

1677-21

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 5 2008

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

Subject: **Mikro-Quat**
EPA Registration Number 1677-21
Application Dated September 18, 2008
Received Date September 19, 2008

Dear Ms. Schulz:

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

Proposed Labeling:

° Per Agency letter dated June 17, 2008

Conditions:

Revise the label as follows:

1. On page 2, revise the HIV "Personal Protection" instructions by deleting the term, or and replace with the term, "**and**," such that the end of the statement reads "and eye coverings."
2. On page 3, revise the HIV "Disposal Infectious Material" instructions by deleting the term, "should" and replace it with "**must**" such that the statement complies with PR Notice 2000-5, Mandatory Labeling.
3. On page 3, revise the "Kills Pathogenic Fungi" and "Kills Mildew Fungi" directions by deleting the term, "recommended" so that the statement is in compliance with PR Notice 2000-5. Also, delete "allow 10 minute contact time" and state "**Follow the disinfection directions.**"
4. Since your product is sold in one gallon container, the label must support "Storage & Disposal" for the smaller container size per PR Notice 84-1 and label manual. Add the following instructions to the "Storage and Disposal" section:

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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(Containers 1 gallon or less)

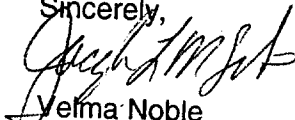
Storage and Disposal: Store in original container in locked storage area. Store at ambient temperature. Keep container tightly closed when not in use. Do not reuse or refill this container. Clean container promptly after emptying. Wrap (container) and put in trash or offer for recycling or reconditioning if available

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy 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 Drusilla Copeland at (703) 308-6224 or Velma Noble on (703) 308-6233.

Sincerely,



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

Enclosure: Stamped label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Mikro-Quat

Detergent•Germicide•Deodorizer

ACCEPTED
with COLLETS
in 1994 for use as a disinfectant

DEC 5 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA registration number 1077-21

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

(Note to reviewer – The following is optional marketing language)

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.

DIRECTIONS FOR USE

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

Use Mikro-Quat on washable, hard, non-porous surfaces of: glazed ceramic, glazed enamel, glazed porcelain, laminated surfaces, metal, plastic, stainless steel

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.

To Clean and Deodorize

Use 1/3 oz. Mikro-Quat per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

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

Use 1/3 oz. *Mikro-Quat* per gal. of warm or hot water (235 ppm). 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 1 oz. *Mikro-Quat* per gal. of water (700 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 1 oz. per gallon in the presence of protein (5% blood serum):

<i>Staphylococcus aureus</i> (ATCC 6538)	<i>Escherichia coli</i> (ATCC 11229)
<i>Salmonella typhi</i> (ATCC 6539)	<i>Staphylococcus aureus</i> HL121 (Methicillin resistant)
<i>Trichophyton mentagrophytes</i> (ATCC 9533)	<i>Vibrio cholerae</i> (ATCC 25873)
<i>Clostridium difficile</i> (vegetative form)	<i>Pseudomonas aeruginosa</i> (ATCC 15442)
<i>Enterococcus faecalis</i> (vancomycin resistant) (ATCC 51299)	
<i>Proteus vulgaris</i> (ATCC 13315)	
<i>Salmonella enterica</i> (ATCC 10708)	

Virucidal: Disinfects the following viruses on inanimate environmental surfaces at a use dilution of 1:128 (1 oz. per gal. of water). *Mikro-Quat* has been found effective against the following viruses at 1 oz. per gallon in the presence of protein (5% blood serum):

HIV-1 (AIDS virus)	Vaccinia (ATCC VR-119)
Herpes Simplex, type 1 (ATCC VR-733)	Influenza A2/Hong Kong (ATCC VR-544)
Newcastle Disease virus (ATCC VR-108)	
Adenovirus type 3	
Norovirus (Feline calicivirus surrogate - (ATCC VR-782)	

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 1 oz. per gallon of water (700 ppm). Allow 10 minute contact time.

KILLS MILDEW FUNGI on inanimate surfaces at the recommended use concentration of 1 oz. per gallon of water 700 ppm). Allow 10 minute contact time.

DO NOT MIX WITH ANYTHING BUT WATER

DILUTION TABLE:

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

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

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