



October 12, 2016

Thank you for your concern about Bisphenol-A and UltraSeal XT® pit & fissure sealants.

Bisphenol A (BPA) became a significant concern in the 1990s. Back then, Ultradent undertook efforts to measure BPA content with state-of-the-art instrumentation, and we were unable to detect any BPA at the parts-per-million (ppm) level in our UltraSeal XT sealants. This testing was an important step to show we were below detectable limits and were well below any stated safe exposure limits set by the Food and Drug Administration (FDA).

In 2015, the American Dental Association (ADA) used recent advanced technology to look for BPA in parts-per-billion (ppb), which is at a level one thousand times smaller than what was previously possible to measure. Not surprisingly, they found BPA in tiny ppb in other companies' sealants and in ours¹. However, the ADA also found ppb levels of BPA in some resin chemistries which by all the logics of science should have had no possibility of containing even extreme low levels of BPA. This demonstrates a lack of reproducibility and practicality and leads one to question the logic of attempting to measure to such extreme minute levels. As analytic technology continues to advance, we may eventually be able to find a few atoms or molecules of every substance in most everything.

To put the amount of BPA contained in our sealants in perspective, if one were to rely on the ADA's ppb report, as well as our independent 3rd party testing², in order to exceed the FDA's safe exposure limits, a **30 lb. child would need to consume approximately 1,000,000–3,000,000 syringes (about 1,200–3,600 liters or 316–947 gallons) per day** of our raw, unpolymerized sealant resins. Note that each sealant procedure requires only 1–3 drops of sealant resin. In addition, once the resin is polymerized with the curing light, there is virtually zero release of BPA from our sealants even to the extremely irrelevant ppb level. Based on the above, we feel confident from a practical standpoint, in continuing to state that our sealants are BPA free.

It is important to note that both the American Academy of Pediatrics and the American Dental Association recommend parents continue to use dental sealants³. Additionally, since the 1990s, thousands of studies have been conducted regarding the effects of BPA. Some of these studies have led the FDA to realize that the effects of BPA are far less concerning than what was originally thought. Nevertheless, Ultradent continues to use raw resin sources for sealants that show no detectable BPA as measured at the much more realistic and relevant ppm level.

I hope that the information in this letter addresses your concerns. Thank you for the opportunity to answer your questions regarding Bisphenol-A.

Sincerely,

Dan E. Fischer, DDS

President/CEO of Ultradent Products, Inc.

1. ADA Professional Product Review. Volume 10, Issue 2.
2. Abby F. Fleisch, MD, a Perry E. Sheffield, MD, b Courtney Chinn, DDS, MPH, c Burton L. Edelstein, DDS, MPH, c and Philip J. Landrigan, MD, MSch, et al. 2010. Bisphenol A and Related Compounds in Dental Materials. American Academy of Pediatrics (126:760-768). John T. Wright, DDS, MS, James J. Crall, DDS, MS, ScD, Marherita Fontana, DDS, PhD, E. Jane Gillette, DDS, et al. 2016. Evidence-based clinical practice guideline for the use of pit-and-fissure sealants. JADA, August 2016, Volume 147, Issue 8, Pages 672-682.
3. Polymer Solutions Inc. Project #14845/#14890, September 23, 2015