Kalrez® perfluoroelastomer parts

From DuPont Performance Elastomers

Statement of Compliance

On Dec. 19, 2000, the United States Food and Drug administration (FDA) confirmed the compliance of 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/in^2. This provides further assurance of the low risk of contamination from Kalrez® parts. On page 2 is an excerpt from FCN 000101, the FDA's official notification to DuPont Performance Elastomers, 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 requirements in U.S. FDA regulation 21 CFR 177.2600 and the extractive requirements of 21 CFR 177.2400(d).

Kalrez® 6221, 6230 and 6230A also have been tested in accordance with the United States Pharmacopeia Class VI (USP Class VI) testing protocol and meet the test requirements of a USP Class VI polymer.[1)]

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.

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

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[1]Kalrez® perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made only from compounds 6221, 6230 and 6230A 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 ISO9000 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 Performance Elastomers Medical Applications Policy, H-69237. DuPont Performance Elastomers will not sell or support products for implantation in the human body. DuPont Performance Elastomers does not make surgical or medical grades of Kalrez® perfluoroelastomer parts. DuPont Performance Elastomers will not provide to customers making implantable devices any notice concerning its materials, as specified under 21 CFR, section 820.81, or any other information necessary for medical device use of the materials under any other statute or FDA regulation.

Food Contact Substance Notification FCN 000101

The following is an excerpt from FDA's official FCN notification which covers Kalrez® 6221 and 6230 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

DuPont Performance Elastomers L.L.C.

Manufacturer/Supplier

DuPont Performance Elastomers, L.L.C.

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 000101 became effective December 19, 2000 and has been added to FDA's list of effective notifications for food contact substances.

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