



LUBRAJEL[®] RR

Gamma Sterilizable Medical Grade Lubricant

Description:

Lubrajel RR is a patented water-soluble lubricating gel specially designed for medical use. The lubricant is capable of terminal sterilization with 2.5 Megarads (25 Kgy) of gamma radiation. Several years of extensive research has resulted in this clear, colorless Lubrajel product. Although a radiation stable cosmetic gel had been previously developed by Guardian Laboratories (Lubrajel GRR), the product was characterized by a golden yellow color. To many in the pharmaceutical/medical device industry, this was not a desirable characteristic of a sterile lubricating product.

Lubrajel RR is *clear and colorless*, and virtually odorless and remains so after sterilization by gamma radiation. An initial apparent viscosity of about 25,000 cps (Brookfield RVT or equivalent, spindle #7, 50 rpm, 22° C) exhibits practically no change upon irradiation. Temperature stressed stability studies indicate that pH, viscosity, color, clarity and lubricating qualities are not sacrificed.

Uses:

Lubrajel RR is a pseudo-plastic highly lubricating gel, which is easily pumped, even through tubes of small diameters. Because of its pseudo-plastic properties, Lubrajel RR is an ideal lubricant for thermometers, catheters, enema tips, etc., or for application directly to the skin for lubrication, moisturization or conditioning purposes.

Composition:

Water, Glycerin, Polyacrylic Acid, Propylene Glycol, and Sodium Polyacrylate preserved with methyl and propyl paraben and sodium metabisulfite.

FDA Status:

Drug Master File on record with FDA.

Shelf Life: 18 months

Typical Properties:

These values are typical properties only and not necessarily specifications. Specifications and test methods are available upon request.

Form	Viscous Gel
Color	Colorless
Clarity	Clear
pH as is (20 - 25°C)	5.0 – 6.0
Viscosity, cps (20 - 25°C) (Brookfield DV-II, spindle 7, 50 rpm)	18,000 – 26,500
Refractive Index (20 - 25°C)	1.378 – 1.383

Testing:

Cytotoxicity, implantation, vaginal mucosal irritation

Derivation:

United-Guardian does not use animal derived ingredients in the manufacture of Lubrajel RR. All raw materials used in Lubrajel RR are of synthetic or vegetable origin.

Storage and Handling:

Lubrajel RR is very slippery and appropriate care should be taken during handling. Avoid contact with strong acids, alkalis or oxidizing agents.

Availability:

Lubrajel RR is available in 45-pound and 500 pound polyethylene pails and drums.

NOTE: The suitability of Lubrajel RR for a specific use is the sole responsibility of those providing the final dosage form. It is their responsibility to secure approvals from those regulatory agencies concerned with the use, sale and distribution of the product.

Contact Guardian Laboratories for samples and sales information.

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