ophtha futur®

sil

oertli ophthalmedic®

www.oertli-ophthalmedic.ch

EYE SURGERY ESSENTIALS.

High patient and product safety

Multi-step proven and tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

36 months shelf life

ophthafutur® sil
technical data-sheet

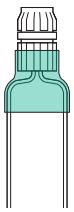
Product Name	ophthafutur® sil 5000	ophthafutur® sil 2000	ophthafutur® sil 1000
Active compound	silicone oil	silicone oil	silicone oil
Physical and Chemical Parameters			
Viscosity (25 °C)	5,000 mPas	2,000 mPas	1,000 mPas
Density (25 °C)	0.97 g/cm³	0.97 g/cm³	0.97 g/cm³
Refractive Index n_D25	1.404	1.404	1.404
Chemical Control			
Polydispersity (GPC)			
Specified Range	1.0 – 2.3	1.0 – 2.3	1.0 – 2.3
Typical Range	1.6 – 1.7	1.6 – 1.7	1.6 – 1.7
Content of Volatile Oligosiloxanes (HS-GC/MS)			
HMCTS/D3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
OMCTS/D4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D5	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D6	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MM/L2	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MDM/L3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MD2M/L4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
∑	≤ 25 ppm	≤ 25 ppm	≤ 25 ppm
Microbial control			
Product Sterility ensured by	Heat Sterilization	Heat Sterilization	Heat Sterilization
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins[1]	≤ 0.2 EU/ml	≤ 0.2 EU/ml	≤ 0.2 EU/ml

[1] LAL test acc. to EP 2.6.14/USP <85>

Biocompatibility acc. to DIN EN ISO 10993			
Cytotoxicity[2]	Non cytotoxic	Non cytotoxic	Non cytotoxic
Sensitization[3]	Non sensitizing	Non sensitizing	Non sensitizing
Irritation[4]	Non irritating	Non irritating	Non irritating

[2] Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

[3] Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

[4] Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

Presentation	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur® sil5000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur® sil2000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur® sil1000	10 ml	Glass Syringe	Pouch	36 months