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42964-25

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 24 1997

Aikem Professional Products  
Division of Ecolab Inc  
Ecolab Center  
St. Paul, MN 55102

Attn: Ann M. Oxford

Subject. A-33 DRY  
EPA Registration Number 42964-25  
Amendment Dated August 28, 1996

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to make a product name change, to include a disinfection claim against Vancomycin Resistant Enterococcus faecalis, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling
  - (A) In the proposed labeling under subheading "Effective as a virucide:" the word "Adenovirus Type 2" was omitted. Please include this virucidal claim on the label.
  - (B) On the proposed labeling, add the ATCC ID number to read: Enterococcus faecalis ATCC 51299.

2. The registration record for the product referenced above has been amended to include the additional brand name listed below:

"A-500"

It is understood that the label will be identical with that of the basic label accepted under this registration except for the product name.

3. We have adjusted our records accordingly

OLD PRODUCT NAME. A-500

NEW PRODUCT NAME A-33 DRY

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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2. Submit one (1) copy of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell  
Acting Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7504C)

Enclosure

# Airkem®

# 61180220

# A-33® DRY

**1/2 OZ. PREMEASURED PACKET  
DETERGENT DISINFECTANT ODOR  
COUNTERACTANT FOR HOSPITAL  
AND INSTITUTIONAL USE**

96 SEP -4 A9 58

RECD EPA/OPP/DPD1

Effective in hard water up to 500 ppm (calculated as CaCO<sub>3</sub>) in the presence of 5% blood serum.

**ACTIVE INGREDIENTS**

Octyl decyl dimethyl ammonium chloride .....	1.536%
Dioctyl dimethyl ammonium chloride.....	0.768%
Didecyl dimethyl ammonium chloride.....	0.768%
Alkyl (67% C <sub>12</sub> , 25% C <sub>14</sub> , 7% C <sub>16</sub> , 1% C <sub>8</sub> , C <sub>10</sub> , C <sub>18</sub> ) dimethyl benzyl ammonium chloride .....	12.288%

**INERT INGREDIENTS**.....84.640%

(Includes essential oil odor control agents)

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

*See statement of practical treatment and other precautions on side panel.*

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

EPA Reg. No. 42964-25  
EPA Est. 1677-NJ-1 (W), 1677-MN-1 (P), 46275-IL-1 (M)  
SUPERSCRIP REFERS TO FIRST LETTER OF DATE CODE

**KEEP FROM FREEZING**

**Net Weight:** 23.4 lbs.  
**Net Contents:** Approx. 750-1/2 oz.  
water soluble packets

ACCEPTED  
with COMMENTS  
in EPA Letter Dated  
MAR 24 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
has submitted for the pesticide  
registration under EPA Reg. No.  
42964-25



**Position Only**



**0 00 25469 60220 6**

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A-33 Dry has been found effective against Human Immunodeficiency Virus, HIV-1, commonly known as the AIDS virus, on inanimate surfaces when tested according to EPA virucidal test requirements.

A-33 Dry is a complete one-step disinfectant cleaner-fungicide-mildewstat-virucide-odor counteractant which is effective in water up to 500 ppm hardness in the presence of 5% blood serum and soap film residue when used as directed.

Airkem's A-33 Dry is a concentrated, premeasured disinfectant odor counteractant. It is low foaming and phosphate free and scientifically formulated with nonionic synthetic detergents and alkaline builders giving it exceptional cleaning and wetting properties.

A-33 Dry with its cleaning and odor counteraction abilities is recommended for disinfecting and cleaning of floors, walls and other hard nonporous environmental surfaces such as tables, chairs, counter tops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, rubber, linoleum, vinyl, asphalt, porcelain, plastic, metal, glass, or painted, varnished or lacquered surfaces.

Areas Of Use: Hospitals, nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, USDA inspected food processing facilities and other food processing plants, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

When used as directed, this product will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause mal odors.

**DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Prepare a fresh solution daily or when it becomes soiled or diluted.

Disinfection: For hospital disinfecting and cleaning of nonporous hard surfaces, dilute one packet per gallon of warm water. Stir gently for a uniform solution. Apply solution with cloth, mop, sponge, brush, scrubber, coarse spray device, or by soaking, so as to wet all surfaces thoroughly. Allow to remain wet for at least ten minutes. Remove solution and entrapped soil with a clean, wet mop, cloth or wet vacuum pickup. For heavily soiled areas, a pre-cleaning step is required. A-33 Dry may be used at recommended dilution on conductive flooring without any deleterious effect. When used as a hospital disinfectant (1/2 oz. to 1 gallon), A-33 Dry provides 600 ppm of one of the more potent combinations of germicides commercially available to provide effectiveness in up to 500 ppm hard water, and in the presence of protein (5% blood serum) and dried soap film residues.

