

Product Safety Assessment

Bisphenol A

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Names

- CAS No. 80-05-7
- Bisphenol A
- Bisphenol-A

- BPA
- 4,4'-Isopropylidenediphenol
- p,p'-isopropylidenediphenol

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Product Overview

- As sold by The Dow Chemical Company and its foreign affiliates, bisphenol A (BPA) is a white to tan flake or powder. See Product Description.
- BPA is an important chemical building block used primarily to make epoxy and polycarbonate resins. Epoxy resins are most commonly used as protective coatings and adhesives for transportation, marine, civil engineering, and metal applications. Polycarbonate resins are light-weight, high-performance plastics used in applications ranging from eyeglass lenses and electronics to safety equipment and some food-contact containers. See <u>Product Uses</u>.
- Dow does not sell BPA or polycarbonate and epoxy resins made from BPA for direct consumer use. Closed systems are designed to minimize or eliminate workplace exposure to BPA. Nevertheless, some workplace exposure could potentially occur during BPA manufacturing operations or operations that use BPA as a raw material. Workers could be exposed during sampling, testing, packing, maintenance, transport, or other procedures. If a fire occurs where BPA is present, the smoke may contain BPA, in addition to its combustion products of varying composition, which may be toxic and/or irritating.² See Exposure Potential and Physical Hazard Information.
- The safety of BPA has been extensively studied. Numerous scientific studies and government assessments show that human exposure to BPA from consumer products made using epoxy and polycarbonate resins is extremely small and poses no known risk to human health.³ Direct exposure of the eye or skin to BPA can cause eye and skin irritation or may produce allergic skin reactions when in combination with exposure to ultraviolet radiation from the sun or other sources.⁴ See Health Information.
- BPA is readily biodegradable and its bioconcentration potential is low.⁵ Numerous validated environmental fate studies, combined with the scientific understanding of BPA ecotoxicity and available environmental monitoring data, indicate that the current manufacturing and use patterns of BPA are not expected to adversely impact the environment.⁶ See Environmental Information.

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Revised: September 25, 2012 The Dow Chemical Company

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Manufacture of Product

- Capacity⁷ Global production capacity for bisphenol A (BPA) was 5.2 million metric tonnes (11.5 billion pounds) in 2008. The Dow Chemical Company and its foreign affiliates have a global BPA capacity of about 290 thousand metric tonnes (639 million pounds), with production sites in Freeport, Texas, U.S.A. and Stade, Germany.
- **Process** BPA is made by using an acid catalyst to react acetone with phenol in a continuous, enclosed process under mild conditions of temperature and pressure.

BPA has different isomers (arrangements of the atoms within the molecule). The para, para' (p,p') isomer, which is the desired commercial product, is shown above. This process reaction also produces the ortho, para'-BPA (o,p'-BPA) isomer in low levels. The o,p'-BPA impurity is removed by recrystallization.

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Product Description

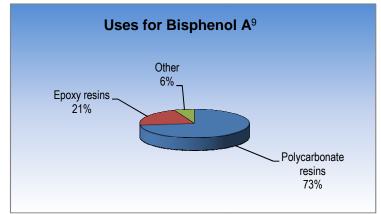
Bisphenol A (BPA), as produced by The Dow Chemical Company and its foreign affiliates, is a white to tan crystal, flake or powder. It has a mild phenolic odor, but is not volatile.⁸

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Product Uses^{9,10,11}

Almost all of the bisphenol A (BPA) produced by The Dow Chemical Company and its foreign affiliates is consumed at Dow manufacturing sites to make epoxy resins or is supplied to epoxy and polycarbonate resin producers. In general, BPA is used to make the following materials:

- Epoxy resins versatile resins used for many applications, such as industrial floorings, adhesives, sealants, industrial protective coatings, powder coatings, automotive primers, can coatings and printed circuit boards.
- Polycarbonate resins a lightweight, high-performance plastic that is used to make eyeglass lenses, medical equipment, water bottles, digital media (e.g., CDs and DVDs), cell phone components, consumer electronics, computers and other business equipment, electrical equipment,



- household appliances, security shields, construction glazing, automobile headlight lenses, sports safety equipment and some reusable food and drink containers.
- **Other** specialized, lower volume applications, including flame retardants, and high-performance resins (*e.g.*, unsaturated polyester, polysulfone, polyetherimide, and polyarylate).

