Declaration of Compliance



Date of issue: 16-12-2024 / Date of update: 17-12-2024



Product Reference: HDglass

Color / variant

Natural and all colored variants

Type of product

3D printing filament / granules

Polymer Type (main component): Polyethylene terephthalate glycol (PETG)

Application: 3D Printing

The supplier of the polyester polymer as well as the supplier of the color masterbatch have confirmed compliance with (in each case including all amendments in their currently valid versions):

Statement of compliance with food contact regulations

- 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) 2023/1627 of 10 August 2023

In addition, the manufacturer of the color masterbatch has confirmed that the used colorants meet the requirements of:

- Resolution AP (89) 1 on the use of colorants 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 colored HDglass 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 resp. 0,002 mg/kg food. 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 Page 2/3 application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular foodstuff being used.

Compounds with a specific migration limit

Compound	<u>FCM</u>	CAS number	<u>Limit [mg/kg]</u>
Ethylene glycol	227	107-21-1	SML(T) = 30
Terephthalic acid	785	100-21-0	SML(T) = 7.5

SML : Specific Migration Limit [mg/kg]

ND : Non Detectable

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

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



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Bisphenol A

The raw materials used are manufactured without the intentional use of Bisphenol A.

REACH - Regulation (EU) No. 1907/2006 of 18 December 2006

FormFutura BV is considered as downstream user. The manufacturer of raw materials used have ensured that any substance in the scope of REACH used has been registered. In addition, none of the potential Substances of Very High Concern > 0,1% as published on the candidate list of Substances of Very High Concern issued by ECHA are used.

ROHS - Directive 2011/65/EU of 8 June 2011

- Lead
- Mercury
- Cadmium
- · Hexavalent chromium
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)

In the production of the polylactic acid polymer as well as the color masterbatch none of the above listed substances are used.

Silicones

The raw materials used are manufactured without the intentional use of silicones.

VOC - volatile organic compounds

The raw materials used are manufactured without the intentional use of volatile organic compounds.

Limitation of Liability

The filament itself has not been tested for trace amounts of the substances mentioned above or listed within the regulations indicated above. It is the responsibility of the user to verify its suitability for his own intended application. No liability is accepted for losses arising from the inadequate suitability of the product for the particular filling material being used.

This declaration is established on the base of our existing knowledge. It replaces all previous compliance statements relating to the subject(s). 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.

Authorized signature

Ir. R.J. Schuurhuis

(Managing Director Formfutura BV)

Drs. A. Medenblik

(Managing Director Formfutura BV)



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