

1677-58

10/19/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OCT 19 2012

Ron Derbyshire
Manager, NA Biocides
Ecolab, Inc.
EUC 9
370 Wabasha Street North
St. Paul, MN. 55102-1390

Subject: Mikroklene DF
EPA Registration Number: 1677-58
Notification Date: September 27, 2012

Dear Mr. Derbyshire:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

Add an upper range of 25 ppm titratable iodine for Sanitizing Dairy and Food Process Equipment in accordance with 40 CFR 180.940(b).

General Comments

Based on a review of the material submitted, the notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Luminello".

Jacqueline Campbell
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 1677-58	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) Mikroklene DF	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

Amendment - Explain below. Final printed labels in response to 2/10/03 Agency letter.
 Resubmission in response to Agency letter dated _____. "Me Too" Application.
 Notification - Explain below. Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)
 Notification per PRN 98-10 to add an upper range of 25 ppm titratable iodine for Sanitizing Dairy and Food Process Equipment to Reg. No. 1677-58 (Mikroklene DF). This upper level is allowed for these use sites in 40 CFR 180.940(b) for the active ingredients Iodine (max. 25 ppm) and Phosphoric Acid (unlimited). Other wording was also modified for consistency.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. Per Unit Package wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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* Certification must be submitted

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 gallon, 5 gallons, 15 gallons, 50 gallons, 300 gallon tote	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Other _____ <input type="checkbox"/> Stenciled		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)

Name Ron Derbyshire	Title Manager, NA Biocides	Telephone No. (Include Area Code) (651) 293-2848
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Certification
 I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Manager, NA Biocides	6. Date Application Received (Stamped)
4. Typed Name Ron Derbyshire	5. Date 9/27/12	



Ron Derbyshire
MANAGER, NA BIOCIDES
370 WABASHA STREET NORTH
EUC 9
ST. PAUL, MN 55102-1390
Ronald.Derbyshire@ecolab.com

☎ 651 293 2848
☎ 651 225 3122

September 27, 2012

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

ATTN: Jacqueline McFarlane, PM-34

Re: Mikrokylene DF, EPA Reg. No. 1677-58

Dear Ms. McFarlane:

This notification is pursuant to PRN 98-10 and serves as a request to add an upper range of 25 ppm titratable iodine for Sanitizing Dairy and Food Process Equipment. This upper level is allowed for these use sites in 40 CFR 180.940(b) for the active ingredients Iodine (max. 25 ppm) and Phosphoric Acid (unlimited). Other wording was also modified for consistency. All additions have been highlighted in red.

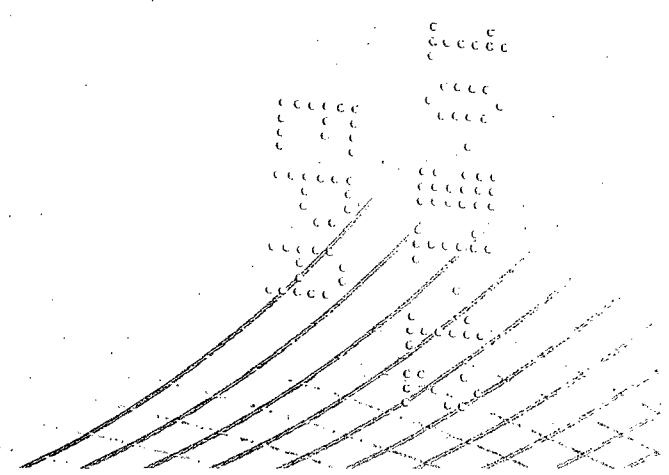
The following documents are enclosed to support this notification:

- EPA Form 8570-1 Notification Form
- Three copies of the proposed labeling
- Certification with Respect to Label Integrity
- Label Disk

If you have any questions, please do not hesitate to contact me directly at the above listed number or email address.

Sincerely,

Ron Derbyshire
Manager, NA Biocides



MIKROKLENE DF

Iodine Based Detergent Sanitizer

Active Ingredients:

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

*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 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 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 immediately for treatment advice. Have 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.

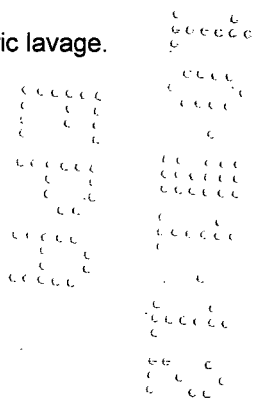
FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

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.

Contains not more than 2.1% Phosphorus, 0.2 g 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 PROCESS 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 – 25 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 12.5 - 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 12.5 - 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.

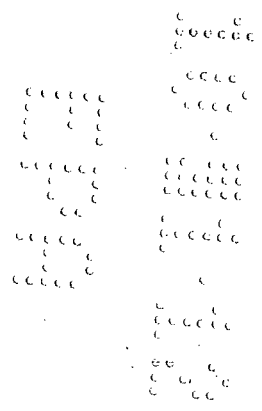
FOR MANUAL OPERATIONS: Fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

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 -1 ounce of this product per 5 gallons of water (or equivalent use dilution)(12.5 - 25 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.



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:

(≤ 55-gallon rigid) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Offer for recycling, if available, or discard in trash.

Net Contents:
1 U.S. gal. (3.78 L)
55 U.S. gal. (208.2 L)

EPA Reg. No. 1677-58

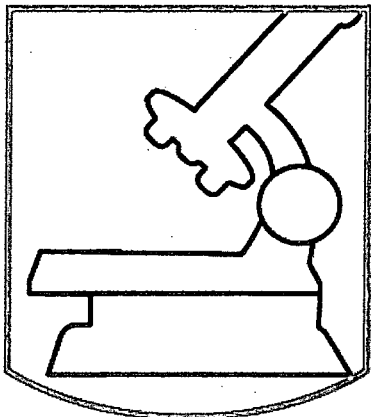
EPA Est.: 1677-IL-2 (J), 1677-TX-1 (D), 1677-CA-1 (S), 1677-MN-1 (P), 1677-CA-2 (R), 1677-NC-1 (N), 1677-WV-1 (V), 1677-GA-1 (M), 1677-IN-1 (L), 70271-CA-2 (C)

Superscript refers to first letter of date code

Ecolab Inc.
Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

Optional marketing language:

- "See side/back panel for First Aid..."



Sanitizer
Desinfectante

