Rubber Fab
a Garlock Hygienic Technologies company

26 Brookfield Drive • Sparta, NJ 07871
Tel: 973-579-2959 • Toll Free: 866-442-2959
Fax: 973-579-7275 • www.rubberfab.com

Certificate of Compliance

CUSTOMER:	
PURCHASE ORDER:	
ITEM NUMBER:	
ITEM DESCRIPTION:	
PRODUCT NAME:	
MATERIAL:	Gylon Style 3522
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)
USP part 31, 281 & 661
FDA 21CFR177.1550
EC1935/2004 and EC2023/2006 (GMP)
EC 10/2011
NSF 61 Standard
3A-20-27
ADI Free, BSE&TSE Free
REACH/RoHS

Physical Properties:

Physical Properties	Test Method	Results
Tensile Strength, (PSI)	ASTM D1708	4500
Elongation, (%)	ASTM D1708	320
Temperature Range (°C)	-268°C to +260°C	
Specific Gravity (g/cm³)	ASTM D792	2,14
Compressibility, %	ASTM F36	20-25
Color	White	
Shelf Life	Unlimited	

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

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Declaration of Compliance

Subject: Rubber Fab Gylon-BIO-PRO® PLUS Style 3522 Material

To whom it may concern,

we hereby confirm that the material from which our Gylon-BIO-PRO® PLUS Style 3522 sanitary gaskets are manufactured is in compliance with and meets the requirements of the following regulations governing polymer materials for food contact applications.

- EC1935/2004 and EC2023/2006 Good Manufacturing Practice (GMP)
- EU10/2011 on Plastic Materials and Articles intended to come into contact with food.
- GB 4806.7-2016 Food Contacting Plastic Materials and Articles
- Title 21 CFR 177.1550 Perfluorocarbon resins
- 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
- 3-A 20-27 Certified
- USDA Sanitary Standards
- ASME-BPE Standards
- TA-Luft + Blowout
- NSF 61
- BAM
- 62. BFR

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.

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Compliance Statement

Material: Gylon-BIO-PRO® PLUS Style 3522

Subject: FDA 21CFR177.1550

Dear Business Partner,

We hereby confirm that our Gylon-BIO-PRO® PLUS Style 3522 material is in full compliance with the requirements of:

1. FDA Code of Federal Regulations Title 21, Section 177.1550 for perfluorinated hydrocarbons.

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.]
21CFR177.1550	2	0.2

As per 21CFR177.1550 our Gylon-BIO-PRO® PLUS Style 3522 material is 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 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.

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Compliance Statement

Material: Gylon-BIO-PRO® PLUS Style 3522

Subject: USP Class VI <87> <88> - Biocompatibility

Dear Customer,

We hereby confirm that our Gylon-BIO-PRO® PLUS Style 3522 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.

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Compliance Statement

Material: Gylon-BIO-PRO® PLUS Style 3522

Subject: 3-A 20-27

Dear Business Partner,

We hereby confirm that our Gylon-BIO-PRO® PLUS Style 3522 material is in full compliance with the requirements of:

1. 3-A Sanitary Standards 20-27 for Multiple-Use Plastic Materials

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.

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Compliance Statement

Material: Gylon-BIO-PRO® PLUS Style 3522

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 decease (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.

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Compliance Statement

Material: Gylon-BIO-PRO® PLUS Style 3522

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, Gylon-BIO-PRO® PLUS Style 3522 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 Gylon-BIO-PRO® PLUS Style 3522 gaskets complies with REACH SVHC List 2018.

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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:

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Plastic Classesa						Tests to be Conducted			
I	II	III	IV	V	VI	Test Material	Animal	Dose	Procedureb
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

[a] Tests required for each class are indicated by "x" in appropriate columns.

[b] Legend: 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.