

Sanitary 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.

Guidelines

Main Goals

Exposure Limits

FDA and USP Qualifications

Curing Methods

What Material(s) Can Be Used

What Material(s) Should Be Used

Gasket Material Reference

Sanitary Hygienic Seal Material Guidelines

In determining correct sanitary gasket materials, the following criteria is used:

- 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), Tuf-Flex®, 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 hygienic seal material.
- To protect facilities from unnecessary downtime associated with sanitary hygienic seal failure and replacement from use of improper hygienic seal material.
- To provide a standard of consistency of sanitary seal selection between multiple facilities.

Most decisions driving seal type selection are based on chemistry, temperature, exposure limits, USP, FDA qualifications, and curing methods.