REGULATORY INFORMATION SHEET

14/11/2024

1. PRODUCT IDENTIFICATION

Biodegradable polymer compund, suitable for 3D printing filament

2. EUROPEAN UNION FOOD CONTACT

The product is in compliance with the rules of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/ EEC, Official Journal of the European Union L 338/4 of 13 November 2004, modified by app. No. 5.17 of the regulation (EC) No. 596/2009 of 18 June 2009, Official Journal of the European Union L 188 of 18 July 2009, article 3.

Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code- LFGB) in the version of the notification of 3 June 2013 (BGBl. P. 1426), last amended by article 4 section 20 of the law of 7 August 2013 (BGBl. I p. 3154), §§ 30 and 31.

The product meets the demands of the Decree on Consumer Goods in the version of the communication of 23 December 1997 (BGBl. 1998 I p. 5), last amended by Article 1 of the Decree of 24 June 2013 (BGBl. I p. 1682).

The composition of the product complies with the requirements of the Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Official Journal of the European Union L 12/1 of 15 January 2011, last amended and corrected by Comission Regulation (EU) 2016/1416 of 24 August 2016, Official Journal of the European Union L 230/22 of 25 August 2016 and by Comission Regulation (EU) 2017/752 of 28 April 2017, Official Journal of the European Union L 113/18 of 29 April 2017.

The product complies with the FDA (U.S. Food and Drug Administration) regulations as defined in 21 CFR (U.S. Code of Federal Regulations) and can also be used in contact with all types of food from “I” to “IX” as described in Table 1 of Section 176.170(c) of this chapter (except of infant formula, breast milk and alcoholic foods), and under conditions of use from “B” to “H” as described in Table 2 of Section 176.170(c) of this chapter.

SML AND SML(T)	Specific migration limits
QM	Maximum permitted quantitiy of residual in the final product.
ND	Not detectable, the substance must not migrate in detectable amounts.

3. OTHER ABSENT SUBSTANCES

Furthermore we confirm that this compound is manufactured without the intentional use of the following substances:

- Substances of Very High Concern (SVHC) (regarding to ECHA-list of 16 July 2019)
- Substances listed in Annex II of the EU Regulation 1223/2009
- Substances listed in California Proposition 65 (updated list from September 13, 219)
- CMR substances (categories 1, 1A, 1B and 2) as defined in EU Regulation 1272/2008
- Halogenous Compounds (e.g. HFC, HBFC, CFC, HCFC, PFAS etc.)
- N-Nitrosamines (e.g. NDMA, NDPA, NDBA etc.)
- Secondary and tertiary amines (e.g. Triethanolamine, Cocamide etc.)
- Glycol Ethers (e.g. EGME, DEGME, EGEE, EGEEA, TEGDME, DEGDME, EGDME, 1PG2MEA, 1PG2ME, DEGME, PGMEA, 2PGME etc.)
- Phthalates (e.g. DEHP, DBP, BBP, DMEP, DnPP, DnOP, DiDP, DiNP, DMP, DEP, DIBP, DPP, DMGP, DCHP, DnHP etc.)
- Bisphenol A (BPA), Bisphenol F (BPF), BFGDE and derivates, BADGE and derivates
- Organostannic compounds (e.g. Tetramethyltin)
- Hydrazine and derivates (e.g. Azodicarbonamide)
- Dimethylformamide
- Polyoxymethylene (POM)
- Chlorine containing polymers like PVC and PVDC
- Cadmium-, arsenic-, chromium VI-, mercury- and selenium-based mineral pigments (e.g. used for the production of inks)
- Lead- and antimony-based mineral pigments (e.g. used for the production of inks)
- Organic colorants based on aromatic amines (e.g. azoic dyes)
- Special additives which promote the oxo-degradation of polymers
- Other polymers based on styrene or acrylic derivates
- Residual solvents (e.g. Toluene, Propylene acetate, Isopropylene acetate, Ethyl acetate, Methanol, 2-Butanon, 1-Propanol, Acetone, 2 Isopropylthioxanthone, 1-Methoxy-2-propanol etc.)
- Heavy metals like chromium, cadmium, mercury, nickel and lead and their compounds
- Silicones
- Silver salts
- Sunscreen filters: benzophenone, 2-hydroxy-4-methoxybenzophenone, 2-Ethylhexyl 4-Methoxycinnamate
- Nanomaterials based on titan dioxide, zinc oxyde, carbon black and silica

4. REACH & ECHA

The material is free of Substance of Very High Concern (SVHS) listed in the REACh candidate by the ECHA on the 10. July 2022 is present in a concentration above 0,1%.

