

EXTRACTABLES EPDM-BENCHMARK



In food and pharmaceutical industries production today, everything revolves around the issue of purity.



Processing purity for sealing materials is normally assured through a **leachables study**, which looks at the environmental factors that could impact the material. An **extractables study** is another important tool in assessing material purity and suitability in particular applications. An extractables study identifies the substances that migrate out of elastomers in the presence of solvents - in particular environmental conditions. For example, extractables figures can provide information on how an O-ring used to seal an inhalation spray head behaves when coming into contact with medication or whether seals used in the baby food industry will be negatively impacted by exposure to the food.

In fact, customary USP and FDA certifications are not sufficient when it comes to determining material purity and compatibility in the food and pharmaceutical industries because they do not take the interactions between seals and the processing media into account.

Freudenberg realizes that no standard test suffices when it comes to purity and compatibility. Instead, the company has investigated its own **EPDM materials in a benchmark study**. The result: EPDM materials from Freudenberg display only a few peaks in comparison with the extraction values of other materials. This means they are superbly suited for sensitive applications. **Total organic carbon (TOC) levels** – a clear indicator of organic contamination – are lower in Freudenberg materials than in competing materials, thus offering customers better sealing value and more system security.

VALUES FOR THE CUSTOMER

FFKM and Fluoroprene® XP materials were explored in a second benchmark study. Fluorinated materials display improved temperature and media resistance. The TOC values and extraction quantities are even lower than the EPDM materials from Freudenberg, which in themselves are superior for use over traditional offerings. With this in mind, Freudenberg offers its customers tremendous value by:

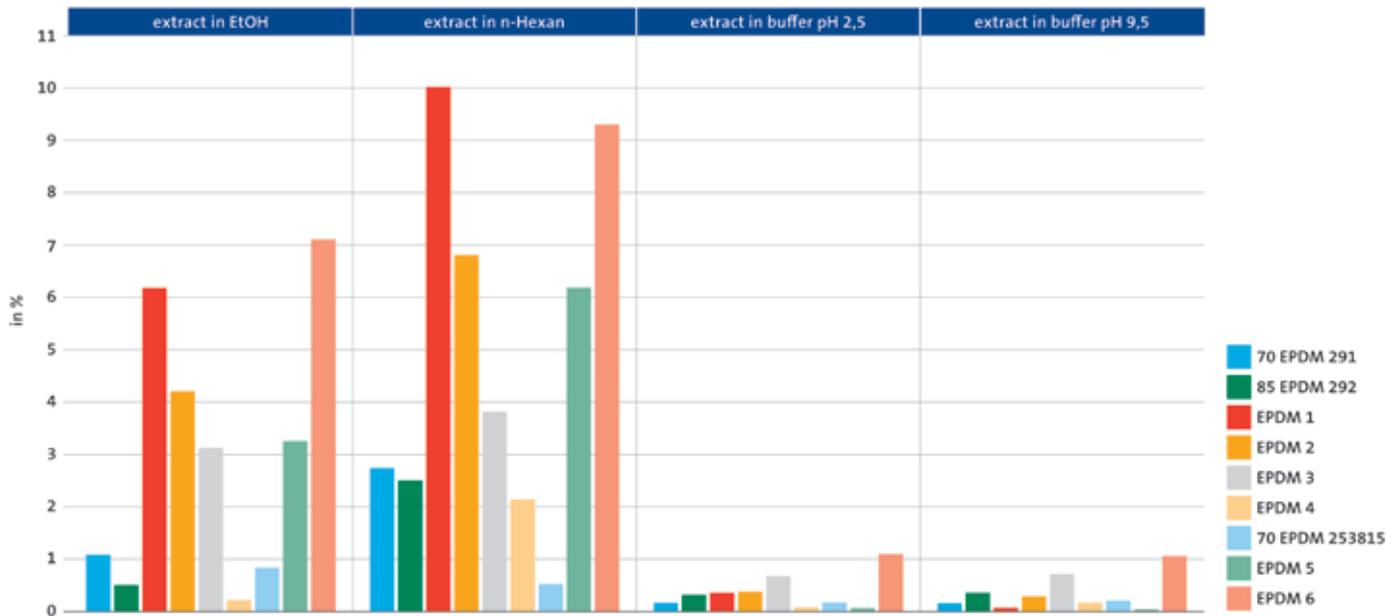
- Identifying what migrating substances are present and how sealing materials will respond to them.
- Using and building upon customers' own leachable studies to determine superior purity and compatibility.
- Providing data and analysis about the purity of pharmaceutical and food processes.
- Carrying out material testing under the most aggressive and robust conditions possible to achieve superior material understanding, knowledge and recommendations.

| MATERIAL | COLOR | HARDNESS SHORE A |
|---------------------------|-------|------------------|
| EPDM 291 (Freudenberg) | Black | 70 |
| EPDM 292 (Freudenberg) | Black | 85 |
| EPDM 1 | Black | 70 |
| EPDM 2 | Black | 80 |
| EPDM 3 | Black | 70 |
| EPDM 4 | Black | 75 |
| EPDM 253815 (Freudenberg) | White | 70 |
| EPDM 5 | White | 70 |
| EPDM 6 | White | 70 |



BENCHMARK RESULTS

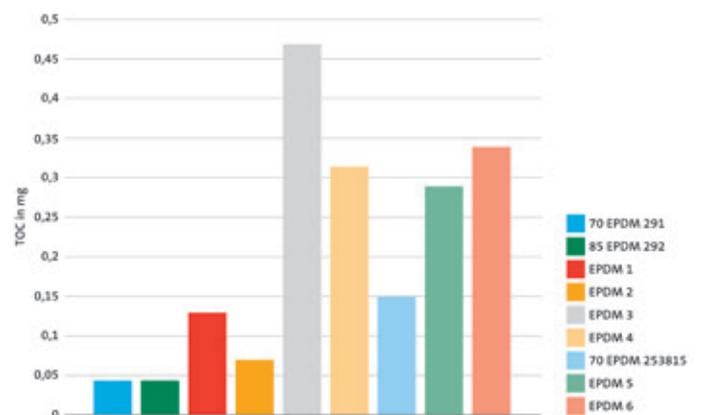
Extraction quantities in relation to original sample weight



When the extraction values of black EPDM materials are compared, the two materials from Freudenberg as well as EPDM 4 are the clear winners in the benchmark comparison. Among the white materials, EPDM 253815 and EPDM 5 prevail. But the latter shows excessive extraction values in EtOH and n-hexane, and thus only EPDM 253815 is recommended overall. EPDM 4 also can not be recommended in general, as it shows a higher TOC value.

The TOC value is an indicator of organic contamination in the process chain. Compared to the other two white materials, EPDM 5 and EPDM 6, Freudenberg's EPDM 253815 has a clearly lower carbon content and is thus better suited for hygienically demanding processes. Among the black EPDM materials, only the values of the Freudenberg compounds can convince.

TOC values in relation to original sample weight



The information contained herein is believed to be reliable, but no representation, guarantees or warranties of any kind are made to its accuracy or suitability for any purpose. The information presented herein is based on laboratory testing and does not necessarily indicate end product performance. Full scale testing and end product performance are the responsibility of the user.

www.fst.com