

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Medical Instrument Disinfectant; Glutaraldehyde 2%

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

1.1. Product identifiers

Product Name	: Medical Instrument Disinfectant; Glutaraldehyde 2 %
Trademark	: SANITAROSA™ GA
Product Ref No	: 6071

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

High-level disinfection and cold sterilization of medical devices, surgical equipment, endoscopic and thermosensitive equipment.

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. IMES 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

Acute toxicity, Category 4; H302

Skin corrosion, Category 1B; H314

Skin sensitization, Category 1A; H317

Respiratory sensitization, Category 1A; H334

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

2.2. Label Elements

Labeling according to Regulation (EC) No 1272/2008

Pictogram



Signal word : Danger

Hazard statement(s) :

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement(s) :

P260: Do not breathe dust/fume/gas/mist/vapors/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P301+312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P301+330+331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+361+353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P304+341: IF INHALED: If breathing is difficult, remove the victim to fresh air and keep at rest in a position comfortable for breathing.

P305+351+338: IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.

Supplemental Hazard Statements : None.

2.3. Other hazards: None.

3. Composition/information of ingredients:

3.1. Substance:

Not applicable.

3.2. Mixture:

Component	Classification	Concentration
Glutaraldehyde, 50% CAS No: 111-30-8	Met. Corr. 1; H290 Acute Tox. 3; H331 Acute Tox. 3; H301 Skin Corr. 1B; H314 Skin Sens. 1A; H334 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	>= 3 - < 5%

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. Immediately consult a doctor/medical service.

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 the victim to an ophthalmologist if irritation persists.

If swallowed.

Rinse mouth with water. Give nothing to drink. Do not induce vomiting. Immediately consult a doctor/medical service. 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 spray.

Unsuitable extinguishing media

Water jet.

5.2. Special hazards arising from the substance or mixing.

No data available.

5.3. Advice for firefighters

Special protective masks and protective clothing should be worn during firefighting. Use a 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 and skin. 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

Stop leaks if possible. 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

Wear personal protective equipment. Avoid contact with eyes. Make sure there is good ventilation. Avoid direct contact with the substance. For precautions see section 2.2.

7.2. Conditions for safe storage, including any incompatibilities

Ensure adequate and good ventilation. The tank must be cool and dry. Smoking, eating, and drinking should be prohibited in the environment. Store the substance/preparation in its original container.

For the 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

Glutaraldehyde, 50% [CAS No 111-30-8]:

NIOSH REL: 0,2 ppm (0,8 mg/m³) TWA

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 dust.

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	Yellowish.
Odor	No data available.
Odor threshold	No data available.
pH	6.0±0.4
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	No data available.
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

Reacts with strong alkalis.

10.4. Conditions to avoid

Open flame. Overheating.

10.5. Incompatible materials

Acids, bases, amines.

10.6. Hazardous decomposition products

Carbon monoxide, carbon dioxide.

11. Toxicological information:

11.1. Information on toxicological effects

Acute toxicity

Glutaraldehyde, 50% [CAS No 111-30-8]:

LD50 Oral – rat – 158 mg/kg (OECD Guideline 401)

LD50 İnhalation – rat – 0,48 mg/L/4 hour (OECD Guideline 403)

LD50 Dermal – rabbit – >2000 mg/kg (OECD Guideline 402)

Skin corrosion/irritation

Causes severe skin burns.

Serious eye damage/eye irritation

Causes severe eye damage.

Respiratory or skin sensitization

No data available.

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****Glutaraldehyde, 50% [CAS No 111-30-8]:**

LC50/96 hour Cyprinodon variegatus: 39 mg/L

LC50/96 hour Lepomis macrochirus: 9,4 mg/L

EC50/48 hour Daphnia magna: 5,75 mg/L

EC50/96 hour Crassatrea virginica: 0,75 mg/L

LC50/96 hour Mysidopsis bahia: 5,5 mg/L

EC50/72 hour Desmodesmus subspicatus: 0,6 mg/L (OECD Guideline 201)

EC50/72 hour Skeletonema costatum: 0,92 mg/L (ISO/DIS 10253)

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	: 8
UN Number	: 1760
Packaging Group	: II
Proper Shipping Name	: CORROSIVE LIQUID, N.O.S. (GLUTARALDEHYDE)
Label	: 8



Tunnel Code	: E
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IMDG

IMDG Class	: 8
UN Number	: 1760
Packaging Group	: II
Proper Shipping Name	: CORROSIVE LIQUID, N.O.S. (GLUTARALDEHYDE)
EmS	: F-A; S-B

ICAO/IATA

ICAO/IATA Class	: 8
UN Number	: 1760
Packaging Group	: II
Proper Shipping Name	: CORROSIVE LIQUID, N.O.S. (GLUTARALDEHYDE)

15. Regulatory information:

15.1. Safety, health, and environmental regulations/legislation specific to 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.

- H290 May be corrosive to metals.
H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long-lasting effects.

Abbreviations:

- ADR European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS No Chemical Abstracts Service number
EC50 Effective concentration, 50 percent
EmS Emergency Schedule
IATA International Air Transport Association
ICAO International Civil Aviation Organization
IMDG International Maritime Dangerous Good
LC50 Lethal concentration, 50 percent
LD50 Lethal dose, 50 percent
NIOSH National Institute for Occupational Safety and Health
OECD Organization for Economic Co-operation and Development
PBT Persistent, Bioaccumulative and Toxic
REL Recommended exposure limit
RID International Carriage of Dangerous Goods by Rail
TWA Time-weighted average
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.