



ZHIVAS LTD

INSTRUCTION FOR USE

OXISEPT

**CONCENTRATE FOR HIGH LEVEL
DISINFECTION OF MEDICAL INSTRUMENTS,
MEDICAL DEVICES AND EQUIPMENT.**



CE 0120

Application

Oxisept is a concentrate in granule form intended for:

- Disinfection and cleaning of invasive and non-invasive medical and dental instruments, medical and laboratory equipment
- High-level cold chemical disinfection (sterilization) of medical instruments, thermo-sensitive and thermo-resistant medical devices (anesthetic equipment, endoscopes, bronchoscopes).

Properties

Oxisept granules are dissolved in water, "in situ" peracetic acid is formed, which releases oxygen. At relatively low concentrations Oxisept shows a broad spectrum of microbiological activity.

The product contains corrosion inhibitors and is compatible with various materials, from which the medical instruments and medical devices are made. It does not fix the protein soiling and its activity is not affected by it. The working solutions of the product are odorless, environmentally friendly and not inducing allergic reactions. Oxisept possesses excellent cleaning power.

Appearance:	Fine granulate with evenly spread colored particles (green, light-blue or white) depending on the color of TAED used,
pH (1% solution)	10.0 - 11.0 (20°C)
Solubility:	Soluble in water. Presence of insignificant residue is allowed.

Content

Active ingredients:

Sodium percarbonate (CAS 15630-89-4) and Tetraacetyl ethilene diamine (CAS10543-57-4) producing "In situ" Peracetic acid (CAS 79-21-0) 1000 ppm in 1-% solution

Auxiliary ingredients:

Cationic surfactant, corrosion inhibitors, chelating agent.

Classifications

Oxisept meets the requirements for chemical disinfectants of the European Medical Device Directive 93/42 / CEE and is classified as a medical device - Class IIb.



Spectrum of activity

Bactericidal – mycobactericidal – fungicidal – virucidal and sporicidal.

Microbiological activity		Concentration of the working solution	Standard	Exposition
Bactericidal (<i>P.aeruginosa</i> , <i>S.aureus</i> , <i>E.hirae</i>)		0.5%	EN 13727 EN 14561	30 min
		1.0 %		15 min
		2.0%		10 min
Fungicidal (<i>C.albicans</i> , <i>A.niger</i>)		0.5%	EN 13624 EN 14562	30 min
		1.0 %		15 min
		2.0%		10 min
Mycobactericidal/tuberculocidal (<i>M.terrae</i> , <i>M.avium</i>)		1.0 %	EN 14348	30 min
		2.0%		10 min
Sporocidal (<i>Bacillus subtilis</i>)		2.0%	EN 14347	10 min
Virucidal	Envelope viruses <i>HIV/HBV/HCV</i>	0.5 %	EN 14476	15 min
	<i>Adeno, polio</i>	1.0%	EN 14476	15 min
		2.0%		10 min

Method of Application:

Oxisept is a concentrate in granule form and is applied dissolved in water at concentration of the working solution and exposition time as shown in the table below.

Use the supplied measuring scoop to prepare the working solution with tap water at room temperature. Allow 15 – 20 minutes to dissolve, while stirring gently. There are no requirements about the hardness of the water.

Disinfection is conducted by immersing the medical instruments and devices in the solution. All inner cavities should be fully covered with the solution. After disinfection – rinse with sterile water

Target	Microbiological activity	Concentration of working solution	Exposition
Disinfection of invasive and non-invasive medical instruments and medical devices	Bactericidal, Fungicidal, Virucidal	0.5% 5 g / 1 l water	30 minutes
		1.0% 10 g / 1 l water	15 minutes
		2.0% 20 g / 1 l water	10 minutes
	Bactericidal, Fungicidal, Virucidal, Mycobactericidal, Sporocidal	2.0% 20 g / 1 l water	10 minutes



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Storage conditions

Store in tightly closed original container in a dry and ventilated area, protected from direct sunlight at temperatures from 0 to 35° C. Keep out of reach of children.

Precautions and instructions:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water. If swallowed, do not induce vomiting, immediately seek medical advice and show this container or label. For more details consult the Safety Data Sheet.

Treatment of waste and packaging – according to local regulations

Do not release the concentrate in the environment – for disposal of waste, residuals and empty packaging see special instructions in the safety data sheet.

Packaging

Containers of 1 kg , 3 kg and 5 kg

Shelf life:

2 years

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