

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Hemodialysis Machine Disinfectant; Citric Acid 21%

1. Identification of the substance/mixture and of the company/undertaking:

1.1. Product identifiers

Product Name	: Hemodialysis Machine Disinfectant; Citric Acid 21%
Trademark	: GBL® CITRO PLUS™
Product Ref No	: 6106

1.2. Relevant identified uses of the substance or mixture and uses advised against

It is an invasive medical device disinfectant used for cleaning, thermochemical disinfection, decalcification, and removal of inorganic and organic debris in hemodialysis devices.

1.3. Detailers of the supplier of the safety data sheet:

Company Name : GBL Gül Biyoloji Laboratuvarı Sanayi ve Ticaret Anonim Şirketi
Address : HQ: Serifali Mah. Hattat Sk. No:10 P.O.: 34775 Ümraniye İstanbul TÜRKİYE
Factory: Dudullu OSB Mah. İMES C Blok 305 Sk. No:16 P.O.: 34775 Ümraniye İstanbul TÜRKİYE
Telephone : +90 216 364 15 00
Fax : +90 216 314 15 69
E-mail : export@gbl.com.tr

1.4. Emergency telephone number:

Company: +90 216 364 15 00 or contact your local emergency telephone number

2. Hazard identification:

2.1. Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008

Eye Irritation, Category 2; H319

For the full text of the H-statements mentioned in this Section, see Section 16.

2.2. Label Elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal word : Warning
Hazard statement(s) :
H319: Causes serious eye irritation.
Precautionary statement(s) :

P280: Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+313: If eye irritation persists get medical advice/attention.
Supplemental Hazard : None.
Statements

2.3. Other hazards: None.

3. Composition/information of ingredients:

3.1. Substance:

Not applicable.

3.2. Mixture:

Component	Classification	Concentration
Citric Acid Monohydrate CAS No: 5949-29-1 EC No: 201-069-1	Eye Irrit. 2; H319	$\geq 21 - < 25\%$
Lactic Acid CAS No: 79-33-4 EC No: 201-196-2	Skin Irrit. 2, H315 Eye Dam. 1, H318	$\geq 2 - < 3\%$
Malic Acid CAS No: 6915-15-7 EC No: 230-022-8	Eye Irrit. 2, H319	$\geq 2 - < 3\%$

For the full text of the H-statements mentioned in this Section, see Section 16.

4. First aid measures:

4.1. Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

Remove the victim into fresh air. In the event of symptoms refer for medical treatment.

In case of skin contact

Wash immediately with lots of water. Remove clothing before washing. Consult a doctor/medical service.

In case of eye contact

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Take victim to an ophthalmologist if irritation persists.

If swallowed /medical service.

Rinse out mouth and give plenty of water to drink. Immediately consult a doctor Take the container/vomit to the doctor/hospital.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

5. Firefighting measures:

5.1. Extinguishing media

Suitable extinguishing media

Water, carbon dioxide, foam and dry powder.

Unsuitable extinguishing media

No data available.

5.2. Special hazards arising from the substance or mixing

In the event of fire the following can be released:

Carbon monoxide (CO) and carbon dioxide (CO₂)

5.3. Advice for firefighters

Special protective masks and protective clothing should be worn during fire fighting. Use self-contained breathing apparatus.

5.4. Further information

No data available.

6. Accidental release measures:

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes. Wear full face mask, plastic boots and plastic gloves. Avoid substance contact. Make sure there is good ventilation. Do not breathe waste. For personal protection see section 8.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up

Collect spillage with non-combustible absorbent materials (sand, soil) and place in waste containers in accordance with local/national regulations.

6.4. Reference to other sections

For disposal see section 13.

7. Handling and storage:

7.1. Precautions for safe handling

Observe the precautions on the label.

Change contaminated clothing. Wash hands after working with substance.

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

For recommended storage temperature, see product label.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. Exposure controls/personal protection:

8.1. Control parameters

No data available.

8.2. Exposure controls

Appropriate engineering controls

Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts

Skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection: Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let the product enter drains.

