

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

NOV 09 1999

Subject: A428-N
EPA Registration No. 42964-30
Received Date of August 12, 1999

Attn: Ann M. Oxford
Manager, Regulatory Services

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable.

The findings are:

1. Certified limits for both the basic and alternate formulations have been revised and are acceptable.
2. Suggested changes have been incorporated into the revised label. More specifically, "bedframes" were deleted and the statement "Not for use on medical devices or medical equipment surfaces" was added to the label text.
3. The Confidential Statement of Formula (CSF) complies with PR Notice 91-2 in that the product label and CSF agree.
4. Basic Formulation CSF correctly shows nominal concentration (n) for amine oxide (40%) as 1.6%. The Alternate Formulation CSF should in a similar manner show the (n) for amine oxide.
5. The certified limits for amine oxide should be based on the (n) and not the formula weight of amine oxide in both the basic and alternate formulations.
6. In the alternate formulation, certified limits for Tetrasodium EDTA should be based on the (n) of 1.13% and not the formula weight percentage of 2.82%.

The Basic and Alternate Confidential Statements of Formula for A-428-N and the product label are acceptable. Comments given under Findings should be incorporated into both CSFs by you at the earliest convenience. According to ~~CONFIDENTIAL~~ Manual (2nd Edition), Chapter 6, the

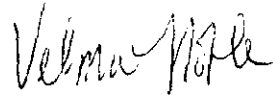
SYMBOL	7510W						
SURNAME	S. Jones						
DATE	11-4-99						

ingredient statement should be revised to reflect the following:

Active Ingredient:
Inert Ingredient:
Total: 100%

Please make the above changes to the label. A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment. If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510W)

airkem
brand

DISINFECTANT

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 CaCO₂) in the presence of 5% blood serum

ACTIVE INGREDIENTS:

Didecyl Dimethyl Ammonium Chloride	4.61%
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 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

ECOLAB[®]

Net Contents: 1 U.S. gal/3.78 L

main panel 25.6 picas

Style Sheets & Art Library available for this Master.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes eye damage and severe skin irritation. Do not get in eyes, on skin or on clothing. Wear chemical goggles, rubber gloves and protective clothing 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: 1-800-328-0026.

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.

24.6 picas

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

NOV - 9 1999

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

7/27
42964-30

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COPY 4 1/16—24.6 (PICAS/POINTS)

A-428-N is a neutral pH, "one-step" disinfectant-cleaner 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, shelves, racks, carts, refrigerators, coolers, 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. Safe for use on all 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 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 precleaning 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>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)

24.6 picas

PFD Master Format: 1 gal poly/disinf/epa 2/99 Quark XPress
 1 gallon polyethylene specification with or without back up (cylinder) plate.
 SIZE: 19" x 4 7/16" (back up cylinder) 18 5/8" x 4 1/16" copy/art print area.

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*, *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.

For service or additional information, call 1-800-247-5362.

EPA Reg. No. 42964-30

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-OH-1 (H), 303-IN-1 (L), 1677-CA-2 (R).

Superscript refers to first letter of date code.

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

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25.6 picas

Inks: PMS 3258 aqua, 5483 blue/gray & Black
 Cylinder backup color: white
 Form number: 700187/89

ACCEPTED
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 in EPA Letter Dated:

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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 42964-30

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