

INSTRUCTION FOR USE

Endoscope Disinfectant; Ortho-Phthalaldehyde 0,55%



PRODUCT NAME : Endoscope Disinfectant; Ortho-Phthalaldehyde 0,55%

TRADEMARK : GBL® SANITAROSA™ OPA

PROCUT REF CODE: 6026

PACKING TYPE	ORDER NO
5 Liter HDPE; Cannister	436026025000

INTENDED USE: SANITAROSA™ OPA solution is a convenient, ready-to-use, high-level disinfectant that provides a broad spectrum of microbiological activity. It can disinfect a wide range of endoscopes and other heat-sensitive semi-critical medical devices. SANITAROSA™ OPA solution is ideal for both automated and manual instrument reprocessing. It is designed for use in central processing, gastrointestinal departments, surgery centers, and other areas where high-level disinfection is required.

PRODUCT SPECIFICATION

Form	Liquid
Color	Light Lemon
Odor	Slight Odor
OPA %	0,55±0,05
pH @ 25°C (ca):	7.4±0.3
pH @ 25 °C (ca) (1%):	~ 7,3 (10% ~ 7,5)

COMPOSITION

Ortho-Phthalaldehyde (0,55%), benzotriazole, buffers, antioxidant, and stabilizing agents. Does not contain quaternary ammonium salts, chlorine, or phenol.

MICROBIOLOGICAL PROPERTIES

Effect	Contact Time	Standard (Phase 2, Step 1-Step 2)	Microorganism (with ATCC)	Use Concentration
Bactericidal	20 min. 10 min.	EN 13727 EN 14561	<i>Staphylococcus aureus</i> 6538 <i>Enterococcus hirae</i> 10541 <i>Pseudomonas aeruginosa</i> 15442	Ready to use.
Sporocidal	32 hours	AOAC	<i>Bacillus subtilis</i> 6633	Ready to use.
Fungicidal	10 min.	EN 13624 EN 14562	<i>Candida albicans</i> 10231 <i>Aspergillus brasiliensis</i> 16404	Ready to use.
Tuberculocidal	60 min.	EN 14348	<i>Mycobacterium terrae</i> 15755	Ready to use.
Mycobactericidal	5 min.	EN 14563	<i>Mycobacterium avium</i> 15769 <i>Mycobacterium terrae</i> 15755	Ready to use.
Virucidal	60 min.	EN 14476 + A1	<i>Adenovirus type 5</i>	Ready to use.

Effect	European Standard	Microorganism (with ATCC)	Contact Time
Bactericidal	EN 13727 EN 14561	<i>Staphylococcus aureus</i> 6538 <i>Enterococcus hirae</i> 10541 <i>Pseudomonas aeruginosa</i> 15442	20 min. 10 min.
Sporocidal	AOAC	<i>Bacillus subtilis</i> 6633	32 hours
Fungicidal	EN 13624 EN 14562	<i>Candida albicans</i> 10231 <i>Aspergillus brasiliensis</i> 16404	10 min.
Tuberculocidal	EN 14348	<i>Mycobacterium terrae</i> 15755	60 min.
Mycobactericidal	EN 14563	<i>Mycobacterium avium</i> 15769 <i>Mycobacterium terrae</i> 15755	5 min.
Virucidal	EN 14476 + A1	<i>Adenovirüs type 5</i>	60 min.

HOW TO USE

Ready for use. Do not dilute.

1. Pre-Cleaning:

The healthcare personnel should wear protective gear such as a gown, gloves, eyewear, and/or a face mask to protect their body from hazardous substances from medicinal agents and infection when conducting cleaning and disinfection. Immediately clean the endoscope that is removed from the patient while it is still connected to the light source. This is because the external surfaces of the endoscope and the internal suction and air & water supply channels are exposed to fluids and other contaminants or pollutants. If the endoscope is not immediately cleaned, the contaminants adhere to the scope and dry up, and it becomes harder to clean.

