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STAINLESS STEEL EQUIPMENT

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SANITARY GASKET MATERIAL GUIDELINES

This information has been carefully prepared to help in selecting the correct elastomer or perfluorocarbon utilized in high purity sanitary hygenic 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 gasket material for each application**. The following criteria is used in determining correct sanitary gasket 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**

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

The 3 main goals are:

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

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

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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-N. 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-N, EPDM, FKM Fluoroelastomer, Silicone) and perfluorocarbon resins PTFE.

USP defines the criteria for testing biological reactivity and the amount/type of extractables. The gaskets 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 Technologies Group verifying compliance with regulatory requirements, traceability lot and batch and certification lot and batch.

Note: Not all sanitary gaskets meet these requirements.

Curing Methods

Curing agents have an affect on the amount and type of extractables a material will emit. Typically, the gasket 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 gasket identification for curing methods. For example, EPDM: one green dot (•) means sulfur cured and three green dots (• • •) means 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 gaskets and compounds meet the CFR and USP requirements, and have a certificate to verify compliance.

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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 gasket 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 gasket memory 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. PTFE envelope gaskets with a 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-N 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.

- Color coding - identification of gasket materials

material	description	color code
Tuf-Steel	no dot	
PTFE	no dot	
PTFE Type 3 envelope gaskets		
FKM Fluoroelastomer filler	one white, one yellow dot	○ ●
EPDM filler	three green dots	● ● ●
FKM Fluoroelastomer	one white, one yellow dot	○ ●
EPDM		
sulfur cured	one green dot	●
peroxide cured	three green dots	● ● ●
Silicone		
peroxide cured	one pink dot	●
platinum cured	no dot	
Buna	one red dot	●

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GASKET MATERIAL REFERENCE SUMMARY

Preferred Material(s) 1 = Most Suitable 5 = Least Suitable 0 = Not Suitable

Gasket Type	Continuous Stream	Intermittent Steam	Pure Water Ambient	Pure Water Hot	Process Fluids Ambient	Process Fluids Hot	Process Fluids Variable (<0'C->100'C)	Color	Comments
Tuf-Steel®	1	1	1	1	1	1	1	bronze*	Maintains seal with wide temp. variations
PTFE	1	1	1	1	1	1	3	white*	Wide temp. variations may cause leakage
Silicone (platinum)	2	2	2	2	2	2	1	translucent*	Very flexible low temp
FKM Fluoroelastomer	0	3	3	3	3	3	2	black or white	Degrades quickly in steam applications
EPDM	0	4	4	4	4	4	4	black or white	Low pressure steam only
Buna-N**	0	0	5	5	5	5	5	black or white	Not recommended for strong acids & ozone

* No pigmentation

Tuf-Steel® is the material of choice if the application involves wide temperature variations, exceptional chemical resistance (such as hydrocarbons, ethanol, ketones, etc.), outstanding service life.

PTFE is the material of choice except if the application requires wide temperature variations (leakage will develop).

Silicone (platinum) is the third choice due to wide temperature compatibility range and resistance to chemicals.

FKM Fluoroelastomer is the fourth choice, however, service life must be considered and monitored.

EPDM is the fifth choice in most applications due to temperature limitations.

Buna-N is the sixth choice in most applications due to temperature limitations and ****does not pass U.S. Pharmacopeia Class VI Certification and Cytotoxicity**.

This sheet indicates general preferences. Unique applications may require further considerations and analysis. When selecting gasket materials it is important to consider many factors: resistance to heat, resistance to SIP, resistance to chemicals like; hydrocarbons, ethanol, ketones, etc, tear strength, and flexibility. **The service life of a material depends on the application**. Many of the materials are acceptable if the expected service life is very short in duration, however, in extended exposure situations the material can degrade quickly rendering it ineffective or less desirable overall. This analysis was intended for sanitary gasket applications specifically. Sanitary gasket applications are inherently static and can be dynamic. When different performance attributes are a consideration in dynamic applications, **Tuf-Steel** may be the material of choice.

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® Torque-Rite is a registered trademark of Rubber Fab Technologies Group.