CENDRES+ MÉTAUX

Material Data Sheet

for: Pekkton® ivory

1. Composition

	Cas No.
Polyetherketoneketone (PEKK)	54991-67-2
Titanium Dioxide	13463-67-7

2. Physical properties

Glass temperature	Tg= 157 °C	ASTM-D3418
Melting temperature	Tm=364 °C	ASTM-D3418
Color	whitish	

3. Mechanical properties

Young's modulus	4.7 GPa	ASTM-D638
Tensile strength@break	117 MPa	ASTM-D638
Flexural modulus	4.9 GPa	ASTM-D790
Flexural strength@5% strain	200 MPa	ASTM-D790

Values for mechanical properties are based on standard geometries.
The values may vary depending on shape, design and processing parameters.

4. Sterilization

Due to its high glass transition temperature (157°C) above normal steam sterilization temperatures of 121°C to 134°C and thanks to its natural hydrolysis resistance, Pekkton® ivory is particularly suited to steam sterilization without any noticeable changes in mechanical or physical properties.

5. Monitoring

Manufacture, packing and delivery are constantly monitored by the quality management system standards according to ISO 9001 and ISO 13485.

6. Biological evaluation

Scientific Background and Normative Requirements

For the risk assessment of biological risks, the procedures and provisions of EN ISO 10993-1:2009 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", were applied. Based upon the criteria set out in this standard, the product is biologically classified as an "external communicating device" with "permanent" (> 30 days) contact to "tissue, bone or dentin".

Therefore, in accordance with the aforementioned standard and in accordance with EN ISO 7405:2008 Dentistry – Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry – Test Methods for Dental Materials", the following biological risks were particularly evaluated:

-Cytotoxity	EN ISO 10993-5:2009
-Irritation	EN ISO 10993-10:2010
-Delayed type hypersensitivity	EN ISO 10993-10:2010
-Acute systemic toxicity	EN ISO 10993-11:2009
-Subchronic systemic toxicity	EN ISO 10993-11:2009
-Chronic systemic toxicity	EN ISO 10993-11:2009
-Implantation	EN ISO 10993-6:2009
-Genotoxicity	EN ISO 10993-3:2009
-Carcinogenicity	EN ISO 10993-3:2009
-Chemical characterization	EN ISO 10993-18:2009
-USP Class VI	USP 34 <88>

For sample preparation and dosing EN ISO 10993-12:2009, respectively USP 34 <88> is applicable.

Conclusion

Based upon the study results and evaluation arguments and considering the provisions of the current version of the harmonised standards EN ISO 10993-1 and EN ISO 7405 it is concluded that the dental material Pekkton® ivory can be evaluated as biocompatible if manufactured appropriately and applied in compliance with its intended use as outlined in the manufacturer's Instruction for Use.

Author of Evaluation

Dr. Dieter R. Dannhorn
md registration support Ltd.
Grenzstrasse 13
D-88416 Ochsenhausen

Cendres+Métaux SA

Dr. Thierry Copponnex
Director of Development

Dr. Theo Gautschi
Director of Quality