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Hygienic Seal Material Guidelines

This information has been carefully prepared to help in selecting the correct elastomer or perfluorocarbon utilized in high purity sanitary hygienic seals where critical pure water, process fluids (both ambient and hot), and SIP environments exist. The intention is to consider the different uses, applications and conditions to determine the **most favorable hygienic seal material for each application.**

The following criteria is used in determining correct hygienic seal materials;

- **U.S. Pharmacopeia Class VI Certification**
- **Cytotoxicity Criteria**
- **CFR Title 21 Section 177.1550**
- **CFR Title 21 Section 177.2600**
- **Traceability: Lot and Batch**
- **Certification: Lot and Batch**
- **ASME-BPE Standards**
- **USDA Standards**
- **3-A Sanitary Standards**
- **Current Good Manufacturing Practices (CGMP)**
- **Manufacturer data and specifications**
- **Consultation with various pharmaceutical users**
- **Animal Derived Ingredient Free**

The gasket materials considered are Tuf-Steel® (PTFE/Stainless Steel), Tuf-Flex®,PTFE, Silicone (platinum), FKM Fluoroelastomer, EPDM and Buna.

The 3 main goals are:

- **To protect products from contamination,** spalling, particulates and TOCs resulting from the use of improper hygienic seal material.
- **To protect facilities from unnecessary downtime** associated with hygienic seal failure and replacement from use of improper hygienic seal material.
- **To provide a standard of consistency** for hygienic seal selection between multiple facilities.

Most decisions driving seal type selection are based on chemistry, temperature, exposure limits, USP, FDA qualifications, and curing methods. The following briefly addresses each of these issues.

Exposure Limits

It is important to define the operating parameters of a new or existing processing sanitary system. The user specifications for exposure limits and reactivity to process fluids are compared with process operating parameters. All materials are acceptable for steam excluding Buna. All materials should meet process fluid reactivity parameters. Even though all compound exposure limits fall within operating parameters, the service life of some compounds will be different under certain conditions. This must be considered when selecting a compound.

FDA and USP Qualifications

CFR's define the criteria for extractables and for compounds used in the manufacture of rubber and plastic articles. The two applicable categories are; rubber articles (Buna, EPDM, FKM Fluoroelastomer, Silicone) and perfluorocarbon resins (PTFE).

USP defines the criteria for testing biological reactivity and the amount/type of extractables. The hygienic seals in service must meet USP Class VI specifications, and be manufactured using the proper compounds as stated in the CFR, Title 21, Sections 177.1550 and 177.2600 respectively. Certificates are available from Rubber Fab verifying compliance with regulatory requirements, traceability lot and batch and certification lot and batch.

Note: Not all hygienic seals meet these requirements.

Curing Methods

Curing agents have an affect on the amount and type of extractables a material will emit. Typically, the hygienic seal group in service uses three methods; sulfur cured*, peroxide cured and platinum cured. When dealing with elastomers, peroxide cured is the most favorable method. When dealing with silicone, platinum cured is the most favorable. All gaskets shall be post cured. Using these methods minimize potential reactions with the respective process fluid applications and can uphold pure water and process fluid standards.

* **Sulfur cured** elastomers can significantly alter a process fluids integrity and negatively affect mammalian cell yields.

Note: hygienic seal identification for curing methods. For example, EPDM: one green dot (•) means sulfur cured and three green dots (•••) means peroxide cured.

RUBBER FAB EPDM HYGIENIC SEALS ARE ALL PEROXIDE CURED.

What Material(s) Can Be Used

By reviewing manufacturer data and compiling information regarding regulatory requirements, it appears that any of the aforementioned compounds are suitable for both utility and process equipment use. However, you must ensure that all hygienic seals and compounds meet the CFR and USP requirements, and have a certificate to verify compliance.

What Material(s) Should Be Used

- Tuf-Steel® is the material of choice when purity, **long service life** performance, chemical and heat resistance is required. Leak free when torqued correctly. Minimum creep and-cold flow. Non-stick, ultra-low absorption and no pigmentation. Maintains seal integrity in applications where large temperature variations occur frequently. It can remain in service **for extended periods of time** in both water and frequent SIP use. The Torque-Rite® is recommended for use with clamps (See Torque-Rite literature for complete details).
- PTFE is the material of choice whenever low temperature flexibility or hygienic seal memry is not required (not recommended where large temperature variations occur frequently, leakage can occur). PTFE has almost no extractables, has a low absorption rate and excellent resistance to process fluids. It can remain in service for longer periods of time in both water and steam for continuous use, high pressure clamps are recommended to prevent leakage resulting from temperature variations. A PTFE envelope hygienic seal with an FKM Fluoroelastomer inner core should be used if slight misalignment is observed.
- Platinum cured silicone is the material of choice in sanitary water systems when PTFE is not feasible due to severely misaligned fittings, or if the cost of high pressure clamps does not outweigh the benefits of PTFE (extended service life).
- FKM Fluoroelastomer, EPDM and Buna compounds are specified by many of our process equipment manufacturers. They are generally suitable for these applications, however, service life must be considered and a **preventative maintenance program** be implemented to mitigate degradation. They are not recommended for continuous use in SIP procedures.

