



REGULATORY INFORMATION SHEET

PLA NX1

1. PRODUCT IDENTIFICATION

TRADE NAME	Extruder PLA NX1
MANUFACTURER	FD3D GmbH Klosterstrasse 13 6923 Lauterach AUSTRIA info@extruder.com
USE OF PRODUCT	Biodegradable polymer compound, 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 Commission Regulation (EU) 2016/1416 of 24 August 2016, Official Journal of the European Union L 230/22 of 25 August 2016 and by Commission 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.

The following restrictions have to be ensured:

SML AND SML(T)	Specific migration limits
QM	Maximum permitted quantity 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, 2019)
- 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, DEGDM, 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 derivatives, BADGE and derivatives
- Organostannic compounds (e.g. Tetramethyltin)
- Hydrazine and derivatives (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 derivatives
- 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 07. July 2017 is present in a concentration above 0,1%.

5. 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 influence on the properties.

FD3D GmbH shall be responsible 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.