



Kalrez® perfluoroelastomer parts for

integrity and improved efficiency

in pharmaceutical processing



Kalrez®

From DuPont Performance Elastomers



Efficiently protecting **process integrity** is a challenge for all pharmaceutical manufacturers

Today's pharmaceutical and biopharmaceutical manufacturing processes require the efficient handling of a wide range of process fluids under varying conditions of temperature and pressure. From basic chemical storage and handling to manufacturing and waste management, process lines and vessels must be resistant to a variety of fluids. Many of these are toxic and corrosive, including raw materials, intermediate chemicals, active pharmaceutical ingredients (APIs), cleaning/sterilizing agents and by products. What's more, during sterilization, temperatures can reach up to 160°C. Whatever the finished product, tablet, capsule, ointment or liquid suspension, the fluid-handling system plays a critical role.

Seal Performance is paramount

Experience has shown that the weakest links in manufacturing processes are often the seals at couplings, flanges and other connection points in piping and equipment.

Degradation of these joint seals can result in

- contamination of the final or intermediate products during manufacture and/or
- leakage that may require a process shutdown.

Even with the availability of specialty elastomers such as Viton® fluoroelastomer (FKM) or chemically-inert Teflon® polytetrafluoroethylene (PTFE), the problems of seal failure have not been solved. With increased awareness and stricter guidelines regarding product and environmental safety, selection of proper sealing materials is critical for maximizing production up-time. High-performance sealing materials should offer the chemical inertness and cleanliness of PTFE without sacrificing the resilience and associated sealing benefits of true elastomers.



Kalrez® parts in pumps and valves help maintain purity in process fluids and meet critical health and safety requirements.



Kalrez® perfluoroelastomer parts **improve sealing** for today's processes

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 and medical manufacturing. Similar to PTFE in cleanliness, heat and chemical resistance, Kalrez® has the resilience and compressive strength that are characteristic of 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® 6230 (black) and 6221 (white) parts 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.

FDA and USP compliancy

The U.S. Food and Drug Administration (FDA) confirmed the compliance of Kalrez® 6221 and 6230 perfluoroelastomer parts 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 (21 U.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. Designated Kalrez® 6221 and 6230 products have been tested in accordance with United States Pharmacopeia Class VI (USP Class VI) and met those requirements. In addition, designated Kalrez® products also comply with the requirements in U.S. FDA regulation 21 CFR 177.2600.



Providing
new standards of protection
 against contamination and process interruption

Unmatched resistance to aggressive process chemicals

Kalrez® delivers near universal compatibility with over 1800 chemicals which provides added insurance against exposure to proprietary or unknown ingredients. Acids, bases, solvents, and amines are among the many corrosive chemicals that can be safely handled by Kalrez® seals. Kalrez® does not readily absorb liquids or solids present in the process stream. This protects against premature seal failure due to swelling and loss of mechanical properties while minimizing the chance for product contamination due to chemical desorption of previously used chemicals from the elastomer seals.

Each type of elastomeric seal can be different depending on the grade of elastomer used as well as how it was formulated and manufactured. "Food Grade" O-rings were obtained from the marketplace

and tested along with Kalrez® 6230 and 6221 O-rings. It should be noted that EPDM can be less resistant to mineral oils and aromatic hydrocarbons; silicones to solvents, oils, concentrated acids and dilute sodium hydroxide; and FKM to amines, some bases and alcohols – depending on the formulation. Steam resistance can also be affected by the grade and formulation used.

