

55364-3

09-11-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
Office of Prevention, Pesticides, and Toxic Substances

SEP 11 2007

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

Subject: Control III Disinfectant Germicide
EPA Registration No.: 55364-3
Amendment Date: June 8, 2007
EPA Receipt Date: June 13, 2007

Dear Mr. MacDonald,

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

- Response to Agency letter dated March 24,

Conditions

Revise the label as follows:

- 1) Revise the second to last sentence under the "Precautionary Statements" to read "Wash thoroughly with soap and water after handling and before eating, drinking, or smoking tobacco."
- 2) Revise the 2nd paragraph under "What is Control III Disinfectant Germicide" by deleting references to infection and state "..... will help prevent cross contamination from a variety of organisms...."

General Comments

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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Should 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 with Conditions

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 11 2007

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide

55364-3

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 pre-clean 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 instruments, 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 lbs. (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% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chloride..... 10%

n-alkyl (68% C12, 32% C14) 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 A2 virus •
Escherichia coli • Herpes simplex virus •
Staphylococcus aureus (MRSA) • HIV-1

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 tuberculosidal 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 through 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 or 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 control center or doctor for further 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.

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CONTROL III®
Disinfectant Germicide

Bulletins:

For
Home Care

And

Efficacy of
Control III® Products
For the Control of the
Human Immunodeficiency Virus Type 1
(AIDS Virus)

- Odorless
- Time Tested Since 1974
- EPA Registered Disinfectant

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WHAT IS CONTROL III DISINFECTANT GERMICIDE?

This product is a time-proven germicide. It is an excellent disinfectant for inanimate hard surfaces and noncritical equipment in the home. This product has been used by Visiting Nurse Associations, Home Care Organizations, and Hospital Home Rehabilitation programs since 1974.

This product, when used in an overall cleaning program, will help control infection or re-infection due to contamination from a variety of organisms, including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus aureus* (MRSA), *Salmonella choleraesuis*, *Escherichia coli*, Herpes simplex virus type 1, Herpes simplex virus type 2, Influenza virus type A, Vaccinia virus, Adenovirus type 5 and HIV-1*.¹

¹ CONTROL III DISINFECTANT GERMICIDE has not been tested for effectiveness against *Mycobacterium tuberculosis* and must not be relied upon when a tuberculocidal product is desired.

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HOW TO PREPARE CONTROL III® DISINFECTANT GERMICIDE

Prepare a disinfecting solution of CONTROL III DISINFECTANT GERMICIDE by adding ½ ounce (1 Tablespoon) of this product to 2 quarts of water in a plastic container**. This solution may be reused for up to 14 days. Solution may be checked daily with test strips to ensure adequate disinfection level of this solution. If the solution becomes visibly dirty or falls below 1,000 ppm, dump the used solution and make a fresh solution. Keep disinfecting solution covered when not in use.

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 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 product. Bacterial stability of use solution does not apply to open containers such as buckets or pails without lids. If using a bucket or pail without a lid, prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

**Re-use container must be labeled with the product name (Re-use solution of Control III Disinfectant Germicide), signal word, preparation date (mm/dd/yy) and expiration date (mm/dd/yy).

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DISINFECTION OF SURFACES AND NONCRITICAL EQUIPMENT IN THE HOME WITH CONTROL III DISINFECTANT GERMICIDE

1. Disassemble equipment according to manufacturer's recommendations.
2. Wash all surfaces thoroughly in Mild detergent (such as liquid dishwashing detergent) and warm tap water. DO NOT USE SOAP. Rinse parts with tap water.
3. Immerse equipment parts in solution of CONTROL III DISINFECTANT GERMICIDE, ensuring that there are no-trapped air bubbles and all surfaces are wet. Soak for 10 minutes.
4. Rinse all equipment parts with hot tap water (allow water to run for 3 minutes before rinsing parts) and allow to air dry.
After parts are dry, cover them with a clean towel until they are ready for use.

Control III Disinfectant Germicide kills the HIV-1 (AIDS Virus) on hard, non-porous surfaces in the presence of organic soil (5% blood serum) when diluted at a minimum level of 1,000 ppm active quaternary for a contact time of 10 minutes at room temperature.

Control III Disinfectant Germicide diluted at 1 ounce per gallon of water equals 1562 ppm active quaternary.

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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 infectious waste disposal.

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