Material	Dot Description	Color Code
Tuf-Steel®	no dot	
Tuf-Flex®	no dot	
PTFE	no dot	
PTFE - Type III Envelope Style with FKM Fluoroelastomer Filler	one white dot & one yellow dot	
PTFE - Type III Envelope Style with EPDM Filler	three green dots	
FKM Fluoroelastomer	one white dot & one yellow dot	
EPDM - peroxide cured	three green dots	
Silicone - white platinum	one pink dot if requested	
Silicone - platinum cured	no dot	
Buna	one red dot	

1 = Excellent 2 = Good 3 = Acceptable 4 = Marginal 5 = Poor 0 = Do Not Use

Gasket Comments	Continuous Steam	Intermittent Steam	Pure Water Ambient	Pure Water Hot	Process Fluids Ambient	Process Fluids Hot	Process Fluids Variable (<0°C - >100°C)	Temp. Range
Tuf-Flex®/Ansi-Flex	1	1	1	1	1	1	1	-20°F to 300°F
Maintains seal with wide temperature variations. Has extended service life.**								
Tuf-Steel®	1	1	1	1	1	1	1	-320°F to 550°F
Maintains seal with wide temperature variations. Has extended service life.**								
PTFE	1	1	1	1	1	1	3	-100°F to 500°F
Wide temperature variations and may cause leakage at ΔT.								
Silicone (platinum)	2	2	2	2	2	2	1	-40°F to 450°F
Very flexible low temperature.								
FKM Fluoroelastomer	2	2	2	2	2	2	2	-30°F to 400°F
Acceptable for steam applications.								
EPDM (peroxide cured)	3	3	3	3	3	3	3	-30°F to 300°F
Low pressure steam only.								
Buna*	0	0	*5*	*5*	*5*	*5*	*5*	-30°F to 200°F
Not recommended for strong acids and ozone								

*Buna does not pass U.S. Pharmacopeia Class VI Certification and Cytotoxicity and is not ADI free. ** Application dependent.

- Tuf-Flex® is the world's first unitized gasket, setting new standards for purity, performance and flexibility. A Tuf-Flex® Gasket's contact surface is PTFE unitized to an EPDM rubber inner core. This totally bonded construction provides a PTFE gasket with the mechanical characteristics, including memory, of an elastomer gasket. Designed to meet critical requirements in biopharmaceutical, ultra-pure water, WFI (water for injection) and difficult food and beverage processing.
- Tuf-Steel® is composed of a unique 50/50 blend of non-pigmented PTFE and 316L passivated and atomized stainless steel. Testing and seven years of documented application usage has demonstrated that Tuf-Steel® is the choice for perfect surface performance, outstanding durability and extended service life in both SIP (steam in place) and WFI (water for injection) applications. Tuf-Steel® is ideal for sanitary steam pipe connections in extreme temperatures ranging from -320°F to 550°F. The superior strength of Tuf-Steel® eliminates creep and cold flow providing a leak-free seal and preventing maintenance problems and system downtime.
- PTFE is the material of choice whenever low temperature flexibility or gasket memory is not required and can remain in service for longer periods of time in both water and steam applications. PTFE is not recommended with large temperature variations due to creep and cold flow. PTFE has minimal extractables, has a low absorption rate and excellent resistance to process fluids.
- Platinum Cured Silicone is the material of choice in sanitary water systems when PTFE is not feasible due to severely misaligned fittings, or if the cost of high pressure clamps does not outweigh the benefits of PTFE (extended service life). See Rubber Fab's Platinum Silicone Hygienic Seal literature for more information.
- FKM Fluoroelastomer and EPDM compounds are specified by many of our process equipment manufacturers. They are generally suitable for these applications, however, service life must be considered and a preventative maintenance program be implemented to mitigate degradation.
- Buna is the last choice in most applications due to temperature limitations and does not pass U.S. Pharmacopeia Class VI Certification and Cytotoxicity.