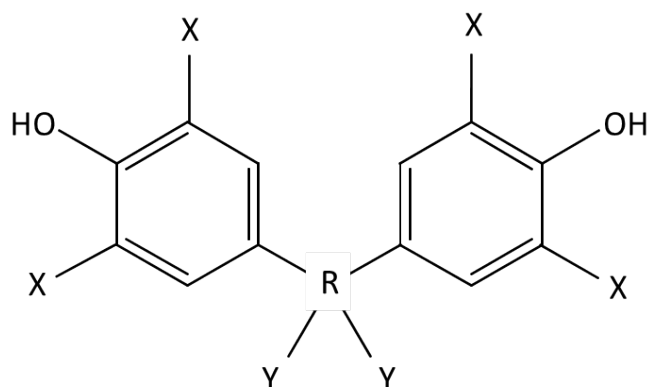


p,p'-Bisphenols and Diglycidyl Ethers of p,p'-Bisphenols

Materials for November 8, 2012 Meeting of Scientific Guidance Panel (SGP)
Biomonitoring California¹

Agenda Item: "Potential Designated Chemicals"



*Representative structure of a p-p'-bisphenol
(Adapted from Kitamura et al. 2005)*

Legend:

- R** represents bridging atom linking two phenol groups (i.e., carbon or sulfur atom)
- X** represents hydrogen or various substituents attached to a phenol group
- Y** represents hydrogen or various substituents attached to the bridge between two phenol groups, by either single or double bonds

** For diglycidyl ethers of p,p' bisphenols, the hydroxyl groups are replaced by epoxypropyl ether groups.

Introduction

At the March 16, 2012 Scientific Guidance Panel (SGP) meeting, Biomonitoring California staff presented a preliminary screening document on some bisphenols and related chemicals for discussion (Office of Environmental Health Hazard Assessment [OEHHA], 2012a). The SGP made recommendations to Biomonitoring California on

¹ California Environmental Contaminant Biomonitoring Program, codified at Health and Safety Code section 105440 et seq.

next steps for this set of chemicals. At the July 26, 2012 SGP meeting, the Program provided an interim update on additional screening of a subset of these chemicals (OEHHA, 2012b). Based on Panel advice and further research, Program staff developed this document on the group “p,p'-Bisphenols and Diglycidyl Ethers of p,p'-Bisphenols” for consideration as potential designated chemicals. Bisphenol A (BPA), one member of this general group, is already a priority chemical for Biomonitoring California.

p,p'-Bisphenols (hereafter referred to as “bisphenols” in this document) have the basic structure of two phenol groups, with the hydroxyl groups at the para positions, joined by a carbon or sulfur bridge. Substituents attached to the phenolic rings and the bridge can vary and can include alkyl groups or halogens, for example. Diglycidyl ethers of p,p'-bisphenols (hereafter referred to as “diglycidyl ethers” in this document) have a basic bisphenol structure, with epoxypropyl ether groups in place of the hydroxyl groups (see example structures on page 19).

Some bisphenols and diglycidyl ethers are currently used in or are candidates for use in various consumer product applications. For example, some are being used to line food and beverage cans and lids and others are used in thermal paper and other paper products. Increased use of some of these compounds is expected with declining use of BPA in certain applications. The U.S. Environmental Protection Agency's Design for the Environment program (U.S. EPA DfE, 2012 draft) has released a draft alternatives assessment on thermal paper substitutes. A number of p,p'-bisphenols were included in U.S. EPA's assessment.

This document provides information relevant to the possible identification of “Bisphenols and diglycidyl ethers of bisphenols” as designated chemicals for Biomonitoring California. The following criteria for designating chemicals, as specified in Health and Safety Code section 105449, are addressed:

- Potential for exposure
- Known or suspected health effects
- Need to assess efficacy of public health action
- Availability of a biomonitoring analytical method
- Availability of adequate biospecimen samples
- Incremental analytical cost

Most of these criteria are discussed for the whole group of compounds in single sections, including: known or suspected health effects, need to assess efficacy of public health action, and criteria related to analytical methods. Chemical-specific information on possible exposure and factors related to the potential for biomonitoring are addressed individually for seven chemicals highlighted in this document. The seven chemicals, listed below, were chosen based on evidence of use, existence of biomonitoring data, and/or potential for health effects.

Bisphenol S (BPS) CAS No. 80-09-1

Bisphenol AF (BPAF) CAS No. 1478-61-1

Bisphenol F (BPF) CAS No. 620-92-8

Bisphenol B (BPB) CAS No. 77-40-7

Bisphenol A diglycidyl ether (BADGE) CAS No. 1675-54-3

Bisphenol F diglycidyl ether (BFDGE) CAS No. 2095-03-6

4,4'-Sulfonylbis[2-(2-propen-1-yl)phenol] (TGSA) CAS No. 41481-66-7

Examples of other bisphenols and diglycidyl ethers are provided in a table at the end of the document.

Need to assess efficacy of public health action

Biomonitoring bisphenols and diglycidyl ethers of bisphenols would help the State determine whether these chemicals are found in California residents and at what levels. Considering these chemicals as a group would facilitate the use of broader laboratory screening methods, allowing the state to determine which of these pose the highest exposure concerns in California. Based on this broad laboratory screening, the most important of these chemicals could be identified and tracked over time to monitor potential increasing levels.

Analytical methods

Analytical methods have been published for measuring a number of bisphenols in a range of biological media, including urine, serum, and breast milk (Ye et al., 2006; Cobellis et al., 2009; Cunha, et al., 2010; Cariot et al., 2012; Liao et al. 2012c). Commercial standards are available for a number of bisphenols, diglycidyl ethers, and other possible targets for measurement (e.g., hydrolysis products). Analytical methods would need to be adapted or developed by Biomonitoring California. The method(s)

would likely involve analysis of urine samples using LC-MS/MS. Analysis of these compounds can be bundled to a certain degree, depending on the aim of the analysis (e.g., qualitative identification versus quantitation), thereby limiting the incremental analytical cost.

Known or suspected health effects

Some bisphenols and diglycidyl ethers exhibit binding affinity for hormone receptors, including estrogen and/or androgen receptors in receptor-binding assays (Perez et al., 1998; Blair et al., 2000; Coleman et al., 2003; Fang et al., 2003; Yamasaki et al., 2003a and 2004; Satoh et al., 2004; Laws et al., 2006; Okada et al., 2008).

Studies using cell-based reporter gene assays to measure transcriptional activation of estrogen and other hormone-related receptors report varying degrees of activity for a number of bisphenols and diglycidyl ethers (Yoshihara et al., 2001; Chen et al., 2002; Rivas et al., 2002; Yamasaki et al., 2002 and 2003a; Coleman et al., 2003; Satoh et al., 2004; Kitamura et al., 2005; Bermudez et al., 2010; Cabaton et al., 2009; Okuda et al., 2011; Grignard et al., 2012). Some bisphenols increased proliferation of human breast cancer MCF-7 cells (Perez et al., 1998; Hashimoto et al., 2001; Kanai et al., 2001; Rivas et al., 2002; Coleman et al., 2003; Stroheker et al., 2004).

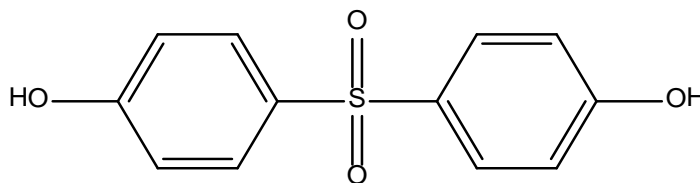
Several bisphenols, including bisphenol F, bisphenol AF, and bisphenol S, were positive in *in vivo* uterotrophic assays in rats, indicating estrogenic activity (Stroheker et al., 2003; Yamasaki et al., 2003a and 2004).

