

Rubber and PTFE Recommendations for Food Contact Materials (FCM)

The below suitability and restrictions must be taken into consideration for products used in food and drug applications according to FDA CFR 21: 177.2600 / FDA CFR: 21:177.1550 / EU 1935/2004 / EU 2023/2006/ EU10/2011:

- EPDM:** Good resistance to alcohol, ketones, mineral acids and alkalis. Suited for CIP¹⁾, but not suited with oils and hydrocarbons and fatty foods. Not recommended for milk fat concentrations higher than 8%.
Temperature range: -40°C to +140°C.
- FPM/FKM:** High resistance to most commonly used chemicals in food, dairy and pharmaceutical applications. Not suited in ketones, esters, hot concentrated caustic solutions or steam.
Temperature range: -20°C to +200°C.
- VMQ/SIL:** Chemical resistant to most commonly used chemicals in food, dairy and pharmaceutical applications. Good resistance to oxidizing agents, alkali solutions, animal and vegetable fat. Not recommended in steam, strong acids and alkalines. Poor mechanical properties.
Temperature range: -60°C to +200°C.
- NBR:** Good resistance to mineral oil, animal and vegetable fat. Not recommended for CIP¹⁾.
Temperature range: -30°C to +100°C.
- PTFE:** Universal chemical resistance. Caution to be taken for cold flow and overtightening
Temperature range: -100°C to +250°C.
- PTFE:
(Envelope)** Universal chemical resistance. Composite gasket, outer PTFE shell and an inner FPM insert providing elasticity.
Temperature range: -20°C to +200°C.
- KALREZ:** Outstanding universal chemical resistance. Suitable for CIP¹⁾, SIP²⁾ and WFI³⁾.
Temperature range: -20°C to +250°C.
- PUR:** Good resistance to mineral oil, fat and water. Not suited for SIP²⁾.
Temperature range: -20°C to +100°C.

In accordance with FDA cfr21: 177.2600(g), good manufacturing practice, rubber articles intended for contact with food must be thoroughly cleaned prior to food contact.

- 1) **“CIP”:** Common abbreviation for *“Cleaning in Place”*. Normally a multi-step cleaning process involving an alkaline rinse (such as NaOH, 1 %) and one or two dilute, non-oxidizing acids (e.g. citric acid, nitric acid). Total process time normally in the order of 30-45 minutes.
- 2) **“SIP”:** *“Sterilisation in Place”*. Disinfection process, normally carried out by using strong oxidants, such as hydrogen peroxide, per-acetic acid or hypochlorite. In the presence of chloride, strongly oxidising disinfectants imply the risk of corrosion of most common grades of stainless steel. Consequently, the contact time must be kept short.
- 3) **“WFI”:** *“Water for Injection”*. Super-pure water, usually made through reverse osmosis and/or a distillation process. Used for diluting medicine for injection.

The results given in this document are obtained on standard specimen following standard test procedures and are not comparable to finished products due to differences in the products profile. It is the customer's responsibility to evaluate parts prior to use in order to assure that parts will perform satisfactorily in their application.