01246 TECAPEEK MT CLASSIX white

Stock Shapes
Base Polymer: PEEK
Referenz Nr./Reference No.: SH01246MT0101_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), PEEK CLASSIX BC1-WH, from the company Invibio Ltd.
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 planning or cutting is performed dry, without the use of coolant. The following statement includes planed or cut products. During grinding coolant is used.

According to the manufacturer's statement, PEEK CLASSIX BC1-WH 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

As per manufacturer's specifications, PEEK CLASSIX BC1-WH is in compliance with the requirements imposed by the U.S. Pharmacopeia (USP) for Class VI plastics. According to that, the following tests were performed on the raw material: USP systemic toxicity, USP intracutaneous toxicity and USP muscle implantation test. The test samples were extracted at 121 °C and 1h [1]. PEEK CLASSIX BC1-WH is biologically qualified for temporary applications (<30 days) with blood and tissue contact [2+3].

Information on tests on stock shapes:

TECAPEEK MT CLASSIX white 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 [4]. The specimens were taken from stock shape after the annealing process and the product-specific finishing steps.

Application: Semi-finished product for the manufacture of medical devices with contact to tissue or mucous membrane and indirect with blood up to 30 days. The indication includes healing caps, provisional abutments and gingival formers, used during the healing phase of dental implants, and/or temporary devices for tooth regulation/orthodontics, being intended for temporary use only in the oral environment for periods of less than 180 days. TECAPEEK MT CLASSIX white is not suitable for any medical implants [(1)] [3].

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	9 cm²/ml DMEM-FBS (inkl.1,5 % DMSO), 7 days, 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 CLASSIX white natural for the following reasons:

- Cytotoxicity, EN ISO 10993-5: No cytotoxic effects were induced in the presence of the 7 days eluate.
- Hemolysis, EN ISO 10993-4: There were no hemolytic-acting substances released from the material in the presence of the 24 h eluate.
- 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 and subchronic toxicity, genotoxicity (in compliance with 10993-3, -10, -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, systemic and subchronic toxic properties in accordance with EN ISO 10993-11 and genotoxic properties in accordance with EN ISO 10993-3 are not to be expected with the material in question.

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

Information on validity:

(1) As specified by the raw material manufacturer, Invibio Ltd, an “Implant" means any device which is intended; (I) to be totally introduced into the human body or, to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure or, (II) to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days or (III) for temporary and/or permanent use in the oral environment, in particular including posts and devices for root canal

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treatment and/or removable dentures and/or fixed dentures and/or combinations thereof, especially crowns, bridges, superstructures, attachments, locks, telescopic and conical crowns, construction parts, or any other device as may be agreed from time to time with Invibio [3].

The present statement on biocompatibility has been issued specifically for one particular order and cannot be transferred to other delivery or production numbers.
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.
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] Invibio Ltd.: PEEK CLASSIX BC1-WH USP VI, 16.03.2011
[2] Victrex: Policy Statement on use of VICTREX® PEEK™ polymer in ISO10993 Type A applications, no date
[3] Invibio Ltd.: Use of PEEK-CLASSIX polymers, 2013
[4] Evaluation of the biological safety - Toxicology, EN ISO 10993-1, Directive 93/42/EEC; Medical Device Services, Report No. 120854-40-A , 15.05.2012.

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.: SH01246MT0101_V01 of this document replaces Reference No.: HZ01246MT0101_V07