

1677-22

10/16/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 16, 2008

Rhonda K. Schulz
Associate Director, Product Registration & Compliance
Regulatory Affairs
EcoLab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: **Mikroklene**
EPA Registration No. 1677-22
Application Dated: August 22, 2008
Receipt Date: August 26, 2008

Dear Ms. Schulz:

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

Proposed Amendment:

- Updated labeling

Other comments:

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>. If you have questions concerning electronic labeling, a list of contacts is available at the following site: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

A stamped copy of the accepted labeling is enclosed.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA stamped approved labeling

MIKROKLENE

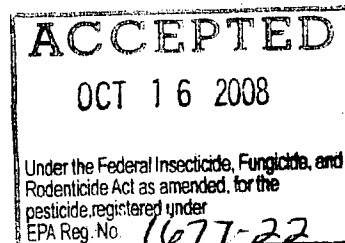
FOOD CONTACT SURFACE SANITIZER-IODOPHOR-FOOD SERVICE SANITATION-DETERGENT-GERMICIDE-VIRUCIDE*-DEODORIZER-FOOD SERVICE SANITATION-HOSPITAL DISINFECTION PROGRAMS

Active Ingredients:

Iodine*	2.00%
Phosphoric Acid.....	6.55%
Inert Ingredients**:	<u>91.45%</u>
Total:	100.00%

*From Butoxypolypropoxypolyethoxyethanol-iodine complex

** 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 or skin burns. Harmful if swallowed or absorbed through the skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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.

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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS: Avoid contact with strong alkalis and other oxidizers. Mix only with water. Use clean, dry utensils and other equipment. Contamination with organic matter and chlorinated products may cause the violent evolution of toxic gases.

DIRECTIONS FOR USE

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

Disinfection: Remove heavy soil or gross filth prior to disinfection step. To disinfect hard, non-porous surfaces use 2/3 oz. *Mikroklene* per gallon of tepid (75°-100°F) water (≥75ppm titratable iodine). Apply with cloth, mop or *Mikro-Spray*. Allow surfaces to remain wet for 10 minutes then wipe dry. When amber color of solution fades noticeably, mix a fresh solution.

Virucidal*: Disinfects the following viruses on inanimate environment surfaces at the use dilution containing 2/3 oz. *Mikroklene* per gallon of water (75 ppm tit. I) with a 10 minute contact time:

Herpes simplex Type 1	Influenza A (PR-8)	Poliovirus, Type 1
Newcastle Disease	Vaccinia	Adenovirus, Type 3

Dilution Table

ppm titratable iodine	12 1/2	25	75
oz. <i>Mikroklene</i> per 2 1/2 gallons water	1/4	1/2	1 1/2

NOTE: 1 oz.=2 tablespoonfuls or 6 teaspoonfuls

Directions for Sanitizing Food Contact Surfaces

Use to sanitize previously cleaned, hard, nonporous food contact surfaces. Use 1/2 oz. *Mikroklene* per 2 1/2 gallons of 75-100 deg. water for sanitizing (provides 25 ppm titratable iodine). No rinsing necessary. Renew solution daily or before amber color disappears. Not recommended for use on silver and silverplate. May cause blackening.

Sanitizing Eating, Drinking and Food Prep Utensils

1. Remove gross food particles by prescrape, preflush, and when necessary, a presoak treatment.
2. Wash in a solution of 1/2 oz. *Mikroklene* to 2 1/2 gallons of water (25 ppm titratable iodine) or other recommended detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1/4 oz. *Mikroklene* to 2 1/2 gallons of water (12 1/2 ppm titratable iodine). Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code. Renew solution before amber color disappears.
5. Drain and air dry.

NOTE: For mechanical operations, the prepared use solution may not be re-used for sanitizing but may re-used for other purposes, such as cleaning. For manual operations a fresh sanitizing solution should be prepared at least daily or more often if solution becomes diluted or soiled.

As a sanitizer for previously cleaned hard non-porous surfaces at 25 ppm titratable iodine, this product is effective against *Vibrio cholerae*.

When used at a concentration providing a minimum 12.5 ppm titratable iodine, *Mikroklene* had been tested and shown to be an effective sanitizer up to pH 7.5 in use solution.

Mikroklene is approved by the National Sanitation Foundation for use in spray and brush type glass washing machines. Keep reservoir full. Adjust control as directed by machine manufacturer and local health authorities.

When used as directed *Mikroklene* complies with FDA Regulation 21 CFR 178.1010(b)(4) for sanitizing solutions which are not to be rinsed from food contact surfaces. Consult local health department for additional information.

STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Store only in original or properly marked container. Keep container closed between uses. If spilled, flush to drain with a large quantity of water.

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

(greater than 1 gallon): 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.

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Net Contents:
1 U.S. gallon (3.78 L)
5 U.S. quarts (4.725 L)

EPA Reg. No. 1677-22

EPA Est.: 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-CA-1 (S), 1677-MN-1 (P), 1677-PR-1 (B),
1677-OH-1 (H), 1677-CA-2 (R), 1677-NC-1 (N), 1677-MO-1 (K), 1677-WV-1 (V)

Superscript refers to first letter of date code

Ecolab Inc., Institutional Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390

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