HEXION™

Product Stewardship Summary

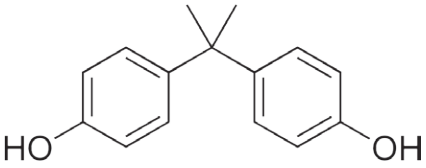
Bisphenol-A

Introduction

This document is intended to provide the general public with a high-level overview of Bisphenol-A, including its uses, properties, and health and environmental considerations. It is not intended to replace the Safety Data Sheet (SDS), which is available from suppliers. All purchasers and users of this substance should read the SDS carefully to understand the hazards and appropriate precautions and practices for safe use of this substance. It is also not intended to replace or supercede manufacturer's instructions and warnings for products that may contain this substance. This information is being provided for information only. This information does not constitute a product specification, warranty, or approval for specific uses. This information does not alter or affect Hexion's standard terms and conditions of sale. It is the sole responsibility of the purchaser to select a particular Hexion product, determine its suitability for the purchaser's application, follow appropriate handling and processing procedures, and to comply with all applicable statutory, regulatory, compatibility and industry requirements and standards for testing, safety, efficacy and labeling.

Chemical Identity

Bisphenol-A (BPA) with a molecular formula of $C_{15}H_{16}O_2$ or $(CH_3)_2C(C_6H_4OH)_2$ (CAS No. 80-05-7) has the following structure:



Synonyms for BPA: 4,4'-isopropylidenediphenol; 2,2-bis(4-hydroxyphenyl)propane; bis(4-hydroxyphenyl)dimethylmethane; bis(4-hydroxyphenyl)propane; 4,4'-bisphenol a; DIAN; p,p'-dihydroxydiphenyldimethylmethane; p,p'-dihydroxydiphenylpropane; 2,2-(4,4-dihydroxydiphenyl)propane; 4,4'-dihydroxdiphenylpropane; 4,4'-dihydroxydiphenyl-2,2-propane; 4,4'-dihydroxy-2,2-diphenylpropane; dimethylmethylene-p,p'-diphenol; beta-di-p-hydroxyphenylpropane; dimethyl bis(p-hydroxyphenyl)methane; diphenylolpropane; 2,2-di(4-phenylol) propane; p,p'-isopropylidenebisphenol; 4,4'-dimethylmethylenediphenol; and Phenol, 4,4'-(1-methylethylidene)bis-; 2,2-bis(4,4'-hydroxyphenyl)propane.

Uses

BPA is used primarily to make plastics, and products based on BPA technology have been in use for more than 50 years. It is also a building block component in the production of epoxy resins, which are used in paints and coatings, adhesives, industrial tooling, electrical systems and electronic components. BPA is a building block chemical used in the production of polycarbonate plastics, which are found in many common products including sports equipment, medical and dental devices, eyeglass lenses, and CDs and DVDs.

Epoxy resins are used as coatings on the inside of almost all food and beverage cans. Coatings in metal cans ensure food safety by enabling high-temperature sterilization that eliminates the dangers of food poisoning from microbial contaminants, such as E. coli and listeria. BPA-based epoxy resin coatings are essential to prevent contamination, deterioration and spoilage of food products stored or distributed in metal packaging. No alternative to epoxy-resin coatings in metal food and beverage packaging is effective for the broad range of canned products. Metal cans in fact reduce the potential for serious illness, protecting children and adults alike, and epoxy coatings continue to be the best available material for this purpose.[1,2,3,4,5]

Physical/Chemical Properties

BPA is a white to tan flake or powder with a mild odor. It is not volatile. Other properties include:

- Melting point: 150–159°C
- Boiling point: 220°C @ 4 mm Hg
- Flash point: 227°C
- Specific gravity: 1.195 @ 25°C
- Vapor pressure: 5.3×10^{-9} kPa
- Solubility in water: <1 mg/mL @ 21.5°C (insoluble)
- Autoflammability: circa 532°C

