



# REGULATORY INFORMATION SHEET

## PLA NX2

### 1. PRODUCT IDENTIFICATION

TRADE NAME	Extrudr PLA NX2
MANUFACTURER	FD3D GmbH Klosterstrasse 13 6923 Lauterach AUSTRIA  info@extrudr.com
USE OF PRODUCT	Biodegradable polymer compound, suitable for 3D printing filament

### 2. EUROPEAN UNION FOOD CONTACT

EU-Framework Regulation on materials and articles intended for food contact: (EC) No 1935/2004 of 27. October 2004

German Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) of 07. September 2005

EU-Regulation on good manufacturing practice for materials and articles intended to come into contact with food: (EC) No. 2023/2006 of 22 December 2006

#### 2.1 SPECIFICATION OF THE INTENDED USE OR LIMITATIONS

TYPES OF FOOD WITH WHICH IT IS INTENDED TO BE PUT IN CONTACT	dry, aqueous, acidic and fatty foodstuffs
TIME AND TEMPERATURE OF TREATMENT AND STORAGE IN CONTACT WITH FOOD	any condition of time at room temperature and below
RATIO OF FOOD CONTACT SURFACE AREA TO VOLUME USED TO ESTABLISH THE COMPLIANCE OF THE MATERIAL	6 dm <sup>2</sup> /kg food (maximum thickness 10 µm)

This material is composed of substances listed in Annex I of Regulation EU No 10/2011 of 14. January 2011 only. For some of these substances limitations and/or specifications have been stipulated in Regulation EU No 10/2011.

If the compound is being processed according to good manufacturing practice it is feasible to manufacture plastic parts in such way to avoid migration above 10 mg of substances per dm<sup>2</sup> of surface area of the plastic material. It is the responsibility of the finished food contact part's manufacturer to verify its compliance with the given standard.

## 2.1 COMPLIANCE WITH THRESHOLD VALUES / OVERALL MIGRATION

Overall Migration test was carried out on the compound or on compounds with comparable composition under the following contact conditions:

SIMULANT	CONTACT TIME	TEMPERATURE [°C]
3% Acetic Acid	10	40
10% Ethanol	10	40
Vegetable Oil	10	40

Overall Migration is well below the limit of 10 mg/dm<sup>2</sup> without application of permitted reduction factors for the above stated conditions of use.

## 3. US FOOD AND DRUG ADMINISTRATION (FDA)

The raw materials of this compound meet the requirements of the US FDA for materials in contact with food: the US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the U.S. Food and Drug Administration (FDA), provided the use is in accordance with good manufacturing practices. For both aforementioned regulations the duty of care regarding the compliance of the compound within the legislation governing food contact applications has been fulfilled. It is the responsibility of every downstream user to verify the suitability of the compound for their own intended application. Liability for losses arising from inadequate use of the compound or any missing compliance is excluded.

## 4. COSMETICS PACKAGING

Regulation (EU) 1223/2009 of 30. November 2009

We confirm this material is manufactured in accordance with this EU Regulation.

## 5. PACKAGING WASTE

Directive 94/62/EC of 20. December 1994

The heavy metals cadmium, lead, mercury and chromium (VI) are not intentionally used in the manufacture of this compound. The sum of the heavy metals cadmium, lead, mercury and chromium incidentally present in this compound is below 100 ppm. Therefore the compound complies with the limits set out in Directive 94/62/EC.

## 6. ROHS

Directive 2011/65/EU of 8 June 2011

We hereby confirm that this compound is manufactured without the intentional use of the following chemical substances:

- Lead
- Mercury
- Cadmium
- Hexavalent chromium
- Polybrominated diphenyl ethers (PBDE)

## 7. SAFETY OF TOYS

EN 71-3

This compound complies with the requirements of European standard EN 71 regarding the safety of toys part 3: "migration of certain elements". Please note this standard refers to finished toys only.

## 8. VOC

Swiss ordinance on Volatile Organic Compounds (VOC) of 12 November 1997.

This compound is in compliance with the Swiss Ordinance on volatile organic compounds (VOC).

## 9. TSCA

US Toxic Substances Control Act

We confirm the listing of all raw materials of this compound within the TSCA inventory.

## 10. ALLERGENS

This compound is manufactured without the intentional use of substances currently known to be or suspected of being food allergens. Furthermore it is manufactured without the use of ingredients listed in Annex IIIa of Directive 2007/86/EC and Annex III LMKV.

## 11. ACTIVE AND INTELLIGENT MATERIALS

Regulation (EC) No. 450/2009:

This compound is manufactured without the use of active and intelligent materials.

## 12. RECYCLING

Regulation (EC) No. 282/2008:

This compound is manufactured without any recycled plastic materials.

## 13. BSE INFECTION

This compound is manufactured without any derivatives of animal origin. There is no scientific reason to assume any risk of BSE transfer through this compound.

## 14. OTHER ABSENT SUBSTANCES

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

- Primary aromatic amines
- Polycyclic aromatic hydrocarbons (PAH)
- Phenols & Phenylphenole
- Bisphenol A and its derivatives
- Bisphenol F and its derivatives
- Bisphenol S and its derivatives
- Phthalates
- Adipates
- Maleicacid-di-(2-ethylhexyl)-ester
- Formaldehyde
- 2,2'-Dimethoxy-2-phenylacetophenone
- 2,4-Pentadione (synonyme acetylacetone)
- Acrylamide
- Adsorbable organically combined halogens (AOX)
- Azo dyes
- Benzophenone and 4-methylbenzophenone and their derivatives
- Brominated fire retardants
- Cobalt(II)-chloride (CAS 7646-79-9 (anhydrous))
- Cyanuric acid (1,3,5-triazin-2,4,6-triol)
- Dimethylfumarate (DMF)
- Elastomers or N-nitrosamines may be released
- Epoxidised soybean oil (ESBO)
- Ethyl-4-dimethylaminobenzoate
- Halogens
- Isopropylthioxanthone (ITX)
- Latex
- Melamine hydrocarbons")
- Chain- and ring-shaped hydrocarbons (MOSH, "mineral oil saturated
- Nanoparticles and -materials (< 100 nm)
- Aromatic hydrocarbons (MOAH, "mineral oil aromatic hydrocarbons")
- Diphenyl-2-ethylhexylphosphate (DPO)
- Tributyltin oxide (TBTO)
- Tributyltin (TBT)
- Perfluorinated organic compounds & fluorinated surfactants
- Perfluorooctanoic acid (PFOA)
- Polycyclic aromatic hydrocarbons (PAHs)
- Semicarbazide (SEM)
- Titan-acetylacetonate (TAA)
- Triclosan
- Vinylchloride

## 15. 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 .

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