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JAN - 6 1989

ADM Medical Division, Inc.
dba Omnitec Medical Corporation
25431 Cabot 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							

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- 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

STERILIZING and DISINFECTING SOLUTION

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

28 Day Activated Dialdehyde

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

Qty. 1 Gallon
(3.79 liters)

Non-Busting

Complete Sterilant

Pleasant Fragrance

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.

EPA ESTABLISHMENT # 303-IN-01
EPA ESTABLISHMENT # 37265-CA-01
EPA ESTABLISHMENT # 7368-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.

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

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: Tie in use 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1989

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

BEST AVAILABLE COPY

DIRECTIONS FOR USE:

To activate solution, add activator contents to this solution in a container or receptacle. Shake. The solution will change color to green or blue. Always clean away excess organic material, rinse and rough dry instruments or equipment before immersion. Omnicide may be used as a disinfectant or sterilant in a metal bucket or tray system for up to 28 days after activation. Do not use after 28 days beyond 28 days.

FOR DISINFECTION

Immerse articles for a minimum of 1 hour. Destroy vegetative bacteria, fungi, and viruses. Tuberculocidal. Bactericidal. Fungicidal. Virucidal. Sporidical. Pseudomonacidal. Active ingredients: Glutaraldehyde, 2.0%. Inert ingredients, 98.0%. Total, 100.0%. Use in a metal bucket or tray system for up to 28 days after activation. Do not use after 28 days beyond 28 days. Rinse and rough dry articles before immersion. Omnicide may be used as a disinfectant or sterilant in a metal bucket or tray system for up to 28 days after activation. Do not use after 28 days beyond 28 days.

For Complete Sterilization — to destroy resistant pathogenic spores including Bacillus subtilis and Clostridium sporogenes. Immerse articles for a minimum of 10 hours at 25°C. Rinse instruments using aseptic technique and rinse thoroughly in sterile water. All instruments and devices must be thoroughly cleaned to remove excess organic debris before immersion. Hypodermic needles cannot be effectively sterilized or sterilized with Omnicide.

REUSABLE

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



ACTIVATED

EXPIRATION