Department of Agriculture
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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).

DIRECTIONS FOR USE:

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

ACTIVATION: Activate the **PSS SELECT GLUTARALDEHYDE PLUS** solution by adding the entire contents of the *Activator Plus* activator vial which is attached to the **PSS SELECT GLUTARALDEHYDE PLUS** solution container. Shake well. When activated, solution changes color to bluish-green. Record the date of activation on the indicated space, 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 **PSS SELECT GLUTARALDEHYDE PLUS** solution. Cleanse and rinse the lumens of hollow instruments before filling with **PSS SELECT GLUTARALDEHYDE PLUS** solution. See package insert for additional cleaning/decontamination instructions.

STERILIZATION: Immerse medical instruments/equipment completely in **PSS SELECT GLUTARALDEHYDE PLUS** 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 **PSS SELECT GLUTARALDEHYDE PLUS** 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.

Select medical products

PSS GULF SOUTH MEDICAL SUPPLY

GLUTARALDEHYDE PLUS

Sterilizing and Disinfecting Solution

A 28-Day Glutaraldehyde, Long-Life, Activated Dialdehyde Solution

ACTIVE INGREDIENT

Glutaraldehyde.....3.4%
Inert Ingredient.....96.6%
TOTAL.....100.0%

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.

CONTENTS: 1 Gallon (3.785 liters) **REORDER NO. 344**

Keep Out of Reach of Children

DANGER: See Side Panel for Additional Precautionary Statements

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals
DANGER: Keep Out of Reach of Children
Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Wear goggles or face shield and protective gloves (butyl rubber, nitrile rubber, polyethylene or double-gloved latex), when handling or pouring. Avoid contamination of food. Use in well ventilated area in closed containers.

STATEMENT OF PRACTICAL TREATMENT:

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

STORAGE AND DISPOSAL:

Store at room temperature.
Solution Disposal: Discard residual solution in drain. Flush thoroughly with large quantities of water in accordance with federal, state and local regulations.
Container Disposal: Do not reuse empty container. Wrap container and put in trash.
Refer to package insert for material compatibility information and more detailed usage/product data.

CONTROL NUMBER AND EXPIRATION DATE FOR UNACTIVATED SOLUTION ON BOTTLE
For emergency, safety, or technical information, contact Metrex at 800-841-1428.

Note Dates Here:

Activation Date:_____ Expiration Date For Activated Solution:_____

Do not use beyond 28 days or sooner as indicated by a 1.8% glutaraldehyde test indicator.

DISTRIBUTED BY:
SELECT MEDICAL PRODUCTS
4345 SOUTHPOINT BLVD.
JACKSONVILLE, FL 32216

+M3403443

70-0670-3

4) **Monitoring of Germicide to Ensure Specifications are Met**
During the usage of **PSS Select Glutaraldehyde Plus**, as a high-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 **PSS Select Glutaraldehyde Plus** be tested with a **1.8% glutaraldehyde test indicator** 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

1) Prior to activation, **PSS Select Glutaraldehyde Plus** should be stored in its original sealed container at room temperature. Once the **PSS Select Glutaraldehyde Plus** 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 room temperature.
2) The expiration date of the unactivated **PSS Select Glutaraldehyde Plus** will be found on the immediate container.
3) The use period for activated **PSS Select Glutaraldehyde Plus** is for no longer than 28 days following activation or as indicated by a **1.8% glutaraldehyde test indicator.** Once activated, the solution requires no further dilution prior to its usage.

G) EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about **PSS Select Gluaraldehyde Plus** solution can be obtained by contacting your PSS Select sales representative or by contacting Metrex Research Corporation Customer Service Department at 1-800-841-1428.

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 **PSS Select Glutaraldehyde Plus** can be obtained by contacting your PSS Select 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.

J) HOW SUPPLIED

Reorder	Description	Case Containers
343	One Quart (946 mL) Container	4 x Quarts (4 x 946 mL)/box; 4 boxes/case; 16 x Quarts (16 x 946 mL)/case
344	One Gallon (3.8 L) Container	4 x Gallons (4 x 3.8 L)/case

References supplied upon request.

Distributed By:
Select Medical Products
4345 Southpoint Blvd.
Jacksonville, FL 32216

70-0671-2

Select medical products PSS GULFSOUTH

PSS SELECT GLUTARALDEHYDE PLUS

28-DAY STERILIZING & DISINFECTING SOLUTION (GLUTARALDEHYDE 3.4%)

A) INDICATIONS FOR USE

1) **Germicide Level of Activity**
PSS Select Glutaraldehyde Plus is a liquid chemical sterilant and high-level disinfectant, when used according to the **Directions for Use**.
Sterilant: PSS Select Glutaraldehyde Plus is a sterilant when used or reused, according to **Directions for Use**, at full strength for a maximum of 28 days at 25°C with an immersion time of at least **10 hours**.
High-Level Disinfectant: PSS Select Glutaraldehyde Plus is a high-level disinfectant when used or reused, according to **Directions for Use**, at full strength for a maximum of 28 days at 25°C with an immersion time of at least **90 minutes**.

