

PM 31

42964-17

1 of 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 15 1997

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

Attention: Ann M. Oxford
Manager, Regulatory Services/North America

Subject: ASEPTICARE
EPA Registration No. 42964-17
Your Amendment Dated May 14, 1996
EPA Received Date May 20, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to delete efficacy claims against certain microorganisms (*Streptococcus pyogenes*, *Candida albicans*, *Vaccinia*, *Influenza B*, *Canine distemper*, and *Feline pneumonitis*), add two new virucidal efficacy claims (*Respiratory Syncytial Virus (RSV)* and *Rhinovirus type 37*), and remove certain product use directions (air sanitizer, bacteriostat, and medical device precleaner/decontamination uses), has been reviewed by the Agency and found to be acceptable, provided that you make the following label changes before you release the product for shipment bearing the amended labeling.

- Under the heading "KILLS MOST GERMS-ON ENVIRONMENTAL SURFACES:", delete the phrase "and most disease germs."
- Under the "To Disinfect:" section, of the "DIRECTIONS FOR USE:", revise the statement "Allow to air dry without wiping" to read "Allow to remain wet for 10 minutes and then air dry without wiping."

Please note that the submitted data are acceptable to support effectiveness of ASEPTICARE as a virucide against *Respiratory Syncytial Virus (RSV)* ATCC VR-26 and *Rhinovirus type 37* ATCC VR-1147, when used as an undiluted pressurized spray on hard, non-porous surfaces in the presence of 2-5% blood serum for a contact time of 10 minutes at room temperature.

CONCURRENCES

SYMBOL	7505W						
SURNAME	David						
DATE	4/1/97						

A stamped copy of the ASEPTICARE product labeling is enclosed for your records. Submit one (1) copy of the final printed labeling before you release the product for shipment.

If you have any questions concerning this letter, please contact Doreen Aviado of my staff at (703) 308-6344.

Sincerely,



Marshall Swindell
Acting Product Manager (31)
Regulatory Management Branch I
Antimicrobial Division (7504C)

Enclosure

DISINFECTANT VIRUCIDE

DISINFECTANT VIRUCIDE

Aerosol
Disinfectant
Virucide*

Asepticare®

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 15 1997

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

42964-17

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RECD EPA/OPP/DPDI

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%
(Includes Essential Oil Odor
Control Agents)

**KEEP OUT OF REACH
OF CHILDREN**

WARNING

Do not spray in face.

**PRECAUTIONARY
STATEMENTS**

**HAZARDS TO HUMANS & DOMESTIC
ANIMALS**

WARNING: Avoid getting into eyes. Avoid
contamination of food.

First Aid: In case of contact, flush with
water. If irritation persists, get medical
attention.

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.

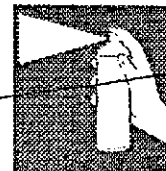
FOR EMERGENCY MEDICAL INFORMATION,
CALL TOLL-FREE 1-800-328-0026.



Net Weight:
14 oz. (397 G)

EPA Reg. No. 42964-17
EPA Est. 334-IL-2

KILLS MOST GERMS—ON ENVIRONMENTAL SURFACES:
Staphylococcus, Pseudomonas, Mycobacterium tuberculosis, *viruses
like: Influenza A2 (Aichi), Rhinovirus 37, Parainfluenza 1 (Sendai),
Herpes simplex (Types 1 and 2), Adenovirus (Type 2), as well as
Athlete's Foot fungi and most disease germs.



Respiratory
syncytial
Virus
(RSV)

*KILLS HIV ON PRE-CLEANED ENVIRONMENTAL
SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY
FLUIDS in health care setting 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 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, wear personal
protection such as disposable latex 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.

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

Use Asepticare on door handles, clean-up carts, light switches, dressing or linen carts,
hamper, diaper pails, toilet seats, bedpans, plastic mattress covers, and lockers. Asepticare is
designed for use in hospitals, offices, pet care areas, motels, and other areas where odor and
bacterial control is desired.

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 air dry without wiping, or allow to remain on
treated surface for 10 minutes before 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.

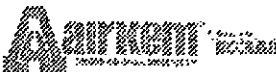
To Eliminate Odors: Spray 1-2 seconds in room as required.

STORAGE AND DISPOSAL

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. **Disposal:** This container may be
recycled in aerosol recycling centers. At present, there are only a few such centers in the
country. 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.

**ADVERTENCIA: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS
INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.**

Manufactured for



Achem Professional Products, Division of ECOLAB INC.
370 Wabasha Street, St. Paul, MN 55102
5105 Tomken Road, Mississauga, Ont. Canada L4W 2X5

708131/8910/0596
Made in U.S.A. © 1996

Handwritten initials/signature