

FDA APPROVED POLYURETHANE BELT MATERIALS

Certain polyurethane materials have been approved by the Federal Drug and Food Administration (FDA). Belt applications for these materials include packaging equipment, conveying of dairy and meat products, and other miscellaneous food processing machines. The laws, regulations, and test methods for certain types of materials are summarized below.

FDA Laws and Regulations

The law that governs the use of urethane elastomers under FDA regulations is the Federal Food Drug and Cosmetic Act of 1938 and several subsequent amendments, among them including the Food Additives Amendment of 1958.

Based on the April 1, 1997 Edition of 21 CFR (Code of Federal Regulations), polyurethane products are addressed in Parts 177.1680 ("Polyurethane Resins") and 177.2600 ("Rubber Articles Intended for Repeated Use"). These Parts address elastomers, antioxidants, plasticizers, fillers, colorants, lubricants, and emulsifiers.

In addition to urethane materials, approved reinforcement cords are addressed in Part 177.2800 ("Textiles and Textile Fibers") and silicone materials are addressed in Part 177.2600.

Test Methods and Criteria FDA approved polyurethane materials must satisfy several test criteria as summarized below:

- All polyurethane resins approved in Part 177.1680 must meet certain abrasion resistance requirements. An appropriate sample of the finished resin in the form in which it contacts food, when subjected to ASTM method D968-81, "Standard Test Methods for Abrasion Resistance of Organic Coatings by the Falling Abrasive Tester, shall exhibit an abrasion coefficient of not less than 20 liters per mil of film thickness.
- Polyurethane resins approved in Part 177.2600 intended for use in contact with aqueous food when extracted with distilled water at reflux temperature, shall yield total extractives not to exceed 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction
- Polyurethane resins approved in Part 177.2600 intended for use in contact with fatty foods when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 7 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction

FDA Approved Applications

For specific formulation development or test data, please contact the Engineering Department for assistance.

Chemi-Flex believes the information presented is accurate at the time of publication and is intended for comparison purposes only. It is the end users responsibility to test products to insure they meet requirements for each application. Reference to products not manufactured by Chemi-Flex is neither an endorsement nor unsuitability of similar products.
