



Intralox, L.L.C.

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Issue Date: April 3, 2017

Dear Valued Customer,

The following is in response to your request regarding the material Intralox uses in the manufacture of finished articles intended for food contact use:

<u>Product:</u>	Thermodrive Polyurethane (36530)
<u>Colorant:</u>	Blue, White
<u>Intended Application (s):</u>	Contact with all food types at temperatures <70 degrees C for 2 hours or up to 100 degrees C for <15 minutes

1. U.S. Food and Drug Administration (“FDA”)

Our supplier has notified us in writing that the above material complies with the following FDA Regulations and is suitable for use in direct food contact applications:

- 21 CFR 177.1680 – *Polyurethane Resins*
- 21 CFR 177.1210 – *Closures with Sealing Gaskets for Food Containers*
- 21 CFR 177.2600 – *Rubber Articles Intended for Repeated Use*. This regulation describes rubber articles intended for repeated use that may be safely used in processing food.

Our supplier has notified us in writing that the colorants comply with one or more of the following FDA Regulations and is suitable for use in direct food contact applications:

21 CFR 178.3297 - *Colorants for Polymers*.

- 21 CFR 178.2010 - *Antioxidants and/or Stabilizers for Polymers*.

Samples of the finished article were tested to the extraction requirements of 21 CFR 177.2600. From the extraction data obtained, the finished product is in full compliance with FDA regulations and may safely be used with the following listed food types at temperatures \leq 70 degrees C:

- 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.
- 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.
 - b. Oil-in water emulsions, high-or low-fat.
- V. Low-moisture fats and oils.
- VI. Beverages:
 - a. Containing up to 8% alcohol.
 - b. Nonalcoholic
- VII. Bakery products other than those included in Types VIII or IX (below)
 - a. Moist bakery products with surface containing free fat or oil.
 - b. Moist Bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil.
- IX. Dry solids with the surface containing free fat or oil.

Since the above material complies with the applicable FDA regulations, it should be chemically acceptable to the USDA for repeat use applications in slaughtering, processing, transporting and storage areas in direct contact with meat or poultry products.

2. European Commission (“EC”)

Intralox finished articles comply with:

- a. **No.1935/2004/EC:** Materials and Articles intended to come into contact with food, including Article 3 (General Requirements) and Article 17 (Traceability).
- b. **No. 2023/2006/EC:** Good Manufacturing Practice Regulation for materials and articles intended to come into contact with food. The finished articles are manufactured under a quality assurance system that meets the requirements of this regulation.
- c. **Regulation (EU) No.10/2011** on Plastic Materials and Articles Intended to Come into Contact with Food, including amendments 1282/2011, 1183/2012 and 202/2014. Monomers, additives and other starting substances are all included in the Union List of authorized substances. A Declaration of Compliance is attached as a separate document.
- d. **Regulation (EU) No.1895/2005.** Intralox, L.L.C., does not intentionally use any BADGE, BFDGE or NOGE material in the manufacturer of articles intended to come into contact with food.
- e. **No. 94/62/EC** regarding concentration levels of heavy metals in packaging: The sum of the concentrations of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight.

3. Other

- a. **CONEG** (Coalition of Northeastern Governors) Model Legislation regarding heavy metals content: The sum of the concentrations of lead, mercury, cadmium and hexavalent chromium is less than 100 ppm by weight.
- b. **Latex:** Intralox does not intentionally use latex or natural rubber materials as plasticizers, additives or raw materials in the belt manufacturing process.
- c. **Phthalates:** Intralox does not intentionally use Butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), di(2-ethylhexyl) phthalate (DEHP), Diisononyl phthalate (DINP), Di-n-octyl phthalate (DNOP), or Diisodecyl phthalate (DIDP) as plasticizers, additives or raw materials in the belt manufacturing process.
- d. **Bisphenol A:** Intralox does not intentionally use Bisphenol A (BPA) as an additive or a raw material in the belt manufacturing process.
- e. **Silicone:** Intralox does not use low molecular weight silicone in the belt assembly process. We mold polymers containing high molecular weight silicone, and we have identified suppliers that may use silicone in their production process. If you need specific information or an updated list of products that may be manufactured with silicone, please contact your Customer Service Representative.

This guarantee is ongoing, generic and is not limited to a specific shipment. It will continue until revoked in writing by Intralox. An updated statement will be provided if the information on which the declaration is based changes or regulatory requirements impact its validity. Intralox believes this information to be accurate and consistent with existing laws, regulations and standards as they apply to Intralox products on the date this letter was issued. Intralox does not warrant that its products conform to any laws, regulations and standards relating to public safety, worker safety, safety guards, sanitation safety, fire safety or any other safety regulations. Customers should not rely exclusively on this information and should consult the relevant agency or regulatory body.



Gloria Bowman, Product Stewardship Manager
Intralox, L.L.C.



Declaration of Compliance

Plastic Materials Intended to Come Into Contact with Food

<u>Product:</u>	Thermodrive Polyurethane (36530)
<u>Colorant:</u>	Blue, White
<u>Intended Application (s):</u>	Contact with all food types at temperatures <70 degrees C for 2 hours or up to 100 degrees C for <15 minutes

This product is in conformity with the applicable requirements of the following regulations:

- (EC) No.1935/2004 on Materials and Articles intended to come into contact with food.
- No. 2023/2006/EC on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (including amendments).

Migration Testing: Data obtained on representative samples of the finished article.

Overall Migration: OM3, 3 x 2 hours at 70 degrees C or equivalent, repeat use.

Test Simulant	Migration (mg/dm ²)	Mean (mg/dm ²)	EU Limit (mg/dm ²) excluding analytical tolerance
10% Ethanol (Simulant A)	1.5, 2.3, 2.2	2.0	10
3% Acetic Acid (Simulant B)	1.7, 1.5, 1.7	1.6	10
95% Ethanol (Simulant D2 - vegetable oil substitute (3 x 2 hours at 60°C))	3.5, 5.0, 4.5	4.3	10 - 50 (depending on fatty food reduction factor)

Specific Migration Testing:

No associated primary aromatic amines were detected in a 2 hours at 70°C test with 3% acetic acid. (Limit of detection 0.010 mg/kg). Migration of proprietary substances into food will not exceed their respective SML restrictions.

Dual Use Food Additives:

No dual use food additives or authorized food flavorings covered respectively by regulation (EC) No. 1333/2008 or Regulation (EC) No. 1334/2008 or their implementing measures are understood to be used in the manufacture of the belting.

Colorant: The colorant used meets the requirements of the Council or Europe Resolution AP (89)1 on the use of colorants in plastic materials coming in to contact with food.

This Declaration is valid for 2 years from 3-Apr-17. Updated statements will be provided if the declaration's validity is affected by changes in the information or regulatory requirements.

Gloria Bowman, Product Stewardship Manager
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