Sterile ultrasound transmission gel
Transonic

Product description

Sterile ultrasound gel is 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.

The sterile product is recommended for diagnostic and therapeutic ultrasound applications when sterility is indicated.

CE 2797

Product charasteristics

- Does not irritate skin.
- Non greasy.
- Hydrosoluble.
- Does not contain salt. Does not damage the transducer.
- 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), Propylène Glycol, Carbomer, Sodium Hydroxide, Diazolidinyl Uréa, Methylparaben, Propylparaben, Disodium EDTA.

Materials

- Gel composition: Water-based gel with polymers.
- Packaging:
    - Sachet: PET/Pet-metalized/PE film
    - Thermo-sealed pouch:
        - Cellulose paper, medical grade
        - Transparent PA/PP film

Physico-chemical properties

- Colour, Odour, Appearance: Colourless or slightly yellowish, transparent and viscous gel. Odour to its raw materials (it does not contain perfume).
- Density: 1.00 – 1.02 g/mL.
- pH: 5.8 – 6.4.
- Viscosity (22ºC): >1.300.000 cps
- Acoustic impedance: 1.62MRayls.
- Efficiency (from 0.5MHz): >99.5%.

Microbiological properties

- Sterile according the normative EN 556-1 standard

Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: No sensitizing.
- ISO 10993-10: Negative intracutaneous irritation test.

Conclusion: The product is biocompatible.

Sterilization and expiry date

- Sterile product by radiation.
- Shelf life: 2 years upon manufacturing date.

Storage and maintenance

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

Packaging

- G-15/E: Double packaging, monodose, 20 ml, 48 unit service box.

Instructions for use

- Apply over the selected area.
- Remove using a disposable towel.

Date: September 2023 **Specification Nº:** ETP/208/16

Regulatory information

TELIC, S.A.U. guarantees that this product is in conformity with **Regulation (UE) 2017/745** 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 sterile** product according to Annex XI of Regulation (UE) 2017/745, rule 5.
- GMDN code: 58735 – Coupling gel, sterile.
- EMDN code: Z11040185 (Ultrasound scanners-consumables)