

11621 42964-5 1041

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 26 1995

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

Attention: Ann M. Oxford
Manager, Regulatory Services

Subject: A-33
EPA Registration No. 42964-5
MOU Compliance Amendment dated December 13, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, will be acceptable provided that you make the labeling change listed below before you release the product for shipping bearing the amended label.

1. Revise disclaimer statement to conform with the wording in PR-Notice 94-4 to read "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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".

A stamped copy of your labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

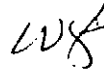
CONCURRENCES

SYMBOL							
SURNAME							
DATE							

10/4

If you have any questions concerning this letter, please
contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

ACCEPTED
WITH COMMENTS
Insecticide, Fungicide, and Rodenticide Act

MAY 26 1995

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

CENTER | PANEL 3

429645

CENTER | PANEL 4

A-33[®]

DETERGENT/DISINFECTANT ODOR COUNTERACTANT FOR HOSPITAL AND INSTITUTIONAL USE

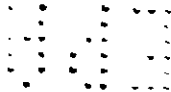
Active Ingredients:
n-alkyl (60% C₁₂, 30% C₁₄, 5% C₁₆, 5% C₁₈) dimethyl benzyl ammonium chlorides ... 3.0%
Inert Ingredients: ... 97.0%

KEEP OUT OF REACH OF CHILDREN WARNING

See back panel for additional precautionary statements and first aid instructions.
EPA Reg. No. 42964-5
EPA Est. 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-
CA-1 (S), 1677-PR-1 (B), 1677-IL-3 (F)
Superscript refers to the first letter of the date code.

Net Contents: 1 Gal. (3.78 liters)

A **Airkem**[®] A Service of **ECOLAB**[®]
PROFESSIONAL PRODUCTS



main panel 27 picas

RECOMMENDED MINIMUM TYPE
IS: 8 PT. REGULAR FOR POS. TYPE
AND 8 PT. BOLD FOR REVERSE PRINTING

TYPE SMALLER THAN 8 PT. MAY RESULT
IN BROKEN, OR FILLED IN CHARACTERS

BEST AVAILABLE COPY

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved or local regulations for infectious waste disposal.
As a Fungicide: Apply use dilution (1:64) to pre-cleaned hard nonporous surface. Wet surface, rubbed off, will control the growth of mold and mildew on environmental surfaces for a period of 30 days. For long-term control, repeat application in 7 days or when new growth appears.
A-33 is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that may come in direct contact with the human body, either into or in contact with the bloodstream or normally sterile sites. A-33 is not to be used on mucous membranes but which does not ordinarily penetrate the blood barrier of the area of the body. A-33 may be used to pre-clean or decontaminate critical or semi-critical instruments or high level disinfection.

ADVERTENCIA: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS PRECAUCIONES ANTES DE TRABAJAR CON ESTE PRODUCTO

PRECAUTIONARY STATEMENTS—HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: May cause eye damage or skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles and rubber gloves. Harmful if swallowed. Remove contaminated clothing and wash immediately.

STATEMENT OF PRACTICAL TREATMENT
IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 15 minutes. 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. Call a poison control center or physician immediately.
FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
Storage: Store at ambient temperature. Keep container tightly closed when not in use. Do not store in areas where food is prepared or stored.
Container Disposal: Do not reuse container. Wrap container and put in trash.
Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved disposal facility.
Airkem Professional Products Division of ECOLAB INC.
Ecolab Center, St. Paul, MN 55102
5105 Tomken Road, Mississauga, Ont., Canada L4W 2K5

23.6 picas

INK COLOR: PMS 300 blue and black PAPER: Clear poly sleeve
COLOR BREAK: Bar and rules in color, all copy and logo print black

CENTER | PANEL 1

CENTER | PANEL 2

A-33 has been found effective against *Human Immunodeficiency Virus*, HIV-1, commonly known as the AIDS virus, on hard, nonporous inanimate surfaces when tested according to EPA virucidal test requirements. A-33 is a balanced formulation combining Airkem's odor counteractants, a non-ionic synthetic detergent, a quaternary ammonium compound, chelating agents and synergizing builders...for effective one-stop cleaning, disinfecting and counteracting of odors in the presence of protein (5% blood serum) and soap film residue when used as directed.

A-33 is intended as a cleaner where disinfection and odor counteraction are also indicated. It is for washing hard, nonporous inanimate environmental surfaces such as glazed porcelain, glazed tile, glass, stainless steel, chrome, rubber, plastic (such as polyolefins, polyesters, ABS, PVC), metal, and does not damage washable hard, nonporous painted, varnished or lacquered surfaces. It can be used on hard, nonporous surfaces such as walls, tables, floors, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, and other similar surfaces. Because A-33 rinses without spotting, it is particularly suitable for linoleum, rubber sealed cork, vinyl and asphalt tile floors. It has rinsing qualities and is a cleaner for marble or terrazzo. A-33 is recommended for use on conductive flooring.

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 malodors.

