

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

April 19, 2022

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Bob MacDonald Agent for Maril Products, Inc. Maril Products, Inc. 15421 Red Hill Avenue, Suite D Tustin, CA 92780

Subject: Notification per PRN 98-10 – To update label language

Product Name: Control III Laboratory Germicide

EPA Registration Number: 55364-4

Received Date: 1/28/2022

Action Case Number/Decision Number: 00338480

Dear Mr. MacDonald:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

If you have any questions, you may contact Oiguenblik. Emilia@epa.gov or Hebert. John@epa.gov.

Sincerely,

Kathryn V. Montague Senior Regulatory Advisor

Antimicrobials Division, 7510M

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US EPA

CONTROL III

LABORATORY GERMICIDE

READY TO USE

BACTERICIDAL FUNGICIDAL *VIRUCIDAL

REQUIRES NO ACTIVATORS
CONTENTS ARE READY FOR USE

ACTIVE INGREDIENTS

n-alkyl (60% C14, 30% C16, 5% C18, 5% C12) dimethyl benzyl ammonium chloride0.0781%

n-alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride

TOTAL......100.000%

OF CHILDREN

CAUTION

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ONE GALLON (128 FL. OZ.)

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

EPAREG. #55364-4

MARIL PRODUCTS, INC.

15421 Red Hill Avenue, Suite D Tustin, CA 92780 USA 800-546-7711 • 714-544-7711

NOTIFICATION

55364-4

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/19/2022

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 visible filth or visible 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 visibly wet for ten (10)minutes. Allow to air dry.
- 4. Control III Laboratory Germicide

is a disinfectant for non-critical devices or surfaces.

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 surfaces to remain visibly wet for 10 minutes. Allow to air dry.

SURGICALINSTRUMENT STOR-AGE:

For aseptic storage of surgical instruments prior to being sterilized. 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.

Effective Against:

Pseudomonas aeruginosa (PRD-10); Staphylococcus aureus (ATCC 6538); Salmonella choleraesuis (ATCC 10708); SARS-Related Coronavirus* [SARS-COV-2] [USA-WA1/2020][BEI NR-52281]; Influenza A2 virus*; Herpes simplex type 1*; Adenovirus type #5; Vaccinia virus*; Trichophyton interdigitale, on hard, non-porous, inanimate surfaces.

Kills SARS-CoV-2*[COVID19 virus] [virus] on hard non-porous surfaces.

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

HIV-1: See Technical Bulletin "Efficacy of Control III Products For the Control of the Human Immuno- deficiency Virus Type 1 (AIDS VIRUS).

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 DECONTAMINA-TION 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 visibly 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 and disposal.

PESTICIDE STORAGE:

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

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 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. B