101 ISO Parkway
Gray Court, SC 29645
864-724-8100
**www.isoflexpackaging.com**

September 23, 2024

**Subject: ISOFlex Packaging Compliance Information – FDA, EU, Canada All Products**

Dear Customer:

This letter will provide compliance information for all ISOFlex Films (hereinafter "the Products"). The information contained herein is based on the state of our actual knowledge (including information obtained from our raw material suppliers), and is neither part of a specification, nor may it be construed as a warranty, express or implied.

## FOOD CONTACT: FDA

All ISOFlex Products used for Food and Medical packaging comply with US FDA regulations for food contact per 21 CFR 177.1520. The Products can be used in non-cooking applications. For Specific Conditions of Use please contact Regulatory@ISOFlexpkg.com. The Products cannot be used in single use contact with liquid infant formula and human milk. However, the Products may be used in repeated use applications for liquid infant formula and human milk and single use applications for powdered infant formula.

## FOOD CONTACT: EU

All ISOFlex Products used for Food and Medical packaging meet the applicable requirements for intermediate materials intended to come into contact with food as described in **EU Regulation No. 1935/2004** (Framework Regulation). In addition, the Products are manufactured under the relevant requirements of good manufacturing practices (GMP) applicable to intermediate materials established by **EU Regulation No. 2023/2006** (GMP Regulation). Finally, all Products comply with relevant requirements in **EU Regulation No. 10/2011 and its amendments** (Plastics Regulation) for intermediate materials.

## FOOD CONTACT: CANADA

ISOFlex Products have not been assessed by Health Canada's Health Protection and Food Branch (HPFB).

However, our assessment of the Products according to section B.23 of the Canada Food and Drug Act is as follows:

Section B.23.001 states "No person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food." Sections B.23.002 through B.23.008 speak of specific materials that cannot be used in packaging. ISOFlex does not intentionally use organo-tins, polyvinyl chloride (PVC) or vinyl chloride in the manufacture of the Product. We also do not intentionally use acrylonitrile in the manufacture of the Product. However, we do not test our products for these substances.

In addition, many of the components of the Product have been reviewed in the past by the HPFB in other

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products and “no objection” letters (LONOs) have been obtained on those products. Furthermore, the product meets FDA and EU requirements as stated earlier in this letter. With all this information taken into account, we believe that this product complies with section B.23 of the Canadian Food and Drug Act. However, customers must ultimately make their own determination that use of our product(s) in a specific end use application is safe, lawful and technically suitable.

For other country specific compliance please contact Regulatory@ISOFlexpkg.com.

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, ISOFlex Packaging recommends that customers continuing to use our product verify status every year from the issue date of this letter.

Please contact Regulatory@ISOFlexpkg.com if you need additional information.

Sincerely,

*Ranga Soundararajan*

Dr. Ranga Soundararajan
Technical Director