

55364-3

1 of 12

APR 8 2010

Mr. David Swain
Agent for
Maril Products, Inc.
320 West 6th Street
Tustin, CA 92780

Subject: **Control III Disinfectant Germicide**
EPA Registration Number 55364-3
Notification Application Dated March 10, 2010
EPA Received Date March 12, 2010

Dear Mr. Swain:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Revise the Storage and Disposal Per PR Notice 2007-4

General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Drusilla Copeland
Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

209/12



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 55364-3	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Control III Disinfectant Germicide	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Maril Products, Inc. 320 West 6th Street Tustin, CA 92780 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Notification of updated storage and disposal language per PR Notice 2007-4. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please contact David Swain for questions and provide an electronic response to dswain@srconsultants.com or at 260-244-6273 (fax).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 16 fl oz	5. Location of Label Directions <input checked="" type="checkbox"/> On label		
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name David Swain	Title Agent for Maril Products, Inc.	Telephone No. (include Area Code) (260) 244-6270
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
Signature 	3. Title Agent for Maril Products, Inc.	
4. Typed Name David Swain	5. Date 3/10/10	

SRC

Scientific & Regulatory
Consultants, Inc.

March 10, 2010

Ms. Velma Noble, PM 31
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, 4th Floor
One Potomac Yard
2777 S Crystal Drive
Arlington, VA 22202

SUBJECT: Notification (Container and Containment Regulations) per PR Notice 2007-4
Control III Disinfectant Germicide
EPA Reg. No.: 55364-3

Dear Ms. Noble,

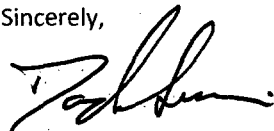
On behalf of our client, Maril Products, Inc., enclosed is a notification revising the storage and disposal section to comply with the Final Pesticide Container and Containment Regulations. This is a Notification per PR Notice 2007-4; therefore, no PRIA fee is required.

The new statements, as specified in the guidance, have been included as required text in the attached labeling. The new statements are highlighted in yellow on the enclosed label. No other changes in the existing labeling have been made.

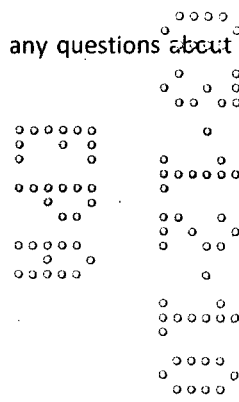
This notification, as stipulated by the guidance, is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action, and penalties under sections 12 and 14 of FIFRA.

Please contact me at (260) 244-6270 or at dswain@srconsultants.com if you have any questions about this notification.

Sincerely,



David Swain
Agent for Maril Products, Inc.
cc: A. Whitehead



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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.

NON-CRITICAL INSTRUMENT DISINFECTION

Clean non-critical instruments with detergent and rinse 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 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 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 for Maril Products, Inc.

(714) 544-7711

HOSPITAL DISINFECTION

For disinfecting walls, non-critical equipment and surfaces in operating rooms. Apply use solution of 1/2 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 and before eating, drinking or smoking tobacco. Remove and wash contaminated clothing.

STORAGE AND DISPOSAL:

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

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 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.

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.

CONTROL III® Disinfectant Germicide

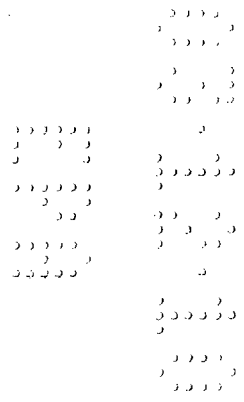
Bulletins:

For
Home Care

And

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

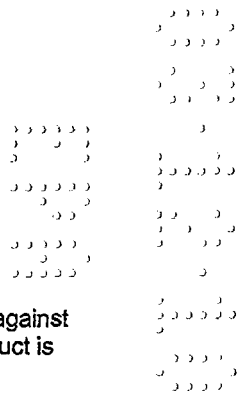
- Odorless
- Time Tested Since 1974
- EPA Registered Disinfectant



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 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.

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, discard 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).

