Viton® fluoroelastomer

From DuPont Performance Elastomers

Viton® GF-600S & Viton® Extreme™ ETP-600S Provides FDA Repeat Use Food Contact Compliance and More

Viton® GF-600S and Viton® Extreme™ ETP-600S represent two of the latest specialty types of Viton® fluoroelastomers (FKM) made with APA – Advanced Polymer Architecture. Laboratory testing has shown that vulcanizates based on these polymers provide superior performance in seals and gaskets for pharmaceutical, food and beverage applications where FDA repeat use food contact compliance is needed.

Compared to other sealing materials, including conventional types of bisphenol-cured fluoroelastomer, vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S exhibit:

- **Superior steam resistance** (See Figure 1, Page 2)
- **Superior resistance to commercial cleaning fluids** (See Figures 2, 3, 4, and 5, Pages 3 and 4)
- **Superior resistance to a wide variety of chemicals, fluids used as food flavorings** (See Table I, Figure 6, Pages 5 and 6)
- **LOW Total extractable metals - similar to PTFE** (See Figure 7 & 8, Pages 6 & 7)
- **LOW Total Organic Carbon extractives - similar to PTFE** (See Figure 9, Page 7)

Improved Steam and Fluids Resistance

Pharmaceutical and food manufacturers often use EPDM or silicone. While EPDM is capable of providing excellent steam resistance, it exhibits relatively poor resistance to some commonly used cleaning fluids. On the other hand, silicone may provide good resistance to a wide variety of cleaning fluids but it exhibits relatively poor steam resistance.

As an alternative to EPDM, bisphenol-cured types of Viton®, such as Viton® A-401C, provide significant improvements in steam resistance, compared to older, diamine-cured types of fluoroelastomers (FKM). Despite its improved steam resistance, however, bisphenol-cured Viton® exhibits relatively poor resistance to some of the cleaning fluids that are used in sterilization processes.

*The results presented in this bulletin are based on laboratory tests run on seals made with EPDM, platinum-cured silicone, bisphenol-cured fluoroelastomer, and PTFE that were obtained from a commercial supplier of seals for use in the food and pharmaceutical industry. Samples of vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S were prepared in a DuPont Performance Elastomers laboratory, and were tested along with the samples of commercial seals. As with any material, evaluation of a compound under end-use conditions prior to specification is essential.

Viton® GF-600S and Viton® Extreme™ ETP-600S Provide a New Level of Performance

Viton® made with APA is a proprietary development by DuPont Performance Elastomers that improves the performance of specialty fluoroelastomers. The following section offers a brief description of Viton® fluoroelastomers that are compliant with FDA repeat use food contact regulations.

- **Viton® GF-600S** is a high-fluorine, peroxide-cure type of Viton®. Compared to bisphenol-cured dipolymer FKM, such as Viton® A-401C, vulcanizates based on Viton® GF-600S exhibit excellent steam resistance and superior resistance to a much wider variety of cleaning fluids. Vulcanizates based on Viton® GF-600S exhibit excellent physical properties, including resistance to compression set. FDA food contact compliance for Viton® GF-600S with limitations/specifications for repeat-use applications is outlined in Food Contact Notification (FCN) 510. Information relative to FCN 510 can be reviewed at the FDA's website http://www.cfsan.fda.gov/~dms/opa-fcn.html of effective notifications for food contact substances.

