



# STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: ReFill PLA

Color / variant: Natural and all colored variants

Type of product: 3D printing filament Polymer Type (main component): Polylactic acid (PLA)

We confirm that the composition of this product and all ingredients used to produce the filament mentioned above complies with the following Regulations, Legislations, Recommendations or Communications for the production of food packaging and other food contact applications as described in this declaration:

#### EU

As a raw material covered by Regulation (EC) 1935/2004 of the European Parliament and of the Council and Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food as amended by Regulations 1282/2011, 321/2011, 1183/2012, 202/2014 and 174/2015, applicable to all EU Member States. The biopolymer is produced using the ingredients listed in Table 1 of Annex I to Regulation 10/2011. For these ingredients, there are no SML and SML(T) listed in Table 1 of Annex I.

## **Belaium**

Royal Decree 92-1952 of 11-05-1992, including subsequent changes.

#### Germany

Regulation on consumer goods (Bedarfsgegenständeverordnung). Federal Law Gazette (Bundesgesetzblatt (BGBI.)) I, No. 1, p. 5, December 23, 1997, amended by 2003 BGBI. I, No. 14, p. 486, 10 April 2003.

#### France

"Brochure 1227 (Journal Officiel de la République Française du 4 juin 1997)" as amended.

## Italy

"Decreti Ministeriale" of 21/03/1973 and 26/04/1993, including further modifications. DPR (Decreto del Presidente della Repubblica) 777/82 as amended.

## Spain

"Reales Decretos" 1125/1982 of 30/04/1982 and 211/1992 of 06/03/1992, including further modifications.

## **Switzerland**

Ordinance on materials and items made of plastic (Verordnung über Materialien und Gegenstände aus Kunststoff (Kunststoffverordnung, KsV), 1995 Official Federal Law Collection No. 28, p. 3350, July 25, 1995, amended in 1998.

# **Netherlands**

Decree on packaging and consumer goods (Besluit inzake verpakkingen en gebruiksartikelen), amended in the Official Journal (Staatsblad) of 1979 No. 558, amended in Official newspaper (Staatscourant) No. 161, August 22, 1996.

## **Great Britain**

The Plastic Materials and Articles in Contact with Food Regulations of 1998, Statutory Instrument (SI), No. 1376. Modified by SI of 2002, No. 3008, December 11, 2002.

Commission Directive 2002/72/EC specifies total migration below 10 mg/dm2 . Lactic acid can be considered a dual-use substance because it can be used as a direct and indirect food additive. However, there is no SML (specific migration limit) for the abovementioned classes or there are no restrictions for substances or degradation products in Regulation 10/2011 (as amended by 1282/2011, 321/2011 and 1183/2012, 202/2014, 174/2015). In addition, the grade complies with Regulation (EC) No. 1895/2005 as regards the limitation of the use of epoxy derivatives in contact with food. The grades concerned are suitable for use with all food types under the conditions of the OM6 test.







When used as described above, and provided that the appropriate restrictions set out above are met, the raw material should meet the requirements of Article 3 of Framework Regulation (EC) No. 1935/2004.

This grade complies with Regulation (EC) No. 2023/2006 and meets Directive 94/62/EC of the European Parliament and of the Council of December 20, 1994 on packaging and packaging waste, in terms of heavy metal content as described in art. 11. It is recoverable in the form of material recycling, energy recovery, composting and biodegradable per Annex II, point 3, subject to local community standards. The manufacturer of the finished food contact product is responsible for determining whether the use of the product is safe, legal and technicallyappropriate for the intended use. Although the aforementioned product is authorized by including its ingredients in the directive, ready to use food-contact article must comply with all applicable restrictions and specifications described in this legislation.

This statement of Compliance is established on the base of our existing knowledge. It replaces all previous compliance statements relating to the subject. This statement is valid until further revision. This information is valid for the material as it leaves the Formfutura warehouse facility and does not include any additives, pigments etc. subsequently used or added by the buyer or a third party.

Authorised Signature:

Ir. R.J. Schuurhuis (Managing Director Formfutura BV) Drs. A. Medenblik (Managing Director Formfutura BV)

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