Rubber Fab
a Garlock Hygienic Technologies company

Leading Innovator of Sanitary Gaskets, Hoses, Hose Assemblies and Pump Parts

More than just a commodity!?
Next Generation Elastomeric TC Gaskets

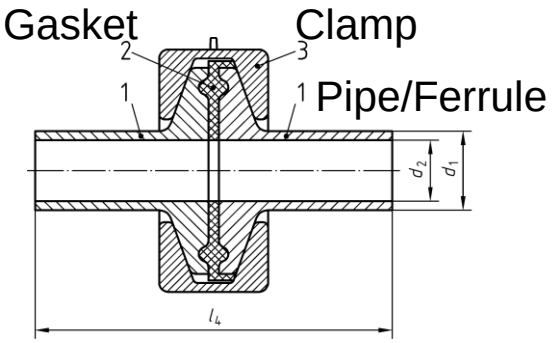
24.07.2020 – Webinar VI

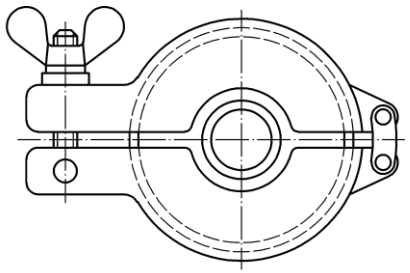
by Sascha Butter, Christoph Neuffer, Dominik Wiese

Products

Elastomeric Tri-Clamp gaskets according to industry standard DIN 32676 (metric and imperial):

- Row A (DIN 11850 / DIN 10357)
- Row B (ISO 1127)
- Row C (ASME BPE)





Materials:

- EPDM (Ethylene Propylene Diene Monomer rubber - Peroxide Cured)
- FKM (Fluoroelastomere - Peroxide Cured)
- VMQ (Silicone - Platinum cured)

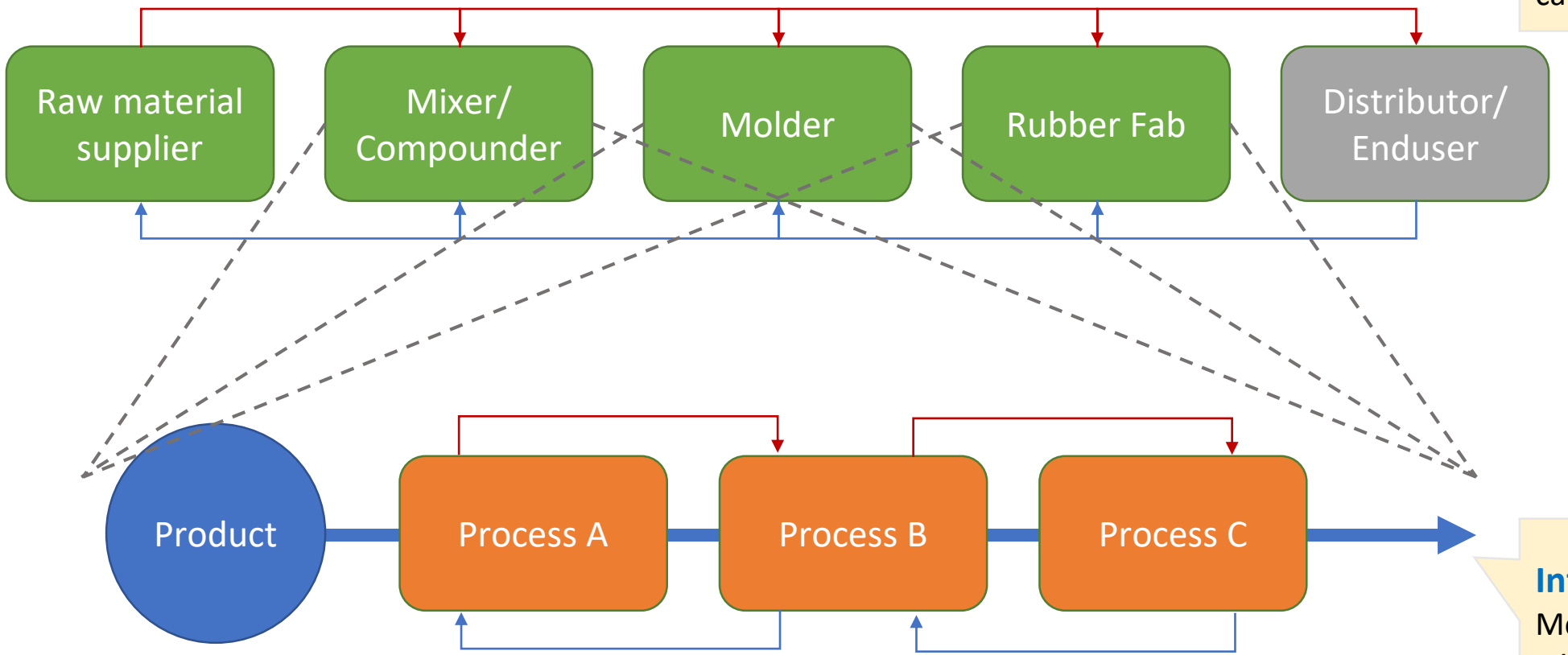
Good Manufacturing Practice (How?)

