



CHEMRAZ[®]

Perfluoroelastomer parts

Statement of Compliance

The United States Food and Drug Administration (FDA) confirmed the compliance of **CHEMRAZ[®] SD585** perfluoroelastomer parts for repeated use in contact with food by publication of **Food Contact Substance Notification (FCN) 000247**. The 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)), emerged in 2000 as the primary method by which the FDA authorizes the use of food additives that are food contact substances. CHEMRAZ[®] SD585 meets the extractive limitations as prescribed in 21 CFR 177.2400(d) *Perfluorocarbon cured elastomers*. This compliance is further assurance of the low risk of contamination from CHEMRAZ[®] parts.

In addition to meeting the requirements of the FDA for repeated use in contact with food, CHEMRAZ[®] SD585 has also been tested per the United States Pharmacopeia (USP) testing protocol and are compliant with the requirements of the **USP Class VI** polymer¹.

¹ Extraction test per 21 CFR 177.2400, USP Class VI, and Cytotoxicity test completed by NAMSA.

CHEMRAZ[®] perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made only from compound SD585 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 CHEMRAZ[®] 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 CHEMRAZ[®] 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: For all medical applications, consult the Greene, Tweed & Co., Medical & Biotechnology Group Engineering Department.

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