

USP & FDA Specialty Elastomers

No. 5408B1-USA

USP Class VI and FDA "White List" Silicone and Organic Elastomer Compounds for Healthcare Products

The Parker JBL Division offers a wide range of USP Class VI and FDA elastomeric materials for the Healthcare Industry. These materials can be supplied as precision extruded and cut seals used as static face or static radial seals, long length precision extruded profiles, or precision extruded and spliced rings or gaskets.

USP Class VI Materials

JBL's offering of United States Pharmacopia (USP) XXII Class VI materials have been tested to (USP) XXII Class VI testing requirements which include: System Toxicity, and Intracutaneous Toxicity. JBL products are sold as industrial grade products only, for use in non-implant devices. It is the customer's responsibility to determine the suitability of JBL products for each specific application and to comply with all applicable statutory, regulatory, and health care industry requirements and/or standards for efficacy, labeling, safety and testing. JBL's USP Class VI materials and products have batch traceability (CBI) for each lot of product produced.

FDA "White List" Materials

JBL's FDA "White List" materials are formulated exclusively from ingredients listed in Federal Regulation Title 21 "Food and Drugs," CFR 177.2600, "Rubber Articles Intended for Repeated Use," and have batch traceability. Please note that the FDA does not "approve" rubber compounds. It is the responsibility of the manufacturer to compound food-grade materials from the FDA list of ingredients and establish whether they pass the requisite requirements.



Specify JBL USP Class VI and FDA Silicone Materials

Silicone Compounds Meeting USP Class VI Requirements

Typical Physical Properties

Compound	S7577-40	S7433-50	S7489-50	S7530-55	S7492-70	S7383-80
Material	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Color	Translucent	White	Translucent	Translucent	Translucent	White
Durometer +/- 5	40	50	50	55	70	80
Tensile	850	1100	1150	1000	1300	1000
Elongation	700	750	600	350	450	300
100% Modulus	90	125	150	200	400	500
Specific Gravity	1.10	1.12	1.10	1.13	1.15	1.19
Compression Set *	20	20	30	25	20	25

* Compression Set 22 Hrs. @ 177° C

Applications:

- Infusion Pumps • Check Valves • Specimen Vials
- Luers and Connectors • Dental Products • Surgical Instruments/Tools • Fittings
- Lid or Cap Seals for Bottles • Filters • Intravenous Feeding Devices
- Drug Doseage Packs • Flow Controls • Laboratory Ware • Culture Containers
- Dental Implants • Endoscopes • Syringes • Catheters • Face Mask Respirators
- Injection Sites

Parker Silicone Compounds made With FDA "White List" Ingredients Typical Physical Properties

Compound	S7317-40	S7561-40	S7318-50	S7405-50	S7435-50	S7469-50	S7311-55
Material	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Color	Translucent	White	White	Translucent	Rust	Red	Rust
Durometer +/- 5	40	40	50	50	50	50	50
Tensile	1257	1000	1100	1200	1250	1300	1100
Elongation	638	550	325	400	400	350	300
100% Modulus	111	80	150	150	100	150	300
Specific Gravity	1.14	1.10	1.11	1.13	1.14	1.21	1.21
Compression Set *	12	30	25	20	16	15	20

Compound	S7396-55	S7349-60	S7350-60	S7351F-60	S7354-60	S7355-60	S7359-60
Material	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Color	White	Red	Green	White	Blue	White	Black
Durometer +/- 5	55	60	60	60	60	60	60
Tensile	925	1000	1000	950	1200	1100	1100
Elongation	250	300	300	225	350	300	400
100% Modulus	375	300	400	400	350	300	200
Specific Gravity	1.26	1.23	1.27	1.27	1.25	1.34	1.23
Compression Set *	22	25	25	16	20	20	20

Compound	S7413-60	S7526-60	S7314F-70	S7494-70	S7525-70	S7386F-75	S7300F-80
Material	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Color	Rust	Yellow	Black	Red	White	White	White
Durometer +/- 5	60	60	70	70	70	75	80
Tensile	1000	850	900	900	850	900	900
Elongation	200	300	150	150	150	100	100
100% Modulus	350	300	450	500	504	700	800
Specific Gravity	1.24	1.23	1.30	1.33	1.33	1.36	1.40
Compression Set *	30	25	25	20	16	20	20

Compound	S7309-80	S7313-80	S7548-80	S7568-80
Material	Silicone	Silicone	Silicone	Silicone
Color	Black	Blue	Blue	Red
Durometer +/- 5	80	80	80	80
Tensile	800	800	800	825
Elongation	100	100	100	100
100% Modulus	500	700	600	700
Specific Gravity	1.42	1.40	1.42	1.39
Compression Set *	25	30	25	25

Parker Organic Compounds made with FDA "White List" Ingredients Typical Physical Properties

Compound	E7110-55	E7190-60	E7182-70	E7752-70	E7893-70	E7925-70	E7871-75
Material	EPDM	EPDM	EPDM	EPDM	EPDM	EPDM	EPDM
Color	Black	Black	Black	Black	Off-White	Black	Black
Durometer +/- 5	55	60	70	70	70	70	75
Tensile	1400	1400	1500	1600	600	1600	1900
Elongation	600	300	300	450	300	100	200
Specific Gravity	1.16	1.17	1.19	1.14	1.42	1.37	1.17
Compression Set *	25	19	20	45	17	8	13
Curative	Peroxide	Peroxide	Peroxide	Sulfur	Peroxide	Peroxide	Peroxide

Compound	E7126-80	E7823-80	E7885-90	V7826-65	V7108-70	V7832-75	V7839-90
Material	EPDM	EPDM	EPDM	Fluorocarbon	Fluorocarbon	Fluorocarbon	Fluorocarbon
Color	Black	Black	Black	Black	White	Black	White
Durometer +/- 5	80	80	90	65	70	75	90
Tensile	1700	1750	1900	1150	2000	1400	1600
Elongation	175	100	100	150	200	250	125
Specific Gravity	1.2	1.17	1.22	1.94	2.11	1.77	2.41
Compression Set *	17	10	27	15	24	8	20
Curative	Peroxide	Peroxide	Peroxide	Bisphenol	Bisphenol	Bisphenol	Bisphenol

Compound	N7068-70	N7747-70	N7747-70	N7212-80	N7219-80	N7203-90
Material	Nitrile	Nitrile	Nitrile	Nitrile	Nitrile	Nitrile
Color	Black	Black	Black	Black	Black	Black
Durometer +/- 5	70	70	70	80	80	90
Tensile	1300	1800	1700	1800	2300	2400
Elongation	500	350	300	150	150	150
Specific Gravity	1.40	1.05	1.27	1.41	1.44	1.32
Compression Set *	21	17	26	13	31	17
Curative	Peroxide	Peroxide	Sulfur	Peroxide	Peroxide	Sulfur

*Silicone Materials - Compression Set 22 Hrs. @ 177°C
 EPDM Materials - Compression Set 22 Hrs. @ 70°C
 Fluorocarbon Materials - Compression Set 22 Hrs. @ 175°C
 Nitrile Materials - Compression Set 22 Hrs. @ 100°C

For complete Test Reports and samples, contact:

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