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Exposure Potential

Bisphenol A (BPA) is used primarily to make polymers that are subsequently used to produce industrial and consumer products. It is not sold directly for consumer use. Based on the uses for BPA, humans could be exposed through:

- Workplace exposure 12,13 Exposure can occur either in a BPA manufacturing facility or in the various industrial and manufacturing facilities that use this product. BPA exposure could also occur accidentally during transport. Closed systems are used to manufacture BPA and the epoxy and polycarbonate resins made from BPA, providing little or no opportunity for workplace exposure. However, those working with BPA in manufacturing operations could potentially be exposed during maintenance, sampling, testing, transfer, or other procedures. Chemical goggles, gloves, and protective equipment should be worn to avoid contact of eyes, skin, and clothing with BPA. Each manufacturing, industrial, and service facility should have appropriate work processes and safety equipment policies in place to limit BPA exposure. Good industrial hygiene practices minimize the risk of exposure. The manufacture of epoxy and polycarbonate resins leaves very low BPA residual levels in the uncured resins and plastic. These residuals are not a significant source of exposure. See Health Information.
- Consumer exposure to products containing BPA Although Dow does not sell BPA or polycarbonate and epoxy resins made from BPA directly for consumer use, consumers come into contact with BPA since it is present in the environment and because epoxy coatings and polycarbonate plastic have many applications in consumer goods. These products could contain trace quantities of BPA, which may be present either as a result of hydrolysis or as an unreacted monomer from the production process. According to the U.S. National Toxicology Program, "[u]nderstanding the degree to which bisphenol A is metabolized is very important to determining whether bisphenol A poses a potential risk to human reproduction and development. While free bisphenol A and its major metabolites...can all be measured in humans, only free bisphenol A is considered to be biologically active." 16
 - In 2011, the results of a study that had been conducted on 20 adult human volunteers to "...better understand the internal exposure of adult humans to BPA..." were published. 17 Shortly after publication, the lead author stated "[i]n a nutshell ... we can now say for the adult human population exposed to even very high dietary levels, blood concentrations of the bioactive form of BPA throughout the day are below our ability to detect them, and orders of magnitude lower than those causing effects in rodents exposed to BPA." This study was funded by the U.S. Environmental Protection Agency and conducted by U.S. government scientists associated with the U.S. Food and Drug Administration, the U.S. Centers for Disease Control and Prevention, and the Pacific Northwest National Laboratory.
 - In 2010, two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), jointly organized an expert panel to assess the safety of BPA. The FAO/WHO panel stated in their Final Report that "...the available information...suggests that BPA does not accumulate in blood or tissues from daily dietary exposure...In general, comparison of urine-derived daily exposure estimates, which would account for exposure to bioavailable BPA from all routes, showed good concordance with exposure estimations derived from dietary surveys. This suggests that diet is the main route of exposure to BPA."

For questions specifically about consumer products made with epoxy or polycarbonate resins, please contact the consumer product manufacturer. Regulations and legislation exist that govern the manufacture, sale, transportation, use, and/or disposal of BPA. These regulations and laws may vary by city, state, country, or geographic region. Information may be found by consulting the relevant <u>Safety Data Sheet</u> or <u>Contact Us</u>. See <u>Health Information</u>.

• Environmental release – Small amounts of BPA may be released to the environment from production and processing facilities as well as wastewater-treatment facilities. In the environment, the aquatic compartment has been identified as the primary place in which BPA may be found because of its physical properties. BPA is readily biodegradable, which means it is not expected to be persistent in the environment. In the event of a spill, the focus should be on containing the spill to prevent contamination of soil, surface water or

- groundwater. Should BPA reach nearby soil and water, it is toxic to fish and aquatic organisms on an acute basis; human and animal contact with contaminated soil should be avoided. Because BPA can form an explosive dust/air mixture, ignition sources should be removed. Consult the relevant Safety Data Sheet for more information about protective equipment and procedures. See Environmental, Health, and Physical Hazard Information.
- Large release²³ Industrial spills or releases are infrequent and generally contained. If a large spill does occur, isolate the area. Keep unnecessary and unprotected personnel from entering the area. The product should be captured, collected, and reprocessed or disposed of according to relevant federal, state/provincial, or local regulations. Emergency personnel should wear proper protective equipment and follow emergency procedures carefully. See Environmental, Health and Physical Hazard Information.
- In case of fire²⁴ Under fire conditions, smoke may contain the original material, in addition to combustion products of varying composition, which may be toxic and/or irritating. Combustion products may include and are not limited to phenolic compounds, carbon monoxide, and carbon dioxide. Isolate the fire area and deny unnecessary entry (keep people away). Avoid contact with the material and smoke during firefighting operations. Avoid accumulation of dust. See Environmental, Health and Physical Hazard Information.

