Technical Information

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From DuPont Performance Elastomers

Perfluoroelastomer Parts for Pharmaceutical and Food Handling Applications

Kalrez[®] 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. 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.

*Kalrez® 6230A used exclusively for Sanitary Gaskets

Table 1
Elastomer Chemical Compatibility*

Chemical	Kalrez [®] 6221/6230/6230A	EPDM	SI	FKM
Acetic Acid	А	А	А	В
Acetone	А	Α	С	U
Citric Acid	A	А	А	А
Hydrogen Peroxide	A	В	В	В
Isopropyl Alcohol	А	Α	А	А
Methyl Ethyl Ketone	A	А	U	U
Mineral Oil	A	U	В	А
NaOH	A	А	В	В
Nitric Acid	A	В	В	А
Sodium Hypochlorite	A	В	В	А
Soybean Oil	A	С	А	А
Steam (<150°C [302°F])	A	Α	С	U
Steam (>150°C [302°F])	A	С	U	U
Toluene	A	U	U	А
Xylene	A	U	U	А
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 Performance Elastomers 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 Performance Elastomers 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

Table	2
Typical Physical	Properties**

Compound	Kalrez [®] 6221	Kalrez [®] 6230/6230A
Durometer Hardness, Shore A, points ±5	70	75
100% Modulus, MPa (psi)	7.24 (1,050)	7.03 (1,020)
Tensile Strength at Break ¹ , MPa (psi)	15.16 (2,200)	16.54 (2,400)
Elongation at Break ¹ , %	150	170
Compression Set ² , 70 hr at 160°C (320°F)	31	30
Color	White	Black*

**Typical physical properties should not be the basis of design decisions. Contact DuPont Performance Elastomers for further information. ¹ASTM D412, 20 in/min (500 mm/min)

²ASTM D412, 20 II//IIII (500 IIII//IIII

²ASTM D395 B, Size 214 O-rings

For further information please contact one of the addresses below, or visit us at our website at <u>www.dupontelastomers.com/kalrez</u>

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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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