


Document Number	Release date	Revision No	Revision date
TD.05.122	10.06.2019	06	24.05.2021



ONESEPT GA
**HIGH LEVEL DISINFECTANT FOR MEDICAL
INSTRUMENTS AND ENDOSCOPES**

	OneSept GA High Level Disinfectant For Medical Instruments And Endoscopes Instruction For Use			
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General Features

All kinds of invasive surgical instruments, dental surgical instruments, surgical laparoscopy instruments, flexible and it is used to provide high-level disinfection of rigid endoscopes. ACTIVATION AFTER USED. Our products are offered for sale as 5 liters

Product package content; OneSEPT GA - Activator / Product Efficacy Control strip / 30 gr Sodium bi Sulphate for Disposal


Chemical Composition

Chemical Composition	Contents
Active ingredient	Glutaraldehyde 2%
Excipients	*HEDP * Essence *Benzotriazole *Deionized Water

Purpose of usage:

All kinds of surgical instruments, surgical laparoscopy instruments, flexible and rigid endoscopes it is used to provide level disinfection. Rust, corrosion, endoscope it does not cause any damage such as softening or color change in the covers. It is anticorrosive. It is suitable for endoscope washing machines and manual use.

Products	Shelf Life	Tub Life Time	Usable surface materials	Microorganisms and Effect times
OneSept GA	2 years	28 days	<ul style="list-style-type: none"> - Glass - Ceramic - Silicone - Plastic - PVC - Acrylic - polymer - Polycarbonate - Polystyrene - HDPE - Stainless steel - Porcelain 	<i>Staphylococcus aureus</i> (EN 13727)- 5 minutes <i>Staphylococcus aureus</i> (EN 14651)- 5 minutes <i>Pseudomonas aeruginosa</i> (EN 13727)- 5 minutes <i>Pseudomonas aeruginosa</i> (EN 14651)- 5 minutes <i>Enterococcus hirae</i> (EN 13727)- 5 minutes <i>Enterococcus hirae</i> (EN 14651)- 5 minutes <i>Mycobacterium avium</i> (EN 14348)- 5 minutes <i>Mycobacterium avium</i> (EN 14563)- 5 minutes <i>Mycobacterium terrae</i> (EN 14348)- 5 minutes <i>Mycobacterium terrae</i> (EN 14563)- 5 minutes <i>Candida albicans</i> (EN 13624)- 5 minutes <i>Candida albicans</i> (EN 14562)- 5 minutes <i>Aspergillus niger</i> (EN 13624)- 5 minutes <i>Aspergillus niger</i> (EN 14562)- 5 minutes <i>Bacillus subtilis</i> – 15 minutes (EN 17126 ve EN 13704)

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				Poliovirus type 1 virus- 5 minutes (EN 14476) human adenovirus type 5 virus- 5 minutes (EN 14476) murine norovirus-5 minutes (EN 14476)
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** Corrosion effect when our products are subjected to corrosion test according to TS 6773 standard was not shown.

The mechanism of action of our OneSept GA product as a disinfectant is bactericidal, virucidal, mycobactericidal, sporicidal and fungicidal. It provides disinfection by alkylating sulfhydryl, hydroxyl, carboxy and amino groups of microorganisms in the medical device and disrupting RNA, DNA and protein synthesis. Vegetative forms of spore-forming bacteria are killed with disinfectants, preventing them from doing sports again.

Usage

Our product is used by immersion method. GA Activator supplied with our products empty the entire vial into 5 liters of Onesept GA solution.

- Disassembled medical instruments are immersed in the container/container filled with the product.
- It is kept for 15 minutes for the activity period.
- Medical instruments are removed from the Container/Container.
- It is rinsed with distilled water.

Usage Concentration


Ready to use after activation, do not dilute!

INDICATIONS-CONTRAINDICATIONS,SIDE EFFECTS, WARNINGS AND PRECAUTIONS

Indications

It contains glutaraldehyde and is used to clean the surfaces of invasive medical devices such as Endoscopes, surgical-medical and Indicated for high level disinfection of heat sensitive equipment.

Staphylococcus aureus , Pseudomonas aeruginosa , Enterococcus hirae , Mycobacterium avium ,Mycobacterium terrae , Candida albicans , Aspergillus niger , Bacillus subtilis , Polyvirus type 1 virus,It is indicated in human adenovirus type 5 virus, Murine norovirus microorganisms.

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Contraindications

- It should not be used directly (without pre-cleaning) on surfaces and instruments containing organic compounds (blood, tissue, urine, etc.).
- It should not be used together with other chemicals as it may react with chemicals.
- It should not be used by people who are sensitive to glutaraldehyde

Side effects

Our products have no known side effects.

WARNINGS and PRECAUTIONS

- Be sure to read the instructions for use before using the product.
- Avoid contact with eyes.
- Use protective clothing (gloves and eye/face protection) equipment.
- **IF SWALLOWED:** Rinse your mouth, do not try to vomit.
- In case of prolonged contact with the skin, wash with plenty of soap and water. In case of skin irritation get medical attention.
- Do not reuse the packaging of the finished product .
- **IF IN EYES:** Rinse carefully with water for a few minutes. mention of eye irritation If so, consult your doctor.
- Avoid spreading to the environment.
- Store in its original container.
- Dispose of waste and used packaging in accordance with official regulations.

Storage and Shipping Conditions:

- Store at 0°C -25°C in its original packaging in a cool and dry place.
- Product shelf life is 2 years from the date of production.
- Use the opened product within 6 (six) months.
- Keep out of reach of children











➤ Sterilization

Our products are used non-sterile.

➤ Symbols Used on the Label and Their Meanings




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	Notified Body Number		Expiration date
	Production date		Non-sterile
	Read the Instructions for Use.		Protect from sunlight.
	Store in dry place.		Storage temperature range
	Manufacturer Information		Do not use damaged package.

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	Barcode number	REF	Referance number
LOT	Lot number		Caution (Warnings)
	The product inside may cause irritation in case of contact with the skin.		

