

46851-4

PM 31 11 2

24 DEC 1985

Omnitec Medical Corporation
25283 Cabot Road
Suite 106
Loguna Hills, CA 92653

Attn.: Palmer B. Ford, President

Subject: Omnicide 14 TM
EPA Registration No. 46851-4
Submission Dated December 19, 1982

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment:

a. The correct company name and address must appear on the label, as it appears in our files.

b. The misuse statement, "It is a violation of Federal Law xxxx must appear immediately following the heading DIRECTION FOR USE.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

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)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

FRONT PANEL

STERILIZING and DISINFECTING SOLUTION

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

14 Day Activated Dialdehyde

Cat. No. U8008

- Sporidical
- Virucidal†
- Fungicidal
- Tuberculocidal
- Bactericidal
- Pseudomonacidal

Qty. 1 Gallon
(3.78 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 and vaccinia virus.

Complete Sterilant

Pleasant Fragrance

E.P.A. Establishment No. 7388-CA-3

E.P.A. Registration No. 46851-4

TM of ADM Medical Division

KEEP OUT OF REACH OF CHILDREN

DANGER: See side panel for

additional precautions and first aid instructions.

Active Ingredient

Glutaraldehyde

2.0%

Inert Ingredients

98.0%

Total

100.0%

Manufactured for & Distributed by

ADM MEDICAL DIVISION

25283 Cabot, Laguna Hills, Ca. 92653

ACCEPTED
with COMMENTS
EPA Letter 10-1-85

DEC 24 1985

Trade
Ac
postmark
registered under EPA Reg
46851-4

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 14 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.

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.

DIRECTIONS FOR ACTIVATION AND 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 14 TM may be used and reused in a manual system as a disinfectant for up to 14 days after activation. For Tuberculocidal activity, use the sterilization procedure or employ a previously unused solution for the disinfection procedure.

REUSEABLE

All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and rough dried before immersion in Omnicide 14. Hypodermic needles cannot be effectively disinfected or sterilized with Omnicide 14.

RIGHT PANEL

LEFT PANEL

Immerse articles for a minimum of 10 minutes to destroy resistant pathogens including — *Escherichia coli* 0113, *Staphylococcus aureus*, *Salmonella typhosa*, *Pseudomonas aeruginosa*, *Mycobacterium tuberculosis*; 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). The ability of this product to destroy the etiologic agent for viral hepatitis has not been established or demonstrated.

Rinse articles thoroughly with sterile water after disinfection or sterilization.

For Complete Sterilization — to destroy resistant pathogenic spores including — *Bacillus subtilis* and *Clostridium sporogenes* — immerse articles for a minimum of 10 hours. Remove instruments using aseptic technique and rinse thoroughly in sterile water.

DA

Dating Record
OMNICIDE 14
HAS A 14-DAY SHELF
LIFE AFTER
ACTIVATION.

ACTIVATED _____

EXPIRATION _____

JA