

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 6, 2003

Mr. Steve Cassinis
Vice President
Cottrell International, LLC
Cottrell, LTD
5450 Joliet Street
Denver, CO 80239

Subject: **OMNI II**
EPA Registration No. 46851-1
Letter Dated December 9, 2002

Dear Mr. Cassinis:

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

Proposed Amendment

- Updated labeling

Label Comments:

1. The heading "Statement of Practical Treatment " must be changed to "First Aid" and 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 ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 1-20 minutes. Call 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.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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 emergency call (insert toll-free emergency number if available)."

"Have the product container or label with you when calling a Poison Control Center or doctor or going in for treatment."

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

For detailed information, refer to PR Notice 2001-1

2. The Precautionary Statement heading must read as follows:

Precautionary Statement
Hazards to Humans and Domestic Animals
Danger

3. The Agency noticed that the precautionary statement language has been changed from the original label, which was accepted on September 2, 1982. There are no acute toxicity data on file to support the current label language. Therefore, the precautionary statement must be revised to read as follows:

Precautionary Statement
Hazards to Humans and Domestic Animals


Danger: Corrosive. Causes eye damage or skin burns. Fatal if 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.

General Comments

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,


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

Enclosure

Omni II™

Concentrated Surface Disinfectant and Holding Solution

Tuberculocidal, Virucidal*, Bactericidal, Fungicidal

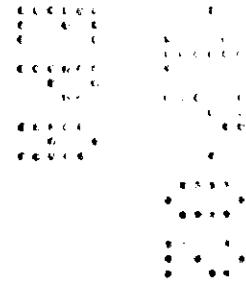
Active Ingredients

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. OIMN232

EPA Reg. No. 46851-4
EPA Est. No. 46851-CO-003

DANGER: Keep Out of Reach of Children



SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OF 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.

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.

DIRECTIONS FOR USE

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

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 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.

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.



46851-003-003

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 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. MANUFACTURED BY: **CERTOL INTERNATIONAL, LLC** 5450 JOLIET STREET DENVER, CO 80239 USA 1 800 THE EDGE (1 800 843 3343) OIMN232R/US

ACCEPTED with COMMENTS
EPA Letter Dated:

FEB - 6 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. H6851-1