

55364-3

12/2/2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Bob Mac Donald
Agent for Maril Products, Inc
Scientific and Regulatory Consultants, Inc
PO Box 1014
Columbia City, IN 46725

DEC -2 2009

Subject: Control III Disinfectant Germicide
EPA Reg. No.: 55364-3
Notification Date: October 27, 2009
EPA Receipt Date: November 2, 2009

Dear Mr. Mac Donald,

This letter acknowledges receipt of your notification submitted in connection with registration under the provisions of PR Notice 98-10 and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

Adding 2009 H1N1 Marketing Claims

General Comments

Based on a review of the submitted materials, your notification to add 2009 H1N1 Marketing Claims in accordance with the Agency guidance for testing labeling claims against Pandemic 2009 H1N1 Influenza A (Formerly called Swine Flu) is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble
Velma Noble

Product Manager (31)

Regulatory Management Branch I
Antimicrobial Division (7510P)

CONCURRENCES						
SYMBOL						
SURNAME						
DATE						



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 V. 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 W. 6th St. 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 (optional text additions in regards to Influenza A virus and Pandemic 2009 H1N1) per PR Notice 95-2. This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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 Bob MacDonald at bmacdonald@srconsultants.com or at 260-244-6273 with any questions.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> 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 Bob MacDonald	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 Bob MacDonald	5. Date 10/27/09	

SRC
Scientific & Regulatory
Consultants, Inc.

October 27, 2009

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 (Influenza A and Pandemic 2009 H1N1)
Control III Disinfectant Germicide
EPA Reg. No.: 55364-3

Dear Ms. Noble:

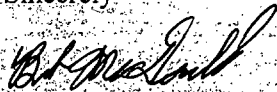
On behalf of our client Maril Products Inc. enclosed is a notification in compliance with the recent Agency "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)".

This notification, as stipulated by the guidance, is consistent with the provisions of PR Notice 95-2 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 95-2 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.

The new statements, as specified in the guidance, have been included as an additional page of optional text that follows the currently accepted labeling. No other changes in the existing labeling have been made.

Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at bmacdonald@srconsultants.com.

Sincerely



Bob MacDonald
Agent for Maril Products Inc.

P.O. Box 1014
Columbia City, IN 46725

www.srconsultants.com

Phone: 260-244-6270
Fax: 260-244-6273

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.

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 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 and before eating, drinking or smoking tobacco. 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.

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.

P/N: 10002 REV B

CONTROL III®
Disinfectant Germicide

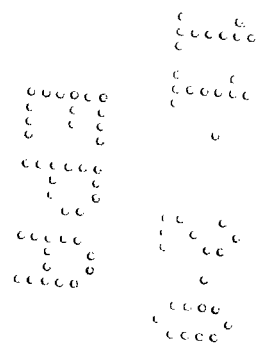
Bulletins:

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

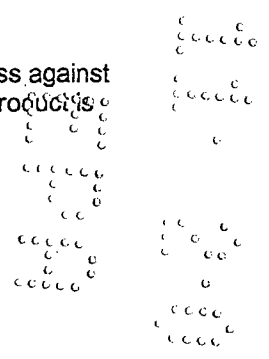


WHAT IS CONTROL III DISINFECTANT GERMICIDE?

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.

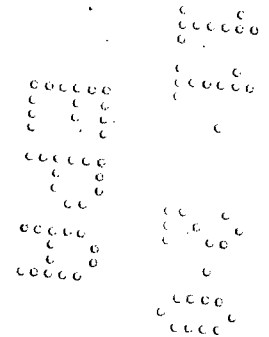


HOW TO PREPARE CONTROL III® DISINFECTANT GERMICIDE

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).

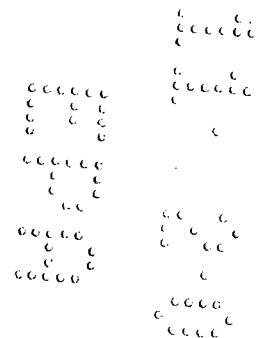


DISINFECTION OF SURFACES AND NONCRITICAL EQUIPMENT IN THE HOME WITH CONTROL III DISINFECTANT GERMICIDE

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.



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).

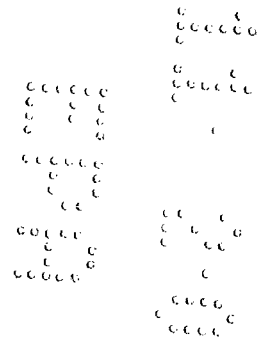
SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

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.



{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.

