46581-2 PM31 183

FEB 44" ! - 6 1989

ADM Medical Division, Inc. dba Omnited Medical Corporation 25431 Crbot Rond, 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.

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EPA Perm 1320-1 (12-70)

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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 yes release the product for shipment.

Your release for ships ut of the product bearing the amended that sling constitutes accept. ce of these conditions.

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

Sincerely yours,

John H. Lee Product Nameger (31) Antimicrobial Program Branch

Registration Division (TS-767C)

Inclosures

ACCEPTED

with COMMENTS

in EPA La der Dated:

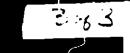
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Under the Federal Insecticide, Fungicide, and Redenticide Act as amended, for the peaticide registered under EPA Rog. No.

PANEL

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STERILIZING and DISINFECTING SOLUTION

28 Day Activated Dialdchyde

Cat. No.TO/GL-BLK . Sporicidal

Virucidal†

Fungicidal

Qly. 1 Gallon

(3.79 liters)

Non-Rusting

Complete Sterilant

Pleasant Fragrance

finituenza virus types A1 (New Jorsey) and B (Maryland), Herpes simplex virus types 1 and 2, Pelio virus types 1 and 2, Vaccinia virus, and MIV-1 (AIDS Virus), on insnimate hard surfaces. EFA ESTABLISHMENT # 303-IN-01 EPA ESTABLISHMENT # 37265-CA-01 EPA ESTABLISHMENT 0 7360-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 Engredient Glutaraldeh, de 2015 Inort Ingredients 🌲 🚉 93 G%

Manufactured for 8 Distributed by ADM MEDICAL DIVISION 25283 CABOT, Laguna Hills, Co. 98653

Recommended for Disinfection or Sterilization of: MEDICAL INSTRUMENTS, CARBON STEEL CUTTING INSTRUMENTS, BURS, ALUMINUM, GLASS, PLASTIC of 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.

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 lace 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.

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DIRECTIONS FOR USE:

To activate solution - add activator concents to this one gallon container - recep - shake. Activated solution changes color to green. Do not dilute. Always clean away excess organic debris, rinse and rough dr. 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. use activated solution beyond 28 days.

FOR DISINFECTION

Immerse articles for a minimum of 10 minutes at 20°C to destroy vegetative pathogers including - Escherichte cold C113, Staphylocuccus aureus. Salmonella typhosm, Pseudomones aeruginosa, fungi including - Trichophyton interdigitele, viruses including - Trichophyton interdigitele, viruses including - Herpes simplex virus types 1 & 2. Folic virus types 1 & 2. Vaccinia virus, Influents virus types 1 & 2. Vaccinia virus, Influents virus types 1 & 100 Merytand). To destroy HIV-1 (AIDS Virus) immerse stricles for a minimum of 60 seconds at 20°C in activated unused solution. Rinse articles thoroughly with sterile wate, after disinfection. For tuberculocidel activity during 28 day rouse, immerse articles for a minimum of 45 ruberculocidel 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.

Appropriate a negates cannot be addisorfected of secrilized with a a a Canicide.

REUSABLE.

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



ACTIVATED. EXPIRATION .