

HPF8

IN PREFILLED SYRINGE

HIGH PURITY STERILE PERFLUORO-n-OCTANE IN PREFILLED SYRINGE, 5 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 _{value} | ≤ 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 ⁻¹ |
| Form | sterile liquid |
| Volume | 5 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 | 446649/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 019-00

Contents:

- ▶ 1 10ml-glass syringe with Luer Lock, prefilled with 5 ml of high purity perfluoro-n-octane
- ▶ 1 piston
- ▶ 1 package insert
- ▶ 3 labels for product traceability

GS1-128 barcode

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