For more information, see the relevant Safety Data Sheet.

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Health Information

Eye contact – If bisphenol A (BPA) comes into contact with the eye as a result of being handled improperly, it may cause moderate irritation of the eye with corneal injury. Dust may irritate eyes.

Skin contact – Brief contact is essentially nonirritating to the skin. However, prolonged or repeated contact may cause skin irritation. Contact may cause an allergic skin reaction, especially when combined with exposure to ultraviolet radiation from the sun or other sources. In Europe and North America, BPA is classified as a skin sensitizer. Neither short duration nor prolonged skin contact is likely to result in absorption of harmful amounts of BPA. 27

Ingestion – Small amounts swallowed accidentally or incidentally by handling BPA are not likely to cause injury. Swallowing larger amounts or repeatedly swallowing larger amounts might cause damage to the liver or kidneys. ²⁸

Inhalation – Dust may irritate the membranes of the nose and throat

Other – The weight of the evidence from animal studies shows that BPA does not have the potential to be a carcinogen. ²⁹ BPA has not been shown to cause adverse effects on reproduction or the development of offspring in animal studies unless the doses were high enough to be toxic to the mother. Animals that were repeatedly fed high doses of BPA exhibited effects on the liver and kidney.

For more information, see the relevant Safety Data Sheet.

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Questions of Low-Dose Health Effects

In recent years, a hypothesis has been advanced claiming that exposure to extremely low doses of substances with endocrine (hormonal) activity could cause adverse health effects in humans, including disruption of normal fetal development or reproductive functions. According to this "low-dose hypothesis," health effects might occur at doses far below levels previously determined to be safe using well-established toxicological procedures and principles.³⁰ Bisphenol A (BPA) is one of the substances included in this low-dose hypothesis.^{31,32}

Claims of possible effects from low-dose exposure to BPA were first reported in the early 1990s. Since then, many studies have been conducted to determine the validity of the associated claims. A number of these studies regarding BPA have been conducted in accordance with test methods that have been shown to be scientifically sound (also called "validated methods" and "guideline studies"); these studies do not show a risk of cancer, 33 reproductive, developmental, or endocrine effects. 4 Many of the studies cited in support of the low-dose hypothesis have been criticized on a number of scientific bases. For example:

- In March 2012, the U.S. Food and Drug Administration rejected a citizen petition that sought a BPA ban. The petition included a claim that "...the evidence of adverse effects of low doses of BPA... is a 'great cause for concern..."³⁵ and asked FDA to lower its no observed adverse effect level (NOAEL) based in part on this concern. In its response, FDA disagreed and stated that its current NOAEL "...is an appropriate safety level relevant to dietary exposures and public health."³⁶
- In March 2011, the Advisory Committee of the German Society of Toxicology published a paper that found "...BPA exposure represents no noteworthy risk to the health of the human population, including newborns and babies." This review affirmed the scientific strengths of the guideline studies and concluded, after a critical review, that the findings of the low-dose studies were "... not valid" and "...are unsubstantiated."³⁷
- In September 2010, the panel on food-contact materials, enzymes, flavourings and processing aids (CEF) of the European Food Safety Authority (EFSA) concluded: "The animal studies on developmental and reproductive toxicology reporting effects at doses lower than 5 mg/kg b.w./day have severe shortcomings and were considered to be invalid." 18
- An expert scientific panel convened by the Harvard Center for Risk Analysis concluded that
 the weight of evidence does not support low-dose effects from BPA. Using a comprehensive
 and systematic framework for their evaluation, the panel found no consistent affirmative
 evidence of low-dose effects for any endpoint which they evaluated. This conclusion has
 since been reaffirmed by two additional comprehensive evaluations by expert panels that
 included some of the same Harvard panel authors. 41,42

The health information presented in this product safety assessment is based on reviews of a large number of toxicological and environmental studies conducted by industry, government, and academia.

