ophtha futur®

octa & deca

oertli ophthalmedic®

www.oertli-ophthalmedic.ch

EYE SURGERY ESSENTIALS.

- High patient and product safety
- Multi-step proven & tested ultra-purification process
- Safe, biocompatible, sterile, endotoxin-free products
- Novel high performance polymer syringes (HPPS)
- 36 months shelf life

ophthafutur® octa & deca
technical data-sheet

Product Name	ophthafutur® octa	ophthafutur® deca
Active compound	perfluorooctane	perfluorodecalin
Physical and Chemical Parameters		
Sum Formula	C_8F_{18}	$C_{10}F_{18}$
Refractive Index n_D^{20}	1.27	1.31
Density (20 °C)	1.77 g/ml	1.93 g/ml
Vapor pressure (at 37°C)	8.8 kPa	3.4 kPa
Compound Surface Tension	14 mN/m	19 mN/m
Interfacial Tension against Water	54 mN/m	53 mN/m
Chemical Control		
Fluorination level	100 %	100 %
H-value	≤ 10 ppm	≤ 10 ppm
Additionally controlled Impurities (GC/MS)		
• concentration of C-H components	< 10 ppm	< 10 ppm
• 1H-PFO content	< 1 ppm	n.a.
• Perfluorofurane content	< 0.4%	n.a.
Microbial control		
Product Sterility ensured by	Sterile Filtration	Sterile Filtration
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins[1]	≤ 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
Sensitization[3]	Non sensitizing	Non sensitizing
Irritation[4]	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

Cell Toxicity (%)	0	8	14	36	72	87	92
H-value (ppm)	≤ 10	175	350	700	1,400	2,100	2,800

Menz D-H, Feltgen N, Menz H, et al. How to ward off retinal toxicity of perfluorooctane and other perfluorocarbon liquids? *Invest Ophthalmol Vis. Sci.* 2018; 59: 4841-4846.

Presentation	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur® deca	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur® deca	5 ml / 7 ml	Syringe	Pouch	36 months
ophthafutur® octa	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur® octa	5 ml / 7 ml	Syringe	Pouch	36 months