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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 2 4 2005

Mr. Bob MacDonald
Agent for Maril Products, Inc.
Scientific & Regulatory Consultants, Inc.
PO Box 1014
Columbus City, IN 46725

Subject: Control III Disinfectant Germicide
EPA Registration No. 55364-3
Amendment Date: September 24, 2004
EPA Receipt Date: September 28, 2004

Dear Mr. MacDonald,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Response to Agency letter dated April 1, 2004

Conditions
Revise the label as follows:

1. Revise the list of organisms mitigated by your product to include HIV-1 and *Staphylococcus aureus* - MRSA.

2. The Technical Bulletin must be revised by deleting the "Respiratory Therapy Equipment Use." According to PR Notice 98-2, Liquid Chemical Sterilant Products, any liquid chemical sterilant product intended for use on critical or semi-critical devices are no longer regulated by the EPA. FFDCA section 201 states that a semi-critical device "includes any device which contacts intact mucous membranes which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body." The respiratory equipment, nebulizers, mouth pieces, flex tubing, manifold valve, and reservoirs, fall into the semi-critical device category. Any product bearing an FDA regulated claim on an EPA pesticide product must delete those claims from the label.

   Please Note: You may wish to pursue a separate registration through FDA to continue the use of your product on Respiratory Therapy Equipment.

CONCURRENCES								
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3. You must add the following information regarding this product's 14 Day Bacterial Stability Use Solution:

Bacterial Stability of Use Solution: Tests confirm that the use solution remains effective against the organisms listed on the label for up to 14 days when stored in a sealed container such as a spray bottle. If the product becomes visibly dirty or contaminated, the use-dilution must be discarded and a fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bacterial stability of use solutions does not apply to open containers such as buckets or pails.

If using a bucket or pail, prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

Data Summary

Data Requirement	Means of Support	Status
14 Day Bacterial Stability Protocol - *P. auruginosa, S. aureus, S. choleraesuis*	Submitted Study, MRID No. 463725-01	Acceptable
14 Day Bacterial Stability AOAC Use Dilution- *P. aurugionsa, S. aureus, S. choleraesuis*	Submitted Study MRID No.463725-02	Acceptable
14 Day Bacterial Stability AOAC Use Dilution - E. coli	Submitted Study MRID No. 463725-03	Acceptable
14 Day Bacterial Stability AOAC Use Dilution - *S. aureus* - MRSA	Submitted Study MRID No. 463725-04	Acceptable
14 Day Bacterial Stability Virucidal Efficacy against Herpes Simplex Type 1	Submitted Study, MRID No. 463725-05	Acceptable
14 Day Bacterial Stability Virucidal Efficacy against Herpes Simplex Type 2	Submitted Study MRID No. 463725-06	Acceptable
14 Day Bacterial Stability Virucidal Efficacy against Influenza Virus Type A	Submitted Study MRID No. 463725-07	Acceptable
14 Day Bacterial Stability Virucidal Efficacy against HIV-Type 1	Submitted Study MRID No. 463725-08	Acceptable

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling

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If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
Efficacy Data Evaluation

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USED FOR: Disinfection of walls, equipment, heat sensitive instruments and tubing in operating rooms, recovery rooms and intensive care rooms.

DIRECTIONS FOR USE:

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

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

General:

1. Remove heavy soil as required.
2. Apply this product as directed.

NONCRITICAL INSTRUMENT DISINFECTANT

Clean noncritical instruments with detergent and rinse with potable water before disinfection. Prepare use solution of 1 oz per gallon of water. Immerse noncritical instruments for 10 minutes. Remove instuments, rinse thoroughly with sterile water, and pat dry or allow to air dry. Active concentration is 1560 ppm.

HIV-1 AND HOME CARE INSTRUCTIONS

See Technical Bulletins for Home Care and Efficacy of Control III Products for the Control of the Human Immunodeficiency Virus Type 1 (AIDS Virus). *

LAUNDRY BACTERIOSTAT FOR COMMERCIAL, INDUSTRIAL, AND NON-MEDICAL INSTITUTIONAL LAUNDRY APPLICATIONS:

This product provides the fabric with residual bacteriostatic activity against odor-causing gram-negative and gram-positive bacteria when this product is added to the final rinse at a rate of 1.2 ounces per 25 bls. (4.8 ounces per 100 lbs.) of dry laundry. This is based on water being at full capacity, temperature of 20-38°C and 5 minute contact.

CONTROL III

DISINFECTANT

GERMICIDE

ACTIVE INGREDIENTS:

n-alkyl (60% C_{14}, 30% C_{16}, 5%C_{12}, 5% C_{18}) dimethyl benzyl ammonium chloride.....	10%
n-alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chloride	10%
INERT INGREDIENTS	80%
TOTAL	100%

ON INANIMATE ENVIRONMENTAL SURFACES EFFECTIVE AGAINST

Pseudomonas aeruginosa • Adenovirus type 5 • Staphylococcus aureus • Vaccinia viruses • Salmonella choleraesuis • Influenza A_2 virus • Escherichia coli • Herpes simplex virus

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements.

NOTE: This product has not been tested for effectiveness against Mycobacterium Tuberculosis and must not be relied upon when a tuberculocidal product is desired.

This product is a concentrate and must be diluted before use.

NET 16 FL. OZ. (1 PINT)

EPA Est. No. 40873 CA-01

EPA Reg. No. 55364-3

MARIL PRODUCTS, INC.

320 West 6th St., Tustin, California 92780 U.S.A.

Manufactured by Maril Products, Inc.

(714) 544-7711

HOSPITAL DISINFECTION

For disinfecting walls, noncritical equipment and surfaces in operating rooms. Apply use solution of ½ oz per gallon of water to hard surfaces with cloth, mop, sponge, or sprayer. Allow surfaces to remain wet for 10 minutes, then allow to air dry. Prepare a fresh solution for each use. Active concentration is 780 ppm.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER:

Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling. May be harmful if swallowed or absorbed thorough the skin. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing.

STORAGE AND DISPOSAL:

Store in original container in a locked storage area inaccessible to children. Do not reuse. Empty container. Wrap container and discard in the trash.

P/N: 10002 REV B

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 five minutes, then continue rinsing eye. Call a poison control center doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin 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 a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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 centrol center or doctor for turther treatment advice.

HOT LINE NUMBER

For emergency medical advice, call your local poison control center (1-800-222-1222) or doctor. Have the product container or label with you when seeking medical advice or treatment.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAR 24 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 55364-3

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CONTROL OF THE AIDS VIRUS

***KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV) (associated with AIDS).

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

Personal Protection: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, masks, or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of Control III Disinfectant Germicide.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infections waste disposal.

Contact Time: Allow surface to remain wet for 10 minutes.

Company Logo Here

Maril Products, Inc.

320 West 6th Street
Tustin, CA 92780

800-546-7711
714-544-7711

control3@earthlink.net

EPA No. 55364-3 P/N 10004 Rev. D