# DuPont™ Kalrez®

## Perfluoroelastomer parts

## Statement of Compliance for Pharmaceutical, Biotech, Food and Beverage Applications

Technical Information—September 2015

**Kalrez® Products for the Pharmaceutical, Biotech, Food, and Beverage Industry**

| Kalrez® Product | Color | Durometer Shore A | FDA/ FCN# | USP <87> | USP <88> | 3-A* | Japan Pharmacopeia |
|---|---|---|---|---|---|---|---|
| **LS205** | White | 75 | 1116 | ● | ● | | ● |
| **LS222** | Black | 75 | 1116 | ● | ● | | |
| **LS390** | Grey | 88 | 1116 | ● | ● | | ● |
| **6221** | White | 70 | 101 | ● | ● | ● | ● |
| **6230** | Black | 75 | 101 | ● | ● | ● | |
| **6230A** | Black | 75 | 101 | ● | ● | | |
| **6236** | Black | 90 | | ● | ● | | ● |

● denotes the product is compliant; otherwise the product has not been evaluated for this standard

*3A compliance testing is complete and the packaging requirement is in process for 6221 and 6230. Testing has not been done on other Kalrez® products at this time

### FDA/FCN #101

On Dec. 19, 2000, the United States Food and Drug administration (FDA) confirmed the compliance of DuPont™ Kalrez® 6221, 6230 and 6230A perfluoroelastomer parts for repeated use in contact with food by publication of Food Contact Notification (FCN) 101. FDA's Food Contact Substance Notification process, described in section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 348(h)), is the primary method by which the FDA authorizes the use of food additives that are food contact substances. FCN 101 requires Kalrez® 6221, 6230 and 6230A to meet extractable levels not to exceed 0.2 mg/in$^2$. This provides further assurance of the low risk of contamination from Kalrez® parts. Appendix A is an excerpt from FCN 101, the FDA's official notification to DuPont that designates constituents of Kalrez® 6221, 6230 and 6230A as suitable for repeated use in contact with food.

Kalrez® 6221, 6230 and 6230A parts also comply with the extractive limitations prescribed in U.S. FDA regulations 21 CFR 177.2400(d)(1)(2) and 21 CFR 177.1550(e)(3)(i)(ii).

### FDA/FCN #1116

On November 24, 2011, the United States Food and Drug administration (FDA) confirmed the compliance of DuPont™ Kalrez® LS205, LS222, and LS390 perfluoroelastomer parts for repeated use in contact with food by publication of Food Contact Notification (FCN) 1116. FDA's Food Contact Substance Notification process, described in section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 348(h)), is the primary method by which the FDA authorizes the use of food additives that are food contact

substances. FCN 1116 requires Kalrez® LS205, LS222, and LS390 to meet extractable levels not to exceed 0.2 mg/in$^2$. This provides further assurance of the low risk of contamination from Kalrez® parts. Appendix B is an excerpt from FCN 1116, the FDA's official notification to DuPont that designates constituents of Kalrez® LS205, LS222, and LS390, as suitable for repeated use in contact with food.

Kalrez® LS205, LS222, and LS390 also comply with the extractive limitations prescribed in U.S. FDA regulations 21 CFR 177.2400(d)(1)(2) and 21 CFR 177.1550(e)(3)(i)(ii).

## USP compliance

Kalrez® 6221, 6230, 6230A, 6236, LS205, LS222, and LS390 also have been tested in accordance with the United States Pharmacopeia <87> (or ISO 10993-5) and <88> Class VI (or ISO 10993-6, -10, -11) testing protocol at 121°C and meet the test requirements of a USP Class VI polymer.

Migration and USP Class VI testing was performed by an external testing facility in compliance with 21 CFR, Part 58 Good Laboratory Practice for Nonclinical Laboratory Studies.

Kalrez® perfluoroelastomer parts are not routinely tested using the USP testing protocol. While USP <87> and <88> 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.

## 3A compliance

Kalrez® 6221 and 6230 parts meet the requirements of the following: 3-A Sanitary Standards Inc., Multiple-Use Rubber and Rubber-like Materials Use as Product Contact Surfaces in Dairy Equipment, Number 18-03, Class I.

