

Material Information

cara Temp PMMA

Tooth-coloured PMMA for the manufacture of temporary crowns and bridges using CAD/CAM technology.

Manufacturer: Kulzer GmbH

Composition

- Polymethylmethacrylate and cross-linked copolymers of methacrylic acid
- Colouring agent
- Residual peroxide
- May contain a max. of 1 % methylmethacrylate as a residual monomer



Biocompatibility:

We confirm that the product has been evaluated in accordance with the internationally accepted standards EN ISO 7405: "Dentistry: Preclinical evaluation of biocompatibility of medical devices used in dentistry – Test methods for dental materials" and EN ISO 10993-1: "Biological evaluation of medical devices". Among other things, the evaluation comprised potential risks of cytotoxicity, sensitisation, irritation and genotoxicity. Studies were conducted at independent testing facilities according to the requirements defined in the OECD guidelines and met the GLP (good laboratory practice) requirements. The evaluation verifies the biological compatibility of this dental material.

Chemical, physical and mechanical material properties:

Chemical solubility was tested according to the procedure defined in standard EN ISO 10477:

"Dentistry – Polymer-based crown and bridge materials".

Tests showed that the solubility of the tested PMMA temp. is $< 7.5 \mu\text{g}/\text{mm}^3$, meaning that the standard requirement for low chemical solubility (not more than $40 \mu\text{g}/\text{mm}^3$) is met. In addition, the physical and mechanical properties of the material were tested in accordance with EN ISO 10477 and EN ISO 1567 and were rated as "very good".

Evaluation:

Based on the tests and evaluations mentioned above, the tooth-coloured PMMA temp. and PMMA temp.-light are classified as biocompatible when used for their intended purposes.

This Material Information is subject to an internal approval process. It was created electronically and is therefore valid without a signature.

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Giving a hand to oral health.



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