Biological Properties

- When compared to estrogen, BPA shows weak estrogen-like activity in a variety of test systems. The potency of this activity in these assays generally has ranged from 1,000 to 100,000 times less than that of estrogen. Because of this activity, BPA has been identified as a potential endocrine-disrupting chemical.[12,13]
- Numerous studies have examined the absorption, metabolism and elimination (i.e., excretion) of BPA in mice, rats, monkeys and humans. All indicate that BPA is rapidly absorbed from the intestine and quickly bound to glucuronic acid (BPA-G) in the blood which, in humans, is rapidly eliminated from the body. However, due to substantial differences between rodents (i.e., rats and mice) and humans with respect to how BPA is metabolized, it appears that effects observed in rodents are unlikely to be predictive of similar effects in humans.[10,11,17]
- The main metabolite of BPA (i.e., the conjugated form, BPA-G) has no significant estrogenic activity in either in vitro or in vivo test systems. Because of this, accurately determining the amounts of unconjugated (i.e., free) BPA in target tissues of test species at sensitive life stages (e.g., fetuses) is important in assessing the safety of BPA. Development of analytical methods to measure free BPA in blood and urine are an important area of active research.[14]
- Recently, scientists conducted a dietary study in which human volunteers were fed during one day food and beverages containing “worst case” levels of BPA. Based upon analysis of the volunteers’ blood and urine, the study authors concluded that it is very unlikely that BPA could ever cause health effects in humans. This study also pointed out the flaws of many other studies that have tried to look for internal doses of BPA and determined that many of those studies showed false results due to inadequate sample handling and laboratory contamination issues.[10,11,31]

General Health Effects

If handled improperly in the workplace, BPA may come in contact with the eyes or skin. For the eyes, depending on the amount, BPA may cause moderate irritation and possible corneal injury. BPA dust also may irritate the nose and throat. While brief skin contact is essentially non-irritating, prolonged or repeated contact may cause skin irritation. Skin contact may also cause an allergic skin reaction, especially when combined with exposure to ultraviolet light from the sun. In Europe, BPA is classified as a skin sensitizer.[15]

Neither short duration nor prolonged skin contact is likely to result in absorption of harmful amounts of BPA. A recent report that BPA can be absorbed through the skin did not involve free BPA, but rather the non-estrogenic conjugated form, BPA-G.[16] Oral exposure to a single large amount, or repeated oral exposure to larger amounts, might cause damage to the liver or kidneys.[15] The weight of the evidence from animal studies shows that BPA does not have the potential to be a carcinogen. BPA has not been shown in animal studies to cause birth defects or adverse effects on reproduction unless the doses were high enough to be toxic to the parental animals. Animals that were fed high doses of BPA repeatedly exhibited effects on the liver and kidney.[6,7,8,9]

Other Health Effects

For a number of years, a controversial concept referred to as the "low dose hypothesis" has been widely debated. This hypothesis is based on the concept that exposure to extremely low doses of substances with endocrine (i.e., hormonal) activity might cause adverse health effects in humans. The two main aspects of this hypothesis are that exposure during pregnancy to such substances could either impair normal fetal development, or could adversely affect later reproductive functions in men and women. According to this "low-dose hypothesis," adverse health effects could occur at doses of these substances that are far below levels previously determined to be safe using well-established toxicological procedures and principles and conducted according to stringent global testing guidelines and Good Laboratory Practices (GLP). BPA is one of the substances included in this "low-dose hypothesis." However, although many studies have been conducted on BPA to test whether this hypothesis can be proven, the results of these studies are still being debated. Another issue which has fueled the controversy surrounding BPA is that several key studies conducted in rats by some investigators cannot be replicated for a number of reasons by other scientists using GLP tests with more animals and more doses of BPA.[3]

A number of independent scientific and government bodies as well as comprehensive weight-of-evidence reviews have assessed the evidence on the "low dose hypothesis" and have concluded that current levels of exposure experienced by the general public in non-workplace settings are safe. Although it is beyond the scope of this Product Stewardship Summary to describe this controversial issue in detail, the following is a summary of the most recent conclusions from two key agencies with primary regulatory or advisory responsibility for BPA in food.

