



## INVISTA 13T25A MEDICAL GRADE POLYPROPYLENE DATA SHEET

### Conflict Mineral Compliance Letter:

The provisions of the section 1502 of the 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act requires that certain companies are to disclose the use of “conflict minerals” in their products (I.E. certain minerals, including tin, tantalum, tungsten and gold, that may have originated in The Dominican Republic of Congo or adjoining countries). While we are not regulated by this Act, we provide this statement to our customers who request our assistance in assessing their “conflict minerals” status. We take seriously the concerns that profits from conflict minerals may be fueling human rights violations, labor abuses and environmental degradation and are committed to the ethical sourcing of any minerals used in our manufacturing and supply chain.

### Food Contact (US Food and Drug Association FDA)

This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR177.1520(a)(3)(i) & (c)3. All other ingredients used in the formulation meet their respective regulations as 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, excluding cooking applications. This product can be used with all food types (Conditions of Use C through H 21 CFR 176.170(c) table 2).

### Sterilization:

ETO. Suitable for autoclave sterilization processes in the presence of aqueous solutions. Please note, This Invista material meets certain requirements for use in medical applications. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that this Invista product is safe, lawful or suitable for the intended use. We recommend customers to review their application with a Invista representative to ensure proper use.

### Drug Master File:

This product is listed in DMF#7478. Letters Of Authorization to reference this DMF can be obtained through the Product Service Specialist.

### US Pharmacopeia (USP):

This product has been certified to the USP class VI Plastic (USP<88>, Biological Reactivity Tests, *In Vivo*) requirements. Endotoxin (USP<85>) testing has also been performed. Certificates available upon request.

### Tallow/BSF/TSE:

Invista Resources does not intentionally use tallow or any other animal derived materials in the formulation of this product.

### Declaration of Conformity to EU RoHS:

Invista 13T251 conforms to the RoHS Directive (2011/65/EU) and/or amendments (EU 2015/863 – RoHS 3) restricting the use of Heavy Metals, PBB's, PBDE's and Phthalates.

### Declaration of Conformity to EU REACH

Products manufactured by L&A Plastic Molding are in compliance to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemical (REACH). Specifically, products manufactured do not contain substances listed in the following sections of the directive:

- L&A Plastic Molding products do not contain any of the substances of very high concern (SVHC) as defined in Article 57 and Annex XIV with amendments dated:
  - o 9 October 2008, 13 January 2010, 30 March 2010, 18 June 2010, 15 December 2010, 20 June 2011, 19 December 2011, 18 June 2012, 19 December 2012, 20 June 2013, 16 December 2013, 16 June 2014, 17 December 2014, 15 June 2015, 17 December 2015, 20 June 2016, 12 January 2017, 15 July 2021

### Substances Of Very High Concern

As of the date listed on this document, Invista Resources, LP (FHR) does not believe any chemicals listed on the EU Candidate List of Substances of Very High Concern are present in our polypropylene products at levels greater than 0.1%. Testing has indicated that some of our polypropylene products may contain trace residues (<8ppm) of Dibutyl phthalate, Diisobutyl phthalate, and Bis (2-ethylhexyl) phthalate. Benzyl butyl phthalate was below the detection limit of the instrument used to test.

### Reduction of Toxics in Packaging

We certify that all packaging and packaging components sold from L&A Plastic Molding comply with the requirements of the Toxics in Packaging laws. Specifically: Polypropylene Hinged Lid Round / Square Containers.

1. We certify that the regulated metals – lead, mercury, cadmium and hexavalent chromium – were **not intentionally added** to any packaging or packaging component during the manufacturing process.
2. We further certify that the **sum of the incidental concentration levels** of lead, mercury cadmium and hexavalent chromium present in any package or package component does not exceed 100 parts per million by weight.

### CA Prop 65 Compliance Certification

In regards to products sold by L&A Plastic Molding and our subsidiaries, we hereby certify that as of the date listed below, items produced by L&A Plastic Molding are in compliance with California Proposition 65.

### Shelf Life:

Containers made of Invista 13T25A Polypropylene have a shelf life of 25 years from the date of manufacture.

Content in this form was updated on 1/19/2022 and is deemed current and valid for 1 year from this date.