



STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: EasyFil ePLA
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-Framework Regulation on materials and articles intended for food contact: (EC) No 1935/2004 of 27 October 2004, in particular Article 3, 11(5), 15 and 17
- EU-Regulation on good manufacturing practice for materials and articles intended to come into contact with food: (EC) No. 2023/2006 of 22 December 2006
- EU-Regulation on plastic materials and articles intended to come into contact with food (EU) No 10/2011 of 14 January 2011, amended up to (EU) 2020/1245 of 02 September 2020
 - With regards to the polylactic acid polymer all monomers, starting substances and additives used in the manufacturer are listed in Annex I. For none of these substances limitations and/or specifications have been stipulated in Regulation EU No 10/2011; as dual use additive lactic acid (E 270) is indicated.
 - With regards to the colour masterbatch only raw materials (polymer carrier) are used in compliance with Regulation EU No 10/2011.

In addition, the manufacturer of the colour masterbatch has confirmed that the used colourants meet the requirements of:

- Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food of 13 September 1989 with respect to the maximum permissible limits of heavy metal, primary aromatic amines, sulfonated amines, aromatic and polychlorinated biphenyls.
- BfR - Recommendation IX on colorants for plastics and other polymers used in commodities of 01 June 2019 with regards to purity requirements.

Please note that analytical tests have not been carried out on the coloured PLA filament. Compliance with overall (OML) and specific migration limits (SML) apply to the final article intended to come in contact with food, which shall be measured from the finished food contact article by using real food or appropriate food simulants. In addition the final article shall not release primary aromatic amines in a detectable quantity into food or food simulants, with a detection limit of 0.01 mg/kg. Furthermore, testing is required being able to assess NIAS (non-intentionally added substances). It is the responsibility of the user to verify its suitability for his own intended food application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular foodstuff being used.

Regulation (EU) No. 1169/2011 of 25 October 2011 - Allergens

The raw materials used are manufactured without the intentional use of substances currently known to be or suspected of being food allergens.

Absence declaration for substances of animal origin

The raw materials used either do not contain any substances derived from animal fats or the substances from animal origin used fulfill the requirements of Directive 1069/2009/EC and guidance EMEA/410/01 REV03-July2011.





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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