9. Physical and chemical properties:

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Color	Colorless.
Odor	No data available.
Odor threshold	No data available.
pH	1,5±0,3
Melting point	No data available.
Boiling point	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability	No data available.
Upper/lower flammability or explosive limits	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Density	1,09±0,1 g/cm ³
Water solubility	No data available.
Partition coefficient: n-octanol/water	No data available.
Auto-ignition temperature	No data available.
Viscosity	No data available.
Explosive properties	No data available.
Oxidizing properties	No data available.

9.2. Other safety information

No data available.

10. Stability and reactivity:

10.1. Reaction

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

May have severe reactions with metals, oxidizing agents, bases, reducing compounds.

10.4. Conditions to avoid

Overheating.

10.5. Incompatible materials

Oxidizing agents, bases, reducing compounds, nitrates.

10.6. Hazardous decomposition products

No data available.

11. Toxicological information:

11.1. Information on toxicological effects

Acute toxicity

Citric Acid Monohydrate [CAS No: 5949-29-1]:

LD50 Intraperitoneal – rat – 375 mg/kg

Lactic Acid [CAS No: 79-33-4]:

LD50 Intraperitoneal – mouse – 3194 mg/kg

Malic Acid [CAS No: 6915-15-7]:

LD50 Intraperitoneal – mouse – 50 mg/kg

LD50 Oral – mouse – 1600 mg/kg

LD50 Intraperitoneal – rat – 100 mg/kg

Skin corrosion/irritation

Causes severe skin burns.

Serious eye damage/eye irritation

Causes severe eye damage.

Respiratory or skin sensitization

Prolonged or repeated exposure may cause allergic reactions in some susceptible individuals.

Carcinogenicity

No data available.

Reproductive Toxicity

No data available.

Specific target organ toxicity – single exposure

No data available.

Specific target organ toxicity – repeated exposure

No data available.

Aspiration hazard

No data available.

11.2. Additional information

No data available.

12. Ecological information:

12.1. Toxicity

Citric Acid Monohydrate [CAS No: 5949-29-1]:

LC50/96 hour (Pisces): 440 mg/L

EC50/72 hour (Daphnia Magna): 120 mg/L

LC50/96 hour (Leuciscus idus): 440-760 mg/L

Lactic Acid [CAS No: 79-33-4]:

LC50/96 hour (Oncorhynchus mykiss): 100-180 mg/L

LC50/96 hour (Lepomis macrochirus): 320 mg/L

EC50/48 hour (Daphnia magna): 180-320 mg/L

Malic Acid [CAS No: 6915-15-7]:

LC50/96 hour (Carassius auratus): 295 mg/L

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

13. Disposal considerations:

13.1. Waste treatment methods:

Waste materials must be disposed of in accordance with Directive 2008/98/EC and other National and Local Regulations. Leave chemicals in original containers. Do not mix with other waste. Treat uncleaned containers as the product itself.

14. Transport information:

ADR/RID

ADR/RID Class : -
UN Number : -
Packaging Group : -
Propper Shipping Name : Not dangerous good.

IMDG

IMDG Class : -
UN Number : -
Packaging Group : -
Propper Shipping Name : Not dangerous good.
Environmental Hazard : No.

ICAO/IATA

ICAO/IATA Class : -
UN Number : -
Packaging Group : -
Propper Shipping Name : Not dangerous good.

This product is not classified as a Dangerous Good by ADR/RID, IMDG or IACO/IATA criteria. No special transport conditions are necessary unless required by other regulations.

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

16. Other information:

Full text of H-statements referred to under sections 2 and 3.

- H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

Abbreviations:

- CAS No Chemical Abstracts Service number
EC No European Inventory of Existing Commercial Chemical Substances
LC50 Lethal concentration, 50 percent
LD50 Lethal dose, 50 percent
PBT Persistent, Bioaccumulative and Toxic
vPvB Very Persistent and very Bioaccumulative

Notice to Reader: The information contained herein is accurate to the latest knowledge and describes the product from the point of view of health and environmental protection as well as safe handling. The information presented in this SDS refers to the technical product only and will not apply to any processed product. Final determination of suitability of any materials is the sole responsibility of the user.