00585 TECAPEEK MT black

Stock Shapes
Base Polymer: PEEK
Referenz Nr./Reference No.: SH00585MT0101_V01

Ensinger GmbH · Rudolf-Diesel-Str. 8 · 71154 Nufringen

Declaration on Biocompatibility

Information on the raw materials and the manufacturing process:

The present statement refers to semi-finished products supplied by Ensinger GmbH in Nufringen. For the production of the above-mentioned semi-finished product made of thermoplastic polymer , defined stock shape recipes are used. The raw material used is polyetheretherketone (PEEK), Victrex PEEK 450G natural, from the company Victrex Europa GmbH with an addition of color concentrate.
In the manufacturing and processing of the raw material the manufacturer's recommendations are taken into account. Following extrusion, where appropriate, the semi-finished product is subjected to an annealing process in order to reduce tension. If appropriate, there is a tailoring in our cutting service. At Ensinger processing in form of planing or cutting is performed dry, without the use of coolant. The following statement includes planed or cut products. During grinding coolant is used. The influence of the coolant on the properties of the biocompatibility was not examined and has to be evaluated yet in the downstream processing step.

According to the manufacturer's statement, the basic polymer Victrex PEEK 450G natural is in compliance with the requirements for repeated contact with food as per FDA § 21 CFR 177.2415 (poly(aryletherketone) resins). For the final product requirements exist regarding extraction limits. Compliance with these requirements can only be demonstrated in the finished product [1].
The precise details of § 21 CFR 177.2415 may be accessed from the following website:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

According to the manufacturer's statement, the colour concentrate corresponds to the requirements of FDA § 21 CFR 178.3297 (colorants for polymers), and FDA § 21 CFR 177.2415 (Poly(aryletherketone) resins) [2].
The precise details of § 21 CFR 178.3297 and § 21 CFR 177.2415 may be accessed from the following website:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

Information on tests on stock shapes:

TECAPEEK MT black stock shape has been tested and assessed on a specific lot of a representative stock shape dimension in accordance with EN ISO 10993 series for the specified application in medical products [3]. The specimens were taken from semi-finished product usually after the annealing process.

Application: Semi-finished product for the manufacture of medical devices (such as instruments, trial implants, sterilization containers).

Contact: Limited contact (<24 h) with skin, tissue, where applicable indirect contact with blood.

Remarks: The assessment refers only to the possible release of toxicologically relevant ingredients from the examined material. The test material was cleaned in order to remove superficial dirtying. Any further-reaching biological effects that depend on the design, manufacturing, sterilization and application conditions of the end product, and any possible material changes as a result of reprocessing have not been taken into consideration. This is the responsibility of the medical product manufacturer.

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Test matrix: Toxicological tests performed on a specific lot of a representative stock shape dimension.

Test	Test Conditions	Result
Cytotoxicity EN ISO 10993-5	4,5 cm²/ml DMEM-FBS (inkl.1,5 % DMSO), 24 h, 37 °C L 929 cell cultures, 72 h, 37 °C, quantitative determination of the cell proliferation	n.d.
Hemolysis EN ISO 10993-4	4,5 cm²/ml PBS, 24 h, 37 °C human erythrocytes, 4 h, 37 °C, quantitative determination of the cell lysis	n.d.
Chemical Analysis EN ISO 10993-18	3 cm²/ml ethanol/Water (1:20), 24 h, 37 °C GC-FID, quantification of soluble organic substances	n.d. (< 2 µg/cm²/24 h)
	3 cm²/ml Isopropanol, 24 h, 37 °C GC-MS, characterization of soluble organic substances	n.d.

n.d. = toxicologically relevant effects in comparison with control samples not detected.

Biological evaluation:

The biological safety of the patient is not compromised by soluble material contents of the semi-finished product TECAPEEK MT black for the following reasons:

- Cytotoxicity, EN ISO 10993-5: No cytotoxic effects were induced in the presence of the 24 h eluate.
- Hemolysis, EN ISO 10993-4: There were no hemolytic-acting substances released from the material.
- Chemical analysis, EN ISO 10993-18 (GC-FID, GC-MS): In water/ethanol extracts, the overall weight of soluble organic constituents is below the quantification limit of 2 µg/cm²/24 h. Also no extractable material contents were detected in the solvent extract (isopropanol, 24 h, 37 °C, GC-MS), manufactured under strongly material stressing conditions.
- No further-reaching toxicological analyses (such as sensitization, irritation, systemic toxicity (in compliance with 10993-10 and 10993-11)) were performed on material extracts. This is justified due to the adequate inert properties indicated using highly sensitive biological and chemical tests. Therefore, it can be excluded that material extracts suitable for toxicological testing contain any toxic substances or any toxic substances in an adequate concentration for test-specific verification. Thus, sensitizing properties in accordance with EN ISO 10993-10, irritating properties in accordance with EN ISO 10993-10 and systemic toxic properties in accordance with EN ISO 10993-11 are not to be expected with the material in question.

The material insolubility of TECAPEEK MT black (stock shapes) corresponds with the requirements of EN ISO 10993-1 for the intended application in medical products.

Information on validity:

The present statement on biocompatibility has been issued specifically for one particular order and cannot be transferred to other delivery or production numbers. The material specified here is not suitable for use in medical implants.
The above information and statements are based on our current knowledge and are intended to provide information about our products and their uses. Thus, they do not assure or guarantee the chemical stability or the consistency of the products and their suitability for the trade in a legally binding way.

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Declaration on Biocompatibility

This statement refers to semi-finished products supplied by Ensinger GmbH in Nufringen and does not relieve the user of performing additional material testing which may be required to obtain product-specific approvals for the final product.
The suitability of the semi-finished products for a particular purpose must be ascertained by the component manufacturer or supplier under practical conditions of use.

Ensinger GmbH

i.V. Iris Schuller
Product Compliance Management

This document has been generated electronically and is therefore valid without signature.

Documentation:

[1] Victrex: Certificate of Compliance with the FDA Regulations for Plastics for Food Contact, 2011
[2] Manufacturer of the color concentrate: Product Statement, 19.05.2011
[3] Evaluation of the biological safety - Toxicology, EN ISO 10993-1, Directive 93/42/EEC; Medical Device Services, Report No. 120854-40-D , 27.04.2012.

The documents listed in this reference can be made available on request to the competent authorities or inspection bodies for the purpose of conformance testing.

The Reference No.: SH00585MT0101_V01 of this document replaces Reference No.: HZ00585MT0101_V06