Fluoroelastomers for Food Contact (FDA)
FDA APPLICATIONS
Fluoroelastomers (ASTM designation FKM, FFKM and FEPM) are used in sealing components such as o-rings, gaskets, shaft seals and flexible connectors where heat and/or aggressive chemicals will quickly degrade other types of rubber. In food processing high temperatures are used for cooking and preserving foods, which may be acidic, oily or fatty. In addition, rubber components are exposed to steam and caustic chemicals used to sanitize the equipment. In this environment fluoroelastomers will retain their sealing ability long after other elastomers have failed. Fluoroelastomer o-rings, gaskets and other seals therefore offer longer replacement cycles, less unplanned downtime and better protection against product contamination, which saves money and ensures a safer food processing environment.

FDA REGULATIONS
The United States Code of Federal Regulations (CFR) Title 21, Section 177.2600, identifies substances that can be safely used in rubber articles that come into contact with food. These include various elastomers and the fillers, plasticizers, crosslinkers and protective agents that are compounded into them to make them processable and to meet finished part performance requirements. Many of these substances are listed in Section 177.2600 and many more are incorporated by reference, such as substances that are generally recognized as safe (GRAS) and substances that have been given prior sanction or approval by the FDA.

Since about the year 2000, new substances cleared by the FDA for contact with food are no longer added to Section 177.2600 or other applicable Food Additive Regulations, but instead are included on an Inventory of Effective Food Contact Notifications (FCNs), which FDA publishes on its website. Approval to use a substance under an FCN is specific to the company that submitted the FCN and its customers. If a competitor wants to use the same substance in a food contact application it must submit a separate FCN.

It is a common misconception that a new rubber compound must be submitted to the FDA for analysis and approval. What is required is to use “approved” substances (subject to any limitations in the regulations); to ensure that the finished part passes the applicable extractives tests in Section 177.2600; and to thoroughly cleanse the parts prior to their first use in contact with food. That is why it is more correct to say FDA cleared or compliant than FDA approved.

FDA CRITERIA FOR FLUOROELASTOMERS
FKM copolymers with a minimum molecular weight of 70,000 and terpolymers with a minimum molecular weight of 100,000 are permitted for use under Section 177.2600. Since molecular weight affects viscosity these tend to be medium to high Mooney viscosity grades, though there are exceptions.
ADVANTAGES OF USING DAI-EL FKM

Daikin offers several FDA compliant DAI-EL fluoroelastomers, both polyol and peroxide curable and our state of the art polymerization technology ensures consistent processing and excellent long term sealing ability. Call our customer service department at (800) 365-9570 or visit www.daikin-america.com for literature, samples or to request technical support. We will recommend the right product for your application and assist you with compound development and testing.

Prefer ready-to-mold compound? Our Cri-Tech, Inc. subsidiary offers FDA compliant compounds to meet various processing, physical property and environmental resistance requirements in black, white and other colors. And if one of these compounds does not meet your needs they will develop one that does. Call Cri-Tech customer service at (800) 826-5699 or visit www.critechinc.com.