



Chemraz®

Perfluoroelastomer parts

Statement of Compliance

The United States Food and Drug Administration (FDA) confirmed the compliance of **Chemraz® SD625** perfluoroelastomer parts for repeated use in contact with food by publication of **Food Contact Substance Notification (FCN) 000245**. 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® SD625 meets the extractive limitations as prescribed in 21 CFR 177.2400(d) *Perfluorocarbon cured elastomers*¹. This compliance is further assurance of the low risk of contamination from Chemraz® perfluoroelastomer parts.

In addition to meeting the requirements of the FDA for repeated use in contact with food, Chemraz® SD625 has also been tested per the United States Pharmacopeia (USP) testing protocol and are compliant with the requirements of the **USP Class VI** polymer¹.

Furthermore, Chemraz® SD625 has been evaluated according to the test procedures contained in the **3-A®** "Sanitary Standards for Multiple-Use Rubber and Rubber-Liked Material Used as Product Contact Surfaces in Dairy Equipment," Number 18-3. The material is covered by the scope and applicable definitions in these standards. The material complies with the applicable material and compatibility criteria found in sections C and D for a **Rubber Class I** material².

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

²Compatibility tests per 3-A® Sanitary Standard completed by AKRON RUBBER DEVELOPMENT LABORATORY, an independent test laboratory.

Chemraz® perfluoroelastomer parts are not routinely tested using the USP testing protocol. Cured samples made only from compound SD625 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 Greene Tweed & Co.