55364-4 12/2/2009 1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC -2 2009

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

Subject: Control III Laboratory Germicide
EPA Reg. No.: 55364-4
Notification Date: October 28, 2009
EPA Receipt Date: November 2, 2009

Dear Mr. MacDonald,

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
Product Manager (31)
Regulatory Management Branch I
Antimicrobial Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
55364-4	V. Noble	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Control III Laboratory Germicide	31	

5. Name and Address of Applicant *(Include ZIP Code)*

Maril Products Inc.
320 W. 6th St.
Tustin, CA 92780

☐ *Check if this is a new address*

6. Expedited Reveiw. 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

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☑ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ 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@srcconsultants.com or at 260-244-6273 with any questions.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On label

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Bob MacDonald	Agent for Maril Products Inc.	(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 knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Bob MacDonald	Agent for Maril Products Inc.	
4. Typed Name	**5. Date**	
Bob MacDonald	10/28/09	

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SRC
Scientific & Regulatory
Consultants, Inc.

October 28, 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 Laboratory Germicide
EPA Reg. No.: 55364-4

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@srcconsultants.com.

Sincerely

Bob MacDonald
Agent for Maril Products Inc.

P.O. Box 1014
Columbia City, IN 46725
www.srcconsultants.com
Phone: 260-244-6270
Fax: 260-244-6273

(Front Panel)

CONTROL III®

LABORATORY GERMICIDE

READY TO USE

BACTERICIDAL
FUNGICIDAL
***VIRUCIDAL**

REQUIRES NO ACTIVATORS
CONTENTS ARE READY FOR USE

ACTIVE INGREDIENTS	
n-alkyl (60% C_{14}, 30% C_{16}, 5% C_{18}, 5% C_{12}) dimethyl benzyl ammonium chloride	**0.0781%**
n-alkyl (68% C_{12}, 32% C_{14}) dimethyl ethyl benzyl ammonium chloride	**0.0781%**
INERT INGREDIENTS	**99.8438%**
TOTAL	**100.000%**

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ONE GALLON (128 FL. OZ.)

EPA EST. #40873 CA-01/GA-01

EPA REG. # 55364-4

MARIL PRODUCTS, INC.
320 West 6th Street
Tustin, CA 92780 USA
800-546-7711 • 714-544-7711

(Left Panel)

Effective Against:

Pseudomonas aeruginosa (PRD-10); Staphylococcus aureus (ATCC 6538); Salmonella choleraesuis (ATCC 10708); Influenza A_2 virus*; Herpes simplex type 1*; Adenovirus type #5; Vaccinia viruses*; Trichophyton mentagrophytes, on hard, non-porous, inanimate surfaces.

Note: Control III Laboratory Germicide has not been tested for effectiveness against Mycobacterium Tuberculosis and must not be relied upon when a Tuberculocidal product is desired.

KILLS HIV-1 ON PRE-CLEANED 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 blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS).

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

PERSONAL PROTECTION:
Clean-up should always be done wearing protective latex gloves, masks, and eye protection.

CLEANING PROCEDURES:
Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME:
Allow surface to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS:
Bloody body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION:
Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling.

STORAGE AND DISPOSAL:
Do not contaminate water, food or feed by storage or disposal.

CONTAINER DISPOSAL:
Do not reuse empty container. Wrap container and put in trash.

STORAGE:
Store in a dry place no lower in temperature than 50°F or higher than 120°F.

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 immediately 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 10005 Rev. A

(Right Panel)

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.

DISINFECTION:

Control III Laboratory Germicide is a "Ready-To-Use" disinfectant which is designed for use as a disinfectant in hospitals, doctors' offices, dentists' offices, nursing homes, clinics and surgi-centers. It is formulated to disinfect hard, non-porous, inanimate surfaces such as counter tops, beds, instruments, fixtures and equipment.

1. Prior to disinfection with Control III Laboratory Germicide, all surfaces must be thoroughly cleaned to remove gross filth or heavy soil.

2. Use full strength. Do not dilute.

3. Apply Control III Laboratory Germicide with a clean sponge, cloth or by a trigger sprayer so as to wet all surfaces thoroughly. For disinfection, surfaces must remain wet for ten minutes. Allow to air dry.

4. Control III Laboratory Germicide is classified as a low-level disinfectant.

OPERATING ROOM GERMICIDE:

Apply CONTROL III Laboratory Germicide solution to a clean sponge or cloth. Wipe down surgery tables, instrument stands, and other equipment so as to wet all surfaces thoroughly. Allow to air dry. (See DISINFECTION directions)

SURGICAL INSTRUMENT STORAGE:

Place instruments in clean storage tray container. Fill container with CONTROL III Laboratory Germicide solution to fully immerse instruments. Cover container. In normal use storage solution can be retained for thirty days. Replace solution more often if frequent instrument removals and additions are made. Instruments should be autoclaved after soaking in Control III prior to reuse. (See DISINFECTION directions)

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

Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by influenza A virus. This product (Control III Laboratory 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.