

RS-OIL ECS 5000

EASY CONNECTION SYRINGE

HIGH PURITY STERILE SILICONE OIL 5000 cSt, 10 ML IN SYRINGE WITH ADAPTER

SILICONE OIL

	RS-OIL ECS 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	chemically inert unbreakable syringe with adapter 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	3607/R
Medical device class	IIb
CE mark	CE 0546

RS-OIL ECS is highly purified silicone oil (100% pure polydimethylsiloxane), 5000 cSt, 10 ml, sterile and apyrogenic, packaged in pre-filled syringe, 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. The ready-to-use syringe is made of inert, plastic and silicone oil compatible material to increase patient's safety by reducing the risk of breakage during handling or surgery.

Ref.: RSO 007-00

Contents:

- ▶ 1 chemically inert unbreakable syringe of high purity sterile RS-OIL ECS 5000 (100% high purity, sterile silicone oil 5000 cSt, 10 ml)
- ▶ 1 plunger
- ▶ 3 labels for product traceability
- ▶ 1 package insert

GS1-128 barcode

ALCHIMIA

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