

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 29 1997

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

Subject: A-33 Dry  
EPA Registration No. 42964-25  
Notification Per PR-Notice 95-2

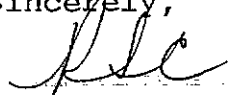
Attn: Ann M. Oxford  
Manager, Regulatory Services

This will acknowledge receipt of your notification regarding two additional sizes to the 1/2 ounce size submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

If you have any questions concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Rebecca S. Cool  
Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7510W)

CONCURRENCES

SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	5-27-97						



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
Other

OPP Identifier Number  
243405

Application for Pesticide - Section I

1. Company/Product Number 42964-25	2. EPA Product Manager B. Cool	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) A-33 Dry	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. Ecolab Center St. Paul, MN 55102 <input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

*8 gallons per 5/14/97 conversation of Anne Oxford*

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
Notification of an additional sizes of 1.5 ounces and 4 ounces. The dilutions will reflect new packet size. Use will be 1.5 ounces in 3 gallons of water and 4 ounces in 12 gallons of water. This notification is consistent with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt. No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
8. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Ann M. Oxford	Title Manager, Regulatory Services	Telephone No. (Include Area Code) (612) 293-2848
2. Signature <i>Ann M. Oxford</i>		3. Title Manager,
4. Typed Name Ann M. Oxford		5. Date Regulatory Services May 13, 1997
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)



# A-33<sup>®</sup> DRY

## 1/2 OZ. PREMEASURED PACKET DETERGENT DISINFECTANT ODOR COUNTERACTANT FOR HOSPITAL AND INDUSTRIAL USE

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

**ACTIVE INGREDIENTS**

Octyl decyl dimethyl ammonium chloride.....	1.536%
Diocetyl dimethyl ammonium chloride.....	0.768%
Didecyl dimethyl ammonium chloride.....	0.768%
Akyl (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%
<b>INERT INGREDIENTS</b> .....	<b>84.640%</b>

(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); 48275-IL-1 (M)  
SUPERScript REFERS TO FIRST LETTER OF DATE CODE

**KEEP FROM FREEZING**

A-33 Dry has been found effective against Human Immuno when tested according to EPA virucidal test requirements. A-33 Dry is a complete one-step disinfectant cleaner-fungic hardness in the presence of 5% blood serum and soap film. Airkem's A-33 Dry is a concentrated, premeasured disinfectant formulated with nonionic synthetic detergents and alkaline b A-33 Dry with its cleaning and odor counteraction abilities is environmental surfaces such as tables, chairs, counter tops tile, rubber, linoleum, vinyl, asphalt, porcelain, plastic, metal Areas Of Use: Hospitals, nursing homes, other health-care industrial facilities, USDA inspected food processing facilities facilities, retail and wholesale establishments.

When used as directed, this product will deodorize surfaces storage areas, and other places where bacterial growth can

**DIRECTIONS FOR USE:**

It is a violation of federal law to use this product in a manner soiled or diluted.

**Disinfection:** For hospital disinfecting and cleaning of no: for a uniform solution. Apply solution with cloth, mop, spot: thoroughly. Allow to remain wet for at least ten minutes. Re: For heavily soiled areas, a pre-cleaning step is required. A-3: deleterious effect. When used as a hospital disinfectant (1:1 combinations of germicides commercially available to provide blood serum) and dried soap film residues.

**Effective as a Virucide:** On environmental surfaces A-33 D the AIDS virus), *Influenza A Japan 305/57 (Asian)*, *Parainflu parvovirus*, *Feline pneumonitis*, *Feline rhinotracheitis*, *Adc* water and protein provided as 5% blood serum. \*Tested in the presence of residual soap scum.

**Special Instructions for cleaning and decontamination:** A-33 Dry is effective as a virucide against HIV-1 (AIDS virus (10% blood serum) when used in health care settings where

**PERSONAL PROTECTION:** When handling items soiled wit: gowns, masks, or eye coverings.

**CLEANING PROCEDURE:** Blood and other body fluids mus: CONTACT TIME: 10 minutes.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other: infectious waste disposal.

