

The High Purity Kalrez® concept

Kalrez® perfluoroelastomer parts improve sealing for today's processes

FDA and USP compliancy

The U.S. Food and Drug Administration (FDA) confirmed the compliance of Kalrez® 6221 and 6230 for repeated use in contact with food by Food Contact Notification (FCN) 000101. FCN 000101 was established through the FDA Premarket Notification Process for food contact substances as described in section 409(h) of the Federal Food, Drug, and Cosmetic Act 21U.S.C.348(h) and is the primary method by which the FDA authorizes the use of food additives that are food contact substances.

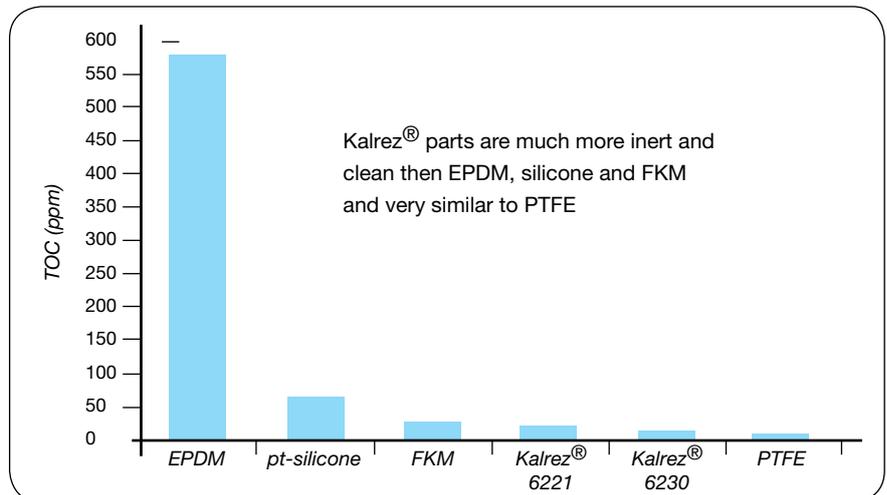
FCN 000101 requires materials to have extractable levels less than 0.2 mg/in². Kalrez® 6221 and 6230 have also been tested in accordance with United States Pharmacopeia Class VI (USP Class VI) and met those requirements.

To meet the demand for greater sealing integrity while maintaining process purity, DuPont Performance Elastomers has a family of high-performance perfluoroelastomer sealing materials uniquely suited for pharmaceutical medical manufacturing. Similar to PTFE in cleanliness, heat and chemical resistance, Kalrez® has the resilience and compressive strength that are characteristic for frequently used materials such as ethylene propylene polymers (EPDMs), fluoroelastomers (FKMs) and silicone rubber.

With its combination of thermal/chemical performance and rubber like sealing ability, Kalrez® offers the pharmaceutical industry a new level of protection against process contamination and seal failure. Multi-purpose Kalrez® seals increase process and equipment flexibility and may make it possible to standardize on a single seal material for all process environments.

Kalrez® compounds 6230 (black) and 6221 (white) have been developed to meet the unique sealing needs of today's high-speed, fully automated pharmaceutical and biopharmaceutical manufacturing processes. Kalrez® parts are manufactured by DuPont Performance Elastomers to ensure excellent quality, cleanliness and performance.

Kalrez® 6221 and 6230 have extractable levels compared to PTFE



EPA method 415; TOC tests performed on 1" sanitary seals, immersed in 50 ml of sterile WFI at 100°C/24hrs. The solution was then diluted to 100 ml and analysis.