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Safety Reviews of BPA by Regulatory Agencies and Other Authorities

- The use of epoxy resins and PC plastics for food contact applications has been and continues to be recognized as safe by regulatory authorities globally, including the U.S. Food and Drug Administration (FDA), 43,44 the European Food Safety Authority (EFSA), 45 the United Kingdom Food Standards Agency, 46 the Japanese National Institute of Advanced Industrial Science and Technology, 47 the German Federal Institute for Risk Management, 48 the Swiss Federal Office of Public Health Food Safety 49 and Food Standards Australia/New Zealand. 50
 - In addition, some authorities have expressed concerns about BPA's safety and have recommended further research and/or taken precautionary action. ^{51,52,53,54,55} Canadian authorities have expressed their position as "Science tells us that exposure levels are below those that could cause health effects; however, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government of Canada is taking action to enhance the protection of infants and young children" and "...the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and infants."
 - The U.S. FDA currently authorizes the use of epoxy and polycarbonate resins in food-contact applications and continues to support the safety of BPA in these applications.⁵⁸ In 2010, FDA expressed "some concern" for potential effects in infants and children and indicated that more research is needed.⁵⁹ In March 2012, the FDA rejected a citizen

- petition which sought a BPA ban and reaffirmed its dietary safety level, although it stated that further BPA research is ongoing. ⁶⁰
- In late 2006, EFSA completed a comprehensive safety assessment of BPA. ⁶¹ At that time, as a result of reviewing all of the published literature, it raised the tolerable daily intake (TDI) set in 2002 by a factor of five to 0.05 mg/kg b.w./day. ⁶² The tolerable daily intake is an estimate of the amount of BPA that can be ingested daily over a lifetime without appreciable risk. Since 2006, EFSA has published several updates ^{63,64} to its 2006 assessment; in each case, EFSA has confirmed its 2006 conclusions.

EFSA's 2010 update considered recently published science on many endpoints and found "These studies had many shortcomings. At present the relevance of these findings for human health cannot be assessed, though should any new relevant data become available in the future, the Panel will reconsider the current opinion." EFSA also reported "...[N]ew findings in nonhuman primates (both adults and newborns) further strengthen the view that BPA is eliminated faster in humans than in rodents. This fast BPA elimination in primates results in substantially lower internal exposure to free BPA in humans as compared to rodents. Even human premature infants can metabolise and excrete BPA efficiently..."

In its most recent update (November 2011), EFSA stated "...the TDI would be protective for the whole human population, including pregnant and breastfeeding women, infants (0–12 months) and young children (12–36 months)." EFSA plans to release another update in May 2013. 68

In July 2008, the Japanese Ministry of Health, Labor, and Welfare requested that the
Japanese Food Safety Commission update its current risk assessment⁶⁹ of BPA to take
into account recent scientific publications and regulatory activity in the United States,
Canada, and Europe.⁷⁰ This update was published in 2011 and found "...the risk of BPA
with regard to human health was believed to be very small."⁷¹

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Environmental Information

Numerous validated environmental fate studies, combined with the scientific understanding of bisphenol A (BPA) ecotoxicity and available environmental monitoring data, indicate that the current manufacturing and use patterns of BPA are not expected to adversely impact the environment. 72,73,74

BPA is readily biodegradable, which means the substance is not expected to be persistent in the environment. Additionally, numerous studies have demonstrated short environmental half-lives in surface waters and soils. Small amounts discharged to wastewater-treatment facilities are expected to be effectively treated. To naverage, the reported removal efficiencies from wastewater by full-scale facilities is 84% for BPA.

BPA also has low potential for bioaccumulation. However, when released to the environment, BPA is toxic to aquatic organisms on an acute basis.⁷⁷

The acute and chronic toxicity of BPA has been assessed in a wide range of aquatic and terrestrial organisms covering a broad range of trophic levels, and no observable effect concentrations range from 16 to 7,800 μ g/L. Since the late 1990s, extensive monitoring has been conducted, particularly of fresh surface waters, and levels of BPA have been reported in various environmental media. Based on a statistical analysis of studies reporting BPA levels in fresh surface waters, concentrations were generally less than 1 μ g/L; median concentrations were less than 0.1 μ g/L.

For more information, see the relevant Safety Data Sheet.

