

BVI

Safety Assured with Cytotoxicity Tests by IOBA*

Perfluorocarbon Liquids

ARCOTANE C₈F₁₈

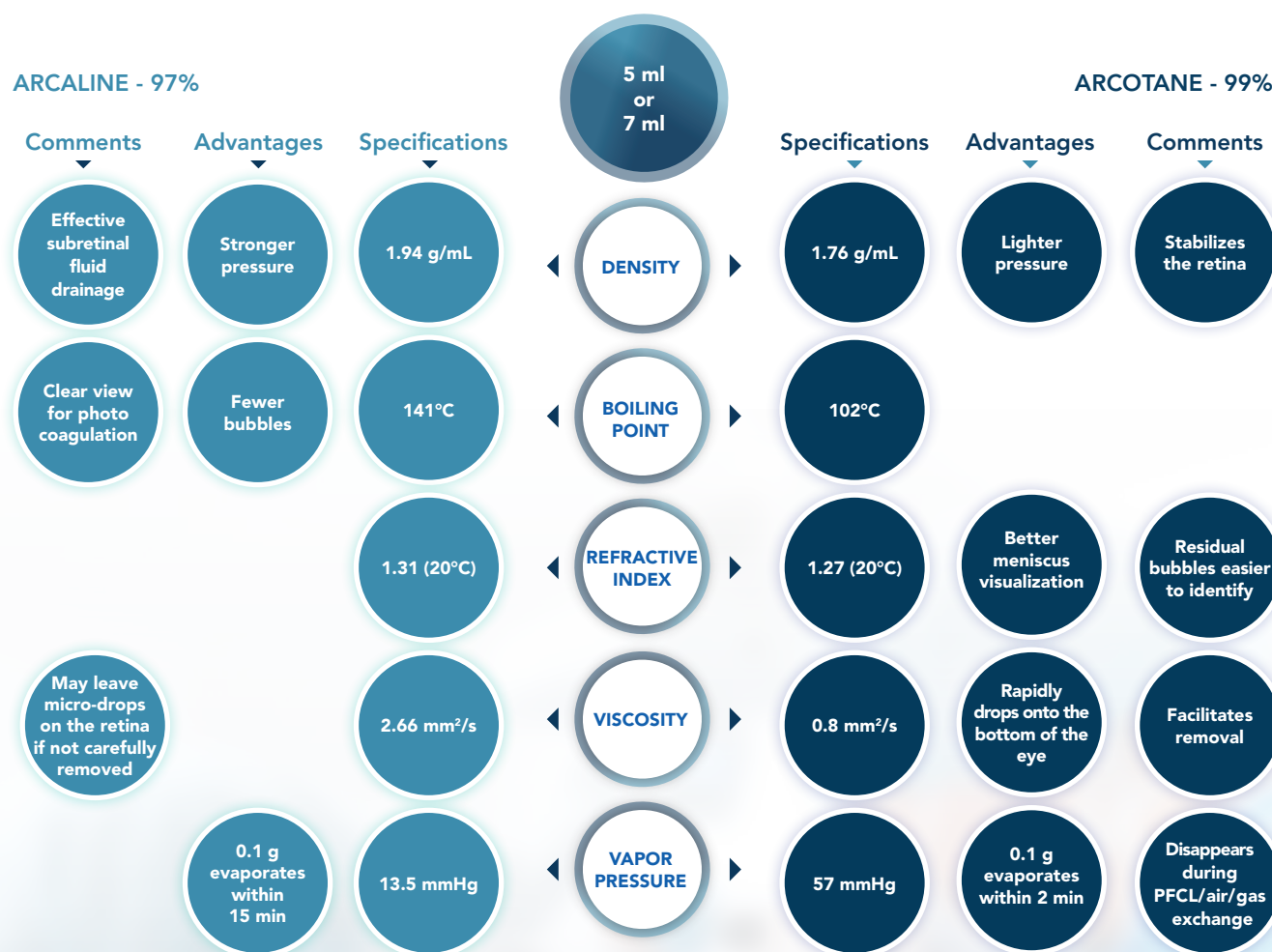
ARCALINE C₁₀F₁₈



*Instituto Universitario de Oftalmobiología Aplicada.

ARCOTANE and ARCALINE Introduction

The highly purified perfluorocarbon liquids (PFCLs) have several indications in vitreo-retinal surgery, including drainage of subretinal fluids to favor re-adhesion of detached retina to the underlining tissue. Limiting the presence of free fluoride anions and any other toxic compound like fluoro-acid, fluoro-alcohol is key to ensure perfluorocarbon liquids are safe for use¹.



