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FEB 9 1988

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

Attention: Ann M. Oxford

Gentlemen:

Subject: MIKRO-BAC
EPA Registration No. 1677-39
Your Application Dated December 14, 1987
EPA Received Date January 15, 1988

This is in response to the subject matter. The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

- Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.

Recommendations

Current Submitted Data (Virucidal against HIV)

Efficacy Supported by the Data--The submitted data are acceptable to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of moderate amounts of organic soil (10% blood serum) when used at a 1/128 dilution (1 ounce to 1 gallon of deionized water) for a contact time of 10 minutes at room temperature (20 to 25 °C). The data do not support efficacy in hard water.

Previously Submitted Data (Bactericidal, Fungicidal, Virucidal, and Tuberculocidal)

Since the proposed amendment consists of expansion of efficacy claims against microorganisms related to human health, a rereview of

56618;I;Dutch;K-5;KENCO;12/21/88;1/4/89;CL;VO;CT

CONCURRENCES

SYMBOL	1677-39						
SURNAME	J. Dutch						
DATE	12-6-87						

previously submitted efficacy data, as well as the proposed labeling, in the light of current requirements is justified and necessary.

Efficacy NOT Supported by the Data--Previously submitted data consisting of 10 carriers each against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa with one batch of product in the presence of organic soil (5% blood serum) by the AOAC Use-Dilution Method are not adequate to meet current requirements to support effectiveness of the product as a "one-step" germicidal cleaner in the presence of moderate amounts of organic soil. The only previously submitted data which meet current requirements in this regard are those developed for the tuberculocidal claim in response to the Tuberculocidal Data Call-In Notice. All previously submitted bactericidal, fungicidal (pathogenic), and virucidal data do not support efficacy of this product in the presence of organic soil.

Previously submitted data for basic (S. aureus, S. choleraesuis, and P. aeruginosa) and supplemental (eight additional bacterial pathogens) bactericidal claims, and one additional fungal pathogen (Candida albicans) meet current requirements to support effectiveness of the product in the presence of hard water (400 ppm CaCO₃). Other previously submitted fungicidal (Trichophyton mentagrophytes), tuberculocidal, and virucidal data do not support efficacy of this product in the presence of hard water.

Additional Data Required to Support Label Claims

To support basic efficacy of this product as a hospital "one-step" germicidal cleaner in the presence of organic soil and hard water, data must be submitted as indicated in the DIS/TSS-1 enclosure, item (c), modified to include both 5% blood serum and 400 parts per million (ppm) CaCO₃ hard water as indicated in the DIS/TSS-2 enclosure, items 3 and 4, with the reduced batch replication indicated in the DIS/TSS-2 enclosure, item 8 (two samples representing two different batches, instead of three). In addition, data must be submitted to show quantitative recovery of viable bacteria (plate counts) from untreated control carriers after drying with each test culture in the presence of 5% blood serum as indicated in the DIS/TSS-2 enclosure, item 6.

To support supplemental efficacy of this product as a disinfectant against additional bacterial pathogens in the presence of organic soil and hard water, data must be submitted as indicated in the DIS/TSS-1 enclosure, item (d), modified to include both 5% blood serum and 400 ppm CaCO₃ hard water, with reduced batch replication (one sample instead of two) and control carrier plate count data, as indicated above.

To support supplemental efficacy of this product as a fungicide (pathogenic), virucide, and tuberculocide in the presence of organic soil and hard water, data must be submitted as indicated in the DIS/TSS-6 enclosure, items (A) and (B), and the DIS/TSS-7 enclosure, modified to include both 5% blood serum and 400 ppm CaCO₃ hard water, with the reduced batch replication (one sample instead of two), as indicated above.

Labeling

Product Label

1. Front Panel

- a. The claim in the heading "Disinfects As It Cleans In One Operation" is not supported by data demonstrating efficacy in the presence of organic soil against all microbial pathogens claimed on the label. In lieu of the required data, delete the claim and provide directions for precleaning of surfaces prior to disinfection. If the claim for use of the product as a cleaner is retained, separate directions for use of the product as a cleaner must be provided as an initial step prior to use of a separately prepared solution of the product for disinfection of the precleaned surfaces.
- b. Under "Inert Ingredients," the claim "Active as cleaning agents" must be revised to read "Includes cleaning agents" or "Contains cleaning agents," if the cleaning claims are retained. The term "Active" must be limited to antimicrobially active ingredients only.

