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,

Denise L. Whitake

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

CONCURRENCES								
SYMBOL	7510C							
SURNAME	AHay							
DATE	7-2-04							

Copy to M. Sherrill 6-7-04

2 3 4

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	2. EPA Product Manager	3. Proposed Classification
46851-1	Adam Heyward	☑ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Cottrell International. LLC/ OMNI II	34	

5. Name and Address of Applicant *(Include ZIP Code)*

Cottrell International, LLC
6120 E. 58th Avenue
Commerce City, CO 80022

☑ *Check if this is a new address*

6. Expedited Reveiw. 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

☑ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ 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	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☑ No	☐ Yes ☑ No	☐ Yes ☑ No	☐ Metal ☑ Plastic ☐ Glass ☐ Paper ☐ 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	4. Size(s) Retail Container	5. Location of Label Directions
☑ Label ☐ Container	1 oz., 16 oz., 32 oz., 64 oz.	☑

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

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 knowlingly 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
[signature]	Vice President
4. Typed Name	**5. Date**
Steve A. Cassinis	June 7, 2004

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 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

Omni II™

Concentrated Surface Disinfectant and Holding Solution

Tuberculocidal, Virucidal*, Bactericidal, Fungicidal

Active Ingredients

[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
Total	[illegible]

[illegible]

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

DANGER: Keep Out of Reach of Children
See Side 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 autoclaved 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). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

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.

In case of an emergency for additional information call toll free 800-535-5053. 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.

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 preclean 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 affect 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 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 0113, 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.

TO PREPARE 1:32 USE-DILUTION	
WATER	OMNI II
To Make: 1 Pint	
15½ fl. oz.	½ fl. oz. (15 ml.)
To Make: 1 Quart	
31 fl. oz.	1 fl. oz. (30 ml.)
To Make: 1/2 Gallon	
62 fl. oz.	2 fl. oz. (60 ml.)
To Make: 1 Gallon	
124 fl. oz.	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 incinerate. Used disinfectant solutions are toxic. Store, use and dispose of according to label instructions.

+H816OMN232K

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

OMN232/BL08

NOTIFICATION
Date Reviewed: 6-14-04
Reviewed By: [signature]

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