BASIS STATEMENT FOR

CHAPTER 882: DESIGNATION OF BISPHENOL A AS A PRIORITY CHEMICAL AND REGULATION OF BISPHENOL A IN CHILDREN'S PRODUCTS

AND

SAFER CHEMICALS PROGRAM SUPPORT DOCUMENT FOR

DESIGNATION AS A PRIORITY CHEMICAL OF

Bisphenol A
CA Name: Phenol, 4,4'-(1-methylethylidene)bis-
CAS RN: 80-05-7

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JUNE 2, 2010

PREFACE

In April 2008, the Legislature adopted *An Act to Protect Children's Health and the Environment from Toxic Chemicals in Toys and Children's Products* [Public Law Chapter 643, 38 MRSA §§1691 through 1699-B]. The goal of the law as set forth in the Legislature's Declaration of Policy under 38 MRSA §1692 is to reduce the exposure of children and other vulnerable populations to chemicals of high concern by substituting safer alternatives when feasible. To accomplish this goal, the law confers upon the department the regulatory power to collect information on chemical use and prohibit the sale of children's products containing priority chemicals when safer alternatives are available.

The Board of Environmental Protection adopted regulations to implement the law in February 2010. Chapter 880, *Regulation of Chemical Use in Children's Products,* established rulemaking as the process by which the department will designate priority chemicals. The law and rule require that a substance meet certain criteria to be designated a Priority Chemical, and that the department provide Findings of Fact in support of a proposed designation. This document sets forth Findings of Fact supporting the designation of Bisphenol A as a Priority Chemical, and is intended to serve as the Basis Statement for the designating rule, Chapter 882, *Designation of Bisphenol A as a Priority Chemical and Regulation of Bisphenol A in Children's Products.*

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INTRODUCTION

Through this rulemaking, the Department of Environmental Protection designates bisphenol A as a Priority Chemical and implements a prohibition on sales of certain consumer products that contain bisphenol A.

Concern over potential health effects from bisphenol A has grown in recent years due to findings that show BPA migrating into food and beverages from storage containers, including baby bottles, and studies that show the possibility for effects at low doses, including disruption of the endocrine, or hormone, system of the body. The greatest source of non-workplace human exposure to BPA appears to be through food in BPA-containing packaging. Babies who are fed liquid canned formula from polycarbonate bottles have the highest consumer exposure through diet to BPA.[1]

The US National Toxicology Program Center for the Evaluation of Risks to Human Reproduction rated BPA third on its five-level scale of concern, stating the chemical poses "*some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A," [original emphasis].[2] In January 2010 the US Food and Drug Administration released an update to its stance on BPA, reflecting the National Toxicology Program's level of concern. Both the US Department of Health and Human Services[3] and the Maine Center for Disease Control[4] offer guidance on limiting infants' exposure to BPA.

The US Environmental Protection Agency has developed an Action Plan on BPA as part of an effort to enhance the agency's chemical management plans under the Toxic Substances Control Act (TSCA). The plan addresses industrial emissions of BPA and assesses alternatives to BPA use in thermal paper. In addition, several states and Canada have restricted sales of certain products containing BPA, such as baby bottles, to reduce exposure of infants and young children to the chemical.

The department proposes to designate bisphenol A as a priority chemical in accordance with 38 MRSA §1694, to gathering information on certain specified uses of the chemical and prohibiting sales of some BPA-containing products that have been banned in other states.

BISPHENOL A IDENTITY AND PHYSICAL PROPERTIES[5]

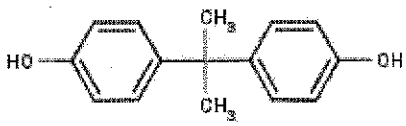
Bisphenol A

Name: Phenol, 4,4'-(1-methylethylidene)bis-

CAS Number: 80-05-7

Chemical Formula: $C_{15}H_{16}O_2$

Structural Formula:



Molecular Weight: 228.289 g mol^{-}

Select Synonyms:

