

METRICIDE®
ACTIVATED DIALDEHYDE SOLUTION
(GLUTARALDEHYDE 2.6%)

When using potable water for rinsing, the user should be aware of the increased risk of recontaminating the device or medical equipment with **Pseudomonas** and **atypical** (fast growing) **Mycobacteria** often present in potable water supplies. A device (e.g.: colonoscope) that is not completely dried provides an ideal situation for rapid colonization of bacteria. Additionally, **Mycobacteria** are highly resistant to drying; therefore, rapid drying will avoid possible colonization but may not result in a device free from **atypical Mycobacteria**. Although these bacteria are not normally pathogenic in patients with healthy immune systems, AIDS patients or other immunocompromised individuals may be placed at high risk of infection by these opportunistic microorganisms. A final rinse using a 70% isopropyl alcohol solution is useful to speed the drying process and reduce the numbers of any organism present as a result of rinsing with potable water.

e) Reusage

METRICIDE Solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. This solution may be used and reused within the limitations indicated above for up to 14 days after activation. Do not use activated solution beyond 14 days. Efficacy of this product during its use-life must be verified by the **METRISTRIPS Glutaraldehyde Test Strips** to determine that the minimum effective concentration (MEC) of 1.5% is present.

4) Monitoring of Germicide to Ensure Specifications are Met

During the usage of **METRICIDE** Solution, as a high- or intermediate-level disinfectant and/or sterilant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. In addition, it is recommended that the **METRICIDE** Solution be tested with the **METRISTRIPS Glutaraldehyde Test Strips** prior to each usage. This is to ensure that the appropriate concentration of glutaraldehyde is present and to guard against a dilution which may lower the effectiveness of the solution below its MEC. The pH of the activated solution may also be periodically checked to verify that the pH of the solution is between 7.5 and 8.5.

5) Post-Processing Handling and Storage of Reusable Devices

Sterilized or disinfected reusable devices are either to be immediately used or stored in a manner to minimize recontamination. Note that only terminal sterilization (sterilization in a suitable wrap) provides maximum assurance against recontamination. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

F) STORAGE CONDITIONS AND EXPIRATION DATE

- Prior to activation, **METRICIDE** Solution should be stored in its original sealed container at controlled room temperature 15° to 30°C (59° to 86°F). Once the **METRICIDE** Solution has been activated, it should be stored in the original container until transferred to the containers in which the immersion for disinfection or sterilization is to take place. Containers should be stored in a well-ventilated, low traffic area at controlled room temperature.
- The expiration dates of the unactivated **METRICIDE** Solution and activator will be found on the bottom of the immediate containers.
- The use period for activated **METRICIDE** Solution is for no longer than 14 days following activation or as indicated by the **METRISTRIPS Glutaraldehyde Test Strips**. Once activated, the solution requires no further dilution prior to its usage.

G) EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about **METRICIDE** Solution can be obtained from Metrex Research Corporation Customer Service Department at 1-800-841-1428, or by contacting your local Metrex Corporation sales representative.

H) USER PROFICIENCY

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. The user should be adequately trained in the decontamination and disinfection or sterilization of medical devices and the handling of toxic substances such as liquid chemical germicides. Additional information about **METRICIDE** Solution can be obtained from Metrex Research Corporation Customer Service Department at 1-800-841-1428, or by contacting your local Metrex Research Corporation sales representative.

I) DISPOSAL INFORMATION

Germicide Disposal

Discard residual solution in drain. Flush thoroughly with water.

Container Disposal

- One Quart (946 mL) and One Gallon (3.8 L) Size Containers**
Do not reuse empty container. Wrap container and put in trash.
- 2-1/2 Gallon (9.5 L) and 5 Gallon (18.9 L) Size Containers**
Triple rinse empty container with water and dispose of in an incinerator or landfill approved for pesticide containers.

