

# HPF8

HIGH PURITY

HIGH PURITY STERILE PERFLUORO-n-OCTANE, 5 ML

## PERFLUOROCARBONS

	HPF8 - HIGH PURITY
<b>Ingredient</b>	100% fluorinated perfluoro-n-octane
<b>Molecular formula</b>	$n-C_8F_{18}$
<b>Molecular weight</b>	438 g/mol
<b>Purity</b>	≥ 99%
<b>H<sub>value</sub></b>	≤ 10 ppm
<b>PFOA (perfluorooctanoic acid)</b>	absent
<b>Bacterial endotoxins</b>	< 0.5 EU/ml
<b>Cytotoxicity test</b>	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)
<b>Density (20°C - 25°C)</b>	1.76 - 1.733 kg/l
<b>Refractive index at 20°C</b>	1.29
<b>Boiling point</b>	110 °C
<b>Viscosity, dynamic (from 15°C to 35°C)</b>	from 1.7 to 1.1 mPas
<b>Viscosity, kinematic (from 15°C to 35°C)</b>	from 1.1 to 0.5 cSt
<b>Vapour tension</b>	56 mm Hg
<b>Substances reducing potassium permanganate</b>	passes test
<b>Acidity</b>	none detected
<b>Infrared absorbance</b>	0.167 AU cm <sup>-1</sup>
<b>Form</b>	sterile liquid
<b>Volume</b>	5 ml
<b>Packaging</b>	vial
<b>Sterilization</b>	moist heat according to EN 556-1 and EN ISO 17665-1
<b>Storage temperature</b>	+15°C / +32°C
<b>Shelf-life</b>	36 months
<b>Intended use</b>	intraocular tamponade during vitreoretinal surgery
<b>Category</b>	medical device
<b>GMDN code</b>	P 45283
<b>CND code</b>	Q 02030205
<b>MD registration number</b>	3724/R
<b>Medical device class</b>	Ila
<b>CE mark</b>	CE 0546

HPF8 is high purity perfluoro-n-octane, 5 ml, sterile and apyrogenic, packaged in vial, to be used intraoperatively to defold and stabilize detached retina. Product allows a clear visualization of the perfluorocarbon/aqueous, a rapid vaporization and elimination of any residual material and easy product injection and removal.

**Ref.:** HPF 001-00

**Contents:**

- ▶ 1 high purity perfluoro-n-octane, 5 ml vial
- ▶ 1 package insert
- ▶ 3 labels for product traceability

**GS1-128 barcode**

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