**Mold and Mildewcide:** Apply to surface, wetting it thoro: odors caused by them on environmental surfaces for a perio: new growth appears.

**Fungicide:** Kills *Trichophyton mentagrophytes* (Athletes Foo: human), and *Microsporum canis* (human, animal pathogen) i: when tested according to A.O.A.C. Fungicidal Test. Is an effe: rooms, shower and bath areas, exercise facilities.

# airkem

787648/89

print area: 16-3/4"x6"

ink color(s): PMS 355 green and Black

Crop marks are for print area

pa

# BEST AVAILABLE COPY

4095

# 33<sup>®</sup> 3 Y

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/detergent-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, pressurized 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 three (3) gallons 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 3 gallons), 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, Adenovirus type 2, 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, non-porous 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 Mildewicide:** 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 Fungi), *Candida albicans* (pathogenic yeast), *Geotrichum candidum* (isolated from human), and *Microsporum 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.O.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-gram negative organisms

*Staphylococcus aureus*

*Salmonella choleraesuis*

*Pseudomonas aeruginosa*

*Proteus vulgaris*

*Escherichia coli*

*Enterobacter aerogenes*

*Micrococcus tendens*

*Pseudomonas cepacia*

*Salmonella gallinarum*

*Salmonella typhi*

*Shigella dysenteriae*

*Staphylococcus aureus*

*Streptococcus faecalis*

*Streptococcus pyogenes*

*Staphylococcus species*

*Vibrio cholerae*

*Corynebacterium jeikeium*

*Neisseria gonorrhoeae*

This product is not to be used on the human body, either membranes or mucous membranes but which may be used to protect

A-33 Dry has been tested

**PRECAUTIONARY STATEMENT:** Corrosive. P

gloves when handling.

**STATEMENT OF PRACTICE:** IF IN EYES: Flush immediately with plenty of water.

IF ON SKIN: Wash with plenty of water.

IF SWALLOWED: Rinse mouth with water. Do not induce vomiting.

CALL A POISON CENTER OR PHYSICIAN FOR EMERGENCY MEDICAL ADVICE.

In-use solution has a pH of 12.

**STORAGE:** Store in a cool, dry place.

Do Not Contaminate Water.

**Container Disposal:** If not to be used, dispose of in accordance with local regulations.

**Pesticide Disposal:** Pesticides should be disposed of in accordance with local, state, and federal regulations.

**Environmental Control:** Contains phosphorus. Do not release into the environment.

**Canister/packet weight:** 1.0 lb (454 g).

**Empty space at the top:** 1.0 lb (454 g).

## TANTALUM IAL USE

## CHILDREN GER

and Other Precautions on Side Panel

EN INGLES, PREGUNTE A  
INSTRUCCIONES DE USO  
BAJAR CON ESTE

IPY: 45275-JL-1 (M)  
EFFECT OF DATE CODE

JG



Green and Black



Crop marks are for print area

paper: silkscreened canister

# BEST AVAILABLE COPY

50/5

as HIV-1, commonly known as the AIDS virus, on inanimate surfaces

virucide-odor counteractant which is effective in water up to 500 ppm used as directed.

acterant. It is low foaming and phosphate free and scientifically n exceptional cleaning and wetting properties.

d for disinfecting and cleaning of floors, walls and other hard nonporous urses, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, ired, varnished or lacquered surfaces.

ols, colleges, veterinary clinics, animal life science laboratories, od processing plants, dietary areas, office buildings, recreational

behind and under sinks and counters, garbage cans and garbage ors.