Effective as a Virucide: On environmental surfaces A-33 Dry kills viruses such as Human Immunodeficiency Virus, HIV-1 (commonly known as the AIDS virus), Influenza A Japan 305/57 (Asian), Parainfluenza 1, Herpes simplex type 1, Herpes simplex type 2\*, Canine distemper\*, Canine parvovirus\*, Feline pneumonitis\*, Feline rhinotracheitis\*, Reovirus type 3, and Vaccinia in the presence of 500 ppm hard water and protein provided as 5% blood serum.

\*Tested in the presence of residual soap scum.

Special instructions for cleaning and decontamination against HIV on surfaces/objects soiled with blood/body fluids.

A-33 Dry is effective as a virucide against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of moderate amounts of organic soil (10% blood serum) when used in health care settings where the potential for the presence of HIV-1 (AIDS virus) on inanimate surfaces is likely.

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 PROCEDURE: 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.

Mold and Mildewcide: Apply to surface, wetting it thoroughly. If not washed or rubbed off, it will control the growth of mold and mildew and the odors caused by them on environmental surfaces for a period of 14 days. To maintain fungistatic control, repeat application in 14 days or when new growth appears.

Fungicide: Kills Trichophyton mentagrophytes (Athletes Foot Fungus), Candida albicans (pathogenic yeast), Geotrichum candidum (isolated from human), and Microsporium canis (human, animal pathogen) in the presence of protein (5% blood serum) and soap scum in 500 ppm hard water when tested according to A.D.A.C. Fungicidal Test. Is an effective fungicide when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities.

Other Organisms: A-33 Dry has been found to be an effective disinfectant against a broad spectrum of bacteria, both gram positive and gram negative organisms under the same severe test conditions listed.

<i>Staphylococcus aureus</i>	ATCC # 8328	<i>Salmonella typhimurium</i>	ATCC # 13311
<i>Salmonella choleraesuis</i>	ATCC # 10708	<i>Vibrio cholerae</i>	ATCC # 25673
<i>Pseudomonas aeruginosa</i>	ATCC # 15442	<i>Corynebacterium diptheriae</i>	ATCC # 11813
<i>Proteus vulgaris</i>	ATCC # 13315	<i>Neisseria gonorrhoea</i>	ATCC # 19424
<i>Escherichia coli</i>	ATCC # 11229	<i>Serratia marcescens</i>	ATCC # 9103
<i>Enterobacter aerogenes</i>	ATCC # 13046	<i>Shigella flexneri</i>	ATCC # 25075
<i>Micrococcus pseudominimus</i>	ATCC # 27573	<i>Mycobacterium parvum</i>	ATCC # 4352
<i>Pseudomonas cepacia</i>	ATCC # 25416	<i>Brevibacterium ammoniagenes</i>	ATCC # 6872
<i>Salmonella gallinarum</i>	ATCC # 9184	<i>Listeria monocytogenes</i>	(clinical isolate)
<i>Salmonella typhi</i>	ATCC # 6538	<i>Proteus mirabilis</i>	ATCC # 9240
<i>Shigella dysenteriae</i>	ATCC # 29026	<i>Staphylococcus mutans</i>	ATCC # 25175
<i>Staphylococcus aureus</i>	ATCC # 14194	<i>Micrococcus luteus</i>	ATCC # 14482
<i>Shigella sonnei</i>	ATCC # 29831	<i>Escherichia coli</i>	ATCC # 29181
<i>Streptococcus faecalis</i>	ATCC # 826	<i>Campylobacter fetus</i>	ATCC # 27374
<i>Streptococcus pyogenes</i>	ATCC # 19615	<i>Haemophilus influenzae</i>	ATCC # 19418
<i>Staphylococcus species</i>	ATCC # 12213	<i>Staphylococcus aureus</i>	HL121 (methicillin resistant)
<i>Staphylococcus epidermidis</i>	ATCC # 12228		
<i>Salmonella enteritidis</i>	ATCC # 13076		
<i>Salmonella choleraesuis</i>	ATCC # 10719		

**Enterococcus faecalis (Vancomycin resistant)**

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 medical devices prior to sterilization or high level disinfection.

A-33 Dry has been tested and determined safe to use on conductive flooring without any deleterious effects.

**PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**

DANGER: Corrosive. Powder causes eye and skin damage. Do not get in eyes, on skin or clothing. Wear chemical goggles and rubber gloves when handling packets. Harmful if swallowed. Remove contaminated clothing and wash before reuse. Avoid contamination of food.

**STATEMENT OF PRACTICAL TREATMENT**

IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF SWALLOWED: Rinse mouth at once; then drink one or two glasses of water. DO NOT INDUCE VOMITING. Never give anything by mouth to an unconscious person.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0626.

In-use solution has a primary skin irritation value of 0.33.

**STORAGE AND DISPOSAL**

Do Not Contaminate Water, Food or Feed by Storage or Disposal.

Storage: Store in a cool, dry place. Do not handle packets with wet hands. Do not remove packets before use. Keep container tightly closed when not in use.

DO NOT FREEZE.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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.

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

ACCEPTED  
with COMMENTS  
in EPA Letter Detail

774909/8900/0596

Made in U.S.A. © 1996

Fabricado en los EE.UU. © 1996

MAR 24 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
49904-25