

# HPF8

IN PREFILLED SYRINGE

HIGH PURITY STERILE PERFLUORO-n-OCTANE IN PREFILLED SYRINGE, 7 ML

## PERFLUOROCARBONS

	HPF8 - HIGH PURITY IN PREFILLED SYRINGE
Ingredient	100% fluorinated perfluoro-n-octane
Molecular formula	$n-C_8F_{18}$
Molecular weight	438 g/mol
Purity	≥ 99%
H <sub>value</sub>	≤ 10 ppm
PFOA (perfluorooctanoic acid)	absent
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)	1.76 - 1.733 kg/l
Refractive index at 20°C	1.29
Boiling point	110°C
Viscosity, dynamic (from 15°C to 35°C)	from 1.7 to 1.1 mPas
Viscosity, kinematic (from 15°C to 35°C)	from 1.1 to 0.5 cSt
Vapour tension	56 mm Hg
Substances reducing potassium permanganate	passes test
Acidity	none detected
Infrared absorbance	0.167 AU cm <sup>-1</sup>
Form	sterile liquid
Volume	7 ml
Packaging	prefilled syringe
Sterilization	moist heat according to EN 556-1 and EN ISO 17665-1
Storage temperature	+15°C / +32°C
Shelf-life	24 months
Intended use	intraocular tamponade during vitreoretinal surgery
Category	medical device
GMDN code	P 45283
CND code	Q 02030205
MD registration number	446657/R
Medical device class	Ila
CE mark	CE 0546

HPF8 is high purity perfluoro-n-octane, sterile and apyrogenic, packaged in prefilled 10-ml glass syringe with Luer Lock, to be used intraoperatively to defold and stabilize detached retina. Products 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 020-00

#### Contents:

- ▶ 1 10ml-glass syringe with Luer Lock, prefilled with 7 ml of high purity perfluoro-n-octane
- ▶ 1 piston
- ▶ 1 package insert
- ▶ 3 labels for product traceability

**GS1-128 barcode**

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