

Safety of Bisphenol A (BPA)

Benefits of BPA-based materials

Bisphenol A (BPA) is the starting monomer (intermediate) for polycarbonate and epoxy resins. Polycarbonate plastic provides unique performance characteristics, through its virtual unbreakability, biocompatibility, ease of sterilisation, heat resistance, transparency, fire resistance and ductility. Epoxy resins are selected because of their corrosion protection, thermal stability and mechanical strength. They are used primarily as coatings for a number of consumer and industrial applications. Because of their special characteristics, they are the material of choice for high performance products in areas where safety, hygiene and durability are of key importance. CDs, medical equipment for intensive care, transparent roofs, safety helmets, automotive parts, housings for electronic equipment and food contact products such as water bottles and multiple use food storage containers are all examples of articles made from polycarbonate. Epoxy resins are, for example, used as corrosion protection coatings in building and construction or for windmill blades, as strong composites for automotive parts and leisure articles, or as hygiene-providing linings for food contact materials.

Safety of BPA in food contact applications confirmed

During the production of polycarbonate plastic and epoxy resins, the BPA molecules are firmly bound to one another to form the polymeric structure of the material itself. Numerous studies show that the level of BPA migration from polycarbonate and epoxy-coated food contact articles is extremely low, and far below any safety-based standards set by governmental bodies worldwide. In fact, as stated by the European Food Safety Authority (EFSA), "after exposure to BPA the human body rapidly metabolises and eliminates the substance". EFSA explicitly considered newborns and small children in their assessment. Scientific studies have proven that trace amounts of BPA which might enter the human body are rapidly metabolised into an inactive kind of sugar which is excreted from the body within 24 hours with no detrimental health

effect. EFSA set the safe level for life-long daily uptake of BPA (the "Tolerable Daily Intake" or TDI) at 0.05 mg/kg bodyweight/day. When using food contact articles based on BPA, it is practically impossible to consume the amount of food or beverage necessary to cross this safety limit. In order to reach the TDI, a person weighing 60kg would need to eat or drink everyday for his or her entire life:

- at least 600kg of food (10 times his or her own bodyweight) using polycarbonate utensils, or
- the content of at least 120 food cans (each 500g), or
- 600 litres of water from polycarbonate containers.

Science confirms BPA safety through comprehensive studies

Over the past several decades, BPA has been investigated extensively for potential health effects. This testing has been conducted by highly reputable research institutes, academic laboratories, governmental institutes and industry laboratories. It has included studies with key relevant parameters, such as potential systemic toxicity, carcinogenicity, mutagenicity, reprotoxicity, hormonal activity, persistency, bioaccumulation, and potential effects on body weight, development and behaviour. The overwhelming weight of the evidence provided by the results of this testing demonstrates that BPA causes no significant health effects at any realistic exposure level and that polycarbonate and epoxy resin coated items used in food contact are safe when used as intended.

The possibility that BPA could cause hormone-like effects at very low doses is one aspect that has been extensively investigated. Since the end of the nineties, a series of studies on alleged "endocrine" (hormone-like) effects of BPA were completed by governmental bodies and recognised research laboratories. These comprehensive studies were conducted using validated test methods and rigorous Good Laboratory Practice guidelines. They included two large-scale multi-generation reproduction studies in which several generations of laboratory animals ingested BPA. These studies have been regarded as the "gold standard" by regulatory bodies worldwide.





One of these studies examined more than one million data points from four generations of laboratory animals exposed to BPA in ranges from extremely low doses up to very high doses. This study is clearly the most comprehensive to date on BPA.

Each of the published studies refuted claims about supposed low dose effects of BPA.

Only at very high doses, which already cause general systemic toxic effects, did BPA show very weak, oestrogen-like effects. These effects are similar to the effects of substances occurring naturally in vegetables such as soya beans or carrots. But most importantly, the potential effects of BPA cannot be compared with the naturally-occurring oestrogen, oestradiol, because its potency is 10,000 – 100,000 times weaker.

The overwhelming weight of the scientific evidence clearly demonstrates that the ingestion of low doses of BPA causes no adverse effects on health. Therefore, there should be no concerns regarding the safety of BPA-based food contact applications, including polycarbonate plastic and epoxy resin coated items.

Authorities confirm safety of BPA-based materials for consumers

Regulatory authorities responsible for consumer safety have thoroughly assessed the characteristics of BPA. Over 50 years of research and extensive use throughout the world have provided convincing evidence about the safety of BPA. With greater understanding of the metabolic processes in the body, and after evaluating the available scientific data as well as data on realistic, low exposure to BPA-based food contact applications, the regulatory authorities in Europe, the US and Japan have concluded that the use of polycarbonate plastic and epoxy resin coatings in applications that come into direct contact with food poses no concern.

The uses of BPA in the manufacture of plastic food contact articles meet the strict safety requirements of the European Commission and its expert body, EFSA. Consequently, BPA is positively listed for approved use in food contact applications in the European Union (EU). Similarly, polycarbonate and epoxy food contact coatings meet the safety requirements of the US Food and Drug Administration (FDA), the Japanese Ministry of

Health, Labour and Welfare and other responsible international regulatory bodies. The standards set by all of these bodies incorporate considerable margins of safety. This is unchanged in updated opinions on BPA published in 2008 and 2009 by EFSA, the FDA and other competent authorities in the world. These views are mirrored by the EU's risk assessment of BPA which concluded in 2008 that there is no concern related to consumer uses of BPA-based materials.

BPA manufacturers are committed to ensuring that their products meet the highest level of safety

The manufacturers of BPA are working through PlasticsEurope (the European Association of Plastics Manufacturers), the American Chemical Council (ACC) and the Japanese Polycarbonate Manufacturers Group (JPMG) to ensure that the safety of their product is supported by sound science. Through PlasticsEurope, ACC and JPMG, the BPA manufacturers have and will continue to actively engage with government agencies, the media, and others to support BPA, polycarbonate and epoxy resins. There is overwhelming scientific evidence demonstrating that BPA is safe when used as intended.

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