

HPF10

HIGH PURITY

HIGH PURITY STERILE PERFLUORODECALIN, 7 ML

PERFLUOROCARBONS

	HPF10 - HIGH PURITY
Ingredient	100% fluorinated perfluorodecalin
Molecular formula	$C_{10}F_{18}$
Molecular weight	462 g/mol
Purity	≥ 95%
H_{value}	≤ 10 ppm
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)
Density (20°C - 25°C)	1.94 - 1.917 kg/l
Refractive index at 20°C	1.31
Boiling point	140 °C
Viscosity, dynamic (from 15°C to 35°C)	from 6.2 to 4.4 mPas
Viscosity, kinematic (from 15°C to 35°C)	from 2.9 to 1.9 cSt
Vapour tension	13 mm Hg
Substances reducing potassium permanganate	passes test
Acidity	none detected
Infrared absorbance	0.175 AU cm ⁻¹
Form	sterile liquid
Volume	7 ml
Packaging	vial
Sterilization	moist heat according to EN 556-1 and EN ISO 17665-1
Storage temperature	+15°C / +32°C
Shelf-life	36 months
Intended use	intraocular tamponade during vitreoretinal surgery
Category	medical device
GMDN code	P 45283
CND code	Q 02030205
MD registration number	3727/R
Medical device class	Ila
CE mark	CE 0546

HPF10 is high purity perfluorodecalin, 7 ml, sterile and apyrogenic, packaged in vial, to be used intraoperatively to defold and stabilize detached retina. Product allows a safe delivery of laser energy and a reduced number of bubbles.

Ref.: HPF 004-00

Contents:

- ▶ 1 high purity perfluorodecalin, 7 ml vial
- ▶ 1 package insert
- ▶ 3 labels for product traceability

GS1-128 barcode

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