

STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: STYX-12
Color / variant: Clear (natural, uncolored filament)
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:

- Regulation (EC) 1935/2004 of the 27th October 2004¹
- Regulation (EC) 2023/2006 of the 21st of December 2006 as currently amended
- Regulation (EU) No 10/2011 dated from the 14th January 2011, up to its amendment of the 8th of August 2019 (No 2019/1338), as further described below
- FDA 21 CFR of the USA of 1st April 2016, as further described below

¹applicable articles 3.1, 11.5, 15 and 17.

Dual use Additives:

This material may contain dual use additives (DUA), however it has not been confirmed yet.

Compounds with a specific migration limit:

Compound	FCM	CAS number	Limit [mg/kg]
bis(4-aminocyclohexyl)methane	429	1761-71-3	SML = 0.05

SML : Specific Migration Limit [mg/kg]

Compliance verification EU

It is the responsibility of the converter or packer to verify for the finished product the overall and the specific migrations required by Regulation (EU) 10/2011, as well as the sensory performance.

The overall migration should not exceed the Overall Migration Limit (OML) of 10 mg/dm² (60 mg/kg of simulant). For each substance subject to specific migration (see table above), the migration of the substance should not exceed its limit (SML). For further details about migration testing, please refer to the current version of the regulation (EU) No 10/2011.

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 MCPP production 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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