

46581-2 PM 31 1983

FEB 6 1989

ADM Medical Division, Inc.  
dba Omnitec Medical Corporation  
25431 Carbot Road, Suite 202  
Laguna Hills, CA 92653

Attention: Palmer B. Ford

Gentlemen:

Subject: Omnicide\* Sterilizing and Disinfecting Solution  
EPA Registration No. 46851-2  
Your Amended Application Dated June 23, 1988

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. Refer to the enclosed Efficacy Evaluation and Technical Efficacy Review - II, and revise your labeling in accordance with the labeling comments outlined there.
  - b. Refer to the enclosed document "Label Requirements for Antimicrobial Pesticides Used on Hard Surfaces Against HIV-1 (AIDS Virus)" for EPA's current labeling policy for efficacy claims. Your labeling must be revised in accordance with the requirements outlined in this policy notice.
  - c. Delete the word "milk."
  - d. Under the "Directions For Use" heading, add the following misuse statement:

It is a violation of Federal law to use  
this product in a manner inconsistent  
with its labeling.

50393:1:DeLaney:LL-9:KENCO:12/21/88:2/6/89:rw:vo:rw

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							


-2-

- e. Change "EPA Registration No. 46851-4" to "EPA Registration No. 46851-2."
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,

John H. Lee   
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosures

# Omnicide\*

3-63

## STERILIZING and DISINFECTING SOLUTION

For use in hospitals, dental offices, nursing homes, and health care institutions.

### 28 Day Activated Dialdehyde

Cat. No. TD/GL-BLK • Sporidical • Virucidal† • Fungicidal  
• Tuberculocidal • Bactericidal • Pseudomonacidal

Qty. 1 Gallon  
(3.79 liters)

#### Non-Rusting

Influenza virus types A1 (New Jersey) and B (Maryland), Herpes simplex virus types 1 and 2, Polio virus types 1 and 2, Vaccinia virus, and HIV-1 (AIDS Virus), on inanimate hard surfaces.

#### Complete Sterilant

Active Ingredient  
Glutaraldehyde ..... 2.0%  
Inert Ingredients ..... 98.0%  
Total ..... 100.0%

#### Pleasant Fragrance

EPA ESTABLISHMENT # 303-IN-01  
EPA ESTABLISHMENT # 37265-CA-01  
EPA ESTABLISHMENT # 7366-CA-3  
EPA REGISTRATION # 46851-4

• TM of ADM Medical Division  
**KEEP OUT OF REACH OF CHILDREN**  
**DANGER:** See side panel for additional precautionary statements

Manufactured for & Distributed by  
**ADM MEDICAL DIVISION**  
25283 CABOT, Laguna Hills, Ca. 92653

Recommended for Disinfection or Sterilization of: MEDICAL INSTRUMENTS, CARBON STEEL CUTTING INSTRUMENTS, BURS, ALUMINUM, GLASS, PLASTIC or RUBBER ARTICLES, THERMOMETERS, MIRRORS, RESPIRATORY EQUIPMENT.

#### STORAGE AND DISPOSAL

**STORAGE.** Keep Omnicide covered in storage or use. Store in a cool place. Do not contaminate water, food or feed by storage or disposal.

**DISPOSAL.** Triple rinse container (or equivalent) then puncture and dispose of in a sanitary landfill or incinerate. Used disinfectant / sterilant solutions are acutely hazardous. Store, use, and dispose of according to label instructions.

#### BEST AVAILABLE COPY

#### DIRECTIONS FOR USE:

To activate solution - add activator contents to this one gallon container - recap - shake. Activated solution changes color to green. Do not dilute. Always clean away excess organic debris, rinse and rough dry instruments or equipment before immersion. Omnicide™ may be USED AND REUSED as a disinfectant or sterilizer in a manual (bucket or tray) system for up to 28 days after activation. Do not use activated solution beyond 28 days.

#### FOR DISINFECTION

Immerse articles for a minimum of 10 minutes at 20°C to destroy vegetative pathogens including - Escherichia coli 0157, Staphylococcus aureus, Salmonella typhosa, Pseudomonas aeruginosa, fungi including - Trichophyton interdigitale, viruses including - Herpes simplex virus types 1 & 2, Polio virus types 1 & 2, Vaccinia virus, Influenza virus types A1 (New Jersey) and B (Maryland). To destroy HIV-1 (AIDS Virus) immerse articles for a minimum of 60 seconds at 20°C in activated unused solution. Rinse articles thoroughly with sterile water after disinfection. For tuberculocidal activity during 28 day reuse, immerse articles for a minimum of 45 minutes at 20°C. For single use of activated unused solution at 20°C immerse completely for 10 minutes. Remove articles and rinse thoroughly.

#### PRECAUTIONARY STATEMENTS:

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS.**  
**DANGER.** Corrosive to tissue. Causes burns. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. May be absorbed through skin. Wear goggles or face shield and rubber gloves when handling.

**HARMFUL IF SWALLOWED.** Avoid contact with food. Use in ventilated area. Use containers which can be tightly closed during use or storage of solution.

#### STATEMENT OF PRACTICAL TREATMENT

Eyes - in case of eye contact, immediately flush thoroughly with water. Skin - in case of skin contact, immediately flush thoroughly with water. Ingestion: If swallowed, drink milk, egg whites, gelatin solution or, if these are not available, large quantities of water. Avoid alcohol. Call a physician. Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

MT  
4/7/88

**For Complete Sterilization** - to destroy resistant pathogenic spores including - Bacillus subtilis and Clostridium sporogenes - immerse articles for a minimum of 10 hours at 20°C. Remove instruments using aseptic technique and rinse thoroughly in sterile water. All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and rough dried before immersion in Omnicide. Hypodermic needles cannot be effectively disinfected or sterilized with Omnicide.

REUSABLE.

Dating Record  
OMNICIDE  
HAS A 28-DAY SHELF  
LIFE AFTER  
ACTIVATION.



ACTIVATED \_\_\_\_\_

EXPIRATION \_\_\_\_\_

FRONT PANEL

RIGHT PANEL

ACCEPTED  
with COMMENTS  
in EPA Label Dated:

FEB 06 1989

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

46851-2

LEFT PANEL

BEST AVAILABLE COPY