

42964-34

10/01/2004

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 1 2004

Mr. Brian Brosdahl  
Ecolab  
370 N. Wabasha Street  
St. Paul, MN 55102

Subject: A-464-N  
EPA Registration No. 42964-34  
Amendment Date: June 9, 2004  
EPA Receipt Date: June 14, 2004

Dear Mr. Brosdahl,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions.

- Addition of microorganisms, Hepatitis B and Hepatitis C Virus

**Conditions**

Revise the label as follows:

1. Since your product may be used in dietary areas on food contact surfaces such as tables, counters, and food storage shelves, racks, or carts. Under the "Disinfection" directions, add the statements, "Food contact surfaces must be thoroughly rinsed with potable water. Do not use this product to clean or disinfect glassware, dishes, or silverware."
2. Under "Disinfection", revise the statement "rinsing is not necessary" by stating "rinsing is not necessary on non-food contact surfaces."
3. Since your product may be used in toilet areas for deodorization and cleaning, your consumers may infer that this product may be used to disinfect toilet bowls. You must either state "this product is not for use as a toilet bowl disinfectant or add the following directions to your label:

Toilet Bowls: To clean, swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying diluted solution around the bowl and under the rim. Stubborn stains may require brushing.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

To disinfect, first pre-clean to remove heavy soil. Then remove or expel the boil water over the inner trap. Pour 3 oz. Of the diluted solution. Swab bowl completely using a scrub brush or mop, making sure to get under the rim. Let stand for 10 minutes or overnight, the flush.

- 4. Under the "Veterinary Clinics, Animal Care, and Animal Laboratories" directions, add the statement, "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." It should appear after the contact time statement.

General Comments

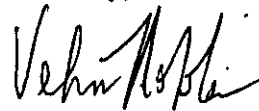
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above 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.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

**A-464-N**

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

3/5

Neutral Detergent/Disinfectant/Fungicide/  
Virucide\*/Odor Counteractant For Hospital  
Veterinary and Industrial Use  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 42964-34

OCT 1 2004

**Active Ingredients:**

Didecyl dimethyl Ammonium Chloride ..... 2.57%  
n-Alkyl (50% C14, 40% C12, 10% C16)  
Dimethyl Benzyl Ammonium Chloride ..... 1.72%

**Inert Ingredients:** ..... 95.71%

**Total:** ..... 100.0%

Effective in hard water up to 400 ppm hardness  
(Calculated as CaCO3) In the presence of 5% blood serum

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

**FOR INDUSTRIAL USE ONLY**

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Corrosive: Causes irreversible eye and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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 (5 gallon or greater):** Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other 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.

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

A-464-N is a neutral pH, "one-step" disinfectant-cleaner and odor counteractant effective in hard waters up to 400 ppm hard water (calculated as CaCO<sub>3</sub>), plus 5% blood serum.

A-464-N with its cleaning and odor counteractant abilities is recommended for disinfecting and cleaning floors, walls, and other hard non-porous environmental surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators exteriors, non-food contact surfaces of coolers, glazed tile, linoleum, vinyl, asphalt, glazed porcelain, plastic (such as polyethylene, polypropylene, polystyrene, polyvinylchloride, polycarbonate and polymethyl methacrylate), metal, glass, or painted, varnished or lacquered surfaces. Will not harm finished floors. Not for use on medical devices or medical equipment surfaces.

**Areas of Use:** Hospitals, nursing homes, other health care-facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, 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.

**DISINFECTION:** For hospital disinfection against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* and cleaning of hard non-porous surfaces use 2 ounces per gallon of water (1:64) up to 400 ppm hardness and 5% blood serum. Apply solution with a wet cloth, mop, brush, scrubber, or by soaking. Allow to remain wet for at least 10 minutes. Remove solution and entrapped soil with a clean, wet mop, cloth or wet vacuum pickup. For heavily soiled areas, a precleaning step is required. Rinsing is not necessary. Prepare a fresh solution at least daily or when solution is visibly dirty.

