FILFORME
FILAMENT 3D
• MADE IN FRANCE •

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To Whom It May Concern,

This letter provides our assurance that the biopolymer , a polylactic acid polymer, as supplied from our factory gate is suitable for use in food-contact applications in the European Union (EU).

The product complies with Article 3, 11(5), 15, and 17 of Regulation (EC) No 1935/2004, as amended (the Framework Regulation), and Commission Regulation (EU) No 10/2011 (the Plastics Regulation), as amended (2023/1627), which apply in all EU Member States. All monomers, other starting substances, and additives used in the manufacture of this material are listed in Table 1 of Annex I of the Plastics Regulation. There are no specific migration limits (SML) or total specific migration limits SML(T) listed in Table 1 of Annex I for these ingredients. Moreover, the product does not contain any substances listed in Annex II of the Plastics Regulation. Any unintentionally added substances that are not subject to listing in the Plastics Regulation, as well as any reaction intermediates, decomposition products, and reaction products, comply with the Framework Regulation, and a risk assessment has been performed for any such substances in accordance with Article 19 of the Plastics Regulation.

While the components of this product are not subject to any SMLs or SML(T)s, the Plastic Regulation (Regulation (EU) 10/2011) specifies that plastic materials and articles shall meet an overall migration limit (OML) of 10 mg/dm2 (however, a more restrictive limit applies for products intended for use for infants or young children). The product complies with this limit based on the testing that has been performed. The finished material or article manufacturer is responsible for ensuring that the finished product in which this material is used complies with the OML.

Lactic acid is a Dual Use Additive based on its clearance for direct addition to food in the EU. However, it is cleared for use at quantum satis levels, and any lactic acid that may be contributed to food based on the use of this product in contact with food will not impact the status of the food with respect to lactic acid levels. Based on the testing performed, the referenced grade(s) are expected to be suitable for use with all food types at temperatures not exceeding 40°C (comparable to OM6 testing conditions).

In addition, Commission Regulation (EC) 1895/2005/EC on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food does not apply.

Furthermore, the product is not made with 2,2-bis (4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether and its derivatives; bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers; or other novolac glycidyl ethers.

This grade complies with Commission Regulation (EC) 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food. The product also complies with European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste with respect to the heavy metal content limits described in Article 11. It is recoverable in the form of material recycling, energy recovery, and composting per Annex II point 3, subject to the standards of the local community.

It is the responsibility of the manufacturer of the finished food-contact article to determine that the use of a product is safe, lawful, and technically suitable for the intended application. The marketer of the finished food-contact material or article is responsible for ensuring that any applicable limitations and specifications found under the Plastics Regulation are met by the finished food-contact product.

Since the manufacture of the finished food-contact article is outside of [nome omesso]'s control, [nome omesso] makes no warranties, express or implied, and assumes no liability in connection with any use of this information. In addition, our assurance statement is subject to the terms and conditions set forth in the invoice or other contract or shipping document issued by [nome omesso] with respect to any limitations on liability.

Best Regards,

Filforme filament 3d
Angelo Vizzi

Déclaration de Confidentialité et Conformité Légale

Conformément aux réglementations en vigueur sur la protection des secrets industriels et commerciaux, et en application de l'article L.151-1 du Code de commerce français, les noms spécifiques des polymères utilisés dans cette documentation ont été intentionnellement omis. Cette mesure a été prise afin de protéger des informations commerciales confidentielles, sans compromettre l'intégrité et la véracité des certifications présentées.

Les polymères utilisés dans ce produit sont certifiés à l'origine par le fabricant, garantissant ainsi leur conformité avec les normes de qualité et de sécurité pertinentes avant toute transformation. Cette certification d'origine atteste que les matériaux respectent les réglementations applicables et sont aptes à être utilisés dans les conditions spécifiées.

Les informations techniques et de sécurité contenues dans cette documentation restent exactes et inchangées. Toutes les propriétés pertinentes, les caractéristiques de conformité et les garanties de qualité des matériaux décrits s'appliquent au produit final tel que certifié. La conformité du produit aux réglementations nationales et internationales applicables, y compris mais sans s'y limiter, celles relatives à la sécurité alimentaire, reste inchangée.

L'entreprise s'engage à garantir que les informations fournies sont conformes à toutes les réglementations pertinentes, et se réserve le droit de fournir des détails spécifiques supplémentaires sous conditions de confidentialité, sur demande des autorités compétentes ou de partenaires commerciaux autorisés.