

Brian C. Brosdahl
Manager, North American Registrations
Ecolab Inc.
370 N. Wabasha Street

St. Paul, MN 55102

JUL 03 2002

Subject: Amendment per FIFRA
A-428-N
EPA Registration No. 42964-30
Application Dated: March 19, 2002
EPA Received Date: April 4, 2002

Dear Mr. Brosdahl:

The following amendment, submitted in connection with registration under 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable subject to the conditions listed below.

Proposed Amendment

- Submission of Alternate CSFs to change the concentration of the Active Ingredients
- Submission of Label Changes

Product Chemistry

1. The Confidential Statements of Formula for the Basic and Alternate Formulations 1 and 4, formulated with the 50% concentrated active source, are acceptable to the Agency.
2. The Confidential Statements of Formula for the Alternate Formulations 2, 3, and 5, formulated with the 80% concentrated active source, are acceptable to the Agency.

Efficacy

This increase in the active ingredient requires submission of confirmatory efficacy data to the Agency for review.

Label Comments

1. Revise the Precautionary Statements to read:
DANGER. Corrosive. Causes irreversible eye damage 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 the ~~hands~~ **CONCERNED** soap and water after handling. Remove

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contaminated clothing and wash before reuse.

2. Revise the First Aid Statements to include the phrase:
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
3. Revise the Environmental Hazards Statement to read:
Environmental Hazards (5 gallons 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 the 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.
4. Revise the hard, non-porous environmental surface "tile" to read "*glazed tile*," and "refrigerators, coolers " to read "*refrigerator exteriors and non food contact surfaces of coolers*, "
5. Revise the statement "Safe for use on all finished floors." to read "Will not harm finished floors."
6. Since this product includes the use sites "veterinary clinics and animal life science laboratories", revise the Directions for Use to include the following directions:
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.
7. Revise the Disinfection directions of the Directions for Use section to include the following statement:
Prepare a fresh solution at least daily or when solution becomes visibly dirty.
8. Revise the Fungicidal Directions to read:
FUNGICIDAL: Fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) in areas such as 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 1:128.
9. Move the heading "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS." to be placed before the phrase "**Personal protection**:...contact with these fluids."

- 10. Revise the section "KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS" by placing the statement "A-428-N is effective as a virucide against HIV-1 (AIDS Virus) at 1 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." with the Virucidal Directions under the Directions for Use section.
- 11. Since this product is sold in containers ranging from 1 gallon to 5 gallons, you must revise your storage and disposal instructions accordingly:

Containers 1 gallon or less:

Storage and 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 and Disposal

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

Pesticide Storage: Store this product in a cool, dry area, away from direct sunlight and heat.

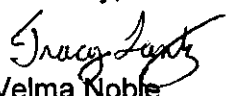
Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact you State Pesticide or Environmental Control Agency, or Hazardous 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 a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

General Comments

A stamped copy of the label is enclosed for your records. Please submit one (1) final printed label before releasing this product for shipment. Should you have any questions regarding this letter, please contact me at 703-308-6233.

Sincerely,

for 
Velma Noble

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

A-428-N

4/6

Neutral Detergent/Disinfectant/Fungicide/ Virucide*/Odor Counteractant For Hospital, Veterinary and Industrial Use

Active Ingredients:

Didecyl dimethyl Ammonium Chloride 5.15%
n-Alkyl (50% C14, 40% C12, 10% C16)
Dimethyl Benzyl Ammonium Chloride 3.43%

Inert Ingredients: 91.42%

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**

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL - 3 2002

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

42964-30

FOR INDUSTRIAL USE ONLY

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 and wash 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

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 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 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-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 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, 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, colleges, veterinary clinics and animal life science laboratories, industrial facilities, dietary areas, food service, recreational facilities, retail and wholesale establishments.

AOAC APPROVED
in EPA Letter Dated:

JUL - 3 2002

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.

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

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 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.

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)

FUNGICIDAL: 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: *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.

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

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). A-428-N is effective as a virucide against HIV-1 (AIDS Virus) at 1 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 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.

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:

(1 gal., 1 L, 1.3 L, 2 L) - Do not reuse container. Wrap container and put in trash.

(2.5 gal, 5 gal.) - 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)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL - 3 2002

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

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), 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