Rapid Response
1402 Third Avenue, Suite 1420
Seattle, Washington 98101
Tel 206-352-2050
Fax 206-352-2049
www.pprc.org

Rapid Research
Safety of Plastics in Dental Appliances
Requested by Anonymous

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Request

What kinds of plastics are used in making custom dental bite guards (night guards)? Specifically, is bisphenol-A (BPA) an ingredient? Are there safe alternatives?

Key Findings

- A wide range of material types are used to manufacture dental products. Sealants, fillings, mouth guards and other dental appliances can and may contain bisphenol-A, phthalates and other chemicals of concern.
- The US Food and Drug Administration (FDA) does not require testing for BPA-exposure from dental materials. A new evaluation of BPA in food packaging is expected soon.
- New federal regulations require that manufacturers stop using phthalates in toys intended for children, but it is not clear whether mouth guards also would be affected.
- Both the American Dental Association (ADA) and Canadian Dental Association suggest that exposure to BPA from dental materials is not a safety concern, as the exposures are likely small compared with other environmental sources. Many foods and beverages pose significantly higher exposure risk from BPA.
- While there is uncertainty about the human health risk from exposure to BPA, some experts advise avoiding BPA exposure (the precautionary principle), rather than wait for proof of harm.
- Those particularly concerned about exposures to BPA or phthalates should contact their dental-care provider and product manufacturer for information on chemical content and exposure risk.
- Concerned consumers can ask for products that do not contain BPA or phthalates. It would be prudent to avoid polyvinyl chloride (PVC) products, as these commonly contain phthalates and possibly lead. Polycarbonates (PC) are made with BPA and are known to leach BPA under certain conditions.

Background

Concern about potential bisphenol-A (BPA) contamination from food and beverage containers is widespread. Most of the attention has been given to water bottles and baby products made from polycarbonate, which is manufactured using BPA. Due to consumer pressure, manufacturers have largely replaced polycarbonate with (presumably) BPA-free plastics. On the other hand, food cans may still pose risks as they are often lined with BPA-containing epoxies or plastics to preserve shelf-life. A recent study by Consumers Union found BPA in a host of canned foods, including organic products and products sold in BPA-free cans (1).

BPA is one of a number of synthetic chemicals known to mimic the effects of the human hormones, often labeled as endocrine-disrupting chemicals (EDCs). EDCs can interfere with normal hormonal processes in the body, however, the degree to which these chemicals are responsible for human health problems has not been well established. Polycarbonate is considered safe for use in food and beverage packaging by US and European regulatory agencies (2; 3). Critics argue that the regulations are out-of-date and ignore the latest

research into low-level effects of EDCs like BPA (4). A recent scientific statement from the Endocrine Society[1] suggests applying the precautionary principle, i.e., there is sufficient reason to suspect harm and measures should be taken to avoid BPA exposure (5). A US government report by the National Toxicology Program (part of NIH) states that they "…[have] *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A." Risks were otherwise considered negligible for adults (except for occupational exposures) (6). In September 2009, the US Environmental Protection Agency (USEPA) announced that a new chemical action plan for BPA would be forthcoming in December 2009, but as of this writing, no details have emerged (7). The FDA is also due to release a new evaluation of BPA-containing materials in food packaging.

BPA in Dental Materials

Dental materials are made from dozens to hundreds of plastics, adhesives, and other compounds, and BPA has a long history of application in dentistry. Most of the press and internet coverage has been given to dental sealants, due to concerns about exposure to children, but BPA is also a component of tooth-colored filling materials (used to minimize filling visibility). As the ADA reports, "BPA may become part of dental sealants or composite resin filling materials in three ways: as a direct ingredient, as a by-product of some ingredients in dental composites or sealants that may have degraded, or as a trace material left-over from the manufacture of some ingredients used in making dental composites or sealants" (8).

Both the ADA and Canadian dental authorities suggest that the risk of BPA from dental materials is small compared with other human exposures (8; 9), and the FDA does not require testing of dental materials for BPA. The Canadian reference (9) offers suggestions to minimize exposure during application of sealants.

Many types of low-cost bite guards are made of polycarbonate, which, as mentioned earlier, contains BPA. Just as with bottles and food containers, BPA is more likely to leach from plastic if it is heated or exposed to corrosive liquids (even cleaning liquids). It seems reasonable to avoid boil-and-bite guards (like those used for sports protection) that contain polycarbonate plastics.

