
FEP/PFA ENCAPSULATED O-RINGS

REGULATORY COMPLIANCE

FEP / PFA Encapsulation

FDA

The clear TEFLON FEP/PFA Encapsulation of our FEP/PFA Encapsulated O-Rings complies with Part 177 of Title 21 of the Food and Drug Administration regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food in accordance with FDA regulation 21.CFR.177.1550.

3A® Sanitary Standard

Further, we can advise that Table One (attached) of number 20-22 3A® Sanitary Standard documents that FEP and PFA materials, to the previously mentioned FDA 21.CFR.177.1550 Compliance standard, is also compliant to this 3A® Sanitary Standard Number 20-22.

USP Class VI

Teflon® FEP/PFA fluoropolymers have been tested in accordance with USP Protocol and meet the requirements of a USP Class VI plastic.

Silicone Core

FDA

The Silicone core of our FEP/PFA Encapsulated O-Rings complies with Part 177 of Title 21 of the Food and Drug Administration regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food in accordance with FDA regulation 21.CFR.177.2600.

USP Class VI

The Silicone compound has been tested in accordance with USP Protocol and meets the requirements of a USP Class VI plastic.

All information is correct at time of publication. However, as we constantly review and improve specifications, we reserve the right to change without prior notice. For any specific query regarding regulatory approval please contact our technical department.

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Viton Core

FDA

FDA compliant Viton Core can be specified but is subject to minimum order restrictions. Please contact us for details.

Please contact me if you require any further information on any aspect of RALICKS FEP/PFA O-Rings.

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TABLE 1- Plastics included in these standards

Generic Classes (code of Federal Regulations citation)	Maximum % Weight Gain		
	Section E Cleanability Response	Section F Product Treatment (Solution I)	Section F Product Treatment (Solution J)
Acrylics (21 CFR 177.1010)	0.20	0.50	1.50
Acrylonitrile butadiene styrene (21 CFR 177.1020)	0.30	0.45	0.90
Chlorinated polyether (21 CFR 177.2430)	0.05	0.05	0.05
Cross-linked polyester resins (vinyl ester-styrene copolymer) (21 CFR 177.2420)	0.20	0.02	0.20
Epoxy resin as coating (21 CFR 175.300) (a) Isopropylidenediphenol Hardener-TETA Triethylenetetramine (b) Phenol-Formaldehyde Polymer, glycidyl ether (silica filled) Hardener - DETA Adduct	0.10 0.15	0.15 0.15	0.25 2.00
Ethylene-vinyl acetate copolymers (21 CFR 177.1350)	0.25	0.55	0.10
Fluorocarbons (21 CFR 170.39, 177.1380, 177.1550, 177.2510) (a) CTFE, PTFE, FEP, PFA, and ETFE types (b) Vinylidene fluoride types	0.05 0.05	0.05 0.05	0.05 0.15
Nylon (21 CFR 177.1500) (a) Nylon Type 66 (b) Nylon Type 610 (c) Nylon Type 6	2.00 1.00 2.00	3.00 2.00 3.00	8.00 4.00 8.00
Nylon 66-Nylon 6-aramid fiber blend (21 CFR 177.1500, 177.1632)	2.00	3.00	8.00
Nylon 66-Nylon 6-aramid fiber-PTFE blend (21 CFR 177.1500, 177.1380, 177.1632)	2.00	3.00	8.00
Plasticized polyvinyl chloride (21 CFR 175.300) (a) For contact with high-water, low-fat products (~8% milk fat) (b) For contact with high-fat products (>8% milk fat)	0.25 0.10	0.55 0.20	0.90 0.55
Poly (aryletherketone) resins (21 CFR 177.2415)	0.10	0.20	0.50
Polyarylsulfone resin (21 CFR 177.1560)	0.40	0.80	1.50
Polycarbonates (21 CFR 177.1580)	0.10	0.15	0.25

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Polyetherimide (21 CFR 177.1595)	0.20	0.25	0.75
Polyethylene (21 CFR 177.1520)			
(a) ASTM Type I	0.20	0.50	0.20
(b) ASTM Type II	0.20	0.20	0.20
(c) ASTM Type III	0.20	0.20	0.20
(d) Ultra-high molecular weight polyethylene (UHMWPE)	0.20	0.50	0.20
Polyethylene phthalate polymers (21 CFR 177.1630)	0.10	0.15	0.65
Polymethylpentene (21 CFR 177.1520)	0.10	0.20	0.20
Polyoxymethylene copolymer (21 CFR 177.2470)	0.25	0.60	1.00
Polyoxymethylene homopolymer (21 CFR 177.2480)	0.40	0.50	1.40
Polyphenylene oxide (21 CFR 177.2460)	0.10	0.15	0.25
Polyphenylene sulfide (21 CFR 177.2490)	0.06	0.08	0.08
Polyphenylene sulfide-PTFE (alloy) (21 CFR 177.2490, 177.1380)	0.06	0.08	0.30
Polyphenylsulfone (repeated use)	0.40	0.80	1.50
Polypropylene - (unmodified and modified for impact resistance) (21CFR 177.1520)	0.10	0.20	0.20
Polystyrene - Normal (unmodified) Type 3 of ASTM D703-78 (21 CFR 177.1640)	0.10	0.10	0.10
Polystyrene - Modified (impact), Type III, Grade 6, of ASTM D1892-78 (21 CFR 177.1640)	0.10	0.10	0.10
Polysulfone resin (21 CFR 177.1655)	0.05	0.10	0.10
Polysulfone-PTFE (alloy) (21 CFR 177.1655, 177.1380)	0.30	0.45	0.45
Polytetramethylene terephthalate (21 CFR 177.1660)	0.10	0.15	0.65
Polytetramethylene terephthalate-PTFE blend (21 CFR 177.1660, 177.1380)	0.10	0.15	0.65
Polyurethane (21 CFR 177.1680)	1.22	1.59	1.29
Propoxylated bisphenol-A fumarate polyester-styrene copolymer (21 CFR 177.2420)	0.20	0.20	0.20
Reinforced epoxy, molded, natural (no color added), and black (21 CFR 175.300)	0.20	0.25	0.35
Styrene-acrylonitrile (21 CFR 177.1040)	0.20	0.50	0.50
Thermoplastic polyether-ester (21 CFR 177.2600)	0.35	1.10	0.50

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