Extremely low extractables

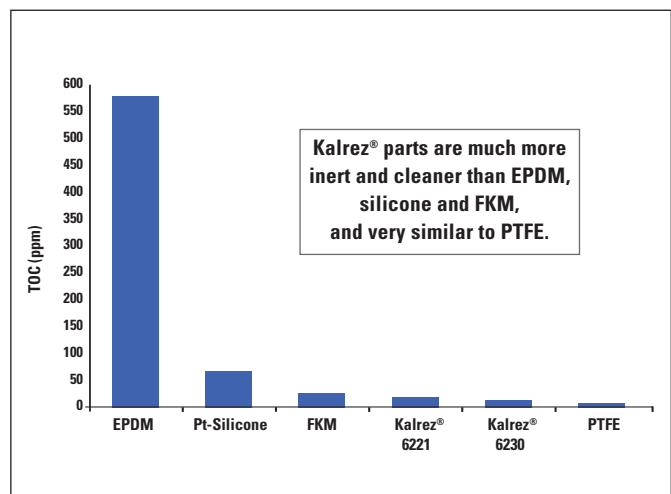
Kalrez® parts contain fewer extractable materials (additives and fillers) than other elastomer seals. This significantly reduces the risk of product contamination by ingredients leached from a sealed joint by the process flow. Total Organic Carbon (TOC) testing was used to show the levels of organic extractables of the various materials – Kalrez® parts are much more inert and cleaner than EPDM, silicone and FKM and very similar to PTFE.

Kalrez® seals have low volume swell for better sealing functionality

Chemical	Temp (°C)	EPDM	pt-Si	FKM	Kalrez® 6230	Kalrez® 6221
Hexane	60	41	4	6	7	7
Acetic Acid	100	135	1	199	3	19
Acetone	50	-6	2	65	4	3
Ethanol	60	-9	10	18	1	1
Ethylene Carbonate	100	-3	0	64	0	0
Toluene	100	155	50	86	6	6
Glycerol	100	0	1	0	0	0
Benzyl Alcohol	100	-7	2	10	1	1
Ethyl Acetate	60	3	11	118	5	5
Methanol	60	-5	-2	67	1	1
20% Nitric	100	139	-2	309	1	10
15% NaOH	100	0	0	10	1	1

 <0% volume swell (desorption)
 >10% volume swell

Kalrez® 6221 and 6230 have extractable levels comparable to PTFE



% volume swell, ASTM D471, 70 hours immersion at specified temperatures.

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



Delivering high-temperature stability and long-term elasticity

Properties

Kalrez® seals based on 6230 and 6221 deliver outstanding performance in high-temperature service (up to 260°C), even after exposure to aggressive chemicals and fluids. This means that Kalrez® provides a measure of safety, because it can comfortably operate in the middle of its temperature range, rather than near its temperature limit.

Sealing force retention (force under constant stress) and compression set resistance are standard test methods used to predict seal longevity. Kalrez® seals have good compression set resistance in process fluids at elevated temperatures.

In long-term testing of sealing force, Kalrez® and FKM retain their sealing force better than both EPDM and

silicone at 140°C in hot air. FKM, however, can be limited in certain fluid and steam conditions, depending on the type and formulation.

Permanent deformation is the major drawback of seals made from PTFE and other non-resilient thermoplastics. Over time, these materials will undergo compression set or “creep”, and lose their sealing force, even under moderate temperatures and loads. As a result, thermoplastic gaskets must be re-torqued to maintain a leak-proof joint.

In most cases, plastic seals cannot be reused because surface deformation and leak paths are permanent. Kalrez® seals are made from a true elastomer; they maintain long-term sealing force and are inherently resistant to permanent deformation or compression set.

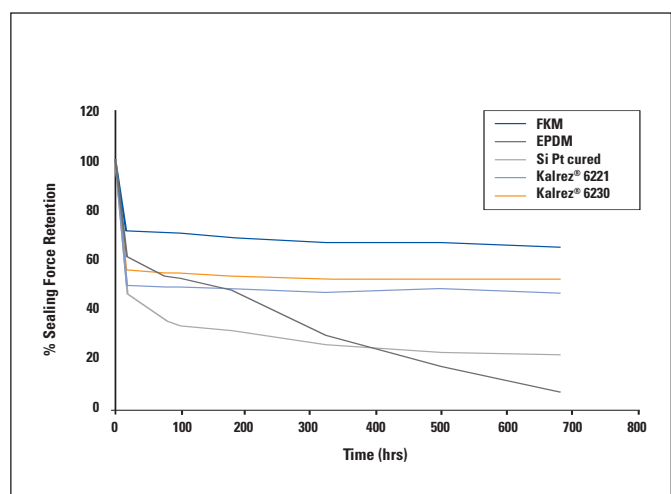
Kalrez® 6230 retains its sealability in harsh conditions

