

Certificate of Compliance

CUSTOMER:	
PURCHASE ORDER:	
ITEM NUMBER:	
ITEM DESCRIPTION:	
PRODUCT NAME:	
MATERIAL:	PTFE/FKM Fluoroelastomer
LOT NUMBER:	
DOM:	
HEAT NUMBER:	

Compliance:

Rubber Fab, a Garlock Hygienic Technologies company certifies that the material from which we manufacture the above mentioned parts has passed:

USP CLASS VI <87><88> (121°C) (PTFE Only)
3A-20-27 (PTFE Only)
3A-18-03 (FKM Only)
FDA 21CFR177.1550
ADI Free, BSE&TSE Free
REACH/RoHS

Physical Properties: PTFE

Physical Properties	Test Method	Results
Hardness, (Shore D)	D2240	63 +/- 5
Tensile Strength, (PSI)	D4894	4360
Elongation, (%)	D4894	320
Temperature Range (°C)	-26°C to +205°C (Due To FKM Insert)	
Specific Gravity (g/cm³)	D792	2.16
300% Modulus (PSI)	D695	50000
Color	Black & White	
Shelf Life	10 Years	

The preceding Physical Properties data gives the typical properties of the mentioned material. It is intended to be used as a guide at your discretion and risk.

Certified by:

Date:

L. Levai Quality Assurance

Detectomer® • Sanitary Gaskets • Hoses • Hose Assemblies • Tubing • Fittings • Pump Parts

Garlock Hygienic Technologies, LLC

d/b/a PSI Products GmbH, a Garlock Sealing Technologies company

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Declaration of Compliance

Subject: Rubber Fab PTFE (Polytetrafluoroethylene) Material w/FKM Fluoroelastomer inlay

To whom it may concern,

we hereby confirm that the material from which our Virgin PTFE (Polytetrafluoroethylene) sanitary gaskets are manufactured is in compliance with and meets the requirements of the following regulations governing polymer materials for food contact applications.

- Title 21 CFR 177.1550 Perfluorocarbon resins
- Title 21 CFR 177.2600 Rubber articles intended for repeated use (FKM Fluoroelastomer Only)
- U.S. Pharmacopeia Class VI Plastics - General Chapter <88> Biological Reactivity tests, *In Vivo*, at 121° C for 1 hour.
- U.S. Pharmacopeia, General Chapter <87>, Biological Reactivity Tests, *In Vitro*, non-cytotoxic effect
- Free from Bovine Spongiform Encephalopathy (BSE) & Transmissible Spongiform Encephalopathy (TSE)
- Animal Derived Ingredient Free (ADIF)
- REACH & RoHS
- Phthalate Free
- Bisphenol A Free
- Nitrosamines Free
- 3A 20-27 Certified (PTFE Only)
- 3A 18-03 Certified (FKM Only)
- USDA Sanitary Standards
- ASME-BPE Standards

It is the end-users responsibility to evaluate and verify the suitability of the equipment and its components for the intended purpose and service conditions. Should you require additional information please feel free to contact Rubber Fab at your convenience.

Compliance Statement

Material: PTFE/FKM Fluoroelastomer

Subject: FDA 21CFR177.1550 Compliance and 21CFR177.2600 Compliance

Dear Business Partner,

We hereby confirm that our Envelope Gasket materials PTFE and FKM Fluoroelastomer are in full compliance with the requirements of:

1. FDA Code of Federal Regulations Title 21, Section 177.2600 for rubber articles intended for repeated use. (FKM Fluoroelastomer Only)
2. FDA Code of Federal Regulations Title 21, Section 177.1550 for perfluorinated hydrocarbons. (PTFE Only)

In addition to the ingredients being acceptable for food contact applications, the permitted degree of release or extraction of the authorized ingredients from the polymer/elastomer is also specified. The extraction is carried out using specified test conditions and media such as water, ethanol and hexane as displayed in the table below.

Method	Test duration [h]	Max. permissible extraction amount [mg/sq.in.]
21CFR177.2600 (first extraction)	7	20
21CFR177.2600 (second extraction)	2	1
21CFR177.1550	2	0.2

As per 21CFR177.1550 and 21CFR177.2600 our Envelope Gasket materials are generally recognized as safe (GRAS) and may be safely used as articles or components of articles intended to come in contact with food.

Part of CFR 21 Section 177.2600:

- e) Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction.
- f) Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n -hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction.
- g) In accordance with good manufacturing practice finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food.

