

Bisphenol A and Polycarbonate Plastics Questions and Answers

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1. What is bisphenol A?

Bisphenol A is an industrial chemical used to make for polycarbonate plastic resins and epoxy resins. It has been used safely for more than 40 years.

2. Where is polycarbonate plastic used?

Many familiar consumer products are made from polycarbonate plastics, including compact disks, impact resistant eye glass lenses, and food and beverage containers, including bottled water cooler containers. Polycarbonate plastic is also used to make streetlight globes, small and large household appliances, components of electrical/electronic devices, automotive applications, telephones, and safety and sports helmets. Polycarbonate sheets are used extensively in signs, windows and window protection, walkways, roofing structures, greenhouses, solar and construction glazing, and skylights.

In addition, many food and medical devices are produced from polycarbonate (e.g., blood oxygenators used to purify blood and intravenous harnesses). Because of its use in food contact and medical products, polycarbonate and bisphenol A have undergone extensive safety testing, which has been reviewed by the U.S. Food and Drug Administration.

3. How is polycarbonate plastic used in food packaging?

Polycarbonate plastic is used in both beverage and food containers because it is hygienic and provides protection from food contamination and spoilage. Plastics have proven to be excellent in protecting food and beverages from bacteria, which is vitally important in safeguarding public health.

All plastics intended for contact with foods or beverages are regulated by the U.S. Food and Drug Administration to assure their safety. In addition, all products for food contact applications made from bisphenol A must meet health and safety regulatory guidelines throughout the world. Polycarbonate resins are employed in food-contact uses primarily in such applications as components of food processors, microwave ovenware, table ware, refrigerator crisper drawers, food-storage containers, and returnable water, milk and juice containers.

4. What bottled water containers are made with polycarbonate plastic?

Polycarbonate can be used to manufacture a variety of plastic bottled water containers from one liter to five gallon. The plastic used in all bottled water containers is shown to be safe through extensive laboratory testing. Bottled water and the containers it is placed in are brought to consumers under full regulation of the U.S. Food and Drug Administration. This regulatory oversight, reinforced with strong industry standards, ensures that consumers will receive a clean, safe product each time they enjoy a serving of bottled water, whether packaged in glass or plastic.

5. Is bottled water in plastic containers safe to drink?

Yes. The FDA investigates the potential toxicity of leaching chemicals and establishes safe levels for any contaminants in bottled water. There is currently no indication that contaminants from leaching or from the water source are a problem in bottled water.

The August 2004 issue of Risk in Perspective, published by the Harvard Center for Risk Analysis (HCRA), summarizes a weight of the evidence evaluation of low-dose reproductive and developmental effects of bisphenol A (BPA). BPA is used to make polycarbonate plastic; 5-gallon plastic bottles commonly used in water coolers are made from polycarbonate plastic. The Harvard Center for Risk Analysis convened an expert scientific panel to evaluate the weight of evidence for low-dose reproductive and developmental effects of BPA. In their overall conclusion:

"[T]he panel found no consistent affirmative evidence of low-dose BPA effects for any endpoint."

The full details of the study are published in the October 2004 issue of the peer-reviewed scientific journal Human and Ecological Risk Assessment (HERA), which is available on the Bisphenol-A.org Web site at <http://www.bisphenol-a.org/pdf/Gray-HERA-2004.pdf>. The August 2004 issue of Risk in Perspective is available on the HCRA Web site at www.hcra.harvard.edu/pdf/August2004.pdf.

A new weight of evidence evaluation, in which studies published in February 2006, were critically reviewed by an expert scientific panel that reached a similar conclusion. Overall the panel concluded:

"Taken together, the weight of evidence does not support the hypothesis that low, oral dosages of BPA adversely effect human reproductive and developmental health."

The full details of the study are published in the May 2006 issue of the peer-reviewed scientific journal, "Critical Reviews in Toxicology," which is available online at www.dx.doi.org/10.1080/10408440600758317. A summary of the study is

available in the June 2006 issue of the "Risk in Science Bulletin," online at www.gradientcorp.com/coinfo/RiskBull.html.

These conclusions are consistent with and support numerous assessments conducted by scientific bodies worldwide, all of which support the safety of BPA and bottled water in polycarbonate containers.

6. I heard that a study on animal cages and water bottles made from polycarbonate plastics became dangerous after they were scrubbed. Aren't watercooler bottles cleaned for re-use?

Bottled watercooler containers are cleaned and sanitized in accordance with guidelines as dictated by FDA Good Manufacturing Practices (GMPs). These include specifics related to cleaning agents used, water/rinse temperature and duration. These containers are cleaned and sanitized on specialized equipment designed specifically for that purpose. The methods and materials used in the study would not be utilized in a bottled water plant. For instance, researchers conducting the study mistakenly used a highly caustic floor cleaning detergent that would not be used to clean and sanitize bottled watercooler containers.

