

Perfluoroelastomer Parts

For Pharmaceutical and Food Handling Applications

Technical Information — August 2015

Product Description

DuPont™ Kalrez® 6221 perfluoroelastomer parts are a white product that provide superior chemical resistance and low contamination from extractables in pharmaceutical and food handling applications where FDA compliance is required. DuPont™ Kalrez® 6221 parts are especially suited for Water for Injection (WFI) systems, Steam-in-Place (SIP) cleaning and other critical systems. Kalrez° 6221 parts are thermally stable up to 260°C (500°F), permitting them to be used in Stage II Sterilization processes, where other elastomers lose their sealing ability. Kalrez® 6221 is available as O-rings. For white custom parts, please refer to Kalrez® LS205 parts.

Typical Physical Properties ¹	
Color	White
Maximum Application Temperature ² , °C (°F)	260 (500)
Durometer, Shore A ³	70
100% Modulus ⁴ , MPa (psi)	7.24 (1049)
Tensile Strength at Break ⁴ , MPa (psi)	15.16 (2199)
Elongation at Break ⁴ , %	150
Compression Set ⁵ , %, 70 hr at 200 °C (392 °F)	27

¹ Not to be used for specification purposes

Aggressive Water Resistance

In aggressive pharmaceutical 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.

^{*}For additional information on FDA compliance, please refer to Food Contact Notification (FCN) number 101. USP <87> and <88> class VI compliance was tested at 121°C



² DuPont proprietary test method

³ ASTM D2240 (plied sheet test specimen)

⁴ ASTM D1414

⁵ ASTM D395B (Pellet test specimen)

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. The following table lists the chemical compatibility of Kalrez® 6221 perfluoroelastomer parts and other elastomers used as sealing materials in the pharmaceutical and food handling industries.

Chemical/Product	Kalrez® 6221	EPDM	Si	FKM
Acetic Acid	Α	Α	Α	В
Acetone	Α	Α	С	U
Citric Acid	Α	Α	Α	Α
Hydrogen Peroxide	Α	В	В	В
Isopropyl Alcohol	Α	Α	Α	Α
Methyl Ethyl Ketone	Α	Α	U	U
Mineral Oil	Α	U	В	Α
NaOH	Α	Α	В	В
Nitric Acid	Α	В	В	Α
Sodium Hypochlorite	Α	В	В	Α
Soybean Oil	Α	С	Α	Α
Steam (<150°C)	Α	Α	С	С
Steam (>150°C)	Α	С	U	U
Toluene	Α	U	U	Α
Xylene	Α	U	U	Α
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

Visit us at kalrez.dupont.com

Contact DuPont at the following regional locations:

North America Latin America Europe, Middle East, Africa 800-222-8377 +0800 17 17 15 +41 22 717 51 11

Greater China ASEAN Japan +86-400-8851-888 +65-6586-3688 +81-3-5521-8484

The information provided in this data sheet corresponds to our knowledge on the subject at the date of its publication. This information may be subject to revision as new knowledge and experience becomes available. The data provided fall within the normal range of product properties and relate only to the specific material designated; these data may not be valid for such material used in combination with any other materials, additives or pigments or in any process, unless expressly indicated otherwise.

The data provided should not be used to establish specification limits or used alone as the basis of design; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use and disposal conditions, DuPont does not guarantee favorable results, makes no warranties and assumes no liability in connection with any use of this information. All such information is given and accepted at the buyer's risk. It is intended for use by persons having technical skill, at their own discretion and risk. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent. DuPont advises you to seek independent counsel for a freedom to practice opinion on the intended application or end-use of our products.

CAUTION: Do not use DuPont materials in medical applications involving implantation in the human body or contact with internal body fluids or tissues unless the material has been provided from DuPont under a written contract that is consistent with DuPont policy regarding medical applications and expressly acknowledges the contemplated use. For further information, please contact your DuPont representative. You may also request a copy of DuPont POLICY Regarding Medical Applications H-50103-5 and DuPont CAUTION Regarding Medical Applications H-50102-5.

Copyright © DuPont. The DuPont Oval Logo, DuPont[™], The miracles of science[™] and Kalrez[®] are trademarks or registered trademarks of E.I. du Pont de Nemours and Company or its affiliates. All rights reserved.

(07/10) Reference No. KZE-A40032-00-A0815 previously KZE-H82109-00-E0710

