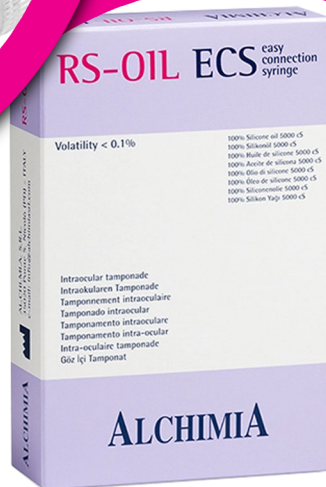
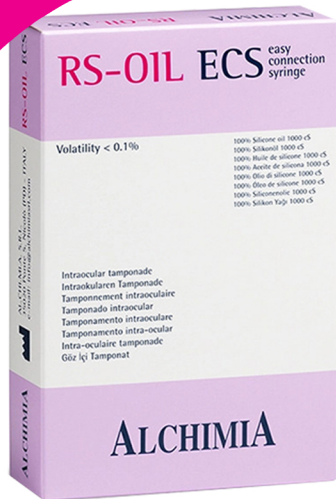


ALCHIMIA

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VITREORETINAL Surgery Products



Silicone oil 1000



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	< 0.2 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 0477

Silicone oil 5000



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	< 0.2 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 0477

Perfluorodecalin



HPF10 - HIGH PURITY IN PREFILLED SYRINGE	
Ingredient	100% fluorinated perfluorodecalin
Molecular formula	C ₁₀ F ₁₈
Molecular weight	462 g/mol
Purity	≥ 95%
H ₂ O value	≤ 10 ppm
Bacterial endotoxins	< 0.2 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)
Density (20 - 25°C)	1.91 - 1.93 g/cm ³
Refractive index (20 - 37°C)	1.32 - 1.30
Boiling point	140 - 142°C
Viscosity, dynamic (15 - 35°C)	6.2 - 4.4 mPas
Viscosity, kinematic (15 - 35°C)	2.9 - 1.9 cSt
Vapour tension	13 mmHg
Substances reducing potassium permanganate	passes test
Acidity	none detected
Infrared absorbance	0.175 AU cm ⁻¹
Form	sterile liquid
Volume	7 ml
Packaging	prefilled syringe
Sterilization	moist heat according to EN 556-1 and EN ISO 17665-1
Storage temperature	+15°C / +32°C
Shelf-life	24 months
Intended use	intraocular tamponade during vitreoretinal surgery
Category	medical device
GMDN code	35907
CND code	Q 02030205
MD registration number	446660/R
Medical device class	Ila
CE mark	CE 0477

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