2. Side Panel

- a. The paragraph heading "MIKRO-BAC has been found effective against Human Immunodeficiency Virus . . ." must be revised to read "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."
- b. In lieu of data to support efficacy in the presence of organic soil against all microbial pathogens claimed on the label, the "Directions For Use" under "General Uses" and "Special Uses" must specify thorough cleaning of surfaces and objects prior to application of the product as a disinfectant. If claims for use of this product as a cleaner are retained, separate directions must be provided for using the product for cleaning as an initial step prior to disinfection.
- c. In the paragraph headed "TB Disinfection," the claim "in the presence of 5% blood serum" is misleading since the pattern of use for efficacy in the presence of organic soil against all microbial pathogens claimed on the label is not supported by data. Therefore, either delete the claim or add a statement similar to the following "Although efficacy in the presence of 5% blood serum has been shown for tuberculocidal activity, it has not been shown for other organisms. Therefore, thoroughly preclean surfaces for efficacy against all of the organisms claimed on the label."

- d. Under "Procedure," the claims for Use-Dilution Confirmation (AOAC) in "400 ppm Hard Water and 5% Organic Load" are misleading since the pattern of use for efficacy in the presence of organic soil and hard water is not supported against all microbial pathogens claimed on the label. Therefore, delete "5% Organic Load" under this heading since it is supported only for tuberculocidal activity and virucidal efficacy against HIV-1, and delete "400 ppm Hard Water" or add a statement similar to the following "Although efficacy in the presence of 400 ppm hard water has been shown for bacteria by the AOAC Use-Dilution Method, it has not been shown for other organisms. Therefore, do not use hard water with this product to provide efficacy against all of the organisms claimed on the label."
- e. Under "Procedure," the claim for Tuberculocidal Test (AOAC) is "5% Organic Load" is misleading. Refer to 2.c., above.
- f. Under "Procedure" and "Organism," reference to the "Use-Dilution Mildew Fungicidal Test (EPA)" and "Aspergillus niger" are not considered relevant to claims related to human health for this product and must be deleted. Alternately, a separate section must be provided with claims and directions for use of the product against mildew fungi which are not related to human health.
- g. Under "Organism," the claims in the paragraph headed "Human Immunodeficiency Virus . . ." must be revised to read "Human Immunodeficiency Virus Type 1 (commonly known as the AIDS virus), Herpes simplex Type 1, Adenovirus Type 3, Vaccinia virus."

Technical Bulletin

1. Page 1

- a. The claim in the heading "Disinfects As It Cleans" is objectionable. Refer to 1.a., above.
- b. Under "Broad Spectrum Antimicrobial," the claims for activity in the presence of organic matter and effectiveness in hard water are misleading. Refer to 2.d., above. In addition, only 15 hospital pathogens instead of "17 hospital pathogens" could be identified from the data.
- c. If the cleaning claims are retained, refer to 1.a., above.

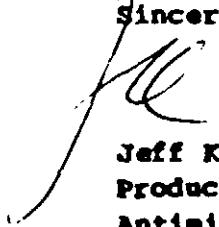
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2. Page 2

- a. Under "Microbiological Efficacy," the claim for effectiveness in hard water is misleading. Refer to 2.d., above.
- b. Under "Gram negative bacteria," "Corynebacterium diphtheriae" should be removed and placed under "Gram positive bacteria."
- c. The paragraph headed "AOAC Phenol Coefficient" is not in compliance with current requirements for permitted "Phenol Coefficient" tables in collateral literature, such as technical bulletins. Such "Phenol Coefficient" tables must be prominently prefaced with a statement such as "The following Phenol Coefficients are intended only to indicate the broad-spectrum activity of this product. This information must not be interpreted as having any relevance to patterns recommended, effective dosages, or activity against specific microorganisms when used as directed." Refer to the DIS/TSS-6 enclosure, item (C)(3)(b).
- d. The paragraph headed "Organic Load Tolerance" is objectionable and must be deleted. Refer to 2.d., above.
- e. In the paragraph headed "Additional efficacy . . ." under "Procedure" and "Organism," reference to the "Use-Dilution Mildew Fungicide Test (EPA)" and "Aspergillus niger" are not relevant to human health-related claims for this product. Refer to 2.f., above.
- f. In the paragraph headed "Additional efficacy . . ." under "Organism," the claims beginning with "Human Immunodeficiency Virus . . ." must be revised to read as follows "Human Immunodeficiency Virus Type 1 (commonly known as the AIDS virus), Herpes simplex Type 1, Adenovirus Type 3, Vaccinia virus."