Some *in vitro* studies have reported indications of activity related to adipogenesis for a few bisphenols and BADGE (Masuno et al., 2005; Chamorro-Garcia et al., 2012).

Two diglycidyl ethers (BADGE and BFDGE) were positive in some assays for genotoxicity (Suárez et al., 2000; Sueiro et al., 2001 and 2003).

Not all bisphenols and diglycidyl ethers have been studied in these *in vitro* or *in vivo* assays. In the individual chemical sections below, lists of published references related to known or suspected health effects are provided.

Bisphenol S (BPS)
[CAS No. 80-09-1]
4,4'-Sulfonylbisphenol



Exposure or potential exposure to the public or specific subgroups

The annual U.S. production/import volume of bisphenol S (BPS) was 1 to 10 million pounds for the reporting years 1986, 1990, 1994, 1998, 2002, and 2006 (U.S. EPA, 2002; 2006).

BPS is used as a developer in thermal paper, including in products marketed as “BPA-free paper” (U.S. EPA DfE, 2012 draft). Detectable levels of BPS were found in 16 types of paper and paper products (n=268) such as cash register receipts, currency, tickets, airline luggage tags, and flyers from the United States and some Asian countries (Liao et al., 2012a). Liao et al. (2012a) collected thermal receipts in the United States, (n=81) (New York, North Carolina, Illinois, Vermont, and Massachusetts), Japan, Korea, and Vietnam (n=31). Currency (n=52) was collected from 20 countries. Other paper products (n=105) were collected mainly from New York and divided into 14 categories. BPS was detected in 100% of thermal receipt samples, at concentrations ranging up to 22.0 milligram/gram (mg/g), and in about 90% of currency samples at microgram/gram levels. They also found BPS at microgram/gram levels in currency samples (90%), food cartons (57%), flyers (80%), magazines (40%), and many other types of paper products (Liao et al., 2012a). Becerra and Odermatt (2012) reported that levels of BPS in six samples of thermal paper labeled “BPA-free” ranged from less than the limit of detection (<LOD) to more than 100 mg/kg.

BPS is also commonly used as a reagent in polymer reactions to produce resins, such as polysulfone and polyethersulfone (PES), which can be an alternative to polycarbonate (Simoneau et al., 2011). These polymers can be used to make epoxy resins for can linings or plastics for, storage containers and plastic bottles (Simoneau et al., 2011). Viñas et al. (2010) detected BPS in seven out of nine canned vegetable samples. When BPS was detected, it was found in the supernatant liquid from the

canned food at higher levels than in the food itself. The highest BPS concentration measured was in a sample of supernatant liquid from canned peas and carrots (170 or 175 ng/g, depending on the derivatization method) (Viñas et al., 2010). Viñas et al. (2010) also tested migration of BPS from cans using an aqueous food simulant (distilled water) and an acidic food simulant (3% acetic acid). They found increased migration with higher acidity, temperature and duration of contact with packaging. Gallart-Ayala et al. (2011a) did not detect BPS in samples of canned beverages, such as sodas, beer and tea, purchased in Barcelona, Spain. Simoneau et al. (2011) tested thirty PES baby bottles from twelve European countries using a simulant for milk. They did not detect migration of BPS into the milk simulant.

Liao et al. (2012b) detected BPS in 100% of indoor dust samples from New York (Albany, n=38), China (n=55), Japan (n=22), Korea (n=41), at concentrations ranging from 0.00083 to 26.6 µg/g (geometric mean [GM] = 0.34 µg/g) (Liao et al., 2012b). For comparison, the same study found BPA in 98.7% of the dust samples, at concentrations up to 39.1 µg/g (GM = 1.33 µg/g). The geometric mean for BPS in dust samples from New York was 0.62 µg/g (maximum 26.6 µg/g), versus 1.7 µg/g for BPA (maximum 9.38 µg/g). Liao et al. (2012b) also reported the percent composition for each bisphenol in dust, relative to the total bisphenol concentration. The largest contributions to the total bisphenol concentration were from BPA (65 ± 26%) and BPS (24 ± 23%).

Known or suspected health effects of BPS

References for published studies that indicate biological activity of BPS are listed below.

In vivo uterotrophic assay

Yamasaki et al., 2004

In vitro assays - potential endocrine activity

Blair et al., 2000

Chen et al., 2002

Fang et al., 2003

Grignard et al., 2012

Hashimoto and Nakamura, 2000

Hashimoto et al., 2001

Kitamura et al., 2005

Kuruto-Niwa et al., 2005

Laws et al., 2006

Yamasaki et al., 2004

In vitro assays – potential activity related to adipogenesis

Masuno et al., 2005

Potential to biomonitor

Physical chemical properties:

Molecular weight = 250.27 g/mol

Parameter	PBT Profiler* (2012)	U.S. EPA DfE** (2012, draft)
Octanol/water partition coefficient: LogK _{ow}	1.64 (exp)	1.2 (exp)
Vapor pressure (mm Hg at 25°C)	4.72 x 10 ⁻¹⁰	<1 x 10 ⁻⁸
Water solubility (mg/L)	500 (25°C)	1,100 (20°C) (exp)***

* Values estimated using PBT Profiler, except where noted as experimental (exp).

**Values estimated by U.S. EPA DfE using EPI Suite, except where noted as experimental (exp).

***Measured value obtained from the [record for BPS on the European Chemicals Agency \(ECHA\) website](#), cited by U.S. EPA DfE (2012, draft).

Bioaccumulation and persistence:

	PBT Profiler (2012)	U.S. EPA DfE (2012, draft)
Bioaccumulation	BCF = 5.7	Low ^b BCF: < 2.2 ^c , < 0.2 ^c
Persistence	<i>Half-lives (days)</i> Water 38 Soil 30 Marine Sediment 140 ^a Ambient Air 1.1	Moderate ^b

^a Predicted to be *persistent* according to U.S. EPA criteria.

^b U.S. EPA DfE (2012, draft) analyzed published parameters and parameters estimated using EPI Suite and PBT Profiler to make an overall determination of “Low”, “Moderate” or “High.” Details on the basis for these determinations are available in U.S. EPA DfE (2012, draft).

^c Measured in carp at concentrations of 50 µg/L and 500 µg/L, respectively.

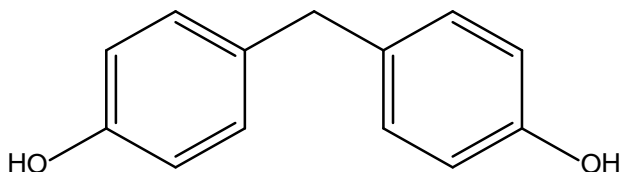
In laboratory biodegradation tests, Ike et al. (2006) demonstrated that BPS was more resistant to degradation than BPA under aerobic conditions in river water and equivalent to BPA under anaerobic conditions in pond sediments. Danzl et al. (2009) did not observe degradation of BPS in laboratory tests with seawater. Sakai et al. (2007) performed biodegradation studies using a bacterium isolated from offshore seawater samples collected in Japan. The bacterium (*Sphinogomonas* sp. BP-7') did not degrade BPS.

Pharmacokinetics and metabolism: No studies located.

