FDA and USP Class VI O-Ring Materials for Life Sciences

Application Bulletin

No. 5737

Description:
The Life Sciences Industry (medical, drug discovery, pathogen detection, pharmaceutical and bio-tech) has a variety of sealing challenges for critical components and processes. Typically, these applications require the elastomeric seals be made from materials compliant to either FDA or USP Class VI standards.

The Food and Drug Administration (FDA) has established a list of rubber compounding ingredients which tests have indicated are neither toxic nor carcinogenic. Rubber compounds produced entirely from those ingredients and which also pass the FDA extraction tests are said to "fully meet the FDA requirements." 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 necessary extraction requirements to be fully compliant. In addition, compounds that are made from exotic technologies can be tested to the extraction tests only for compliance.

The U.S. Pharmacopoeia (USP) Class VI outlines requirements for system toxicity and intracutaneous toxicity for these "cleaner" compounds. The USP Class VI compounds must be made from ingredients with clear histories of biocompatibility that meet tighter requirements for low extractables.

Parker offers o-rings from 24 specially formulated recipes compliant to FDA Standards; five of these recipes are also compliant to USP Class VI.

Typical Applications:
FDA and USP Class VI materials are available in all standard o-ring dimensions (AS568), custom o-ring sizes, and specialty molded products. Parker's recipes are formulated for excellent long term sealing properties in many Life Science applications, which include: steam, high temperature, and fluid resistance to aggressive chemistries, high purity, and low extractables.

Features and Benefits:
- ✓ 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

More than Manufacturing
Parker Hannifin is a leading supplier of o-ring sealing products. Parker has a range of customer support tools, including a dedicated sales and applications engineering staff, research and development team, finite element analysis (FEA) capabilities, Total inPHorm™ seal design software, and unparalled worldwide local logistics through Parker Distributors and Service Centers.

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Properties of Commonly Used Elastomers in the Life Sciences

P - Poor
F - Fair
G - Good
E - Excellent

Elastomer Type (Polymer)	Parker Compound Prefix Letter	Abrasion Resistance	Acid Resistance	Chemical Resistance	Cold Resistance	Dynamic Properties	Electrical Properties	Flame Resistance	Heat Resistance	Impermeability	Oil Resistance	Ozone Resistance	Set Resistance	Tear Resistance	Tensile Strength	Water / Steam Resistance	Weathering Resistance	Vegetable Oil Resistance
Ethylene Propylene (EPDM)	E	GE	G	E	GE	GE	G	P	G	G	P	E	GE	GE	GE	E	E	P
Fluorocarbon (FKM)	V	G	E	E	PF	GE	F	E	E	E	E	E	GE	F	GE	FG	E	E
Nitrile (NBR)	N	G	F	FG	G	GE	F	P	FG	FG	E	P	GE	FG	GE	FG	F	E
Perfluorinated (FFKM)	FF	P	E	E	PF	F	E	E	E	E	E	E	G	PF	FG	GE	E	E
ESilicone (VMQ)	S	P	FG	GE	E	P	E	F	E	P	FG	E	GE	PF	P	FG	E	E

FDA and USP Class VI O-Ring Materials for Life Sciences

PARKER COMPOUND	POLYMER	HARD-NESS	COLOR	TEMP RANGE (°F)	SERVICE
EJ150-75 (3077)	EPDM	75	Black	-70 to 250	FDA
E3609-70	EPDM	70	Black	-70 to 250	FDA**, USP Class VI
E1028-70	EPDM	70	Black	-70 to 250	FDA
V8545-75	FFKM	75	Black	5 to 572	FDA **
V8562-75	FFKM	75	White	5 to 572	FDA **
FF200-75	FFKM	75	Black	5 to 608	FDA**
FF350-75	FFKM	75	White	5 to 600	FDA**, UPS Class VI
FF500-75	FFKM	75	Black	5 to 525	FDA**
V0680-70	FKM	70	Red	-15 to 400	FDA
HF351-65	FKM	65	Translucent	-15 to 400	FDA**, USP Class VI
NJ253-70 (7077)	NBR	70	Black	-35 to212	FDA
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
S0317-60	VMQ	60	Rust	-103 to 450	FDA, USP Class VI
S1138-70	VMQ	70	Rust	-60 to 400	FDA
SM150-40 (11354)	VMQ	40	Rust	-60 to 400	FDA
SM151-50 (11355)	VMQ	50	Rust	-70 to 400	FDA
SM152-60 (11356)	VMQ	60	Rust	-60 to 450	FDA
SM153-70 (11357)	VMQ	70	Rust	-60 to 450	FDA
S0355-75	VMQ	75	Rust	-60 to 450	FDA
S1538-55	VMQ	55	Translucent	-60 to 450	FDA, USP Class VI

* Note, Compound numbers in (xxxxx) are the obsolete Wynn's Precision compound numbering system.
** Meets extraction requirements

09/03-2.5M-CE

Questions? Contact a Parker Applications Engineer for assistance (859) 335-5101.

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