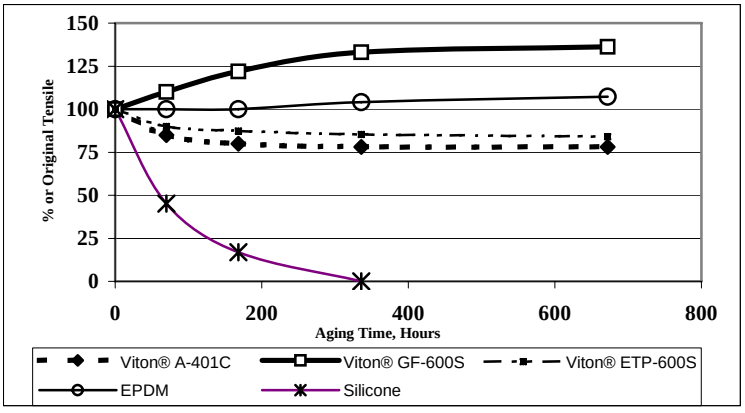
- **Viton® Extreme™ ETP-600S** is a very unique fluoroelastomer that exhibits excellent steam resistance and resistance to attack by an exceptionally broad variety of chemicals and fluids, including aliphatic and aromatic hydrocarbons, acids, bases, all types of alcohols and even low molecular weight ketones, esters, and aldehydes. FDA food contact compliance for Viton® Extreme™ ETP-600S with limitations/specifications for repeat-use applications is outlined in Food Contact Notification (FCN) 539. FCN 539 can be reviewed at the FDA's website http://www.cfsan.fda.gov/~dms/opa-fcn.html of effective notifications for food contact substances.

Viton® GF-600S and Viton® Extreme™ ETP-600S Provide Improved Steam Resistance

Bisphenol-cured Viton® has been the standard for applications where steam resistance is required. However, as shown in Figure 1, vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S provide even better resistance to property loss in steam.

Test results demonstrate that Viton® polymers based on APA technology provide excellent retention of tensile properties in steam aging, whereas the strength of the vulcanizate made with silicone drops off to essentially zero in less than 400 hours.

Figure 1
Viton® made with APA vs Viton® A-401C and Other Elastomers
% of Original Tensile Strength* in 80 psi Steam (156°C) After 672 Hours

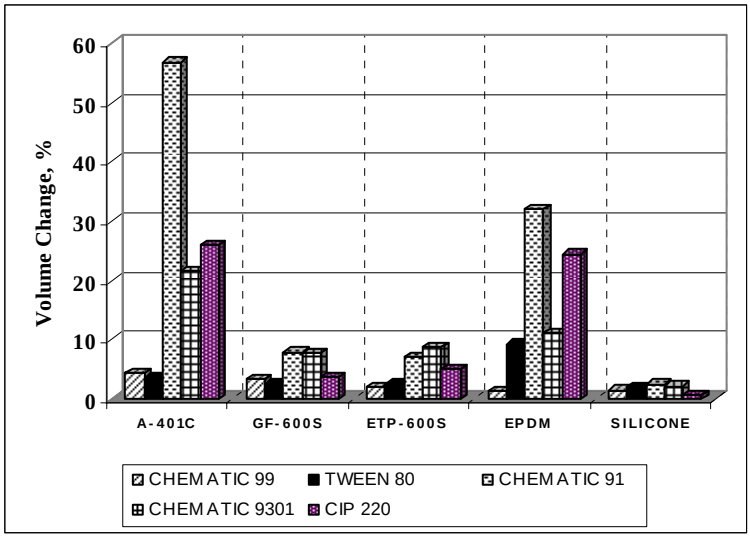


**ASTM Test Method D471*

Viton® GF-600S and Viton® Extreme™ ETP-600S Demonstrate Excellent Fluids Resistance

In addition to maintaining its tensile properties in steam, APA polymers also demonstrate improved resistance to volume change in cleaning fluids, such as Chematic® 91, Chematic® 9301, and CIP 220® compared to bisphenol-cure dipolymer FKM, and EPDM (Figure 2).

Figure 2
Viton® made with APA vs Viton® 401C and Other Elastomers
% Volume Change* in Various Cleaning Fluids After 1008 Hours @ 70° C



