

Material information

BISPHENOL- A

Manufacturer: Kulzer GmbH

Dental materials are manufactured without bisphenol-A additives!

Bisphenol-A (BPA) is a commonly used industrial raw material that is used in the manufacture of numerous consumer goods, such as plastic bottles, plastic toys or even in till receipts. However, many authorities have now imposed stricter restrictions on the use of bisphenol-A^[1].

Many dental composite materials contain Bis-GMA (bisphenol A glycidyl methacrylate) as an essential component, but this is not the same as BPA. Although BPA is used in the production of Bis-GMA, the BPA structure is chemically bound into it. Minimal traces of BPA may be present as a result of the manufacturing process. However, the American Dental Association (ADA) states that there is no cause for concern regarding the possible release of BPA from composites or bonding materials and confirms the safety of current dental materials^[2,3]. This is also the conclusion of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Based on available publications, the committee concludes that long-term oral exposure to BPA from dental materials is within the tolerable daily intake^[4].

Products from Kulzer:

Kulzer also uses Bis-GMA and EBADMA (ethoxylated bisphenol A dimethacrylate) in the manufacture of some dental products, whereby Kulzer only uses BPA-based quality raw materials with confirmed limits of maximum 10 ppm (0.001%). However, Kulzer does not use BPA as a raw material or additive for the production of composites or adhesive systems. In addition, for the latest composites, such as Charisma Diamond and Charisma Topaz, Kulzer has developed a patented composition based entirely without EBADMA or Bis-GMA matrix, so that no BPA structure is contained at all. Investigations of an external analytical laboratory could not find any BPA release from unpolymerized and polymerized Charisma Diamond/Charisma Topaz composite above the detection limit^[5].

[1] FDI World Dental Federation Statement: Bisphenol-A in Dental Restorative and Preventive Materials, 2013

[2] ADA Statement on Bisphenol A and Dental Materials, 2013

[3] ADA Policy Statement 6.27 – Bisphenol-A in Dental Restorative Materials, 2021

[4] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR): The safety of the use of bisphenol A in medical devices, 2015

[5] Testreport, 10-2023

Research & Development

Kulzer GmbH
Leipziger Straße 2
63450 Hanau

Contact:
Global Safety Management
Kulzer GmbH
Leipziger Straße 2
63450 Hanau
GSM@kulzer-dental.com



KULZER
MITSUI CHEMICALS GROUP