



INSTRUCTION FOR USE

OXISEPT

GRANULATED CONCENTRATE FOR HIGH-LEVEL DISINFECTION OF INVASIVE AND NON-INVASIVE MEDICAL INSTRUMENTS, THERMO-SENSITIVE AND THERMO-RESISTANT MEDICAL DEVICES



Application

Oxisept is a concentrate in granule form with oxygen release intended for:

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

Properties

Oxisept granules, when dissolved in water form "in situ" per acetic acid, 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.
pH (1% solution)	8.0 - 9.0 (20°C)
Solubility:	Soluble in water. Presence of insignificant residue is allowed.

Content

Active ingredients:

Peracetic acid (CAS №79-21-0) 1000 ppm in 2-% solution, obtained "In situ" from sodium per carbonate (CAS №15630-89-4) and TAED (CAS №10543-57-4)

Auxiliary ingredients:

Cationic surfactant, corrosion inhibitors, chelating agent.



Classifications

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

Spectrum of activity

Bactericidal – mycobactericidal/tuberculocidal – fungicidal – virucidal and sporicidal.

Microbiological activity	Standard	Concentration of the working solution	Exposition
Bactericidal (<i>P.aeruginosa</i> , <i>S.aureus</i> , <i>E.hirae</i> , <i>E.coli</i>)	EN 14561	2.0%	10 min
		0.25%	20 min
	EN 13727	0.25%	30 min
Fungicidal (<i>C.albicans</i> , <i>A.niger</i>)	EN 14562	2.0%	10 min
Fungicidal (<i>C.albicans</i>)	EN 13624	0.25%	30 min
Mycobactericidal/tuberculocidal (<i>M.terrae</i> , <i>M.avium</i>)	EN 14348	2.0%	10 min
	EN 14563	0.75%	15 min
Sporicidal (<i>B. subtilis</i> , <i>B.Cereus</i> , <i>C.difficile</i>)	EN 17126	3.0%	10 min
Sporicidal (<i>C.difficile</i>)	EN 17126	2.0%	15 min
Virucidal (<i>Adeno</i> , <i>Noro</i> , <i>Polio</i> , <i>Vaccinia</i> , <i>Rhino</i> , <i>Papova</i> , <i>Rota</i> , <i>HPV</i> , <i>HAV</i> , <i>HBV</i> , <i>HCV</i> , <i>HIV</i> , <i>HSV</i> , <i>Corona</i>)	EN 14476	2.0%	10 min

Method of Application:

Oxisept is a concentrate in granule form and is applied dissolved in water. 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.

Threat by **immersion** (disassemble the instruments, open all their openings as far as possible and immerse them in the solution. Make sure all surfaces and cavities of the instruments are fully covered);

by **wiping** (use appropriate application means - cloth, napkin, nonwoven textile - soak it thoroughly with the solution, and wipe the surfaces until fully wetted and leave the preparation to act).

After disinfection – rinse thoroughly with water.

The working solution of Oxisept is good for use up to 24 hours depending on the intensity of use.

Target	Microbiological activity	Concentration of working solution	Exposition
Disinfection of invasive and non-invasive medical instruments, thermo-sensitive and thermo resistant medical devices	Bactericidal and Fungicidal	2.0%	10 min
	Mycobactericidal/tuberculocidal	2.0 %	10 min
	Sporicidal	2.0 %	15 min

Attention! Avoid mixing with chlorine containing substances! Can be corrosive to metals such as aluminium, copper, brass and zinc.



Quantity measured by the measuring scoop: Completely filled up - 20g,

Control of the content of peracetic acid (PAA) in the working solution (WS) of Oxisept with "Quantofix" test strips:

- **Strips with range 500 – 2000 ppm PAA**

- Recommended for testing of 2% WS. Dip the strip into the solution for 2-3 seconds. Take it out and keep for 20 – 30 seconds. Compare the color of the strip with the color scheme on the outer packing and determine the value

- If the strip shows content of PAA 750 – 1000 ppm the solution is good for use

Oxisept is suitable for use on endoscopes manufactured by the following brands: Olympus, Pentax, Karl Storz, Fujinon and etc.



(GHS05)

Signal word: Danger

Hazard statements:

H318 Causes serious eye damage.

Precautionary statements:

P280 Wear protective gloves/eye protection/face protection.

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.

P301+P312- IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.

Storage conditions:

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

Packaging

Buckets of 1 kg, 2 kg, 3 kg and 5 kg

Shelf life:

2 years

ZHIVAS Ltd,

14, Assen Yordanov Blvd. 1592 Sofia, Bulgaria

Tel/fax: +359 2 9817823, +359 2 9802507

zhivas@techno-link.com

www.zhivas.com