

A. Bisphenol A

CAS Number 80-05-7

NOTE: THE FOLLOWING DOCUMENT WAS CREATED IN 2011 TO SUPPORT DEVELOPMENT OF THE “PRIORITY CHEMICALS” LIST AND IMPLEMENTATION OF THE MN TOXIC FREE KIDS ACT (Minn.Stat.2010 116.9401-116.9407). THE FOLLOWING INFORMATION REFLECTS THE BISPHENOL A (BPA) INFORMATION AVAILABLE IN EARLY 2011. FOR CURRENT MDH INFORMATION ON TOXICITY, EXPOSURE, AND MINNESOTA/FEDERAL LEGISLATIVE ACTIVITIES FOR BPA, SEE [\[Bisphenol A http://www.health.state.mn.us/div/eh/risk/chemhazards/bisphenola.html\]](http://www.health.state.mn.us/div/eh/risk/chemhazards/bisphenola.html) [\[Regulations Regarding BPA... http://www.health.state.mn.us/div/eh/risk/chemhazards/bpalaw.html\]](http://www.health.state.mn.us/div/eh/risk/chemhazards/bpalaw.html).

(Note added October 2014).

1. Overview

Bisphenol A (BPA) is used to manufacture polycarbonate plastics and epoxy resins, which are used in products like baby bottles, high impact plastics, thermal paper, and some toys (Centers for Disease Control and Prevention [CDC], 2010; Environmental Protection Agency [EPA], 2010a). This substance has been used in manufacturing for many years, but recently there has been concern about possible latent health effects from exposure to this chemical, especially as it relates to exposures to fetuses, infants and young children.

Currently, there is little information on the effect of BPA specifically on human health. However, laboratory studies indicate that this chemical could cause developmental damage, and the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) has stated, “The NTP has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.” (National Toxicology Program [NTP] (original emphasis), 2008; EPA, 2010a). The category of “some concern” is the mid-point of the NTP CERHR rating system (NTP, 2008). There is still much uncertainty and much research is still in progress or proposed for BPA (CDC, 2010). Governmental agencies continue to evaluate the outcomes of the research (FAO/WHO, 2010).

As described below, while the toxicity of BPA to humans is still being studied and debated, some of the concern related to BPA is based on the ubiquity of this man-made chemical and its presence in humans. In the National Health and Nutrition Examination Survey (NHANES), 93% of the participants sampled in 2003-2004 showed BPA present in the urine (NTP, 2010). Because the chemical is eliminated quickly from the body, these results signal that the exposure was recent and could be occurring frequently (CDC, 2010; NTP, 2008).

In an effort to reduce human exposure to this chemical, a statute passed by the Minnesota Legislature in 2009 (Minn. Stat. 2010 325F.723) prohibits BPA in children’s food or beverage containers sold in retail stores in Minnesota as of January 1, 2011.



The information below provides an overview of potential human exposure to BPA, the toxicity of BPA, and current state and federal actions related to BPA:

2. Exposure and Environmental Disposition

(Note: This section includes examples of exposure and environmental information retrieved from several sources. This summary is not intended to be comprehensive.)

There is substantial evidence that humans are exposed to BPA at all life stages, including during the time before birth. BPA has been found in serum, breast milk, urine, amniotic fluid, fetal blood, and umbilical cord blood, as well as other human tissues and body fluids (EPA, 2010a; NTP, 2008). Diet is one of the main sources of human exposure to BPA (CDC, 2010; NTP, 2008). BPA can leach into food and beverages that are held in containers, such as baby bottles, made with BPA. According to the NTP, the extent of migration of BPA to a liquid appears to be temperature dependent: warmer temperatures result in greater migration (NTP, 2008). Very young children may have additional exposure to BPA through breast milk and as a result of crawling and mouthing behavior, whereby BPA in household dust, toys, or other products may be transferred to the skin and mouth (CDC, 2010; EPA, 2010a; NTP, 2008).

a. Centers for Disease Control and Prevention (CDC)

National Health and Nutrition Examination Survey (NHANES)

In the National Report on Human Exposure to Environmental Chemicals produced under NHANES, the CDC reports that in the 2003-2004 survey, children, women, and people at lower income levels were more likely to have higher levels of BPA in their urine. This level reflects recent and possibly frequent exposure to BPA, because BPA does not accumulate in the body (CDC, 2010; NTP, 2008).

b. Environmental Protection Agency (EPA)

(1) EPA Inventory Update Reporting (IUR)

According to the EPA IUR from 2006, this chemical is used in rubber and plastic products where it can be 61-90% of the product mass. The IUR data indicate that some of these products are intended for children (EPA, 2010b). Because these data are several years old, it is unknown how well current use is reflected.