Past biomonitoring studies:

Liao et al. (2012c) detected BPS in 81% of urine samples from populations in New York (Albany, n=31) and seven Asian countries (China, n=89; India, n=38; Japan, n=36, Korea, n=33; Kuwait, n=30; Malaysia, n=29; and Vietnam, n=29). The urinary BPS concentrations varied among countries, with the highest geometric mean concentrations found in samples from Japan (GM 1.18 ng/mL, 0.933 µg/g creatinine) and New York (GM 0.299 ng/mL, 0.304 µg/g creatinine).

Bisphenol F (BPF)
[CAS No. 620-92-8]
4,4'-Methylenebisphenol



Exposure or potential exposure to the public or specific subgroups

BPF is used to make epoxy resins and coatings for various applications, such as lacquers, varnishes, liners, adhesives, plastics, water pipes, dental sealants, and food packaging (Cabaton et al., 2009). No U.S. production/import volume was reported for Bisphenol F (BPF) (U.S. EPA 2002; 2006). However, an epoxy resin made from the reaction of bisphenol F with epichlorohydrin is available (The Dow Chemical Company [Dow] [D.E.R.™ 354](#); CAS No. 28064-14-4). The production/import volume for this CAS No. was <500,000 pounds in the reporting year 2006, down from a volume of 10 to 50 million pounds in 1998 and 2002. Dow states that this type of epoxy resin, when properly formulated and cured, complies with regulations for food contact applications under Title 21, CFR, Section 175.300 (b)(3)(viii)(a) (“Epoxy resins, as basic polymer”) (available on the U.S Food and Drug Administration [FDA] website).

Liao et al. (2012b) evaluated the presence of bisphenols in dust samples from New York (Albany, n=38), China (n=55), Japan (n=22), and Korea (n=41). BPF was detected in 68.4% of dust samples from New York, compared to 74.4% for samples from all countries combined (Liao et al., 2012b). The geometric mean for BPF in dust samples from New York was 0.022 µg/g (maximum 0.24 µg/g), versus 1.7 µg/g for BPA (maximum 9.38 µg/g). Liao et al. (2012b) also reported the percent composition for each bisphenol in dust, relative to the total bisphenol concentration. The contribution to the total bisphenol concentration from BPF was 9.6 ± 17%, compared to 65 ± 26% for BPA and 24 ± 23% for BPS.

Gallart-Ayala et al. (2011a) tested eleven canned beverages purchased in Barcelona supermarkets. They detected BPF in two of the eleven samples: a sample of orange soda (0.218 µg/L) and a sample of lemon soda (0.141 µg/L). Goodson et al. (2002) did not detect BPF isomers in a study of 62 different canned foods from retail markets in

England. In the same study, BPA was detected in 38 samples (LOD = 2 µg/kg). Jordáková et al. (2003) reported that BPF was detected in samples of packaging materials, including cans (1 detection/2 samples tested), lids (1/2), and lacquers (1/5).

BPF has been detected in environmental samples, including municipal landfill leachate in Sweden; surface water, sewage water, and sediments in Germany; influent and effluent from wastewater treatment plants in southern Spain; and riverine sediment in Belgium) (Öman et al., 1993; Fromme et al., 2002; Ruiz et al., 2007; Ballesteros-Gómez et al. 2007; Schmitt et al., 2011).

Known or suspected health effects of BPF

References for published studies that indicate biological activity of BPF are listed below.

In vivo uterotrophic assay

Stroheker et al., 2003

Yamasaki et al., 2002

Yamasaki et al., 2004

In vitro assays - potential endocrine activity

Blair et al., 2000

Cabaton et al., 2009

Chen et al., 2002

Coleman et al., 2003

Hashimoto and Nakamura, 2000

Hashimoto et al., 2001

Kanai et al., 2001

Kitamura et al., 2005

Okada et al., 2008

Okuda et al., 2011

Perez et al., 1998

Satoh et al., 2004

Stroheker et al., 2004

Yamasaki et al., 2002

Yamasaki et al., 2004

Zhang et al., 2010a

In vitro assays - potential activity related to adipogenesis

Masuno et al., 2005

In vitro assays - genotoxicity

Audebert et al., 2011

Other *in vitro* assays

Kanai et al., 2001

Potential to biomonitor

Physical chemical properties:

Molecular weight = 200.24 g/mol

Parameter	PBT Profiler* (2012)	U.S. EPA DfE** (2012, draft)
Octanol/water partition coefficient: LogK _{ow}	2.91 (exp)	2.91 (exp)
Vapor pressure (mm Hg at 25°C)	3.7 x 10 ⁻⁷	<1 x 10 ⁻⁸
Water solubility (mg/L at 25°C)	190	190

* Values estimated using PBT Profiler, except where noted as experimental (exp).

** Values estimated by U.S. EPA DfE using EPI Suite, except where noted as experimental (exp).

Bioaccumulation and persistence:

	PBT Profiler (2012)	U.S. EPA DfE (2012, draft)
Bioaccumulation	BCF = 39	Low ^b BCF ^c = 6.6, 11
Persistence	<i>Half-lives (days)</i> Water 38 Soil 30 Marine Sediment 140 ^a Ambient Air 1.1	Low ^b

^a Predicted to be *persistent* according to U.S. EPA criteria

^b U.S. EPA DfE (2012, draft) analyzed published parameters and parameters estimated using EPI Suite and PBT Profiler to make an overall determination of “Low”, “Moderate” or “High.” Details on the basis for these determinations are available in U.S. EPA DfE (2012, draft).

^c Measured values as reported in U.S. DfE (2012, draft). The measured BCF varied with concentration, 25 µg/L and 2.5 µg/L, respectively

Ike et al. (2006) found that BPF was more biodegradable than BPA and BPS under both aerobic (river water) and anaerobic (pond sediment) conditions. Danzl et al. (2009) found that BPF was degraded more efficiently than BPA in laboratory tests with seawater. Sakai et al. (2007) performed biodegradation studies using a bacterium

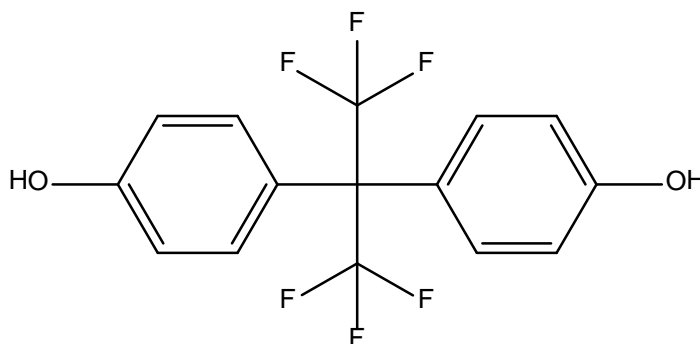
isolated from offshore seawater samples collected in Japan. The bacterium (*Sphinogomonas* sp. BP-7') did not degrade BPF.

Pharmacokinetics and metabolism:

Cabaton et al. (2006) reported that following a single dose of BPF via gavage to pregnant and nonpregnant rats, BPF was efficiently absorbed and metabolized, with at least six metabolites identified. The primary metabolites were (4,4-dihydroxybenzophenone (DHB) and hydroxylated-BPF [BPF-OH]) (Cabaton et al., 2009). Cabaton et al. (2006) found that BPF and its metabolites were excreted primarily in the urine (43-54% of administered dose) and to a lesser extent in the feces (15-20%). In pregnant rats, [³H]BPF residues were measured the placenta, amniotic fluid and the fetuses (Cabaton et al., 2006).