2) **Reuse Period**
PSS Select Glutaraldehyde Plus has also demonstrated efficacy in the presence of 2% organic soil contamination and a simulated amount of microbiological burden during reuse.
PSS Select Glutaraldehyde Plus can be reused for a period not to exceed 28 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 a 1.8% glutaraldehyde test indicator to determine that at least the minimum effective concentration (MEC) of 1.8% 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. 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 or semi-critical 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.

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

Critical Device	Sterilization required (e.g.: products that enter sterile tissue or the vascular system, such as laparoscopes and micro-surgical 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.).

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) **Microbicidal Activity**
The following table indicates the spectrum of activity as demonstrated by testing of **PSS Select Glutaraldehyde Plus***:

BACTERIA		FUNGI	VIRUSES	
SPORES	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_2HK
	Pseudomonas aeruginosa		Adenovirus Type 2	HIV-1 (AIDS Virus)
	Mycobacterium tuberculosis		Vaccinia	Herpes simplex Types 1 & 2
			Coxsackievirus B5a	

*Testing was done after 28 days of simulated reuse using prescribed testing methods.

5) **Material Compatibility**
PSS Select Glutaraldehyde Plus is compatible with the following reusable devices and materials: 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 **PSS Select Glutaraldehyde Plus**, see Table 1 below.

Table 1. Manufacturers Reporting Device Compatibility with **PSS Select Glutaraldehyde Plus**

Company	Instrumentation
Acoustic Imaging	Transducers
Advanced Technology Lab	Ultrasound Scanheads
Hewlett Packard	Omniplane TEE Probe
Instrumentation Industries	Respiratory Therapy Equipment

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

PLEASE NOTE: PSS Select Glutaraldehyde Plus is incompatible with the following specific reusable devices: Acuson V510B transesophageal transducers, high-frequency cables, coagulating forceps, resectoscope instruments, and devices that have the potential for electrosurgical malfunctioning.

6) **Precleaning Agent Compatibility**
PSS Select Glutaraldehyde Plus is compatible with enzymatic detergents 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 **PSS Select Glutaraldehyde Plus** by altering its pH.

B) CONTRAINDICATIONS

1) **Sterilant Usage**
Routine biological monitoring is not feasible with **PSS Select Glutaraldehyde Plus**, and therefore, **PSS Select Glutaraldehyde Plus** 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.
PSS Select Glutaraldehyde Plus should not be used for sterilization of critical devices intended for single use (e.g.: catheters).

2) **High-Level Disinfectant Usage**
PSS Select Glutaraldehyde Plus should **NOT** be used to high-level disinfect a semi-critical device when sterilization is practical.

3) **Endoscope Usage**
PSS Select Glutaraldehyde Plus Long-Life 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.: **PSS Select Glutaraldehyde NS** solution) are more appropriate for flexible endoscopes, because glutaraldehyde solutions containing surfactants (e.g.: **PSS Select Glutaraldehyde or PSS Select Glutaraldehyde Plus** 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

PSS SELECT GLUTARALDEHYDE PLUS LONG-LIFE 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.

Emergency, safety, or technical information about **PSS Select Gluaraldehyde Plus** solution can be obtained by contacting your PSS Select sales representative or by contacting Metrex Research Corporation Customer Service Department at 1-800-841-1428.

D) PRECAUTIONS

1) Protective gloves (butyl rubber, nitrile rubber, polyethylene or double-gloved latex), 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 **PSS Select Glutaraldehyde Plus.**

5) The use of **PSS Select Glutaraldehyde Plus** 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 **PSS Select Glutaraldehyde Plus.**
Use a **1.8% glutaraldehyde test indicator** to monitor glutaraldehyde concentration before each cycle to detect unexpected dilution.

E) DIRECTIONS FOR USE

1) **Activation**
Activate the **PSS Select Glutaraldehyde Plus** by adding the entire contents of the *Activator Plus* activator vial which is attached to the **PSS Select Glutaraldehyde Plus** container. Shake well. Activated solution immediately changes color to bluish-green, thereby indicating solution is ready to use.
PSS Select Glutaraldehyde Plus 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 **PSS Select Glutaraldehyde Plus** 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 **PSS Select Glutaraldehyde Plus.** Cleanse and rinse the lumens of hollow instruments before filling with **PSS Select Glutaraldehyde Plus. 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 **PSS Select Glutaraldehyde Plus** 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 **PSS Select Glutaraldehyde Plus** for a minimum of **90 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) **Rinsing Instructions**
Following immersion in **PSS Select Glutaraldehyde Plus**, 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.

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.

d) **Reusage**
PSS Select Glutaraldehyde Plus 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 **28 days** after activation. **Do not use activated solution beyond 28 days. Efficacy of this product during its use-life must be verified by a 1.8% glutaraldehyde test indicator to determine that the minimum effective concentration (MEC) of 1.8% is present.**