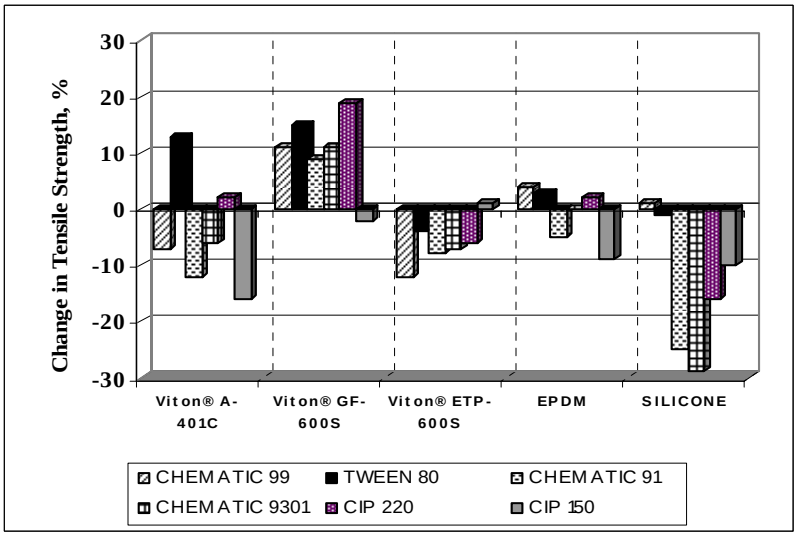
**ASTM Test Method D471*

As indicated in Figure 2, vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S exhibit lower volume swell in a wider variety of cleaning fluids than any of the other polymers tested except silicone. The combination of steam resistance and resistance to a wide variety of cleaning solutions make these APA polymers attractive candidates for food and pharmaceutical sealing applications compared to silicone and EPDM.

Volume change in fluids is an indication of the ability of a vulcanizate to maintain sealing performance in a given fluid. If a vulcanizate exhibits excessive swelling, it also tends to exhibit significant losses in hardness and strength, which may result in a reduction in the ability of a gasket or O-ring made from the vulcanizate to maintain a seal under pressure.

Figure 3 shows that after aging in various commercial cleaning fluids, compounds based on Viton® GF-600S and Viton® Extreme™ ETP-600S show very modest changes in tensile strength, whereas vulcanizates based on silicone demonstrate a considerably greater loss of tensile strength after the 1008 hour aging.

Figure 3
Viton® made with APA vs Viton® 401C and Other Elastomers
Change in Tensile Strength* in Various Cleaning Fluids After 1008 Hours @ 70° C

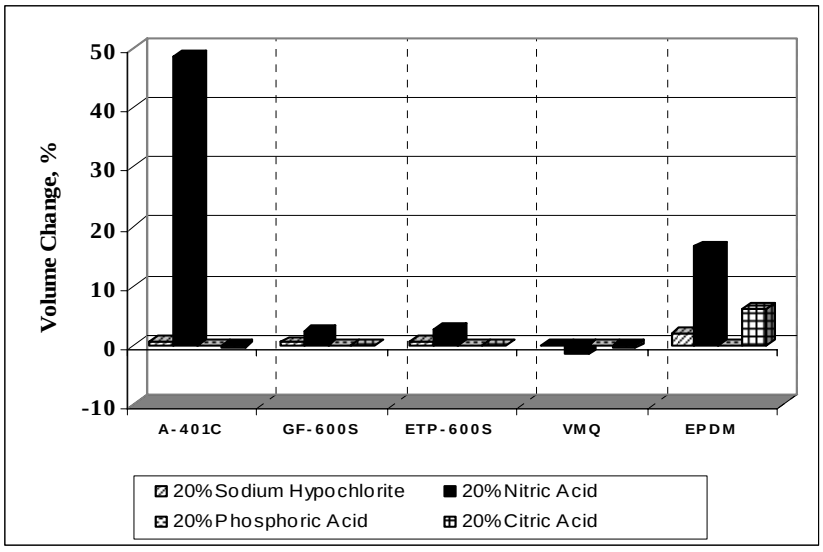


**ASTM Test Method D471*

Vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S exhibit similar advantages compared to bisphenol-cure types of fluoroelastomer, EPDM and silicone in various mineral and organic acids that are commonly used in cleaning food and pharmaceutical process equipment.

As shown in Figure 4, vulcanizates based on EPDM and the bisphenol-cured Viton® A-401C, exhibited considerably higher degrees of volume change in 20% nitric acid than the vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S.

