

# ophtha futur® octa & deca



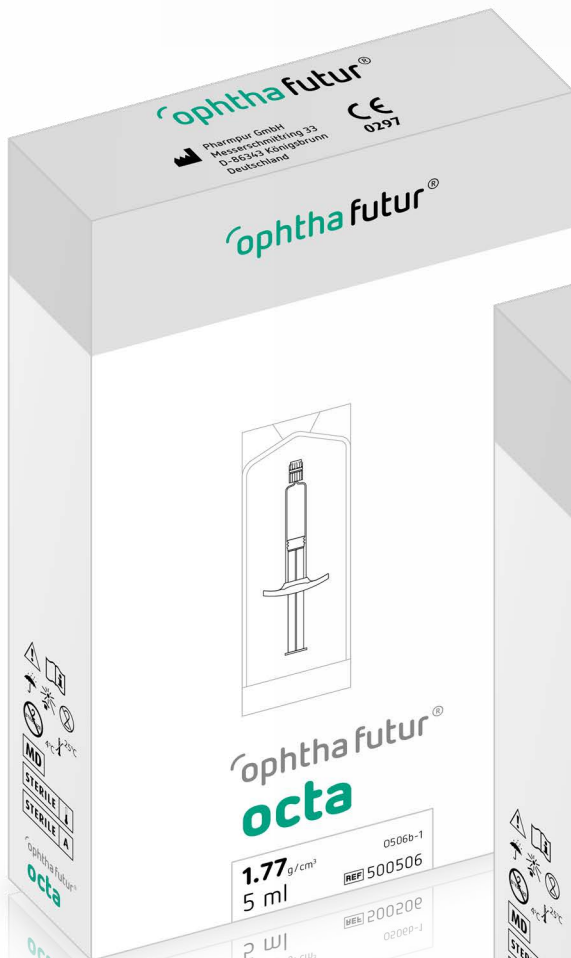
High patient and product safety

Multi-step proven & tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

3 years shelf life

Novel high performance polymer syringes (HPPS)



# ophthafutur<sup>®</sup> octa & deca

## technical data-sheet

### Product Name

Active compound

### ophthafutur<sup>®</sup> octa

Perfluorooctane

### ophthafutur<sup>®</sup> deca

Perfluorodecalin

### Physical and Chemical Parameters

Sum Formula	C <sub>8</sub> F <sub>18</sub>	C <sub>10</sub> F <sub>18</sub>
Refractive Index n <sub>D</sub> <sup>20</sup>	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 <sup>1</sup>	≤ 0.2 EU/ml	≤ 0.2 EU/ml

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

### Biocompatibility acc. to DIN EN ISO 10993

Cytotoxicity <sup>2</sup>	Non cytotoxic	Non cytotoxic
Sensitization <sup>3</sup>	Non sensitizing	Non sensitizing
Irritation <sup>4</sup>	Non irritating	Non irritating

<sup>2</sup> Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

<sup>3</sup> Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

<sup>4</sup> Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

### Cell Toxicity (%)

H-value (ppm)	0	8	14	36	72	87	92
	≤ 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 <sup>®</sup> deca	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur <sup>®</sup> deca	5 ml / 7 ml	Syringe	Pouch	36 months
ophthafutur <sup>®</sup> octa	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur <sup>®</sup> octa	5 ml / 7 ml	Syringe	Pouch	36 months