First, the current perspective from the U.S. Food and Drug Administration (FDA)—the principal agency with responsibility for food safety in the United States—shares the observations of the National Toxicology Program (NTP) that recent studies in rats provide reason for some concern about the potential effects of BPA on the brain, behavior, and prostate gland of fetuses, infants and children. However, FDA also has recognized that there are substantial uncertainties with respect to the overall interpretation of the studies relied upon by NTP and their potential implications for human health effects of exposure to BPA. These uncertainties relate to issues such as the routes of exposure employed (many animal studies rely on inappropriate dosing approaches, such as direct injection into the blood or abdominal cavity instead of via the diet); the lack of consistency among some of the measured endpoints or results between studies; the relevance of some animal models to human health; differences in the metabolism (and detoxification) of and responses to BPA both at different ages and in different species; and limited or absent dose response information for some studies. FDA recently reaffirmed the safety of BPA based on new research and concluded that (1) exposure to dietary BPA in infants, the population of most potential concern, is 10 times less than previously estimated; (2) supportive evidence in pregnant rodents orally dosed with 100–1,000 times more BPA than people are exposed to through food demonstrate that the level of the active form of BPA passed from expectant mothers to their unborn offspring was so low that it could not be measured in fetuses 8 hours after the mother's exposure; and (3) primates of all ages effectively metabolize BPA to its inactive form and excrete it much more rapidly and efficiently than rodents, thus reducing concerns about results from some rodent studies using oral and, particularly, non-oral exposures which result in higher actual internal exposures of rodents than of primates, including humans, exposed to the same dose.[17,18,32]

Second, similar conclusions come from the European Food Safety Authority (EFSA), a scientific advisory body with responsibility for assuring food safety in the European Union (EU), which establishes Tolerable Daily Intakes (TDI) for substances in food. The most recent EFSA evaluation followed a detailed and comprehensive review of recent scientific literature and studies on the toxicity of BPA at low doses. Scientists on the EFSA panel concluded that they could not identify new evidence which would lead them to revise the current TDI for BPA set by EFSA in its 2006 opinion and re-confirmed in its 2008 opinion. The EFSA panel also concluded that the data currently available do not provide evidence that low levels of BPA increase the risk of neurodevelopmental effects in rats. EFSA acknowledged that some recent studies have reported adverse effects on the brain and immune system in animals exposed to BPA during development, at doses well below those used to determine the current TDI. However, the EFSA panel also concluded that these studies have many shortcomings, particularly with respect to assessing potential effects on human health, which were of sufficient concern that the relevance of these findings for human health could not be assessed.[10,11]

Environmental Effects

Environmental Fate Information

The vast majority of BPA (> 99.9%) is consumed at manufacturing sites. Therefore, only low levels of BPA are expected to be released to the environment in the effluent water from biological wastewater treatment plants, with numerous studies showing greater than 90% treatment efficiency. The relatively small amount of vapor released to the atmosphere is rapidly degraded by sunlight.

Based on the results of standard laboratory biodegradation tests recommended by the Organization for Economic Cooperation and Development (OECD), BPA is classified as readily biodegradable.[19]

Because BPA is readily biodegradable, it is not expected to be persistent in the environment. This is confirmed by numerous studies showing short environmental half-lives. Small amounts of BPA that might be inadvertently discharged to wastewater treatment systems are, as noted above, effectively treated.[19, 20]

In the atmosphere, BPA has a short half-life and atmospheric levels are low. Therefore, BPA is not considered to be a contributor to low-level ozone or greenhouse gas formation.[20,21]

Aquatic and/or Terrestrial Toxicity

BPA does not bioaccumulate in aquatic organisms to any appreciable extent, and it is not classified as bioaccumulative by the U.S. Environmental Protection Agency or the European Union. Studies in fish and clams show bioaccumulation factors below the regulatory levels of concern.[20,22,23,24]

