ULTRADENT
PRODUCTS, INC.

Dear Doctor,

In the past few days, both national and local media have published reports regarding the health concerns over Bisphenol-A and its use in plastic bottles, cans and even home electronics. Unfortunately, the general category of "dental sealants" has been incorrectly added to the items of concern.

This alarm over Bisphenol-A is not new and typically comes and goes in the media. Ultradent is very aware of this subject and has successfully addressed this issue repeatedly over the past 12 years! Most media attention to this comes from the original "Granada" study done some years ago that incorrectly lumped all dental sealants as a possible risk by using only one competitive manufacturer's sealant material.

Included in this message to you are past letters and research that clearly state that Bisphenol-A is not a component within Ultradent's 9 year award winning sealant, UltraSeal XT plus.

It's important to understand that there is a significant molecular difference between the Bis-GMA (used in UltraSeal XT plus) and Bisphenol-A Dimethacrylate. Bis-GMA is a very stable resin monomer whereas Bisphenol-A Dimethacrylate is a much less stable resin monomer. Bis-GMA is well known, well established, and has been widely used by many dental manufacturers since the sixties and seventies. Ultradent has had the position for quite some time that our raw material Bis-GMA has no Bisphenol-A.

Ultradent, as you all know, prides itself on the integrity of our employees and the quality of our products and we want to provide you with the information you may need to ensure your customers have the highest confidence in our materials.

Please take the time to read the additional information attached for further understanding and contact Ultradent's Customer Service Department if you have additional questions or customer concerns.

Best Regards,

505 West 10200 South, South Jordan, Utah 84095, USA • 800.552.5512 • Fax: 801.572.0600 • www.ultradent.com

ULTRADENT PRODUCTS, INC.
The Syringe People™

We wish to commend you for your communication demonstrating concern for use of sealants relative to a study referencing Bisphenol-A. Bisphenol-A is, in significant quantities, harmful.

Please note that the sealant material used in the "Granada" study was **NOT** bis-GMA based, but was in fact bisphenol-A dimethacrylate based (Delton®*). The "Granada" study should be disregarded, in that they failed to investigate the true chemical composition of the Analyte. This could have been done as easily as reading the chemical contents on their MSDS or by contacting the manufacturer. Delton was the only material that showed any significant level of bisphenol-A. For the authors, other researchers or clinicians to extrapolate from one sealant containing bisphenol-A dimethacrylate resin to bis-GMA based sealants, composites, etc., is neither logical nor appropriate.

There are some who have incorrectly suggested that the composites in the "Granada Study" did not release any significant bisphenol-A due to having a higher filler loading than the sealant. This might have some effect, everything else being equal, if the composites, just like the sealant were bisphenol-A dimethacrylate based rather than bis GMA based with no bisphenol-A dimethacrylate resin as part of their formulation. Bis-GMA is a very stable resin monomer. Bisphenol-A dimethacrylate is a much less stable resin monomer.

Many composites and sealants don't contain bisphenol-A dimethacrylate resin. We do <u>not</u> use bisphenol-A dimethacrylate in any of our resin products including our bis-GMA based pit and fissure sealant, UltraSeal XT *plus* (Incidentally, the XT *plus* is a flowable composite sealant with 60% filler loading weight to weight. This is the same level of filler loading found in most microfills, example Silux®* and Durafil®*).

505 West 10200 South, South Jordan, Utah USA 84095

Bis-GMA is well known, well established, and has been widely used by many dental manufacturers since the sixties and seventies. We have had the position for some time that our raw material bis-GMA has no residual bisphenol-A. Our quality supplier of bis-GMA has provided us with a letter (on file) guaranteeing no trace of bisphenol-A impurity in the bis-GMA resin we use. Bis-GMA resin is very stable even as the uncured monomer. The polymerized polymer is more stable yet.

I hope the above information is of value to you.

Thank you for your concerns.

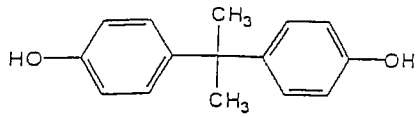
Sincerely,

Dan E. Fischer, D.D.S.
Director of Research and Development
and President

*Delton, Silux and Durafil are not trademarks of Ultradent Products, Inc.

Technical:

bis-phenol A

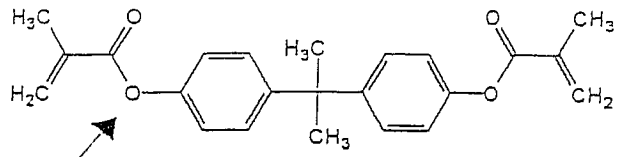


Suspected health hazard - ???????

BPDMA

bis-phenol A dimethacrylate

(found in a variety of other pit and fissure sealants)



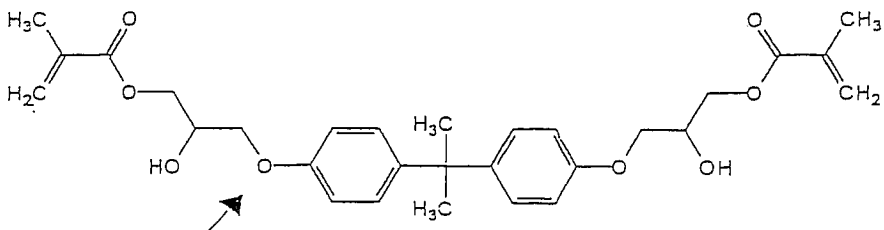
Methacrylic acid is bonded to bis-phenol A via an ester group. This ester group is slightly unstable and somewhat suceptible to decomposition by saliva back into its base components: methacrylic acid and bis-phenol A.

BPDMA is not found in any product manufactured by Ultradent Products Inc.

Bis-GMA

2,2-bis(p-2'-hydroxy-3'-methacryloxypropoxylphenyl)propane

(Ultradent polymer products utilize Bis-GMA)



Bis GMA is bonded via an ether group. This ether group is very stable and not suceptible to decomposition by conditions found in the oral cavity.

Comments: BPDMA should not be confused with Bis-GMA. These molecules are very much different from each other.