J) HOW SUPPLIED

Reorder	Description	Case Containers
MX-1405	One Quart (946 mL) Container	4 x Quarts (4 x 946 mL)/box; 4 boxes/case; 16 x Quarts (16 x 946 mL)/case
MX-1400	One Gallon (3.8 L) Container	4 x Gallons (4 x 3.8 L)/case
MX-1425	2-1/2 Gallon (9.5 L)	2 x 2-1/2 Gallons (2 x 9.5 L)/case
MX-1450	5 Gallon (18.9 L)	1 x 5 Gallon (1 x 18.9 L)/case
MX-203	MetriStrips Glutaraldehyde Test Strips	50 strips/bottle; 12 bottles/case

References supplied upon request
 Manufactured by:



P. O. Box 646
 Parker, CO 80134
 1-800-841-1428

A) INDICATIONS FOR USE

1) Germicide Level of Activity

METRICIDE® Activated Dialdehyde Solution is a liquid chemical sterilant and high- or intermediate-level disinfectant, when used according to the **Directions for Use**.
Sterilant: **METRICIDE** Solution is a sterilant when used or reused, according to **Directions for Use**, at full strength for a maximum of 14 days at 25°C with an immersion time of at least 10 hours.

High-Level Disinfectant: **METRICIDE** Solution is a high-level disinfectant when used or reused, according to **Directions for Use**, at full strength for a maximum of 14 days at 25°C with an immersion time of at least 45 minutes.

Intermediate-Level Disinfectant: **METRICIDE** Solution is an intermediate-level disinfectant when used or reused, according to **Directions for Use**, at full strength for a maximum of 14 days.

A 10-minute immersion at 20°C to 25°C will destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathogenic fungi and specified viruses, as indicated in Section E - **Directions for Use** - Item 3(c).

A 10-minute immersion at 20°C will kill 87.9% **Mycobacterium tuberculosis** (Quantitative TB Method).

A 10-minute immersion at 25°C will kill 99.8% **Mycobacterium tuberculosis** (Quantitative TB Method).

2) Reuse Period

METRICIDE Solution has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse. **METRICIDE** Solution can be reused for a period not to exceed 14 days provided the required conditions of glutaraldehyde concentration, pH, and temperature exist based upon monitoring described in **Directions for Use**. DO NOT rely solely on days in use. Efficacy of this product during its use-life must be verified by the **METRISTRIPS® Glutaraldehyde Test Strips** to determine that at least the minimum effective concentration (MEC) of 1.5% glutaraldehyde is present.

3) General Information on Selection and Use of Germicides for Medical Device Reprocessing

Choose a germicide with the level of microbicidal activity that is appropriate for the reusable medical device or equipment surface. Follow the reusable device labeling and standard institutional practices. In the absence of complete instructions, use the following process:

First, for patient-contacting devices, determine whether the reusable device to be reprocessed is a critical, semi-critical, or noncritical device.

- A critical device presents a high risk of infection if not sterile. Critical devices routinely penetrate the skin or mucous membranes during use, or are otherwise used in normally sterile tissue of the body.
- A semi-critical device makes contact with mucous membranes, but does not ordinarily penetrate normally sterile areas of the body.
- A noncritical device contacts only intact skin during routine use.

Second, determine the level of germicidal activity that is needed for the reusable device.

Device Type	Disinfection Requirement
Critical Device	Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and microsurgical instruments).
Semi-critical Device	Sterilization recommended when practical, otherwise, High-Level Disinfection is acceptable (e.g.: GI endoscopes, anesthesia equipment for the airway, diaphragm-fitting rings, etc.).
Noncritical Device	Intermediate-Level Disinfection recommended when there is a risk of cross-contamination, otherwise Low-Level Disinfection acceptable (e.g.: bed pans, blood pressure cuffs, linens, etc.).

Third, select a germicide that is labeled for the appropriate germicidal level and is compatible with the reusable device. Follow directions for the germicide.

4) Microbial Activity

The following table indicates the spectrum of activity as demonstrated by testing of **METRICIDE** Solution*:

SPORES	BACTERIA		FUNGI	VIRUSES	
	VEGETATIVE ORGANISMS			NON-ENVELOPED	ENVELOPED
Bacillus subtilis	Staphylococcus aureus		Trichophyton mentagrophytes	Poliovirus Types 1 & 2	Cytomegalovirus
Clostridium sporogenes	Salmonella choleraesuis			Rhinovirus Type 14	Influenza virus Type A ₂ HK
	Pseudomonas aeruginosa			Adenovirus Type 2	HIV-1 (AIDS Virus)
	Mycobacterium tuberculosis			Vaccinia	Herpes simplex Types 1 & 2

*Testing was done after 14 days of simulated reuse using prescribed testing methods.

