

1677-22

09/17/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 17 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Rhonda K. Schulz
Associate Director, Product Registration
Ecolab, Inc.
370 N, Wabasha Street
St. Paul, MN 55102

Subject: MikroKlene
EPA Registration No. 1677-22
Application Date: June 19, 2009
Receipt Date: June 23, 2009

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 comments.

Proposed Amendment:

- Revised Labeling removing use sites from label
- Updated container disposal section

General Comments:

1. Under the directions for Sanitizing Food Contact Surfaces, third line, second sentence revise to read: "Do not use on silver and silverplate" as per PR Notice 2000-5 **Guidance on Mandatory and Advisory Labeling Statements**. Problems can arise when advisory statements are either vague or ambiguous in meaning, or are inconsistent with mandatory labeling statements and can be unclear as to whether they are mandatory or advisory.
2. In the Note section on the second page revise the second sentence to read: "For manual operations a fresh sanitizing solution is to be prepared..." as per PR Notice 2000-5.

A copy of the accepted labeling is enclosed for your files.

Other Comment:

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: Carlisle.shaRon@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,



ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: EPA Stamped Labeling

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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**:	91.45%
Total:	100.00%

*From Butoxypolypropoxypolyethoxyethanol-iodine complex

** Active as cleaning and buffering agents

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 17 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1671-27

**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.

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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.

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:

(≤ 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. gallon (3.78 L)
 5 U.S. quarts (4.725 L)

**ACCEPTED
 with COMMENTS
 in EPA Letter Dated:**

SEP 17 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1677-22



