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1677-96 6/27/2002 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 2 7 2002

Brian C. Brosdahl Manager, North American Registrations Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102

Subject: Amendment per FIFRA Oasis 499 EPA Registration No. 1677-96 Application Dated: March 13, 2002 EPA Received Date: March 29, 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 with the comments listed below.

# **Proposed Amendment**

- Clarification of the label text pursuant to the Agency letter dated November 5, 1999
- Update First Aid Statements pursuant to PR Notice 2001-1
- Addition of Environmental Hazards text to the master label

# Label Comments

- 1. Revise the Precautionary Statements to read: **DANGER**: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, faceshield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.
- Revise the "IF SWALLOWED" section of the First Aid Statements to read: IF SWALLOWED: Call a poison control center or doctor *immediately* 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.

CONCURRENCES									
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EPA Form 1320-1A (1/90)		Printed on Recycled Paper			OFFICIAL FILE CORV				

- 3. Revise the Environmental Hazards Statement to read: 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 Disinfection directions of the Directions for Use section to read: Disinfection/Cleaning/Deodorizing - For heavily soiled areas, a preliminary cleaning is required. To disinfect hard, non-porous surfaces, add 0.5 oz. per gallon of water by thoroughly wetting the surfaces with a cloth, mop, sponge, or sprayer. Treated surfaces must remain wet for 10 minutes. Wipe with a dry cloth, sponge, or mop or allow to air dry. Rinse all surfaces that come in contact with food such as counter tops and tables with potable water before reuse. Do not use on utensils, glassware, dishes or cookware. The activity of this product has been evaluated in the presence of 5% serum and

400 ppm hard water by the AOAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by: (This statement is to be followed by the various organisms that this product mitigates.)

- Revise the Directions for Use section to include the statement:
  "Food Processing Industry: Before use in food processing plants, all food products and packaging materials must be removed from the room or carefully protected." This statement is to be placed on the product label following the Disinfection/Cleaning/Deodorizing directions.
- 6. Since this product is sold in containers ranging from 1 gallon to 55 gallons, you must revise your storage and disposal instructions accordingly. (Refer to PR Notice 83-3 and 84-1)

Containers 1 gallon or less:

### Storage and Disposal

Store in original container in areas inaccessible to children and persons unfamiliar with the product. Do not reuse container. 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 in original container in areas inaccessible to children and persons unfamiliar with the product. Keep from freezing. **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**: 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.

7. The Reusable Container Statements are to follow the Storage and Disposal Statements for containers greater than one gallon.

### **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,

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

Oasis 499 label

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# **OASIS 499**

### Germicidal Non-Acid Cleaner Concentrate

Disinfectant - Cleaner - Sanitizer - Fungicide - Mildewstat - Virucide\* - Deodorizer

#### **Active Ingredients**

Octyl decyl dimethyl ammonium chloride	6.5.10%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium chloride	
Alkyl ( 50% C <sub>14</sub> , 40% C <sub>12</sub> , 10% C <sub>16</sub> ) dimethyl benzyl ammonium chloride	
Inert Ingredients	

# KEEP OUT OF REACH OF CHILDREN DANGER

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

### **PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER:** Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, faceshield, or safety glasses), clothing and rubber gloves. Harmful if swallowed and/or absorbed through skin. 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

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.

### FOR HOSPITALS, INSTITUTIONAL AND INDUSTRIAL USE

Cross-contamination is a major housekeeping concern not only in hospitals, but in schools, hetels, restaurant and the food processing industry. This product has been formulated to aid in the reduction of cross-contamination in these areas. This product is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria, is virucidal, fungicidal and will prevent the growth of **incleant fund** dew and their odors when used as directed. This product is an effective one-step sanitizer-cleaner for withon the Contact surfaces.

JUN 2 7 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the peuticide, registered under EPA Reg. No 1677-96 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. This product is a proven "one-step" disinfectant-cleaner-sanitizer-fungicide-mildewstat-virucide-deodorizer which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination.

Apply this product to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, counter tops, sinks, glazed tile, glazed porcelain with a cloth, mop or hand spray bottle so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visibly dirty.

**Disinfection** - To disinfect hard, non-porous surfaces, add 0.5 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. The activity of this product has been evaluated in the presence of 5% serum and 400 ppm hard water by the AOAC use dilution test and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by:

Pseudomonas aeruginosa	Pseudomonas cepacia			
Staphylococcus aureus	Salmonella schottmuelleri			
Salmonella choleraesuis	Streptococcus faecalis			
Escherichia coli	Shigella dysenteriae			
Streptococcus pyogenes	Brevibacterium ammoniagenes			
Klebsiella pneumoniae	Salmonella typhi			
Enterobacter aerogenes	Serratia marcescens			
Staphylococcus aureus HL121 (methicillin resistant)				

**Fungicidal Performance** - this product is an effective fungicide against *Trichophyton mentagrophytes* (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas, exercise facilities at 0.5 oz/gallon.

Mold and Mildew Control - At 0.5 oz/gallon, this product will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, non-porous surfaces (as indicated in direction for use). Allow to dry on surface and repeat when mildew growth returns.

\*Virucidal Performance - At 0.5 oz/gallon use-level, this product was evaluated in the presence of 5% serum and 400 ppm hard water for a contact time of 10 minutes at room temperature (20-25 deg C) against the following viruses found on hard non-porous environmental surfaces: HIV-1 (AIDS virus), Influenza A/Brazil, Herpes simplex type 1, Herpes simplex type 2 and Vaccinia.

\*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 the transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

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

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and object: before application of disinfectant.

CONTACT TIME: Leave surfaces wet for 10 minutes.	• •	··· · ·
DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids should be an	itoclaved and dis	posed of
according to federal, state and local regulations for our periods waste disposal.	••	• • •
with COMMENTS	•••••	<b>* =</b> u v
in EPA Letter Dated;	* * * * *	•
JUN 27 2002		• • •

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesicide, registered under EPA Reg. No. 16 77-96 Oasis 499 label

Sanitizing Non-Food Contact Surfaces (such as floors, walls, tables) - At 0.5 oz/5.5 gallon use-level, this product is an effective sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds.

For service or additional information, call 1-80035-CLEAN (352-5326)

#### **STORAGE & DISPOSAL**

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL **PESTICIDE STORAGE:** Keep from freezing.

**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 gl) Do not reuse empty container. Wrap container and put in trash.

(2.5, 5, 15, 55 gl plastic) 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.

(Reusable container statement) Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser [specific equipment such as "Dynamix dispenser" can be named to replace "dilution dispenser".] Dispenser will automatically dilute a sanitizer [or disinfectant] solution. Remove concentrate label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

Net Contents:

1 gallon (3.78 l) 2.5 gallons (9.45 l) 5 gallons (18.9 l) 15 gallons (56.8 l) 55 gallons (208.8 l)

EPA Reg. No. 1677-96 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-CA-2 (R), 1677-OH-1 (H), 1677-WV-1 (V), 1677-CA-1 (S) The superscript refers to the first letter of the date code.

Ecolab Inc. 370 Wabasha Street N. St. Paul, MN 55102

ACCEPTED with COMMENTS in EPA Letter Dated:

JUN 27 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as <sup>3</sup> amended, for the pesuicide, registered under EPA Reg. No. 16 77-96