

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING:

Gambrosol Trio 10 (2000 – 2500 – 5000 ml)

1.1. Use of the substance/preparation (industrial, professional, private): for professional use only.
Function of the substance/preparation: peritoneal dialysis solution

1.2. Manufacturer/ supplier: **Gambro Dasco S.p.A**
Officina di Canosa Sannita
via delle Valli, 50
IT – 66010 Canosa Sannita (CH)

1.3. Responsible person: Massimo Bormetti

1.5. Emergency telephone number: + 39 0871/937071

2. HAZARDS IDENTIFICATION

Non hazardous preparation.

2.1. Information concerning specific hazards for human and environment:
No specific hazards for human or environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Description: peritoneal dialysis solution in 3 plastic compartments (A + B + C).

A+C (L Light): 1,5% Glucose

B+C (M Medium): 2,5 % Glucose

A+B+C (H High): 3,9 % Glucose

Before Reconstitution each 1000 ml contains:	A	B	C
Glucose anhydrous/ Glucose monohydrate	500 g/ 550 g	500 g/ 550 g	-
Sodium lactate anhydrous (S)	-	-	4,72 g
Sodium chloride	5,38 g	5,38 g	5,38 g
Calcium chloride dihydrate	-	-	0,271 g
Magnesium chloride hexahydrate	-	-	0,054 g
Hydrochloric acid concentrated or sodium hydroxide	pH: 3,1	pH: 3,1	pH: 6,6
Water for injections	1000 ml	1000 ml	1000 ml

Electrolyte content per each 1000 ml of reconstituted solution:	A+C (L)	B+C (M)	A+B+C (H)
Glucose	85 mmol/l	139 mmol/l	215 mmol/l
Lactate	41 mmol/l	40 mmol/l	39 mmol/l
Chloride, Cl ⁻	96,2 mmol/l	96,0 mmol/l	96,0 mmol/l
Calcium, Ca ⁺⁺	1,79 mmol/l	1,75 mmol/l	1,70 mmol/l
Magnesium, Mg ⁺⁺	0,26 mmol/l	0,25 mmol/l	0,24 mmol/l
Sodium, Na ⁺	133 mmol/l	132 mmol/l	131 mmol/l
Calculated osmolarity	357 mOsmol/l	409 mOsmol/l	483 mOsmol/l
pH	5,5 – 6,5	5,5 – 6,5	5,5 – 6,5

4. FIRST AID MEASURES

INFORMATION TO THE PHYSICIAN: no specific prescriptions.

Symptoms: none known.

Handling: no specific prescriptions.

3.1. IN CASE OF INGESTION:

Measures:

- Not characteristic exposure way.

4.2. IN CASE OF INHALATION:

Measures:

- Not characteristic exposure way.

4.3. IN CASE OF SKIN CONTACT:

Measures:

- Wash skin with water and soap

4.4. IN CASE OF EYE CONTACT:

Measures:

- In case of contact with eyes flush immediately with plenty of flowing water for 15 minutes holding eyelids apart.

5. FIRE-FIGHTING MEASURES

Not combustible.

5.1. Suitable extinguishing media:

No data available.

5.2. Unsuitable extinguishing media for safety reasons:

Not known.

5.3. Special protective equipment:

Wear protective clothing .

5.4. Hazardous combustion products:

Not known.

5.5. Other:

No other information.

6. ACCIDENTAL RELEASE MEASURES

6.1. PERSONEL PRECAUTIONS:

No specific data available.

6.2. ENVIRONMENTAL PRECAUTIONS:

Dispose of spillage and waste (product/package) in accordance with all applicable environmental laws.

6.3. METHODS FOR CLEANING UP:

Sweep up spilled substance carefully, then clean with water. Use clean cotton cloth.

7. **HANDLING AND STORAGE**

7.1. Handling:

Precautions for safe handling:

Observe conventional hygiene precautions.

Not for intravenous use.

After reconstitution may be stored for up to 18 h.

After opening the bag should be used immediately. Any unused solution should be discarded after first use.

Do not use the solution unless it is clear and seals are intact.

Technical measures:

No specific prescriptions.

Precautions against fire and explosion:

No specific prescriptions.

7.2. Storage:

Technical measures and storage condition:

Keep only in original closed container with the proper labelling.

Follow all instructions on the label.

Incompatible materials: None known.

Packaging material: no specific prescriptions.

7.3. Specific uses:

No specific instructions available.

8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**

8.1. Exposure limit values:

Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2. Occupational exposure controls:

In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.3. Engineering measures:

Use only under conventional conditions.

Wash the hands before and at the end of work with water and soap.

8.4. Personal protective equipment:

1. Respiratory protection: -

2. Skin protection: -

3. Hand protection: -

4. Eye protection: -

8.5. Occupational exposure controls:

No specific prescriptions.

