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Assessment of PFAS Extractables From Sterilizing-Grade Membrane Filters

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Abstract

Evolving regulations concerning per- and polyfluoroalkyl substances (PFAS) have intensified the need for transparent protocols to measure and test extractables and leachables from materials used in biopharmaceutical manufacturing.

This study, conducted in collaboration with SGS Institut Fresenius, investigates the extractable organic fluorine (EOF) profiles and targeted PFAS of selected sterilizing-grade polyvinylidene fluoride (PVDF)- and polyethersulfone (PES)-based membrane filters.

A comprehensive USP <665>-based extractables approach was used to test filters out of the box, without pre-rinsing, to assess extractables under worst-case conditions. The results demonstrate that no targeted PFAS were detected in the extractables profiles of Sartopore Evo® and Sartopore® 2 XLG filters, which are PES membrane filters manufactured without the intentional use of PFAS-containing materials. Elevated EOF profiles were observed for PVDF membrane filters and the PES membrane filter with PFAS-based surface modifications.

These findings support the continued use of PES-based Sartorius membrane filters in biopharmaceutical manufacturing applications where PFAS extractables are a concern.

Introduction

Per- and polyfluoroalkyl substances (PFAS) comprise a large group of fluorinated organic chemicals widely used for their unique surface, chemical, and thermal properties. In filtration applications, PFAS-based polymers and surface modifications have historically been employed to achieve specific membrane functionalities. However, concerns regarding environmental persistence¹ and potential health effects² have led to increasing regulatory pressure on PFAS use.

Within the European Union, the PFAS restriction proposal³ and existing regulations such as the Packaging and Packaging Waste Regulation⁴ set out stringent limits for PFAS at very low concentrations. Notably, these regulatory frameworks do not provide a uniform definition of the term "PFAS-free," making robust analytical assessment and transparent communication indispensable.

In this context, the concept of non-intentionally added PFAS has gained relevance. This term describes materials in which PFAS are not deliberately used as raw materials or functional components, while acknowledging that trace levels could theoretically arise from process-related sources during manufacturing. Testing whether PFAS extractables and leachables are present in single-use technologies is therefore a key requirement for biopharmaceutical manufacturers.

The objective of this white paper is to report the results of an extractables study on selected sterilizing-grade membrane filter products: polyvinylidene fluoride (PVDF)-based filters, for which PFAS-containing materials are intentionally used in the manufacturing process, and polyethersulfone (PES)-based filters with and without PFAS surface modifications. The study focused on extractable organic fluorine (EOF) and targeted PFAS. The European Commission acknowledges that there is currently no harmonized methodology for PFAS testing in articles. Therefore, the globally recognized USP <665> framework⁵ was selected for this study and combined with validated SGS Institut Fresenius protocols for EOF and targeted PFAS analysis.

Materials & Methods

The study included sterilizing-grade PES-based filters from Sartorius and PVDF- and PES-based filters from other suppliers. All Sartorius filters tested had PES-based membranes; however, Sartopore® Air filters incorporate PFAS-based surface modifications, whereas Sartopore Evo® and Sartopore® 2 XLG filters do not. These filters were selected to enable differentiation between material concepts (Table 1).

Ten-inch filter cartridges, which are among the most widely used filter formats in biopharmaceutical production, were used for testing. This approach also ensures that not only the filter membrane itself but all components of the filter element are evaluated for a potential release of PFAS extractables. All filters were tested out of the box, without pre-rinsing or flushing, to represent worst-case extractables conditions.