ARCALINE AND ARCOTANE IN PROCESS CONTROLS

All the controls, especially gas chromatography and nuclear magnetic resonance, show that **ARCALINE and ARCOTANE specifications comply with up-to-date standards.***

| FDA approved products specification in US* | | ARCALINE / ARCOTANE specification |
|--|-----------|-----------------------------------|
| FLUORIDE (F-) | ≤ 3 ppm** | ≤ 2 ppm |
| NON VOLATILE RESIDUES | ≤ 20 ppm | ≤ 20 ppm |
| (C-H) Link IR | ≤ 1 | ≤ 0,015 |




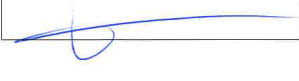


¹ Ophthalmologica Review: Retinal Toxicity of Medical Devices Used during Vitreoretinal Surgery: A Critical Overview acute retinal damage after using a toxic perfluorocarbon for vitreoretinal surgery- retina 37:1140-1151, 2017.

* As per P950018 S019 Perfluron PMA reported in the FDA website.

** Part Per Million, commonly used to express chemicals concentration.

ARCOTANE and ARCALINE Unique Biological Safety Guarantee

Each batch is tested for cytotoxicity on human retinal cells (ARPE*** cells) and on porcine-ganglionar cells.

| IOBA Cell Culture Lab: Preclinical In Vitro | | ioba | |
|---|---|--|--------------|
| Cytotoxicity study of PFO medical devices (-ARCADOPHTA XII-) | | Instituto Universitario de Oftalmobiología Aplicada | |
| <p>IOBA Instituto Universitario de Oftalmobiología Aplicada</p> <p>Study Report</p> <p>In vitro cytotoxicity study of PFO medical devices on cultures of human retinal pigment epithelial cells and porcine neuroretina -ARCADOPHTA-</p> | | | |
| Sponsor: | ARCADOPHTA | 11 Rue Antoine Ricord 31100 Toulouse France | |
| Conclusions: | <p>The product "PFO medical device" lot numbers 310832 and 400929 (A and B) were provided by the company ARCADOPHTA and tested with RPE cell cultures,</p> <ul style="list-style-type: none"> Lots 310832 and 400929 are NON-CYTOTOXIC. <p>It was concluded based on the differences in terms of viability compared to the controls used in the experiments performed following the UNE-EN ISO 10993-5:2009 "Tests for in vitro cytotoxicity".</p> <p>The product "PFO medical device" lot numbers 310832 and 400929 (A and B) were provided by the company ARCADOPHTA and tested with porcine neuroretina cultures,</p> <ul style="list-style-type: none"> Lots 310832 and 400929 are NON-CYTOTOXIC. <p>It was concluded based on the differences in terms of the cell/tissue degeneration compared to the controls used in the experiments performed following the UNE-EN ISO 10993-5:2009 "Tests for in vitro cytotoxicity".</p> | | |
| Version: | 01 | Date: 26/10/2020 | |
| Study Director: | JC Pastor Jimeno |  | |
| Experiments Directors: | Cristina Andrés Iglesias Iván Fernandez Bueno |  | |
| Facilities Director: | MJ Maldonado López |  | |
| Quality Assurance Unit: | MA García Hontoria |  | |
| <p>funce Uva  </p> <p>This report shall not be reproduced except in full without the specific written approval of the IOBA, Valladolid, Spain <small>* The test results relate only to the items tested - IOBA - Campus Miguel Delibes - Paseo de Belén 17 - 47011 - Valladolid Tel. 983 42 35 59 Fax 983 18 37 23 ioba@ioba.med.uva.es www.ioba.es</small></p> | | | |
| | | | Page 1 of 27 |

IOBA Certificate

ARCOTANE and ARCALINE Advantages

- No reports of cytotoxicity² have been communicated to the manufacturer Arcadophta over 15 years of production and commercialization
- Over 600.000 units distributed in more than 70 countries
- Pharmaceutical environment production
- ISO 13485/2016 certified company
- European legal manufacturer

2 ARCAD_PMS-PMCF_01 Version 0 of the 27/04/2020* As per P950018 S019 Perfluoron PMA reported in the FDA website.

***Adult Retinal Pigment Epithelium cells.

ARCOTANE and ARCALINE PFCL Instructions For Use

- Use a long blunt cannula to inject PFCL close to the optic disc and create a single bubble
- Always inject PFCL smoothly into the same bubble, and avoid jet-stream to prevent damaging the retina
- Let the bubble expand until you reach the bottom part of the tear; Stop the injection to avoid any PFCL leakage into the subretinal space
- Apply laser endophotocoagulation through the PFCL
- Thoroughly remove PFCL passively before introducing gas or silicone oil tamponade



Safety First For Our Product Line



ARCIOLANE
Fractionated and Purified
Silicone Oil



ARCEOLE
Ready-to-Use Set
of Ophthalmic Gas



MONOBLUE
Ultra-Purified
Trypan blue solution



OP'COVER
Corneal Protection

FOR COMPLETE PRODUCT INSTRUCTIONS, PLEASE REFER TO THE IFU SUPPLIED WITH THE PRODUCT

<https://www.bvimedical.com/customers-support/>

