MKT-256 rev. 0

## HPF

#### REFERENCES

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# HPF8 & HPF10

### THE MOST CONTROLLED HIGH PURITY PERFLUOROCARBONS

## BIOCOMPATIBLE CHEMICALLY CONTROLLED CYTOTOXICITY TESTED





HPF8 AND HPF10 ARE HIGHLY SAFE MEDICAL DEVICES CONTROLLED BY MEANS OF SOPHISTICATED CHEMICAL METHODS AND WHOSE SAFETY IS CONFIRMED BY CYTOTOXICITY TEST ON TWO CELL LINES.

AFTER HPF8, LONG-TERM TAMPONADE WITH OPHTHALMIC GAS IS INDICATED. AFTER HPF10, LONG-TERM TAMPONADE WITH SILICONE OIL IS INDICATED.

ADVANTAGES	SPECIFICATIONS	CHARACTERISTICS	SPECIFICATIONS	ADVANTAGES	
	1.79	DENSITY	1.94	Few bubbles	
Stable in laser and cryo-applications	110°C	BOILING POINT	141°C	Stable in laser and cryo-applications	
Better visualization	From 1.29 to 20°C	REFRACTIVE INDEX	From 1.31 to 20°C		
Easy to remove	0.8 cSt	VISCOSITY	2.4 cSt		
Quick evaporation	56 mmHg	VAPOUR PRESSURE	13 mmHg		
PERFLUORO-N-OCTANE IS EASIER TO USE WITH GAS PROCEDURES			PERFLUORODECALIN Is efficient on drastic cases with further silicone oil tamponade		

	high purity HPF $8$	high purity HPF $10$			
INGREDIENT	100% FLUORINATED PERFLUORO-N-OCTANE	100% FLUORINATED PERFLUORODECALIN			
BACTERIAL ENDOTOXINS	< 0,5	EU/ml			
SHELF-LIFE	36 MONTHS				
REFERENCE	HPF 001-00 / HPF 002-00 HPF 019-00 / HPF 020-00	HPF 003-00 / HPF 004-00 HPF 021-00 / HPF 022-00			
CONTENTS	5 OR 7 mI IN VIAL OR SYRINGE				

## **SAFETY INFORMATION**

	ALCHIMIA		DORC		PHARMPUR	
COMMERCIAL NAME	HPF8	HPF10	EFTIAR OCTA	EFTIAR DECA	OPHTAFUTUR OCTA	OPHTAFUTUR DECA
ACTIVE INGREDIENT	Perfluoro- n-octane	Perfluoro- decalin	Perfluoro- n-octane	Perfluoro- decalin	Perfluoro- n-octane	Perfluoro- decalin
DECLARED PURITY	> 99%	> 95%	N/A	N/A	> 95%	> 95%
H <sub>VALUE</sub>	< 10 ppm		< 10 ppm		< 10 ppm	
CYTOTOXICITY (BALB 3T3)* cell mortality %	1.7	4.8	4.8	6	N/A	6
CYTOTOXICITY (ARPE-19)* cell mortality %	7.7	12.6	12.8	15.9	N/A	21
PFOA (perfluorooctanoic acid)	not present		N/A		N/A	

THE SAFETY OF OUR PERFLUOROCARBONS IS GUARANTEED BY THE ACCURATE CHECKS CARRIED OUT DURING ALL THE MANUFACTURING STEPS AND CONFIRMED BY GAS CHROMATOGRAPHIC ANALYSES (PURITY), NUCLEAR MAGNETIC RESONANCE (Hydrae) AND CYTOTOXICITY TEST (DIRECT CONTACT ON BALB 3T3 AND ARPE-19 CELLS).

N/A = NOT AVAILABLE

\*CYTOTOXICITY TEST BY DIRECT CONTACT ACCORDING TO ISO 10993-5:2009

> P1805002 2021-05 CE 2021-0

> > **PFOA** (perfluorooctanoic acid), ONE OF THE CONTAMINANTS FOUND IN THE "ALAOCTA" PERFLUORO-N-OCTANE BY ALAMEDICS, WHICH CAUSED LOSS OF VISION IN OVER 100 SPANISH PATIENTS, WAS CYTOTOXIC IN THE CYTOTOXICITY TEST BY DIRECT CONTACT ON ARPE-19 CELLS AT A CONCENTRATION OF 30 PPM CORRESPONDING TO AN  ${\rm H}_{\rm value}$  lower than 10 ppm.

#### THEREFORE, THE H<sub>VALUE</sub> IS NOT A PARAMETER EVIDENCING THE PRODUCT SAFETY.

## Let's talk about Η value