

INSTRUCTION FOR USE Hemodialysis Machine Disinfectant; Citric Acid 21%



PRODUCT NAME : Hemodialysis Machine Disinfectant;
Citric Acid 21%
TRADEMARK : GBL® CITRO PLUSTM
PRODUCT REF NO : 6106

PACKING TYPE	ORDER NO
HDPE; Cannister with 51 mm cap	436106035000

PRODUCT DESCRIPTION

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
pH @ 25°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)

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.

MICROBIOLOGICAL PROPERTIES

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

*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™	HDPE; Cannister with 51 mm cap	5L x 2

LABEL SYMBOL KEYS



Catalog Number



Production Date



Storage Temperature



Manufacturer Information



Batch Code



Expiry Date



Refer to User Guide



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



Recycling Information



Usage time after opening the cap



GHS07 Harmful

MANUFACTURER



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