

Pt 32 1677-22 1.44
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 11 1995

Ecolab Inc.
Ecolab Center
St. Paul, MN 55102

Attention: Ann M. Oxford
Manager, Regulatory Services

Subject: Mikroklene
EPA Registration Number 1677-22
Your Amendment Dated March 2, 1995

This is in response to your request to amend the registration of the subject product to include a sanitizing claim against Vibrio cholerae.

The submitted data developed by the AOAC Chlorine Available Germicidal Equivalent Concentration Tests are adequate to support effectiveness of the product as a terminal sanitizing solution at the dilutions providing 25 ppm titratable iodine (for activity equivalent or better than 200 ppm of available chlorine) in 500 ppm of hard water at 20 C for use on previously cleaned and rinsed food contact surfaces which are thoroughly wetted by the solution for a contact time of at least 1 minute, followed by adequate draining.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provided that you make the following revision:

1. As a sanitizer at 25 ppm titratable iodine this product is effective against Vibrio cholerae..." to read" ... As a sanitizer for previously cleaned hard nonporous surfaces at 25 ppm titratable iodine, this product is effective against Vibrio cholerae.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

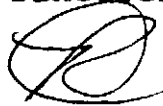
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-2-

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release the product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact me at (703) 305-7964.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

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CENTER | PANEL 3

CENTER | PANEL 4

ECOLAB®

Net Contents
1 Gal. (3.78 liters)

Mikroklene®

Food Contact Surface Sanitizer

Sanitizante para superficies que entran en contacto con los alimentos

ACTIVE INGREDIENTS:

Iodine 1.75%
Phosphoric acid 8.50%
INERT INGREDIENTS*: 91.75%

*From Butoxypolypropoxypolyethoxyethanol-iodine complex

**Active as cleaning and buffering agents

KEEP OUT OF REACH OF CHILDREN
DANGER

See Statement of Practical Treatment and additional precautionary statements on back panel

TO REORDER THIS ITEM USE:
AND CALL 1-800-352-5326

14639

Mikroklene

FOOD CONTACT SURFACE SANITIZER • IODOPHOR • DETERGENT
• DEODORIZER • FOOD SERVICE SANITATION • HOSPITAL DISINFECTANT

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with the label directions.
DISINFECTION: MIKROKLENE can be used to control cross-contamination in contaminated areas such as isolation rooms and for post-surgical disinfection applications. Remove heavy soil or gross filth prior to disinfecting hard surfaces such as porcelain, stainless steel or formica. Mix 1 ounce of MIKROKLENE per gallon of tepid (75°-100°F) water (75 ppm tit. I). Apply MIKRO-SPRAY. Allow surfaces to remain wet for 10 minutes then rinse. When amber color of solution fades noticeably, mix a fresh solution.
TB DISINFECTION: MIKROKLENE passes the rigid requirements as specified in 21 CFR 1677.22. Mix 1 ounce per gallon of water (75 ppm tit. Iodine) in the presence of 5% to 400 ppm hard water on nonporous surfaces at 20 deg. C. Remove filth prior to application of product. Allow surfaces to remain wet for 5 minutes.
VIRUCIDAL*: Disinfects the following viruses on inanimate environments at use dilution containing 2/3 oz. per gallon of water (75 ppm tit. I) within 10 minutes:

Herpes simplex Type 1	Influenza A (PR 8)	Poliomyelitis
Newcastle Disease	Vaccinia	Adenovirus

This product is not to be used as a terminal sterilant/high level disinfectant on an instrument that (1) is introduced directly into the human body, especially with the bloodstream or normally sterile areas of the body, or (2) contacts

membranes but which does not ordinarily penetrate the blood barrier of normally sterile areas of the body. This product may be used to pre-sterilize critical or semi-critical medical devices prior to sterilization or high level disinfection.

EPA Reg. No. 1677-22

EPA Est. 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-CA-1 (S), 1677-PR-1 (B)

The superscript refers to the first letter of the date code.
710228/0424/1194-B Made in U.S.A. © 1994

main panel 27 picas

23.6 picas

RECOMMENDED MINIMUM TYPE
IS: 8 PT. REGULAR FOR POS. TYPE
AND 8 PT. BOLD FOR REVERSE PRINTING

TYPE SMALLER THAN 8 PT. MAY RESULT
IN BROKEN, OR FILLED IN CHARACTERS

COLOR: PMS pms 253 purple ON WHITE BACK

ACCEPTED
with COMMENTS
in EPA Letter Date

OCT 11 1994

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

1/6

Mikroklene.

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

PRECAUTIONARY STATEMENTS-HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER: CORROSIVE. Causes eye damage. Do not get in eyes, on skin or on clothing. Wear goggles or safety glasses when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation develops.

IF SWALLOWED: Drink promptly a large quantity of water. **DO NOT** induce vomiting. Never give anything by mouth to an unconscious person.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

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.

STORAGE AND DISPOSAL

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

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

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: Do not reuse empty containers. Wrap container and put in trash.



Institutional Division
 Ecolab Inc., Ecolab Center
 St. Paul, MN 55102

23.6 picas

1 gallon polyethylene specification with or without back up (cylinder) plate.

SIZE: 18 1/2" x 3 5/8" (back up cylinder) 18 3/8" x 3 1/2" copyart print area.

QUALITY PLATE SPECIFICATION

Dean Ackerman (Quality Platemaking) & Weg (Ecolab) Sept. 1987

Mikroklene

DIRECTIONS FOR SANITIZING FOOD CONTACT SURFACES

Use to sanitize previously cleaned, hard, nonporous surfaces such as food preparation equipment, tables, and storage areas. Use 1/2 oz. MIKROKLENE per 2 1/2 gals. of 75-100 deg. water for sanitizing (provides 25 ppm tit. I). 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 a prescrape, brush 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 tit. I) 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 tit. I). 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 be re-used for other purposes such as cleaning. For manual operations a fresh sanitizing solution should be prepared at least 1/2 day or more often if solution becomes diluted or soiled.

DILUTION TABLE

1/2 oz. MIKROKLENE per 2 1/2 gal. water	12 1/2	25	75
1 oz. MIKROKLENE per 2 1/2 gal. water	14	12	1 1/2

NOTE: 1/2 oz. = 2 tablespoons and 1/4 oz. = 1/2 tablespoon.
 Consult local health department for additional information.
 When used at a concentration providing a minimum 125 ppm titratable iodine, MIKROKLENE has been tested and shown to be an effective sanitizer up to pH 7.5 in use solution.

As a sanitizer at 25 ppm titratable iodine this product is effective against *Vibrio cholerae*.

MIKROKLENE is approved by the National Sanitation foundation for use in spray and brush type glasswashing machines. Keep reservoir full. Adjust control as directed by machine manufacturer and local health authorities.

When used as directed MIKROKLENE complies with FDA Food Additive Reg. 21 CFR 178.1010(b)(4) for sanitizing solutions which are not to be rinsed from food contact surfaces.

BACK UP CYLINDER 3 5/8"
 COPY 3 1/2" — 21.9 (PICAS/POINTS)