2,2-(4,4'-Dihydroxydiphenyl)propane
2,2-Bis(4-hydroxyphenyl)propane
2,2-Bis(hydroxyphenyl)propane
2,2-Bis(p-hydroxyphenyl)propane
2,2-Bis-4'-hydroxyfenylpropan
2,2-Bis-4'-hydroxyfenylpropan [Czech]
2,2-Di(4-hydroxyphenyl)propane
2,2-Di(4-phenylol)propane
4,4'-(1-Methylethylidene)bisphenol
4,4'-Bisphenol A
4,4'-Dihydroxydiphenyl-2,2-propane
4,4'-Dihydroxydiphenyldimethylmethane
4,4'-Dihydroxydiphenylpropane
4,4'-Isopropylidene diphenol
4,4'-Isopropylidenebisphenol
4,4'-Isopropylidenediphenol
4-06-00-06717 (Beilstein Handbook Reference)
AI3-04009
BRN 1107700
Biphenol A
Bis(4-hydroxyphenyl) dimethylmethane
Bis(4-hydroxyphenyl)dimethylmethane
Bis(4-hydroxyphenyl)propane
Bisferol A
Bisferol A [Czech]
Bisphenol
Bisphenol A
Bisphenol-A
CCRIS 95
DIAN
Diano
Dimethyl bis(p-hydroxyphenyl)methane
Dimethylbis(p-hydroxyphenyl)methane
Dimethylmethylene-p,p'-diphenol
Diphenylolpropane
EINECS 201-245-8
HSDB 513
Ipognox 88
Isopropylidenebis(4-hydroxybenzene)
NCI-C50635
NSC 1767
Parabis A
Phenol, (1-methylethylidene)bis-
Phenol, 4,4'-(1-methylethylidene)bis-
Phenol, 4,4'-dimethylmethylenedi-

Phenol, 4,4'-isopropylidenedi-
Pluracol 245
Propane, 2,2-bis(p-hydroxyphenyl)-
Rikabanol
Ucar bisphenol A
Ucar bisphenol HP
beta,beta'-Bis(p-hydroxyphenyl)propane
beta-Di-p-hydroxyphenylpropane
p,p'-Bisphenol A
p,p'-Dihydroxydiphenyldimethylmethane
p,p'-Dihydroxydiphenylpropane
p,p'-Isopropylidenebisphenol
p,p'-Isopropylidenediphenol

Systematic Name
4,4' Isopropylidinediphenol
4,4'-Isopropylidenediphenol
Bisphenol A
Phenol, 4,4'-(1-methylethylidene)bis-
Phenol, 4,4'-isopropylidenedi-

Superlist Name
4,4'-Isopropylidenediphenol
Bisphenol A
Phenol, 4,4'-isopropylidenedi-

BISPHENOL A BACKGROUND

Bisphenol A (BPA) is a monomer manufactured through the condensation of phenol and acetone in the presence of an acid catalyst and used in the manufacture of epoxy, polycarbonate, phenoxy, polysulfone and certain polyester resins, flame retardants and rubber chemicals.[6] BPA was first synthesized in 1905 and went into commercial production in 1957.[7]

The US Environmental Protection Agency non-confidential Inventory Update Rule (IUR) 2006 data indicates that 13 companies manufacture or import BPA and that the aggregate BPA production volume is greater than one billion pounds.[8]

The chemical industry reported that US BPA demand (production plus imports less exports) in 2006 was 2.345 billion pounds, and projected demand in 2010 of 2.76 billion pounds. The industry also reported that the majority of BPA is used in the production of polycarbonate resins (75%), followed by epoxy resins (20%); other uses—including flame retardants (mainly tetrabromobisphenol A, TBBPA), unsaturated polyester, polysulfone, polyetherimide and polyarylate resins—account for 5% of BPA use.[9]

According to an industry-sponsored website, polycarbonate plastic is a lightweight, high-performance plastic whose characteristics of strength, optical clarity, high heat resistance, and electrical resistance make it suited to a variety of product uses, including CDs and DVDs, electronic equipment, automobiles, construction glazing, sports safety equipment, medical devices, tableware, reusable bottles and food storage containers. Epoxy resins are used in engineering applications such as electrical laminates for printed circuit boards, composites, paints and adhesives, as well as in a variety of protective coatings. Cured epoxy resins are used to coat the interior surface of most food and beverage cans to prevent corrosion of the can and contamination of the food by metals or bacteria. The characteristics of epoxy resins that make them suitable to these applications include: toughness, adhesion, formability, and chemical resistance. [10]

Additionally, BPA may be present as an impurity in or be formed through degradation of materials used in dentistry, such as fissure sealants.[11] A 2004 Danish alternatives assessment also found BPA used in thermographic paper, toner and ink.[12]

A BPA Risk Assessment Report developed by the European Union indicates that the main source of repeated exposure to BPA by consumers is through food contact applications, including infant feeding bottles, polycarbonate tableware, wine from epoxy-resin lined vats, canned food and canned beverages.[13] The National Toxicology Program monograph on bisphenol A concludes that "food and beverages accounts for the majority of daily human exposure [to bisphenol A]. The highest estimated daily intakes of bisphenol A in the general population occur in infants and children."[14]

Health and Ecological Concerns

Bisphenol A mimics estrogen and acts as an endocrine disruptor at very low doses.[15] Endocrine disruptors are chemicals that interfere with the hormone mechanisms of the body. While previous high-dose studies of BPA indicated minimal risk, more recent research into the low-

dose effects of BPA on the body's hormone systems has raised concern among researches and Federal agencies.

