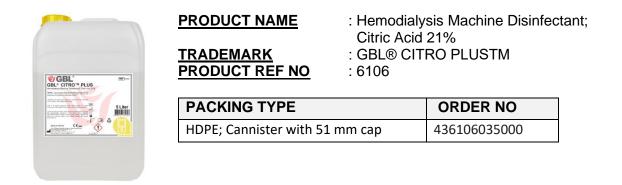


GBL GUL BIYOLOJI LABORATUVARI SANAYI VE TICARET ANONIM SIRKETI HQ: Serifali Mah. Hattat Sk. No:10 P.O.: 34775 Umraniye Istanbul TURKIYE Factory: Dudullu OSB Mah. IMES C Blok 305 Sk. No:16 P.O.: 34775 Umraniye Istanbul TURKIYE

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INSTRUCTION FOR USE Hemodialysis Machine Disinfectant; Citric Acid 21%



PRODUCT DESCRIPTIONaaa

It is an invasive medical device disinfectant containing 21% citric acid. Available in 5L volume.

INTENDED USE: Thermochemical disinfectant for hemodialysis machines with proportional mixing system and recirculation function.

PRODUCT SPECIFICATION

Form	Liquid	
Color	Colorless	
Water Solubility	Soluble	
Odor	Light lemon	
рН @ 25°С	C 1,5±0,3	

COMPOSITION

Citric acid (Lemon acid) (21%), Lactic acid (2.5%), Malic acid (2.5%), buffers, inhibitor agents and demineralized water.

PRODUCT CONCENTRATION

According to the 4008S Hemodialysis Device Operator's Manual (version 4.3);

Dilution: For devices with a disinfection and cleaning program for other models, refer to the device manual. The concentrate is diluted with water produced for hemodialysis devices at a ratio of 1:24 (1 to 4 cleaning programs).

Maximum Dilution Ratio: A dilution of 1:24 must be done in the device. In case of further dilution, the microbiological effects may be reduced or eliminated.

PRODUCT USAGE

According to the 4008S Hemodialysis Device Operator's Manual (version 4.3); chemical hot disinfection; Heat / flow: 84 ° C degree / 450 ml / min.

5008 hot disinfection according to dialysis system; Heat/flow: 85°C /600-800 ml/min (adjustable)



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GBL[®] CITRO PLUS[™] decalcification at 37°C provides disinfection at 84°C (for 4008S).

• Refer to the device user manual for devices with a cleaning and disinfection program.

• Concentrate is diluted with water produced for hemodialysis devices at a ratio of 1:24 (1 to 4 cleaning programs).

• It is used by pulling the hemodialysis device automatically from the disinfection pipette.

• Decalcification (removal of calcium deposits):

(Water temperature in the cleaning program: 37°C) The main active ingredient: Citric acid monohydrate Active concentration: approx. 0,8% (delimited)

• Disinfection:

(Water temperature in the cleaning program: 84°C) The main active ingredient: Citric acid monohydrate Active concentration: approx. 0,8% (delimited)

• If there is no disinfection program in the hemodialysis device, the disinfection process should be done at 84°C (water temperature in the cleaning program: 84°C (for 4008S) for at least 20 minutes after the thermal cleaning process and a closed system washing with distilled water for at least 10 minutes. **To be used according to the device manual at elevated temperatures only.**

Effect	Standard	Contact Time	Microorganisms (with ATCC)	Concentration of use
Bactericidal	EN 14561	5 min.	Enterococcus hirae 10541 Pseudomonas aeroginosa 15442 Staphylococcus aureus 6538	1:25
	EN 13727	20 min.	Enterococcus faecium 6057	Ready-to-use
Fungicidal	EN 14562	5 min.	Aspergillus brasiliensis 16404 Candida albicans 10231	1:25
Mycobactericidal	EN 14563	20 min.	Mycobacterium terrae 15755	1:25
Sporicidal	AOAC	20 min.	Bacillus spizizenii 6633	1:20
Virucidal	EN 14476+A1	60 min.	<i>Murine Parvovirus,</i> minute virus of mice, strain Crawford, ATCC VR-1346	1:24

MICROBIOLOGICAL PROPERTIES

*The product is the activity table with the specified concentration and duration of use.

CONTRAINDICATIONS

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

WARNINGS



Causes serious eye irritation. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

STABILITY AND STORAGE

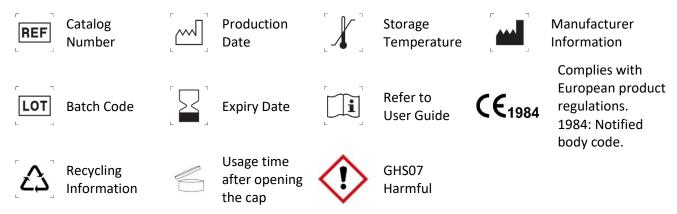
Store in its original packaging, without direct sunlight, in a shady environment. Keep it tightly closed and in a well-ventilated environment.

Storage Temperature	Shelf Life	Usage Time After Opening the Cap	
15/25 °C	2 years	3 months	

PACKAGING

Product	Packaging Type	Packaging Units
GBL [®] CITRO PLUS [™]	GBL [®] CITRO PLUS [™] HDPE; Cannister with 51 mm cap	

LABEL SYMBOL KEYS



MANUFACTURER



GBL® Gül Biyoloji Laboratuvarı Sanayi ve Ticaret Anonim Şirketi

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