

INSTRUCTION FOR USE

Medical Instrument Disinfectant; Glutaraldehyde 2 %



PRODUCT NAME : Medical Instrument Disinfectant; Glutaraldehyde 2 %

TRADEMARK : SANITAROSA™ GA

PRODUCT REF NO: 6071

PACKING TYPE	ORDER NO
5 Liter HDPE Canister	436071025000

INTENDED USE: High-level disinfection and cold sterilization of medical devices, surgical equipment, endoscopic and thermosensitive equipment. No activation is required.

PRODUCT SPECIFICATION

Form	Liquid
Color	Light Yellowish
Odor	Aldehyde
pH @ 25°C (ca)	6.0±0.4
pH 25°C (ca) (%1)	~5,8 (10%~5,9)

COMPOSITION

Glutaraldehyde (2%), corrosion inhibitor and distilled water. Does not contain any acetate, borate, phosphate, detergent, and colorant.

INDICATIONS

Indicated for high-level disinfection and cold sterilization of endoscopes, surgical-medical and heat-sensitive equipment.

CONTRAINDICATIONS

- SANITAROSA™ GA 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.
- SANITAROSA™ GA should not be used for sterilization of critical devices intended for single use (e.g.: catheters).
- SANITAROSA™ GA ACT should NOT be used to achieve high-level disinfection of a semi-critical device when sterilization is practical.
- SANITAROSA™ GA should not be used for sterilization of rigid endoscopes which device manufacturers indicate are compatible with sterilization processes that can be biologically monitored (e.g. steam, dry heat, ethylene oxide, hydrogen peroxide gas plasma).

PRECAUTIONS

- 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.
- Contaminated, reusable medical devices **MUST BE THOROUGHLY CLEANED** prior to immersion in SANITAROSA™GA Solution since residual contamination will decrease the effectiveness of the disinfectant.
- The user **MUST** adhere to the Instruction for Use since any modification will affect the safety and effectiveness of the disinfectant.

HOW TO USE

Pre-cleaning: Wipe down the external surface of the surgical instrument with gauze or a cloth, to remove the mucous membrane, blood and filth that adhere to the external surface. Either moistened gauze or dry gauze is fine. After the outer surface of the instruments is wiped with a cloth, it must be treated with an enzymatic detergent (Ref no: 6160 GBL® WARECLEAN™ EC) before disinfection.

Disinfection:

Ready-to-use. Do not dilute. Pour activated SANITAROSA™ GA disinfectant solution into the disinfection container. Pre-cleaned devices with enzymatic detergent (Ref no: 6160 GBL® WARECLEAN™ EC) are immersed into the container so that all the surfaces and holes will contact the solution. Wait according to the requested activity (contact times given below the microbiological effect table). Rinse with sterile or distilled water. Keep the medical device as aseptically as possible until use. SANITAROSA™ GA can be used up to 14 days.

Product Effectiveness Control with MEC Test Strips:

After 14 days, if the disinfectant solution in the container will be checked with Rosa-Strip GA (REF No: 7001) and be found still active, the disinfectant solution can still be used up to 30 days. It is recommended to replace the solution in case of visible contamination and organic waste.

Directions for ROSA-STRIP GA

Open the ROSA-STRIP GA Test Strips bottle and remove the test strip. Close the bottle. Completely immerse the indicator pad of the strip in glutaraldehyde solution. Remove after 2 seconds. Do not stir the glutaraldehyde solution with the strip. Do not shake the test strip to make it dry. Dry the test strip only by laying down the test strip on a paper towel. Compare the test strip reaction zone color with the color scale on the test strip bottle at 60 seconds. Do not read results past 60 seconds. Close the test strips' bottle caps immediately after use. After the test strips bottle once opened, use all test strips within 90 days. Discard unused test strips within 90 days. Store tightly closed test strip bottle between 15-30 °C and out of direct sunlight.



PASS



FAIL



FAIL



FAIL

DISINFECTANT/CONTAINER DISPOSAL INFORMATION

Dispose of content/container in accordance with local/regional/national/international regulations.

For 5 Liter solution use just 125 g Ref no: 6128 Neutralizer for SANITAROSA GA. Pour the neutralizer to the container. Stir 10 minutes. After 10 minutes you can discharge safely the neutralized solution according to the waste disposal rules of your country. Neutralized solution is not harmful to the environment.

MICROBIOLOGICAL EFFECT TABLE

Effect	Standard	Microorganism (with ATCC)	Contact Time
Bactericidal	EN 13727 / EN 14561	<i>Staphylococcus aureus</i> 6538 <i>Pseudomonas aeruginosa</i> 15442 <i>Enterococcus hirae</i> 10541	10 min.
Fungicidal	EN 13624 / EN 14562	<i>Candida albicans</i> 10231 <i>Aspergillus brasiliensis</i> 16404	10 min.
Mycobactericidal	EN 14563	<i>Mycobacterium terrae</i> 15755 <i>Mycobacterium avium</i> 15769	10 min.
Virucidal	EN 14476+ A1	<i>Adenovirus type 5, strain Adenoid 75, ATCC VR-5</i> <i>Murine norovirus (MNV) strain S99, RVB-651</i> <i>Poliovirus type 1, LSc-2ab</i>	10 min.
Sporicidal	AOAC	<i>Bacillus subtilis</i> 6633	3 hours

WARNINGS AND POTENTIAL ADVERSE EFFECTS

The product is for professional use only.

Danger. Causes skin irritation. Causes serious eye damage. May cause respiratory irritation. Avoid breathing dust/fumes/gas/mist/vapor spray. Wear protective gloves/protective clothing/eye protection/face protection. Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove the person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove the contact lens if present and easy to do – continue rinsing. Store in a well-ventilated place. Keep the container tightly closed.

Glutaraldehyde is an irritant to the skin, eyes, and respiratory system. Skin contact may cause minor irritation with itching and slight local redness. Prolonged contact causes mild to moderate local redness and swelling. In concentrations less than 5% it is considered irritating to eyes, although higher concentrations can present a risk of serious damage to the eyes. These symptoms are generally temporary and should subside when the employee leaves the area of glutaraldehyde exposure. There is no evidence of adverse reproductive or carcinogenic health.

STABILITY AND STORAGE

SANITAROSA™ GA should be stored in its original sealed container in a well-ventilated area at 5°C-35°C, in the shade and away from direct sunlight.

Storage Temperature	Shelf Life	Usage Time After Opening the Cap
5/35 °C	2 years	3 months

PACKAGING

Product	Packaging Type	Packaging Units
SANITAROSA™ GA	HDPE Canister	5 Liter x 2

ACCESSORIES

PRODUCT NAME	REF NO	ORDER NO	Packaging Type	Packaging Units
Glutaraldehyde MEC* Test Strips	7001	457004070025	HDPE; Bottle	25 strips x 72
Neutralizer for SANITAROSA™ GA ACT	6219	436219000125	HDPE; Bottle	125 gr x 100

*MEC: Minimum Effective Concentration

Neutralizer for
SANITAROSA™ GA

Rosa-Chem GA

Ref no: 6219















Glutaraldehyde
MEC Test Strips

ROSA-STRIP GA


Ref no: 7001



LABEL SYMBOL KEYS

 REF	Catalog Number		Production Date		Storage Temperature		Manufacturer Information
 LOT	Batch Code		Expiry Date		Refer to User Guide		Complies with European product regulations. 1984: Notified body number.
	Recycling Information		GHS05 Corrosive		GHS07 Harmful		Usage Time After Opening the Cap

MANUFACTURER

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