

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

September 22, 2005

Joy A. Salverda  
Regulatory Consultant  
Ecolab Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102

Subject: Mikroklene DF  
EPA Registration Number 1677-58  
Application Date: June 27, 2005  
EPA Received Date: June 30, 2005

Dear Ms. Salverda:

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

**Proposed Amendment**

- Revised labeling

**Label Comments**

1. Revise the Environmental Hazards Statement by changing the phrase "...lakes, streams, ponds, estuaries, oceans, or public waters..." to read "...lakes, streams, ponds, estuaries, oceans, or other waters..."
2. Revise the Environmental Hazards Statement by changing the phrase "...previously notifying the sewage treatment plant authority." to read "...previously notifying the local sewage treatment plant authority."
3. Revise the If Swallowed section by changing the phrase "Call a poison control center or doctor for treatment advice." to read "Call a poison control center or doctor *immediately* for treatment advice."

**CONCURRENCES**

SYMBOL	7510c						
SURNAME	Joy						
DATE	9-22-05						

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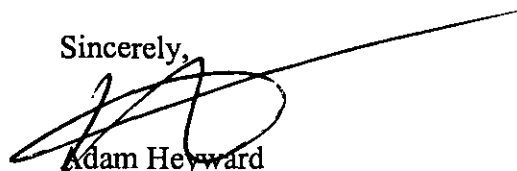
4. Revise the First Aid Statement by including the statement "Have the product container or label with you when calling a poison control center or doctor, or going for treatment."

**General Comments**

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies 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 me at 703-308-6422.

Sincerely,



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

Enclosure: Stamped Label

# MIKROKLENE DF

Iodine Based Detergent Sanitizer

**Active Ingredients:**

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

\*From Butoxypolypropoxypolyethoxyethanol-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.

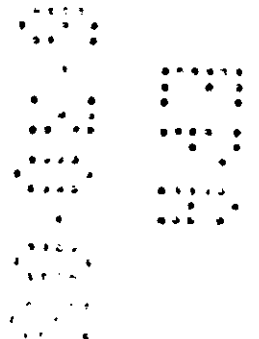
Contains not more than 2.4% Phosphorus, 0.41 gms. per gal. of average recommended use concentration.

ACCEPTED with COMMENTS

EPA Letter Dated:

SEP 22 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1677-58



**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.

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