

DuPont™ Kalrez®

For Pharmaceutical and Food Handling Applications

Technical Information — Rev. 5, July 2010

DuPont™ Kalrez® perfluoroelastomer parts made from compounds 6221 and 6230/6230A* provide superior chemical resistance and low contamination from extractables in pharmaceutical and food handling applications where FDA compliance is required. DuPont™ Kalrez® 6221 and 6230/6230A are especially suited for Water For Injection (WFI) systems, Steam-in-Place (SIP) cleaning and other critical systems.

Thermal Stability

Unlike other elastomeric seals made with FDA compliant elastomers, Kalrez® perfluoroelastomer parts are thermally stable up to 260 °C (500 °F), permitting use in applications such as Stage II Sterilization processes, where other elastomers lose their sealing capabilities.

Aggressive Water Resistance

In aggressive pharmaceutical and semiconductor processing environments, seal failure from excess swelling, embrittlement or decomposition can cause unscheduled downtime or product contamination. Elastomeric materials that come in contact with highly pure and aggressive water (e.g., WFI) must be chosen with care in order to prolong seal life. The perfluoroelastomer compounds used in Kalrez® parts have been shown to have extremely low to non-detectable extractable levels in aggressive water systems. Because the perfluoroelastomer polymer in Kalrez® parts is fully saturated, it is also well suited for ozonated deionized water service. Kalrez® parts also exhibit very low swell and loss of mechanical properties after repeated steam cycling.

General Chemical Resistance

The overall chemical resistance of EPDMs, silicone elastomers and fluoroelastomers (FKM) is limited by their respective polymer structures. Kalrez® parts, on the other hand, offer the same universal chemical resistance as PTFE, but unlike PTFE, they have elastomeric properties, which help them maintain their sealing capabilities. Table 1 lists the chemical compatibility of Kalrez® perfluoroelastomer parts and other elastomers used as sealing materials in the pharmaceutical and food handling industries.

Table 1. Typical Physical Properties**

Product	DuPont™ Kalrez® 6221	DuPont™ Kalrez® 6230/6230A
Durometer Hardness, Shore A, points ±5 ¹	70	75
100% Modulus, MPa (psi) ²	7.24 (1,050)	7.03 (1,020)
Tensile Strength at Break ² , MPa (psi)	15.16 (2,200)	16.54 (2,400)
Elongation at Break ² , %	150	170
Compression Set ³ , 70 hr at 160 °C (320 °F)	27	24
Color	White	Black*

** Typical physical properties should not be the basis of design decisions. Contact DuPont for further information.

¹ ASTM 2240

² ASTM D412, 500 mm/min (20 in/min)

³ ASTM D395, (PelletTest Specimens)

*Kalrez® 6230A used exclusively for Sanitary Gaskets



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Table 2. Elastomer Chemical Compatibility*

Chemical	DuPont™ Kalrez® 6221/6230/6230A	EPDM	SI	FKM
Acetic Acid	A	A	A	B
Acetone	A	A	C	U
Citric Acid	A	A	A	A
Hydrogen Peroxide	A	B	B	B
Isopropyl Alcohol	A	A	A	A
Methyl Ethyl Ketone	A	A	U	U
Mineral Oil	A	U	B	A
NaOH	A	A	B	B
Nitric Acid	A	B	B	A
Sodium Hypochlorite	A	B	B	A
Soybean Oil	A	C	A	A
Steam (<150 °C [302 °F])	A	A	C	U
Steam (>150 °C [302 °F])	A	C	U	U
Toluene	A	U	U	A
Xylene	A	U	U	A
Maximum Service Temperature	260 °C (500 °F)	135 °C (275 °F)	200 °C (392 °F)	200 °C (392 °F)

* Data has been drawn from DuPont tests and industry sources. Data is presented for use only as a general guide and should not be the basis of design decisions. Contact DuPont for further information.

A = little or no effect B = slight swelling and/or loss of physical properties C = moderate to severe swelling and/or loss of physical properties/limited functionality U = not suitable or recommended

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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 customer service representative and read Medical Caution Statement H-50103-3.

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(01/02) Reference No. KZE-H82109-00-E0710



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