Informace o výrobku

SustaPEEK MG semi-finished products

This information relates to following semi-finished products, extruded and purchased from Röchling Industrial Lahnstein SE & Co. KG:

Výrobky		
SustaPEEK MG modrý BL	SustaPEEK MG přírodní	SustaPEEK MG zelená GN
SustaPEEK MG černý	SustaPEEK MG červená RD	SustaPEEK MG žlutá YL

For the production of the above-mentioned semi-finished products made of polyether ether ketone (PEEK), VICTREX 450G PEEK resins from Victrex Manufacturing Ltd (hereinafter “Victrex”) are used. The recommendations of the raw material producers are taken into account during the manufacturing and handling process. This material is not approved for human implants.

Resin compliance

Victrex provides documents including but not limited to the following information regarding the compositional compliance of the resin:

- Polyetheretherketone polymer (CAS No. 29658-26-2 or 31694-16-3); and for Carbon Black (CAS No. 1333-86-4)
- Classification according to Regulation EC No. 1272/2008 [CLP]: None
- Phthalates | Endocrine Disruptors | CMR substances: compliant
- Animal origin, TSE/BSE: no materials of biological origin, complaint with the European Union note for guidance “EMA/410/01 rev.3, 2011” and are free from BSE-Bovine Spongiform Encephalopathy) and TSE-(Transmissible Spongiform Encephalopathy).
- REACh Registration | SVHC ANNEX XIV | ANNEX XVII: compliant
- RoHS: compliant
- Biocompatibility: ISO 10993-5: The Type Testing was performed in support of ISO 10993 Type A medical device applications with a limited contact duration of less than 24 hours.
- FDA food contact compliant (Black, natural, green) | EU 10/2011: compliant (Black, natural)
- EU Medical Device Regulation 2017/745 compliance: the above-mentioned grades meet the requirements as outlined in EU MDR Annex I, Chapter II, Sections 10.4.1a & b. Substances as outlined in Sections 10.4.1 a & b are not contained at concentrations above 0.1% (w/w)
- California Proposition 65: complaint
- Country of Origin – Europe

Risk process / incoming goods

Our risk management process ensures that with the framework of the incoming goods inspection of the raw material the cytotoxicity test according to DIN EN ISO 10993-5 is carried out by an accredited institute on a representative delivery lot of the semi-finished product manufactured by Röchling Industrial Lahnstein SE & Co. KG out of the raw material. The above-mentioned raw materials passed the internal qualification with the result “not cytotoxic”, which is the requirement for the release of the semi-finished product. However, the cytotoxicity test is not part of a continuous production control conducted on each resin batch.

Manufacturing process

No additional additives, plasticizers, or processing aids are added in the manufacturing process. Furthermore, the products listed above contains of no recycled, reconstituted, regrind, recovered or reprocessed resin.

In order to reduce the internal stress after extrusion, the semi-finished products are subjected to an annealing process. Planning, sawing and milling operations are carried out without the use of cooling lubricants. This product information encompasses the working steps planning, sawing and milling – all without the use of cooling lubricants. All medical grade semi-finished products are ultrasonically tested and found to be void free.

Identification and traceability

Our medical grade (MG) materials are marked respectively given a sticker or ink jet printing on each item and therefore fully traceable through their batch number up to the used resin lot number.

Compliance

All the above listed products are focused on ISO 10993 Type A “medical” applications with less than 24 hours exposure. It is intended to be used for medical application in accordance with the Regulation (EU) 2017/745, especially when it comes to direct contact to the human body fluids and/or tissue respectively bones. Röchling Industrial conduct on a defined regular basis biocompatibility test directly on semi-finished products manufactured by Röchling, however not each batch number – this is optional and upon request available.

Please note that the responsibility for the evaluation of the end product for the intended use and compliance with the applicable relevant legal requirements lies exclusively with the user/processor as well as the distributor of the respective product/end product. The manufacturer or seller of parts and articles made out the above-mentioned products have to take the full responsibility regarding applicable legal requirements.

This information was provided by machine and requires therefore no signature.

Röchling Industrial Lahnstein SE & Co. KG

Advice: This product information serves alone for informative purposes. Warranties, assurances and guarantees cannot be derived from this.

Important: This information is accurate as of the date of issue based on the most recent version of any applicable manufacturer's instructions, regulations or standards, unless otherwise stated above. This information should not be construed as a promise or guarantee of specific properties of the products described or their suitability for a particular application. The suitability of Röchling Industrial Lahnstein SE & Co. KG products in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final product to assess and determine the suitability of all components to ensure that the final product is safe for its intended use (Fit for Use) as well as all applicable legal or other regulatory requirements

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