

# Material Information

## BISPHENOL - A



**Manufacturer: Kulzer GmbH**

### Dental Materials are not made of Bisphenol-A

Bisphenol-A is a commonly used chemical for plastic materials such as polycarbonate bottles or in the coatings of cans. For this purpose, the Canadian health authorities banned the use of Bisphenol-A (BPA).

However, Kulzer uses no BPA as a compound in resin-based dental products such as composites and bonding systems.

#### **The American Dental Association (ADA) confirms the safety of resin-based dental materials:**

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Many composite materials contain a monomer component called BisGMA (Bisphenol-A- Glycidyl-MethAcrylate). BisGMA is not the same as BPA; it comprises only the BPA structure in a tightly bonded ether form. Thus, as contaminant, the compound might contain traces of BPA. The ADA states that there is no cause for concern at this time regarding potential BPA exposure from composites or sealants. BPA as a contamination would be several orders of magnitude below the maximum accepted dose of 50 µg/kg body weight per day.

#### **United States Environmental Protection Agency classified the acceptable daily intake:**

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#### **Kulzer products:**

Kulzer uses BisGMA in some of its products. Recent authoritative risk assessments based on the most current information have confirmed the minimal contribution of dental products to the BPA exposure confirming the ADA's statement that "there is no cause for concern regarding potential BPA exposure from composites".

Moreover, Kulzer replaced in some composites (i.e. Charisma Topaz and Charisma Diamond) the BisGMA matrix by a patented monomer mixture that contains no BPA structure at all.

Nevertheless, Kulzer states with confidence that all products are safe for their intended clinical use according to the state-of-the-art.

#### **Global Safety Management**

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