

EXTRACTABLES STUDY FLUORINATED MATERIALS



Extractables and leachables studies pursue a common goal: ensuring and verifying process purity. In this way, the results of an extractables study flow into the leachables study.

The extractables study investigates the interactions between the pharmaceutical product and the elastomer. They frequently appear in a medium with a relatively high solvent strength compared to the product and at a high temperature. The goal of the study is to identify all the extractable components of the elastomer that could migrate from elastomer sealing materials during the production, filling and packaging of foods and pharmaceuticals. In turn, the leachables study documents the components of an elastomer compound that can be dissolved away and that can cross over into the product under moderate conditions over a long period of contact during storage.

Available certifications such as USP (United States Pharmacopeia) and FDA (Food and Drug Administration) are often relied upon in the choice of materials, but they do not take interactions between processing media and sealing materials into account.



Freudenberg Sealing Technologies studied its own fluorinated and EPDM materials. The extractables study on EPDM materials also includes a benchmark consideration: The most severe test parameters with regard to solvent strength and temperature were chosen for the investigation.

Compared to competitors' materials, the benchmark analysis shows that Freudenberg compounds display only very small extraction quantities with clearly identified substances. This greatly simplifies later evaluations in leachables studies. The results of TOC investigations also show major differences that favor Freudenberg materials. The fluorinated materials can even outperform this excellent performance; no extracts could be detected in the tests of the materials.

Fluorinated materials in the extractables study

MATERIAL	COLOR	HARDNESS SHORE A
Fluoroprene® XP 41	blue	75
Fluoroprene® XP 43	blue	85
Simriz® 494	black	75
Simriz® 506	white	75

VALUES FOR THE CUSTOMER

- Extractables results from Freudenberg can be used for own leachables studies
- Unplasticized fluorinated materials show no detectable extract
- Purity of fluorinated materials can be confirmed



FEATURES AND BENEFITS

COMPARISON OF TESTED MATERIALS

Two materials made of highly fluorinated Fluoroprene® XP as well as a white and a black Simriz® from the perfluoroelastomer class were tested.

Compared to EPDM, HNBR and silicone materials, fluorinated materials display better temperature and media resistance. That is why they are used in applications in which seals come into contact with especially aggressive or chemically different media.

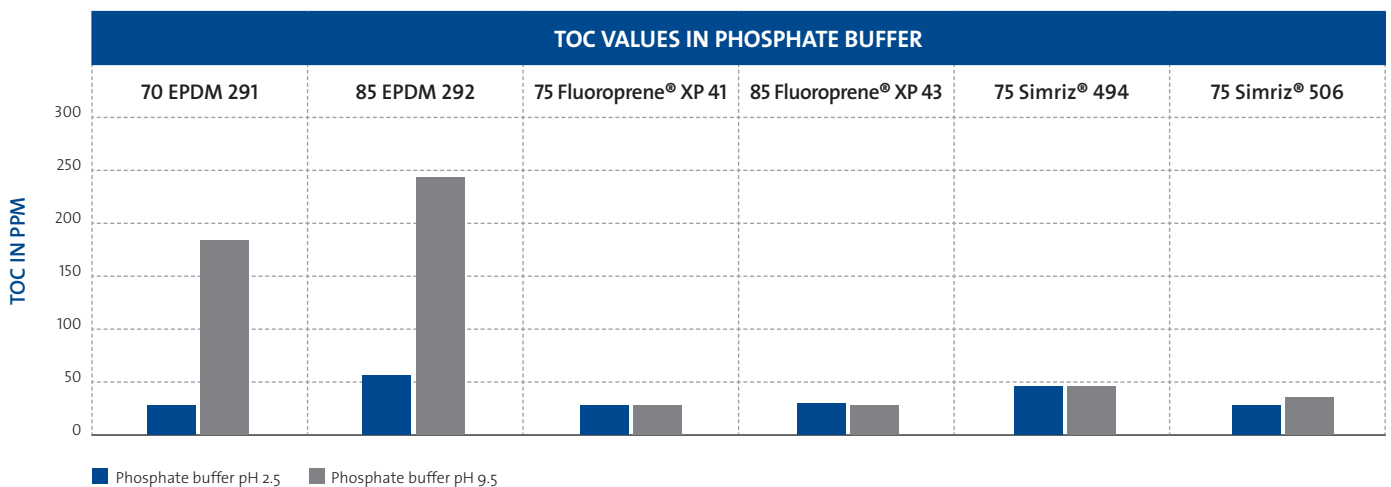
Fluoroprene® XP shows outstanding temperature stability up to +200 °C (+392 °F) and is considered a universal material due to its stability in non-polar and fatty as well as aqueous media.

Among elastomers, Simriz® shows the highest range of temperatures in its applications, from -10 °C to +260 °C (+14 °F to +500 °F), and is resistant to nearly all media.

STUDY RESULTS AT A GLANCE

The qualitative difference between EPDM and fluorinated materials can be seen in the results of this extractables study. 24-hour extractions from fluorinated materials in ethanol and n-hexane produced no detectable extracts. The TOC values for Fluoroprene® XP and Simriz® are less than those for pure EPDM materials by a factor of five.

As a result, fluorinated materials can unhesitatingly be used in sensitive processes in the food and pharmaceutical industries.



The diagram shows the TOC values of the tested materials compared to two black EPDM materials from Freudenberg.

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