
FEP/PFA ENCAPSULATED O-RINGS

REGULATORY COMPLIANCE

FEP / PFA Encapsulation

FDA

The clear FEP/PFA Encapsulation of our FEP/PFA Encapsulated O-Ring 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 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 Chapter 87 & 88 Class VI

FEP/PFA fluoropolymers have been tested in accordance with USP Protocol and meet the requirements of a USP Class VI plastic. In that only the FEP/PFA Encapsulation comes into contact with the product, our FEP/PFA Encapsulated O-Rings are considered to be USP Chapter 87 & 88 Class VI compliant. For information on our Core Materials, please see below.

EU VO 1935/2004 & 10/2011

RALICKS has researched and evaluated BFR documentation especially "Recommendations of the Federal Institute for Risk Assessment on Plastics intended to come in to contact with Food".

The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

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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On our Encapsulated O-Rings, the outer encapsulate is a FEP or PFA melt processable polymer of P.T.F.E. These material P.T.F.E polymers are highly inert and are utilised intensively in industrial Food Processing, and Domestic Food cooking equipment.

RALICKS FEP / PFA Encapsulated O-Rings Encapsulate materials and their manufacture are compliant with all relevant sections 1 to 21 of the E.C Regulation Number 1935/2004 and the subsequent Articles.

We are pleased to advise that FEP/PFA Encapsulated O-Rings are compliant to EU VO 1935/2004 and 10/2011 certification.

PFOA & PFOS

FEP/PFA fluoropolymers have been tested in accordance with US EPA 3550C:2007 protocol and meet the test conditions required. This product is manufactured with technology that meets the goals of the U.S. Environmental Protection Agency (EPA) 2010/15 PFOA stewardship program. Test reports can be submitted upon request. Since 2009 PFOS has been incorporated into the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations, which is compliant with the SVHC list from ECHA which was updated 7th July 2017.

Silicone Core

FDA

The Silicone core of our FEP/PFA encapsulated O-Ring 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. RALICKS FEP/PFA encapsulated with an FDA compliant Silicone core are supplied from stock as standard and at no extra charge.

Restriction of Hazardous Substances (ROHS)

The restrictions of the use of certain Hazardous Substances (ROHS) Directives 2011/65/EC and 2002/96/EG came into force on 1st July 2006.

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RALICKS recognise these requirements and declare that all Silicone Encapsulated O-rings sold by RALICKS do comply with the European Directives.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The EU Regulations (EC 1907/2006) came into force on 1st June 2007. RALICKS is familiar with the European Regulation on chemicals being the producer of products from raw materials. The elements of our product that could be considered chemical based are in actual fact rubber, being Silicone, and is classified in the Regulations as polymers and is therefore exempt.

RALICKS can confirm that the Silicone core complies according to the SVHC list from ECHA which was updated 7th July 2017.

Viton® Core

FDA

The Viton® core of our FEP/PFA encapsulated O-Ring 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. RALICKS FEP/PFA encapsulated O-Rings with an FDA compliant Viton® core are supplied from stock as standard and at no extra charge.

Restriction of Hazardous Substances (ROHS)

The restrictions of the use of certain Hazardous Substances (ROHS) Directives 2011/65/EC and 2002/96/EG came into force on 1st July 2006. RALICKS recognise these requirements and declare that all Viton Encapsulated O-Rings sold by RALICKS do comply with the European Directives.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The EU Regulations (EC 1907/2006) came into force on 1st June 2007 are familiar with the European Regulation on chemicals being the producer of products from raw materials.

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The elements of our product that could be considered chemical based are in actual fact rubber, being Viton®, and is classified in the Regulations as polymers and is therefore exempt.

RALICKS can confirm that the Viton core complies according to the SVHC list from ECHA which was updated 7th July 2017.

Animal Derived Substances and BSE/TSE

All RALICKS Seals, FEP, PFA, Viton and Silicone core materials used within our Encapsulated O-Rings are free from any bovine and other animal derived materials and do not come into contact with any of these during manufacture.

Furthermore, all the equipment used to manufacture these products also does not come into contact with any bovine and other animal derived materials.

BSE - Bovine Spongiform Encephalopathy

TSE - Transmittable Agents of Animal Spongiform Encephalopathy

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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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