Part of the CFR 21 Section 177.1550:

- a) Identity. For the purpose of this section, perfluorocarbon resins are those produced by: (1) The homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene, and (2) the copolymerization of perfluoropropylvinylether and tetrafluoroethylene (CAS Reg. No. 26655-00-5). The resins shall meet the extractives limitations in paragraph (d) of this section.
- d) Specifications --(1) Infrared identification. Perfluorocarbon resins can be identified by their characteristic infrared spectra.
- e) Limitations. 1 (1) Perfluorocarbon-molded articles having a surface area of 6.45 square decimeters (100 square inches) or more and at least 1.27 millimeters (0.05 inch) thick shall be extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, n -heptane, and ethyl acetate.

Compliance Statement

Material: PTFE/FKM Fluoroelastomer

Subject: USP Class VI <87> <88> - Biocompatibility (PTFE Only)

Dear Customer,

We hereby confirm that our PTFE/FKM Fluoroelastomer gasketing material has been independently tested according to USP Class VI <88> and <87> and are in full compliance with the requirements.

Test protocols for biological reactivity tests are defined by the U.S. Pharmacopeia, General Chapters and <88><87>. These test protocols shall include in vitro reactivity tests <87> with mammalian cells and in vivo reactivity tests <88> on animals.

The in vivo reactivity tests consist of three tests: Systemic, Intracutaneous and Implantation. The material extracts used on the systemic toxicity and intracutaneous tests are fixed at set temperatures and exposure times to ensure the results meet a common standard. All material extracts are processed using different temperature and time exposure conditions. The material was initially administered at 70°C (158°F) for 24 hours and finally at 121°C (250°F) for one hour.

The in vitro reactivity test is used to determine the biological reactivity of mammalian cell cultures after contact with elastomers, plastics and other polymeric materials in direct or indirect patient contact. The test protocol includes agar diffusion tests, direct contact tests and elution tests.

Compliance Statement

Material: PTFE/FKM Fluoroelastomer

Subject: 3-A 20-27 and 18-03 Compliance

Dear Business Partner,

We hereby confirm that our Envelope Gasket materials PTFE and FKM Fluoroelastomer are in full compliance with the requirements of:

1. 3-A Sanitary Standards 20-27 for Multiple-Use Plastic Materials (PTFE Only)
2. 3-A Sanitary Standards 18-03 for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment (FKM Fluoroelastomer Only)

The 3-A Sanitary Testing Procedures subject the specimens to accelerated use, simulating tests to determine the cleanability for use in dairy equipment. The specimens exhibited either no appreciable weight gain or weight gains less than the allowable limit.

Compliance Statement

Material: PTFE/ FKM Fluoroelastomer

Subject: Animal Derivates Ingredients Free (ADI Free), BSE & TSE Free

Dear Customer,

we hereby confirm that our formed or cut components and sheets, made for the purpose of sealing, regarding all materials of our product line Sanitary Gaskets, Detectomer® and Hoses in general except of BUNA, are conform to the guidelines of risk minimizing of virus transmission concerning TSE (Transmissible spongiform encephalopathy) from an animal source caused by human and animal medicines (EMEA/410/01 Rev.3 – March 2011). This guideline is accepted by Committee for Proprietary Medicinical Products – CPMP and Committee for Veterinary Medicinical Products – CVMP.

TSE diseases in Example include bovine spongiform encephalopathy (BSE) in cattle, SCRAPIE in sheep and goats, chronic wasting disease (CWD) in cervids like deer and elk, as well as different forms of Creutzfeldt-Jakob Disease (CJD) in humans.

This guideline is announced in the gazette C24 of the European Union at the 28th January 2004 and C73 at 05th March 2011.

Compliance Statement

Material: PTFE (Polytetrafluoroethylene)

Subject: Free of Allergens, Melamine and Other substances

Dear Business Partner,

We hereby confirm that the following substances are not intentionally introduced. Therefore, they are not expected to be present except for trace amounts from incidental environmental contamination. Analytical data is not available:

- Regulation (EU) No 1169/2011, substances listed in Annex II (For example: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans)
- Substances listed in the Food Allergen Labeling and Consumer Protection Act (FALCPA)
- Latex
- Fragrances
- PAH (Polycyclic aromatic hydrocarbons)
- DMF (Dimethylfumarate)
- APEO (Alkylphenol ethoxylates)
- Phthalates
- Azo compounds
- PCDD/PCDF (Polychlorinated dibenzodioxins and dibenzofurans)
- Asbestos
- Melamine
- Natural Rubber
- BPA (Bisphenol A), BPS (Bisphenol S)
- Radioactive substances
- PFOS (Perfluorooctane sulfonate), PFOA (Perfluorooctanoic acid)
- POP (Persistent organic pollutants) as defined in Regulation (EC) 850/2004 (Stockholm Convention)
- SCCP (Short-chain chlorinated paraffins)

Compliance Statement

Material: PTFE/FKM Fluoroelastomer

Subject: RoHS II 2011/65/EU and Amendment (EU) 2015/863; REACH “Substances of Very High Concern List 2018”

Dear Customer,

Rubber Fab, a Garlock Hygienic Technologies company, hereby confirms that to the best of our knowledge, with appropriate due diligence, PTFE-FKM Gaskets comply with the RoHS II Directive 2011/65/EU and Its Amendment (EU) 2015/86 and are free from Asbestos and Polychlorinated Biphenyls (PCB's).

