

MAR 24 1997  
 EPA

AIRKEM PROFESSIONAL PRODUCTS  
 Division of Ecolab, Inc.  
 Ecolab Center  
 St. Paul, MN 55102

ATTN: Ann Oxford

SUBJECT: A-456-N  
 EPA Registration No. 42964-31  
 Amendment of August 28, 1996

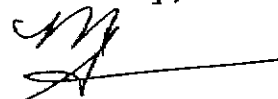
Dear Ms. Oxford:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A stamped copy of the labeling is enclosed for your records.

The submitted efficacy data developed by the AOAC Use-Dilution test method and the AOAC Phenol Coefficient Test Method appear adequate to support effectiveness of the product as a disinfectant against Enterococcus faecalis ATCC 51299 (Vancomycin resistant strain) when used on hard, non-porous surfaces in the presence of 5% blood serum and 400 ppm AOAC hard water in a 1/2 oz per gallon dilution at time of ten minutes at 20 ° C.

If you have any further questions, please contact Ms. Barbara Pringle at (703) 305-6484.

Sincerely,



Marshall Swindell  
 Acting Product Manager 31  
 Antimicrobial Program Branch  
 Registration Division (7505C)

CONCURRENCES							
SYMBOL	7505W						
SURNAME	Pringle						
DATE	3-24-97						

ACCEPTED  
With COMMENTS  
EPA Letter Date

RECD EPA/OPP/DPD1

MAR 24 1997

'96 SEP -4 AIO :00

Under the Federal Insecticide, Fungicide, and Herbicide Act, registration for this product is required under FIFRA. EPA Reg. No. 42-964-34

CENTER PANEL 3

CENTER PANEL 4

# A-456-N<sup>®</sup>

**NEUTRAL DETERGENT-DISINFECTANT-FUNGICIDE-VIRUCIDE\*-ODOR COUNTERACTANT FOR HOSPITAL, VETERINARY AND INDUSTRIAL USE**

Effective in hard water up to 400 ppm hardness (calculated as CaCO<sub>3</sub>) in the presence of 5% blood serum

Active Ingredients:

Didcyl dimethyl ammonium chloride	9.22%
n-Alkyl (50% C <sub>12</sub> , 40% C <sub>14</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride	6.14%
Inert Ingredients:	84.64%

**KEEP OUT OF REACH OF CHILDREN**

## DANGER

See Side Panel for Additional Precautionary Statements and First Aid Instructions.

**FOR INDUSTRIAL USE ONLY**

Net Contents: 1 Gal. (3.78 liters)



### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER: CORROSIVE:** Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear safety glasses or goggles and rubber gloves when handling the product concentrate. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### 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 FOR EMERGENCY MEDICAL INFORMATION. CALL TOLL-FREE 1-800-328-0028**

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

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

### STORAGE AND DISPOSAL

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

**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 empty containers. Wrap container and put in trash.

Airkem Professional Products, Division of ECOLAB INC.  
Ecolab Center, St. Paul, MN 55102  
5105 Tomlinson Road, Mississauga, Ont. Canada L4W 2K5

700203/8609/1094  
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main panel 27 picas

23.8 picas

RECOMMENDED MINIMUM TYPE  
IS: 8 PT. REGULAR FOR POS. TYPE  
AND 6 PT. BOLD FOR REVERSE PRINTING

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

INK COLOR: **PMS 485 red and black** PAPER: **Clear poly sleeve**  
COLOR BREAK: Bar and rules in color, all copy and logo print black

2/2/97

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

MAR 24 1997

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
(FIFRA), the EPA has received  
a petition from the manufacturer  
42-964-31

CENTER | PANEL 1

CENTER | PANEL 2

BACK UP CYLINDER 3 1/4  
COPY 3 1/4" — 20.9 (PICAS/POINTS)

A-456-N is a neutral pH, "one-step" disinfectant-cleanser and odor counteractant effective in hard waters up to 400 ppm (calculated as CaCO<sub>3</sub>), plus 5% blood serum.

A-456-N with its cleaning and odor counteraction abilities is recommended for disinfecting and cleaning of floors, walls and other hard non-porous environmental surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, rubber, linoleum, vinyl, asphalt, glazed porcelain, plastic (such as polyethylene, polypropylene, polystyrene, polyvinylchloride, polycarbonate, and polymethyl methacrylate), metal, glass, or painted, varnished or lacquered surfaces. Safe for use on all finished floors.

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 anal 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 1/2 ounce per gallon of water (1:256) up to 400 ppm hardness and 5% blood serum. Apply solution with a 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 pre-cleaning step is required. Rinsing is not necessary.

Effective at 1:256 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>	

*Enterococcus faecalis* (vancomycin resistant)

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" copy/print area.  
QUALITY PLATE SPECIFICATION  
Dean Ackerman (Quality Platemaking) & Weg (Ecolab) Sept. 1987

Fungicidal against *Trichophyton mentagrophytes* and *Candida albicans* according to the AOAC Fungicidal Test, modified in the presence of 400 ppm hard water and 5% blood serum at 1:256.

\*Virucidal against HIV-1 (AIDS virus), Adenovirus type 4, Herpes simplex Type 1 and Type 2, Influenza type A/Hong Kong, Rubella, Vaccinia, Canine parvovirus, 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 a 1:256.

#### SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

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 the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS). A-456-N is effective as a virucide against HIV-1 (AIDS virus) at 1/2 ounce per gallon of water on hard, non-porous surfaces in the presence of 400 ppm hard water 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 to protect 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: 4 minutes at room temperature (20-25°C). Use a ten minute contact time for disinfection against 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.

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.

For service or additional information, call 1-800-247-8282.

EPA Reg. No. 42864-31

EPA Est. 1677-IL-2 (L), 1677-MJ-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 first letter of date code.

23.6 picas

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