

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 15 1995

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

Attention: Wendy A. Urtel

Subject: Metricide Plus 30
EPA Registration No. 46781-2
Amendment Dated January 5, 1995

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended, to revise your basic product formulation, change your label and to add two alternate formulations would be acceptable provided that you comply with the following instructions:

- 1. Include the following Environmental Hazards statement on your product label in accordance PR Notice 93-10:

Environmental Hazards

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

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

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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If you have any questions concerning this letter please contact Marshall Swindell at (703) 305-6908.

Sincerely yours,



Marion Johnson
Product Manager 31
Antimicrobial Program Branch
Registration Division (7505C)

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REUSABLE Sterilizing and Disinfecting Solution



Long-Life Activated Dialdehyde Solution

**Sporicidal
Virucidal**

**Fungicidal
Tuberculocidal**

**Bactericidal
Pseudomonacidal**

NOTE—Contents of attached vial *must* be added to solution before this product is effective.
See *Directions for Use - Activation*.

Contains Sodium Nitrite as a corrosion inhibitor.

EPA REG. No. 46781-4

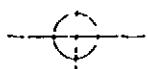
EPA EST. No. 46781-CO-1

Active ingredient	Glutaraldehyde	3.4%
	Inert ingredients	96.6%
	Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER: See right side panel for additional precautionary statements.

ACTIVATED CONTENTS: 3.8 L (ONE GAL.)



BEST COPY AVAILABLE

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals
DANGER: Keep Out of Reach of Children
Direct contact is corrosive to exposed tissues. Do not get into eyes, on skin or clothing. Wear eye protection and rubber gloves when handling or pouring. Store in a well-ventilated area in closed containers.

STATEMENT OF PRACTICE

In case of contact, immediately flush eyes with water for 15 minutes. For eyes, get medical attention. For skin, wash with water and call a physician immediately.

NOTE TO PHYSICIAN: Probable mucous membrane irritation. Consider gastric lavage.

STORAGE AND DISPOSAL

Store at controlled room temperature 15°-30°C.
Pesticide Disposal: Discard residual solution and container in quantities of water in accordance with federal and state regulations.
Container Disposal: Do not reuse empty containers. Refer to package insert for material compatibility and disposal product data.

CONTROL NUMBER AND EXPIRATION DATE ARE LOCATED ON THE BOTTOM OF THE CONTAINER.

NOTE DATES HERE:
ACTIVATION DATE: _____

Do not use beyond 28 days or sooner as indicated on the Glutaraldehyde Test Strips.

EXPIRATION DATE FOR ACTIVATED SOLUTION: _____

Manufactured By: METREX



MADE IN U.S.A. P. O. Box 10270, Parkersburg, WV 26102

For technical information and/or information on other products, call 1-800-841-1428

**ACCEPTED
with COMMENTS
to EPA Letter Dated:**

AUG 15 1995

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

46781-4

INDICATIONS FOR USE:

STERILIZATION: This solution should be used for the sterilization of heat sensitive medical equipment for which alternative methods of sterilization are not suitable. Medical equipment which should always be sterilized is that which is categorized as critical (i.e., used in procedures in which contact will be made with tissue that is normally considered sterile).

HIGH-LEVEL DISINFECTION: This solution should be used for the high-level disinfection of heat sensitive medical equipment for which sterilization is not practical. Medical equipment which should always be subjected to high-level disinfection or sterilization is that which will be used in procedures categorized as semi-critical (i.e., used in procedures in which contact will be made with mucous membranes or other body surfaces which are not normally considered to be sterile).

INTERMEDIATE-LEVEL DISINFECTION: This solution should be used for the disinfection of medical equipment for which a risk of cross contamination exists. Medical equipment which should always be disinfected is that which is to be used in procedures categorized as non-critical (i.e., used in procedures in which contact will only be made with intact skin).

DIRECTIONS FOR USE:

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

ACTIVATION: Activate the METRICIDE PLUS 30 Solution by adding the entire contents of the activator vial which is attached to the METRICIDE PLUS 30 Solution container. Shake well. When activated, solution changes color to bluish-green. Record the date of activation on the indicated space below, in a log book or a label affixed to any secondary container used for the activated solution. See package insert for additional instructions and information regarding activated solution.

CLEANING/DECONTAMINATION: Blood and other body fluids must be thoroughly cleaned from hard, non-porous surfaces and objects before application of the disinfectant or sterilant. For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in METRICIDE PLUS 30 Solution. Cleanse and rinse the lumens of hollow instruments before filling with METRICIDE PLUS 30 Solution. See package insert for additional cleaning/decontamination instructions.

STERILIZATION: Immerse medical instruments/equipment completely in METRICIDE PLUS 30 Solution for a minimum of 10 hours at 25°C. Remove equipment from the solution using aseptic technique and rinse thoroughly with sterile water. See package insert for complete instructions/information on sterilization.

HIGH-LEVEL DISINFECTION: Immerse medical instruments/equipment completely in METRICIDE PLUS 30 Solution for a minimum of 90 minutes at 25°C. Remove from the solution and rinse thoroughly with sterile water or with potable tap water. The quality of rinse water used is dependent upon the intended use of the instrument/equipment. See package insert for complete instructions/information on high-level disinfection.

INTERMEDIATE-LEVEL DISINFECTION: Immerse medical instruments/equipment completely in METRICIDE PLUS 30 Solution for a minimum of 10 minutes at 20°C-25°C to destroy all vegetative bacteria except, for large numbers of Mycobacterium tuberculosis, but including Pseudomonas aeruginosa, pathogenic fungi and specified viruses, as indicated in the package insert.

A 10 minute immersion at 20°C will kill 89.4% Mycobacterium tuberculosis (Quantitative TB Method).

A 10 minute immersion at 25°C will kill 98.4% Mycobacterium tuberculosis (Quantitative TB Method).

Remove instruments/equipment from the solution and thoroughly rinse with sterile water or potable tap water. The quality of the rinse water used is dependent upon the intended use of the instrument/equipment. See package insert for complete instructions/information on intermediate-level disinfection.

ACCEPTED
with COMMENTS
to EPA Better Batch

AUG 15 1995

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

46781-4

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