RoHS Annex II specifies maximum levels for the following restricted materials:

- Lead (Pb): < 1000 ppm
- Mercury (Hg): < 1000 ppm
- Cadmium (Cd): < 100 ppm
- Hexavalent Chromium: (Cr VI) < 1000 ppm
- Polybrominated Biphenyls (PBB): < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
- Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
- Benzyl butyl phthalate (BBP): < 1000 ppm
- Dibutyl phthalate (DBP): < 1000 ppm
- Diisobutyl phthalate (DIBP): < 1000 ppm

Additionally, Rubber Fab confirms that our PTFE-FKM gaskets complies with REACH SVHC List 2018.

Informational letter "Leachables and Extractables"

With regard to compatibility and purity of materials, plant operators often require disclosure of the composition of all components used in the process. In addition, so-called leachables and extractables studies may be required to document the purity of components. The following definitions of Extractables and Leachables apply (ASME BPE 2016):

- **Extractables** Extractables are chemical substances that can be removed from polymeric materials using appropriate solvents (e.g., polar and nonpolar). Extraction studies are conducted under conditions that exceed typical bioprocess manufacturing or storage conditions (e.g., higher temperature, pH, or concentration or longer exposure time) and are used to generate an extractables profile for a given polymeric material. Manufacturers should provide extractables profile data for polymeric materials used in equipment/components on request by the owner/user. The extractables profile generated may vary depending on both the extraction conditions and the extraction fluids used in the study. Depending on the purpose of the study, one or more of the following types of extraction study should be done to generate an extractables profile.
- **Leachables**, typically a subset of extractables, are chemical substances that migrate into the drug product from process equipment or its container under normal conditions of use and/or storage. Leachables may also be created as a result of chemical reactions with other leachables and/or ingredients in the process fluid or drug product. Leachables studies conducted in process and of the final product shall be the responsibility of the owner/user.

Extraction according to FDA 21CFR177.2600 and 21CFR177.1550:

The two most cited guidelines of the Food and Drug Administration (FDA) for sealing products can be found in the Code of Federal Regulations under Title 21 (Food and Drugs), Part 177 (Indirect Food Additives: Polymers). Section 177.1550 focuses on perfluorinated hydrocarbons such as PTFE (polytetrafluoroethylene) or PTFE-based products, and section 177.2600 deals with rubber articles intended for repeated use.

In a first step it must be ensured that the ingredients are on the positive list of the FDA (Food and Drug Administration) 21CFR177.2600 for "Rubber articles" (e.g.: EPDM, NBR, FKM) or 21CFR177.1550 for "Perfluorocarbon resins" (e.g.: PTFE), and to avoid all ingredients that are known to be cytotoxic.

In addition to the ingredients being acceptable for food contact applications, the permitted degree of release or extraction of the authorized ingredients from the polymer/elastomer is also specified. The extraction is carried out using specified test conditions and media such as water, ethanol and hexane.

According to USP Class VI <87> and <88>:

Test protocols for biological reactivity tests are defined by the U.S. Pharmacopeia, General Chapters and <88><87>. These test protocols shall include in vitro reactivity tests <87> with mammalian cells and in vivo reactivity tests <88> on animals. The in vivo tests consist of three tests: Systemic, Intracutaneous and Implantation. The material extracts used on the systemic toxicity and intracutaneous tests are fixed at set temperatures and exposure times to ensure the results meet a common standard. All material extracts are processed using three different temperature and time exposure conditions. Initially it is administered at 50°C (122°F), for 72 hours, then at 70°C (158°F) for 24 hours and finally at 121°C (250°F) for one hour. The materials and their extracts are then classified in plastic classes I to VI according to the test results. The following is an overview of the sampling procedures:

