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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR . 3 1995

ProChem Company  
7399 S. Tuscon Way  
Englewood, CO 80112

Attention: Jack Scoville  
Director, RA/QA

Subject: OMNI-II  
EPA Registration No. 46851-1  
MOU Compliance Amendment dated December 22, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, will be acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. Revise the microorganism Trichophyton interdigitale to read Trichophyton mentagrophytes everywhere it appears on the label.
2. Remove the claim for Polio virus type 1. The Agency letter dated August 12, 1992 accepted removal of label claims for both Polio virus type 1 and type 2.
3. Remove claim for Cocksackie B2 virus. Efficacy data to support this claim has not been submitted to the Agency.
4. Revise the statement "If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution..." to read, "If swallowed, drink promptly a large quantity of water."

A stamped copy of your labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2 9 3  
If you have any questions concerning this letter, please  
contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Ruth G. Douglas  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (7505C)

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:

MAR - 3 1995

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No.  
46851-1

Omni II - Quart Rev. 2B\* 12/20/94 \* Dimension 10" x 4"

COTTRELL

TO PREPARE 1:32 USE-DILUTION	
Water	Omni II
1 pint	1/2 oz. (15 ml)
1 quart	1 oz. (30 ml)
1/2 Gallon	2 oz. (60 ml)
1 Gallon	4 oz. (120 ml)

**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

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

**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.

#### PRECAUTIONARY STATEMENTS

Hazard to Humans.

#### STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately  
flush 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 egg  
whites or gelatin solution, or if  
these are not available, drink large  
quantities 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.

# 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)

EPA Reg. No. 46851-1  
EPA Est. No. 37265-CA-01

Reorder No. OMN232

#### 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 pre-clean or decontaminate critical  
or semi-critical medical devices prior to  
sterilization or high-level disinfection.

Immerse items in diluted Omni II solution  
for instrument soak and/or decontamination  
of medical and dental instruments. For  
disinfection of hard environmental  
surfaces such as walls, floors and  
countertops, diluted Omni II should be  
mopped, sponged, sprayed or wiped in a  
manner to thoroughly wet the surface.  
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,

Manufactured by Cottrell, Ltd.  
7399 South Tucson Way  
Englewood, CO 80112 USA  
1 800 THE EIXGE

OMN232A, Rev. (A)

Keep Out of Reach of Children

**DANGER:** See Side Panel for Additional Precautionary Statements

BEST AVAILABLE COPY