



# REGULATORY INFORMATION SHEET

## PCTG

### 1. PRODUCT IDENTIFICATION

TRADE NAME	Extrudr PCTG
MANUFACTURER	FD3D GmbH Klosterstrasse 13 6923 Lauterach ÖSTERREICH  info@extrudr.com
USE OF PRODUCT	Polycyclohexyldimethylterephthalat mit Glykol modifiziert, geeignet für 3D-Druck Filamente.

### 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.

Commission Regulation (EU) No 10/2011 (and amendments)

Good Manufacturing Practice (GMP) Regulation (EC) No 2023/2006

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 following restrictions have to be ensured:

MONOMER PM REF.	SPECIFIC MIGRATION	Terephthalic acid 24910 7,5, expressed as terephthalic acid
	LIMIT(S) [MG/KG]	Ethylene glycol 16990, 53650 30, expressed as ethylene glycol

### 3. REACH & ECHA

The material is free of Substance of Very High Concern (SVHS) listed in the REACH Candidate List by the ECHA on the 07. July 2017 is present in a concentration above 0,1%.

## 4. FDA

The product complies with FDA regulations regarding food contact substances (FCS) and may also be placed in contact with food as a product or part product under conditions of use C to G. For use in contact with all types of food, except food containing more than 13% alcohol by volume under conditions of use C to G, and for use in food containing up to 25% alcohol by volume under conditions of use E to G.

### Conditions of Use:

- A. High temperature heat-sterilized (e.g., over 212 deg. F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg. F.
- D. Hot filled or pasteurized below 150 deg. F.
- 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.
- I. Irradiation
- J. Cooking temperatures exceeding 250 deg. F.

## 5. ROHS

According to the information transmitted from our raw material suppliers, and our standard production procedures, the products can't contain any of the substances, listed in the Directive 2015/863/EU of 31 March 2015:

- Lead
- Mercury
- Cadmium
- Hexavalent chromium
- Polybrominated biphenyls
- Polybrominated diphenyl ethers
- Di(2-ethylhexyl) phthalate
- Dibutyl phthalate
- Benzyl butyl phthalate
- Diisobutyl phthalate

## 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 influence on the properties.

FD3D GmbH 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.