PM32 ✓ 46851-1 7 of 3

FEB 18 1986

ADM Medical Division, Inc.
dba Omnitec Medical Corporation
25283 Cabot Road, Suite 109
Laguna Hills, CA 92653

Attention: Palmer B. Ford

Gentlemen:

Subject: Omni II
EPA Registration No. 46851-1
Your Submission Dated January 2, 1986

The revised draft label referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the following conditions:

1. Make the labeling changes listed below on the finished printed labels.

   a. Delete the ADA seal. It is misleading labeling in that it indirectly implies recommendation of the pesticide by this agency (§162.10(a)(5)(v) of 40 CFR Ch. 1, July 7, 1985).

   b. Change the precautionary labeling to conform to the regulations, 40 CFR Ch. 1 (July 7, 1985) §162.10, p. 97. Your accepted label of August 17, 1983 was correct in this regard.

   c. The finished printed labels must comply with the general labeling requirements of §162.10 of Title 40 of the Code of Federal Regulations.

2. Submit five (5) copies of your final printed labeling, as defined in the A-79 Enclosure, before you release the product for shipment, to comply with PR Notice 82-2 of June 18, 1982.

86907:Lucke:C-2:KENCO:2/10/86:3/7/86:ab:vo/ek

SYMBOL ▶							
SURNAME ▶	[illegible]						
DATE ▶	FEB 18 1986						

EPA Form 1320-1 (4-81)

OFFICIAL FILE COPY

PM32 46851-1 2 of 3

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

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

Sincerely yours,

A. E. Castillo
Product Manager (32)
Disinfectants Branch
Registration Division (TS-767C)

Enclosures

OMNI-II™

EPA Reg No 46851-1
Est No 7368-CA-3

INSTRUMENT & EQUIPMENT DISINFECTANT

Active Ingredients	
o-phenylphenol	9.0%
o-Benzyl-p-chlorophenol	1.0%
Inert Ingredients	90.0%
	100.0%

- Bactericidal
- Fungicidal — destroys pathogenic fungi
- Virucidal*
- Tuberculocidal

* Viruses including Herpes virus types 1 & 2, Polio virus types 1 & 2, Vaccinia virus, Influenza virus type A1 (New Jersey) and Influenza B (Maryland)

KEEP OUT OF REACH OF CHILDREN

DANGER

Contents ½ gallon (64 fluid oz.)

Manufactured & Distributed by:
ADM MEDICAL DIVISION
25283 Cabot, Laguna Hills, Ca. 92653

DIRECTIONS FOR USE:

Omni II should be diluted 1:32 with water for disinfection of medical and dental instruments and devices. Rinse thoroughly after immersion. Discard the used solution daily, or sooner if it becomes diluted or soiled. IT IS IN VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Clean all excess organic debris from items to be disinfected and rough dry. Immerse in 1:32 concentration of Omni II for 10 minutes to destroy bacteria including *Escherichia coli* 0515, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis* (If tuberculosis contamination is suspected, increase immersion time to 20 minutes, for added safety); fungi including *Trichophyton interdigitale*; Viruses including Herpes virus types 1 & 2, Polio virus types 1 & 2, Vaccinia virus, Influenza virus type A1 (New Jersey) and Influenza B (Maryland).

To prepare 1:32 use dilution	
WATER	OMNI II
1 pint	½ oz. (15 ml)
1 quart	1 oz. (30 ml)
½ gallon	2 oz. (60 ml)
1 gallon	4 oz. (120 ml)

Do not reuse empty container

PRECAUTIONARY

DANGER: Corrosive. Causes eye damage or skin clothing. Wear goggles or face shield. Harmful or fatal if swallowed.

FIRST AID

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. For eyes, call a physician. Wash skin with soap and water. Wash clothing before reuse. If swallowed, drink milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician or poison control center immediately.

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

LABEL CHANGES REQUESTED:

1) PARAGRAPH #1 IN DIRECTIONS FOR USE: TO READ

2) PRECAUTIONS CHANGED TO

3) ADDITION OF ADA SEAL

4) ADDRESS CHANGE TO:
LAGUNA HILLS, CA

DIRECTIONS FOR USE:

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

OMNI II should be diluted 1:32 with water for medical and dental instruments and devices. after immersion. Other hard surface areas su and countertops should be mopped, sponged or thoroughly wet the surface with OMNI II. Dis daily, or sooner if it becomes diluted or so

ACCEPTED with COMMENTS In EPA Letter

FEB 13 1985

46851-1

PR
Harmful if swallowed. Av
rubber gloves recomme
contact with concent
thoroughly. Shield eyes
contact occurs, flush w
medical attention. Avoid
container thoroughly w

BEST AVAILABLE COPY