



U.S. ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Antimicrobials Division (H7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:
46851-11

Date of Issuance:
SEP 17 2002

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
Omni II

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

**Cottrell International, LLC
5450 Joliet Street
Denver, CO 80239**

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a. Add the phrase "EPA Registration Number 46851-11"

Signature of Approving Official:

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

Date:

SEP 17 2002

EPA Form 8570-6

CONCURRENCES

SYMBOL	SURNAME	DATE					
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b. In accordance with PR Notice 2001-1, the first aid and subheading must be revised to read as follows:

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 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 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
In case of an emergency for additional information call toll free (insert toll free number if available). Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

c. Revise Storage and Disposal test to read:

Storage and Disposal

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

Pesticide Storage: Keep Omni II covered in storage or use.

Pesticide Disposal: Pesticide wastes are...Regional Office for guidance.

Pesticide Container: Triple rinse...stay out of smoke.

Refer to PR Notice 83-3 for detailed information.

3. The alternate brand names "Vital Defense-D, and Prophene Plus" are acceptable.

4. Submit three (3) copies of the revised final printed label bearing the revisions prior to releasing this product for sale.

CONCURRENCES

SYMBOL	SURNAME	DATE						

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosure

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

Omni II™ [Alternate Brand Names: "Vital Defense-D" and "Prophene Plus"]

Concentrated Surface Disinfectant and Holding Solution

**Tuberculocidal, Virucidal,*
Bactericidal, Fungicidal**

Active Ingredients

o-phenylphenol	9.0%
o-benzyl-p-chlorophenol	1.0%
Inert Ingredients	90.0%
Total	100.0%

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

E.P.A. Reg. No. 46851-
E.P.A. Est. No. 46851-CO-3

OMN232/FL01

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 heavy duty Nitrile 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.

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

PRECAUTIONARY STATEMENTS

Hazard to Humans

DANGER: Corrosive: Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear protective eyewear and rubber gloves when handling. Harmful if swallowed.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flood eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly a large quantity of water. Avoid alcohol. Call a physician immediately.

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

STORAGE & 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.

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.)

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING. Omni II concentrated solution and must be diluted 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 affect product's 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 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 type 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.

MADE IN U.S.A. BY:
COTTRELL, LTD., A DIVISION OF
CERTOL, INTERNATIONAL, LLC
5450 JOLIET STREET
DENVER, CO 80239 USA
1 800 THE EDGE

OMN232/BL02

**ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 17 2002**

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 46851-11**

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