

SEP 26 1988

ADM Medical Division, Inc.
dba Omnitec Medical Corporation
25283 Cabot Road, Suite 106
Laguna Hills, CA 92653

Attention: William E. Cary
Director, Manufacturing/Product Development

Gentlemen:

Subject: Response to Tuberculocidal Data Call-In Notice
Omni II™
EPA Registration No. 46851-1
Your Submission Dated February 17, 1988

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you make the following revisions before you release the product for shipment bearing the amended labeling.

1. Revise "First Aid" to read "Practical Treatment."
2. The signal word "DANGER" should be located immediately below the words "Keep Out of Reach of Children."
3. We recommend that you revise the ingestion statement by deleting "of milk."
4. Include the company's street address on the labeling.

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

Submit the final printed labeling for inclusion in the product file.

57101:1:Douglas:K-2:KLNCO:9/22/88:10/3/88:CT:vo:ek:rw


CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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It should be noted that further consideration of your request to amend this registration to include an alternate formulation is contingent upon the submission of an acceptable Confidential Statement of Formula and information referred to in our letter dated September 29, 1987.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosure

BEST AVAILABLE COPY

* Colors Same
** Xerox of

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Cat. No. 00/QT-W/O

SEP 26 1988

OMNI-II

E.P.A. Reg. No. 46851-1
E.P.A. Est. No. 37265-CA-01
E.P.A. Est. No. 7368-CA-3
E.P.A. Est. No. 303-IN-01
(See Bottom of Container for Est. No.)

INSTRUMENT & EQUIPMENT DISINFECTANT

Non-Rusting

Pleasant Fragrance

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 type B (Maryland) on inanimate surfaces

DANGER: KEEP OUT OF REACH OF CHILDREN

Danger: Harmful if swallowed. Harmful to eyes and skin. See handling precautions and practical treatments on back panel.
Contents: 1 quart (32 fluid oz)

Manufactured & Distributed by:
ADM MEDICAL DIVISION
Laguna Hills, CA 92653

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH THE 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. Other hard surface areas such as walls, floors and countertops should be mopped, sponged, sprayed or wiped in a manner to thoroughly wet the surface with OMNI II. Discard the used solution daily, or sooner if it becomes diluted or soiled.

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

Remove heavy soil and thoroughly clean surface of items to be disinfected and rough dry prior to application of OMNI II. Immerse in 1:32 concentration of OMNI II for 10 minutes at 20°C (68°F) to destroy bacteria including *Escherichia Coli* 0113, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*.

OMNITEC MEDICAL CORP.
Art #: 88009
Sleeve Size : 4 15/16 x 4
Art Size : 4 1/16 x 3 5/8

present sequence incorrect should be 1 pint 1 quart 1/2 gallon

Clear Mater