

DuPont™ Kalrez®

Perfluoroelastomer parts

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

Technical Information—July 2013

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
6221	White	70	000101	•	•	•	
6230	Black	75	000101	•	•	•	
6230A	Black	75	000101	•	•		
6236	Black	90		•	•		•
LS205	White	75	001116	•	•		•
LS222	Black	75	001116	•	•		

• 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# 000101

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) 000101. 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 000101 requires Kalrez® 6221, 6230 and 6230A to meet extractable levels not to exceed 0.2 mg/in². This provides further assurance of the low risk of contamination from Kalrez® parts. Appendix A is an excerpt from FCN 000101, 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# 001116

On November 24, 2011, the United States Food and Drug administration (FDA) confirmed the compliance of DuPont™ Kalrez® LS205 and LS222 perfluoroelastomer parts for repeated use in contact with food by publication of Food Contact Notification (FCN) 001116. 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 001116 requires Kalrez® LS205 and LS222 to meet extractable levels not to exceed 0.2 mg/in². This provides further assurance of the low risk of contamination from Kalrez® parts. Appendix



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B is an excerpt from FCN 001116, the FDA's official notification to DuPont that designates constituents of Kalrez® LS205, LS222 as suitable for repeated use in contact with food.

Kalrez® LS205, LS222 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, and LS222 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® 6236 and LS205 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 000101

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-dioxo-1-octene) (CAS Reg. No. 69804-19-9), followed by curing with trimethylallyl isocyanurate (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-dioxo-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 000101 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 001116

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 001116 became effective November 24, 2011 and has been added to FDA's list of effective notifications for food substances.

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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-50103-4 and DuPont CAUTION Regarding Medical Applications H-50102-4

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