Viton® fluoroelastomer

A Product of DuPont Dow Elastomers

Bisphenol-Cure Viton® Fluoroelastomers In Compliance With FDA Regulation 21 CFR 177.2600

Introduction

This data sheet pertains to the U.S. Federal Food and Drug Administration regulations that provide for the use of vulcanizates of Viton fluoroelastomer in the formulation of rubber articles intended for use in repeated food contact applications (21 CFR 177.2600).

Prior to the establishment of compliance for the bisphenol-cured types of Viton listed in this data sheet, only Viton A-HV, A, A-500, and E-60 were in compliance with FDA regulation 21 CFR 177.2600. These polymers can be crosslinked using Diak™ No. 1 (hexamethylenediamine carbamate) and Diak No. 4 (4,4,-bis[aminocyclohexyl] methane carbamate) as long as the concentration does not exceed 1.5 phr (parts per hundred rubber) of Diak No.1 or 2.4 phr of Diak No. 4.

Extraction data submitted in the petition to FDA were obtained from vulcanizates of the compounds shown below:

Viton A	100	100
Magnesium Oxide	15	15
Diak No. 1	1.25	—
Diak No. 4	—	2.0

Vulcanizates were press-cured 30 min at 163°C (325°F) and oven post-cured for 24 hr at 204°C (400°F).

Compounds based on Viton dipolymer cured with diamines are relatively scorchy and exhibit poorer resistance to heat aging and compression set than similar polymers crosslinked with the bisphenol cure system. Viton polymers crosslinked with the bisphenol cure system provide compounds having excellent processing safety and bin storage stability, much improved resistance to heat aging and aqueous media, such as steam and acids, and unsurpassed resistance to compression set. Compression set resistance correlates directly with retention of sealing force: the better the resistance of a vulcanizate to compression set, the longer it will function as an effective seal.

As of October 1996, a broad range of Viton bisphenol-cure precompounds, listed below, were determined to be in compliance with the FDA food contact regulation 21 CFR 177.2600. These Viton bisphenol-cure precompounds include a wide range of viscosities, for the maximum versatility in manufacturing processes. In addition, the list includes A-, B-, and F-types of Viton, to provide for the greatest possible flexibility in terms of end-use properties and service capabilities.

Viton Bisphenol-Cure Precompounds In Compliance With FDA 21 CFR 177.2600

A-Types	B-Types	F-Types
A-201C	B-601C	VTR-7277
A-401C	B-200*	F-605C
A-601C	B-600*	
A-200*		
A-500*		
A-HV*		

*In addition to the incorporated cure precompounds listed above, the gum polymers shown are also in compliance with 21 CFR 177.2600, provided that the curative used is VC #50, at levels less than, or equal to, 2.50 phr of rubber.

Only the Viton precompounds and the Viton gum polymers (cured with VC #50) listed above are in compliance with FDA regulation 21 CFR 177.2600. Bisphenol-cured types of Viton not included in the above list have not been established to be in compliance with 21 CFR 177.2600, such as Viton E-60C, E-430, B-910, and any Viton gum polymer cured with Viton Curatives No. 20 and 30.

There have been no changes, relative to compliance with FDA regulations for the previously listed Viton types, including Viton A, A-500, E-60, and A-HV, cured with Diak No. 1 and Diak No. 4 within the limits described above in paragraph 2 of this data sheet.

Compounding Notes

Test Compounds

Data for establishing compliance with the FDA standards for the bisphenol-cured Viton® products were obtained from vulcanizates having the formulation shown below:

Viton Precompound	100
High Activity MgO	3
Calcium Hydroxide	6

Extraction testing was performed on test slabs that were press-cured for 10 min at 177°C (350°F), followed by an oven post-cure of 24 hrs at 232°C (450°F).

Metal Oxides/Acid Acceptors

Magnesium oxide and calcium hydroxide are regulated under the provisions of FDA 21 CFR 184.1(b)(1) as being Generally Recognized As Safe (GRAS) and may be used in fluoroelastomer compounds designed for food contact, provided they meet Food Chemicals Codex specifications and are used in accordance with Good Manufacturing Practice.

Gum Polymers + Viton Curative VC #50

Viton A-200, A-500, A, E-60, A-HV, B-200, and B-600 are readily cured with Viton Curative No. 50, and, provided the level of VC No. 50 does not exceed 2.50 parts per hundred of rubber, such combinations of polymer and curative are also in compliance with the FDA regulations.