A panel of experts (Chapel Hill Expert Panel) that convened in 2007 issued a statement saying, "The wide range of adverse effects of low doses of BPA in laboratory animals exposed both during development and in adulthood is a great cause for concern with regard to the potential for similar adverse effects in humans." The scientists found that more than 95% of people sampled have BPA exposure within the range that is predicted to be biologically active based on animal studies. They also found that animals exposed to low doses of BPA exhibit adverse effects consistent with recent trends in human disease, such as increases in prostate and breast cancer, uro-genital abnormalities in male babies, a decline in semen quality in men, early onset of puberty in girls, metabolic disorders including insulin resistant (type 2) diabetes and obesity, and neurobehavioral problems such as attention deficit hyperactivity disorder (ADHD). The panel also concluded that exposure to BPA during development may not manifest in adverse health outcomes until long after exposure occurs. The panel concluded, "Concern regarding exposure throughout life is based on evidence that there is chronic, low level exposure of virtually everyone in developed countries to BPA. These findings indicate that acute studies in animals, particularly traditional toxicological studies that only involve the use of high doses of BPA, do not reflect the situation in humans."[16]

In its *Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*, published in September 2008, the US National Toxicology Program (NTP), Center for Evaluation of Risks to Human Reproduction (CERHR) indicated it "has *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A," [original emphasis].[17] "Some concern" is the midpoint of the CERHR's five levels of concern scale (i.e., negligible concern, minimal concern, some concern, concern, and serious concern).

In January 2010 the U.S. Food and Drug Administration (FDA) issued an *Update on Bisphenol A for Use in Food Contact Applications*, in which the agency echoed the CERHR's level of concern regarding BPA's health effects in light of results from low-dose studies. The agency stated that it is carrying out further studies to clarify uncertainties around BPA and in the interim the agency is supporting the industry's voluntary move to stop producing baby bottles and infant feeding cups containing BPA; facilitating the development of alternatives to BPA for the linings of infant formula cans; and supporting efforts to replace BPA or minimize BPA levels in other food can linings. The FDA issued its original approvals for use of BPA as a food contact substance in the 1960s.[18]

Regulatory and Voluntary Initiatives to Reduce BPA Use and Exposure

The US Environmental Protection Agency identified BPA as a chemical that poses a concern to the public and for which the agency has produced a chemical action plan as part of a comprehensive approach to enhance its chemicals management program under the Toxic Substances Control Act. EPA released its Bisphenol A Action Plan on March 29, 2010, which indicates that the agency will pursue rulemaking to reduce direct emissions of BPA to the environment from industrial settings and initiate an assessment of alternatives to BPA use in

thermal and carbonless paper through its Design for the Environment program. EPA deferred any action on the basis of human health to the FDA because most human exposure to BPA results from the chemical's use in food-contact applications.[19] BPA is the fifth chemical for which EPA has completed such a plan.

Connecticut. In 2009, Connecticut enacted a bill that prohibits the manufacture, sale, or distribution of any reusable food or beverage container containing bisphenol A, and 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, effective October 1, 2011.[20]

Maryland. In 2010, Maryland enacted a bill that prohibits the manufacture, sale, or distribution of any child care article (defined as "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 under the age of 4 years") containing bisphenol A, effective January 1, 2012.[21]

Minnesota. In 2009, Minnesota enacted a bill that prohibits the sale of an empty bottle or cup to be filled with food or liquid designed or intended to be used by a child under three years of age that contains bisphenol A, effective January 1, 2011.[22]

Washington. In March 2010, Washington passed legislation that 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, effective July 1, 2010.[23]

Wisconsin. In March 2010, Wisconsin enacted a bill that prohibits the manufacture or sale of an empty baby bottle or spill-proof cup that contains bisphenol A and is primarily intended for use by a child five years of age or younger. The law also requires manufacturers and wholesalers to ensure that a child's container sold or offered for sale is conspicuously labeled as not containing bisphenol A, effective June 1, 2010.[24]

Safer Alternatives

According to an industry-sponsored website, BPA is an integral component to the manufacture of both polycarbonate plastic and epoxy resins.[25] This implies that any alternative to BPA would need to be a product or material substitute to either polycarbonate or epoxy resin, rather than a chemical substitute that could be used in the manufacture of either of these materials.