2006 EPA Inventory Update Reporting data		
Chemical	Maximum concentration in product category	Used in a product intended for children up to age 14
Adhesives and sealants	1-30%	NRO
Electrical and electronic products	1-30%	Yes
Paints and Coatings	1-30%	No
Rubber and Plastic Products	61-90%	Yes
NRO = "not readily obtainable" (EPA, 2010b)		

(2) EPA Toxic Release Inventory (TRI)

In 2009, the EPA reports a total of 1.2 million pounds of BPA released in the U.S. from on-site or off-site disposal or through other activities. For Minnesota, there was a total of 190 lbs reported released from one site in 2009. This release was reportedly to an off-site landfill. For the past 20 years, the peak releases in Minnesota occurred in 2001 (21,007 lbs) and 2002 (9,404 lbs). These releases were primarily to off-site landfills or disposal impoundments (EPA, 2010c). The amount of BPA released in Minnesota by manufacturers appears to have been declining over the past 10 years.

c. National Institutes of Health

National Library of Medicine (NLM)

(1) Household Products Database

The NLM Household Products Database currently lists only three products found in the home that contain BPA (National Library of Medicine [NLM], 2010). All of the products are epoxy products, and one is flagged as an “old product” that is probably not produced any longer. This database would not likely include products for which a material data safety sheet (MSDS) is not produced, such as food containers.

(2) Hazardous Substance Data Bank

In addition to the consumer products noted above, BPA has been found in drinking water, surface water, ground water, wastewater, effluents, outdoor air, and in purchased milk (Hazardous Substances Data Bank [HSDB], 2010). There may be additional media where BPA is found that are not reported here.

3. Toxicity

(Note: This section provides examples of toxicity information from several sources. This summary is not intended to be comprehensive.)

a. Centers for Disease Control and Prevention (CDC)

National Health and Nutrition Examination Survey (NHANES)

NHANES reports that reproductive and developmental changes have been found at high BPA dose levels in laboratory studies (CDC, 2010). Some developmental effects have also been reported from low BPA doses in recent studies, but research is ongoing (CDC, 2010).

b. Environmental Protection Agency (EPA)

EPA Integrated Risk Information System (IRIS)

Oral Reference Dose for BPA: 5×10^{-2} mg/kg/day

Uncertainty factor: 1000 (EPA, 1993)

c. Food and Drug Administration (FDA)

In January 2010, the FDA reported that it, along with the National Toxicology Program (NTP), has some concerns about “the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children.” (Food and Drug Administration [FDA], 2010a). FDA plans to work with NTP to clarify the risks of BPA.

d. National Institutes of Health (NIH)

National Toxicology Program (NTP)

NTP has five categories for classifying concern about a chemical. For BPA, NTP has indicated that it has “some concern,” or the middle category, for developmental toxicity for fetuses, infants and children related to the brain, behavior, and prostate gland. For developmental toxicity for fetuses, infants and children related to effects on the mammary gland, early puberty, and reproductive toxicity of workers, NTP has “minimal concern” or the second to lowest category of concern. For reproductive toxicity in adult men and women, NTP states there is “negligible concern,” or the lowest concern category. A summary of this information can be found at <http://www.niehs.nih.gov/health/docs/bpa-factsheet.pdf> (NTP, 2008; NTP, 2010).

4. Statutory Requirements

The following table shows how BPA meets the statutory requirements of Minn. Stat. 2010 116.9401–116.9407, and lists some of the BPA toxicity findings from laboratory tests or human surveys and environmental disposition characteristics.

Statute	Information	References
Minn. Stat. 2010 116.9401		
Subd. (e)(1) harm the normal development of a fetus or child or cause other developmental toxicity	Brain, behavior and prostate effects in fetuses, infants, children	NTP 2008
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	Delayed sexual maturity	CDC 2010
	Prostate gland	NTP 2008
Subd. (e)(3) disrupt the endocrine or hormone system	Weakly estrogenic, endocrine disruption	CDC 2010 EPA 2010a
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	Brain, behavior	NTP 2008
	Body weight	EPA 1993
	Eye irritation, skin sensitization	CDC 2010 HSDB 2010
Subd. (e)(5) be persistent, bioaccumulative, and toxic		
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 2010 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	1 billion pounds or more	EPA 2010b
Subd (2) Meets any of the following criteria:		

Statute	Information	References
Subd. (a)(2)(i): the chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine, or other bodily tissues or fluids	Blood, breast milk, umbilical cord blood, serum, urine and other body fluids and tissues	CDC 2010 NTP 2008
Subd. (a)(2)(ii): the chemical has been found through sampling and analysis to be present in household dust, indoor air, drinking water, or elsewhere in the home environment	Household dust, indoor air, drinking water	HSDB 2010 NTP 2008
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	Surface water, groundwater	HSDB 2010

