

1677-21

2/3/2003

Page 184

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 3 2003

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

Subject: Mikro-Quat
EPA Registration No. 1677-21
Application Date: 11/04/02
Receipt Date: 11/07/02

Dear Mr. Brosdahl:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable:

Addition of the medical device MOU language to the label

GENERAL COMMENTS

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial division)7510C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	Z. Jones						
DATE	1-29-03						

274

Mikro-Quat

Detergent•Germicide•Deodorizer

Active Ingredient:

Alkyl (50%C14, 40%C12, 10%C16)
Dimethylbenzyl Ammonium Chloride 9.5%
Inert Ingredients*: 90.5%
Total: 100.0%

*Active as cleaning and buffering agents.

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes or on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wear protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (only required on containers greater than 5 gallons): 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.

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.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY
FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

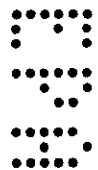
Detergent - Germicide - Deodorizer - Staphylocidal - Pseudomonacidal - Fungicidal - Cleans, Disinfects and deodorizes in one Operation - Pleasant Fragrance - Economical to Use

Mikro-Quat has been found effective against Human Immunodeficiency Virus Type 1 (Commonly known as the Aids virus) on inanimate surfaces when tested according to EPA virucidal testing requirements.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 3 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1677-21



374

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For disinfection, apply *Mikro-Quat* to walls, floors, sinks, counter tops, hard nonporous surface furnishings and equipment with cloth, mop or hand spray bottle. Wet surfaces thoroughly and allow to remain wet for at least 10 minutes. Preliminary removal of gross soil is required. Prepare fresh solution daily or more often if the solution becomes diluted or soiled.

Use *Mikro-Quat* in hospitals (suitable for conductive floors), nursing homes, food service facilities, schools and animal research facilities.

Light-Duty Cleaning and Sanitizing - Non-Food contact Surfaces

Use 1/3 oz. *Mikro-Quat* per gal. (235 ppm) of warm or hot water. Allow 1 minute contact time. At this concentration the product is effective in the presence of protein (5% blood serum) against *Escherichia coli* 0157:H7, *Staphylococcus aureus*, and *Enterobacter aerogenes*.

Combination Disinfection and Cleaning

Use 2/3 oz. *Mikro-Quat* per gal. of water (470 ppm). Allow 10 minutes contact time. Remove solution and entrapped soil with clean wet mop, cloth or wet vacuum pickup.

Mikro-Quat has been found effective against the following bacteria at 2/3 oz. per gallon in the presence of protein (5% blood serum):

- | | |
|---|--|
| <i>Staphylococcus aureus</i> | <i>Escherichia coli</i> |
| <i>Salmonella typhosa</i> | <i>Staphylococcus aureus</i> HL121 (Methicillin resistant) |
| <i>Trichophyton mentagrophytes</i> | <i>Vibrio cholerae</i> |
| <i>Clostridium difficile</i> (vegetative form) | <i>Pseudomonas aeruginosa</i> |
| <i>Enterococcus faecalis</i> (vancomycin resistant) | <i>Proteus vulgaris</i> |
| <i>Salmonella choleraesuis</i> | |

Virucidal: Disinfects the following viruses on inanimate environmental surfaces at the 1:200 use dilution (2/3 oz. per gal.):

- | | | |
|------------------------|-------------------------|------------------------|
| HIV-1 (AIDS virus) | Vaccinia | Herpes Simplex, type 1 |
| Influenza A2/Hong Kong | Newcastle Disease virus | Adenovirus type 3 |

This product 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-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.

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

CONTACT TIME: 10 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

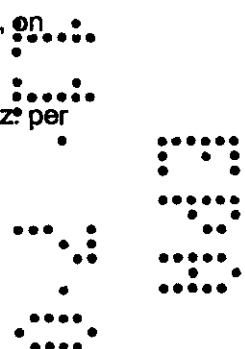
KILLS PATHOGENIC FUNGI (*T. mentagrophytes*), the agent that causes Athlete's foot fungus, on inanimate surfaces such as shower room floors, bath mats, and locker room benches at the recommended use concentration of 2/3 oz. per gallon of water (470 ppm).

KILLS MILDEW FUNGI on inanimate surfaces at the recommended use concentration of 2/3 oz. per gallon of water (470 ppm).

ACCEPTED WITH COMMENTS
in EPA Letter Dated:

FEB 3 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 16 77-21



484

DO NOT MIX WITH ANYTHING BUT WATER

DILUTION TABLE

ppm active quaternary	235	470	700
oz. per gal. water	1/3	2/3	1
dilution equivalent	1:400	1:200	1:128

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 devices prior to sterilization or high-level disinfection.

STORAGE & DISPOSAL

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

Pesticide Storage: Store in original container in a locked storage area. Store at ambient temperature. Keep container tightly closed when not in use. Do not freeze.

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 gallon): Do not reuse container. Wrap container and put in trash.

(15 gallon, 55 gallon): 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.

Net Contents: 1 U.S. Gal. (3.78 L) 15 U.S. Gal. (56.7 L) 55 U.S. Gal. (208 L)

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

EPA Reg. No. 1677-21
 EPA Est.: 1677-MN-1 (P), 1677-IL-2 (J)
 1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H)
 1677-IL-2 (J), 1677-PR-1 (B), 1677-CA-1 (S)
 1677-NJ-1 (W), 1677-GA-1 (M), 1677-WV-1 (V)
 Superscript refers to first letter of date code

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

FEB 3 2003

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No. 1677-21