In the case of BPA-containing products that have been banned in other US states, Maine law allows the department to presume, in the absence of persuasive evidence to the contrary, that safer alternatives are available for these products [see 38 MRSA §1696(2)(B)]. In support of this presumption, the department found that several manufacturers indicate in their online promotional information they carry BPA-free products, including baby bottles and toddler cups from Born Free,[26] Playtex,[27] Avent,[28] and Medela;[29] and refillable water or sports bottles from Nalgene,[30] CamelBak[31] and Life is Good.[32]

Alternative materials used by these manufacturers include high density polyethylene (HDPE), polypropylene (PP), low density polyethylene (LDPE), copolyester, stainless steel and, in the case of baby bottles, glass. An online search indicates that BPA-free baby bottles range in price

from $3-$10, while conventional versions range from $2-$4; both conventional and BPA-free sippy cups range from $5-$10; and BPA-free sports bottles range from $5 to $15. Many companies, including Nalgene, indicate they are phasing out use of polycarbonate in sports bottles. BPA-containing versions are difficult to find, with one model pricing in at $6. Stainless steel bottles, which are considerably more expensive than all plastic and glass versions, were not included in these price ranges.

The extent of BPA-free baby food and formula packaging is unclear. One website indicates that the lids to glass baby food jars contain BPA and that the only BPA-free baby food packaging currently in the marketplace is plastic.[33] Another consumer advocacy organization website indicates that all metal liquid formula cans and most metal lids of powdered formula cans are coated with BPA-containing epoxies.[34]

Some evidence is available that alternatives to BPA in epoxy-lined food containers exist. Eden Foods claims on its website that the company's organic beans "are packed in steel cans coated with a baked on oleoresinous c-enamel lining that does not contain bisphenol-A (BPA). (Oleoresin is a natural mixture of an oil and a resin extracted from various plants, such as pine or balsam fir). These cans cost 14 percent more than the industry standard cans that do contain BPA. This costs Eden $300,000 more a year. To our knowledge Eden is the only U.S. company that uses this custom made BPA-free can."[35] The Eden website does not indicate whether the company's canned products other than beans (e.g., tomatoes) are packaged in BPA-epoxy-resin-containing cans.

General Foods corporation noted in its 2010 Corporate Social Responsibility report that the company is pursuing alternatives to BPA in its packaging applications and will be implementing BPA-free packaging in its organic Muir Glen tomato products with the next tomato harvest.[36]

Additionally, anecdotal information indicates that Japanese manufacturers have voluntarily replaced BPA-containing epoxy resins with PET (polyethylene tetraphthalate) film.[37]

Regardless of available alternatives, the department is limited by statute to addressing only packaging for a food or beverage that is intentionally marketed or intended for the use of children younger than three years of age.

PREREQUISITES FOR DESIGNATION OF BISPHENOL A AS A PRIORITY CHEMICAL/ FINDINGS OF FACT

Chemicals of High Concern List

Bisphenol A appears on the Chemicals of High Concern list[38] published by the department because it has been designated as:

1. An endocrine disruptor on the OSPAR (Oslo-Paris Convention for the Protection of the Marine Environment of the North-East Atlantic) Chemicals of Possible Concern list;

2. A Category 1 endocrine disruptor, "evidence of endocrine disruption activity" in the European Commission Communication on a Community Strategy for Endocrine Disruptors; and

3. A chemical of "some concern" for developmental toxicity for fetuses, infants and children (brain, behavior and prostate gland) by the US Department of Health and Human Services National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction.

Criteria for Designation

Biomonitoring. 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, specifically:

- After reviewing more than 80 published human biomonitoring studies that measured BPA concentrations in human urine, blood, tissues and other fluids, researchers concluded that the general population is exposed to, and at risk from exposure to, BPA.[39]

- Researchers measured the total urinary concentrations of BPA in 2,517 participants 6 years of age and older in the 2003–2004 National Health and Nutrition Examination Survey and detected BPA in 92.6% of people studied.[40]

- Researchers investigated blood samples from 37 pregnant mothers between weeks 32 and 41 of gestation and analyzed placental tissue and umbilical cord blood from the same subjects after birth. Concentrations of BPA ranged from 0.3 to 18.9 ng/mL (median = 3.1 ng/mL) in maternal plasma, from 0.2 to 9.2 ng/mL (median = 2.3 ng/mL) in fetal plasma, and from 1.0 to 104.9 ng/g (median = 12.7 ng/g) in placental tissue.[41]

Home Environment. 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, specifically:

- In studies of indoor exposures to hormonally active agents and endocrine disruptors, researchers found BPA to be prevalent in household dust.[42, 43]