Biomonitoring studies: No studies located.

Bisphenol AF (BPAF)
[CAS No. 1478-61-1]
4,4'-[2,2,2-Trifluoro-1-(trifluoromethyl)ethylidene]bisphenol



Exposure or potential exposure to the public or specific subgroups

BPAF was nominated by the National Institute of Environmental Health Sciences for comprehensive toxicological characterization, based on production, use, potential for endocrine and reproductive effects, and lack of adequate toxicity data (NTP, 2008). Tests underway include: modified one-generation studies, pharmacokinetic studies, and organ systems toxicity studies (NTP website 2012). NTP (2008) identified potential sources of exposure to the general population, such as the possible use of BPAF to make a type of synthetic rubber for gaskets and hoses in food processing equipment. It has also been used in the synthesis of various polymers, including polycarbonate (NTP, 2008; Honeywell website), and specialty polymers for high heat applications (Halocarbon website, 2012). Production/import volume for the reporting years spanning 1986 to 2002 was 10 to 500,000 pounds (U.S. EPA, 2002). Production/import volume for the reporting year 2006 was less than 500,000 pounds (U.S. EPA, 2006).

Liao et al. (2012b) evaluated the presence of bisphenols in dust samples from New York (Albany, n=38), China (n=55), Japan (n=22), and Korea (n=41). BPAF was not detected in dust samples from New York or China. BPAF was detected in 76% of dust samples from Korea, with a maximum level of 0.091 µg/g, and 9% of dust samples from Japan, with a maximum level of 0.011 µg/g.

Known or suspected health effects of BPAF

References for published studies that indicate biological activity of BPAF are listed below.

In vivo uterotrophic assay

Yamasaki et al., 2003a

In vivo reproductive toxicity study in rats

Feng et al., 2012

In vitro assays - potential endocrine activity

Bermudez et al., 2010

Butt et al., 2011

Coleman et al., 2003

Hashimoto et al., 2001

Kanai et al., 2001

Kitamura et al., 2005

Laws et al. 2006

Letcher et al. 2005

Matsushima et al., 2010

Okada et al., 2008

Perez et al., 1998

Rivas et al., 2002

Sui et al., 2012

Zhang et al., 2010a

Other *in vitro* assays

Kanai et al., 2001

Pfeiffer et al., 1997

Tsutsui et al., 2000

Potential to biomonitor

Physical chemical properties:

Molecular weight = 336.24 g/mol

Parameter	PBT Profiler* (2012)	U.S. EPA DfE (2012, draft)
Octanol/water partition coefficient: LogK _{ow}	4.47 (exp)	Chemical not included in DfE assessment
Vapor pressure (mm Hg at 25°C)	5.2 x 10 ⁻⁷	
Water solubility (mg/L at 25°C)	3.8	

* Values are estimated, except where noted as experimental (exp)

Bioaccumulation and persistence:

	PBT Profiler (2012)	U.S. EPA DfE (2012, draft)
Bioaccumulation	BCF = 420	Chemical not included in DfE assessment
Persistence	<i>Half-lives (days)</i> Water 180^a Soil 360^a Marine Sediment 1600^a Ambient Air 0.2	

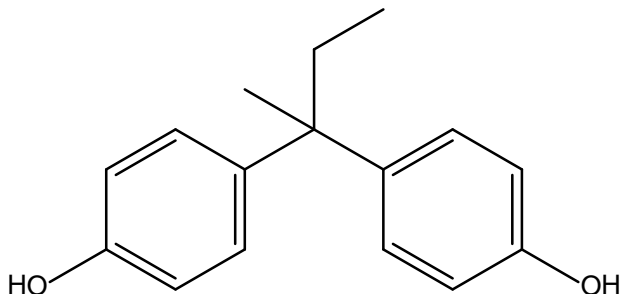
^a Predicted to be **very persistent** according to U.S. EPA criteria

Pharmacokinetics and metabolism:

Yang et al. (2012) detected BPAF in liver, kidney, serum, urine, feces after rats were orally dosed for two weeks. Enzymatic hydrolysis of the samples resulted in higher measured BPAF concentrations, indicating the presence of conjugated BPAF metabolites. Fecal excretion was the dominant route of elimination, with the majority of BPAF excreted in the non-conjugated form.

Past biomonitoring studies: A study by Fernandez et al. (2004) was cited by NTP (2008) as having found BPAF in extracts of human female mammary or abdominal adipose tissue samples. However, Fernandez et al. (2004) provided no specific information on detecting BPAF (for example, detection frequency in the samples). The authors have been contacted to request clarification.

Bisphenol B (BPB)
[CAS No. 77-40-7]
4,4'-(1-Methylpropylidene)bisphenol



Exposure or potential exposure to the public or specific subgroups

Bisphenol B (BPB) has been used in Europe to manufacture polycarbonate resins and for lining food and beverage cans (Grumetto et al., 2008). BPB is listed as a possible component of resinous and polymeric coatings that can safely be used in food-contact surfaces under conditions specified in U.S. regulations (Title 21, CFR, Section 175.300; available on FDA website).

BPB was detected in 21% (9/42) of tested canned peeled tomatoes samples from Italian supermarkets at concentrations ranging from 27.1 – 85.7 $\mu\text{g}/\text{kg}$ (Grumetto et al., 2008). BPA and BPB were detected simultaneously in approximately 20% (8/42) of the samples (Grumetto et al., 2008). Grumetto et al. (2008) concluded that BPB presence was likely due to migration from epoxyphenolic and BADGE coatings based on absence of BPA and BPB in samples of tomatoes in glass bottles which were used as a blank. Cunha et al. (2011) detected BPB in 50% (15/30) of canned beverages purchased in Portugal. Levels ranged from 0.06 to 0.16 $\mu\text{g}/\text{L}$. BPB was detected in all cola samples (6/6) tested. For comparison, BPA was found in 70% (21/30) beverages tested at levels ranging from 0.03 to 4.70 $\mu\text{g}/\text{L}$ (Cunha et al., 2011).

Liao et al. (2012b) evaluated the presence of bisphenols in dust samples from New York (Albany, n=38), China (n=55), Japan (n=22), Korea (n=41). BPB was only detected in 10.9% of dust samples from China, with concentrations ranging from less than the limit of quantitation (LOQ) of 1.0 ng/g to 0.03 $\mu\text{g}/\text{g}$.

Known or suspected health effects of BPB

References for published studies that indicate biological activity of BPB are listed below.

In vivo uterotrophic assay

Yamasaki et al., 2002

In vitro assays - potential endocrine activity

Blair et al., 2000

Coleman et al., 2003

Chen et al., 2002

Fang et al., 2003

Hashimoto et al., 2001

Kitamura et al., 2005

Okada et al., 2008

Okuda et al., 2011

Rivas et al., 2002

Sui et al., 2012

Yamasaki et al., 2002

Yoshihara et al., 2001

Yoshihara et al., 2004

Zhang et al., 2010a

In vitro assays - potential activity related to adipogenesis

Masuno et al., 2005

Potential to biomonitor

Physical chemical properties:

Molecular weight = 242.32 g/mol

Parameter	PBT Profiler* (2012)	U.S. EPA DfE (2012, draft)
Octanol/water partition coefficient: LogK _{ow}	4.13 (exp)	Chemical not included in DfE assessment
Vapor pressure (mm Hg at 25°C)	2.5 x 10 ⁻⁷	
Water solubility (mg/L at 25°C)	27	

* Values are estimated, except where noted as experimental (exp)

Bioaccumulation and persistence:

	PBT Profiler (2012)	U.S. EPA DfE (2012, draft)
Bioaccumulation	BCF = 250	Chemical not included in DfE assessment
Persistence	<i>Half-lives (days)</i> Water 38 Soil 75 ^a Marine Sediment 340^b Ambient Air 0.2	

^a Predicted to be *persistent* according to U.S. EPA criteria

^b Predicted to be **very persistent** according to U.S. EPA criteria

Sakai et al. (2007) performed biodegradation studies using a bacterium isolated from offshore seawater samples collected in Japan. The bacterium ('*Sphingomonas* sp. BP-7') degraded BPB, as well as BPA and bisphenol Z (BPZ). The strain did not degrade BPF, BPS or 4,4'-thiobisphenol (TBP).