Should you have any further questions, please contact Veronica Dutch at (703) 557-6938.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosures

623 2

MIKRO-BAC

PHENOLIC DETERGENT-DISINFECTANT
STAPHYLOCIDAL-PSEUDOMONACIDAL-TUBERCULOCIDAL-
FUNGICIDAL-VIRUCIDAL

Disinfects As It Cleans In One Operation

Active Ingredients	11.1%
Potassium o phenyphenate	4.9%
Potassium O benzyl p chlorophenate	5.3%
Potassium p t amyphenate	0.9%
Inert Ingredients	88.9%
Active as cleaning agents	

KEEP OUT OF REACH OF CHILDREN
DANGER
STATEMENT OF PRACTICAL TREATMENT

In case of contact: Immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed: drink promptly a large quantity of milk, egg whites, gelatin solution. If these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

For emergency medical information, call toll-free 1-800-328-0028.

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

EPA REG. NO. 1677-39AA

EPA EST. 1677-1E-22

NET CONTENTS 55 GALS (208 l)

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

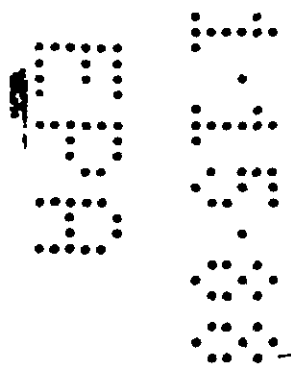
ACCEPTED
WITH COMMENTS
on EPA Letter Dated:

FEB 06 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act amended, for the pesticide registered under EPA Reg. N

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1677-39



MIKRO-BAC

7 of 8

A broad spectrum germicide combined with a highly effective synthetic detergent system. Odorless in use-dilution. Especially suitable for use on conductive floors; nonfilming.

MIKRO-BAC has been found effective against Human Immunodeficiency Virus, Type III, commonly known as the AIDS virus when tested in accordance with the approved EPA protocol.

Use MIKRO-BAC for:

HOSPITALS

Surgical and Obstetrical Suites. Especially suitable for conductive floors, Housekeeping Services, Physical Therapy Departments, Nursing Services, Autopsy Facilities

NURSING HOMES

SCHOOLS

DIRECTIONS FOR USE

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

GENERAL USES

For Cleaning and disinfecting of nonporous hard surfaces such as walls, tables, floors, bed frames, bathroom fixtures and other similar surfaces use 1 ounce of MIKRO-BAC per gallon of water. Apply solution with mop, cloth, scrubber or other suitable applicator so as to wet all surface thoroughly. Allow to remain wet for 10 minutes. For heavily soiled areas a precleaning step is required.

TB DISINFECTION: MIKRO-BAC meets the requirements as a tuberculocide at 1:128 dilution in the presence of 5% blood serum on surfaces that remain wet for 10 minutes at 20° C.

SPECIAL USES

Instruments: for cold disinfection of heat sensitive instruments, soak for 15 minutes in a solution of 2 ounces MICRO BAC per gallon of water. Rinse with water.

Rubber and Plastic Goods: for disinfection of catheters, tubes, gloves, masks, etc., soak 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.

OTHER USES: Technical advice concerning specialized cleaning and disinfection may be obtained from your Colab Specialist.

MICROBIOLOGICAL EFFICACY at 1:128 DILUTION

<u>Procedure</u>	<u>Organism</u>
Use-Dilution Confirmation (AOAC) 400 ppm Hard Water and 5% Organic Load	Staphylococcus aureus (ATCC 6538) Salmonella choleraesuis (ATCC 10708) Pseudomonas aeruginosa (ATCC 15442)
Fungicidal Test (AOAC)	Trichophyton mentagrophytes
Tuberculocidal Test (AOAC) 5% Organic Load	Mycobacterium tuberculosis var. bovis (H37Rv)
Use-Dilution Mildew Fungicidal Test (EPA)	Aspergillus niger
Modified AOAC Use-Dilution Test for Virucidal Efficacy	Human Immunodeficiency Virus, Type III (commonly known as the AIDS virus), Herpes simplex, Adenovirus type 1, Vaccinia virus

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes eye damage or skin irritation. Do not get in eyes, on skin or on clothing. Protect skin and eyes when handling. Harmful if swallowed. Avoid contamination of food.

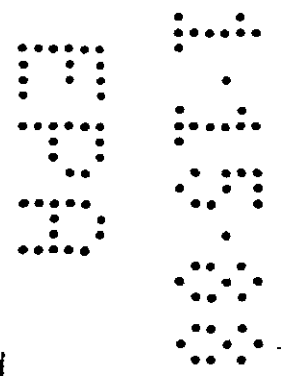
PHYSICAL AND CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame. Do not mix with anything but water.

STORAGE AND 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: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.



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