



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 24, 2015

Bob MacDonald
Agent for Maril Products Inc.
Maril Products, Inc.
15421 Red Hill Ave., Suite D
Tustin, CA 92780

Subject: PRIA Label Amendment – Amend labeling claims related to efficacy against
Pseudomonas aeruginosa.
Product Name: Control III Disinfectant Germicide
EPA Registration Number: 55364-3
Application Date: 04/01/15
Decision Number: 503055

Dear Mr. MacDonald:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact John Cowden by phone at 703-347-0259, or via email at Cowden.johnc@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "E. Miederhoff". The signature is written in a cursive style with a large, stylized initial "E".

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

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{FRONT PANEL}

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%

KEEP OUT OF REACH OF CHILDREN

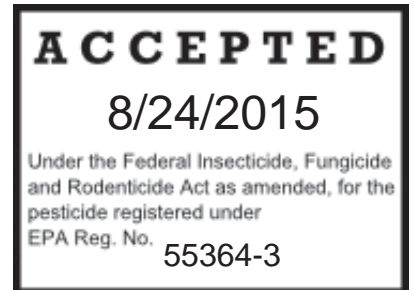
DANGER

See side panel for additional precautionary statements.

NET CONTENTS 16 Fl. Oz. (1 PINT)

EPA Reg. No. 55364-3 {Registration number will appear on printed label}

EPA Est. No. 40873 CA-01 {EPA Establishment number will appear on printed label}



MARIL PRODUCTS, INC.

15421 Red Hill Ave., Suite D, Tustin, California 92780 U.S.A.

Manufactured for Maril Products, Inc.

(714) 544-7711

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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 and before eating, drinking or smoking tobacco. Remove and wash contaminated clothing.

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.

Note to Physician:

Probable mucosal damage may contraindicate the use of gastric lavage.

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.

ON INANIMATE HARD, NON-POROUS, PRE-CLEANED ENVIRONMENTAL SURFACES EFFECTIVE AGAINST

- Pseudomonas aeruginosa
- Adenovirus type 5
- Staphylococcus aureus
- Vaccina viruses
- Salmonella choleraesuis
- Influenza A2 virus
- Escherichia coli
- Herpes simplex virus
- Staphylococcus aureus (MRSA)
- HIV-1

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

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) contact 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 soil as required.
2. Apply this product as directed.

NON-CRITICAL INSTRUMENT DISINFECTION

Clean non-critical instruments with detergent and rise with potable water before disinfection. Prepare use solution of 1 ounce per gallon of water. Immerse non-critical instruments for 10 minutes. Remove instruments, rinse thoroughly with sterile water and pat dry or allow to air dry. Active concentration is 1562 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.

HOSPITAL DISINFECTION

For disinfecting walls, non-critical equipment and surfaces in operating rooms. Pre-clean surfaces with product prior to disinfection. Thoroughly wet pre-cleaned inanimate hard, non-porous environmental surfaces by applying a use solution of 1 oz. per gallon of water 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 1562 ppm.

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal.

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PESTICIDE STORAGE:

Store in original container in a locked storage area inaccessible to children. PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Store rinsate for later disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or wrap container and discard in the trash.

P/N: XXXXX REV X

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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, when used in an overall cleaning program, will help prevent cross contamination on treated surfaces 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*.

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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 1,562 ppm, discard the used solution and make a fresh solutions. Keep disinfecting solution covered when not in use.

Bactericidal 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. Bactericidal 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 dated (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 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, 2/3 ounce per gallon of water (2 ounces per 3 gallons) 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 surface/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.

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Company Logo Here

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EPA No. 55364-3

P/N XXXXX Rev. X

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{OPTIONAL ADDITIONAL TEXT FOR USE ON PRODUCT LABEL OR COLLATERAL LABELING}

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Control III Disinfectant Germicide) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.

Refer to container label, Hospital Disinfection Section, for directions for use.