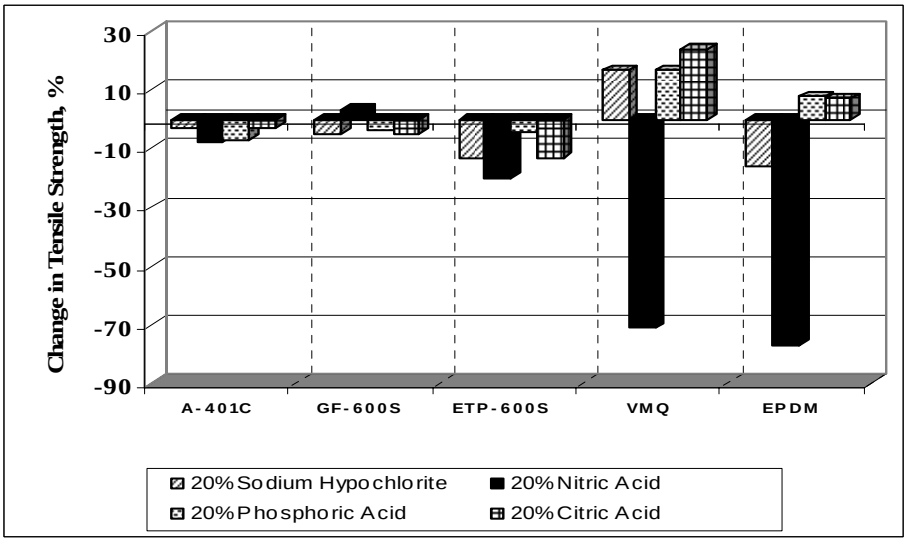
Figure 4
Viton® made with APA vs Viton® 401C and Other Elastomers
Change in Volume* in Various Cleaning Fluid Acids After 168 Hours @ 90° C



**ASTM Test Method D471*

The superior acid resistance of vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S versus other sealing materials is also evident in terms of the excellent retention of tensile strength exhibited by these vulcanizates, particularly after aging in a solution of 20% nitric acid, as shown in Figure 5.

Figure 5
Viton® made with APA vs Viton® 401C and Other Elastomers
Change in Tensile Strength* in Various Cleaning Fluids After 168 Hours @ 90° C



**ASTM Test Method D471*

The superior fluid resistance of vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S to cleaning solutions can also be seen in their resistance to a wide variety of chemicals and fluids that are used as food flavorings. Table I outlines the volume change for various types of Viton®, compared to silicone and EPDM, after immersion for 168 hours at room temperature in ethanol solutions (20 weight percent) in a variety of chemicals used as food flavorings.

Test results indicating greater than 10% increase in volume (and those which had a measurable, negative change in volume) are highlighted in grey. Note that the volume swell for the vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S was lower than 10% for all the chemicals tested.

