

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. For this reason, the FDA provides a standard (21 CFR 177.2600) defining allowable rubber compound ingredients and extractibles based on toxicity and carcinogenicity. For most patient-contact applications, a material that meets US Pharmacopeia (USP) Class VI and/or ISO 10993/3 will be required.

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.



Contact Information:

Parker Hannifin Corporation
O-Ring Division
2360 Palumbo Dr.
Lexington, KY 40509

phone 859 269 2351
fax 859 335 5128

www.parker.com

Features and Benefits:

- 7 USP Class VI materials (EPDM, silicone, fluorocarbon, and perfluoroelastomer)
- 24 materials which are compliant to FDA, 21 CFR177.2600
- 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

Elastomer type (polymer)	Parker compound prefix letter	Alcohol resistance	Abrasion resistance	Acid resistance	Compression set resistance	Cold resistance (< 0°F)	Dynamic properties	Electrical insulation	Flame resistance	Heat resistance	Resistance to gas permeation	Tear resistance	Tensile strength	Weathering resistance	CIP sterilization	Gamma sterilization	Ozone sterilization	Steam sterilization
Silicone (VMQ)	S	G	P	FG	E	E	P	E	F	E	P	PF	P	E	G	E	E	G
Ethylene propylene (EPDM)	E	E	GE	G	GE	GE	GE	G	P	G	G	GE	GE	E	E	E	E	E
Fluorocarbon (FKM)	V	**	G	E	E	F	GE	F	E	E	E	F	GE	E	E	F	E	**
Highly perfluorinated elastomer (HiFluor™)	HF	GE	G	E	G	F	F	E	E	E	G	F	F	E	E	F	E	F
Perfluorinated (FFKM)	FF	E	F	E	G	P	F	E	E	E	G	PF	FG	E	E	F	E	GE
Nitrile (NBR)	N	F	G	F	GE	G	GE	F	P	GF	FG	FG	GE	F	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
EJ280-70	EPDM	70	Black	-70 to 250	FDA, USP VI, Animal-free
E3609-70	EPDM	70	Black	-70 to 250	FDA*, USP VI
E1028-70	EPDM	70	Black	-70 to 250	FDA
FF200-75	FFKM	75	Black	5 to 608	FDA*, animal-free
FF350-75	FFKM	75	White	5 to 600	FDA*, USP VI, animal-free
FF500-75	FFKM	75	Black	5 to 525	FDA*, animal-free
FF580-75	FFKM	75	Black	5 to 525	Steam resistance, animal-free, FDA*
HF355-65	HiFluor™	65	Translucent	-15 to 400	FDA*, USP VI, animal-free
N1219-60	NBR	60	Black	-30 to 225	FDA
N1220-70	NBR	70	Black	-30 to 225	FDA
N1069-70	NBR	70	Black	-30 to 180	FDA
N0508-75	NBR	75	Black	-30 to 180	FDA
S0802-40	VMQ	40	White	-60 to 400	FDA, animal-free
S0317-60	VMQ	60	Rust	-103 to 450	FDA, USP VI, animal-free
S1138-70	VMQ	70	Rust	-60 to 400	FDA, animal-free
S0355-75	VMQ	75	Rust	-60 to 450	FDA, animal-free
S1538-55	VMQ	55	Translucent	-60 to 450	FDA, USP VI, animal-free
V0680-70	FKM	70	Red	-15 to 400	FDA, animal-free
V1274-80	FKM	80	Black	-15 to 400	FDA, USP VI, steam resistance, animal-free

* 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 EMEA 410 Section 6.4 and therefore are unlikely to present a TSE risk.

