

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PM32 Reg. NO. 1677-39

1/6

SEP 1 1991

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

Attn: Ann M. Oxford

Subject: Mikro-Bac
EPA Registration No. 1677-39
Your Resubmission of October 23, 1991

Your response to EPA's letter of September 19, 1991 requesting additional information on the efficacy data originally submitted in February of 1991 to support a proposed virucidal claim has completed review. Please note the following.

Product Efficacy

The forwarded additional information is sufficient to support the virucidal claim against Influenza A2/Hong Kong Virus.

Product Labeling

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Five copies of the finished labeling which incorporates these comments must be submitted before you release the product for shipment.

- In the "Net Contents" statement please include a reference to the 2.5 gallon size container listed in your label's "Storage & Disposal" statement.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7504C)

October 23, 1991

MIKRO-BAC

PHENOLIC DETERGENT DISINFECTANT FOR HOSPITAL AND INSTITUTIONAL USE
STAPHYLOCIDAL - PSEUDOMONACIDAL - TUBERCULOCIDAL - FUNGICIDAL - VIRUCIDAL

ACTIVE INGREDIENTS:

o-Phenylphenol, potassium salt	4.9%
o-Benzyl-p-chlorophenol, potassium salt	5.3%
p-tert-Amylphenol, potassium salt	0.9%
INERT INGREDIENTS*:	88.9%

*Contains cleaning agents

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 7 1991
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

1677-59

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive. Concentrate causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear safety glasses or goggles and rubber gloves when handling this product. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Avoid contamination of food.

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

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 persists.

IF SWALLOWED: Drink promptly large quantities of water. Avoid alcohol. 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

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

PHYSICAL AND CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame. Do not mix with anything but water.

FOR INDUSTRIAL USE ONLY

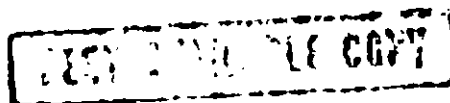
Net Contents: 1 gallon (3.78 l) 5 gallons (18.9 l) 55 gallons (208.8 l)

EPA Reg. No. 1677-59

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-FR-1 (B), 6574-CA-1 (L)

The superscript refers to the first letter of the date code.

Ecolab Inc.
Ecolab Center
St. Paul, MN 55102



October 23, 1991

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MIKRO-BAC disinfects as it cleans in one operation. MIKRO-BAC can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, rubber, linoleum, vinyl, asphalt, porcelain, plastic (such as polypropylene and Teflon), metal, glass, or painted, varnished or lacquered surfaces.

MIKRO-BAC is a broad spectrum germicide combined with a highly effective synthetic detergent system. It is odorless in use-dilution. Nonfilming.

MIKRO-BAC has been found effective against Human Immunodeficiency Virus Type 1 (commonly known as the AIDS virus) on inanimate surfaces when tested according to EPA virucidal testing requirements.

Area of Use: In Hospitals, use MIKRO-BAC for Surgical and Obstetrical Suites (especially suitable for conductive floors); Housekeeping Services; Physical Therapy Departments; Nursing Services; Autopsy Facilities. Also, use MIKRO-BAC in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

DIRECTIONS FOR USE

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

COMBINATION DISINFECTION AND CLEANING: MIKRO-BAC is effective against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa at 1:128 in hard water (400 ppm as CaCO₃) and 5% blood serum. For nonporous hard surfaces use 1 ounce MIKRO-BAC per gallon of water. For heavily soiled areas a pre-cleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, powered or mechanical spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare use solutions daily or in some reasonable quantity expected to be completely used within 1 - 4 months. The used solution (from pail or mop bucket) must be discarded daily or when it becomes soiled or diluted.

TUBERCULOCIDAL: MIKRO-BAC passes the requirements as a tuberculocide at 1 ounce per gallon of water (1:128) in the presence of 5% blood serum and 400 ppm hard water on porous and nonporous surfaces at 20 deg C. Remove heavy soil or gross filth prior to disinfection. Allow surfaces to remain wet for 10 minutes, then remove solution with a clean wet mop, cloth, or wet vacuum pickup.