Chemical	Temp (°C)	EPDM	pt-Si	FKM	Kalrez® 6230
Acetic Acid	100	30	73	100	18
Acetone	50	27	-2	-121	23
Ethanol	60	28	5	14	26
WFI (Water)	100	68	81	94	40
Benzyl Alcohol	100	54	21	27	22
Ethyl Acetate	60	11	-3	-109	11
Methanol	60	30	14	-84	25
20% Nitric	100	62	99	49	2
15% NaOH	100	52	75	60	25

 >30%
 <0% (due to volume swell)

% Compression Set; ASTM 395 Method B (214 O-rings) for 70 hrs. at indicated temperatures and immersions.

Kalrez® maintains its sealing force in long-term testing



ISO 3384 method B, 140°C air, sealing force retention %.



A winning combination

of cleanliness, integrity, quality and traceability

For over 30 years, Kalrez® has demonstrated its value in critical applications in the chemical process, semiconductor, oil and gas recovery and aerospace industries. It has provided the most cost-effective solutions for high-performance sealing applications where other seals have failed.

The entire Kalrez® manufacturing process, from base polymer to finished seal, is controlled by one company, DuPont Performance Elastomers, under strictest standards of quality control (ISO 9001). This supply chain integration is unique among seal suppliers.

Formulations of Kalrez® tend to be more polymer-rich than most other types of elastomer compounds, resulting in fewer ingredients to extract or leach into a process. Kalrez® assures that you get the same formulation every time. Other elastomers have several different grades or compositions.

The combination of grade, filler, cure system, etc., can affect finished part performance (such as resistance to steam). Finding a reliable supplier willing to certify and provide documentation is important in the pharmaceutical industry. Every Kalrez® seal is packaged individually, bar coded and 100% traceable back to raw materials.

Versatility increases flexibility and standardization

A seal material with broad chemical and temperature capabilities not only minimizes contamination and production problems, but also helps reduce the costs of routine maintenance and inventory control. Standardization on a single sealing material may allow the exchange of equipment “mini-modules” without the need to retrofit seals. In new drug development programs or analytical laboratories involving the use of unknown or proprietary fluids, a sealing material with broad chemical versatility can be especially useful.



Kalrez® O-rings provide solid performance vs. encapsulated O-rings

Kalrez® parts (left) are homogeneous throughout to help maintain sealing integrity. The plastic coating on encapsulated O-rings (right) may suffer from abrasion or nicks leading to premature seal failure, process contamination or a place for bacterial growth. The protective sheath is also permeable, which means the underlying elastomer may still suffer chemical attack.

Technical support for achieving optimum results

Depend on DuPont Performance Elastomers for the support you need to achieve optimum results in the shortest possible time. Our worldwide R&D and application expertise can help you with:

- Process development
- Application testing
- New application development



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Kalrez® perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made only from compounds 6221 and 6230 have been tested in accordance with USP protocols and meet the requirements of a USP Class VI polymer. USP testing was done to support use of Kalrez® parts in pharmaceutical processing and food processing applications. While USP Class VI compliance materials are not required for pharmaceutical and food processing applications, many pharmaceutical and food processing customers including customers seeking ISO 9000 certification, have requested compliance. Testing of any finished article that incorporates Kalrez® perfluoroelastomer parts is the responsibility of the manufacturer or seller of the finished article if certification that meets USP standards is required.

Caution: Do not use in medical applications involving permanent implantation in the human body. For other medical applications, discuss with your DuPont Performance Elastomers customer service representative and read Medical Caution Statement H-69237.

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