Table 1: Overview of the sterilizing-grade membrane filters analyzed

Filter	Membrane material	Supplier	Order code
Sartopore® 2 XLG	Hydrophilic PES	Sartorius	5442507G1
Sartopore Evo®	Hydrophilic PES	Sartorius	5992507G1
Sartopore® Air*	Hydrophobic PES	Sartorius	5192507A1
Supor™ Prime	Hydrophilic PES	Cytiva	AB1UASF7PH4
Fluorodyne™ II	Hydrophilic PVDF	Cytiva	AB1DFL7PH4
Corevital™ SVL	Hydrophilic PVDF	Cobetter	ASVLB107SP
SteriLUX®	Hydrophilic PVDF	Meissner	VTH0.2-1F6RS
Durapore®	Hydrophilic PVDF	Merck Millipore	CVGL71TP3

*The specific Sartopore® Air filter configuration used in this study is not commercially available. It was produced under qualified manufacturing conditions in the same format as the other filters to enable direct comparison.

Extraction was performed in accordance with USP <665> procedures using three different media: 50% (v/v) aqueous ethanol, an aqueous solution at pH 3, and an aqueous solution at pH 10. Test articles were fully submerged in the respective extraction media (approximately 1,100 mL) and incubated for 24 h at 40 °C under continuous agitation (Table 2).

The resulting extracts were subsequently screened qualitatively and quantitatively for EOF and targeted PFAS using validated and standardized SGS Institut Fresenius test protocols. Commercially available PFAS reference standards were obtained from qualified suppliers. The targeted PFAS analysis covered 102 non-polymeric PFAS substances, representing all PFAS compounds for which SGS Institut Fresenius has validated test methods.

Results

Quantitative determination of PFAS was carried out using liquid chromatography coupled with tandem mass spectrometry (LC-MS/MS) and gas chromatography–mass spectrometry (GC-MS), depending on analyte-specific properties. EOF was measured using combustion ion chromatography to provide a sum-parameter assessment of the organofluorine content.

Table 2: Overview of testing conditions in accordance with USP <665>

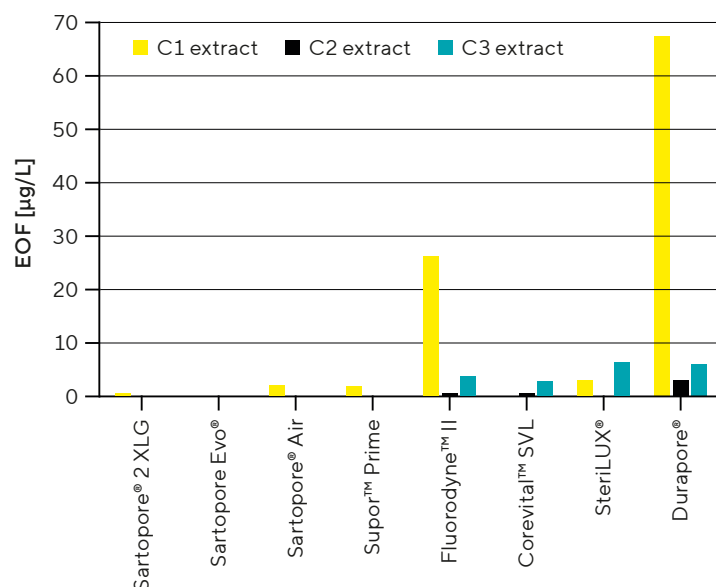
Extraction conditions	Extraction media	Analytical methods
Extraction under agitation for 24 h at 40 °C±2 °C	(C1) 50% aqueous ethanol	PFAS: LC-MS/MS and GC-MS
Filters tested out of the box without pretreatment	(C2) 50 mM KCl, pH 3.0 (pH adjusted using aqueous solutions of 0.2 N HCl or 0.1 N NaOH)	EOF: Combustion ion chromatography
	(C3) 100 mM Na ₂ HPO ₄ , pH 10.0 (pH adjusted using aqueous solutions of 0.1 N HCl or 0.1 N NaOH)	

Note. The reporting limit for EOF determination by combustion ion chromatography was 0.25 µg/L. The reporting limits for the targeted PFAS substances ranged from 10 to 50 µg/L depending on the analyte.

EOF was detected in several filter extracts at concentrations well above the reporting limit of 0.25 µg/L, with the highest values observed in the 50% ethanol extracts (C1 extract; Figure 1). Generally, PVDF-based membranes showed higher EOF values than PES-based membranes.

