



# REGULATORY INFORMATION SHEET

## FLEX SEMISOFT

### 1. PRODUCT IDENTIFICATION

|                |                                                                                           |
|----------------|-------------------------------------------------------------------------------------------|
| TRADE NAME     | Extruder FLEX SEMISOFT                                                                    |
| MANUFACTURER   | Extruder   FD3D GmbH<br>Glaserweg 24<br>6890 Lustenau<br>Austria<br><br>info@extruder.com |
| USE OF PRODUCT | Thermoplastic Polyurethane, suitable for 3D printing filament                             |

### 2. U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The raw materials of this compound are compliant with 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.

### 3. REACH & ECHA

The material is free from substances of very high concern (SVHC) in a concentration above 0.1 %, as published by the European Chemicals Agency (ECHA) in the Candidate List in accordance with Article 59(10) of the REACH Regulation (EC) No. 1907/2006, last updated on June 25, 2025 (250 substances).

Furthermore, no substances are used or, to the best of our knowledge, present that are restricted under Annex XVII of the REACH Regulation concerning the manufacture, placing on the market or use of certain dangerous substances, mixtures and articles. No substances are present that are subject to authorization according to Annex XIV.

### 4. 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.