



FDA Compliance of GLS Product

September 27, 2011

Dear Valued Customer:

This letter contains information concerning the FDA status of **DYNAFLEX™ G7950-1**. Key compliance points in this letter are shown below; please carefully review this letter in its entirety for detailed explanations for the points given.

- **All components used in manufacture of this product comply with Title 21 CFR 177.1210.**
- **Final article compliance may require that extraction testing be performed on the final article.**
- **Extraction testing of the final article is the responsibility of its manufacturer.**
- **It is the responsibility of the customer to determine the applicability of this regulation in the development of the finished food contact article.**

All components used in the manufacture of this product comply with the composition requirements of the Title 21 Code of Federal Regulations (CFR) Part 177.1210 - Closures with sealing gaskets for food containers. In accordance with 21 CFR 177.1210, "Closures with sealing gaskets may be safely used on containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food ...". In accordance with 21 CFR 177.1210, those components in compliance with 21 CFR Parts 174, 175, 176, 177, 178 and 179.45 may be used as material composing the 21 CFR 177.1210 product¹.

Although the components used to manufacture this product are approved under 21 CFR 177.1210, migration testing of the final article may be required (see 21 CFR 177.1210 section (c)). In certain applications, substance migration may be influenced by the part design or the conditions of its use. Since the design of the part is the responsibility of the part manufacturer, it is recommended the part manufacturer certify that their design meets applicable FDA extraction requirements.

Please note that the above provision (21 CFR 177.1210), as well as all others found under 21 CFR Parts 170-199 are not required for houseware items. Houseware items may not be subject to FDA's premarket clearance requirements. Therefore, it may not be necessary for every component to be the subject of an applicable food additive clearance provided that the product would be safe for its intended use and not render the food unsafe. It is up to the customer to determine the applicability of this regulation in the development of the finished food contact article.

Based on references to 21 CFR 176.170 Table 1 and Table 2, this product may be used in contact with the following food types, subject to the Conditions of Use Limitations included below:

¹ All substances used as a component in a CFR 21, 177.1210 gasket are subject to the specifications prescribed in parts 174, 175, 176, 177, 178 and 179.45.



Food Type	Description
I	Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0)
II	Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
IV	Dairy products and modifications: B: Oil-in water emulsions, high- or low-fat.
VI	Beverages: A: Containing up to 8% of alcohol. B: Nonalcoholic C: Containing more than 8% alcohol
VII	Bakery products other than those included in Types VIII or IX (below) B: Moist bakery products with surface containing no free fat or oil
VIII	Dry solids with the surface containing no free fat or oil
Limitations	Condition for use D – Hot filled or pasteurized below 150°F through Condition for use G - Frozen storage (no thermal treatment in the container) Maximum food contact area of 500 in ² .

Food Type	Description
III	Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and include water-in-oil emulsions of low- or high-fat content.
IV	Dairy products and modifications: A: Water-in-oil emulsions, high- or low-fat
V	Low-moisture fats and oils
VII	Bakery products other than those included in Types VIII or IX (below) A: Moist bakery products with surface containing free fat or oil
IX	Dry solids with the surface containing free fat or oil
Limitations	Condition for use D – Hot filled or pasteurized below 150°F through Condition for use G - Frozen storage (no thermal treatment in the container) Maximum food contact area of 500 in ² .

All references to the above Food and Drug regulations and applicable parts of accepted use are based on the GLS interpretation of the Title 21 Code of Federal Regulations Parts 170 to 199, revised April 1, 2011. Our statement that the GLS thermoplastic rubber grade listed above can be used in compliance with the above FDA regulations is predicated on the assumption that the chemical composition will not be altered or adulterated by the addition of other unregulated substances, and that the food contact surfaces will be manufactured and employed in accordance with Good Manufacturing Practices outlined in 21 CFR 174.5 and the general provisions applicable to indirect food additives listed there. Any warranty related to the FDA compliance of this product is limited to the purchase value of the product purchased from GLS Thermoplastic Elastomers.

The use of compounds containing GLS thermoplastic rubber-based polymers in medical devices and drug packaging applications is not covered by the above or any other general regulation. It is the responsibility



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of the device or package manufacturer to establish safety with the FDA through the submission of individual applications on the device or drug.

Sincerely,

Rocky Lee
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