Blends of Different Viscosity Viton Bisphenol-Cure Precompounds

High and low viscosity precompounds can be blended together to obtain intermediate compound viscosities. This capability can be used to optimize the processibility of a compound for particular manufacturing processes. For example, a 50/50 (wt%) blend of Viton A-201C/A-401C will result in a nominal 30 Mooney Viscosity (ML 1+10 at 121°C [249°F]) polymer.

Blends of Viton Gum Polymers With Bisphenol-Cure Precompounds

The Viton gum polymers listed in this data sheet can be blended with bisphenol cure-containing precompounds to lower the state of cure in a compound. Blending gum polymer with curative-containing precompounds reduces the level of curative, resulting in vulcanizates with lower modulus, higher elongation, increased tear resistance, and greater resistance to flex fatigue. Reducing the state of cure of a given compound will also result in some decrease in resistance to compression set (see *Table 3*).

FDA Regulated Fillers

(As of October 1996, the use of all carbon blacks, including those previously approved for use in food contact applications, was under question. Refer to your supplier of carbon black for updated information.)

Recommended fillers for use in compounds of Viton that are in compliance with FDA regulations include USP grade barium sulfate and titanium dioxide. Both these fillers are approved for use in items intended for repeated (food contact) use, under 21 CFR 177.2600, section v., and both of these fillers provide compounds that exhibit excellent processing and physical property characteristics (see *Tables 1*, *2*, and *3*).

Summary

Table 1 outlines representative processing and physical properties of barium sulfate-filled compounds based on various types of bisphenol-cured Viton products which are in compliance with FDA regulation 21 CFR 177.2600, compared to a Viton A-type cured with Diak™ No. 4.

Table 2 compares two different fillers approved for use in food contact applications in 60A and 80A duromoter compounds based on A- and F-types that are in compliance with FDA regulation 21 CFR 177.2600.

Table 3 shows examples of various blends of compliant grades of Viton, demonstrating the effect on physical properties of reducing the level of cross-linking agent by blending precompounds with gum polymer.

Figure 1 depicts the advantages in heat aging, resistance to steam, and compression set provided by bisphenol-cure Viton precompounds, compared to diamine-cured Viton A.

Figure 1a displays the percent change in tensile strength, elongation at break, and hardness (change in number of points) for the formulations listed in *Table 1*, after aging for two weeks at 250°C (482°F). The bisphenol cure provides a marked improvement in retention of elongation at break. Thus, in applications involving exposure to high heat, bisphenol-cure Viton precompounds will retain flexibility significantly better than diamine-cured Viton A.

Figure 1b shows the excellent retention of elongation at break and the much reduced change in hardness typical of bisphenol-cured Viton polymers after aging for two weeks in 80 psi (^{3}160°C [320°F]) steam. Viton A, cured with Diak No. 4, shows a significantly higher loss in elongation at break and a much greater increase in hardness than the bisphenol-cure Viton precompounds. This significant improvement in steam resistance offers the potential for much longer seal life and greater operational capability, particularly with regard to steam cleaning of food-related process systems.

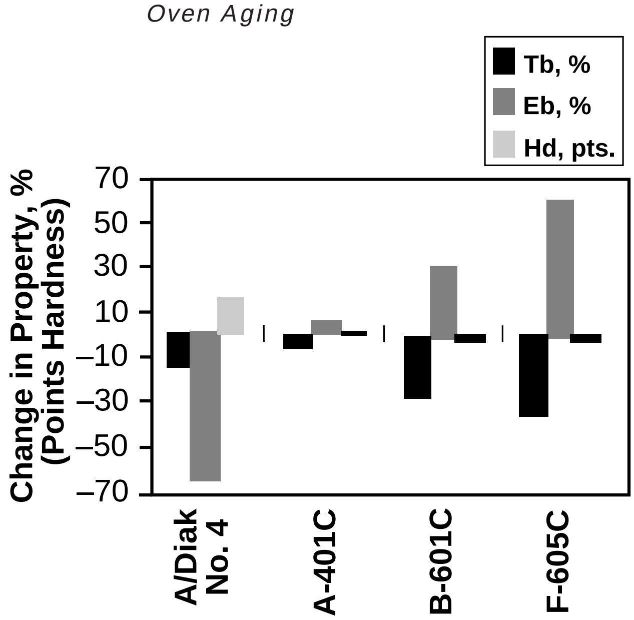
Figure 1c compares compression set values (Method “B,” measured on O-rings) for bisphenol-cured compounds of Viton®, versus a compound based on Viton A, cured with Diak™ No. 4. The crosslinks established during vulcanization using the bisphenol cure system have significantly greater thermal stability than those created using diamines, and this increased stability is reflected in the superior resistance to compression set provided by this cure system. Improved compression set resistance results in improved seal life in actual service.

