

42964-17

4-21-2003

4/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 21, 2003

Brian C. Brosdahl
Manager, North American Registrations
Airkem Professional Products
Division of Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: Asepticare
EPA Registration No. 42964-17
Application Date: February 14, 2003
EPA Received Date: February 20, 2003

Dear Mr. Brosdahl:

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

Proposed Amendment

- Label revision in response to re-registration eligibility decision (RED) guidance dated August 13, 2001 and EPA Agency letter dated February 4, 2003

Conditions

Revise the label as follows:

1. Revise the first statement of the "If Swallowed" section read "Call a poison control center or doctor *immediately* for treatment advice."

CONCURRENCES							
SYMBOL	7510C						
SURNAME	Gray						
DATE	4-21-03						

2/4

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies your final printed labeling before distributing or selling the product bearing the revised labeling.

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 I
Antimicrobials Division (7510 C)

3/4

ACCEPTED
with COMMENTS
EPA Letter Dated:

ASEPTICARE

AEROSOL-DISINFECTANT VIRUCIDE*

APR 21 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under 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

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. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

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

Staphylococcus, *Pseudomonas*, *Mycobacterium tuberculosis*, *viruses like: Influenza A2 (Aichi), Rhinovirus 37, Parainfluenza 1 (Sendai), Herpes simplex (Types 1 and 2), Adenovirus (Type 2), Respiratory Syncytial Virus (RSV) as well as *Trichophyton mentagrophytes* (the cause of athlete's foot fungus).

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, 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.

4/4

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:

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 and 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 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 transmission of human immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

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.

Pesticide 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.

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 directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA 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.

Net Contents: 14 OZ/397 g

EPA Reg. No. 42964-17
EPA Est.: 706-IL-1

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

