

55364-7

4/8/2010

1 of 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 8 2010

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

Subject: **Control III Elite**
EPA Registration Number 55364-7
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
for Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

2005



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 55364-7	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Control III Elite	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)(ii), 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@srcconsultants.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
* 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 checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 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 Elite
EPA Reg. No.: 55364-7

Dear Ms. Noble,

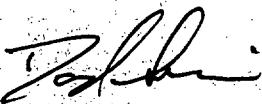
On behalf of our client, Maril Products, Inc., enclosed is a notification revising the storage and disposal section to comply with the Final Pesticide Container and Containment Regulations. This is a Notification per PR Notice 2007-4; therefore, no PRIA fee is required.

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.

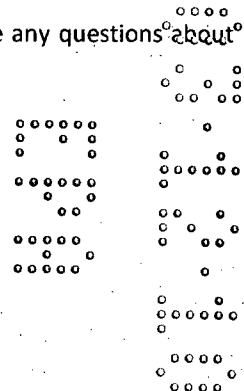
This notification, as stipulated by the guidance, is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46; and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 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



CONTROL III®

Elite

BACTERICIDAL

DO NOT DILUTE

DISINFECTANT *VIRUCIDE TUBERCULOCIDAL CLEANER

ACTIVE INGREDIENTS

n-Alkyl
(60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chlorides
..... 0.105%

n-Alkyl
(68% C12, 32% C14) dimethyl
ethylbenzyl ammonium chlorides
..... 0.105%

INERT INGREDIENTS..... 99.790%

TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN WARNING

SEE LEFT PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

EPA REG. NO. 55364-7

EPA EST. NO. 40873-CA-01, GA-01

Net Contents 32 fluid ounces

MARIL PRODUCTS, INC.

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

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.

Control III Elite is specifically designed for the cleaning and disinfection of non-critical medical devices such as bed frames, wheel chairs, physical therapy equipment and other hard non-porous environmental surfaces in hospitals, nursing homes, durable medical equipment suppliers, doctors offices, schools, gymnasiums, homes and animal clinics. Control III Elite may also be used to pre-clean or decontaminate instruments in hospitals or other medical facilities prior to sterilization or high level disinfection.

DISINFECTION AND CLEANING:

Remove gross filth or heavy soil prior to application of Control III ELITE. Apply solution as is- DO NOT DILUTE - to equipment with a cloth, sponge or by spraying so as to thoroughly wet all surfaces. For disinfection surfaces must remain wet for ten minutes. Allow to air dry or wipe off with a clean cloth or sponge.

PRECLEANING AND SOAKING:

Control III ELITE can be used for pre-cleaning and soaking small medical devices prior to sterilization or high level disinfection. All items to be soaked must be pre-cleaned to remove gross filth or heavy soil. Items should then be fully immersed in Control III ELITE solution for ten minutes; then thoroughly rinsed and allowed to air dry.

TUBERCULOCIDAL ACTIVITY:

This product exhibits disinfectant efficacy against Mycobacterium tuberculosis (BCG) in 10 minutes at 20 degrees Centigrade when used as directed on previously cleaned hard non-porous inanimate surfaces.

BACTERICIDAL ACTIVITY:

When used as directed, this product exhibits effective disinfectant activity against the organisms: Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, Escherichia coli 0157:H7, and meets the requirements for hospital use.

*VIRUCIDAL ACTIVITY:

This product, when used on environmental, inanimate, non-porous surfaces exhibits effective virucidal activity against HIV-1 (associated with AIDS) and Canine Parvo virus.

4085

5045

KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS

in the health care settings (Hospitals, Nursing Homes) or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or 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 Immuno-deficiency 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:
When handling items soiled with blood or body fluids use disposable latex gloves, gowns, masks, or eye coverings.

CLEANING PROCEDURES:
Blood and other body fluids 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:
Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING:
Causes eye and skin irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling.

P/N 10007 REV. B

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE:

Store in original containers 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. Offer for recycling if available or wrap container and put in 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 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 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.

C

B
D