Table I

Volume Change, %: After 336 Hour @ 23°C Fluid Agings*

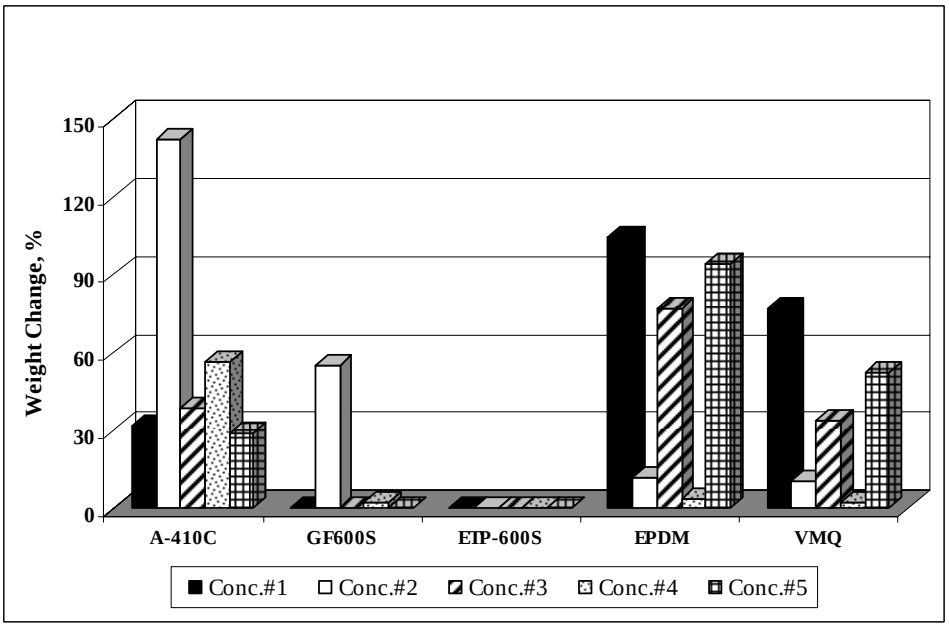
Percent Change in Volume After 336 Hours @ 23°C Fluid Agings**					
	Viton® A-401C	Viton® GF-600S	Viton® ETP-600S	EPDM	Silicone
Ethanol (100%)	5.0	1.1	0.4	1.0	8.0
Acetic Acid (20% Glacial/80% H2O)	24.8	0.5	0.8	9.7	-1.5
Carvacrol	2.5	0.7	0.2	-2.8	6.5
Carvyl acetate	28.3	2.5	1.1	0.8	13.7
Cinnamyl alcohol	4.3	1.6	1.1	0.9	5.3
Citral (terpene)	44.4	3.6	1.0	--	--
Decyl acetate	29.4	3.3	1.4	5.6	18.4
2,4-Dimethoxybenzaldehyde	18.0	2.2	0.5	-0.6	5.4
Dodecanal	2.0	2.3	1.5	3.0	11.5
Ethyl benzoate	36.9	5.2	2.8	3.0	12.0
Ethyl 2-benzylacetoacetate	44.6	3.0	0.9	-0.3	7.3
Ionone	51.0	2.5	0.8	2.0	12.3
Isobutylphenylacetate	26.9	2.7	1.0	1.2	11.1
Isophorone	90.0	7.2	1.0	1.3	9.9
2-Ketobutryic Acid	26.1	2.5	2.3	17.4	3.8
d-Limonene	4.3	1.9	0.9	16.5	25.7
Methyl anisole	22.0	4.7	2.5	4.7	15.1
Nerolidol	4.2	2.2	1.6	-0.2	10.8
2-Undecanone	45.1	4.4	2.0	1.7	16.2

Another example of the superior fluid resistance of vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S is apparent in Figure 6, which outlines the percent of weight change for various vulcanizates, after being immersed in five different soft drink flavoring concentrates for one week at room temperature. As shown in the chart, the vulcanizates made with Viton® GF-600S and Viton® Extreme™ ETP-600S exhibit considerably lower weight increases than the other elastomers tested, including the bisphenol-cured Viton® A-401C.

The vulcanizate made with Viton® GF-600S gained 55% weight in Concentrate #2, but showed less than 2% weight gain in the other four concentrates. The ETP-600S showed less than 1% weight gain in all five concentrates.

Figure 6

Weight % Change After 1 Week @ 23°C in Soft Drink Flavoring Concentrates



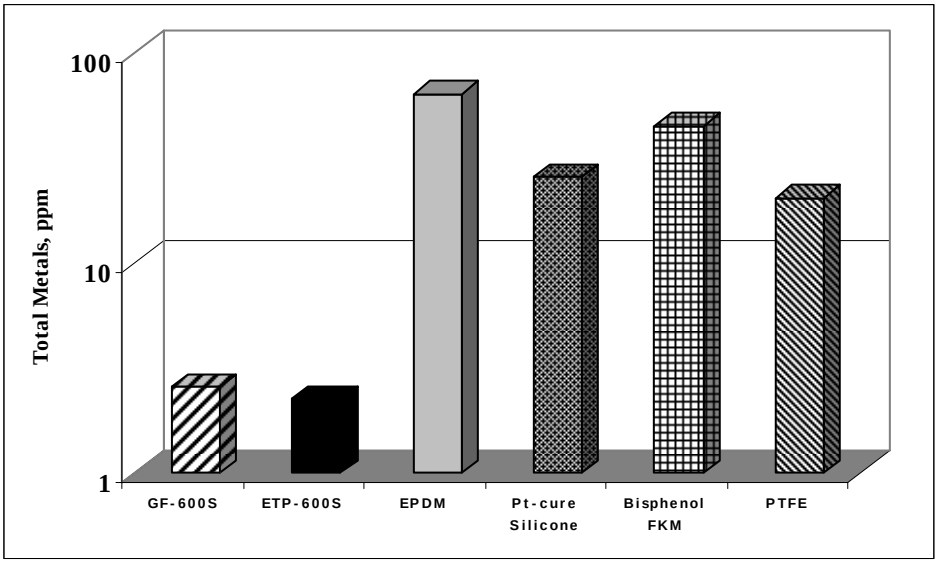
Viton® GF-600S and Viton® Extreme™ ETP-600S Exhibit Very Low Extractables

