

Product Compliance Declaration

PLA Extrafill

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

- the requirements of the European Parliament
- the Council Regulation (EC) No 1935/2004 on Materials and Articles intended to come into contact with food
- the Commission Regulation (EU) No 10/2011 on Plastic Materials and Articles intended to come into contact with food and subsequent amendments up to 2020/1245
- the Section 201(s) and Section 409 of the Federal, Drug and Cosmetic Act, and Parts 182, 184 and 186 of the Food Additive Regulations of the U.S. Food and Drug Administration (FDA)

and they may be used for contact with foodstuffs.

The input material used for the production is only the bioplastic polymer polylactic acid (PLA). According to the Commission Regulation (EU) No 10/2011, the polymer is suitable for food-contact applications. These products can be used with all the food types under OM6. It also complies with the compositional requirements and specifications according to Section 201(s) and Section 409 of the Federal, Drug and Cosmetic Act, and Parts 182, 184 and 186 of the Food Additive Regulations of the U.S. Food and Drug Administration (FDA). The polymer used for production contains bio-based substances and it can be industrially composted.

The colour versions of the product are made from the mixture of primary material with masterbatches. The colours of filament suitable for food-contact applications according to the Commission Regulation (EU) No 10/2011 are stated in Table 1.

Table 1: List of products PLA Extrafill that are suitable for the food-contact application according to the Commission Regulation (EU) No 10/2011 (✓ - suitable, ✗ - unsuitable).

NO.	PRODUCT NAME	RAL SHADE	SUITABLE FOR FOOD CONTACT
1.	PLA Extrafill "Baby Blue"		✓
2.	PLA Extrafill "Chocolate Brown"	8017	✓
3.	PLA Extrafill "Cobalt Blue"	5013	✓
4.	PLA Extrafill "Concrete Grey"	7023	✓
5.	PLA Extrafill "Electric Grey"		✓
6.	PLA Extrafill "Everybody's Magenta"		✗
7.	PLA Extrafill "Gold Happens"		✓
8.	PLA Extrafill "Green Grass"	6010	✓
9.	PLA Extrafill "Iron Grey"	7011	✓
10.	PLA Extrafill "Light Ivory"	1015	✓
11.	PLA Extrafill "Lilac"		✓
12.	PLA Extrafill "Luminous Green"	6038	✗
13.	PLA Extrafill "Luminous Orange"	2005	✗
14.	PLA Extrafill "Luminous Yellow"	1026	✗
15.	PLA Extrafill "Melon Yellow"	1028	✓
16.	PLA Extrafill "Metallic Grey"		✓
17.	PLA Extrafill "Mint"		✓
18.	PLA Extrafill "Mukha"		✓
19.	PLA Extrafill "Natural"		✓
20.	PLA Extrafill "Noble Blue"		✓
21.	PLA Extrafill "Orange Orange"	2008	✓
22.	PLA Extrafill "Pearl Night Blue"	5026	✓
23.	PLA Extrafill "Pearl Ruby Red"	3032	✓
24.	PLA Extrafill "Peppered Mustard"		✓
25.	PLA Extrafill "Purple Red"	3004	✓
26.	PLA Extrafill "Rapunzel Silver"		✓

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27.	PLA Extrafill "Signal Red"	3001	✓
28.	PLA Extrafill "Sky Blue"	5015	✓
29.	PLA Extrafill "Traffic Black"	9017	✗
30.	PLA Extrafill "Traffic Purple"	4006	✓
31.	PLA Extrafill "Traffic Red"	3020	✓
32.	PLA Extrafill "Traffic White"	9016	✓
33.	PLA Extrafill "Traffic Yellow"	1023	✓
34.	PLA Extrafill "Turkey Egg"		✓
35.	PLA Extrafill "Turquoise Blue"	5018	✓
36.	PLA Extrafill "Turquoise Green"	6016	✓
37.	PLA Extrafill "Vertigo Galaxy"		✓
38.	PLA Extrafill "Vertigo Grey"		✓
39.	PLA Extrafill "Vertigo Cherry"		✓
40.	PLA Extrafill "Vertigo Chocolate"		✓
41.	PLA Extrafill "Vertigo Jade"		✓
42.	PLA Extrafill "Vertigo Mystique"		✓
43.	PLA Extrafill "Vertigo Starlight"		✓
44.	PLA Extrafill "Volcanic Dust"		✓
45.	PLA Extrafill "Wizard's Voodoo"		✗

