

GBL GUL BIYOLOJI LABORATUVARI SANAYI VE TICARET ANONIM SIRKETI HQ: Serifali Mah. Hattat Sk. No:10 P.O.: 34775 Umraniye Istanbul TURKIYE Factory: Dudullu OSB Mah. IMES C Blok 305 Sk. No:16 P.O.: 34775 Umraniye Istanbul TURKIYE

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INSTRUCTION FOR USE Hemodialysis Machine Disinfectant; Peracetic Acid Based



PRODUCT NAME : Hemodialysis Machine Disinfectant; Peracetic Acid Based **TRADEMARK** : PEROXY[™] PLUS **PRODUCT REF NO** : 6123

PACKING TYPEORDER NO5 Liter HDPE Green Canister436123045000

INTENDED USE: Cold disinfectant (dialysis machine 37°C) for hemodialysis machines with proportional mixing system and recirculation function. PEROXY[™] PLUS can be used also as cold disinfection for water treatment devices and circuit pipes.

PRODUCT SPECIFICATION

Form	Liquid
Color	Colourless
Odor	Acrid
рН @ 25°С (са)	< 2
pH @ 25 °C (ca) (1%)	~ 3,2 (10% ~ 2,5)

COMPOSITION

Peracetic acid solution (PAA) (3,5%), hydrogen peroxide, acetic acid, stabilizing agents, corrosion inhibitors, distilled water.

Peracetic acid	3,5±0,5 % p/p
Acetic acid	10 ± 1,0 % p/p
Hydrogen peroxide	20 ± 1,5 % p/p

Mechanism of antimicrobial action peracetic acid, hydrogen peroxide

Damage of the cell wall through oxidation of membrane proteins, resulting in oxidation of liberated fatty acids, proteins, DNA, etc. Damage of the envelope of enveloped viruses as well as oxidation of the coat proteins.

PRODUCT USAGE

It is used automatically from the disinfection suction pipette of the hemodialysis machine. Usage and dilution ratio should be followed by hemodialysis machine system instructions.

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MICROBIOLOGICAL PROPERTIES

Effect	European Standard	Concentration	Microorganisms
Bactericidal	(Contact Time) EN 13727 (15 min.) EN 14561 (5 min.)	15 min.) 1:25	(with ATCC) Staphylococcus aureus 6538 Pseudomonas aeroginosa 15442 Enterococcus hirae 10541
Fungicidal	EN 13624 (60 min.) EN 14562 (5 min.)	1:25 Ready-to-use	Candida albicans 10231 Aspergillus brasiliensis 16404
Tuberculocidal	EN 14348 (60 min.) EN 14563 (5 min.)	1:25 1:100	Mycobacterium terrae 15755
Virucidal	EN 14476:2013 + A1:2015 (60 min.)	1:24	Adenovirus type 5, strain Adenoid 75, ATCC VR-5 Murine norovirus (MNV) strain S99, RVB-651 Poliovirus type 1, LSc-2ab
Sporocidal	EN 13704 (60 min.)	1:25	Bacillus spizizeni 6633

- To be used according to the device manual at elevated temperatures only.
- The absence of PEROXY[™] PLUS must be detected by test strips to be sure that no residue is left behind.
- After PEROXY[™] PLUS use, you can easily remove it by rinsing with water.
- PEROXY[™] PLUS is designed for cold disinfection. In principle, it can be used for all hemodialysis systems like hemodialysis machines, water treatment devices and circuit pipes.

Decalcifying: Yes Cleaning: Limited effect Antimicrobial action: Cold disinfectant (dialysis machine 37 °C) Used dilution: 1:25

CONTRAINDICATIONS

Suitable for hot disinfection. In the cleaning program of the hemodialysis device, a wash/rinse process must be performed after disinfecting with PEROXY[™] PLUS. Failure to do so carries a risk for the patient. It is not suitable for the use of devices other than hemodialysis.

WARNINGS

May intensify fire; oxidizer. Harmful if swallowed. Causes severe skin burns and eye damage. May cause respiratory irritation. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not breathe dust/fumes/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): 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. Immediately call a POISON CENTER or doctor/physician. Store locked up. Protect from sunlight.

STABILITY AND STORAGE

Properly stored, the disinfectant remains fully effective for 18 months after production. Keep the container always sealed and store in an upright position. If possible, store in well-aired rooms at 15 to 25°C. Do not be exposed to direct sunlight.

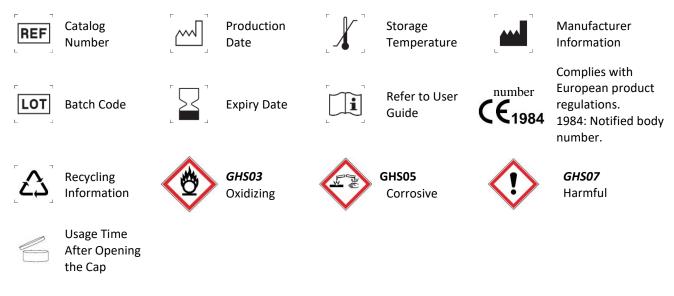
Storage Temperature	Shelf Life	Usage Time After Opening the Cap
15/25 °C	18 months	3 months



PACKAGING

Product	Packaging Type	Packaging Units
PEROXY [™] PLUS	HDPE; Green Canister	5L x 2

LABEL SYMBOL KEYS



MANUFACTURER



□ GBL[®] Gül Biyoloji Laboratuvarı Sanayi ve Ticaret Anonim Şirketi

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