
Leuven, May 18th, 2018¹



Dear GC Europe customer,

You may have been informed about concerns regarding Bisphenol A (BPA) and the use of some of its derivatives in dental materials². As a company dedicated to its customers and products users, we would like to provide some clarifications:

1. **NONE of GC dental products sold within Europe and all other territories under the operational responsibility of GC Europe have Bisphenol A in their chemical formulation.**
2. **The majority of GC products do not contain any BPA derivatives.** The two BPA derived monomers that may be present in GC products are Bisphenol A glycidyl dimethacrylate (also called Bis-GMA) and Ethoxylated Bisphenol A dimethacrylate (also called Bis-EMA). The below Annex lists the GC products that contain one or both of these monomers. Alternatively, GC also offers products that are free of BPA derivatives such as UDMA-based direct composites (e.g. Gradia Direct, G-aenial Anterior) or state-of-the-art glass ionomers (e.g. Fuji IX GP, Fuji Triage).
2. Neither Bis-GMA nor Bis-EMA can be converted into BPA in saliva and a comprehensive scientific literature review concludes that Dental materials containing Bis-GMA or Bis-EMA pose no human health risks.³ This conclusion is consistent with the opinion adopted by the EC Scientific Committee on Emerging and Newly Identified Health Risks stating that oral exposure to BPA via dental material poses a negligible risk to human health and is far below the exposure to BPA via food⁴.

GC Europe, in cooperation with oral health experts, tracks any information of relevance to ensure the safety of its products. Therefore you can reassure your customers and patients that GC Europe only sells products which are safe for dental use, according to national and international regulations and standards.

For further information on this subject, please do not hesitate to contact your local GC representative.

Sincerely,

Mario Minale
Head of Regulatory Affairs

Jacobus Dopheide
Head of Product Management

¹ The content of this statement is applicable under the current situation on signature date. GC Europe cannot be liable for any future changes that may occur.

² European Commission, European Union Risk Assessment Report - Human Health Addendum of April 2008 - 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A) - Part 2 Human Health;

³ Chen L., Suh BI, "Bisphenol A in Dental Materials: A Review.", *JSM Dent 1, 2013*: 1004., p 4

⁴ Opinion on The safety of the use of bisphenol A in medical devices adopted by written procedure on 18 February 2015 by the Scientific Committee on Emerging and Newly Identified Health Risks. p 16, §4 and p 118, §4



List of GC products containing: Bisphenol A glycidyl dimethacrylate (Bis-GMA) and/or Ethoxylated Bisphenol A dimetacrylate (Bis-EMA).

	Bis-GMA	Bis-EMA
Ceramic Primer II	Present	-
G-Multi Primer	Present	-
G-CEM LinkForce	Present	Present
FujiCEM 2	-	Present
Fiber Post	Present	-
everStick product lineⁱ	Present	-
StickRESIN	Present	-
everX Posterior	Present	-
Kalore	-	Present
G-ænial Posterior (NOT in G-ænial Anterior)	-	Present
G-ænial Flo X	-	Present
G-ænial Universal Flo	-	Present
G-ænial Universal Injectable	-	Present
Essentia Light Enamel, Dark Enamel and Opalescent Modifier	Present	Present
Essentia Masking Liner	-	Present
Essentia HiFlo	-	Present
Essentia LoFlo	-	Present
GRADIA PLUS	Present	Present

ⁱ The everStick product line consists of everStickC&B, everStickNET, everStickORTHO, everStickPERIO and everStickPOST (0.9; 1.2; 1.5).