



STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: ReFill PETG
Color / variant: Natural and all colored variants
Type of product: 3D printing filament
Polymer Type (main component): Polyethylene terephthalate glycol (PETG)

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:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC;
- Commission Regulation (EU) No. 10/2011 until amendment 2020/1245 of 2 September 2020;
 Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food;
- BfR Recommendations on Food Contact Materials for XVII - Poly(terephthalic acid diol esters);
- Dutch Packaging and Consumer Articles Regulation, December 20th, 2016.

The following monomers and/or additives are listed on the positive list of Regulation (EU) No. 10/2011 (and amendments).

Monomer	PM Ref.	Specific Migration Limit [mg/kg]
Terephthalic acid	24910	7,5 expressed as terephthalic acid
Ethyleneglycol	16990	30 expressed as ethyleneglycol
	53650	
2,2-dimethyl-1,3-propanediol	16390	0,05
	22437	
Antimony Trioxide	35760	0,04 expressed as antimony

Substances with restrictions according to annex II of European Regulation 10/2011 (and amendments):

Additive	CAS Number	Specific Migration Limit [mg/kg]
Cobalt Acetate Tetrahydrate	6147-53-1	0,05 expressed as cobalt

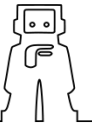
NIAS (non-intentionally added substance) listed in annex I of regulation (EU) N°10/2011 (and amendments):

NIAS	PM Ref.	Specific Migration Limit [mg/kg]
Diethylene Glycol ¹	13326	30 expressed as ethyleneglycol
	15760	
	47680	
Acetaldehyde ²	10060	6 expressed as acetaldehyde

¹ Present in the material, formed due to a side reaction of Ethylene glycol during the esterification phase manufacturing.

² Present in the material, due to an unavoidable degradation by-product of PET-G, which is generated during PET-G polymerization melt phase manufacturing and when extruded and/or injected





The overall migration tests were carried out under recommended conditions (10 days/40°C), using the food simulants: ethanol 50%, acetic acid 3% and vegetable oil. Results show that the polymer meets the migration limits required by EU legislation.

The specific migration tests were made at 50°C during 10 days, using the food simulants: ethanol 10%, ethanol 50%, acetic acid 3% and vegetable oil.

Ratio of the area of the food contact material to the volume used to determine the compliance of the plastic food contact material or article: 0.6 dm² /100 ml food simulant and 0.4 dm² /50 ml food simulant.

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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