

Reg # 42964-30 111 31 104
 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-428-N
 EPA Registration No. 42964-30
 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 changes listed below before you release the product for shipping bearing the amended label.

1. Submit revised Confidential Statement of Formula (CSF) as directed in the Agency letter dated July 15, 1993.
2. 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							

204

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)

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 26 1995

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

42964-3

CENTER | PANEL 3

CENTER | PANEL 4

A-428-N

NEUTRAL DETERGENT-DISINFECTANT-FUNGICIDE-VIRUCIDE[®]-ODOR
COUNTERACTANT FOR HOSPITAL VETERINARY AND INDUSTRIAL USE

Effective in hard water up to 400 ppm hardness (calculated as CaCO₃) in the pres-
ence of 5% blood serum

Active Ingredients:

Didecyl dimethyl ammonium chloride	4.61%
n-Alkyl (50% C ₁₂ , 40% C ₁₄ , 10% C ₁₆) dimethyl benzyl ammonium chloride	3.07%
Inert Ingredients:	92.32%

**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 damage and severe skin irritation. Do not get in eyes. Wear chemical goggles, rubber gloves and protective clothing when handling the product swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 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 or give anything by mouth to an unconscious person.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY FOR EMERGENCY MEDICAL INFORMATION. CALL TOLL-FREE 1-800-328-0025

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

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS MEDIDAS 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 mix, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use of the instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Unit 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 Tomken Road, Mississauga, Ont., Canada L4W 2X5

BEST AVAILABLE COPY

main panel 27 picas

23 6 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

INK COLOR: PMS 131 gold and black PAPER: Clear poly sleeve
COLOR BREAK: Bar and rules in color, all copy and logo print black

4
4
4

CENTER | PANEL 1

CENTER | PANEL 2

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

A-428-N is a neutral pH, "one-step" disinfectant-cleanser and odor counteractant effective in hard waters up to 400 ppm hard water (calculated as CaCO₃), plus 5% blood serum.

A-428-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 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 1 ounce per gallon of water (1:128) up to 400 ppm hardness and 5% blood serum. Apply solution with a cloth, mop, brush, scrubber, or by soaking to wet all surfaces thoroughly. 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. Prepare a fresh solution daily or when solution becomes visibly dirty.

Effective at 1:128 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>Protus 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> | |

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 1:128.

*Virucidal against HIV-1 (AIDS virus), Adenovirus type 4, Herpes simplex Type 1 and Type 2, Influenza A2/Hong Kong, Rubella, Vaccinia, Canine parvovirus, 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 1:128.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care setting 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 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: 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.

A-428-N 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. A-428-N 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 1-800-247-5362.

EPA Reg. No. 429C-30

EPA Est. 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MI-1 (P), 1677-CA-1 (S), 1677-PR-1 (B), 1677-IL-3 (F)

Superscript refers to first letter of date code.

BEST AVAILABLE COPY

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" copy/print area.

QUALITY PLATE SPECIFICATION

Dean Ackerman (Quality Platemaking) & Weg (Ecolab) Sept. 1987