

DECLARATION OF APPROVAL FOR CONTACT WITH FOOD

3D FILAMENT PET-G MDT, x-Ray DT
date of issue: 05.01.2025
date of update: 05.01.2025

Material name: **PET-G MDT, x-Ray DT**
Brand name: PET-G MDT, x-Ray DT filament 1,75 mm

This is to assure that the PET-G MDT, x-Ray DT filament for 3D printing from ROSA3D is produced using raw material suitable for use in food-contact applications in the European Union (EU).

The raw material is compliant with the requirements for plastic materials used for articles or parts of articles intended to come into contact with food in accordance with the following European legislation:

- 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 53650	30 expressed as ethyleneglycol
2,2-dimethyl-1,3-propanediol	16390 22437	0,05
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

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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 15760 47680	30 expressed as ethyleneglycol
Acetaldehyde ²	10060	6 expressed as acetaldehyde

Since the production of the final product intended for contact with food is not controlled by ROSA3D, the company makes no warranty, express or implied, and accepts no responsibility in connection with the use of this information. In addition, our statement of assurance is subject to the conditions set out in the invoice or other contract or shipping document issued by ROSA3D with respect to any limitation of liability.



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

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Filament	Compatible with a declaration of approval for contact with food?	EAN Code
3D Filament ReFill PET-G MDT, x-Ray DT Blue 1kg	YES	5907753137661