

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 21 1990

Metrex Research, Inc.
11270 S. Dransfeldt
Parker, CO 80134

Attention: Kyle H. Sibinovic

Product Name: Metricide Plus 14
Registration Number 46781-3
Application Date 10/25/89

The amendment referred to above, submitted in connection with registration under FIFRA, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

- a. The unqualified recommendation for use on "plastic objects" is not acceptable. The label should indicate the types of plastic (e.g., polystyrene, polypropylene, polyvinyl chloride).

This information can be placed on your label, Technical Bulletin, or company letterhead.

- b. Immediately above the heading "SPECIAL INSTRUCTIONS FOR CLEANING . . ." include the statement "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)."

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CONCURRENCES

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- c. Under the heading "VIRUSES" revise the statement "METRICIDE PLUS 14 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)." to read "METRICIDE PLUS 14 completely inactivates HIV-1 (AIDS virus) on hard, non-porous surfaces when used at a contact time of 30 seconds at room temperature (20°-25°C)."

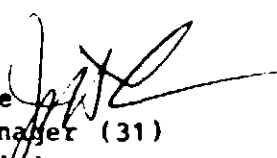
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

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.

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

Sincerely yours,


John H. Lee
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

PRINTS OF ANCE PMS 172

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. **VIROSES:** METRICIDE PLUS 14 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, Poliovirus 1 & 2, Vaccinia virus, Influenza A/HK. After immersion, remove instruments or equipment from METRICIDE PLUS 14 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 8 hours at 20°C to destroy resistant pathogenic spores as represented by *Clostridium sporogenes* and *Bacillus subtilis*. Remove instruments or equipment from METRICIDE PLUS 14 Solution using sterile technique and rinse thoroughly with sterile water.

DIRECTIONS FOR ACTIVATING:

Add contents of attached vial to this container of METRICIDE PLUS 14 Solution. Shake. Solution is ready to use. When activated solution changes color to green. This solution may be used and reused for up to 14 days after activation. Do not use activated stock solution beyond 14 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-3405	
Active ingredient	3.2%
Glutaraldehyde	96.8%
Inert ingredients	
Total	100.0%

MIXING DATE

EXPIRATION DATE

REUSABLE Sterilizing and Disinfecting Solution

Rapid-acting • Non-staining • Non-rusting



14-Day Activated Dialdehyde Solution - 3.2%

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.

E.P.A. Reg. No. 46781-3
E.P.A. Est. No. 46781-CO-1

ACCEPTED WITH COMMENTS in EPA 100-1-100-100

FEB 21 1990

100-1-100-100

46781-3

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