

46851-1

7/2/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 2, 2004

Steve A. Cassinis
Vice President
Cottrell International, LLC
6120 E. 58th Avenue
Commerce City, CO 80022

Subject: OMNI II
EPA Registration No. 46851-1
Application Dates: June 7, 2004
EPA Received Dates: June 7, 2004

Dear Mr. Cassinis:

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

Proposed Notification

- Revised labeling

General Comments

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

The notification application will be acceptable provided you comply with PR Notice 98-10, section VI, i.e. "Certification Statement."

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

Sincerely,

Adam Heyward
 Adam Heyward
 Product Manager 34
 Regulatory Management Branch II
 Antimicrobials Division (7510 C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	Heyward						
DATE	7-2-04						



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) Cottrell International, LLC/ OMNI II	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Cottrell International, LLC 6120 E. 58th Avenue 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 checked="" 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 type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

NOTIFICATION
 Date Reviewed: 6-14-04
 Reviewed By: *[Signature]*

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

Minor Label Revision Amendment as pursuant to PR Notice 98-10. The "Contact Time" language is being added to ensure the product's label continues to conform to EPA guidance document, Label Requirements for Antimicrobials Used on Hard Surfaces Against HIV-1 (AIDS Virus). Use of the highlighted text regarding "pre-cleaning" the surface prior to disinfection is being resumed as it originally appeared on this product's stamped label on August 1, 2000.

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* 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
 Label Container

4. Size(s) Retail Container
1 oz., 16 oz., 32 oz., 64 oz.

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Steve A. Cassinis	Title Vice President	Telephone No. (Include Area Code) 1-800-843-3343
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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.

2. Signature
[Signature]

3. Title
Vice President

4. Typed Name
Steve A. Cassinis

5. Date
June 7, 2004

6. Date Application Received
(Stamp)

3 8 4

ARNOLD & PORTER LLP

Lawrence E. Culleen
Lawrence_Culleen@aporter.com

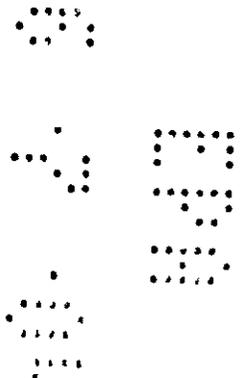
202.942.5477
202.942.5999 Fax

555 Twelfth Street, NW
Washington, DC 20004-1206

VIA HAND DELIVERY

June 7, 2004

Adam Heyward, PM 34
Antimicrobials Division, Mail Code 7501 C
Office of Pesticide Programs
U.S. Environmental Protection Agency
Document Processing Center Room 266A
1921 Jefferson Davis Highway, CM-2
Arlington, VA 22202



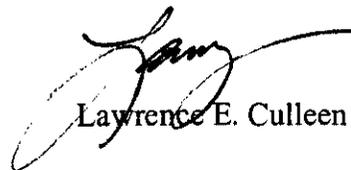
Re: OMNI II (EPA Registration Number 46851-1)

Dear Mr. ^{Adam} Heyward:

Enclosed for your review is an Application Form (8570-1) and revised product label for OMNI II (EPA Registration No. 46851-1) submitted as a Notification for Minor Label Revisions filed pursuant to PR Notice 98-10. We have highlighted on the enclosed label the additional text we intend to add to the most recently stamped (June 19, 2003) label. The "Contact Time" language is being added to ensure that this product's label continues to conform to the EPA guidance document, *Label Requirements for Antimicrobials Used on Hard Surfaces Against HIV-1 (AIDS Virus)*. The text regarding the requirement for "pre-cleaning" the surface prior to disinfection was included in the OMNI II product label as stamped on August 1, 2000, but apparently was inadvertently deleted from the edition stamped by EPA on June 19, 2003.

We are submitting this request as a minor label amendment to enable us to obtain a stamped copy of the label to use in state registrations. During our May 26, 2004 telephone conversation you indicated that you would expedite review of this amendment because it would otherwise qualify as a notification. Please forward to us a stamped, approved label for OMNI II once the revisions have been reviewed and placed within the product's jacket. If you have any questions, please contact me at (202) 942-5477 or by e-mail at Lawrence_Culleen@aporter.com

Sincerely,


Lawrence E. Culleen

cc: Steve A. Cassinis

4 7 4

Omni II™

Concentrated Surface Disinfectant and Holding Solution

Tuberculocidal, Virucidal*, Bactericidal, Fungicidal

Active Ingredients

Quaternary Ammonium Compounds
Sodium Hypochlorite
Sodium Hydroxide
Sodium Chloride
Water

Contents: 1 Quart
132 oz. - 946 ml
Reorder No. OMN232

DANGER: See Safety Precautions for Additional Precautions. *See Directions for Use.

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. The contact time will not control other common types of viruses and bacteria.

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

PRECAUTIONARY STATEMENT
Hazard 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). Wash hands before

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.

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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

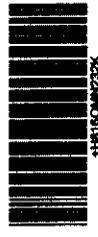
IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

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 treatment and/or decontamination of dental and medical instruments or disinfection of hard environmental surfaces. This product is not to be used as a terminal state-of-the-art disinfectant on any surface or instrument that (1) is saturated directly into the human body, either into or in contact with the blood stream 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.

Semi-critical/instruments - Immerse items in diluted Omni II solution for treatment and/or decontamination of medical and dental instruments. Rinse articles thoroughly following decontamination. Organic materials or water introduced into the diluted product may affect product 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.



TO PREPARE 1:32 USE-DILUTION WATER	OMNI II
15 1/2 fl. oz. (15 ml.)	1/2 fl. oz. (15 ml.)
31 fl. oz. (1.0 quart)	1 fl. oz. (30 ml.)
62 fl. oz. (1.2 gallon)	2 fl. oz. (60 ml.)
124 fl. oz. (1.5 gallon)	4 fl. oz. (120 ml.)

STORAGE AND DISPOSAL

Keep Omni II covered in storage or use. Do not contaminate water, food or feed by storage or disposal. Do not reuse empty container. Triple rinse container, puncture and dispose of in a sanitary landfill or incinerator. Used disinfectant solutions are toxic. Store, use and dispose of according to label instructions.

OMN232R1.08

MANUFACTURED BY:
CERTOL
1620 E. 58TH AVE.
COMMERCE CITY, CO 80022 USA
1 800 776 EDGE
1 800 843 3343

NOTIFICATION
Date Reviewed: 6-14-04
Reviewed By: S. Gray