

1677-22

12-17-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 17 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Theodore D. Head, Manager
Product Registration
Ecolab, Inc.
270 N. Wabasha Street
St. Paul, MN 55102

Subject: Notification per PR Notice 95-2
Mikroklene
EPA Registration Number: 1677-22
Application Date: November 12, 2009
Receipt Date: November 20, 2009

Dear Mr. Head:

This acknowledges receipt of your notification, submitted under the provisions of PR 95-2 and FIFRA section 3 (c) 9.

Proposed Notification:

Optional Marketing Claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1.

General Comments:

The notification is acceptable. A copy has been inserted in your file for future reference.

Thank you for submitting this amendment as an electronic application. Please continue to submit your application(s) electronically.

Should you have further questions concerning this letter, please contact me at 703-308-6427 or by email at carlisle.shaRon@epa.gov or Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "ShaRon R Carlisle".

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



United States Environmental Protection Agency Washington, DC 20460

- Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 1677-22
2. EPA Product Manager: Emily Mitchell
3. Proposed Classification: None
4. Company/Product (Name): Mikrokylene
5. Name and Address of Applicant: Ecolab Inc.
6. Expedited Review: In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to:

Section - II

Amendment - Explain below. Final printed labels in response to
Resubmission in response to Agency letter dated 8/8/01
Notification - Explain below. "Me Too" Application.
Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)
Optional Marketing Claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-22.

Section - III

1. Material This Product Will Be Packaged In:
Child-Resistant Packaging: No
Unit Packaging: No
Water Soluble Packaging: No
2. Type of Container: Plastic
3. Location of Net Contents Information: Label
4. Size(s) Retail Container: 1 gal
5. Location of Label Directions: On Label
6. Manner in Which Label is Affixed to Product: Paper glued

Section - IV

1. Contact Point: Theodore D. Head, Product Registration Manager, (651) 293-2848
Certification: I certify that the statements which I have made on this form and all attachments are true, accurate and complete.
2. Signature: Theodore D. Head
3. Title: Product Registration Manager
4. Date: 11/12/2009
6. Date Application Received: (Stamped)



THEODORE HEAD
Manager, Product Registration
Regulatory Affairs
T 651.293.2848
F 651.225.3122
ted.head@ecolab.com

November 12, 2009

Document Processing Desk (E-SUB)
Office of Pesticide Programs (7502P)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202

ATTN: ShaRon Carilse, PM-34

Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-22

Dear ShaRon:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1.

Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8570-1.
- Certification with Respect to Label Integrity.
- Proposed Labeling (5 copies)
- Label CD

If you have any questions please contact me at the above phone, fax or email address.

Sincerely,

Theodore D. Head
Product Registration Manager
Regulatory Affairs
Ecolab Inc.

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MIKROKLENE

FOOD CONTACT SURFACE SANITIZER-IODOPHOR-FOOD SERVICE SANITATION-DETERGENT-GERMICIDE- DEODORIZER-FOOD SERVICE SANITATION PROGRAMS

Active Ingredients:

Iodine*	2.00%
Phosphoric Acid	6.55%
Inert Ingredients**:	91.45%
Total:	100.00%

NOTIFICATION
 Date Reviewed: 12/17/09
 Reviewed By: *[Signature]*

*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.

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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. Do not use on silver or 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 is to 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.

STORAGE & DISPOSAL

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

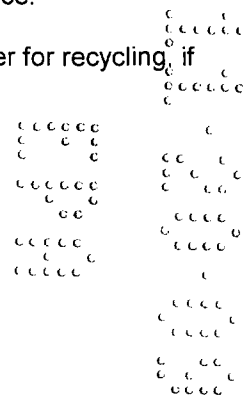
PESTICIDE STORAGE: Store only in original or properly marked container. Keep container closed between uses. If spilled, flush to drain with a large quantity of water.

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.

<p>Net Contents: 1 U.S. gallon (3.78 L) 5 U.S. quarts (4.725 L)</p>



EPA Reg. No. 1677-22

EPA Est.: 1677-IL-2 (J), 1677-TX-1 (D), 1677-CA-1 (S), 1677-MN-1 (P), 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

Optional marketing language:

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.
- This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.