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 more often when the solution becomes diluted or soiled. Do not mix with other chemicals or products including anionic soaps and detergents. Remove gross filth or heavy soil prior to application of this product.

Mix 2 ozs. of A-33 with one gallon of water—hot or cold. Apply use-dilution with a cloth, mop, sponge, brush, scrubber, powered or mechanical spray device or by soaking. Wet all surfaces thoroughly and allow to remain wet for 10 minutes. No rinse necessary.

As a detergent: A-33's detergent in combination with synergizing builders (a) loosen soil through wetting and penetrating action, (b) suspend insoluble matter in solution, and (c) emulsify oil and grease. Low foaming A-33 leaves surfaces without soil and film.

As a disinfectant: Used as directed (2 ozs. per gal. or 1 to 64) A-33 provides approximately 468 ppm active quaternary. On hard, nonporous, inanimate environmental surfaces, A-33 eliminates a broad spectrum of gram positive and gram negative organisms such as those listed below.

A-33 was tested according to A.O.A.C. Use Dilution procedure at 1:64 against the following organisms in the presence of protein (5% blood serum) and soap scum.

<i>Staphylococcus aureus</i>	ATCC # 6538	<i>Serratia marcescens</i>	ATCC # 9103
<i>Salmonella choleraesuis</i>	ATCC # 10708	<i>Shigella flexneri</i>	ATCC # 25875
<i>Pseudomonas aeruginosa</i>	ATCC # 15442	<i>Klebsiella pneumoniae</i>	ATCC # 4362
<i>Proteus vulgaris</i>	ATCC # 13315	<i>Campylobacter fetus</i>	ATCC # 27374
<i>Escherichia coli</i>	ATCC # 11229	<i>Branhamella ammonigena</i>	ATCC # 6872
<i>Enterobacter aerogenes</i>	ATCC # 13048	<i>Listeria monocytogenes</i>	(clinical isolate)
<i>Micrococcus sedentarius</i>	ATCC # 27573	<i>Escherichia coli</i>	ATCC # 29181
<i>Pseudomonas cepacia</i>	ATCC # 25416	<i>Haemophilus influenzae</i>	ATCC # 19418
<i>Salmonella gallinarum</i>	ATCC # 9184	<i>Micrococcus luteus</i>	ATCC # 14452
<i>Salmonella typhi</i>	ATCC # 6539	<i>Proteus mirabilis</i>	ATCC # 9240
<i>Shigella dysenteriae</i>	ATCC # 29226	<i>Salmonella enteritidis</i>	ATCC # 13076
<i>Staphylococcus aureus</i>	ATCC # 14154	<i>Staphylococcus aureus</i> HL121	(methicillin resistant)
<i>Streptococcus faecalis</i>	ATCC # 678	<i>Salmonella schottmuelleri</i>	ATCC # 10719
<i>Streptococcus pyogenes</i>	ATCC # 19615	<i>Salmonella typhimurium</i>	ATCC # 13311
<i>Staphylococcus species</i>	ATCC # 12215	<i>Shigella sonnei</i>	ATCC # 25931
<i>Vibrio cholerae</i>	ATCC # 25873	<i>Staphylococcus epidermidis</i>	ATCC # 12228
<i>Corynebacterium diphtheriae</i>	ATCC # 11913	<i>Streptococcus mutans</i>	ATCC # 25175
<i>Neisseria gonorrhoeae</i>	ATCC # 19424		

As a Fungicide at 1:64: Kills *Trichophyton mentagrophytes* (Athlete's Foot Fungi), *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 when tested according to A.O.A.C. Fungicidal Test.

As a Mildewicide at 1:64: Kills *Aspergillus niger* which causes "Black Mildew" on contact on environmental surfaces.

As a Virucide at 1:64: On hard, nonporous, inanimate environmental surfaces A-33 kills Human Immunodeficiency Virus, HIV-1 (commonly known as the AIDS virus), Influenza A2 (Achi), Parainfluenza 1/Sender/52, Canine distemper, Feline pneumonitis, Herpes simplex type 1 and type 2, Vaccinia/Laderle, Chorioallantoic, Feline herpesvirus (Feline rhinotracheitis/FC-27), and Rotavirus type 3/Abney* in the presence of protein (5% blood serum) with a 10 minute contact time.

*Tested in the presence of residual soap scum.

KILLS HIV ON PRE-CLEANED 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 potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

Special instructions for cleaning and decontamination against HIV 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 PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant. **CONTACT TIME:** 10 minutes.

BEST AVAILABLE COPY

BACK UP CYLINDER 3 1/2
COPY 3 1/2" -- 20.9 (PICAS/POINTS)

23.6 picas

23.6 picas

1 gallon polyethylene specification with or without back up (cylinder) plate.
SIZE: 18 1/2" x 3 5/8" (back up cylinder) 18 3/8" x 3 1/2" copyart print area.
QUALITY PLATE SPECIFICATION
Dean Ackerman (Quality Platemaking) & Weg (Ecolab) Sept 1987