5. ROHS

According to the information provided by our raw material suppliers and our standard production procedures, none of the substances listed in Directive 2011/65/EU of 8 June 2011 are allowed to be present:

- Lead (Pb)
- Mercury (Hg)
- Cadmium (Cd)
- Hexavalent Chromium (Cr VI)
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-Ethylhexyl)phthalate (DEHP)
- Benzylbutylphthalate (BBP)
- Dibutylphthalate (DBP)
- Diisobutylphthalate (DIBP)

6. LIABILITY LIMITATION

Please note that this compound has not been tested for trace amounts of the substances aforementioned or listed within the regulations. However, based on the information obtained from upstream suppliers there is no reason to expect any of the substances listed to be present within this compound. The values listed have been established on standardized test specimens at standard temperature and humidity conditions. The figures should be considered as guide values only. Under certain conditions the processing conditions can have a significant influenceon the properties.

FILOPRINT shall not be liable for the use of this information or of any product, method or equipment mentioned. Customers must undertake their own determination of this product‘s suitability and completeness for their own use, for the protection of the environment, for the health and safety of their employees and purchasers of their products. No warranty is made of the merchantability or fitness of any product, and nothing herein waives any of the seller‘s conditions of sale.

NatureWorks LLC

This letter provides our assurance that Ingeo™ biopolymer 2003D, 2500HP, 3001D, 3052D, 3100HP, 3251D, 3260HP, 4032D, 4043D, 7001D and 8052D as supplied from our factory gate is suitable for use in food-contact applications in the European Union (EU).

EU	As a raw material with 1935/2004/EEC and Plastics Regulation 10/2011 amended by 1282/2011, 321/2011, 1183/2012, 202/2014 and 174/2015, applying to all EU Member States. Ingeo is produced using ingredients listed in Table 1 of Annex 1 of Plastics Regulation 10/2011. There are no SML and SML(T) listed under Table 1 of Annex 1 for these ingredients.
Belgium	Royal Decree 92-1952 of 11-05-1992, including subsequent modifications.
Germany	Bedarfsgegenständeverordnung. 1998 Bundesgesetzblatt (BGBl.) I, number 1 page 5, 23 December 1997. As amended by 2003 BGBl. I, number 14, page 486, 10 April 2003.
France	"Brochure 1227 (Journal Officiel de la République Française du 4 juin 1997)" including subsequent modifications
Italy	"Decreti Ministeriale" of 21-03-1973 and 26-04-1993, including subsequent modifications.
DPR	777/82 as amended.
Spain	"Reales Decretos" 1125/1982 of 30-04-1982 and 211/1992 of 06-03-1992, including subsequent modifications.
Switzerland	Verordnung über Materialien und Gegenstände aus Kunststoff (Kunststoffverordnung, KsV)], 1995 Amtliche Sammlung des Bundesrechts, number 28, page 3350, 25 July 1995, as amended by 1998.
The Netherlands	Besluit inzake verpakkingen en gebruiksartikelen, zoals gewijzigd 1979 Staatsblad number 558 as amended by 1996 Staatscourant number 161, 22 August 1996.
United Kingdom	The Plastic Materials and Articles in Contact with Food Regulations 1998, 1998 Statutory Instrument (SI), number 1376. As amended by 2002 SI, number 3008, 11 December 2002.

Commission Directive 2002/72/EC specify overall migration less than 10 mg/dm^2. Lactic acid can be considered a Dual Use Substance as it can be used as a direct and indirect food additive. However, there are no SML's (Specific Migration Limit) for the above referenced grade(s) nor are there any restrictions for the substance or degradation products in Regulation 10/2011(amended by 1282/2011, 321/2011, and 1183/2012, 202/2014, 174/2015). In addition, the grade(s) is compliant with 1895/2005/EC in the restriction of use of epoxy derivatives in food contact. The referenced grade(s) is suitable for use with all food types under condition OM6 (and below).

When used as described above, and provided the appropriate limitations identified above are met, NatureWorks LLC product should comply with the requirements of Article 3 of the Framework Regulation (EC) No. 1935/2004.



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