

Fillamentum Manufacturing Czech s.r.o, nam. Miru 1217, 768 24 Hulin, Czech Republic ID: 29233275, tel.: +420 720 060 947

e-mail: <u>helpdesk@fillamentum.com</u>

www.fillamentum.com

Hulin, 6th August 2019

Product Compliance Declaration

The company **Fillamentum Manufacturing Czech s.r.o.** declares that the products **Fillamentum CPE HG100** (3D printing filaments) are manufactured according to:

- a) the requirements of the European Parliament
- b) the Council Regulation (EC) No 1935/2004 on Materials and Articles intended to come into contact with food
- c) the Commission Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into contact with food and subsequent amendments

and they may be used for contact with foodstuffs.

The material used for the production is only the biopolymer CPE (copolyester). According to the Commission Regulation (EU) No 10/2011, the polymer is suitable for food-contact applications. These products can be used with all food types (except foods that contain more than 15 % alcohol) at temperatures up to 100 °C and with subsequent long-term storage at room temperature or below. The polymer used for production contains the bio-based substances and it is recyclable.

The primary input material used for production contains the substances restricted by the specific migration limit (SML) listed in Annex I of the Commission Regulation (EU) No 10/2011. According to this regulation, the overall migration limit shall not exceed 10 mg/dm² of food contact surface. The colour versions of product are made from the mixture of primary material with masterbatches. The colours of filament suitable for food-contact applications are stated in Table 1. The restricted substances contained in these products are listed in Table 2.

The production is based on the Good Manufacturing Practice according to the Commission Regulation (EC) No 2023/2006. The company guarantees that all the products placed on the market are in accordance with the technical documentation and the basic product requirements.

The declaration is based on the present knowledge and experience of the material suppliers. According to the Commission Regulation (EU) No 10/2011, it is necessary to determine the migration limits for the final article, that is intended to come into contact with food.



Table 1: List of products Fillamentum CPE HG100 that are suitable for the food-contact application.

No.	Product name			
1.	CPE HG100 "Army Green"			
2.	CPE HG100 "Black Soul"			
3.	CPE HG100 "Caramel Brown Metallic"			
4.	CPE HG100 "Deep Sea Transparent"			
5.	CPE HG100 "Flash Yellow Metallic"			
6.	CPE HG100 "Flirty Plum"			
7.	CPE HG100 "Ghost White"			
8.	CPE HG100 "Grey Mouse Transparent"			
9.	CPE HG100 "Iced Green Transparent"			
10.	CPE HG100 "Jungle Green Metallic"			
11.	CPE HG100 "Lagoon Transparent"			
12.	CPE HG100 "Lemonade Translucent"			
13.	CPE HG100 "Mistake Blue Metallic"			
14.	CPE HG100 "Morning Sun Transparent"			
15.	CPE HG100 "Natural"			
16.	CPE HG100 "Neon Orange Transparent"			
17.	CPE HG100 "Neon Pink Transparent"			
18.	CPE HG100 "Neon Yellow Transparent"			
19.	CPE HG100 "Pink Blush Transparent"			
20.	CPE HG100 "Pistachio Green"			
21.	CPE HG100 "Red Hood Transparent"			
22.	CPE HG100 "UFO Blue Metallic"			
23.	CPE HG100 "Vertigo Grey"			



Table 2: List of substances contained in the products CPE HG100, that are restricted according to the Annex I of the Commission Regulation (EU) No 10/2011.

FCM substance No	Ref. No	CAS No	Substance name	SML [mg/kg]	Restriction and specification
785	24910	0000100-21-0	terephthalic acid	30	-
227	53650	0000107-21-1	ethylene glycol	7,5	-
210	13390	0000105-08-8	1,4-bis(hydroxymethyl)cyclohexane	-	-
364	15404	0000652-67-5	1,4:3,6-dianhydrosorbitol	5	1
411	42080	0001333-86-4	carbon black²	-	3

¹Only to be used as a co-monomer in poly(ethylene-co-isosorbide terephthalate).

Toluene extractables: maximum 0,1 %, determined according to ISO method 6209.

UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis.

Benzo(a)pyrene content: max 0,25 mg/kg carbon black.

Maximum use level of carbon black in the polymer: 2,5 % w/w.

² The substance is contained in colours No. 1, 2, 6, 8, 23.

³ Primary particles of 10 – 300 nm which are aggregated to a size of 100 –1 200 nm which may form agglomerates within the size distribution of 300 nm – mm.