

1677-58

10/02/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 2, 2008

Rhonda K. Schulz
Associate Director, Product Registration & Compliance
Regulatory Affairs

EcoLab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: **Mikroklene DF**
EPA Registration No. 1677-58
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 DF

Iodine Based Detergent Sanitizer

Active Ingredients:

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

*From Butoxypropoxypropoxyethoxyethanol-iodine complex

**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

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 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 sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

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.

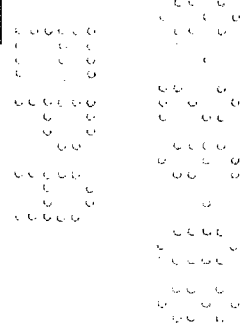
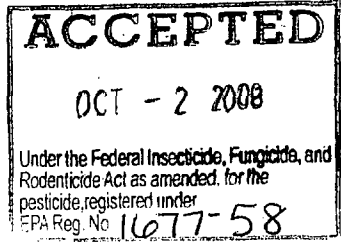
IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

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

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

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

Contains not more than 2.4% Phosphorus, 0.41 gms. per gal. of average recommended use concentration.



DIRECTIONS FOR USE

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

DIRECTIONS FOR SANITIZING DAIRY AND FOOD EQUIPMENT

FOR EQUIPMENT, TANKS, VATS, PAILS, PIPELINES, AND CLOSED SYSTEMS: Remove gross food particles and soil by a preflush, or prescrape, and when necessary presoak treatment. After the equipment has been cleaned and rinsed, just prior to use, sanitize with *Mikroklene DF* at a concentration of 12.5 ppm titratable iodine for at least a two minute exposure time. Use immersion, spray or circulation technique, as appropriate. Drain thoroughly. *Mikroklene DF* may be used as a final sanitizing rinse for returnable and non-returnable bottles at 6 ppm titratable iodine.

DIRECTIONS FOR SANITIZING POULTRY AND MEAT PROCESSING EQUIPMENT

FOR EQUIPMENT: After washing and rinsing equipment and just before use, sanitize with a *Mikroklene DF* concentration of 25 ppm titratable iodine for at least a two minute exposure period. Use immersion, spray or circulation technique, as appropriate. Drain thoroughly.

FOR CONTINUOUS TREATMENT OF MEAT AND POULTRY CONVEYORS: Wash, rinse, and sanitize conveyance equipment. During process, apply *Mikroklene DF* at a 25 ppm titratable iodine level to conveyors with *Mikro Master* feeding equipment. Controlled volumes of sanitizer are applied to return portion of conveyer through nozzles located to allow maximum drainage of sanitizer from equipment and to prevent puddles on top of belt.

NOTE: FOR MECHANICAL OPERATIONS: Prepared use solutions may not be reused for sanitizing, but may be reused for other purposes, such as cleaning.

FOR MANUAL OPERATIONS: Fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR VIRUS DISINFECTION:

Mikroklene DF disinfects the following viruses on inanimate, hard, non-porous surfaces (formica, stainless steel). Clean and rinse the surface. Wet surfaces thoroughly with *Mikroklene DF* solution containing 75 ppm titratable iodine. Use immersion, spray or circulation technique, as appropriate. Allow surface to remain wet for 10 minutes, then wipe dry or drain. For food contact surfaces, a potable water or sanitizing solution rinse is required. Prepare a fresh solution daily or when it becomes soiled or diluted.

Herpes simplex, type 1 *Influenza A2* *Poliovirus*
Newcastle Disease *Vaccinia* *Adenovirus, type 3*

DILUTION TABLE

ppm titratable iodine	6	12.5	25	75
Oz. <i>Mikroklene DF</i> per 5 gallons of water	¼	½	1	3

Use at recommended dilutions and at a temperature not exceeding 115°F. Keep from freezing.

SANITIZING – NON-POROUS GLOVED HANDS: To prevent the spreading of harmful organisms into animal areas and the packaging and storage areas food plants, dip pre-washed (plastic, latex or other synthetic rubber) gloved hands into a suitable clean container that contains enough freshly made sanitizing solution to cover the gloved area. **Do not let sanitizing solution come into contact with the exposed skin.** Make up the sanitizing solution by adding ½ ounce of this product per 5 gallons of water (or equivalent use dilution)(12.5 ppm titratable iodine). Dip (soak) in solution for 60 seconds. **NO POTABLE WATER RINSE IS ALLOWED.** Change the sanitizing solution in the bath at least daily or when solution appears dirty.

STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat.

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.

Net Contents:

1 U.S. gal. (3.78 L)

55 U.S. gal. (208.2 L)

EPA Reg. No. 1677-58

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), 11321-CA-1 (C), 1677-OH-1 (H), 1677-CA-2 (R), 1677-NC-1 (N), 1677-MO-1 (K), 8176-KY-1 (V), 8176-OH-1 (V), 1677-WV-1 (V)

Superscript refers to first letter of date code

Ecolab Food & Beverage Division

Ecolab Inc. 370 Wabasha Street N.

St. Paul, Minnesota 55102-1390 U.S.A.