

Overview of Regulatory Testing and FDA Compliance on Liqui-Cel® Membrane Contactors

Liqui-Cel® Membrane Contactors are used in many diverse applications and markets that require various tests to be completed.

FDA Compliance

Our Food and Beverage applications require our products to be made with FDA compliant materials.

Toxicity Testing

We complete toxicity testing as appropriate for materials being used in the biotechnology, medical and pharmaceutical sectors.

Other Product Testing

In addition to the test summaries here, our products are tested to meet a minimum oxygen removal and/or pressure drop specification. This testing ensures that customers receive consistent products that will meet our performance warranties when installed in a system. These specifications can be found on the back of our data sheets.

CE Mark

Our high purity 10-inch and our 14-inch products also carry the CE Mark and they comply with the Pressure Equipment Directive of the European Union (PED 97/23/EC). Our smaller contactors also comply with the PED but are manufactured under Sound Engineering Practice. These smaller contactors process lower liquid volumes that do not require the CE Mark.

RoHS Compliance

Most of our products meet the requirements of RoHS. If you have a question on a specific product, please ask your account manager for the appropriate documentation.

This TechBrief provides highlights of our test results. If you require additional information, please contact your Membrana representative.

Meets the Following Title 21 Code of Federal Regulations

Component	Materials	Chapter
Hollow Fiber Array	Polypropylene	177.1520
Center Tube	Polypropylene	177.1520
Outer Protective Mesh	Polypropylene	177.1520
O-Rings	EPDM, Viton, Buna-N	177.2600
Potting Compound	Epoxy	177.1210
Potting Compound	Polyethylene	177.1520
Potting Compound	Polyurethane	177.105
Housing, Plastics	Polypropylene, PVDF*, ABS, Polycarbonate	177.1520, 177.1020, 177.1580

*4-inch and 10-inch FRP Inner Housing Surface. Also note that 316L SS Housings do not require testing.

Toxicity and FDA Compliance Summary

Product	Toxicity					FDA
	Cytotoxicity	Mutagenicity (saline extract)	Mutagenicity (ethanol extract)	Physiochemical (water extract)	Physiochemical (isopropanol extract)	Compliant per Title 21 CFR*
0.5 x 1 MicroModule®	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Yes
1 x 5.5 MiniModule®	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Yes
1.7 x 5.5 MiniModule®	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	Yes
2.5 x 8 Cartridge	Pass	Pass	Pass	Pass	Pass	Yes
4 x 13, 4 x 28 Cartridge	Pass	Pass	Pass	Pass	Pass	Yes
6 x 28 in ABS Housing	Pass	Pass	Not Tested	Pass	Not Tested	Yes
10 x 28 Cartridge	Pass	Pass	Pass	Pass	Pass	Yes
14 x 28 Contactor	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested	No

The summary above applies for both X40 and X50 Hollow Fiber. All o-rings and internal seals were also tested. Note that some toxicity tests were not performed on newer products because the tests could be detrimental to animal life. We felt animal testing was not required for our applications.

Extractable Testing

We also perform extractable testing on products that will be sold into high purity markets such as the microelectronics market.

rinse-up to back ground when compared to other installed technologies.

What we have found in the field is that our Membrane Contactors are typically the quickest components to

The table below summarizes the key extractable data. Additional details are available from your Membrana representative if needed.

Extractable Summary

Product Tested	Parameter	Median Background	Time to reach Background
4 x 28 Contactor in PP Housing with Kalrez O-Rings at 5 gpm	TOC, ppb	1.34	35 Minutes*
	Resistivity, MΩ-cm	18.2	11.5 Hours*
	Particle, #/ml ≥ 0.1 μm	0.79	1.35 Hours*
	There was not indication of Metallic or Ion Extraction in samples analyzed by IC, ICP-MS and GFASS.		
10 x 28 Contactor in FRP Housing with PVDF inner surface, EPDM O-Rings at 5 gpm	TOC, ppb	2ppb above background	50 hours*
	Resistivity MΩ-cm	0.2 MΩ-cm below background of 18.27	50 Hours*
	Particle, #/ml ≥ 0.10 μm	< 1 particle/ml	14 Hours*
	There was no indication of Metallic or Ion Extraction in samples analyzed by ICP-MS and GFASS at 24 hours.		

* Note that the 4-inch is operated as high as 30 gpm while the 10-inch is operated to 210-250 gpm. These tests were conducted at 5 gpm. At higher flow rates that are typical for normal operation in our devices, the rinse-up times are much faster.

This product is to be used only by persons familiar with its use. It must be maintained within the stated limitations. All sales are subject to Seller's terms and conditions. Purchaser assumes all responsibility for the suitability and fitness for use as well as for the protection of the environment and for health and safety involving this product. Seller reserves the right to modify this document without prior notice. Check with your representative to verify the latest update. To the best of our knowledge the information contained herein is accurate. However, neither Seller nor any of its affiliates assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of the suitability of any material and whether there is any infringement of patents, trademarks, or copyrights is the sole responsibility of the user. Users of any substance should satisfy themselves by independent investigation that the material can be used safely. We may have described certain hazards, but we cannot guarantee that these are the only hazards that exist.

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