Pharmacokinetics and metabolism: No studies located.

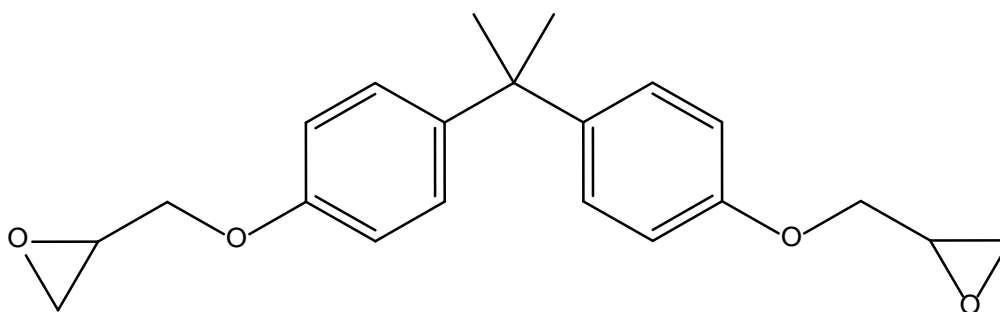
Past biomonitoring studies:

Cunha et al. (2010) measured free and total BPB in urine samples from 20 volunteers in Portugal. Conjugated BPB was detected in 2 of the 20 samples tested at levels ranging from 0.85-3.02 µg/g creatinine. For a comparison, total BPA was detected in 17 of the 20 volunteers at levels ranging from 0.33-8.87 µg/g creatinine.

Cobellis et al. (2009) detected BPB in about 28% (16/58) of serum samples from endometriotic women in Italy. BPB was quantified for the 10 samples that exceeded the LOQ (0.6 ng/mL) and the mean BPB concentration was 5.15 ± 4.16 ng/mL. For comparison, BPA was detected in 51.7% (30/58) of sera samples from endometriotic women in excess of the LOQ (0.5 ng/mL) at a mean concentration of 2.91 ± 1.74 ng/mL. BPB and BPA were not detected in eleven healthy, non-endometriotic women in this study.

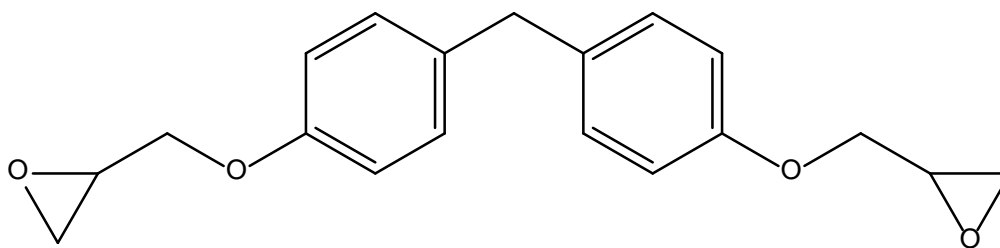
Bisphenol A diglycidyl ether (BADGE)

[CAS No. 1675-54-3]



Bisphenol F diglycidyl ether (BFDGE)

[CAS No. 2095-03-6]



Exposure or potential exposure to the public or specific subgroups

BADGE and BFDGE are produced through the reaction of epichlorohydrin with bisphenol A or bisphenol F, respectively. These reactions can produce the monomers or higher polymers (Dow, 2006).

U.S. production/import volume for BADGE is listed at 1 to 10 million pounds for reporting years spanning 1986 to 2006 (U.S. EPA, 2002; 2006). Numerous epoxy resins made from the reaction of BPA and epichlorohydrin are available. For example, a BADGE-based epoxy resin with the CAS No. 25068-38-6 had a production volume of 1 to 10 million pounds in 2006.

No production volume was located for BFDGE for reporting years spanning 1986 to 2006. However, an epoxy resin made from the reaction of bisphenol F with epichlorohydrin is available (Dow [D.E.R.™ 354](#); CAS No. 28064-14-4). The production/import volume of this epoxy resin was <500,000 pounds in the reporting year 2006, down from a volume of 10 to 50 million pounds in 1998 and 2002. Mixed epoxy

resins made from bisphenol A and bisphenol F, reacted with epichlorohydrin are also available (see for example Dow [D.E.R.™ 356](#)).

Dow notes in the product information sheets that epoxy resins based on BADGE or BFDGE, when properly formulated and cured, comply with regulations for food contact applications under Title 21, CFR, Section 175.300 (b)(3)(viii)(a) (“Epoxy resins, as basic polymer”) (available on FDA website).

Glycidyl ethers have been used as basic components of epoxy resins since the late 1940s (Hanaoka et al., 2002). These chemicals are used as a starting substance in the manufacture of can coatings for food contact applications and as an additive to stabilize organosol polyvinyl chloride (PVC) resins used to make other plastics (Leepipatpiboon et al., 2005; Coulier et al., 2010; Zhang et al., 2010b). BADGE is also used in the manufacture of electronics and in dental restorative materials (Olea et al., 1996; Satoh et al., 2004; Poole et al., 2004; Fleisch et al., 2010).

BADGE and BFDGE can hydrolyze to form several derivatives when they come in contact with aqueous and acidic food including, mono- and dihydrolyzed products (i.e., BADGE forms BADGE.H₂O and BADGE.2H₂O) and chlorohydroxy products (i.e., BADGE.HCl and BADGE.2HCl) through the activity of epoxide hydrolase which opens the epoxide rings (Paseiro Losada et al., 1992 and 1993; Hammarling et al., 2000; Sendón García and Paseiro Losada, 2004). These hydrolysis products have been measured in experimental studies using food simulants (Paseiro Losada et al., 1992; Simal Gándara et al., 1993) and in canned foods and beverages (see below).

Studies of canned foods and beverages

Biles et al. (1999) tested canned fish products and diet cola purchased from grocery stores in Washington D.C. They also tested infant formula liquid concentrates from around the U.S. BADGE was detected in anchovy, sardine, herring and tuna samples, but not in diet cola or infant formula samples. Biles et al. (1999) also detected chlorohydroxy derivatives of BADGE in anchovy and herring samples, noting that testing only for BADGE may not be sufficient for understanding migration from can coatings.

Numerous studies in other countries have analyzed for BADGE and BFDGE and their derivatives in canned foods and/or in the can linings (see for example: Biedermann and Grob, 1998; Summerfield et al., 1998; Simoneau et al., 1999; Theobald et al., 2000; Hammarling et al., 2000; Jordáková et al., 2003; Poustka et al., 2007; Cabado et al.,

2008; Cao et al., 2009; Zhang et al., 2010b; Gallart-Ayala et al., 2011b). A few of these studies are described below.