VIRUCIDAL: At 1 ounce per gallon of water (1:128), MIKRO-BAC passes virucidal modified method against Herpes simplex type 1, Herpes simplex type 2*, Adenovirus type 3, Vaccinia, Canine parvovirus*, Canine Distemper*, Feline rhinotracheitis*, Feline pneumonitis*, Parainfluenza 1*, Influenza A2/Hong Kong* and Reovirus 3* in the presence of 5% serum and 400 ppm hard water on hard inanimate surfaces.

*Tested in the presence of residual soap scum.

MIKRO-BAC kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for the transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, wear personal protection such as disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant. **CONTACT TIME:** 10 minutes

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

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October 23, 1991

FUNGICIDAL: Kills Trichophyton mentagrophytes (athletes foot fungus) at 1 ounce per gallon of water in the presence of 5% blood serum and 400 ppm hard water.

MOLD AND MILDEWCIDE: Kills Aspergillus niger at 1 ounce per gallon (1:128).

SPECIAL USES

COLD DISINFECTION OF HEAT SENSITIVE INSTRUMENTS: Clean, then soak for 15 minutes in a solution of 2 ounces MIKRO-BAC per gallon of water. Rinse with water.

DISINFECTION OF POLYETHYLENE, POLYPROPYLENE, PVC, SILICONE, NYLON AND RUBBER GOODS: Soak catheters, tubes, gloves, masks, etc. for exactly 15 minutes, and no more, in a 2 ounce MIKRO-BAC per gallon of water solution. Rinse with water. Following rinsing, catheters should be soaked for one minute in 70% alcohol. Allow to air dry.

CONVEYORS: Clean all tracks and conveyors. Rinse well. Install and adjust automatic feeding system to feed 1 ounce of MIKRO-BAC per gallon of diluted lubricant solution. Apply to conveyors to disinfect through central distribution and existing application points. Allow a minimum of 10 minutes contact time. Following the 10 minute contact time, the MIKRO-BAC feed can be discontinued. It is not necessary to rinse conveyors following the MIKRO-BAC application.

OTHER ORGANISMS: MIKRO-BAC has been found to be effective against a broad spectrum of bacteria, both gram positive and gram negative organisms in the presence of protein (5% blood serum) and 400 ppm hard water.

<u>Candida albicans</u>	ATCC# 18804	<u>Enterobacter aerogenes</u>	ATCC# 13048
<u>Escherichia coli</u>	ATCC# 11229	<u>Micrococcus luteus</u>	ATCC# 14452
<u>Salmonella typhi</u>	ATCC# 6539	<u>Klebsiella pneumoniae</u>	ATCC# 4352
<u>Serratia marcescens</u>	ATCC# 13880	<u>Listeria monocytogenes</u>	Scott A
<u>Proteus vulgaris</u>	ATCC# 13315	<u>Staphylococcus aureus</u>	ATCC# 14154
<u>Shigella flexneri</u>	ATCC# 25875	<u>Salmonella enteritidis</u>	ATCC# 13076
<u>Staphylococcus sp.</u>	ATCC# 127	<u>Streptococcus pyogenes</u>	ATCC# 19615
<u>Saccharomyces cerevisiae</u>			
<u>Corynebacterium diphtheriae</u>	ATCC# 11913		
<u>Brevibacterium ammoniagenes</u>	ATCC# 6872		
<u>Staphylococcus aureus</u>	HL 121 (methicillin resistant)		

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DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

1. Remove all poultry and feeds from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with a detergent such as Kenzade's High Foaming Liquid Cleaner II or Alkerm's High Foaming Degreaser and rinse with water.
5. Saturate surfaces with a solution of 1 ounce of MIKRO-BAC per gallon of water for a period of 10 minutes.
6. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent such as Kenzade's High Foaming Liquid Cleaner II or Alkerm's High Foaming Degreaser, and rinse with potable water before reuse.

See your Kenzade or Alkerm Representative for specific recommendations for all cleaning and rinsing requirements.

OTHER USES: For other specialized cleaning and disinfecting operation consult your Ecolab Specialist.

For service or additional information, call 1-800-35-CLEAN (352-5326).

October 23, 1991

STORAGE & DISPOSAL

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: (1 gal) Do not reuse empty containers. Wrap container and put in trash.

(5, 55 gal plastic) Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(2.5 gal bladder in box) Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling or dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.