

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 09 1994

Metrex Research Corporation
10270 S. Progress Way
Parker, CO 80134

Attn: Ed Gray, Agent

Subject: MetriCide Plus 30
EPA Registration No. 46781-4
Letter Dated September 9, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, under section 3(c)(7)(A) is acceptable, provided that you:

- 1) Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) At the next printing of your labels, you must place the ingredient section on the front panel.
- 3) 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 sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

The submitted microbiological data supports the efficacy of your product at 10 hours at 25°C.

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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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If you have any questions concerning this letter, please contact Martha Terry at 703-305-6982.

Sincerely,



Marshall Swindell
Acting Product Manager 31
Antimicrobial Program Branch
Registration Division 7505C

Enclosure

3 of 5

REUSABLE Sterilizing and Disinfecting Solution

Rapid-acting • Non-staining • Non-rusting



30-Day Long-Life Activated Dialdehyde Solution—3.2%

Sporicidal Virucidal*	Fungicidal Tuberculocidal	Bactericidal Pseudomonacidal
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**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:**

SEP 09 1994

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

46781-4

BEST AVAILABLE COPY

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals

DANGER. Corrosive. Causes eye damage and skin irritation. Wear goggles or safety glasses and rubber gloves when handling. Avoid skin contact as possibility of sensitization exists. Harmful if swallowed. Avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT:

If swallowed, drink promptly large quantity of water and immediately get medical attention. If on skin, flush immediately and thoroughly with water. If in eyes, flush immediately with water for about 15 minutes and call a physician. Avoid inhalation, use in ventilated areas.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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 or body 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 PLUS 30. 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.

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:



P.O. Box 646
10270 S. Progress Way
Parker, CO 80134
1-800-641-1428

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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 PLUS 30 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 A₁HK. After immersion, remove instruments or equipment from METRICIDE PLUS 30 Solution and rinse thoroughly.

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 from METRICIDE PLUS 30 Solution using sterile technique and rinse thoroughly with sterile water.

DIRECTIONS FOR ACTIVATING:

Add contents of attached vial to this container of METRICIDE PLUS 30 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. Not to be used in metal trays, or as an overnight holding solution.

Activated Contents: One Gallon (128 Fl. Oz.) (3.8 L)

Made in U.S.A.

Control Number on Bottom

E.P.A. Reg. No. 46781-4
E.P.A. Est. No. 46781-CO-1

Product No.

MX-3200

Active Ingredient

Glutaraldehyde.....3.2%

Inert Ingredients.....96.8%

Total.....100.0%

Contains Sodium Nitrite
as a corrosion inhibitor.

MIXING DATE

EXPIRATION DATE

5130-5

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