Canada: Cao et al. (2009) reported that BADGE was detected in all 21 canned liquid infant formula products purchased in Ottawa at levels ranging from 2.4 ng/g to 262 ng/g. BFDGE was detected in one product (40 ng/g), which also had the highest BADGE level (262 ng/g) (Cao et al., 2009).

European Union and Switzerland: Simoneau et al. (1999) tested for BADGE in 382 canned fish in oil samples collected from national retail stores in 15 member states of the European Union (EU) and Switzerland. Twelve samples contained BADGE at levels above 1 mg/kg, the European provisional Specific Migration Limit for BADGE at that time. In the same European survey, Theobald et al. (2000) detected BFDGE in 12% of canned fish in oil samples, 24% of the cans and 18% of the lids. Only 3% of the fish samples contained BFDGE in concentrations above the BADGE migration limit of 1 mg/kg (Theobald et al., 2000). Hammarling et al., (2000) analyzed for BADGE and BADGE derivatives in canned foods purchased from supermarkets in Uppsala, Sweden, including various types of canned fish and a few samples of canned vegetables, pasties (chicken or tuna), and meat sauce. BADGE was found most frequently and at the highest levels in oily fish products, like canned mackerel. BADGE derivatives (BADGE.HCl, BADGE 2.HCl, and BADGE 2H₂O) were found in a few of the samples. When all of the analyzed BADGE compounds were combined, 15 samples exceeded the BADGE migration limit of 1 mg/kg. For 14 of the samples, the limit was exceeded by the concentration of BADGE.2HCl alone. Lintschinger et al. (2000) measured BADGE, BFDGE and their hydrolysis and chlorohydroxy derivatives in oily and aqueous canned food samples randomly chosen from Austrian markets, including canned tuna and sardines in oil, fruit and vegetables. They found that canned food samples contained hydrolysis and chlorohydroxy products of BADGE and BFDGE, but did not contain substantial amounts of BADGE or BFDGE.

Since 2005, the EU has prohibited the use of BFDGE in cans. However, Cabado et al. (2008) still detected low levels of BFDGE in six types of canned fish from local Spanish markets. They also detected BADGE, but at levels below the EU migration limit (EC, 2005). For both BADGE and BFDGE, migration appeared to occur more often from cans containing the fattiest fish, consistent with earlier studies of BADGE. Gallart-Ayala et al. (2011b) tested for BADGE, BFDGE and their derivatives in six canned food samples and seven canned beverages purchased in Barcelona. In food, BADGE.2H₂O was the only derivative detected. In beverages tested, both hydroxy and chlorohydroxy

derivatives were detected. BADGE, BFDGE or BFDGE derivatives were not detected in any of the samples tested.

Asia: Zhang et al. (2010b) analyzed 20 brands of canned food, including fish, meat, fruit, and congee, from China, Taiwan, Thailand, Malaysia and the Philippines. They also analyzed the food contact can linings. The authors found that more than 75% of the can linings contained at least one of the target analytes, with BFDGE, polymers of BFDGE, and BADGE most commonly detected. They also found these compounds at lower levels in the canned foods in less than 50% of the samples.

Environmental samples

BADGE and, less often, BFDGE were detected in influent water to municipal wastewater treatment plants in southern Spain (Ruiz et al., 2007, Ballesteros-Gómez et al. 2007). BADGE, but not BFDGE, was detected in some effluent water samples from some of the treatment plants (Ruiz et al., 2007, Ballesteros-Gómez et al. 2007).

Known or suspected health effects of BADGE, BFDGE and/or derivatives (hydroxy or chlorohydroxy)

References for published studies that indicate biological activity of BADGE, BFDGE and/or their derivatives (hydroxy or chlorohydroxy) are listed below.

In vitro assays - potential endocrine activity

Ahn et al., 2008
Letcher et al., 2005
Nakazawa et al., 2002
Olea et al., 1996
Perez et al., 1998
Sato et al., 2004

In vitro assays - potential activity related to adipogenesis

Chamorro-Garcia et al., 2012
Wright et al., 2000

In vitro assays - genotoxicity

Cabaton et al., 2009
Sueiro et al., 2001
Sueiro et al., 2003
Suárez et al., 2000

Potential to biomonitor*Physical chemical properties:*

BADGE Molecular weight = 340.42 g/mol

BFDGE Molecular weight = 312.37 g/mol

Parameter	PBT Profiler* (2012)		U.S. EPA DfE (2012, draft)
	BADGE	BFDGE	
Octanol/water partition coefficient: LogK _{ow}	3.84 (exp)	2.97 (exp)	Chemicals not included in DfE assessment
Vapor pressure (mm Hg at 25°C)	2.6 x 10 ⁻⁶	2.30 x 10 ⁻⁷	
Water solubility (mg/L at 25°C)	29	230	

* Values are estimated, except where noted as experimental (exp)

Bioaccumulation and persistence:

	PBT Profiler (2012)		U.S. EPA DfE (2012, draft)
	BADGE	BFDGE	
Bioaccumulation	BCF = 160	BCF = 42	Chemicals not included in DfE assessment
Persistence	<i>Half-lives (days)</i> Water 60 ^a Soil 120 ^a Marine Sediment 540^b Ambient Air 0.2	<i>Half-lives (days)</i> Water 38 Soil 75 ^a Marine Sediment 340^b Ambient Air 0.35	

^a Predicted to be *persistent* according to U.S. EPA criteria^b Predicted to be **very persistent** according to U.S. EPA criteria*Pharmacokinetics and metabolism:*

The metabolism of BADGE has been studied in mice (Climie et al., 1981a; Climie et al. 1981b). The majority (88%) of a single oral dose of ¹⁴C labeled-BADGE was eliminated within two days, with 80% of the administered dose excreted in the feces and 11% in

the urine. The major metabolic pathway of BADGE is the hydrolytic opening of the epoxide rings by epoxide hydrolases to yield BADGE.2H₂O, which is excreted in both free and conjugated forms (Hammarling et al., 2000).

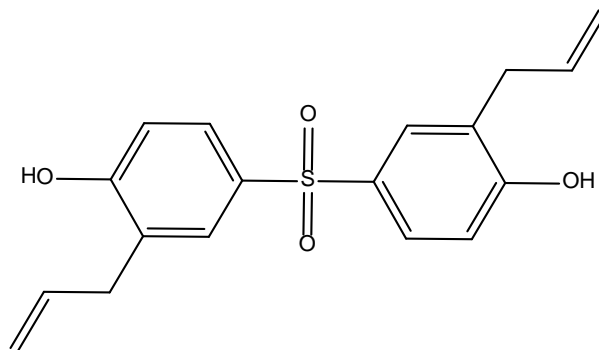
Past biomonitoring studies:

Olea et al (1996) detected BADGE in saliva samples collected after application of a dental sealant. Hanaoka et al. (2002) measured BPA as a surrogate marker for BADGE in the urine of workers who occupationally sprayed BADGE. BPA was measured because BADGE standards were not available at the time of the study. However, Climie et al. (1981b) did not find evidence of BPA in studies of BADGE metabolism.

TGSA

[CAS No. 41481-66-7]

4,4'-Sulfonylbis[2-(2-propen-1-yl)phenol]



Exposure or potential exposure to the public or specific subgroups

TGSA is used as a developer in thermal paper (U.S. EPA DfE, 2012 draft). U.S. production/import volume for TGSA was listed at 1 to 10 million pounds for reporting year 2006 (U.S. EPA, 2006). This is an increase from the volume of 10 to 500 thousand pounds listed for reporting years 1998 and 2002 (U.S. EPA, 2002). No production volume was listed for the reporting years 1986, 1990, and 1994 (U.S. EPA, 2002).