Ecological Sampling. The chemical has been found through monitoring to be present in fish, wildlife or the natural environment, specifically:

- River water sampling and analyses have found concentrations of bisphenol A ranging between non-detectable and 12μ/L.[44]

Consumer Products. The chemical is present in a consumer product used or present in the home, specifically:

- According to a BPA trade group, bisphenol A (BPA) is used primarily to make polycarbonate plastic and epoxy resins. Polycarbonate plastic is used in a wide variety of common products including digital media (e.g., CDs, DVDs), electrical and electronic equipment, automobiles, sports safety equipment, reusable food and drink containers, and many other products. Epoxy resins have many uses including engineering applications such as electrical laminates for printed circuit boards, composites, paints and adhesives, as well as in a variety of protective coatings. Cured epoxy resins are used as protective liners in metal cans.[45]

HPV. The chemical has been identified as a High Production Volume chemical by the federal Environmental Protection Agency.

- HPV chemicals are classified as those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year. The US Environmental Protection Agency Non-confidential IUR Production Volume Information database shows that production (manufacture and importation) of Bisphenol A was greater than one billion pounds in 2006 (the most recent year of data reporting).[46]

Sales Ban. The sale or use of certain products containing bisphenol A has been banned in the following states:

Connecticut: reusable food containers and baby food or instant formula stored in containers that contain BPA.

Maryland: empty bottle or cup intended to be filled with food or liquid designed or intended for use by a child younger than four.

Minnesota: bottles or cups intended for use by children younger than three.

Washington: empty bottle, cup or container designed or intended to be filled with any liquid, food, or beverage primarily for use by children three years of age or younger.

Wisconsin: empty baby bottles or spill-proof cups primarily intended for use by a child five years of age or younger.

PURPOSE OF DESIGNATION

Request for Information

The department is designating bisphenol A as a priority chemical for the purpose of requesting information related to:

1) The extent to which BPA is used in and the likelihood that children will be exposed to BPA as a result of its presence in the following consumer products:

    a) Infant formula and baby food containers;

    b) Reusable or disposable tableware; and

    c) Toys and childcare articles.

2) Existing and available alternatives to BPA, both chemical and functional, in the children's products listed in paragraph 1(a), above, including oleoresinous c-enamel and PET film.

Sales Prohibition

The department is designating bisphenol A as a priority chemical for the purpose of instituting a sales prohibition on any reusable food or beverage container that contains BPA beginning July 1, 2012.

BASIS FOR DEPARTMENT ACTION

Definition of Children's Products

The products listed in the department's request for information and sales prohibition in the proposed rule meet the definition of "children's products" under 38 MRSA §1691(7) because they are products that either are "intended for use by children," such as baby bottles, toys, childcare articles, infant formula and baby food containers, or, when used, they "will likely result in a child's or fetus's being exposed" to BPA, as in the case of reusable food and beverage containers and tableware.

Need for Information Regarding BPA Use in Children's Products

While it is clear from the department's research that bisphenol A is prevalent in polycarbonate plastic, such as that used in infant bottles, toddler cups and reusable sports water bottles, and the epoxy linings of food and beverage cans, there is limited information in the public domain related to the extent to which BPA is used in other products that children are readily exposed to, such as tableware and toys, and the likelihood that children may be exposed from these sources.

Available Alternatives

While the availability of alternatives to BPA in polycarbonate bottles and cups is evident from the prevalence of "BPA-free" options in the marketplace and multiple state bans, it is less clear to the department whether safer alternatives to BPA in baby food and formula containers are available. Under 38 MRSA §1696(2)(B) the Board has the authority to presume that, because Connecticut 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, safer alternatives are available. However, rather than enact a ban now, the department has chosen to gather more information on the known alternatives that are already in use or are being considered by manufacturers of these products. The department will assess this information to ensure that currently-available alternatives to BPA in infant food and formula packaging do not pose equal or greater health or environmental concerns. Request for this information at this time does not preclude the department from requesting a more thorough alternatives assessment under 38 MRSA §1695(2)(B).

Basis for a Sales Prohibition in Certain Products

The department considers it advisable to institute a sales prohibition on reusable food and beverage containers for the following reasons:

- The department's review of available research indicates that the greatest source of human exposure to BPA is through food contact applications.
- Infants fed formula in polycarbonate bottles are the most highly exposed population.
- Because these products have been banned in at least one other state, the Board can presume that safer alternatives are available.
- The prevalence of BPA-free options on the marketplace for baby bottles and sports bottles indicates that alternatives are readily available.
- These products meet the definition of "children's product" under 38 MRSA §1691(7).

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