Quality Control Systems:

- USA: FDA 21CFR174.5
- EU: EC2023/2006
- Quality system in place to ensure product quality
- Manufacturing controls in place to ensure product safety
- Documentation
- Use of material at the level only to achieve technical function
- Materials have suitable purities
- …..

Full Traceability

Chain Traceability
Movement of products in multiple processes (between manufacturers) can be monitored.



Internal Traceability
Movement of products within a single process can be monitored.

Regulatory Compliance & Testing

Third-Party Testing/Compliance:

- FDA 21 CFR177.2600 (Formulation review)
- USP Class VI <87>, <88> 121°C (In-Vivo and In-Vitro Biocompatibility Testing)
- 3A Sanitary Standard 18-03 (Multiple-Use Rubber as Product Contact Surfaces in Dairy Equipment)
- EC1935/2004 (Materials and articles intended to come into contact with food)
- ADI (Animal Derived Ingredient) free (EMEA 410/01)
- FDA 21 CFR 174.5 (Good Manufacturing Practice -GMP- General provisions applicable to indirect food additives)
- EC2023/2006 (Good Manufacturing Practice - GMP)

In-House Testing:

- FDA 21 CFR177.2600 (Extraction Testing)
- Physical Property analysis, Immersion testing, TGA etc.

In-House Testing Capabilities

Chemical lab

Compound lab

Physical lab

Functional lab

Country of Origin (Where?)

Country of Origin Effect:

- Psychological effect describing how the customer's attitude, perception and purchasing decision is influenced by products country of origin labelling.
- Origin is Europe

Supplier Declaration:

- Supplier provides information concerning the originating status of goods.
- Customer needs this information to certify the preferential origin of the goods to be exported
- No legal obligation to make out supplier's declaration.
- Mainly used for deliveries of goods within EU.

FKM (Peroxide cured)

CERTIFICATES/DECLARATIONS

- 3A Sanitary Standard 18-03 Class I
- EC1935/2004 and EC2023/2006 GMP
- FDA21CFR177.2600 (Formulation & Extraction)
- FDA21CFR174.5 (GMP)
- USP Class VI <87>,<88> (121°C)
- ADI free (EMEA410/01)
- …

KEY BENEFITS

- Suitable for SIP and CIP
- Full & Easy Traceability
- Laser marked by default
- Good cleanability
- Excellent chemical resistance
- Wide temperature range
- -34°C (-29°F) to 204°C (400°F)
- Exceptional flexibility

Physical Properties:

Physical Properties	Test Method	Results
Hardness, (Shore A)	ASTM D 2240	71
Tensile Strength, (MPa)	DIN 53504/S2	14,5
Elongation, (%)	DIN 53504/S2	344
Temperature Range (°C)	-26°C to +205°C	
Specific Gravity (g/cm³)	D412-98a, D2240-97	2,09
100% Modulus (MPa)	ISO 37 Type 2	2,6
Color	Black	
Shelf Life	10 Years	

VMQ (Silicone - Platinum cured)

CERTIFICATES/DECLARATIONS

- 3ASanitary Standard 18-03 Class I
- EC1935/2004 and EC2023/2006 GMP
- FDA21CFR177.2600 (Formulation & Extraction)
- FDA21CFR174.5 (GMP)
- USP Class VI <87>,<88> (121°C)
- ADI free (EMEA410/01)
- …

KEY BENEFITS

- Suitable for SIP and CIP
- Full & Easy Traceability
- Laser marked by default
- Good cleanability
- Excellent chemical resistance
- Wide temperature range
- -40°C (-40°F) to 232°C (450°F)
- Exceptional flexibility

Physical Properties:

Physical Properties	Test Method	Results
Hardness, (Shore A)	ASTM D 2240	71
Tensile Strength, (MPa)	ASTM D 412/C	9,5
Elongation, (%)	ASTM D 412/C	590
Temperature Range (°C)	-40°C to +232°C	
Specific Gravity (g/cm³)	ASTM D 297	1,2
Color	Translucent	
Shelf Life	10 Years	