Known or suspected health effects of TGSA

No published references on known or suspected health effects were located for TGSA. U.S. EPA DfE (2012, draft) summarized data from the Nippon Kayaku Corporation on health effects, which are not publicly available. U.S. EPA DfE also predicted health effects for TGSA based on structure-activity relationships. Unlike other bisphenols, TGSA was not found to have endocrine activity *in vitro* or *in vivo* in these unpublished studies. U.S. EPA DfE (2012, draft) identified a toxicity concern for TGSA based on potential formation of the epoxide oxidation product.

Potential to biomonitor

Physical and chemical properties:

Molecular weight = 330.40 g/mol

Parameter	PBT Profiler* (2012)	U.S. EPA DfE** (2012, draft)
Octanol/water partition coefficient: LogK _{ow}	4.43 (exp)	3.22 (exp)
Vapor pressure (mm Hg)	1.3 x 10 ⁻¹¹ (25°C)	9.5 x 10 ⁻¹⁰ (exp)
Water solubility (mg/L)	76 (25°C)	4.79±0.5 at 20.3°C (exp)

* Values estimated using PBT Profiler, except where noted as experimental (exp).

**Experimental values cited by U.S. EPA DfE.(2102, draft)

Bioaccumulation and persistence:

	PBT Profiler (2012)	U.S. EPA DfE (2012, draft)
Bioaccumulation	BCF = 390	Low ^c BCF = 62
Persistence	<i>Half-lives (days)</i> Water 38 Soil 75 ^a Marine Sediment 340 ^b Ambient Air 0.15	High ^c

^a Predicted to be *persistent* according to U.S. EPA criteria

^b Predicted to be **very persistent** according to U.S. EPA criteria

^c U.S. EPA DfE (2012, draft) analyzed parameters estimated using EPI Suite and PBT Profiler to make an overall determination of “Low”, “Moderate” or “High.” Details on the basis for these determinations are available in U.S. EPA DfE (2012, draft).

Pharmacokinetics and metabolism: U.S. EPA DfE (2012, draft) noted that “oxidation of the terminal double bonds in the body via an epoxide intermediate is expected.”

Past biomonitoring studies: No studies located.

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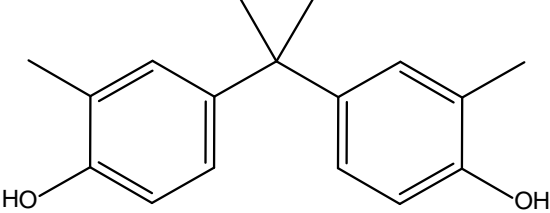
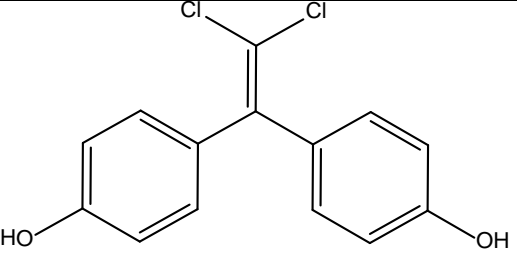
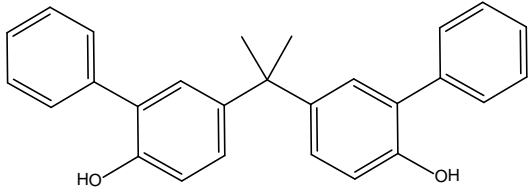
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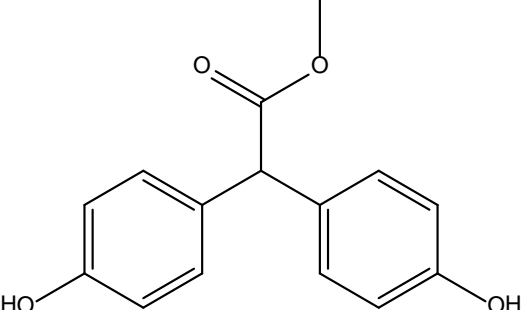
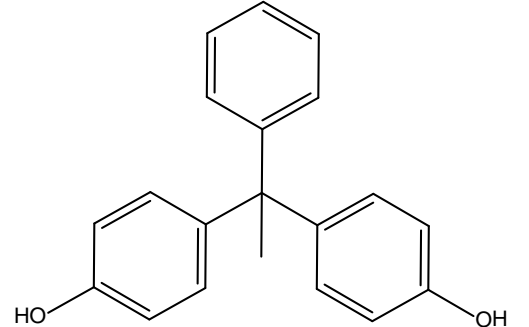
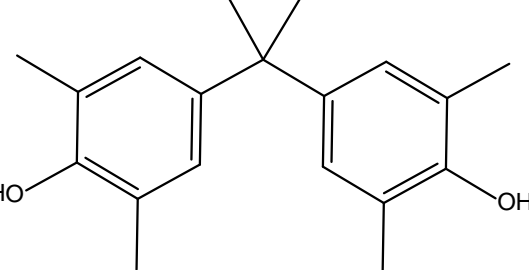
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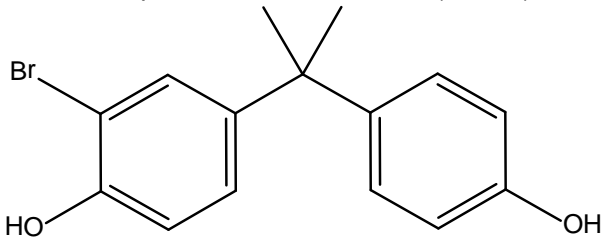
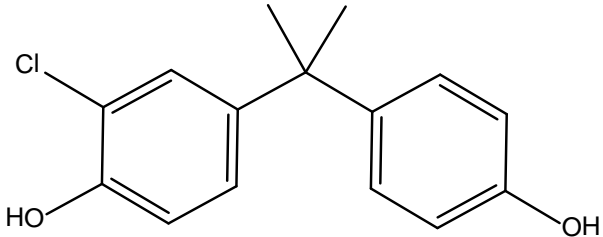
Some other p-p' bisphenols and diglycidyl ethers of p-p' bisphenols

CAS No.	Chemical	Structure	Selected references that mention the chemical
79-97-0	Bisphenol C (BPC) <i>4,4'-(1-methylethylidene)bis[2-methylphenol]</i>		NTP 2008; U,S, EPA DfE, 2012 draft; Ike et al. 2006; Kitamura et al. 2005; Letcher et al. 2005; Sakai et al. 2007; Zhang et al. 2010a
14868-03-2	Bisphenol C2 (BPC2) <i>4,4'-(2,2-dichloroethenyldene)bisphenol</i>		NTP 2008
24038-68-4	BisOPP-A <i>2,2-Bis(3-phenyl-4-hydroxyphenyl)propane</i>		U,S, EPA DfE, 2012 draft