Other Chemicals of Concern in Dental Materials

Another class of endocrine disrupting chemicals called phthalates may be used in dental materials, such as tissue conditions (for denture preparation), dental liners, etc. (10). Phthalates are used to soften plastics, such as (but not exclusively) PVC. PPRC does not have information on specific dental products containing phthalates, but the patent literature clearly mentions phthalates as a possible component of dental materials.

Beginning February 10, 2009, some phthalates were banned from use in the manufacture of children's toys and childcare items (11). It is likely that any mouth guard intended for children 12 years of age and younger should be covered by the new ban. For adults, there is no FDA limit to phthalate use in dental materials.

For some individuals, latex may be of concern due to possible allergic reactions.

Suggestions for Consumers Concerned about Dental Products

While little information is readily available on the internet, both the patent literature and scientific articles clearly indicate that BPA-containing epoxies, plastics or composites are used for some dental fixtures, custom guards or appliances (12). Some manufacturers and suppliers are addressing chemical safety concerns with online disclosures (13; 14; 15)[2].

Consumers should communicate their concerns to their health-care provider and/or product supplier regarding product safety. Limited experience of PPRC staff suggests that dentists often do not know whether specific products contain chemicals of concern. The manufacturer should be able to tell consumers whether a product contains BPA or phthalates, but the process may not be easy.

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[1] An independent organization of physicians and research scientists working in endocrinology.

[2] PPRC does not endorse products nor can it confirm the information provided on these websites. There may be other substances of concern in these or other products.

In a brief experiment, PPRC attempted an investigation of materials supplied by Dentsply, one of the largest suppliers of dental products. A customer service agent stated that Dentsply materials do not contain BPA, but the agent had no information reagarding phthalates. No safety or environment staff person was available for phone inquiries. A search of several Dentsply product websites for "bisphenol" and "phthalates" returned no results.

The Dentsply customer service agent directed PPRC to a website with material safety data sheets (MSDSs) for many Dentsply materials. MSDSs are designed for occupational safety concerns and were never intended for use by end-consumers. MSDSs do not provide information suitable to address the chemical-leaching concerns discussed here. For example, for one Dentsply material, Essix ACE, the MSDS reported a composition of 95% copolyester (of a proprietary formulation), and 5% "Trade secret" (16). While it may not be reasonable to expect companies to disclose trade secrets, they would better serve their customers by providing additional information concerning plastics safety. If consumers cannot find data for their specific product, it may be best to deal with manufacturers that do provide information on chemicals of concern.

Conclusions

BPA and phthalates are used in some dental products, including mouth guards and dental appliances. Regulators offer little help as the FDA does not require tests for BPA-exposure from dental materials. The ADA and other authorities suggest that the risk of contamination from dental materials is low compared with other sources of BPA in the environment and food supply.[3] On the other hand, some experts suggest that while there is uncertainty about the risk of BPA exposure, consumers should take measures to avoid BPA exposure now, rather than wait for proof of harm from future research.

If you are concerned about potential chemical exposures, ask for dental materials without BPA or other contaminants of concern, like phthalates. The myriad of possible materials makes it impossible to recommend specific, "safe" dental products. Contact your dentist and product manufacturer to inquire about product safety, but you may not find the process easy. Over time, inquiries and expressions of concern may induce manufacturers and care-givers to become better informed and more responsive to consumer safety concerns.

Resources

- Environmental Working Group article on BPA in plastics: http://www.ewg.org/bisphenol-a-info
- Industry article on dental resins and sealants and exposure summary: http://www.iaomt.org/articles/files/files276/BPA%20review.pdf
- American Dental Association statement on BPA: http://www.ada.org/prof/resources/positions/statements/bisphenola.asp
- New York Times article on dental sealants and BPA: http://www.nytimes.com/2008/10/21/health/21well.html?_r=1

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2. Bisphenol A. *European Food Safety Authority.* [Online] [Cited: 2009.] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178710289744.htm.
3. Public Health Topics - Bisphenol A (BPA). *US Food and Drug Administration.* [Online] http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm.
4. Battles over Bisphenol A. *DefendingScience.org.* [Online] http://www.defendingscience.org/case_studies/Battles-Over-Bisphenol-A.cfm.

[3] To reduce your exposure to BPA, it would be advisable to minimize use of canned foods, avoid polycarbonate water bottles, and avoid heating food in polycarbonate storage containers.

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