

46851-1

06/29/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 29, 2005

Steve Cassinis
Vice President
Certol International, LLC
6120 E. 58th Ave.
Commerce City, CO 80022

Subject: Notification Application Per PR Notice 98-10
OMNI II
EPA Registration No. 46851-1
Application Dated June 3, 2005

Dear Mr. Cassinis:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- Addition of the words "Lemon Scent" to the label

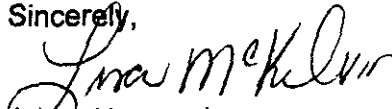
General Comment:

Based on a review of the material submitted, the following comment apply:

A copy of the notification has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,


Lisa McKelvin
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

June 3, 2005

VIA Regular Mail:

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
Antimicrobials Division
Attention: Product Manager 34
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

NOTIFICATION
Date Reviewed: 6/13/05
Reviewed By: Steve Cassinis

**Notification of Odor added to Label per PR Notice 98-10
OMNI-II (EPA No. 46851-1)**

This notification is submitted as a follow up to your letter dated June 14, 2004 (copy attached) in which you approved a Minor Formulation Amendment for our registered product, OMNI II (EPA Registration No. 46851-1). Pursuant to your June 14, 2004 letter, we have been authorized to distribute this product with a lemon fragrance. Thus, this Notification Letter, with the enclosed EPA Form 8570-1, and one copy of our draft amended label serve to notify the Agency of our addition of the words "Lemon Scent" to our basic product label (OMNI II – EPA No. 46851-1) and the labels for all alternative brand names which have been registered for this product (specifically: [Prophene Plus, Vital Defense D, ProSpray C-60]). This label change/amendment can be made by notification pursuant to PR Notice 98-10.

Please let me know by email (scassinis@gocertol.com) or fax (303-799-9408) or phone (303-799-9401) when you have received this notification.

Thank you for your assistance in this matter.

Sincerely Yours,


Steve Cassinis, Vice President



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

 Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 46851-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Certol International, LLC / OMNI II	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Certol International, LLC 6120 E. 58th Ave., Commerce City, CO 80022 <input checked="" type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), 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.

Notification: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Odor (Lemon Scent) added to label per PR Notice 98-10. 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.

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
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 32 fl oz bottle and 1/2 fl oz packet		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper, glued Stenciled				<input checked="" type="checkbox"/> Other plastic sleeve	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Steve Cassinis	Title Vice President	Telephone No. (Include Area Code) 303-799-9401
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)
2. Signature 	3. Title Vice President	
4. Typed Name Steve Cassinis	5. Date 6/3/05	

Omni II™

Concentrated Surface Disinfectant
and Holding Solution

Tuberculocidal, Virucidal*, Bactericidal,
Fungicidal

Active Ingredients

o-phenyl phenol	8.0%
o-benzyl-p-chloropheno	1.0%
Other Ingredients	80.0%
Total	100.0%

E.P.A. Reg. No. 4885-1-1
E.P.A. Est. No. 4885-1-00-013

Contents: 1 Quart
(32 oz. - 946 ml)
Reorder No. OMN232

DANGER: Keep Out of Reach of Children
See Safety Panel for Additional Precautionary Statements

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR 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 items such as disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES:

Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.

CONTACT TIME: Omni II when diluted 1:32 has been shown to be effective in destroying the HIV-1 (AIDS virus) in 60 seconds at 20°C. This contact time will not control other common types of viruses and bacteria.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids should be auto-claved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENT

Hazards to Humans and Domestic Animals

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled, swallowed or absorbed through skin.

Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shields (safety glasses), protective clothing (long-sleeve shirt and long pants, sock, plus shoes and chemical resistant gloves such as water proof gloves).

USER SAFETY REQUIREMENTS:

Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

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 5 minutes, then continue rinsing. 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 person sip a glass of water if able to swallow. Do not induce vomiting unless told by a 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 mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

In case of an emergency for additional information call toll free 800-535-9053. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

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

Omni II is designed for use on hard non-porous surfaces and/or in holding solutions in medical, dental, laboratory and veterinary facilities. Thoroughly clean surface of items to be disinfected and rough dry. Omni II is a concentrated solution and must be diluted 1:32 with water prior to instrument soak and/or decontamination of dental and medical instruments or disinfection of hard environmental surfaces. 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.

Soak/Decontamination - Immerse items in diluted Omni II solution for instrument soak and/or decontamination of medical and dental instruments. Rinse articles thoroughly following soak/decontamination. Organic materials or water introduced into the diluted product may effect products effectiveness. Discard the used solution daily or sooner if it becomes diluted or soiled.

Ultrasonic Cleaning - Place instruments into diluted Omni II and activate ultrasonic unit. When instruments are clean, remove and rinse thoroughly. Change solution daily or sooner if it becomes diluted or soiled.

Cleaning - Apply Omni II directly to surface using mop or spray bottle. Wipe surface to remove debris and solution using a clean paper or cloth towel and discard.

Hard Surface Disinfection - diluted Omni II solution should be mopped, sponged, sprayed or wiped onto hard environmental surfaces such as walls, floors and countertops in a manner to thoroughly wet the surface. A properly prepared solution of Omni II intended for use as a hard surface disinfectant, has a shelf life of 60 days (use life) when stored in a closed container such as a spray bottle.

A contact time of 10 minutes at 20°C (68°F) with a 1:32 dilution of Omni II has been shown to be effective on bacteria including: Escherichia Coli O113, Staphylococcus aureus, Salmonella typhosa, Pseudomonas aeruginosa, Mycobacterium tuberculosis; fungi including: Trichophyton mentagrophytes; viruses including Influenza virus type A1 (New Jersey) and Influenza B (Maryland), Herpes virus types 1 and 2, Vaccinia virus, and Polio virus 1.*

Omni II when diluted 1:32 has been shown to be effective in destroying the HIV-1 (AIDS virus) in 60 seconds at 20°C (68°F). Although efficacy in 60 second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use 10 minute contact time for disinfection against all the organisms claimed. Effective in waters up to 400 ppm hardness calculated as calcium carbonate.

For use on metals, plastics, rubber and glass. Glass may etch over prolonged or repeated exposure to concentrated solutions. Do not store lensed articles in concentrated Omni II.

MANUFACTURED BY:
CERTOL
INTERNATIONAL, LLC
6120 E. 58TH AVE.
COMMERCE CITY, CO 80022 USA
1 800 THE EDGE
(1 800 843 3343)

TO PREPARE 1:32 USE-DILUTION

WATER	OMNI II
To Make 1 Pint	
15 1/2 fl. oz.	1/2 fl. oz. (15 ml.)
To Make 1 Quart	
31 fl. oz.	1 fl. oz. (30 ml.)
To Make 1 1/2 Gallon	
62 fl. oz.	2 fl. oz. (60 ml.)
To Make 1 Gallon	
124 fl. oz.	4 fl. oz. (120 ml.)

A contact time of 10 minutes at 20°C (68°F) with a 1:32 dilution of Omni II has been shown to be effective on bacteria including: Escherichia Coli O113, Staphylococcus aureus, Salmonella typhosa, Pseudomonas aeruginosa, Mycobacterium tuberculosis; fungi including: Trichophyton mentagrophytes; viruses including Influenza virus type A1 (New Jersey) and Influenza B (Maryland), Herpes virus types 1 and 2, Vaccinia virus, and Polio virus 1.*

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STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep Omni II covered in storage or in use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse container, puncture and dispose of in a sanitary landfill, or incinerate.

OMN232/BL10

NOTIFICATION
Date Reviewed: 6/22/05
Reviewed By: [Signature]

7/14