Plastic Classes ^a						Tests to be Conducted			
I	II	III	IV	V	VI	Test Material	Animal	Dose	Procedure ^b
x	x	x	x	x	x	Extract of Sample in Sodium Chloride Injection	Mouse	50 mL/kg	A (iv)
x	x	x	x	x	x		Rabbit	0.2 mL/animal at each of 10 sites	B
	x	x	x	x	x	Extract of Sample in 1 in 20 Solution of Alcohol in Sodium Chloride Injection	Mouse	50 mL/kg	A (iv)
	x	x	x	x	x		Rabbit	0.2 mL/animal at each of 10 sites	B
		x		x	x	Extract of Sample in Polyethylene Glycol 400	Mouse	10 g/kg	A (ip)
				x	x		Rabbit	0.2 mL/animal at each of 10 sites	B
		x	x	x	x	Extract of Sample in Vegetable Oil	Mouse	50 mL/kg	A (ip)
			x	x	x		Rabbit	0.2 mL/animal at each of 10 sites	B
			x		x	Implant strips of Sample	Rabbit	4 strips/animal	C
			▲x		x	Implant Sample	Rat	2 Samples/animal	C ▲ USP35

^aTests required for each class are indicated by "x" in appropriate columns.

^bLegend: A (ip)-Systemic Injection Test (intraperitoneal); A (iv)-Systemic Injection Test (intravenous); B-Intracutaneous Test (intracutaneous); C-Implantation Test (intramuscular ▲ or subcutaneous ▲ USP35 implantation).

The above class of testing of elastomers, plastics, polymeric materials and their extracts is carried out in contact with animals. However, it is not sufficient to stop this test alone after completion - the growth of cells and microbes can be delayed or completely stopped by chemicals that can pass the Class VI test. One example of this is sulfur-crosslinked elastomers.

Some elastomers are hardened with sulphur and/or sulphur-containing compounds. Sulfur is listed as GRAS (Generally Recognized as Safe) material which is classified as an indirect food additive and is intended for repeated use when used as a vulcanizing material or agent. Sulfur-crosslinked elastomers therefore meet FDA requirements (GRAS) and can also pass USP<88> Class VI tests, where the elastomer can negatively affect the growth of mammalian cells.

The biological reactivity test of mammalian cells in vitro is described in the U.S. Pharmacopeia General Chapter <87>. This test is used to determine the biological reactivity of mammalian cell cultures after contact with elastomers, plastics and other polymeric materials in direct or indirect patient contact. The test protocol includes agar diffusion tests, direct contact tests and elution tests of the materials or extracts to determine the reactivity of mammalian cells.

In the USP <87> test most sulfur-crosslinked elastomers have a negative effect on mammalian cells and thus a slight to severe degree of reactivity. This can drastically reduce or even stop the cell yield in smaller batches - even if the elastomer can pass the USP <88>Class VI test and is an FDA listed GRAS material.

USP Chapter <1663> and <1664>

The USP chapters <1663> "Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems" and <1664>"Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery systems" are only informational. They provide a framework for the design, justification and performance of extractables/leachables analyses for pharmaceutical packaging systems. They do not constitute specific test conditions, specific tests, analytical methods or approval limits for packaging systems or products.

This letter must not be understood or used as a declaration of compliance with the above listed regulations. The availability of compliance statements depends on the specific material. Thus it is to be checked in each case and under specification with the order whether the required compliance statements are available.

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STORAGE PROCEDURES AND SHELF LIFE

ELASTOMERIC & PTFE AND FEP GASKETS, O-RINGS & HOSES

The shelf life of elastomeric, PTFE and FEP gaskets, O-Rings, tubing and hoses is dependent on many factors pertaining to their storage conditions. Products stored in their original packaging in a dry, cool environment away from direct sun light and artificial light should remain in optimal condition for 10 years. We do, however, recommend visual inspection of gaskets for discoloration, hardening and deformation and the hydro testing of pressure rated hoses after three years.

TEMPERATURE:

In order to avoid certain forms of deterioration that may occur at higher temperatures, storage temperatures should be below 77F (25 C). The effects of low temperatures are not permanently damaging, but articles may stiffen more than usual.

HUMIDITY:

Store in a dry environment to avoid condensation.

LIGHT:

Gaskets & hoses should be protected from light, especially direct sunlight and strong artificial light with high ultraviolet content.

OXYGEN AND OZONE:

Whenever possible, gaskets and hoses should be protected from circulating air, ozone is very abrasive toward rubber, storage rooms should not contain any equipment capable of generating ozone such as mercury lamps, electric motors and any other equipment that produces electrical sparks and discharge.

DEFORMATION:

Whenever possible, gaskets and hoses should be stored in a relaxed condition free from tension, compression or other deformation.

CONTACT WITH LIQUID OR SEMI-SOLID MATERIALS:

Rubber should not come in contact with liquids or semi-solid materials, especially solvents, oils and greases at any time during storage.

ROTATION OF STOCKS:

Gaskets and hoses should remain in stores for as short of a period as possible. Therefore, articles should be issued from stores in strict rotation.