7. Are products made with bisphenol A safe to use?

Yes. Claims of adverse health effects in laboratory animals at extremely low doses are based on small, unvalidated studies. Much larger, more comprehensive studies by several different research groups in the United States and Japan failed to show any adverse effects after exposure of laboratory animals to low doses of bisphenol A over multiple generations. These studies follow internationally accepted guidelines for conducting toxicity tests and also comply with Good Laboratory Practice requirements to ensure valid results.

Products made from bisphenol A are safe if used as intended because bisphenol A has been highly studied. A large number of studies have been conducted to assess the impact of bisphenol A on human and environmental health. Research has shown that bisphenol A is not a carcinogen, not a reproductive or developmental hazard, and is not bioaccumulative because it is rapidly metabolized and eliminated from the body. In addition, bisphenol A degrades rapidly in the environment. The benefits of bisphenol A as an environmentally friendly food packaging material have proven vitally important to public health.

Assessments of the scientific evidence conducted by government agencies worldwide all confirm that polycarbonate products made from bisphenol-A are safe for use. For example, in January 2006, the German Federal Institute for Risk Assessment (known as BFR), which is the German expert body responsible for opinions on food safety and consumer health protection, released a statement with their views of the safety of polycarbonate baby bottles. Overall they noted

that, "BFR does not recognize any health risk for babies that are fed from baby bottles made of polycarbonate."

8. If I eat or drink something that was contained in a plastic container that was made with bisphenol A will I harm my health?

No. Recently, a scientific evaluation of bisphenol A was published by Professor Michael Kamrin, Professor Emeritus at Michigan State University. After systematic evaluation of the extensive scientific literature on bisphenol A, Professor Kamrin concluded "it is very unlikely that humans, including infants and young children, are at risk from the presence of BPA in consumer products." Professor Kamrin's evaluation is available in the peer-reviewed journal Medscape General Medicine at <http://www.medscape.com/viewarticle/484739?src=search> (free registration required).

After consideration of Professor Kamrin's evaluation, the American Council on Science and Health, which includes a board of 350 physicians, scientists and policy advisors, concluded "The current, very low levels of exposure to bisphenol A from plastic bottles and other consumer products do not pose a hazard to human health." The Council's views on bisphenol A are available at http://www.acsh.org/publications/pubID.1033/pub_detail.asp.

There is no known evidence of any effect on human health from exposure to bisphenol A resulting from consumer uses of products made from polycarbonate plastic. Polycarbonate food and beverage containers, as well as other consumer products made from polycarbonate, are safe for their intended uses.

9. How does FDA regulate bisphenol A?

Plastic food and beverage containers, including polycarbonate plastic made with bisphenol A, meet or exceed all requirements of the U.S. Food and Drug Administration which regulates food packaging to assure its safety.

FDA clears food-contact plastics for their intended use based on migration and safety data. The clearance process includes stringent requirements for estimating the levels at which such materials may transfer to the diet. FDA's safety criteria require extensive toxicity testing for any substance that may be ingested at more than negligible levels. This means FDA has affirmatively determined that, when cleared plastics are used as intended in food-contact applications, the nature and amount of substances that may migrate, if any, are safe.

In a statement dated November 28, 2005 on food and beverage contact products made with bisphenol A, including polycarbonate, FDA concluded "FDA continues to closely follow the research in this area. However, based on all the evidence available at this time, FDA sees no reason to change it's long-held position that current uses with food are safe," and "Considering all the evidence, including

measurements by FDA chemists of levels found in canned foods or migrating from baby bottles, FDA sees no reason at this time to ban or otherwise restrict the uses now in practice."

10. Has the U.S. EPA established a safe level for bisphenol A?

The U.S. Environmental Protection Agency's reference dose for humans for bisphenol A is 0.05 mg/kg/day, which is a level expected to cause no adverse effects after a lifetime of exposure. EPA's No Observable Adverse Effect Level (NOAEL) for animals for bisphenol A is 50 mg/kg/day. This is consistent with all of the testing done on bisphenol A. EPA has stated that a "A causal relationship between exposure to a specific environmental agent and an adverse health effect in human operating via endocrine disruption has not been established."

Studies on human exposure to bisphenol A, including a recent study from the US Centers for Disease Control and Prevention, consistently indicate that human exposure to bisphenol A is less than 0.0001 mg/kg/day, which is more than 500 times below the EPA reference dose and more than 500,000 times below the no effect level.

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The International Bottled Water Association (IBWA) is the authoritative source of information about all types of bottled waters. Founded in 1958, IBWA's membership includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with the U.S. Food and Drug Administration (FDA), which regulates bottled water as a packaged food product, and state governments to set stringent standards for safe, high quality bottled water products. In addition to FDA and state regulations, the Association requires member bottlers to adhere to the IBWA Bottled Water Code of Practice, which mandates additional standards and practices that in some cases are more stringent than federal and state regulations. A key feature of the IBWA Bottled Water Code of Practice is an annual, unannounced plant inspection by an independent, third party organization. Consumers can contact IBWA at 1-800-WATER-11 or log onto IBWA's web site (www.bottledwater.org) for more information about bottled water and a list of members' brands. Media inquiries can be directed to Manager of Communications Tom Gardner at 703-647-4607 or tgardner@bottledwater.org.