The primary input materials used for production contain the substances restricted by the specific migration limit (SML) listed in Annex I and II of the Commission Regulation (EU) No 10/2011. The restricted substances contained in these products are listed in Table 2. According to the EU regulation, the overall migration limit shall not exceed 10 mg/dm² of the food contact surface or 60 mg/kg.

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

FCM SUBSTANCE NO	REF. NO	CAS NO	SUBSTANCE NAME	SML [mg/kg]	RESTRICTION AND SPECIFICATION
411	42080	0001333-86-4	carbon black ¹	-	²
458	36960	0003061-75-4	behenamide ³		
500	38560	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene ⁴	0.6	
610	93440	0013463-67-7	titanium dioxide ³		
ANNEX II			⁵	⁶	

¹ This substance is present only in products PLA Extrafill "Chocolate Brown", "Concrete Grey", "Iron Grey", "Traffic Purple", "Vertigo Galaxy", "Vertigo Grey", "Vertigo Chocolate".

² 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.

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.

³ This substance is present only in product PLA Extrafill "Turkey Egg".

⁴ This substance is present only in product PLA Extrafill "Noble Blue".

⁵ Some of these substances are present in some of these products: PLA Extrafill "Baby Blue", "Chocolate Brown", "Cobalt Blue", "Concrete Grey", "Electric Grey", "Gold Happens", "Green Grass", "Light Ivory", "Lilac", "Metallic Grey", "Mint", "Mukha", "Noble Blue", "Orange Orange", "Pearl Night Blue", "Pearl Ruby Red", "Purple Red", "Rapunzel Silver", "Signal Red", "Sky Blue", "Traffic Purple", "Traffic White", "Turkey Egg", "Turquoise Blue", "Turquoise Green", "Vertigo Galaxy", "Vertigo Grey", "Vertigo Cherry", "Vertigo Chocolate", "Vertigo Jade", "Vertigo Mystique", "Vertigo Starlight".

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⁶ Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Aluminium = 1 mg/kg food or food simulant.

Antimony = 0.04 mg/kg food or food simulant.

Barium = 1 mg/kg food or food simulant.

Cobalt = 0.05 mg/kg food or food simulant.

Copper = 5 mg/kg food or food simulant.

Iron = 48 mg/kg food or food simulant.

Lithium = 0.6 mg/kg food or food simulant.

Manganese = 0,6 mg/kg food or food simulant.

Nickel = 0,02 mg/kg food or food simulant.

Zinc = 5 mg/kg food or food simulant.

The sum of Europium, Gadolinium, Lanthanum, Terbium = 0.05 mg/kg food or food simulant.

Ammonium, Calcium, Magnesium, Potassium, Sodium = max 0,01 mg/kg.

Arsenic, Cadmium, Chromium, Lead, Mercury - Not Detectable.

In line with the requirements of Section 201(s) and Section 409 of the Federal, Drug and Cosmetic Act, and Parts 182, 184 and 186 of the Food Additive Regulations PLA Extrafill is approved for all food types for single-use and repeat use articles and conditions of use B through H:

- B. Boiling water sterilized
- C. Hot filled or pasteurized above 150 deg. F. (65,6 °C)
- D. Hot filled or pasteurized below 150 deg. F. (65,6 °C)
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
 - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
 - 2. Aqueous, high- or low-free oil or fat.

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 and FDA regulation, it is necessary to determine the migration limits for the final article, that is intended to come into contact with food.