

Dear Dental Professional,

Thank you for your inquiry related to bisphenol-A (“BPA”) and our dental and orthodontic products. It is our mission at Ultradent Products, Inc. to improve oral health globally and that includes providing the most safe and effective products for you to use on your patients. As a global manufacturer of dental and orthodontic products, we perform biocompatibility evaluations on each of our products to ensure they meet or exceed global safety standards.

We are aware of the ongoing discussions related to BPA and can confirm that we do not use BPA as an ingredient in any of our dental or orthodontic products.

Many dental resin materials, such as composites, sealants, bonding materials and cements, contain monomers synthesized using BPA. When BPA is used to synthesize these monomers, it is chemically bound within their structure and only minimal traces of BPA may still be present as an impurity.<sup>1</sup> Such BPA derivatives include bisphenol A-glycidyl methacrylate (“Bis-GMA”), ethoxylated bisphenol A (“Bis-EMA”), and bisphenol A dimethacrylate (“Bis-DMA”). Of these BPA-derived monomers, only Bis-DMA was shown to break down into BPA under oral conditions.<sup>1</sup> Ultradent does not use Bis-DMA in any dental or orthodontic products.

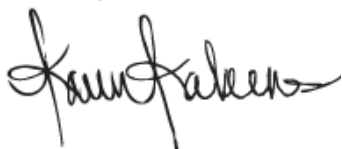
Our dental and orthodontic resin products may contain Bis-GMA and/or Bis-EMA, which do not hydrolyze into BPA in saliva.<sup>1</sup> Clinical studies have shown that any exposure to BPA from bis-GMA based composites and sealants is far lower than current FDA and EPA acceptable daily exposure limits.<sup>2,3,4</sup> The American Dental Association (“ADA”) indicates that “based on current evidence, there is no health concern relative to BPA exposure from any dental material.”<sup>5</sup> In addition, the Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”), an independent committee that provides opinions on health risks to the European Commission, found BPA exposure due to long-term contact with dental materials far below the exposure to BPA via food.<sup>6</sup>

As a precaution, we suggest reviewing the ADA’s “Strategies to Help Minimize Dental Patient BPA Exposure” available on the ADA website ([Bisphenol A | American Dental Association](https://www.ada.org/resources/ada-library/oral-health-topics/bisphenol-a)).<sup>7</sup>

We actively monitor the ever-changing regulatory and scientific landscapes related to the safety of our products and we are confident at the present time that our products are safe for their intended dental use according to global standards.

We hope this letter helps you reassure your patients about the safety of our dental materials. If you have any questions or concerns, please contact our Customer Support at 1-800-552-5512.

Sincerely,



Karen Kakunes  
Senior Vice President - Quality Assurance & Regulatory Affairs

<sup>1</sup> Chen L, Suh BI, Bisphenol A in Dental Materials: A Review. *JSM Dent*. 2013;1: 1004.

<sup>2</sup> American Dental Association Council on Scientific Affairs. Bisphenol A Released from Resin Based Dental Sealants. *J Am Dent Assoc*. 2016;145(7):763-765.

<sup>3</sup> American Dental Association Council on Scientific Affairs. Determination of bisphenol a released from resin-based composite dental restoratives. *J Am Dent Assoc*. 2014;145(7):763-765.

<sup>4</sup> Šimková M, Tichý A, Dušková M, Bradna P. Dental composites - a low-dose source of bisphenol A. *Physiol Res*. 2020;69(Suppl 2):S295-S304.

<sup>5</sup> Dental Sealants. American Dental Association. Retrieved November 6, 2024, from <https://www.ada.org/resources/ada-library/oral-health-topics/dental-sealants#>

<sup>6</sup> SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks). Opinion on the Safety of the Use of Bisphenol A in Medical Devices, 2015 [https://health.ec.europa.eu/document/download/bb2245e3-8c06-468b-931e-ca4aa50a4790\\_en?filename=scenih\\_r\\_o\\_040.pdf](https://health.ec.europa.eu/document/download/bb2245e3-8c06-468b-931e-ca4aa50a4790_en?filename=scenih_r_o_040.pdf)

<sup>7</sup> Bisphenol A. Strategies to Help Minimize Dental Patient BPA Exposure. American Dental Association. Retrieved November 6, 2024, from <https://www.ada.org/resources/ada-library/oral-health-topics/bisphenol-a>