

46851-5

02/03/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


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 WASHINGTON, D.C. 20460

FEB - 3 2011

Lewis Ward
 Certol International, LLC
 6120 E. 58th Avenue
 Commerce City, CO 80022

 OFFICE OF CHEMICAL SAFETY
 AND POLLUTION PREVENTION

Subject: OMC II TM
 EPA Registration No. 46851-5
 Amendment Date: July 26, 2010
 EPA Receipt Date: July 28, 2010

Dear Mr. Ward

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with conditions.

Proposed Amendment

- Add disinfectant claim against *Staphylococcus aureus*- MRSA HA and CA

Conditions

Revise the label as follows:

1.) The HIV-1 directions are incomplete such that its various sections are dispersed throughout the proposed label, these statements must be consolidated to reflect the following:

***KILLS HIV-1 ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings 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 immunodeficiency virus Type-1 HIV-1(associated with AIDS).

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

PERSONAL PROTECTION: Language on label is acceptable.

CLEANING PROCEDURE: Language on label is acceptable.

SYMBOL	CONTACT TIME: Language on label is acceptable.					
SURNAME						
DATE						

DISPOSAL OF INFECTIOUS MATERIALS: Language on label is acceptable.

2.) Revise the 4th statement under the "Precautionary Statements" by adding the phrase, "or using the toilet."

Data Summary

Data from EPA Registration No. 46851-1 may be cited to support this product.

General Comments

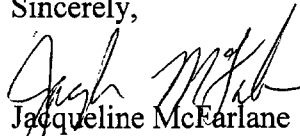
A stamped accepted label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have further questions concerning this letter, please contact me at 703-308-6416 or by email at Campbell-mcfarlane.jacqueline@epa.gov or Killian Swift at (703) 308-6416 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Jacqueline McFarlane
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure:		Stamped Label		CONCURRENCES					
SYMBOL									
SURNAME									
DATE									

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

Directions for Use

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

OMC II is a ready to use surface disinfectant for use in medical, dental, hospital, clinical, and office environments.

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

CONTACT TIME: Leave surface wet for 2 minutes. Use a 10 minute contact time for disinfection against all other virus, bacteria, and fungi claimed.

FOR DISINFECTION: Remove excess organic debris and thoroughly clean surface prior to application of OMC II. The following non-porous surface areas: walls, floors and countertops must be sprayed and mopped, sponged, or wiped in a manner to thoroughly wet the surface with OMC II. Allow surface to remain wet for 10 minutes at 68°F (20°C) and allow to air dry to destroy the following bacteria: Staphylococcus aureus, Escherichia Coli 0113, Salmonella typhosa, Pseudomonas aeruginosa, Mycobacterium tuberculosis var. bovis, the following fungi: Trichophyton mentagrophytes; the following viruses: *Herpes virus types 1 & 2, *Vaccinia virus, *Influenza virus types A1 (New Jersey), * Influenza B (Maryland) and *HIV-1 (AIDS virus).

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other setting in which there is an expected likelihood of soiling 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 immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

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

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear disposable, latex gloves, gowns, masks, and eye coverings.

Lemon
Scent

Certol
International

OMC II™

Surface Disinfectant

Tuberculocidal, Virucidal*, Bactericidal, Fungicidal

For use in medical, dental, hospital, clinical, and office environments.
Kills Pandemic 2009 H1N1 Influenza.

Active Ingredients

o-phenylphenol 0.28%
o-benzyl-p-chlorophenol 0.03%
Inert Ingredients 99.69%
Total 100.00%

Contents: 1 Gallon (3.79 liter)
Reorder No. OMC128

DIN 02231483

E.P.A. Reg. No. 46851-5
E.P.A. Est. No. 46851-CO-003

Keep Out of Reach of Children

CAUTION: Irritant

See side panels for additional precautionary statements.

Add:

Staphylococcus aureus - MRSA

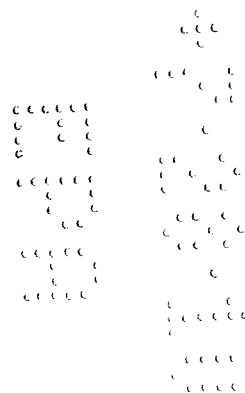
ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB - 3 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

46851-5

Proposed Label



PRECAUTIONARY STATEMENT

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, absorbed through skin or inhaled. Avoid contact with skin or clothing. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

FIRST AID

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 a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

If on skin or on 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 inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

If in eyes: Hold eye open, rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a Poison Control Center or doctor for further treatment advice.

HOTLINE NUMBER

In case of an emergency call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

GENERAL PRECAUTIONS AND RESTRICTIONS

Follow application as a low-pressure or high-pressure spray, do not enter or allow others to enter the treated area until spray has dried. For all spray applications: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For pour, pump, mop and wipe applications: Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application.

USER SAFETY/INSTRUCTIONS

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep securely closed in original container. Store at room temperature.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Rinse and discard empty container. Container is non-refillable. Do not reuse empty container.

Certol®
International

A Limited Liability Company

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