

Lubricating water soluble gel

DORMO

> Product description

Lubricating water-soluble gel, adequate for hospital and nursing processes that require non-specific lubrication.



> Product characteristics

- Hospital and nursing processes where non-specific lubrication is required.
- Easy-to-clean, water-soluble gel.
- Non irritating.
- Does not damage equipment, nor plastic, metal, textile, rubber materials.

> Technical specifications

> Composition (INCI)

Aqua (Water), Glycerin, Propylene Glycol, Hidroxyethyl Cellulose, Polyquaternium-7, Diazolidinyl Urea, Methylparaben, Propylparaben, Disodium EDTA, Sodium Benzoate.

> Materials

- Coex tube PEBD-EVOH-PEBD.
- PP cap with plastiband.
- Printed cardboard box.

> Physico-chemical properties

- Colour, odour, appearance: yellowish transparent viscous gel, slippery, odour to its raw materials (it does not contain perfume).
- Viscosity (22°C) :> 200.000—400000cps
- pH (22°C): 5,5 – 6,5
- Density (22°C): 1,01 – 1,03 g/ml

> Microbiological properties

- Total aerobes: <10ufc/ml
- Moulds and yeasts: <10ufc/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.

> Sterilization and expiry date

- Non-sterile product.
- Shelf life: 3 years upon the manufacturing date.

> Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Single use product. No maintenance required.

> Packaging

#	Ref	Packaging
TOGH1	G-20	100ml tube in an unitary case. 24 cases per service box.

> Instructions for use

1. Apply to the selected area or instruments, spreading the gel evenly. Perform the medical procedure in accordance with the usual protocols.
2. When appropriate, remove the remaining product from the instruments with a disposable wipe and clean according

Date: November 2022

Specification N°: ETP/138/11

> 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** product according to Rule 5 of Annex VIII of Regulation (UE) 2017/745.
- GMDN code: 33587 General-body orifice lubricant, non-sterile
- EMDN code: M9002 (Protective sprays and lubricant sprays gels, fluids and creams).