

10/5

FEB 09 1994

Metrex Research Corporation  
 P.O. Box 646  
 Parker, CO 80134

**Subject: Metricide 28 Long Life Activated Dialdehyde Solution  
 EPA Registration Number 46781-2  
 Amendment Dated December 21, 1993**

Dear Sir:

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the items listed below. The intent of this amendment is to increase the sterilization temperature use condition from 20° C to 25° C.

1. Submit/cite all data required for registration/-reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Metrex must submit a full set of valid AOAC data performed at 25° C. A full set of data consists of a 720 carrier AOAC test on three batches of the product, with an additional 120 day carrier confirmatory test at a second laboratory. We anticipate that these data can be generated and submitted to the Agency within 90 days from the date of this letter.
3. A red label containing the notice below as suggested by Metrex must be affixed to the necks of bottles of existing stocks.

\*Please note label change for sterilization:  
 Immerse instruments or equipment completely  
 for a minimum of 10 hours at 25° C. This is  
 a change from 10 hours at 20° C.

CONCURRENCES							
SYMBOL	H7505C	H7505C					
SURNAME	Quindell	Wells					
DATE	2/9/94	2/9/94					

4. New production must also bear the red label in addition to the newly approved label for a period of 30 days.
5. A report must be submitted to the Agency within 2 weeks, detailing how much of the existing stocks of Metricide 28 has already been relabeled, and the location and dates of that relabeling.
6. A report must also be submitted to the Agency within two weeks after all existing stocks have been distributed or sold, detailing the quantity of Metricide 28 existing stocks that were distributed or sold.
7. Metrex will not sell or distribute any Metricide 28 with 20° C on the label, regardless of 40 CFR 152.130(c), unless such product also bears the red label described above.
8. Metrex may place the red label on existing stocks in distributor's, dealer's, and user's facilities, as long as the labeling is done by Metrex personnel.
9. Metrex may sticker new sterilization instructions (these instructions are to be identical to the last EPA accepted instructions with the exception of the change from 20° C to 25° C) onto existing product labels for a period of six weeks.
10. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely yours,



Marshall Swindell  
 Acting Product Manager 31  
 Antimicrobial Programs Branch  
 Registration Division (H7505C)

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[FRONT PANEL]

REUSABLE

Sterilizing and Disinfecting Solution

Long-Life Activated Dialdehyde Solution

**M E T R I C I D E**

Rapid-Acting • Non-Staining • Non-Rusting **28**

Sporicidal  
Virucidal\*

Fungicidal  
Tuberculocidal

Bactericidal  
Pseudomonacidal

KEEP OUT OF REACH OF CHILDREN  
DANGER

See side panel for additional precautionary statements.

Note: Contents of attached vial must be added to fluid before this product is effective.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

**FEB 09 1994**

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

46781-2

# 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.

**KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

## SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

**Personal Protection:** Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of activated METRICIDE 28. **Contact Time:** While the HIV-1 virus is inactivated in 5 minutes, use the recommended contact time for disinfection of other organisms on this label. **Infectious Materials Disposal:** Cleaning materials that may contain blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate gastric lavage.

## 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, sharp instruments, burs, and aluminum objects.

**Manufactured by: METREX RESEARCH® CORPORATION**  
Parker, Colorado 80134

ACCEPTED  
with COMMENTS  
FEB 09 1994  
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 44781-2

**BEST AVAILABLE COPY**

**BEST AVAILABLE COPY**

**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 and dental 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.** \***VIRUSES:** **METRICIDE 28** completely inactivates HIV-1 (AIDS virus) on hard, non-porous surfaces when used at a contact time of 5 minutes at room temperature (20-25°C). Although efficacy at a 5 minute 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 20 minutes at 20°C. The following viruses are completely inactivated in 10 minutes at 20°C: Cytomegalovirus; Respiratory Syncytial Virus; Rhinovirus; Rotavirus SA-11; Herpes simplex virus 1 & 2; Adenovirus 2; Coxsackievirus B5A; 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 10 hours at 25°C to destroy resistant pathogenic spores as represented by *Clostridium sporogenes* and *Bacillus subtilis*. Remove instruments or equipment for METRICIDE 28 Solution using sterile technique and rinse thoroughly with sterile water.

Product No.	
MX-2800	
Active ingredient	
Glutaraldehyde	2.0%
Inert ingredients	98.0%
Total	100.0%

**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.

Contains Sodium Nitrite as a Corrosion inhibitor.

MIXING DATE

**General Classification**—For use in Hospitals, Dental Offices, Nursing Homes and Health Care institutions. For repeated use in manual (bucket and tray) systems. Not to be used in metal trays, or as an overnight holding solution.

EXPIRATION DATE

Activated Contents One Gal. (128 fluid oz.) (3.785L)  
Made in U.S.A.  
Control Number on Bottom  
E.P.A. Reg. No. 46781-2  
E.P.A. Est. No. 46781-CO-1

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46781-2