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Environmental Assessments of BPA by Regulatory Authorities

Regulatory authorities in several parts of the world have conducted assessments of the available scientific research regarding bisphenol A (BPA) and the environment.

- In 2003, the European Commission completed a comprehensive environmental risk assessment on BPA. This review was updated in 2008 to include new information; a report that combines the results of each of these reviews was published in 2010. The overall conclusion of the EU review is that "...no risks are indicated...for any scenario..." The EU assessment also called for further research on certain aquatic species to clarify "some uncertainties."
- In 2005, the Japanese National Institute of Advanced Industrial Science and Technology completed a comprehensive BPA risk assessment. Its conclusions included "...the current exposure levels of BPA will not pose unacceptable risks to the local populations of aquatic life, particularly fish." Japan is currently in the process of updating its assessment.
- In 2008, Environment Canada released its final "Screening Level Risk Assessment" for BPA. As part of this "screening" assessment, Environment Canada proposed adding BPA to Schedule 1 of the Canadian Environmental Protection Act, 1999 (CEPA 1999). Environment Canada's regulatory process regarding BPA was further advanced in October 2010 (this process will be completed by October 2012), when BPA was officially added to Schedule 1 of CEPA 1999. In their review, Canadian authorities stated that "...the potential impacts of bisphenol A in the Canadian environment are of sufficient magnitude to warrant use of a precautionary approach in response to uncertainties in the evaluation of risk. The "uncertainties" referenced by Environment Canada were considered by the European Union in its BPA Risk Assessment and "...considered to be of low relevance for the environmental update report. In March 2012, an emissions limit of 1.75 μg/L for users and producers of BPA was adopted.
- In 2010, the United States Environmental Protection Agency (EPA) released a draft "Chemical Action Plan" for BPA. This proposal targets environmental exposures and focuses on the development of rulemaking that would determine whether BPA should be listed as a "chemical of concern," thereby requiring the development of additional environmental effects data.⁸⁸ In July 2011, EPA issued an "advance notice of proposed rulemaking" regarding possible environmental testing of BPA. Following a public comment period and internal agency review, further EPA action is expected in 2012.⁸⁹

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Physical Hazard Information⁹⁰

Bisphenol A (BPA) is not soluble in water (<0.1%). Spilled BPA flakes or powder may cause a slipping hazard.

BPA may form an explosive dust-air mixture. Under fire conditions, the smoke may contain the original material in addition to combustion products of varying composition, which may be toxic and/or irritating. Combustion products may include and are not limited to: phenolic compounds, carbon monoxide and carbon dioxide. Isolate the fire area and deny unnecessary entry (keep people away). Avoid contact with the material and smoke during firefighting operations. Avoid accumulation of dust.

For more information, see the relevant Safety Data Sheet.

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Regulatory Information

Regulations and legislation exist that govern the manufacture, sale, transportation, use, and/or disposal of bisphenol A (BPA). Since early 2010, precautionary bans relating to the use of BPA in certain products intended for children have been enacted by several countries. ^{91,92,93,94,95,96,97,98,99,100,101,102,103,104,105,106}

In July 2012, FDA responded to a 2011 petition from the American Chemistry Council and amended "...the food additive regulations to no longer provide for the use of polycarbonate (PC) resins in infant feeding bottles (baby bottles) and spillproof cups, including their closures and lids. designed to help train babies and toddlers to drink from cups (sippy cups) because these uses have been abandoned..." in the United States pursuant to 21 CFR 171.130(a). 107

These regulations and laws may vary by city, state, country, or geographic region. Information may be found by consulting the relevant Safety Data Sheet or Contact Us.

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Additional Information

- Safety Data Sheet (www.dow.com/webapps/msds/msdssearch.aspx)
- Contact Us (http://epoxy.dow.com/contact/index.htm)
- Facts About BPA, American Chemistry Council, (http://FactsAboutBPA.org)
- Bisphenol A Global Industry Group (http://www.bisphenol-a.org/)
- European Information Centre on Bisphenol A (http://www.bisphenol-a-europe.org/)
- National Resources Defense Council (http://www.nrdc.org/living/chemicalindex/bisphenola.asp) - for alternative views

For more business information about bisphenol A (BPA), visit the Dow Epoxy resins (http://epoxy.dow.com/index.htm) or Plastics (http://plastics.dow.com/) websites.

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