Sporicidin® BRAND

STERILIZING AND DISINFECTING SOLUTION

A. INDICATIONS FOR USE

(1) Germicide Level of Activity

Sporicidin Sterilizing and Disinfecting Solution (SSDS) is a liquid chemical Sterilant and High Level Disinfectant, when used according to the Directions for Use. **SSDS is intended for reprocessing only heat-sensitive medical devices.**

Sterilant: Sporicidin Sterilizing and Disinfecting Solution is a Sterilant when used and reused according to the Directions for Use for a maximum of 14 days at 25°C with an immersion time of at least 12 hours.

High Level Disinfectant: Sporicidin Sterilizing and Disinfecting Solution is a high level disinfectant when used and reused according to directions for use for a maximum of 14 days at 25°C with an immersion time of at least **20 minutes.**

(2) Reuse

Sporicidin Sterilizing and Disinfecting Solution may be reused for a maximum of 14 days provided the minimum recommended concentration of 0.6% glutaraldehyde and 1.3% phenol, time and temperature are maintained. Indicator strips should be used before each use of this solution to determine whether glutaraldehyde is at or above its minimum recommended concentration of 0.6% and phenol is at or above its minimum recommended concentration of 1.3%.

DO NOT RELY SOLELY ON DAYS IN USE. Use patterns may reduce the established reuse life of this product. Discard if the concentrations of active ingredients in the solution fall below the minimum recommended concentrations stated above.

DO NOT USE BEYOND 14 DAYS EVEN IF THE RESPECTIVE CONCENTRATION OF ACTIVE INGREDIENTS IS ABOVE THE MINIMUM RECOMMENDED CONCENTRATION AS INDICATED BY THE INDICATOR STRIPS.

This Sporicidin product is effective as a sterilant and high level disinfectant only if devices are cleaned thoroughly, the solution is at or above the minimum recommended concentrations of 0.6% glutaraldehyde and 1.3% phenol and the solution is used according to the Directions for Use.

B. 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. See the reusable device labeling or contact the reusable device manufacturer for further instructions.

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

•**Critical reusable devices** routinely penetrate the skin or mucous membranes during use or are otherwise used in normally sterile tissues of the body (e.g. products that enter sterile tissue or the vascular system, such as microsurgical instruments).

•**Semi-critical reusable devices** make contact with mucous membranes but do not ordinarily penetrate normally sterile areas of the body. (e.g. GI endoscopes, anesthesia equipment for the air ways, diaphragm-fitting rings, etc.)

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

Critical Reusable Device:	Sterilization required NOTE: Liquid chemical germicide sterilization is acceptable only for those heat sensitive reusable critical devices which are incompatible with all available methods of sterilization that can be biologically monitored
Semi-critical Reuseable Device	Sterilization between uses is recommended whenever possiible, but at a minimum, HighLevel Disinfection is acceptable.

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

Microbial Activity

The following table indicates the spectrum of activity as

demonstrated by testing Sporicidin Sterilizing and Disinfecting Solution.

SPORES	VEGETATIVE ORGANISMS	FUNGI	VIRUSES
Bacillus subtilis	Mycobacterium tuberculosis	Trichophyton mentagrophytes	Poliovirus (Types 1 and 2)
Clostridium sporogenes	Staphylococcus aureus	Pathogenic fungi	Coxsackie
	Salmonella choleraesuis		Vaccinia
	Pseudomonas aeruginosa		Herpes Simplex (Types 1 and 2)
			Influenza virus (Type A)
			Cytomegalovirus
			Rotavirus
			HIV-1 (AIDS)

C. MATERIAL COMPATIBILITY

Sporicidin Sterilizing and Disinfecting Solution is recommended for use with medical devices made from the materials shown below.

Plastics	Teflon
	Polyacetal
	Polysulfone
	Polyetherimide
	Polycarbonate
	Vinyl chloride
	Polybutylene terephthalate (PBT)
Synthetic rubber	Silicone rubber
	Acrylonitrile-butadiens rubber (NBR)
	Neoprene
	Nitrile rubber
	Fluoro rubber
Glass	Optical glass
Alumite	Anodized aluminum
Steel	Stainless steel
Adhesive	Epoxy adhesive
Sealing material	Silicone sealing compound

Each of the above materials demonstrated satisfactory material compatibility with Sporicidin Solution containing 0.5% glutaraldehyde and 1.64% phenol through continuous immersion for:

- 5 days (120 hours) without rinsing.
- 12 days (288 hours) with rinsing on the 5th day.
- 20 days (480 hours) with rinsing on the 5th and 12th days.
- 30 days (720 hours) with rinsing on the 5th, 12th and 20th days.

Refer to the reusable device labeling for additional material compatibility information.

Precleaning Agent Compatibility

Sporicidin Sterilizing and Disinfecting Solution is compatible with anionic enzymatic detergents which are mild in pH, low foaming, and easily rinsed from equipment. Detergents that are either highly acidic or highly alkaline are contraindicated as precleaning agents since improper rinsing could affect the efficacy of the solution by altering its pH.

D. CONTRAINDICATIONS

(1) Sterilant Usage

Routine biological monitoring is not feasible with liquid germicides and, therefore, **Sporicidin Sterilizing and Disinfecting 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.: dry heat, steam, ethylene oxide, or peroxide gas plasma.

