

RS-OIL ECS 1000

EASY CONNECTION SYRINGE

HIGH PURITY STERILE SILICONE OIL, 1000 cSt, 10 ML IN SYRINGE WITH ADAPTER

SILICONE OIL

	RS-OIL ECS 1000
Ingredient	100% silicone oil (100% polydimethylsiloxane)
Viscosity (25°C)	950 - 1050 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	3536/R
Medical device class	IIb
CE mark	CE 0546

RS-OIL ECS is highly purified silicone oil (100% pure polydimethylsiloxane), 1000 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 006-00

Contents:

- ▶ 1 chemically inert unbreakable syringe of high purity sterile RS-OIL ECS 1000 (100% silicone oil 1000 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