In order to effect crosslinking, bisphenol cure fluoroelastomer compounds require the use of metal-based acid acceptors, such as magnesium oxide and calcium hydroxide, typically at levels of about 6-9 weight percent of the total compound. Viton® GF-600S and Viton® Extreme™ ETP-600S do not require the addition of these materials, and as a result, can be formulated in a manner that results in measurably lower levels of extractable metals, when tested per EPA Method 6010A in WFI (water for injection) and in a 5% nitric acid solution.

This test method employs inductively coupled plasma emission spectroscopy to analyze for the presence of metals in solutions in Soxhlet extractions for 24 hours at reflux. Figure 7 depicts the levels of total metals extracted from vulcanizates based on a number of different elastomers, after extraction in WFI. Vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S exhibit considerably lower levels of metals than compounds based on EPDM and platinum-cured silicone, PTFE, and bisphenol-cured, dipolymer FKM.

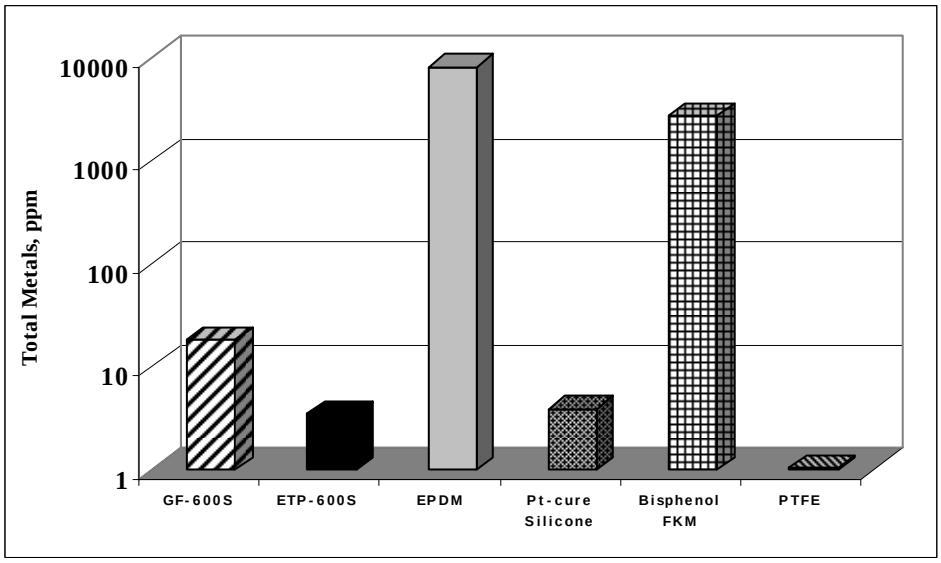
Figure 7

Total Level (ppm) of Metals Extracted in WFI – 24 Hours @ Reflux



Even greater advantages for vulcanizates based on Viton® GF-600S and Viton® Extreme ETP-600S are seen in extraction tests conducted in 5% nitric acid, as shown in Figure 8.