- (1) Wipe down the external surface of the endoscope 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.
- (2) After the outer surface of the endoscope is wiped with a cloth, it must be treated with an enzymatic detergent (GBL-6160 GBL® WARECLEAN™ EC) before disinfection. After washing, the device should be thoroughly rinsed and dried.

2. Process:

After use, if the endoscope is disinfected without cleaning first, the microorganisms will bind to the endoscope. As a result, this will not only obstruct cleaning but will also in fact protect the pathogenic microorganisms. This invites the possibility and cause for infection and should never be done. Consequently, effective concentration and time limits should be followed when using various pharmaceutical and medicinal agents.

1. Manual Processing: 20 liters soaking tray is used for disinfection. Immerse the device completely, filling all lumens and eliminating air pockets, in SANITAROSA™ OPA solution for a minimum of 12 minutes at 20°C or higher to destroy all pathogenic microorganisms.
2. Automatic Endoscope Reprocessor that can be set to a minimum of 25°C: High-Level Disinfectant at a minimum of 25°C. For use in a legally marketed Automatic Endoscope Reprocessor (AER) that can be set to a minimum of 25°C with a minimum immersion time of five minutes. As with all high-level disinfectants, it is critical that temperature is monitored when using SANITAROSA™ OPA solution in an AER at 25°C.

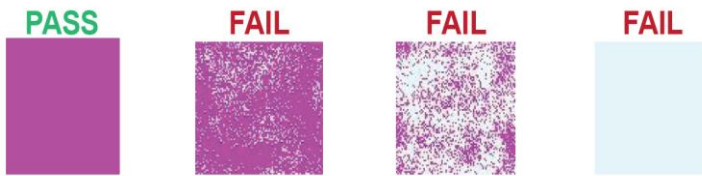
3. Control with Test Strips (GBL-7002 ROSA-STRIP OPA):

It is recommended that the disinfectant be tested before each disinfection cycle to ensure that the ortho-phthalaldehyde is above the MEC.

SANITAROSA™ OPA can be re-used for up to 14 days in soaking baths.

Do not use OPA solution beyond the use-life of 14 days regardless of the test strip results.

- Completely submerge the indicating pad of the strip into the disinfectant solution for 2 seconds and remove.
- Do not shake the strip.
- Remove excess solution by standing the strip upright on a paper towel.
- Read results at 60 seconds. Do not read past 60 seconds.
- Pad will be completely PURPLE to indicate an effective solution.
- IF ANY BLUE remains on the pad apart from the top line, the solution is ineffective and must be discarded.
- Compare the reaction zone with the color scale on the product label.



DISINFECTANT/CONTAINER DISPOSAL INFORMATION

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

OPA-based disinfectants must have been neutralization before disposal. **GBL-6218 ROSA-CHEM OPA** can be used for the neutralization of all OPA-based disinfectants. After neutralization, it can be discharged to the sewage system as household waste. If not neutralized, it must be discharged as chemical waste. Do not reuse empty containers.

WARNINGS AND POTENTIAL ADVERSE EFFECTS

Do not breathe dust/fumes/gas/mist/vapors/spray. Wear protective gloves/ protective clothing/eye protection/face protection. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

STABILITY AND STORAGE

Product; in the shade, in the original packaging, the package should be kept tightly closed and in a well-ventilated environment.

Storage Temperature	Shelf Life	Usage Time After Opening the Cap
15/25 °C	2 years	3 months

PACKAGING

Product	Packaging Type	Packaging Units
GBL® SANITAROSA™ OPA	HDPE; Canister	5L x 2

ACCESSORIES

PRODUCT NAME	REF NO	ORDER NO	Packaging Type	Packaging Units
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ROSA-STRIP OPA	7002	457002070025	HDPE; Bottle	25 Strips
OPA Neutralizer	6218	436218000032	HDPE; Bottle	32 gr

REF No: 7002
OPA MEC Test StripsREF No: 6218
OPA neutralizer

LABEL SYMBOL KEYS



Catalog Number

Production
DateStorage
TemperatureManufacturer
Information

Batch Code



Expiry Date

Refer to User
GuideRecycling
InformationComplies with European
product regulations.
1984: Notified body number

MANUFACTURER

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