

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

42964-5

06/04/2003

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUN - 4 2003

Brian Brosdahl
Manager, North American Registrations
Ecolabs Inc
370 n. Wasbasha Street
St. Paul, MA 55102

Subject: A-33
EPA Registration No. 42964-5
Amendment dated: ~~November 14, 2003~~ 3-4-2003
EPA Received date: ~~November 21, 2003~~ 3-6-2003

Dear Mr. Brian Brosdahl,

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

Proposed Amendment

- Response to Agency letter dated February 19, 2003

Conditions

- Under the disinfecting directions add the following to the end of the statement.
"Avoid breathing spray mist"
- Since your product is used in food processing plants and facilities you must add the following guidance to the disinfection directions:

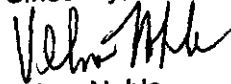
Before use in Federally Inspected Food Processing plants/facilities, all food products and packaging materials must be removed from the room or carefully protected. After disinfection, all food contact surfaces must be thoroughly rinsed with potable water.

General Comment		CONCURRENCES			
MBOL	75106				
RNAME	APeter	A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.			
TE	63103				

If the aforementioned conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions regarding this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch1
Antimicrobial Divisions (7510c)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

A-33

Detergent/Disinfectant/Odor Counteractant For Hospital and Institutional Use

Active Ingredients:	
n-Alkyl (60% C 14, 30% C16, 5% C12, 5% C18)	
Dimethyl Benzyl Ammonium Chlorides.....	3.0%
Inert Ingredients	97.0%
Total	100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 4 - 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
42964-5

KEEP OUT OF REACH OF CHILDREN
DANGER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear chemical goggles, protective clothing, and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated 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 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.

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.

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

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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 builder for effective one-step 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 and does not damage washable hard, non-porous painted, varnished or lacquered surfaces. It can be used on hard, nonporous surfaces such as walls, floors, countertops, bathroom fixtures, sinks, shelves, racks, carts, and the outside of refrigerators. Because A-33 rinses without spotting, it is particularly suitable for linoleum, 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.

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.

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, restaurants, hotels, motels, 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 malorders.

DIRECTIONS FOR USE

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

Clean/Deodorize/Disinfect: 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 (1:64) – hot or cold. Apply use-dilution with a cloth, mop, sponge, brush, scrubber, or coarse spray device. Wet all surfaces thoroughly and allow to remain wet for 10 minutes. No rinse necessary. For sprayer application, spray 6-8 inches from surface, then rub with brush, sponge, or cloth.

As a detergent: A-33's detergents 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 (1:64) A-33 provides approximately 469 ppm active quaternary. On hard, nonporous, inanimate environmental surfaces, A-33 eliminates a broad spectrum of gram positive and gram negative organisms 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 #4352
<i>Proteus vulgaris</i>	ATCC #13315	<i>Campylobacter fetus</i>	ATCC #27374
<i>Escherichia coli</i>	ATCC #11229	<i>Brevibacterium ammoniagenes</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 #29026	<i>Salmonella enteritidis</i>	ATCC #13076
<i>Staphylococcus aureus</i>	ATCC #14154	<i>Staphylococcus aureus H1121</i>	methicillin resistant
<i>Streptococcus faecalis</i>	ATCC #828	<i>Salmonella schottmuelleri</i>	ATCC #10719
<i>Streptococcus pyogenes</i>	ATCC #19615	<i>Salmonella typhimurium</i>	ATCC #13311
<i>Staphylococcus species</i>	ATCC #12715	<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: Use as a disinfectant (1:64), on shower room floors, locker room benches, bath mats, A-33 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 when tested according to A.O.A.C. Fungicidal Test.

As a Mildewcide: Use as a disinfectant (1:64), A-33 kills *Aspergillus niger* which causes "Black Mildew" on contact on hard, nonporous environmental surfaces.

As a Virucide: Use as a disinfectant (1:64) on hard, nonporous, inanimate environmental surfaces. A-33 kills Human Immunodeficiency Virus; HIV-1 (commonly known as the AIDS virus), Influenza A2 (Aichi), Parainfluenza

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1/Sendai/52, Canine distemper, Feline pneumonitis, Herpes simplex type 1 and type 2, Vaccinia/Lederle-Chorioallantoic, Feline herpesvirus (Feline rhinotracheitis)/C-27*, and Reovirus 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.

As a **Mildewstat**: Apply use dilution (1:64) to precleaned hard, nonporous surface. Wet surface thoroughly. If not washed or rubbed off, it will control the growth of mold and mildew on environmental surfaces for a period of 7 days. To maintain mildewstatic control repeat application in 7 days or when new growth appears.

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 (AIDS VIRUS) OF 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 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.

Disinfection and Deodorizing of Animal Housing Facilities (Barns, Kennels, Cages, Hutches, etc): Remove animals and feed from facilities. Remove litter, waste matter, and gross soils. Empty all troughs, rack and other feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Disinfect surfaces as described under **For Disinfection**. Ventilate buildings and other closed spaces. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse. Allow to air dry before reintroducing animals.

STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store at ambient temperature. Keep container tightly closed when not in use. Do not freeze.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal:

(packet) - Do not reuse packet. Wrap packet and put in trash.

(1 gallon or less) - Do not reuse container. Wrap container and put in trash.

(greater than 1 gallon) - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Net Contents:
1 ounce
1 U.S. Gal. (3.78 L)
2 L
2.5 U.S. Gal. (9.45 L)
5 U.S. Gal. (18.9 L)
55 U.S. Gal. (207.9 L)
350 U.S. Gal. (1,323 L)

Airkem Professional Products
Division of Ecolab Inc.
North Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 42964-5
EPA Est.: 303-IN-1(L), 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-OH-1(H), 1677-CA-2(R), 1677-WV-1(V),

Alternate Directions for Use

DIRECTIONS FOR USE

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

For Disinfection: 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 products.

Mix 1 oz. of A-33 with one quart of water (1:32) – hot or cold. Apply use-dilution with a cloth, mop, sponge, brush, scrubber, or coarse spray device. Wet all surfaces thoroughly and allow to remain wet for 10 minutes. No rinse necessary. For sprayer application, spray 6-8 inches from surface, then rub with brush, sponge, or cloth.

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As a Disinfectant: Used as directed (1 oz. per quart or 1:32) A-33 provides approximately 938 ppm active quaternary. On hard, nonporous, inanimate environmental surfaces, A-33 eliminates a broad spectrum of gram positive and gram negative organisms 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:

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*Tested in the presence of residual soap scum.

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