5. Current Regulations

a. Federal

There are currently no U.S. federal-level restrictions on BPA in consumer products, though several bills have been introduced in Congress (Library of Congress, 2010).

b. States and Cities

As of November 2010, there are seven states (Connecticut, Maryland, Minnesota, New York, Vermont, Washington, and Wisconsin), four New York counties (Albany, Rock Island, Schenectady, Suffolk) and two cities (San Francisco, CA and Chicago, IL) that have implemented restrictions on BPA, such as prohibitions on manufacture, sale, or distribution of a children's product containing BPA (Lowell Center for Sustainable Production, 2010). The states of Maine and Washington have proposed to designate BPA as a Priority Chemical or a Chemical of High Concern for Children (CHCC), respectively (Maine Department of Environmental Protection [Maine DEP], 2010; Washington Department of Ecology [Washington Ecology], 2010). Reporting requirements and other restrictions may follow this designation in these states.

The Minnesota statute is as follows:

“BISPHENOL-A IN CHILDREN'S PRODUCTS

325F.172 DEFINITIONS.

Subdivision 1.Scope.

For the purposes of sections 325F.172 to 325F.173, the following terms have the meanings given them.

Subd. 2.Child."Child" means a person under three years of age.

Subd. 3.Children's product. "Children's product" means an empty bottle or cup to be filled with food or liquid that is designed or intended by a manufacturer to be used by a child.

325F.173 BISPHENOL-A IN CERTAIN CHILDREN'S PRODUCTS.

- (a) By January 1, 2010, no manufacturer or wholesaler may sell or offer for sale in this state a children's product that contains bisphenol-A.
- (b) This section does not apply to sale of a used children's product.
- (c) By January 1, 2011, no retailer may sell or offer for sale in this state a children's product that contains bisphenol-A.”
- (Minn. Stat. 2010 325F.172 - 325F.173)”

Specific State and Local Government Regulations

Within U.S. states, several pieces of legislation have been introduced. The following legislation involves enacted law on the state and local levels that contains prohibitions on BPA. The summaries are from the Lowell Center for Sustainable Production U.S. State Chemical Policy Database, available at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>:

Minnesota

Year: 2009

S.F. 247, 86th Leg., Reg. Sess. (Minn. 2009).

As noted above, the state of Minnesota has passed a ban on BPA in children's food containers, effective January 1, 2010 for manufacturers and wholesalers and January 1, 2011 for retailers.

San Francisco, California

Year: 2006

San Francisco Board of Supervisors, Ordinance No. 120-06 (June 15, 2006).

Prohibits the manufacture, sale, or distribution in commerce of any toy or child care article that is intended for use by a child under three years of age if it contains bisphenol-A or phthalates. Requires manufacturers to use the least toxic alternative to those substances.

Connecticut

Year: 2009

H.B. 6572, 2009 Gen. Assemb., Jan. Sess. (Conn. 2009).

Prohibits the manufacture, sale, or distribution of any reusable food or beverage container containing bisphenol A. Prohibits the manufacture, sale, or distribution of any instant formula or baby food that is stored in a plastic container, jar, or can that contains bisphenol A.

Chicago, Illinois

Year: 2009

Chicago City Council, Ordinance No. 7-28-637 (2009).

Prohibits the sale of any container that is composed of bisphenol A that is sold or distributed without containing any liquid, food, or beverage. Requires containers to be affixed with a label indicating that the product is not composed with bisphenol A.

Maryland

Year: 2010

H.B. 33, 427th Gen. Assemb., Reg. Sess. (Md. 2010); S.B. 213, 427th Gen. Assemb., Reg. Sess. (Md. 2010).

Prohibits the manufacture, sale, or distribution of any children's toy or child care article containing bisphenol A. Requires the replacement of bisphenol A with the least toxic alternative. Prohibits the replacement of bisphenol A with a carcinogen, reproductive toxicant, developmental toxicant, or a chemical that causes birth defects.

New York

Year: 2010

A. 6919, 232nd Leg., Reg. Sess. (N.Y. 2009); S. 3296, 232nd Leg., Reg. Sess. (N.Y. 2009).

Prohibits the sale of any child care product intended for use by a child three years of age or younger containing bisphenol A. Permits the Commissioner to authorize product labeling of products that do not contain bisphenol A.

Albany County, New York

Year: 2009

Albany County Legislature, Local Law No. 5, (Apr. 13, 2009).

Prohibits the sale of children's beverage containers that contain bisphenol A within the County of Albany.

Rockland County, New York

Year: 2010

Rockland County Legislature, Local Law No. 5 (April 20, 2010).

Prohibits the sale of any children's beverage container or sucking/teething product that contains bisphenol A.

Schenectady County, New York

Year: 2009

Schenectady County Legislature, Local Law No. 02-2009 (Aug. 11, 2009).