5) Material Compatibility

METRICIDE is compatible with the following reusable devices and materials: Rigid and flexible endoscopes, respiratory therapy equipment, anesthesia equipment, rubber, most stainless steel instruments, plastic, most dental instruments (not including dental handpieces), many types of metals, such as stainless steel, carbon steel, and aluminum, and plated metals such as nickel plating or chrome plating.

For a listing of specific device manufacturers that have reported device compatibility with **METRICIDE**, see Table 1 below.

Table 1. Manufacturers Reporting Device Compatibility with **MetriCide**

Company	Instrumentation
Acoustic Imaging	Transducers
Acuson Computed Sonography	Biplane Transesophageal and External Transducers
Bard Interventional Products	Automatic Endoscope Washers (Models 000187, 000387, and 000487)
Circon - ACMI	Cystoscopes
Hewlett Packard	Omniplane TEE Probe
Instrumentation Industries	Plastics used in Respiratory Therapy
Medivators, Inc.	Automatic Endoscope Washers
Olympus Corporation	Olympus Flexible Endoscopes
Pentax Precision Instrument Corporation	Upper GI Fiberscopes, Video Duodenoscopes, Bronchofiberscopes, Video Colonoscopes
Pilling Surgical Instruments	Rubber Bougies
Karl Storz	Rigid Cystoscopes
Welch Allyn	Flexible Sigmoidoscopes

Please refer to labeling of the reusable device for additional instructions, or call the reusable device manufacturer directly.

PLEASE NOTE: **METRICIDE** is incompatible with the following reusable devices and materials:
Type IV dental stone impression material and Heidbrink Expiratory Valve.

6) Precleaning Agent Compatibility

METRICIDE Solution is compatible with enzymatic detergents (e.g.: MetriZyme® Dual Enzymatic Detergent) which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the **METRICIDE** Solution by altering its pH.

B) CONTRAINDICATIONS

1) Sterilant Usage

Routine biological monitoring is not feasible with **METRICIDE** Solution, and therefore, **METRICIDE** Solution should **NOT** be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or peroxide gas plasma.

METRICIDE Solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

2) High-Level Disinfectant Usage

METRICIDE Solution should **NOT** be used to high-level disinfect a semi-critical device when sterilization is practical.

3) Endoscope Usage

METRICIDE Activated Dialdehyde Solution is not the method of choice for sterilization of rigid endoscopes which the device manufacturer indicates are compatible with steam sterilization. In general, glutaraldehyde solutions that do not contain surfactants (e.g.: **METRICIDE** Solution) are more appropriate for flexible endoscopes, because glutaraldehyde solutions containing surfactants (e.g.: **METRICIDE**® 28 Solution or **METRICIDE PLUS 30**® Solution) are more difficult to rinse from the devices. However these surfactant-containing disinfectants may be used for reprocessing of flexible endoscopes if a validated protocol for rinsing and leak testing is employed.

C) WARNINGS

METRICIDE ACTIVATED DIALDEHYDE SOLUTION IS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

**DANGER: Keep Out of Reach of Children
Contains Glutaraldehyde**

- 1) Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin, or on clothing.
- 2) Avoid contamination of food.
- 3) Use in well-ventilated area in closed containers.

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, get medical attention.

Harmful if swallowed. Drink large quantities of water and call a physician immediately.

Probable mucosal damage from oral exposure may contraindicate the use of gastric lavage.

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D) PRECAUTIONS

- 1) Disposable latex gloves, eye protection, face masks, and liquid-proof gowns should be worn when cleaning and sterilizing/disinfecting soiled devices and equipment.
- 2) Contaminated, reusable devices **MUST BE THOROUGHLY CLEANED** prior to disinfection or sterilization, because residual contamination will decrease effectiveness of the germicide.
- 3) The user **MUST** adhere to the **Directions for Use**, because any modification will affect the safety and effectiveness of the germicide.

4) The reusable device manufacturer should provide the user with a validated reprocessing procedure for that device using **METRICIDE** Solution.

