# ATES ENVIRONMENTAL PROTECTION AGENCY

SEP - 8 2003

**Bob MacDonald** Agent for Maril Products Maril Products 320 W 6th Street Tustin , CA 92780

Subject:

Control III Elite

EPA Registration No. 55364-7

June 9, 2003 Amendment Dated: EPA Received Date: June 16, 2003

Dear Mr. Bob MacDonald,

The following amendment submitted in connection with registration under section 3(c)(7)(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is acceptable with the following condition.

# **Proposed Amendment**

Update First Aid Statements in compliance with PR Notice 2001-1

## Condition

Revise the Storage and Disposal section as follows

Store in original containers in a locked storage area in accessible to children. Do not reuse empty container. Wrap and discard in the trash.

## **General Comments**

A stamped label is enclosed for your records. Please submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. If the above condition is not compiled with, the registration will be subject to cancellation in accordance with FIFRA section (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of this condition.

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	CONCURRENCES duct Manager (31)							
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SURNAME )			·		Antimicrobial	Division (7510)	)	
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EPA Form 1320-1A (1/90)

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

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

#### **PRECAUTIONARY STATEMENTS**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### WARNING

Causes eye and skin imitation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Avoid contamination of food. Remove contaminated clothing and wash soap and water after handling.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or

#### CONTAINER DISPOSAL:

Do not neuse container Wrap container and put in trash.

#### STORAGE:

Store in a dry place no lower in temperature than 50°F or higher than

#### FIRST AID

If in eyes: Hold eye open and owly and gently with water for 15-20 minutes. Remove contart lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center doctor for treatment advice

If an aide 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 conral center or doctor immediately for treatment advice. Have person sip a glass of water if able to swal-low. 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 ar tificial respiration, preferably by mouth-to-mouth, it possible. Call a poison control center or doctor for further treatment advice.

Plote to Physician: Probable mucosal damage may contraindicate the use of gastric

#### HOT LINE NUMBER

For emergency steelical advice, call your local poleum control center (1-909-222-1222) or doctor. How the product container or label with you when seeding medical advice or treatment.

# CONTROL III

Elite

## DISINFECTANT \*VIRUCIDE **TUBERCULOCIDAL CLEANER**

ACTIVE INGREDIENTS

n-Alkvi (60% C14 30% C16 5% C12 5% C18) dimethyl benzyl ammonium chloric es ...... 0.105%

n-Alkvi (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides

...... 0.105% MERT INGREDIENTS......99.790%

TOTAL ..... 100.000%

### KEEP OUT OF REACH OF CHILDREN **WARNING**

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENT EPA REG. NO. 55364-7 EPA EST. NO. 40873-CA-01, GA-0 Net Contents 32 fluid oundes

MARIL PRODUCTS, INC. 320 West 6th Street Tustin, CA 92780 USA 714-544-7711 • 800-546-7710

#### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistant with its labeling.

This product is not to be used as a terminal sterilent/high level disinfectant on any surface or human body, either into or in contact with the bloodstream or normally starile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally startie areas of the body. This product enter normany stante areas or 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, rursing homes, durable medical equipment suppliers, doctors offices, schools, gymnesiums, 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 fifth or heavy soil prior to application of Control III ELITE. Apply solution as is-DO NOT DILITE - to equipment with a cloth, sponge or by spraying so as it theroughly wet all surfaces. For distribution surfaces. election surfaces must remain wet for ten minutes. Allow to air dry or wipe off with a clean cloth or sponge.

PRINCLEANING 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 fifth or heavy soil. Items should then be fully immersed in Control III ELITE solution for ten minutes; then thoroughly rinsed and flowed to air dry.

TUBERCULOCIDAL ACTIVITY:

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

**EACTERICIDAL 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, inenemate, non-porous surfaces exhibits effective virucidal activity inst HIV-1 (associated with AIDS) and

ACCEPTED with COMMENTS in EPA Letter Dated:

8EP 8 - 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as registered under tPA Rog. No. 55364-7

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