

JUN 09 1989

Metrex Research, Inc.
10270 South Dransfeldt Road
P.O. Box 965
Parker, CO 80134

Attn: Kyle H. Sabinovic, Ph.D.

Subject: Metricide 28 Long-Life Activated Dialdehyde
Solution
EPA Reg. No. 46781-2
Submission dated March 3, 1989

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 document "Label Requirements for Antimicrobial Pesticide 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.

b. The signal word "DANGER" must be placed directly below the statement "KEEP OUT OF REACH OF CHILDREN". (Front Panel Only)

c. Revise the referral statement to read:

"See side panel for additional precautionary statements"

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.

CONCURRENCES

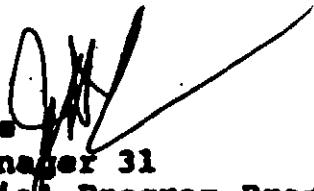
SYMBOL							
SURNAME							
DATE							

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.

If you have any questions concerning this letter, please contact Martha DeLaney at (703) 557-6982.

Sincerely,


John H. Lee
Product Manager 31
Antimicrobial Program Branch
Registration Division (H7504C)

Enclosures

H7504C:JLee:APB:RD:md:Rm 711:557-3675:6/8/89

DIRECTIONS FOR USE:

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

For complete sterilization or disinfection of medical instruments and equipment, thoroughly clean, rinse and rough-dry objects before immersing in full strength solution. Cleanse and rinse the lumens of any hollow instruments before filling with solution. Avoid entrapment of air bubbles.

DISINFECTION: Immerse instruments or equipment completely for a minimum of 10 minutes at 20°C. to destroy vegetative organisms including *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, and pathogenic fungi as represented by *Trichophyton mentagrophytes*. For 100% kill of *Mycobacterium tuberculosis*, immerse instruments or equipment completely for a minimum of 20 minutes at 20°C. or 10 minutes at 25°C. **VIRUSES:** METRICIDE 28 completely inactivates HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at a contact time of 30 seconds at room temperature (20-25°C). Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms (e.g., *M. tuberculosis*), which require a contact time of 10 minutes at 25°C. or 20 minutes at 20°C. The following viruses are completely inactivated in 3 minutes at 20°C.: Cytomegalovirus; Respiratory Syncytial Virus; Rhinovirus; Rotavirus SA-11; Herpes simplex virus 1 & 2; Adenovirus 2; Coxsackievirus B5a; Echovirus 6; Poliovirus 1 & 2; Vaccinia virus; Influenza A₂HK. After immersion, remove instruments or equipment from METRICIDE 28 Solution and rinse thoroughly. All times and temperatures are based on EPA-approved testing on inanimate surfaces.

STERILIZATION: Immerse instruments or equipment completely for a minimum of 6 hours at 20°C. to destroy resistant pathogenic spores as represented by *Clostridium sporogenes* and *Bacillus subtilis*. Remove instruments or equipment from METRICIDE 28 Solution using sterile technique and rinse thoroughly with sterile water.

DIRECTIONS FOR ACTIVATING:

Add contents of attached vial to this container of METRICIDE 28 Solution. Shake. Solution is ready to use. When activated, solution changes color to bluish-green. This solution may be used and reused for up to 30 days after activation. Do not use activated stock solution beyond 30 days.

General Classification—For use in Hospitals, Dental Offices, Nursing Homes and Health Care Institutions. For repeated use in manual (bucket and tray) systems. This product is not formulated as a "holding" solution.

Product No.

MX-2800

Active ingredient	
Glutaraldehyde	2.0%
Inert ingredients	98.0%
Total	100.0%

Contains Sodium Nitrite as a corrosion inhibitor.

MIXING DATE

ACCEPTED

EXPIRATION DATE

JUN 09 1989

E.P.A. Reg. No. 46781-2
E.P.A. Est. No. 46781-CO-1

Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, this product is registered under EPA Reg. No.

46781-2

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PRECAUTIONARY STATEMENTS:

DANGER: Hazard to Humans and Domestic Animals

Follow All Label Directions

Eyes - Safety glasses or goggles are recommended. Contact with eyes causes damage. In case of contact, flush with water immediately and get medical attention.

Skin - Avoid skin contact as possibility of sensitization exists. May cause skin irritation. Use gloves. For skin contact flush immediately and thoroughly with water.

Ingestion - Avoid contamination of food. Harmful if swallowed.

Inhalation - Use in ventilated area.

STORAGE AND DISPOSAL:

KEEP IN A COOL PLACE.

Pesticide Disposal - Discard residual solution in drain. Flush thoroughly with water.

Container Disposal - Do not reuse empty container. Wrap container and put in trash.

Especially recommended for sterilization or disinfection of...

Anesthesia equipment

Respiratory therapy equipment

Metallic equipment or instruments

Rubber objects

Plastic objects

Thermometers

Contents One Gal. (128 fluid oz.)

Made in U.S.A.

Control Number on Bottom

Manufactured by:



**METREX RESEARCH®
CORPORATION**

Forten, Colorado 80134