PolyOne
GLS Thermoplastic Elastomers

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Date: August 15, 2016
Expiration Date: Earlier of one year from issue date or if change to law(s) cited below

Karibu Baby Limited
Unit 12, 18/F, Rear Block, Wah Fat Ind. Bldg.,
10-14 Kung Yip St, Kwai Chung, N.T., Hong Hong

Re: FDA Compliance – 21 CFR 177.2600

Product Name/Number
GLS 466-018 NATURAL / EM10035634OS
GLS 466-096 NATURAL / EM10038785OS
LC 466-019 / EM1003563562

Dear Valued Customer:

This letter contains information concerning the FDA status of the product named above. 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 177.2600.**
- **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 and is not part of our quality control.**
- **It is the responsibility of the customer to determine the applicability of this regulation in the development of the finished food contact article.**

All of the components used in the manufacture of this product comply with the Code of Federal Regulations (CFR) Section 21, Part 177, subsection 2600. The CFR 21, 177.2600 classification covers “Rubber articles intended for repeated use”. In accordance with this CFR 21 subsection, those materials complying with this subsection may be “… safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, trans-porting, or holding food ...”. In accordance with 21 CFR 177.2600, those components in compliance with 21 CFR Parts 170-189 may be used as material composing the 21 CFR 177.2600 product, subject to the

provisions of such parts. Also, in accordance with 21 CFR 177.2600 (c)(4), substances listed within that paragraph (c)(4), may be used as materials composing the 21 CFR 177.2600 product, provided that any substance that is the subject of a regulation in parts 174,175,176,177,178 and 179.45 of this chapter conforms with any specification in such regulation.

Although the components used to manufacture this product are approved under 21 CFR 177.2600, migration testing of the final article may be required (see 21 CFR 177.2600 sections (e) and (f)). 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 177.2600), 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 and Restrictions included below:

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% 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[1]	Condition for use D – Hot filled or pasteurized below 150°F ***through*** Condition for use G – Frozen storage (no thermal treatment in the container).

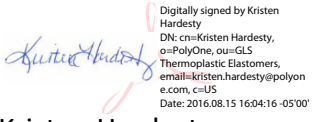
All references to the above Food and Drug regulations and applicable parts of accepted use are based on the GLS interpretation of the Title 21 Code of Federal Regulations Parts 170 to 199,

[1] For Limitations see CFR 21, 176.170 Tables

revised April 1, 2015. 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 PolyOne GLS Thermoplastic Elastomers. All disclaimers and warranty limitations contained in this letter continue after the expiration of the letter.

PolyOne Corporation does not approve the use of this product in any application classified as a medical device, drug packaging or any other application in contact with drugs/pharmaceuticals.

Sincerely,



Kristen Hardesty
Regulatory Manager