Handling Precautions

Under ordinary handling conditions, Viton fluoroelastomer polymers and products based on them present no health hazards of which DuPont Dow Elastomers is aware. However, there are potential hazards that result from the use of certain compounding ingredients or from high temperature processing and service conditions. Before proceeding with any compounding or processing work, consult and follow label directions and handling precautions from suppliers of all ingredients.

Figure 1. Bisphenol-Cured Viton Precompounds versusDiamine-Cured Viton A

Figure 1a. Change in Properties After Two Weeks at 250°C (482°F) Oven Aging



For a complete review of handling precautions and the health and hazard-related information on Viton, see Bulletin H-71129-02, “Handling Precautions for Viton® and Related Chemicals,” and the Material Safety Data Sheet for the specific products of interest.

Figure 1b. Change in Properties After Two Weeks in 80 psi Steam

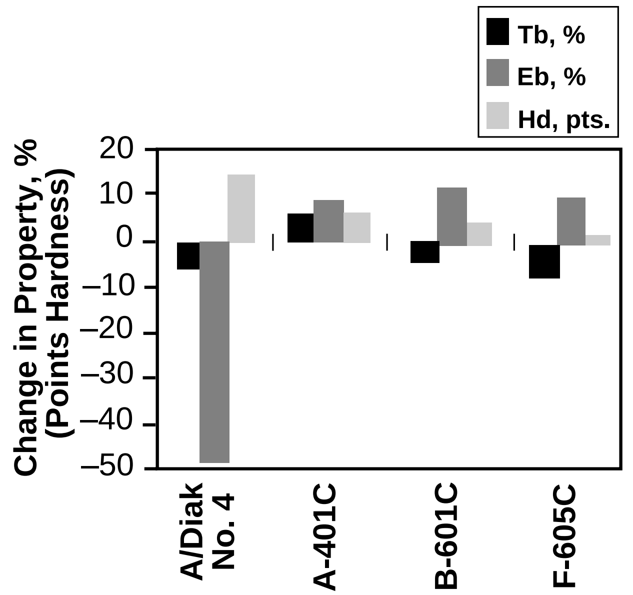


Figure 1c. Compression Set–”B,” O-Rings: After Aging at 150°C (302°F), 200°C (392°F)

