UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2020

Jamie Venable
Agent
Maril Products, Inc.
15421 Red Hill Avenue, Suite D
Tustin, CA 92780

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Control III Laboratory Germicide
EPA Registration Number: 55364-4
Application Date: April 20, 2020
Decision Number: 562199

Dear Ms. Venable:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.

3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
   a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

      i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:

         A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
         B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
         C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)

      ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).

         A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.

         B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Adenovirus type 5 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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) list 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 Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

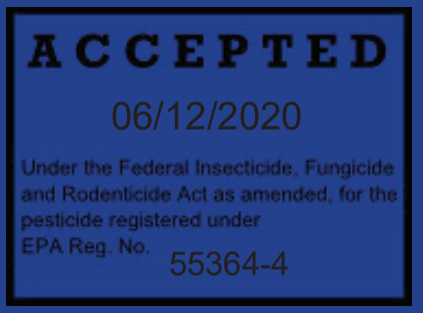
Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

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 chloride	0.0781%
n-alkyl (68% C12, 32% C14) 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.
15421 Red Hill Avenue, Suite D
Tustin, CA 92780 USA
800-546-7711 • 714-544-7711

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.

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)

Effective Against:

Pseudomonas aeruginosa (PRD-10); Staphylococcus aureus (ATCC 6538); Salmonella choleraesuis (ATCC 10708); Influenza A2 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.

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 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 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. A

{Emerging Viral Pathogens}

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging pathogens from the following viral categories:

- Enveloped viruses

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Adenovirus type 5

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging enveloped virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging enveloped virus] when used in accordance with the directions for use against Adenovirus type 5 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging enveloped virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging enveloped virus] when used in accordance with the directions for use against Adenovirus type 5 on hard non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information