendal)

Use **Asepticare** on door handles, clean-up carts, light switches, dressing or linen carts, hampers, diaper pails, toilet seats, bedpans, plastic mattress covers, and lockers. Asepticare is designed for use in hospitals, clinics, nursing homes, extended care, educational institutions, offices, pet care areas, motels and institutional and industrial facilities where odor and bacterial control is desired.

Not to be used on food preparation surfaces or in food-handling areas.

CONTROLS MOLD & MILDEW-Asepticare controls mold and mildew on hard nonporous surfaces if not washed or rubbed off.

GENERAL PRECAUTIONS AND RESTRICTIONS

Do not spray in face.

This product 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:

In the U.S.: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Disinfect: Clean surface prior to application. Hold container 6-8 inches from the surface. Spray 3-5 seconds or until surface is wet. Allow to remain wet for 10 minutes then air dry without wiping. Avoid using spray on delicate fabrics, lacquered, shellacked, or other finished wood surfaces.

To Control Mold & Mildew: Clean surface prior to application. Spray as above. Repeat application in 7 days or as necessary to maintain control.

***KILLS HIV ON PRECLEANED ENVIORNMENTAL 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 transmission of human immunodeficiency Virus Type 1 (HIV-1).

Special instructions for cleaning and decontamination against HIV-1 on surfaces/objects

Soiled with blood/body fluids.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex or vinyl gloves, gowns, masks or eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

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.

STORAGE & DISPOSAL:

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

Product Storage: Store in cool, dry place away from flames, sparks or other sources of heat or ignition. Containers heated above 130° F (54° C) may burst.

Product Disposal: Wastes are acutely hazardous. Improper disposal of excess product, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label directions, contact your State, Provincial, or Environmental Control Agency, or the Hazardous Waste representative at the nearest U.S. EPA or Environment Canada Regional Office for guidance.

Container Disposal: This container may be recycled in aerosol recycling centers. Before offering for recycling, empty the can by using the product according to the label (DO NOT PUNCTURE!). If recycling is not available, wrap the container and discard in the trash. 5/5

Net Weight/ Poids net: 14 oz / 397 g

EPA Est.: 706-IL-1

Distributed by:

Airkem Professional Products, Division of Ecolab Inc.
370 North Wabasha Street, St. Paul, MN 55102

Distributed in Canada by:

Ecolab Co
5105 Tomken Road, Mississauga, Ont. Canada L4W 2X5
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