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INSTRUCTION FOR USE
Cold Sterilant For Dialyzer Reprocessing

PRODUCT NAME : Cold Sterilant For Dialyzer Reprocessing
TRADEMARK : GBL® PEROXY PLUS™ RP
PRODUCT REF NO : 6127

PACKING TYPE	ORDER NO
5 Liter HDPE Green Jerrycan	436127045000

PRODUCT DESCRIPTION
Invasive medical device disinfectant containing 5±0.5% peracetic acid.

INTENDED USE: GBL® PEROXY™ PLUS™ RP is an invasive medical device disinfectant for the reuse of hollow fiber type dialyzers and for the in vitro cleaning and disinfection of dialysis equipment (e.g. kidney machines) and supplies (e.g. port caps) to prevent risks to patients.

GBL® PEROXY PLUS™ RP Cold Sterilant is not designed, sold or intended for use other than as directed.

PRODUCT SPECIFICATION

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

COMPOSITION
Peracetic acid solution (PAA) (5 %), hydrogen peroxide, acetic acid, stabilizing agents, and RO water.

Peracetic acid	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.
Decalcifying: Yes
Cleaning: Limited effect
Antimicrobial action: Cold disinfectant

PRODUCT USE CONCENTRATION
No manual dilution required. GBL® PEROXY™ PLUS RP is designed to be automatically diluted by the dialysis machine.

General Product Application

GBL® PEROXY PLUS™ RP Cold Sterilant is intended for dialyzer reprocessing. GBL® PEROXY PLUS™ RP Cold Sterilant maintains stability for 18 months when stored according to label directions. GBL® PEROXY PLUS™ RP Cold Sterilant may be used for manual dialyzer reprocessing. Facilities practicing manual dialyzer reprocessing must independently validate their reprocessing protocols to establish safety and effectiveness according to ANSI/AAMI guidelines. Once properly diluted, the active ingredients will begin to decay.

Dilution rates for 11-hour exposure time:

Dialyzer cleaning	2,00 %
Dialyzer disinfection	3,50 %
Accessories disinfection	1,00 %

PRODUCT USE

GBL® PEROXY™ PLUS RP is indicated for in vitro cleaning and disinfection of hollow fiber type dialysis machines for dialysis machine reprocessing systems. GBL® PEROXY™ PLUS RP can also be used to disinfect dialysis equipment (e.g. kidney machines) and materials (e.g. port caps). The hollow fiber dialysis machine reprocessed and disinfected with GBL® PEROXY™ PLUS RP is filled with a proportionate amount of GBL® PEROXY™ PLUS RP (hydrogen peroxide and peroxyacetic acid). The proportioned GBL® PEROXY™ PLUS RP in the dialysis machine must be adequately and completely rinsed prior to clinical use.

WARNING

- GBL® PEROXY™ PLUS RP will undergo rapid degradation if allowed to come into contact with cold metal, dust, organic matter or diluted with water that does not meet ANSI/AAMI standards.
- All drums are sealed with vented lids to prevent excessive pressure buildup. These caps should not be modified or replaced with other caps. Please store in an upright position.
- Do not store GBL® PEROXY™ PLUS RP in direct sunlight.
- The storage temperature should be between 15/25°C.
- The expiration date of GBL® PEROXY™ PLUS RP is indicated on the can label. 1% GBL® PEROXY™ PLUS RP solution has an expiration date of 24 hours from the moment of dilution. Contact your sales/technical representative for additional information on other applications that may require dilution of GBL® PEROXY™ PLUS RP.
- Use AAMI quality water for dilution of GBL® PEROXY™ PLUS RP.
- Use only caps specified for use with GBL® PEROXY™ PLUS RP to cover dialysis machine ports and blood ports.
- After storage and before rinsing, dialysis machines should be filled with a proportionate solution of GBL® PEROXY™ PLUS RP. The size of the air bubble in the cap should not exceed one-third (1/3) of the total cross-sectional area of the cap.
- After storage and before the dialysis machine is rinsed and used clinically, it should be tested for the presence of GBL® PEROXY™ PLUS RP with the peracetic acid residue test strips “Ref no: 7005 GBL® ROSA-STRIP PAA RES”.
- After rinsing the dialysis machine and immediately prior to clinical use, a GBL® PEROXY™ PLUS RP residue test should be performed. Rinse the kidney machine according to the manufacturer's instructions following the disinfection steps.
- Use AAMI quality water to rinse kidney machines after disinfection with GBL® PEROXY™ PLUS RP solution. Recontamination of the machines is possible if the rinse water does not meet AAMI quality standards.
- Do not heat GBL® PEROXY™ PLUS RP above 25°C when used with kidney machines.
- When using with renal machines, check with the machine manufacturer to verify the suitability of the materials.
- In case of spillage, rinse with plenty of water.