EPDM (Peroxide cured)

CERTIFICATES/DECLARATIONS

- 3A Sanitary Standard 18-03
- EC1935/2004 and EC2023/2006 GMP
- FDA21CFR177.2600 (Formulation & Extraction)
- FDA21CFR174.5 (GMP)
- USP Class VI <87>,<88> (121°C)
- ADI free (EMEA410/01)
- …

KEY BENEFITS

- Suitable for SIP and CIP
- Full & Easy Traceability
- Laser marked by default
- Good cleanability
- Good chemical resistance
- Wide temperature range
- -34°C (-29°F) to 149°C (300°F)
- Exceptional flexibility

Physical Properties:

Physical Properties	Test Method	Results
Hardness, (Shore A)	ASTM D 2240	70 +- 5
Tensile Strength, (MPa)	ISO 37 Type 2	13
Elongation, (%)	ISO 37 Type 2	218
Temperature Range (°C)	-34°C to +149°C	
Specific Gravity (g/cm³)	D412-98a, D2240-97	1,12
100% Modulus (MPa)	ISO 37 Type 2	4,9
Color	Black	
Shelf Life	10 Years	

Supporting Activities

- Product-One-Pager
- Compliance statements
- New certificate layout
- Product Presentation
- Updated brochures


Rubber Fab

FKM Fluoroelastomer

Next Generation

FKM Fluoroelastomer

Gasket Dimensions and Item Numbers

Rubber Fab

Rubber Fab
a Garlock Hygienic Technologies company

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Fax: 973-579-7275 • www.rubberfab.com

Compliance Statement

Material: Platinum Cured Silicone

Subject: FDA 21CFR177.2600 Compliance

Dear Business Partner,

We hereby confirm that our Platinum Cured Silicone material is 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.

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

As per 21CFR177.2600 our Platinum Cured Silicone 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 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.

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Certificate of Compliance

CUSTOMER:	
PURCHASE ORDER:	
ITEM NUMBER:	
ITEM DESCRIPTION:	
PRODUCT NAME:	
MATERIAL:	Platinum Cured Silicone Next Generation
COMPOUND NUMBER:	CPO-RF4101
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)
EC1935/2004 and EC2023/2006
3A 18-03 Class I
FDA 21 CFR 177.2600
FDA 21 CFR 174.5 cGMP
ADI Free, BSE&TSE Free
Phthalate Free

Physical Properties:

Physical Properties	Test Method	Results
Hardness, (Shore A)	ASTM D 2240	71
Tensile Strength, (MPa)	ASTM D 412/C	9,5
Elongation, (%)	ASTM D 412/C	590
Temperature Range (°C)	-40°C to +232°C	
Specific Gravity (g/cm³)	ASTM D 297	1,2
Color	Translucent	
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. Leval Quality Assurance

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E-Mail: rubberfab.europe@psi-products.de
www.rubberfab.com

And more…

Additional Benefits (Summary)

- Manufactured in Europe
- Laser marked by default (Batch-No. and Material)
- Full and Easy traceability
- Easy material identification (NO Color Coding)
- Only peroxide and platinum curing agents
- EC1935/2004 (Food Contact Regulation)
- EC2023/2006 GMP (Good Manufacturing Practice)
- FDA21CFR174.5 (cGMP)

- Same selling price as current range of products
- Complete portfolio (DIN/ISO/ASME) of elastomeric Tri-Clamp gaskets
- Additional supply chain - Improved sourcing flexibility and minimized risk of bottlenecks
- Higher level of Quality Control and on-site audits

EC 1935/2004

MADE IN THE EU MADE IN THE

MANUFACTURED TO cGMP STANDARDS

TRACEABILITY

FDA

BPA FREE

Feedback and outlook

- Feel free to address additional feedback in regards to content, style of presentation, presentation skills of referents or similar by mail

  - Dominik Wiese – Area Sales Manager – dwiese@rubberfab.com
  - Sascha Butter – Product Manager – sbutter@rubberfab.com
  - Christoph Neuffer – Application Engineer – cneuffer@rubberfab.com

- Training handout

- Webinars
  - Webinar 04: It's all about hygiene – hygienic seals for highest process (GYLON® BIO-LINE)
  - Webinar 05: Mastering challenges of hygienic assemblies (Gasket Installation)
  - Webinar 06: More than just a commodity!? Next Generation Elastomeric TC Gaskets (New product launch)