The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

9. **PHYSICAL AND CHEMICAL PROPERTIES:**

9.1. Physical and chemical properties:

Parameter:

Test method:

Remarks:

1. **Physical state:**

liquid

2. **Colour:**

colourless

3. **Odour:**

odourless

4. Melting point:

n.d.

5. Density (20 °C):

n.a

6. Solubility/Miscibility:

n.a

7. Boiling point:

n.a.

8. Viscosity:

n.a

9. Ignition temperature:

n.a.

- 10. Flash point: n.a.
- 11. Auto-ignition temperature: n.a.
- 12. pH – value, aqueous solution: 5,5 - 6,5
- 13. Flammability: n.a.
- 14. Oxidizing properties: n.a.
- 15. Vapour pressure: n.d.
- 16. Specific gravity: n.a.
- 17. Evaporation rate: n.a.
- 18. Partition co-efficient (n-Octanol/water): n.d.
- 19. Vapour density: n.a.
- 20. VOC-content (Volatile Organic Compounds): n.a.

9.3. Other information:
No data available.

10. STABILITY AND REACTIVITY

10.1 Stability:

- 1. At normal temperature: at general conditions of work stabile.
- 2. Hazardous decomposition products: None known.
- 3. Hazardous reactions, materials to avoid: None known.

11. TOXICOLOGICAL INFORMATION

11.1. Acute toxicity (LD₅₀):

No product specific data available.

11.2. Other:

Specific symptoms observed in animal studies: Not known.

In case of inhalation: -

Skin contact: -

Ingestion: -

Eye contact: -

Irritation: not known.

Sensitization: No sensitizing effects known.

Sub acute and chronic toxicity:

Symptoms of overexposure or repeated exposure: Not known.

CMR effects:

Carcinogenity: not known

Reproductive toxicity: not known.

Mutagenicity: not known.

Summarized evaluation of the CMR properties: -

12. ECOLOGICAL INFORMATION

Ecological information: no data available.

Mobility: no data available.

Persistence and biodegradation: no data available.

Bioaccumulation potential: no data available.

Results of PBT assessments: no data available.

Other adverse effects: no data available.

13. DISPOSAL CONSIDERATIONS

Product: Disposal should be done in accordance with federal, state and local environmental control regulations.

European waste code:

It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste- disposal operator.

Packaging: Disposal should be done in accordance with federal, state and local environmental control regulations.

14. TRANSPORT INFORMATION

No dangerous good in sense of the transport regulations.

14.1. Land transport:

1. ADR/RID Class: -

2. UN Number: -

3. Packaging group: -

- 14.2. Marine transport:
1. IMDG Class: -
2. UN Number: -
3. Packaging group: -
4. Marine pollutant: -

- 14.3. Air transport:
1. ICAO/IATA: -
2. UN Number: -
3. Packaging group: -

15. REGULATORY INFORMATION

- 15.1. Chemical safety assessment: -

- 15.2. Labelling:
Hazard symbols: **No hazard symbol required.**

Risk phrases: -

Safety phrases: -

- 15.3. Authorisations and/or restrictions on use: -

- 15.4. National and EU regulations:

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulation 2004 (SI 2004 No 568)

Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulation 2005 (SI No 1732)

Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (SI 2002 No 1689)

Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2005 (SI 2005 No 2571)

Control of Substances Hazardous to Health Regulations 2002 (COSHH) (SI 2002 No 2677)

Hazardous Waste Regulations 2005 (SI No 894)

The List of Wastes Regulations 2005 (SI 895)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets)

Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the twenty-ninth time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

Commission Directive 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

16. OTHER INFORMATION

Relevant R-Phrases (number and full text) of Section 2 and 3.

Training instructions.

Recommended restrictions on use (non-statutory recommendations by supplier).

Data sources.

This safety data sheet had been prepared on the basis of information provided by the manufacturer.

The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information. The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required. Since the conditions of the handling, the storage and the disposal of this product are beyond the control of the manufacturer, the distributor or the preparer of this SDS, no warranty, expressed or implied, regarding

the product described in this SDS shall be created or inferred by any statement in this SDS. No responsibility is assumed regarding the accuracy, completeness or suitability of all or any of the information contained herein or the results to be obtained from the use thereof at the time of use. In no way shall the manufacturer, the distributor or the preparer of the be liable for any claims, losses or damages of third parties, personal injury, property damage, lost profits or any special, direct, indirect, incidental, consequential or exemplary damages resulting from the use of or reliance upon such information. Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction: PBT: Persistent, bioaccumulative and toxic. n.d.: not defined. n.a.: Not applicable.

(*) Modified sections: -