

RS-OIL 5000

HIGH PURITY STERILE SILICONE OIL, 5000 cSt, 10 ML FOR INTRAOCULAR TAMPONADE

SILICONE OIL

	RS-OIL 5000
Ingredient	100% silicone oil, obtained from the mixture of long and short molecular chains (100% polydimethylsiloxane)
Viscosity (25°C)	4750 - 5250 cSt
Specific gravity (25°C)	0.967 - 0.975
Refractive index (25°C)	1.40
Acidity index	< 0.15 ml NaOH 0.01 N
Heavy metals	< 5 ppm
Phenolic compounds	< 0.20 (250 - 270 nm)
Volatility (10g/24h/150°C)	< 0.10 %w/w
Bacterial endotoxins	< 0.5 EU/ml
Cytotoxicity Test	Non-cytotoxic according to ISO 10993-5, direct contact test performed on two cell lines: - retinal pigment epithelial cells (ARPE-19) - mouse fibroblasts cells (BALB 3T3 clone A31)
Form	sterile fluid
Volume	10 ml
Packaging	vial in medical pouch
Sterilization	moist heat according to EN ISO 17665-1
Storage temperature	room temperature
Expiry date	36 months
Intended use	intraocular tamponade during vitreoretinal surgery
Class	medical device
GMDN code	P 45125
CND code	Q 02030202
MD registration number	3530/R
Medical device class	IIb
CE mark	CE 0546

RS-OIL is highly purified silicone oil (100% pure polydimethylsiloxane), 5000 cSt, 10 ml, sterile and apyrogenic, packaged in vial, intended for long-term replacement of the vitreous humour extracted during vitreoretinal surgery. Product warrants a stable tamponade over the time and reduced incidence of complications.

Ref.: RSO 005-00

Contents:

- ▶ 1 RS-OIL 5000 vial (100% high purity, sterile silicone oil 5000 cSt, 10 ml)
- ▶ 3 labels for product traceability
- ▶ 1 package insert

GS1-128 barcode

ALCHIMIA

Viale Austria, 14
35020 Ponte S.Nicolò (PD)
Italy