

Ultrasound transmission gel

Trasonic

> Product description

Ultrasound gel are intended are intended for general use as a transmission media for acoustically coupling a transducer to a human body surface during external therapeutic and diagnostic ultrasound imaging procedures. It is placed on the patient's skin or on the transducer prior to initiating an ultrasound examination.



> Product characteristics

- Does not irritate skin.
- Non greasy.
- Hydrosoluble.
- Does not contain salt. Does not damage the transducer.
- High density. It spreads out easily and uniformly.
- This product is free to natural latex, phthalatos and animal or biological origin compounds.

> Technical specifications

> Ingredients

Aqua (Water), Glycerin, Carbomer, Propylene Glycol, Sodium Hydroxide , Diazolidinyl Urea, Methylparaben, Disodium EDTA, Propylparaben, CI 42051.

> Materials

- 250 mL white bottle: PEHD
- 500 mL white bottle: HDPE
- 1L white bottle: PEHD
- 5L flexible container: LLDPE
- 5L rigid container: HDPE 5L rigid container: HDPE

- Pump:

Tube: Polyethylene PE BD

Push-button: PP

Bagel: PP

> **Physio-chemical properties**

- Colour, Odour, Appearance: Blue gel, transparent, viscous. Odour to its raw materials (it doesn't contain perfume)
- Density: 1.00 – 1.02 g/mL (20°C)
- pH: 5.5 – 6.5
- Viscosidad (22°C): >1.000.000 mPa·s
- Acoustic impedance: 1.63 MRayls
- Efficiency (from 0.5 MHz): > 99.5%

> **Microbiological properties**

- Total aerobes: <10 UFC/mL
- Moulds and yeasts: <10 UFC/mL
- Pathogens (Staphylococcus aureus, Candida albicans, Pseudomonas aeruginosa, Escherichia coli): Absence

> **Biocompatibility**

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.
- Conclusion: The product is biocompatible.

> **Sterilisation and expiry date**

- Non-sterile product.
- Shelf life: 3 years upon the manufacturing date.
- Validity period after bottle opening:
- Bottle 250 mL/500 mL/1L: It is recommended to be consumed within one day. However, security is guaranteed for 30 days if good practices are maintained: put the cap immediately after use. Store in a cool and dry place. Keep away from direct sunlight.

- 5L containers: Security guaranteed for one month, always if good practices are maintained: refill working bottles and put the cap on immediately. Store in a cool and dry place. Keep away from direct sunlight. Disinfect any compound (cannule, dosing pump) before putting in contact with gel.

> Storage and maintenance

- Keep protected from direct sunlight / the outside
- Keep in a dry place
- Temperature range: 5-40°C
- Single use product. No maintenance required

> Packaging

#	REF	Packaging
TOG02	G-15	250 mL bottle: Service box of 25 units.
TOG04	G-15/1	1L bottle: Service box of 20 units.
TOG25	G-15/05	Flacon blanc de 500 ml. Carton d'emballage de 20 unités.
TOG05	G-15/5	5L flexible container with cannula: Service box of 4 units and refillable bottle of 250 mL.
TOG07	G-15/5RB	5L rigid container + pump: Service box of 4 units and refillable bottle of 250 mL.

> Instructions for use

- Apply on the selected area and remove with a disposable towel.

Date: April 2023

Specification N°: ETP/010/022

> Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with **Regulation (UE)2017/745** and the **UK MDR Regulation 2002 on Medical Devices** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

This product is classified as:

Class I product according to Annex VIII of Regulation (UE) 2017/745, rule 5 and **Class I** product according to Rule 5 of Annex IX of the UK MDR Regulation 2002 on Medical Devices.

- GMDN code: 15321 – Ultrasound transmission gel.
- EMDN Code: Z11040185 (Ultrasound scanners-consumables).