SSDS should NOT be used for sterilization of critical devices intended for single use (e.g.: catheters).

High Level Disinfectant Usage

SSDS should NOT be used for High Level Disinfection of semi-critical devices when sterilization is practical.

Endoscope Usage

Sporicidin Sterilizing and Disinfecting Solution is not the method of choice for sterilization of rigid endoscopes if the device manufacturer indicates they are compatible with steam sterilization. Surfactant containing disinfectants, may be used for reprocessing of flexible endoscopes if a validated protocol for rinsing and leak testing is employed.

E. WARNINGS

Keep Out of Reach of Children

Contains Glutaraldehyde plus Phenol/Sodium Phenate

(1) Direct contact with **SSDS** may be 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 eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention if necessary. In case of skin contact, rinse

thoroughly.

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

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

Emergency, safety, or technical information regarding **Sporicidin Sterilizing and Disinfecting Solution** can be obtained from Sporicidin International at 1-301-231-7700.

F. PRECAUTIONS

(1) Disposable 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, since residual contamination will decrease effectiveness of the germicide.

(3) The user **MUST** adhere to the directions for use since 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 **SSDS**.

(5) The use of **SSDS** 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 that may be used before refilling with fresh SSDS. Use the Sporicidin Indicator Kit to monitor glutaraldehyde and phenol concentrations before each cycle to detect unexpected dilution.

G. DIRECTIONS FOR USE AND REUSE

(1) Activation

Activate Sporicidin Sterilizing and Disinfecting Solution (SSDS) by adding the entire contents of the **Activator** bottle to the **Buffer** bottle. **DO NOT DILUTE.**

This provides a solution ready for use and reuse as a sterilant, and high level disinfectant containing 1.12% glutaraldehyde and 1.93% phenol/sodium phenate. SSDS 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 in a log book or on a label affixed to the 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.

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

(3) Usage

(a) Sterilization (Bucket/Tray Manual System)

Sporicidin Indicator Strips should be used before each use of this solution to determine whether glutaraldehyde is at or above its minimum recommended concentration of 0.6% and phenol is at or above its minimum recommended concentration of 1.3%.

Immerse medical equipment/devices completely in **SSDS** for a minimum of 12 hours at 25°C. Remove 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)

Sporicidin Indicator Strips should be used before each use of this solution to determine whether glutaraldehyde is at or above its minimum recommended concentration of 0.6% and phenol is at or above its minimum recommended concentration of 1.3%.

Immerse medical equipment/devices completely in **SSDS** for a minimum of 20 minutes at 25°C. Remove from the solution and rinse thoroughly following the rinsing instructions below.

(c) Rinsing Instructions

Following immersion in SSDS, thoroughly rinse the equipment or medical devices by immersing them completely in three separate copious volumes of water. Each rinse should be a minimum of 1 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 residual solution.

Endoscopic instruments with lumens: a minimum of 500 ml of water should be flushed through lumens during each separate rinse, unless otherwise noted by the endoscope manufacturer.

Refer to the reusable device/equipment manufac-

turer'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, or potential immunocompromised patients based on institutional procedures (e.g., high risk population served).

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

DEIONIZED OR FILTERED WATER RINSE

For all other devices a sterile water rinse is recommended when practicable, otherwise a high quality potable tap water rinse is acceptable, e.g. deionized water or tap water which has been filtered through a 0.2μ filter.

Although microorganisms in high quality potable water 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.

(4) Monitoring of Germicide to Ensure the MRC are Met

During the usage of **SSDS**, as a sterilant or high level disinfectant, it is recommended that a thermometer and timer be utilized to ensure that the optimum usage conditions are met. Sporicidin Sterilizing and Disinfecting Solution may be reused for a maximum of 14 days provided the minimum recommended concentration of 0.6% glutaraldehyde and 1.3% phenol, time and temperature are maintained. Indicator strips should be used before each use of this solution to determine whether glutaraldehyde is at or above its minimum recommended concentration of 0.6% and phenol is at or above its minimum recommended concentration of 1.3%.

(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. Refer to the reusable device-equipment manufacturer's labeling for additional storage and/or handling instructions.

H. STORAGE CONDITIONS AND EXPIRATION DATE

(1) Prior to activation, **SSDS** Activator and Buffer solutions should be stored in original sealed containers. Avoid freezing and extremely high temperatures-store at 15° to 30°C (59°-86°F).

Once **SSDS** 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 kept closed and stored in a well ventilated, low traffic area at room temperature.

(2) The expiration dates of the unactivated **SSDS Buffer** and **Activator** will be found on the bottom of the immediate containers.

(3) The use period for activated **SSDS** is for no longer than 14 days following activation or as indicated by the Sporicidin Indicator Strips. See label for directions.

I. EMERGENCY AND TECHNICAL PRODUCT INFORMATION

Emergency, safety, or technical information about **SSDS** can be obtained from Sporicidin International at 1-301-231-7700.

J. USER PROFICIENCY

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.

K. DISPOSAL INFORMATION

Germicide Disposal:

- Discard residual solution in drain. Flush thoroughly with water.

Container Disposal:

- Do not reuse empty containers. Wrap containers and place in trash.

SIZES AVAILABLE

QUART	**Reorder No. SSS-3216**
GALLON	**Reorder No. SSS-1284**