Nomenclature

For clarity, the following nomenclature will be used in this guide;
AAMI QUALITY WATER - water that meets or exceeds the following requirements:
AAMI/ANSI Hemodialysis Systems Standard 1 and pre-filtration through a 1.0 micron or smaller filter.

MICROBIOLOGICAL PROPERTIES

Effect	European Standard	Microorganisms (with ATCC)	Contact Time	Concentration of use	Test Conditions
Bactericidal	EN 13727	*Staphylococcus aureus* 6538 *Pseudomonas aeroginosa* 15442	15 minutes	1:25	Dirty Conditions
	EN 14561	*Enterococcus hirae* 10541	15 minutes	1:100	Clean Conditions
Fungicidal	EN 13624	*Candida albicans* 10231	60 minutes	Ready-to-use	Dirty Conditions
	EN 14562	*Aspergillus brasiliensis* 16404	10 minutes	1:100	Clean Conditions
Tuberculocidal	EN 14348	*Mycobacterium terrae* 15755	60 minutes	1:100	Clean Conditions
	EN 14563		5 minutes	1:100	Dirty Conditions
Virucidal	EN 14476:2013 + A1:2015	*Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 *Murine norovirus (MNV)* strain S99, RVB-651 *Poliovirus* type 1, LSc-2ab	60 minutes	1:24	Clean Conditions
Sporicidal	EN 13704	*Bacillus spizizeni* 6633	60 minutes	1:25	Dirty Conditions

** Activity table with product, indicated concentration and duration of use.*

CONTRAINDICATIONS

In the cleaning program of the hemodialysis device, after disinfection with GBL®PEROXY™ PLUS RP, washing/rinsing must be performed. Failure to rinse carries a risk for the patient. Not suitable for use with devices other than hemodialysis.
GBL® PEROXY™ PLUS RP is not intended or sold for use other than the intended use. Patients with known hypersensitivity to hydrogen peroxide and/or peroxyacetic acid should not be treated using dialysis machines reprocessed with GBL® PEROXY™ PLUS RP.

WARNINGS

May intensify fire; oxidizer. Harmful if swallowed. Causes severe skin burns and eye damage. It causes 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. Keep out of reach of children.

STABILITY AND STORAGE

The product should be stored in the shade, in its original packaging, tightly closed and in a well-ventilated area in an upright position.

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

** The product should be used within 7 days of dilution.*

- GBL® PEROXY™ PLUS RP is stable for 18 months when stored according to label directions. The expiration date is determined by the date of manufacture.
- When diluting GBL® PEROXY™ PLUS RP exhibits a gradual loss of potency at a rate of 50% of the active substances remaining after 7 days. This degradation is taken into account when calculating the amount of GBL® PEROXY™ PLUS RP used with dialysis machine reprocessing systems.
- Fresh GBL® PEROXY™ PLUS RP should be used each time GBL® PEROXY™ PLUS RP is added to a 1% solution (e.g. port cover disinfection). Do not allow the 1% GBL® PEROXY™ PLUS RP solution to stand for more than 24 hours.

Temperature Stability of the Diluted Solution:

- The factors of degradation time and degradation temperature were taken into account when determining the concentration of GBL® PEROXY™ PLUS RP to be supplied to the dialysis machine.
- The level of peracetic acid pre-diluted and then diluted by the Dialysis Machine reprocessing system is such that the disinfecting effects of GBL® PEROXY™ PLUS RP are maintained when 50% degradation is allowed. However, to achieve this level, the product must be labeled as follows:

1. Once diluted, the product must be used within 7 days,
2. Storage and use temperature should be kept below 25°C (77°F).

The product should be kept well closed after each use.

PACKAGING

Product	Packaging Type	Packaging Units	Order No
GBL® PEROXY PLUS™ RP	HDPE; Green Jerrycan	5L x 2	436127045000

LABEL SYMBOL KEYS

Catalog Number


Production Date


Storage Temperature


Manufacturer Information

Batch Code


Expiry Date


Refer to User Guide


Usage Time After Opening the Cap


Recycling Information


GHS03 Oxidizing


GHS05 Corrosive


GHS07 Harmful

CE 1984 Complies with European product regulations.
1984: Notified body code.

MANUFACTURER

GBL® Gül Biyoloji Laboratuvarı Sanayi ve Ticaret Anonim Şirketi

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