For Sartopore® 2 XLG and Sartopore Evo® filters, which are used in liquid filtration applications and manufactured without the intentional use of PFAS-containing materials, EOF was either not detected or detected at very low concentrations, slightly above the reporting limit (Figure 1).

Figure 1: EOF content measured by combustion ion chromatography



Discussion

With one exception, no targeted non-polymeric PFAS were detected at concentrations above the reporting limits across the tested filters. A single PFAS substance, 2-(perfluorohexyl) ethanol (6:2 FTOH), was detected in the 50% ethanol extract of the Sartopore® Air filter (Table 3).

Table 3: Non-polymeric targeted PFAS content measured by LC-MS/MS and GC-MS

Filter	Extract C1 [µg/L]	Extract C2 [µg/L]	Extract C3 [µg/L]
Sartopore® 2 XLG	■	■	■
Sartopore Evo®	■	■	■
Sartopore® Air*	190 µg/L (6:2 FTOH)	■	■
Supor™ Prime	■	■	■
Fluorodyne™ II	■	■	■
Corevital™ SVL	■	■	■
SteriLUX®	■	■	■
Durapore®	■	■	■

■ No targeted PFAS detected at or above the reporting limit

The results clearly demonstrate the presence of PFAS in extracts of PVDF-based membrane filters. Specifically, EOF was detected not only in the ethanol extracts but also in the aqueous extracts, with the highest values observed for the Durapore® and Fluorodyne™ II filters across all three extraction media.

EOF values for Sartopore® Air and Supor™ Prime filters were similar. The EOF results for the Sartopore® Air filter are explained by the hydrophobic PFAS-based surface modification of the PES membrane (i.e., intentional PFAS use), while the origin of the EOF detected in the Supor™ Prime filter extract remains unclear.

In contrast, EOF was either not detected or measured only at concentrations near the reporting limit for Sartopore Evo® and Sartopore® 2 XLG filters, which are manufactured without the intentional use of PFAS-containing materials. The EOF concentration of 0.36 µg/L measured for the ethanol extract of the Sartopore® 2 XLG filter, close to the reporting limit of 0.25 µg/L, illustrates the challenge of interpreting the results near this threshold.

The detected EOF values generally differed depending on the selected extraction medium. Usually, higher EOF concentrations were measured with 50% ethanol extraction, whereas lower concentrations were measured in aqueous extracts of all PVDF-based membrane filters. The detection of EOF in the acidic and basic aqueous extracts may indicate hydrolytic degradation under these conditions. Together, these findings may explain why EOF was detected across all three extraction media for the PVDF-based membrane filters. However, the chemical nature of these extractables could not be identified by targeted PFAS analysis.

No targeted PFAS were detected or quantified above the reporting limits in the studied filter extracts, with the exception of the detection of 6:2 FTOH in the Sartopore® Air filter extract. This result can be explained by extractables from the hydrophobic PFAS-based membrane surface modification of this filter. This detection confirms the ability of the applied analytical methods to detect potential PFAS extractables in membrane filter products.

The absence of targeted PFAS above their respective reporting limits in the extracts of Sartopore Evo® and Sartopore® 2 XLG filters, despite worst-case, non-flushed testing conditions, provides strong evidence for the reliable control of material quality and manufacturing processes. The results support the suitability of these membranes for critical biopharmaceutical applications, such as the final filling of the drug product.

Conclusion

This study demonstrates that the extractables profiles of sterilizing-grade Sartopore Evo® and Sartopore® 2 XLG membrane filters, which are manufactured without the intentional use of PFAS-containing materials, contained no targeted PFAS above the applicable reporting limits. Testing was conducted using industry-relevant extractables protocols under stringent worst-case conditions.

As regulatory expectations continue to evolve, comprehensive and transparent extractables studies such as this one will remain essential to support risk assessment and informed material selection in biopharmaceutical processing.

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