Prohibits the sale of children's beverage containers that contain bisphenol A.

Suffolk County, New York

Year: 2009

Suffolk County Legislature, Res. 1017-2009 (Apr. 2, 2009).

Bans the sale or use of children's beverage containers containing bisphenol A.

Vermont

Year: 2010

2010 Vt. Acts & Resolves 112.

Prohibits the manufacture, sale, or distribution of any reusable food or beverage container containing bisphenol A. Prohibits the manufacture, sale, or distribution of any infant formula or baby food stored in a plastic container, jar, or can that contains bisphenol A. Requires manufacturers to use the least toxic alternative when replacing bisphenol A and

are prohibited from replacing bisphenol A with known or likely human carcinogens, reproductive toxicants, or developmental toxicants.

Washington

Year: 2010

S.B. 6248, 61st Leg., Reg. Sess. (Wash. 2010).

Prohibits the manufacture, sale, or distribution of any empty bottle, cup, or other container, except a metal can, that contains bisphenol A if that container is designed or intended to be filled with any liquid, food, or beverage primarily for use by children three years of age or younger.

Wisconsin

Year: 2010

S.B. 271, 2009-2010 Leg., Reg. Sess. (Wis. 2009).

Prohibits manufacturing or selling an empty baby bottle or spill-proof cup primarily intended for use by a child five years of age or younger if the child's container contains bisphenol A. Requires manufacturers and wholesalers to ensure that a child's container sold or offered for sale is conspicuously labeled as not containing bisphenol A.

6. Planned Actions

a. Federal

While there are currently no federal regulations for BPA in consumer products, the U.S. FDA, NTP and EPA are currently reviewing information about the chemical.

(1) Environmental Protection Agency

The EPA has created a Chemical Action Plan that describes the use of BPA, associated health and environmental concerns, physical characteristics, risk management, and planned actions. As EPA notes, the FDA has authority to evaluate risks related to food containers, cosmetics and medical devices, where BPA is commonly used. EPA plans to address the environmental risks related to BPA, particularly related to aquatic species. According to the EPA, the FDA is working with the CDC and the National Institute of Environmental Health Sciences to assess information about BPA and to evaluate the risks to human health. EPA plans to work with FDA and other agencies in attempt to find alternatives to BPA. Some of the actions that EPA plans in 2010-2012 include:

- Consider initiating rulemaking under TSCA 5(b)(4) to add BPA to the Concern List for long-term risks for aquatic species.
- Consider initiating rulemaking under TSCA 4(a) to develop data to help determine actual risks of BPA to the environment. This could include testing or monitoring data in the vicinity of landfills, manufacturing facilities, or other locations in order to assess how much BPA could enter surface water, groundwater, or drinking water.

- Conduct alternative assessments under the EPA’s Design for the Environment program to ultimately enable reduction of BPA use. Assessment of thermal and carbonless paper coatings is one of the planned assessments (EPA, 2010a).

(2) Food and Drug Administration

The FDA lists on its website the following actions related to BPA as it studies the possible related health effects. Some of FDA actions include:

- Supporting the end of BPA usage in food containers, particularly those for infants.
- Considering a more “robust regulatory framework” for oversight of BPA. FDA believes it could react more quickly to hazards under a modernized framework similar to that of the current food contact substances framework.
- Seeking public and technical comment on BPA.
- In concert with Health Canada, FDA is encouraging industry to develop manufacturing methods that reduce the migration of BPA in infant formula can linings to the formula. Further, FDA participated in a World Health Organization and United Nations Food and Agriculture Organization discussion about BPA (FDA, 2010b).

b. States

Maine:

Year: 2010

The state of Maine has proposed BPA as one of the two Priority Chemicals it will designate in 2011 under the Toxic Chemicals in Children’s Products law. Under Maine law, manufacturers with products containing intentionally-added BPA will be required to report information about the product produced, sold or distributed in Maine to the state government. Some uses of BPA in children’s food or beverage containers could be banned from sale or distribution in Maine as of January 1, 2012 (Maine DEP, 2010).

Washington

Year: 2010

Under the Children’s Safe Products Act, Washington has named BPA a Chemical of High Concern for Children (CHCC). Washington intends to require manufacturers to report to the state which products contain CHCC chemicals (Washington Ecology, 2010).

7. Conclusion

Because of the widespread presence of BPA in humans and the uncertainty about effects on human health, together with laboratory evidence of BPA’s toxicity and the likelihood of children’s exposure to the substance, MDH is naming BPA as a Priority Chemical. Per Minn. Stat. 2010 116.9405 (9), food and food or beverage packaging, except a container containing baby food or infant formula, are excluded from this Priority Chemical designation. MDH will continue to monitor ongoing studies of BPA to determine if the status as a Priority Chemical remains appropriate.

8. References

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