27th January 2020

STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: **Python Flex**
Color / variant: Natural / Clear (natural, uncolored filament)
Type of product: 3D printing filament
Polymer Type (main component): Polyurethane (PU)

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 2004[1]
- 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

[1]applicable articles 3.1, 11.5, 15 and 17.

Dual use Additives:
This product contains no Dual Use Additive (DUA).

Compounds with a specific migration limit:

Compound	FCM	CAS number	Limit [mg/kg]
diphenylmethane-4,4'-diisocyanate	198	101-68-8	SML (T) = ND QM = 1 *1 DL = 0.01 *2 *expressed as isocyanate moiety note (10)*
diphenylmethane-2,4'-diisocyanate	490	5873-54-1	
Tetrahydrofuran	246	109-99-9	SML = 0.6
1,4-butanediol	254	110-63-4	SML (T) = 5 *Expressed as 1,4-butanediol*

SML : Specific Migration Limit [mg/kg]
ND : Non Detectable
*1 QM : Quantity in the material [mg/kg]
*2 DL : Quantity behind functional barrier [mg/kg food]
Note (10) Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.

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.

FDA related information

Formfutura filaments are manufactured from compounds containing a mixture of raw materials rather than an article. Therefore, Formfutura requested information from suppliers providing raw materials contained in the above-mentioned filament.
The information provided in this statement addresses the compositional requirements of 21 CFR § 177.2600 “Rubber articles intended for repeated use” or related subparts.

The composition of the above-mentioned filament meets the requirements for use in articles under 21 CFR § 177.2600 “Rubber articles intended for repeated use” or related subparts for all food types (I – IX) and all conditions of use (A – H). Please note that it is the responsibility of the manufacturer of the finished articles to ensure compliance with FDA extraction testing requirements according to the final use.

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All adjuvants used in the above-mentioned filament are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN).

Please note that all limitations regarding the additive content the above-mentioned filament are met. It is the responsibility of the customer to conduct final testing on the article.

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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