



Chemraz® SD517

(FFKM)

Statement of Compliance

Chemraz® SD517 is permitted for use in the fabrication of molded parts (including a-rings, gaskets, diaphragms and other materials that function primarily as components of sealing applications) for food processing equipment in accordance with the United States Food and Drug Administration (FDA) **Food Contact Notification (FCN) 247**.¹

In accordance with the requirements set forth under FCN 247, **Chemraz® SD517** also meets the extractive limitations prescribed in 21 C.F.R. Section 177.2400 ("Perfluorocarbon cured elastomers"), paragraph (d).²

Chemraz® SD517 has been tested in accordance with United States Pharmacopeia (USP) Standards for use in pharmaceutical applications. More specifically, **Chemraz® SD517** has been evaluated under USP <87> ("Biological Reactivity Tests, *In Vitro*") and USP <88> ("Biological Reactivity Tests, *In Vivo*") and meets applicable requirements for Class VI polymers.³

Chemraz® SD517 has been evaluated according to the test procedures contained in the 3-A sanitary standards for multiple-use rubber and rubber-like materials used as product contact surfaces in dairy equipment, number 18-03. 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 material.⁴

Chemraz® SD517 complies to EC1935-2004 per national requirement BfR XXI, category 4 for seals and similar commodity parts.⁵

Medical Use

CAUTION: Chemraz® perfluoroelastomers are not intended for use in medical applications involving implantation in the human body. For all medical applications, consult the Greene, Tweed & Co. LLC Life Sciences Department.

Chemraz® is a registered trademark of Greene, Tweed.

1. See <https://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=247> (effective August 13, 2002).
2. Extraction tests in accordance with 21 C.F.R. Section 177.2400 were conducted by NAMSA, an independent testing laboratory. Results available upon request. (CER 20870, 20514 & 22809)
3. Testing requirements in accordance with USP <87> and <88> (Class VI) were conducted by NAMSA. Results available upon request. Testing of finished articles that incorporates Chemraz® SD517 perfluoroelastomer under USP Standards is the responsibility of the manufacturer or seller of the finished article.
4. Testing requirements in accordance with 3-A sanitary standards for multiple-use rubber and rubber-like materials used as product contact surfaces in dairy equipment, number 18-03 were conducted by ARDL. (CER 21841) Results available upon request.
5. Greene Tweed does not certify SD517 to the requirements of EC1935/2004. Absolute compliance of any device in its end use application is the obligation of the final device manufacturer.

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