



Fluoraz®

Compound 890

Statement of Compliance

Greene Tweed's black Fluoraz® 890 (80 Shore A) conforms to the FDA requirements as a Food Contact Substance under the Food Contact Notification (FCN)¹ number 000246, issued 8/12/02.

Section 409(h)(6) of the FFDCFA (21 U.S.C. 348 (h)(6)) defines a food contact substance as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food." The premarket notification process for food contact substances in section 409(h) of the FFDCFA is the primary method by which the Food and Drug Administration (FDA) authorizes the use of food additives that are food contact substances.

Fluoraz® 890 meets the extractive limitations as prescribed in 21 CFR 177.2600 (e) and (f), and 21 CFR 177.2400(d)(2). Results of the extractable tests conducted by NAMSA are available upon request.

In addition to meeting the requirements of the FDA for repeated use in contact with food, Fluoraz® 890 has also been tested per the United States Pharmacopeia (USP) testing protocol <88> and is compliant with the requirements of the **USP Class VI** polymer².

Furthermore, Fluoraz® 890 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** material.

¹More information on the FCN program can be found at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

²USP Class VI testing completed by NAMSA.

Greene Tweed parts are not routinely tested using the USP testing protocol. Cured samples made only from compound Fluoraz® 890 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 Greene Tweed Fluoraz® 890 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 Greene Tweed Fluoraz® 890 parts is the responsibility of the manufacturer or seller of the finished article if certification meeting USP standards is required.

Medical Use

CAUTION: For all medical applications, consult Greene Tweed & Co.