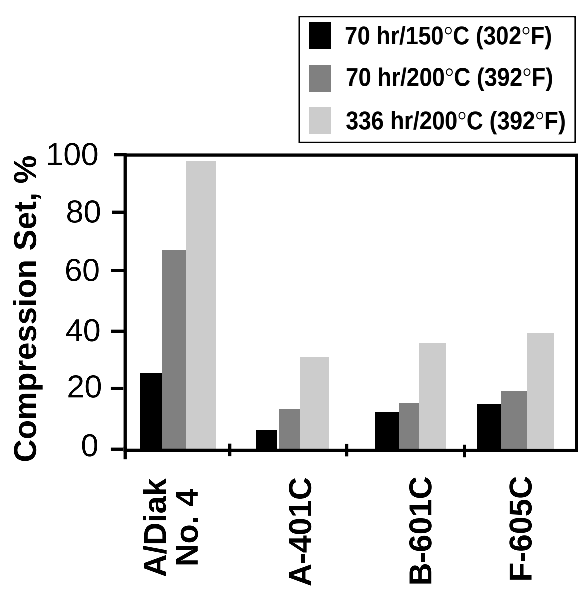


Table 1
Viton® A/Diak™ No. 4 versus Bisphenol-Cured Viton Precompounds

Compound Designation:	A-1	B-1	C-1	D-1	E-1
Compound Formulation					
Viton A	100	—	—	—	—
Viton A-201C	—	100	—	—	—
Viton A-401C	—	—	100	—	—
Viton B-601C	—	—	—	100	—
Viton F-605C	—	—	—	—	100
Low Activity Magnesium Oxide	15	—	—	—	—
High Activity Magnesium Oxide	—	3	3	3	3
Calcium Hydroxide	—	6	6	6	6
Blanc Fixe	35	35	35	35	35
Diak No. 4	2.5	—	—	—	—
	152.5	144.0	144.0	144.0	144.0
Mooney Scorch—MS at 121°C (250°F)					
Minimum Viscosity—Mooney Units	37	22	43	54	61
Time to Increase 2 pts, min	14.6	>30	28.0	26.0	21.4
Time to Increase 5 pts, min	18.5	>30	>30	>30	25.5
ODR at 177°C (350°F), 3° Arc, 12 Min Motor					
Minimum Viscosity—Ml, in·lb	12.3	3.9	10.7	13.3	15.3
Scorch—ts2, min	1.9	2.6	2.3	4.2	2.2
Maximum Torque—Mh, in·lb	95.4	88.3	108.3	94.4	89.0
50% Cure—tc50, in·lb	53.9	46.1	59.5	53.9	52.2
Time to 50% Cure— tc50, min	5.0	3.4	3.2	6.2	3.5
90% Cure— tc90, in·lb	87.1	79.9	98.5	86.3	81.6
Time to 90% Cure—tc90, min	9.1	4.3	4.4	6.8	4.5
MDR at 177°C (350°F), 1° Arc, 12 Min Motor					
Minimum Viscosity—Ml, in·lb	1.2	0.3	1.1	1.5	1.5
Scorch—ts2, min	1.5	1.2	17.6	3.1	1.3
Maximum Torque—Mh, in·lb	15.5	13.8	17.6	17.9	11.7
50% Cure—tc50, in·lb	8.4	7.1	9.4	9.7	6.6
Time to 50% Cure—tc50, min	3.4	1.3	1.3	3.5	2.0
90% Cure—tc90, in·lb	14.1	12.5	15.9	16.2	10.7
Time to 90% Cure—tc90, min	7.5	2.1	2.1	5.2	2.6
Stress/Strain—Original—Cured 10'/177°C (350°F) + Oven—24 hr/232°C (450°F)					
100% Modulus, psi	770	430	500	470	500
Tensile Strength at Break, psi	2,400	1,450	1,600	1,750	1,725
Elongation at Break, %	250	260	265	290	290
Hardness, Durometer A	70	63	64	65	68
Stress/Strain—After Two Weeks at 250°C (500°F)					
100% Modulus, psi	—	400	440	300	290
Tensile Strength at Break, psi	2,075	1,400	1,500	1,275	1,125
Elongation at Break, %	90	265	280	380	470
Hardness, Durometer A	86	65	65	60	66
∆ Stress/Strain—After Two Weeks at 250°C (500°F)					
∆ 100% Modulus, %	—	–7	–12	–36	–42
∆ Tensile Strength, %	–14	–3	–6	–27	–35
∆ Elongation at Break, %	–64	2	6	31	62
∆ Hardness, No. of pts	16	2	1	–5	–2
Stress/Strain—After Two Weeks in 80 psi Steam					
100% Modulus, psi	1,890	610	610	520	520
Tensile Strength at Break, psi	2,250	1,475	1,700	1,675	1,575
Elongation at Break, %	135	250	290	330	315
Hardness, Durometer A	83	69	71	69	70
∆ Stress/Strain—After Two Weeks in 80 psi Steam					
∆ 100% Modulus, %	145	42	22	11	4
∆ Tensile Strength, %	–6	2	6	–4	–9
∆ Elongation at Break, %	–46	–4	9	14	9
∆ Hardness, No. of pts.	13	6	7	4	2
∆ Volume Change, %	–0.5	–1.5	–1.8	–2.1	–1.7
Compression Set—Method "B" (O-Rings)					
70 hr at 150°C (302°F)	20	5	6	9	18
70 hr at 200°C (392°F)	46	6	6	10	19
336 hr at 200°C (392°F)	97	30	34	30	42