with its labeling. Prepare a fresh solution daily or when it becomes

aces, dilute one packet per three (3) gallons of warm water. Stir gently oer, coarse spray device, or by soaking, so as to wet all surfaces and entrapped soil with a clean, wet mop, cloth or wet vacuum pickup. used at recommended dilution on conductive flooring without any ions), A-33 Dry provides 600 ppm of one of the more potent s in up to 500 ppm hard water, and in the presence of protein (5%

s such as Human Immunodeficiency Virus, HIV-1 (commonly known as s simplex type 1, Herpes simplex type 2\*, Canine distemper\*, Canine 2\*, Reovirus type 3, and Vaccinia in the presence of 500 ppm hard

n surfaces/objects soiled with blood/body fluids.

n-porous surfaces in the presence of moderate amounts of organic soil for the presence of HIV-1 (AIDS virus) on inanimate surfaces is likely.

dy fluids, wear personal protection such as disposable latex gloves,

vy cleaned from surfaces and objects before application of disinfectant.

ould be autoclaved and disposed of according to local regulations for

ed or rubbed off, it will control the growth of mold and mildew and the To maintain fungistatic control, repeat application in 14 days or when

ocida albicans (pathogenic yeast), Geotrichum candidum (isolated from se of protein (5% blood serum) and soap scum in 500 ppm hard water e when used on surfaces in areas such as locker rooms, dressing

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 # 6538	<i>Serratia marcescens</i>	ATCC # 9103
<i>Salmonella choleraesuis</i>	ATCC # 10709	<i>Shigella flexneri</i>	ATCC # 25875
<i>Pseudomonas aeruginosa</i>	ATCC # 15442	<i>Klebsiella pneumoniae</i>	ATCC # 4352
<i>Proteus vulgaris</i>	ATCC # 13315	<i>Brevibacterium ammoniagenes</i>	ATCC # 6872
<i>Escherichia coli</i>	ATCC # 11229	<i>Listeria monocytogenes</i>	(clinical isolate)
<i>Enterobacter aerogenes</i>	ATCC # 13048	<i>Staphylococcus aureus</i> HL 121	(methicillin resistant)
<i>Micrococcus tendonegrius</i>	ATCC # 27573	<i>Proteus mirabilis</i>	ATCC # 9240
<i>Pseudomonas cepacia</i>	ATCC # 25416	<i>Salmonella enteritidis</i>	ATCC # 13076
<i>Salmonella gallinarum</i>	ATCC # 9184	<i>Salmonella schottmuelleri</i>	ATCC # 10719
<i>Salmonella typhi</i>	ATCC # 6539	<i>Salmonella typhimurium</i>	ATCC # 13311
<i>Shigella dysenteriae</i>	ATCC # 28026	<i>Shigella sonnei</i>	ATCC # 25931
<i>Staphylococcus aureus</i>	ATCC # 14154	<i>Staphylococcus epidermidis</i>	ATCC # 12228
<i>Streptococcus faecalis</i>	ATCC # 828	<i>Streptococcus mutans</i>	ATCC # 25175
<i>Streptococcus pyogenes</i>	ATCC # 19615	<i>Micrococcus luteus</i>	ATCC # 14452
<i>Staphylococcus species</i>	ATCC # 12715	<i>Escherichia coli</i>	ATCC # 29181
<i>Vibrio cholerae</i>	ATCC # 25873	<i>Campylobacter fetus</i>	ATCC # 27374
<i>Corynebacterium diphtheriae</i>	ATCC # 11913	<i>Haemophilus influenzae</i>	ATCC # 19418
<i>Neisseria gonorrhoea</i>	ATCC # 19424	<i>Enterococcus faecalis</i>	ATCC # 51299
		(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 1-800-328-0026.**

In-use solution has a primary skin irritation value of 0.39.

**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.

Container/packet weight is weighed at production site. Packets may gain/lose weight depending on moisture absorption or evaporation. Empty space at the top of the canister could occur due to compaction/settling during shipping.

cleaned canister

**BEST AVAILABLE COPY**