



**Kalrez®** perfluoroelastomer parts

A Product of DuPont Dow Elastomers

## Pharmaceutical and Food Handling Applications Compound 6221

Kalrez® parts made from compound 6221 are compliant with the Federal Food, Drug and Cosmetic Act and the Food and Drug Administration's regulations for repeated-use contact with food as described by 21CFR177.2600. Kalrez® parts made from compound 6221 have been tested in accordance with The United States Pharmacopeia Class VI (USP Class VI) testing protocol.<sup>1</sup>

Testing using the protocol cited above was performed by an external testing facility in compliance with 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies.

Compound 6221 offers excellent steam cycling resistance and reduces extractables from sealing materials to trace levels.

Kalrez® has been used in the most demanding sealing applications since 1973.

### Typical Physical Properties\*

Compound	6221
Color	White
Hardness, Shore A <sup>ii</sup>	70
100% Modulus, psi <sup>ii</sup>	1,050
Tensile Strength, psi <sup>ii</sup>	2,200
Elongation at Break, % <sup>**</sup>	150
Compression Set <sup>***</sup> 70 hr at 160°C (320°F)	20

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

\*\*ASTM D412, 20 in/min (500mm/min)

\*\*\*ASTM D395 B, Size 214 O-Rings

<sup>1</sup> Kalrez® perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made from compound 6221 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 compliant 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.

#### Medical Use

**CAUTION:** Do not use Kalrez® perfluoroelastomer parts in medical applications involving implantation in the human body. For other medical applications, see DuPont Dow Elastomers Medical Applications Policy, H-69237. DuPont Dow Elastomers will not sell or support products for implantation in the human body. DuPont Dow Elastomers does not make surgical or medical grades of Kalrez® perfluoroelastomer parts and does not guarantee continuity of process in our manufacturing operations as changes may occur from time to time.

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For more information on Kalrez®  
or other elastomers:

(800) 853-5515 (U.S. & Canada)  
(302) 792-4000  
[www.dupont-dow.com](http://www.dupont-dow.com)

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Global Headquarters  
DuPont Dow Elastomers L.L.C.  
300 Bellevue Parkway, Suite 300  
Wilmington, DE 19809 USA  
Tel. (302) 792-4000  
Fax. (302) 892-7390

European Regional  
Headquarters  
DuPont Dow Elastomers S.A.  
2, chemin du Pavillon  
CH-1218 Le Grand-Saconnex  
Geneva, Switzerland  
Tel. +41-22-717-4000  
Fax. +41-22-717-4001

Asia Pacific Regional  
Headquarters  
DuPont Dow Elastomers Pte Ltd.  
1 Maritime Square #10-54  
World Trade Centre  
Singapore 099253  
Tel. +65-275-9383  
Fax. +65-275-9395

South & Central  
America Regional  
Headquarters  
DuPont Dow Elastomers Ltda.  
Rua Henrique Monteiro, 90  
5: andar – Pinheiros  
05423-912  
São Paulo – SP  
Brazil  
Tel. +55-11-816-0256  
Fax. +55-11-814-6845

Kalrez Parts Marketing  
DuPont Dow Elastomers L.L.C.  
P.O. Box 6098  
Newark, DE 19714  
Tel. (800) 323-9806

Kalrez European Parts  
Marketing  
DuPont Dow Elastomers N.V.  
Battelsesteenweg 455d  
B-2800 Mechelen, Belgium  
Tel. +32 15 28 87 00  
Fax. +32 15 28 87 50

Kalrez Asia Parts  
Marketing  
DuPont Dow Elastomers Limited  
Dempa Bldg., 11-15  
Higashi Gotanda 1-chome  
Shinagawa-ku  
Tokyo, Japan 141-0022  
Tel. +81-3-3444-5166  
Fax. +81-3-3444-6095

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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 Dow Elastomers customer service representative and read Medical Caution Statement, H-69237.

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