Effective at 1:64 against the following pathogenic bacteria according to the AOAC Use-Dilution Test modified in the presence of 400 ppm synthetic hard water and 5% blood serum.

<i>Pseudomonas aeruginosa</i>	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus aureus</i> (antibiotic resistant)
<i>Staphylococcus aureus</i>	<i>Proteus vulgaris</i>	<i>Streptococcus faecalis</i> (antibiotic resistant)
<i>Salmonella choleraesuis</i>	<i>Serratia marcescens</i>	<i>Escherichia coli</i> (antibiotic resistant)
<i>Enterobacter cloacae</i>	<i>Shigella flexneri</i>	<i>Klebsiella pneumoniae</i> (antibiotic resistant)
<i>Streptococcus pyogenes</i>	<i>Shigella sonnei</i>	<i>Staphylococcus epidermidis</i> (antibiotic resistant)
<i>Streptococcus faecalis</i>	<i>Salmonella typhi</i>	<i>Pseudomonas aeruginosa</i> (antibiotic resistant)
<i>Enterobacter aerogenes</i>	<i>Proteus mirabilis</i>	<i>Fusobacterium necrophorum</i>
<i>Salmonella typhimurium</i>	<i>Escherichia coli</i>	<i>Enterococcus faecalis</i> (vancomycin resistant)

**FUNGICIDIAL:** Fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) on surfaces in locker rooms, dressing rooms, shower and bath areas and exercise facilities. Fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) and *Candida albicans* according to the AOAC Fungicidal Test modified in the presence of 400 ppm hard water and 5% blood serum at 1:64.

**VIRUCIDAL:** Virucidal against HIV-1 (AIDS virus), HBV (Hepatitis B virus), HCV (Hepatitis C virus), Adenovirus type 4, Herpes simplex Type 1 and Type 2, Influenza A2/Hong Kong, Rubella, Vaccinia, Feline picornavirus (Calicivirus), Feline leukemia, Canine distemper, Rabies, Porcine parvovirus, Pseudorabies, and Infectious bronchitis (Avian IBV) according to the Virucidal Qualification Test, modified in the presence of 400 ppm hard water and 5% blood serum at 1:64.

**KILLS HIV (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C VIRUS) 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 HIV-1 (AIDS virus) or HBV (Hepatitis B Virus) or HCV (Hepatitis C Virus). A-464-N is effective as a virucide against HIV-1 (AIDS Virus) at 2 ounces per gallon of water on hard, non-porous surfaces in the presence of 400 ppm hard water.

5/5

A-464-N Label

06/09/04

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV OR HCV 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 to guard against contact with these fluids.

**Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

**Contact Time:** HIV-1 is inactivated after a contact time of 4 minutes at room temperature (20-25°C).

HBV and HCV are inactivated after a 10 minute contact time. Use a ten minute contact time for all other bacteria, fungi, and viruses claimed (listed on label).

**Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved or incinerated and disposed of according to local regulations for infectious waste disposal.

**For Use in Veterinary Clinics, Animal Care, and Animal Laboratories:**

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries, etc.. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc.. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and water and rinse with water. Saturate surfaces with undiluted product and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Containers: 1 gallon or less:

**STORAGE & DISPOSAL**

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use. Do not reuse container. Wrap container and discard in the trash.

Containers: greater than 1 gallon:

**STORAGE & DISPOSAL**

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

**PESTICIDE STORAGE:** Store this product in a cool, dry area, away from direct sunlight and heat.

**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 DISPOSAL:** Do not reuse container. 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 U.S. gal. (3.78 L)
1 L
1.3 L
2 L
2.5 U.S. gal.
5 U.S. gal. (18.9 L)

EPA Reg. No. 42964-34

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-PA-1 (B), 1677-OH-1 (H), 303-IN-1 (L), 1677-CA-2 (R), 1677-WV-1 (V).

Superscript refers to first letter of date code.

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