Table 2
Bisphenol-Cure Viton® Precompounds
in 60A and 80A Hardness Formulations

Compound Designation:	**A-2**	**B-2**	**C-2**	**D-2**	**E-2**	**F-2**	**G-2**	**H-2**
Formulation:								
Viton A-401C	100	100	—	—	100	100	—	—
Viton F-605C	—	—	100	100	—	—	100	100
High Activity Magnesium Oxide	3	3	3	3	3	3	3	3
Calcium Hydroxide	6	6	6	6	6	6	6	6
Blanc Fixe	15	80	15	80	—	—	—	—
Ti-Pure® R-960 (TiO_2)	—	—	—	—	10	60	10	60
	124.0	189.0	124.0	189.0	119.0	169.0	119.0	169.0
ODR at 177°C (350°F), 3° Arc, 12 Min Motor								
Minimum Viscosity—Ml, in·lb	10.5	13.1	16.2	22.9	10.9	12.3	16.3	23.1
Scorch—ts2, min	2.5	2.0	2.4	1.6	2.7	2.4	2.4	2.1
Maximum Torque—Mh, in·lb	100.5	133.8	83.5	95.0	96.9	110.1	80.8	78.3
50% Cure—tc50, in·lb	55.5	73.5	49.9	59.0	53.9	61.2	48.6	50.7
Time to 50% Cure—tc50, min	3.4	2.9	3.6	2.4	3.6	3.6	3.8	3.3
90% Cure—tc90, in·lb	91.5	121.7	76.8	87.8	88.3	100.3	74.4	72.8
Time to 90% Cure—tc90, min	4.3	5.7	4.3	3.0	4.0	4.8	4.6	4.1
Stress/Strain—Original at 23°C (73°F)—Cured 10'/177°C + Oven—24 hr/232°C (450°F)								
100% Modulus, psi	340	770	280	680	315	1,030	260	810
Tensile Strength at Break, psi	1,650	1,775	1,850	1,800	1,775	2,325	2,200	1,950
Elongation at Break, %	290	260	300	320	275	175	345	185
Hardness, Durometer A	59	78	61	80	58	76	60	80
Compression Set—Method "B" (O-Rings)								
70 hr at 150°C (302°F)	6	7	12	19	7	8	15	36
70 hr at 200°C (392°F)	8	12	17	22	10	14	22	37
336 hr at 200°C (392°F)	28	30	37	39	29	31	38	56

Table 3
Bisphenol-Cure Viton® Precompounds
Blended With Viton Gum Polymer

Compound Designation:	**A-3**	**B-3**	**C-3**	**E-3**	**F-3**	**G-3**
Formulation:						
Viton A-401C	100	80	60	—	—	—
Viton A-500	—	20	40	—	—	—
Viton B-601C	—	—	—	100	80	60
Viton B-600	—	—	—	—	20	40
High Activity Magnesium Oxide	3	3	3	3	3	3
Calcium Hydroxide	6	6	6	6	6	6
Blanc Fixe	35	35	35	35	35	35
	144.0	144.0	144.0	144.0	144.0	144.0
ODR at 177°C (350°F), 3° Arc, 12 Min Motor						
Minimum Viscosity—Ml, in·lb	10.7	13.1	8.9	13.3	12.3	8.7
Scorch—ts2, min	2.3	2.1	1.8	4.2	2.4	3.0
Maximum Torque—Mh, in·lb	108.3	83.5	69.7	94.4	76.7	53.4
50% Cure—tc50, in·lb	59.5	48.3	39.3	53.9	44.5	31.1
Time to 50% Cure - tc50, min	3.2	2.9	2.4	6.2	4.9	4.0
90% Cure—tc90, in·lb	98.5	76.5	63.6	86.3	70.3	48.9
Time to 90% Cure—tc90, min	4.4	3.9	3.4	6.8	5.8	4.5
Stress/Strain—Original at 23°C (73°F)—Cured 10'/177°C (350°F) + Oven—24 hr/232°C (450°F)						
100% Modulus, psi	500	440	320	470	360	245
Tensile Strength at Break, psi	1,600	1,550	1,600	1,750	1,725	1,650
Elongation at Break, %	265	320	380	290	360	530
Hardness, Durometer A	64	62	61	65	63	61
Compression Set—Method "B" (O-Rings)						
70 hr at 150°C (302°F)	6	7	13	9	12	15
70 hr at 200°C (392°F)	8	12	13	10	16	30
336 hr at 200°C (392°F)	28	30	36	30	38	46

For more information on Viton® or other elastomers:

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