Life Sciences

FDA and USP Class VI O-Ring Materials

Innovative sealing:

Parker provides a wide range of specialty elastomers to accommodate the various critical sealing challenges presented by the life sciences industry. Selecting a suitable material is critical to patient health. While the FDA Standard 21 CFR 177.2600 is frequently cited by medical device manufacturers, this is actually a contact food regulation. For most patient-contact applications, a material that meets US Pharmacopeia (USP) Class VI and/or ISO 10993/10 will be appropriate.

Most applications are fairly benign to elastomers. However, some applications such as implantable devices, are extremely complicated. Please contact the division for assistance in selecting materials in these situations.

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Features and Benefits:

- Specially formulated for long term sealing
- Compounds made without animal-derived ingredients (BSE/TSE concerns)

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Properties of commonly used elastomers in the life sciences industry																
(P) Poor (F) Fair (G) Good (E) Excellent Elastomer type (polymer)	Parker compound prefix letter	Alcohol resistance	Abrasion resistance	Acid resistance	Base resistant	Compression set resistance	Cold resistance	Extractibles	Heat resistance	Gas permeation	Tear resistance	Tensile strength	CIP sterilization	Gamma sterilization	Ozone sterilization	Steam sterilization
Silicone (VMQ)	S	G	P	F	F	E	E	G	E	P	P	P	G	E	E	G
Ethylene propylene (EPDM)	E	E	G	G	E	G/E	E	G	G	G	G	G	E	E	E	E
Fluorocarbon (FKM)	V	**	G	E	P	E	F	G	E	E	F	G	E	F	E	**
Perfluorinated (FFKM)	FF	E	F	E	E	G	P	E	E	G	F	F	E	F	E	E
Nitrile (NBR)	N	F	G	F	F	G	G	F	G	G	G	G	G	G	P	F

Sterilization: In many life science applications, the normal usage environment is fairly benign to the elastomer. For equipment or devices that will undergo multiple sterilization cycles throughout its life, only seals rated excellent or good-to-excellent with the intended sterilization method should be selected. For items that will only be sterilized once, a seal material rated good or better in that sterilization method is preferred.
**Parker's V0680-70 is rated fair; V1274-80 is rated good.

FDA and USP Class VI O-ring materials for life sciences					
Parker Compound	Polymer	Hardness	Color	Temperature Range (°)	Service
E3609-70	EPDM	70	Black	-70 to 250	FDA*, USP VI, USP 87, ISO 10993
E1028-70	EPDM	70	Black	-70 to 250	FDA
E1244-70	EPDM	70	Black	-70 to 250	Internally lubed, USP Class VI, USP <87>
E7736-70	EPDM	70	Black	-70 to 250	FDA, extruded parts
E0740-75	EPDM	75	Black	-70 to 250	USP Class VI, low comp. set, animal-free
EJ243-45	EPDM	45	Black	-70 to 250	Not for milk, edible oils
FF156.75	FFKM	75	Black	5 to 525	Broad chemical resistance, USP Class VI
FF500-75	FFKM	75	Black	5 to 525	FDA*, animal-free, USP <87>
FF580-75	FFKM	75	Black	5 to 525	Steam resistance, animal-free, FDA*
N1220-70	NBR	70	Black	-30 to 225	FDA
S0469-40	VMR	40	Rust	-75 to 400	USP VI
S0802-40	VMQ	40	White	-60 to 400	FDA, animal-free
S7442-45	VMQ	45	Rust	-65 to 400	FDA, extruded parts
S7318-50	VMQ	50	White	-65 to 400	FDA, extruded parts
S7405-50	VMQ	50	Translucent	-65 to 400	FDA, extruded parts
S7435-50	VMQ	50	Rust	-65 to 400	FDA, extruded parts
S0317-60	VMQ	60	Rust	-103 to 450	FDA, USP VI, animal-free
SA576-65	VMQ	65	Blue	-65 to 400	FDA, USP Class VI, USP <87>, animal-free, extruded parts
S1138-70	VMQ	70	Rust	-60 to 400	FDA, animal-free, USP VI, USP <87>
S1435-70	VMQ	70	Rust	-65 to 400	FDA,
SJ201-70	VMQ	70	Translucent	-65 to 400	USP Class VI, USP <87>< extruded parts
V0680-70	FKM	70	Red	-15 to 400	FDA, animal-free, USP VI
V7754-75	FKM	75	Black	-15 to 400	USP Class VI, extruded parts
V1274-80	FKM	80	Black	-15 to 400	FDA, USP VI, steam resistance, animal-free, ISO 10993-5, ISO 10993-10

* Meets extraction requirements

Note: Compounds listed as "animal-free" contain no ingredients derived from animal origin. Compounds lacking this description may contain small amounts of animal-derived ingredients that have been processed in accordance with EMA/410/01 Rev 3 Section 6.4 and therefore are unlikely to present a TSE risk.

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