5) The use of **METRICIDE** Solution in automated endoscope washers must be part of a validated reprocessing procedure provided by the washer manufacturer. Contact the manufacturer of the endoscope washer for instructions on the maximum number of reprocessing cycles which may be used before refilling with fresh **METRICIDE** Solution. Use **METRICIDE** **Glutaraldehyde Test Strips** to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

E) DIRECTIONS FOR USE

1) Activation

Activate the **METRICIDE** Solution by adding the entire contents of the Activator Vial which is attached to the **METRICIDE** Solution container. Shake well. Activated solution immediately changes color to green, thereby indicating solution is ready to use. **METRICIDE** Solution is intended for use in manual (bucket and tray) systems made from polypropylene, ABS, polyethylene, glass-filled polypropylene or specially molded polycarbonate plastics. Record the date of activation (mixing date) and expiration date on the **METRICIDE** Solution container label in the space provided, in a log book, or on a label affixed to any secondary container used for the activated solution.

2) Cleaning/Decontamination

Blood and other body fluids must be thoroughly cleaned from surfaces, lumens, and objects before application of the disinfectant or sterilant. Blood and other body fluids should be autoclaved and disposed of according to all applicable federal, state and local regulations for infectious waste disposal.

For complete disinfection or sterilization of medical instruments and equipment, thoroughly clean, rinse and rough dry objects before immersing in **METRICIDE** Solution. Cleanse and rinse the lumens of hollow instruments before filling with **METRICIDE** Solution. Refer to the reusable device manufacturer's labeling for additional instructions on disassembly, decontamination, cleaning and leak testing of their equipment.

3) Usage

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

a) Sterilization (Bucket/Tray Manual System)

Immerse medical equipment/device completely in **METRICIDE** Solution for a minimum of **10 hours at 25°C** to eliminate all microorganisms including **Clostridium sporogenes** and **Bacillus subtilis** spores. Remove equipment from the solution using sterile technique and **rinse thoroughly** with **sterile water** following the rinsing instructions below.

b) High-Level Disinfection (Bucket/Tray Manual System)

Immerse medical equipment/device completely in **METRICIDE** Solution for a minimum of **45 minutes at 25°C** to destroy all pathogenic microorganisms, except for large numbers of bacterial endospores, but including **Mycobacterium tuberculosis** (Quantitative TB Method). Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

c) Intermediate-Level Disinfection (Bucket/Tray Manual System)

Immerse medical equipment/device completely in **METRICIDE** Solution for a minimum of **10 minutes at 20°C to 25°C** to destroy all vegetative bacteria, except for large numbers of **Mycobacterium tuberculosis**, but including **Pseudomonas aeruginosa**, pathogenic fungi, and viruses (Poliovirus Type 1; Adenovirus Type 2; Herpes simplex Type 1, 2; HIV-1 (AIDS virus); Influenza Type A [WS/33]; Vaccinia; Coronavirus; Cytomegalovirus; Rhinovirus Type 14) on inanimate surfaces.

A 10-minute immersion at 20°C will kill 87.9% **Mycobacterium tuberculosis** (Quantitative TB Method).

A 10-minute immersion at 25°C will kill 99.8% **Mycobacterium tuberculosis** (Quantitative TB Method).

Remove devices and equipment from the solution and rinse thoroughly following the rinsing instructions below.

d) Rinsing Instructions

Following immersion in **METRICIDE** Solution, thoroughly rinse the equipment or medical device by immersing it completely in three separate copious volumes of water. Each rinse should be a minimum of one minute in duration unless otherwise noted by the device or equipment manufacturer. Use fresh portions of water for each rinse. Discard the water following each rinse. Do not reuse the water for rinsing or any other purpose, as it will be contaminated with glutaraldehyde.

Refer to the reusable device/equipment manufacturer's labeling for additional rinsing instructions.

STERILE WATER RINSE

The following devices should be rinsed with sterile water, using sterile technique when rinsing and handling.

1. Devices intended for use in normally sterile areas of the body;

2. Devices intended for use in known immunocompromised patients, or potentially immunocompromised patients based on institutional procedures (e.g.: high risk population served) and;

3. When practicable, bronchoscopes, due to a risk of atypical **Mycobacteria** contamination from potable water supply.

POTABLE WATER RINSE

For all other devices a sterile water rinse is recommended when practicable, otherwise a high-quality potable tap water rinse is acceptable. A high-quality potable water is one that meets Federal Clean Water Standards at the point of use.