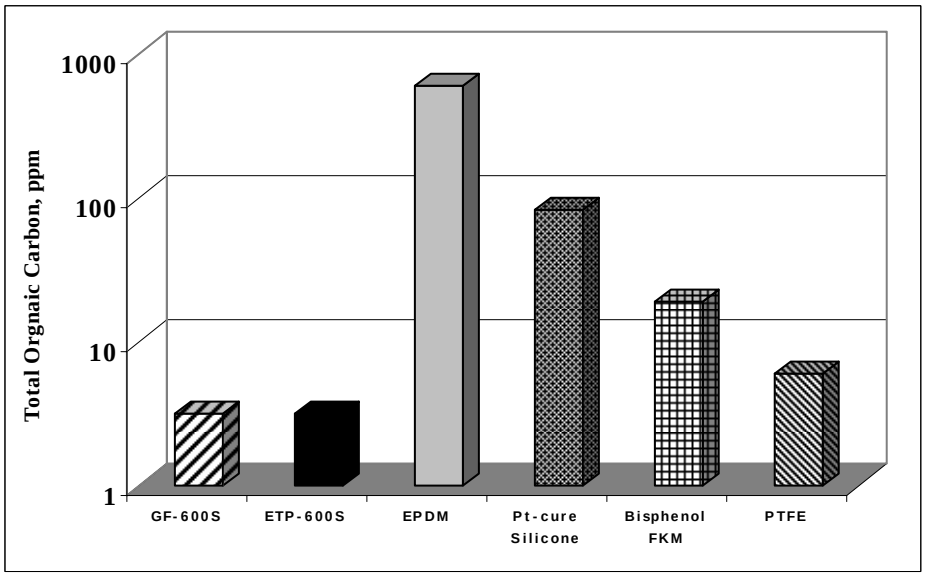
Figure 8
Total Level (ppm) of Metals Extracted in 5% HNO_3 – 24 Hours @ Reflux



Also of great importance for seals used in food and pharmaceutical processing equipment is the level of organic carbon materials that can potentially be extracted from the seals in service. Low levels of extractable organic compounds are desirable for minimizing the risk of contaminating process materials and to minimize the potential effect of altering the flavors of foods.

In this regard, vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S also exhibit significant advantages compared to compounds based on other elastomers, including conventional, bisphenol-cure fluoroelastomers. Figure 9 charts the results of Total Organic Carbon (TOC) extraction tests conducted in WFI at 100°C (212°F) for 24 hours, following the procedure outlined in EPA Method 415.1.

Figure 9
Total Organic Carbon (ppm) Extracted in WFI – 24 Hours @ 100°C



The vulcanizates based on Viton® GF-600S and Viton® Extreme™ ETP-600S show considerably lower levels of extractable carbon compounds than the vulcanizates based on EPDM and platinum-cured silicone.

Summary

Sterilization processes used by food and pharmaceutical manufacturers frequently use steam, aggressive cleaning solutions, or a combination of both. These aggressive conditions are very demanding on the sealing materials that are used in these environments. EPDM is capable of providing excellent steam resistance, but it exhibits relatively poor resistance to some commonly used cleaning fluids. Silicone may provide good resistance to a wide variety of cleaning fluids, but seals made with this polymer typically exhibit relatively poor steam resistance. PTFE seals exhibit excellent resistance to steam and chemical attack, but, because of their plastic nature, exhibit creep under stress, making it difficult to maintain sealing.

Compared to these commonly used sealing materials, and based on laboratory results, Viton® GF-600S and Viton® Extreme™ ETP-600S have been shown to provide an outstanding combination of:

- **Improved resistance to steam and caustic cleaning fluids vs bisphenol-cured FKM**
- **Superior steam resistance compared to silicone**
- **Superior resistance to caustic and acid cleaning fluids vs EPDM.**

The balance of steam and fluid resistance make Viton® GF-600S and Viton® Extreme™ ETP-600S attractive candidates for sealing in food and pharmaceutical processes in comparison to other alternatives, particularly considering that, compared to other elastomeric materials, these polymers also exhibit:

- **Excellent resistance to a wide variety of chemicals and fluids used as food flavorings**
- **Significantly lower total organic carbon extractables**
- **Significantly lower total extractable metals**

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