

HPF10

HIGH PURITY

HIGH PURITY STERILE PERFLUORODECALIN, 5 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	< 0.2 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	5 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	35907
CND code	Q 02030205
MD registration number	3726/R
Medical device class	Ila
CE mark	CE 0477

HPF10 is high purity perfluorodecalin, 5 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 003-00

Contents:

- ▶ 1 high purity perfluorodecalin 5 ml vial
- ▶ 1 package insert
- ▶ 3 labels for product traceability

GS1-128 barcode

ALCHIMIA

Viale Austria, 14
35020 Ponte S.Nicolò (PD)
Italy

VAT IT 00063370282

Phone +39 049 8962074 / 64
Fax +39 049 8962071

www.alchimiasrl.com
info@alchimiasrl.com