Acute toxicity levels for BPA measured in a variety of aquatic organisms, including freshwater and saltwater algae, invertebrates (daphnids and shrimp) and fish, do not indicate a concern for low level toxic effects. The results of a multi-generation study on fathead minnows showed that survival, growth and reproductive fitness for three generations were affected only at concentrations far in excess of BPA levels ever detected in stream or river waters.[25,26,27]

A 2002 comprehensive analysis of the aquatic hazards posed by BPA was conducted with a focus on validated studies and the ecologically relevant endpoints for assessing the potential to cause adverse effects including survival, growth, and reproductive fitness. This analysis included the use of statistical extrapolation techniques in order to assess the full database of reported effect concentrations. The study concluded that no adverse aquatic effects would be expected at the concentrations of BPA measured in numerous streams and rivers.[23]

Exposure Potential

The primary source of exposure to BPA for most people is through the diet. Although air, dust, and water are other possible sources of exposure, BPA in food and beverages accounts for the majority of daily human exposure. Small amounts of BPA may leach into food from the protective internal epoxy resin coatings of canned foods, and from consumer products such as polycarbonate tableware, food storage containers, water bottles, and baby bottles. The degree to which BPA leaches from polycarbonate bottles into liquid may depend more on the temperature of the liquid or bottle, than the age of the container. Low levels of BPA have also been detected in breast milk.[28,29]

Risk Management Recommendations

Appropriate workplace controls should be used during handling and equipment maintenance processes, to minimize dust formation and/or release. Dust should be kept away from heat sources in order to eliminate the possibility of ignition.

Safe handling practices and/or personal protective equipment (PPE) should be used when engineering controls are not feasible, and proper eye and skin protection should be worn in all handling situations. PPE recommendations for working with BPA in the solid or dust forms include work shoes, gloves, long sleeves and pants or a protective suit such as Tyvek®. Safety glasses with side shields or goggles are recommended for eye protection. Gloves that are chemically resistant to BPA should be used.

Additional PPE is recommended when handling BPA samples in liquid form or when performing equipment maintenance. These extra precautions are needed because the liquid reaction mixture used to manufacture BPA contains phenol. When handling phenol, recommended PPE includes a full chemical suit made of non-permeable material equipped with a supplied air respirator. Because skin exposure to phenol can have dangerous health effects, complete protection is needed when performing this type of task.

With respect to workplace exposure limits, to date the Occupational Safety and Health Administration (OSHA) has not established a permissible exposure limit (PEL) for BPA, and the American Conference of Governmental Industrial Hygienists (ACGIH) has not established a threshold limit value (TLV) for BPA. However, general exposure limits for dust should be followed (e.g., the OSHA PEL for Particulates Not Otherwise Regulated (PNOR) of 15 mg/m^3 for total dust and 5 mg/m^3 for the respirable fraction, or the ACGIH TLV for Particulates Not Otherwise Classified (PNOC) of 10 mg/m^3 for total dust and 3 mg/m^3 for the respirable fraction).[30]

In Europe, however, exposure limits have been established for BPA. The AGW, or "Arbeitsplatz Grenzwert," which translates to workplace exposure limit, is a legal limit (published in the TRGS 900) enforceable in Germany, and has been established at 5 mg/m^3 for the inhalable fraction of BPA.

Product Stewardship Commitment

Hexion Inc. is a major producer of bisphenol-A (BPA) that is used primarily in the synthesis of Hexion's epoxy resins. BPA is an important chemical building block that is used primarily to make polycarbonate plastic and epoxy resins, both of which are used in a wide variety of applications. Commercial production of BPA began in the 1950s.

Hexion is committed to providing quality and safe products, as well as technical service and product support, to its customers. The majority of Hexion's BPA production is consumed internally to make epoxy resins. Epoxy resins are most commonly used as protective coatings due to their exceptional combination of toughness, adhesion, formability and chemical resistance. These characteristics make them suitable for numerous other applications as well. We continue to support scientific research on BPA and continually monitor the science and ongoing studies through our participation in the American Chemistry Council PC/BPA Global Group, the North American Metal Packaging Alliance and equivalent organizations in Europe.

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