## Japan Pharmacopeia

Kalrez® LS205, LS390, 6221 and 6236 have been tested in accordance with Japan Pharmacopeia edition 16 requirements for section 7.03 - Rubber Closure for Aqueous Infusions. Japan Pharmacopeia testing was performed by an authorized external testing facility.

Note: DuPont reserves the right to make changes in manufacturing operations from time to time that maintain applicable FDA and regulatory compliance.

Medical Use Caution: Do not use Kalrez® perfluoroelastomer parts 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.

## Appendix A

**Food Contact Substance Notification FCN 101**

The following is an excerpt from FDA's official FCN notification which covers DuPont™ Kalrez® 6221, 6230, and 6230A perfluoroelastomer parts:

***Food Contact Substance***

Perfluorocarbon cured elastomers produced by polymerizing perfluoro(methyl vinyl ether) (CAS Reg. No. 1187-93-5) with tetrafluoroethylene (CAS Reg. No. 116-14-3) and perfluoro (8-cyano-5-methyl -3,6-dioxa -1-octene) (CAS Reg. No. 69804-19-9), followed by curing with trimethylallylocyanurate (CAS Reg. No. 6291-95-8) and/or triallyl isocyanurate (CAS Reg. No.1025-15-6), and with 2,5 -dimethyl -2,5-di (t-butylperoxy) hexane (CAS Reg. No. 78-63-7) and as further described in this notification.

***Notifier***

E.I. du Pont de Nemours and Company

***Manufacturer/Supplier***

E.I. du Pont de Nemours and Company

***Intended Use***

For use in the fabrication of articles intended for repeated use in contact with food.

***Limitations/Specifications***

The perfluorocarbon base polymer shall contain no less than 40 wt% of polymer units derived from perfluoro(methyl vinyl ether), no less than 30 wt% of polymer units derived from tetrafluoroethylene, and no more than 5 wt% polymer units derived from perfluoro(8-cyano-5-methyl-3,6-dioxa-1-octene). The uncured elastomer shall be compounded with no more than 4 parts per hundred of rubber (phr) of trimethylallyl isocyanurate and/or triallyl isocyanurate and no more than 4 phr of 2,5-dimethyl-2,5-di(t-butylperoxy)hexane. The elastomer may also contain up to 1.0 phr of N, N, N', N'-tetramethyl-1-8-naphthalenediamine (CAS Reg. No. 20734-58-1). The perfluorocarbon cured elastomers must meet the total extractive limitations prescribed in 21 CFR 177.2400(d)(1).

FCN 101 became effective December 19, 2000 and has been added to FDA's list of effective notifications for food substances.

## Appendix B

**Food Contact Substance Notification FCN 1116**

The following is an excerpt from FDA's official FCN notification which covers DuPont™ Kalrez® LS222 and LS205 perfluoroelastomer parts:

***Food Contact Substance***

A copolymer of tetrafluoroethylene (CAS Reg. No. 116-14-3) and trifluoromethyl trifluorovinyl ether (CAS Reg. No. 1187-93-5), and optionally employing a halogenated alkene, and as further described in this notification.

***Notifier***

E.I. du Pont de Nemours and Company

***Manufacturer/Supplier***

E.I. du Pont de Nemours and Company

***Intended Use***

For repeat-use in the fabrication of molded parts, such as o-rings, sanitary seals, butterfly valve seats, weir diaphragms, and heat exchanger gaskets.

***Limitations/Specifications***

Articles containing the FCS will be used in contact with all food types under Conditions of Use A through H and J. The FCS may contain food-contact substances that are otherwise cleared for the intended uses, subject to any limitations on use of the adjuvant substances. The uncured perfluoroelastomer shall be compounded with no more than 4 parts per hundred of rubber (phr) of triallyl isocyanurate and 2 phr of 2,5-dimethyl-2,5-di(*tert*-butylperoxy) hexane or 2,5-dimethyl-2,5-di(*tert*-butylperoxy)hexyne-3.

FCN 1116 became effective November 24, 2011 and has been added to FDA's list of effective notifications for food substances.

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