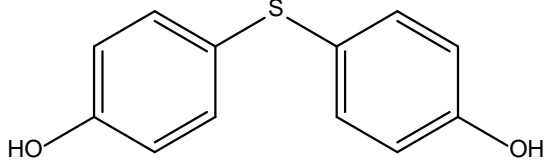
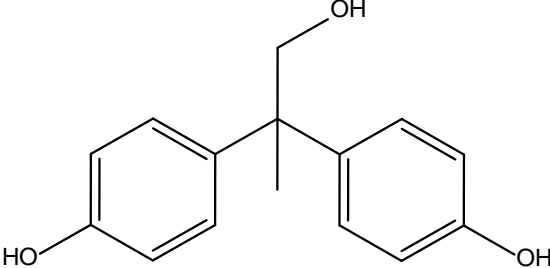
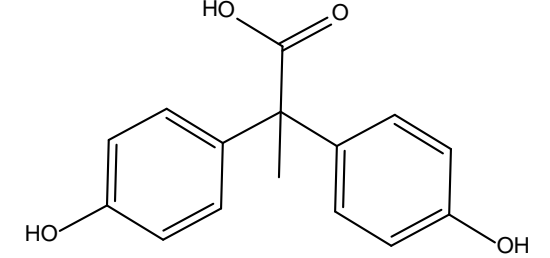
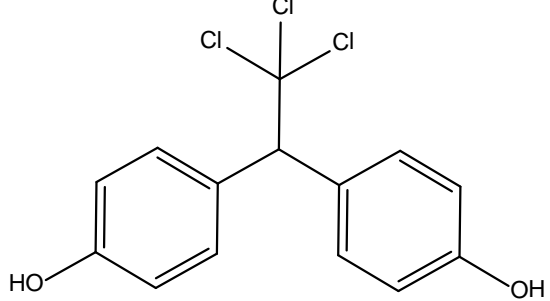
p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
5129-00-0	<p>MBHA</p> <p><i>Methyl bis(4-hydroxyphenyl)acetate</i></p>		<p>U,S, EPA DfE, 2012 draft</p>
1571-75-1	<p>BPAP</p> <p><i>4,4'-(1-Phenylethylidene)bisphenol</i></p>		<p>Zhang et al 2010a; Okada et al., 2008; Liao et al. 2012b; U.S. EPA DfE, 2012 draft; Ministry of Economy, Trade and Industry (METI), 2002</p>
5613-46-7	<p>Tetramethylbisphenol A (TMBPA)</p> <p><i>4,4'-(1-Methylethylidene)bis[2,6-dimethylphenol]</i></p>		<p>NTP, 2008; Kitamura et al. 2005; Letcher et al. 2005; Okuda et al. 2011</p>

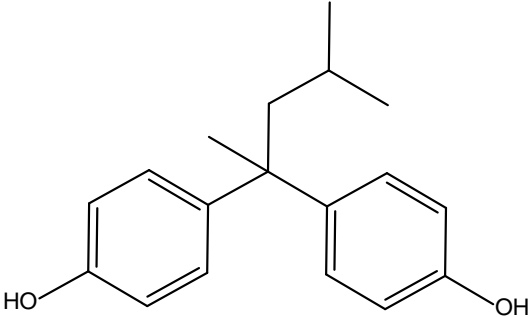
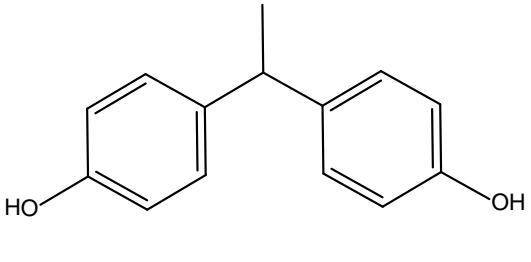
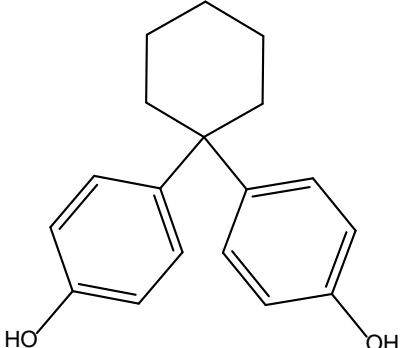
p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
6073-11-6	Bromobisphenol A (BrBPA) <i>2-Bromo-4-[1-(4-hydroxyphenyl)-1-methylethyl]phenol</i>	<p>Example brominated structure (BrBPA)</p> 	NTP, 2008
29426-78-6	Dibromobisphenol A (di-BrBPA) <i>4,4'-(1-Methylethylidene)bis[2-bromophenol]</i>		
6386-73-8	Tribromobisphenol A (tri-BrBPA) <i>2,6-Dibromo-4-[1-(3-bromo-4-hydroxyphenyl)-1-methylethyl]phenol</i>		
74192-35-1	Chlorobisphenol A (ClBPA) <i>2-Chloro-4-[1-(4-hydroxyphenyl)-1-methylethyl]phenol</i>	<p>Example chlorinated structure (ClBPA)</p> 	NTP, 2008; Sui et al 2012 Chlorinated derivatives of BPA have been shown to form in wastewater (Fukazawa et al., 2002)
79-98-1	3,3'-Dichlorobisphenol A (3,3'-di-ClBPA) <i>4,4'-(1-Methylethylidene)bis[2-chlorophenol]</i>		
14151-65-6	3,5-Dichlorobisphenol A (3,5-di-ClBPA) <i>2,6-Dichloro-4-[1-(4-hydroxyphenyl)-1-methylethyl]phenol</i>		
40346-55-2	Trichlorobisphenol A (tri-ClBPA) <i>2,6-Dichloro-4-[1-(3-chloro-4-hydroxyphenyl)-1-methylethyl]phenol</i>		
79-95-8	Tetrachlorobisphenol A (tetra-ClBPA) <i>Phenol, 4,4'-(1-methylethylidene)bis[2,6-dichloro-</i>		

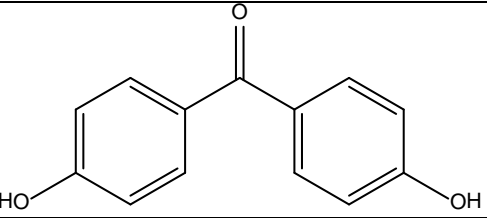
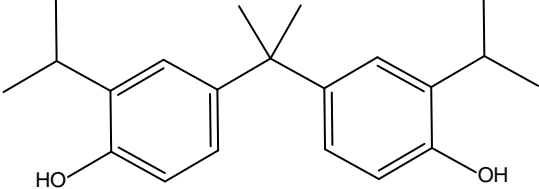
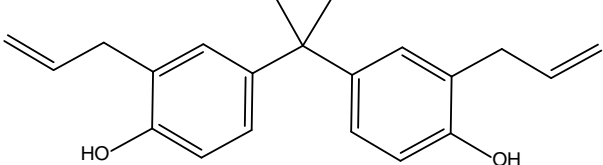
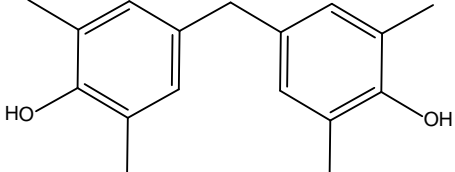
p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
2664-63-3	4,4'-Thiobisphenol (TBP) <i>4,4'-thiodiphenol (TDP)</i> <i>Bis(4-hydroxyphenyl)sulfide</i>		NTP, 2008; Chen et al. 2002; Hashimoto et al. 2001; Ike et al. 2006; Yamasaki et al., 2003a; Sakai et al. 2007; METI, 2002
142648-65-5	2,2-Bis(4-hydroxyphenyl)propanol (BPA ol)		NTP, 2008
92549-67-2	2,2-Bis(4-hydroxyphenyl)propionic acid (BPAacid)		NTP, 2008
2971-36-0	2,2-Bis(p-hydroxyphenyl)-1,1,1-trichloroethane (HPTE) <i>4,4'-(2,2,2-trichloroethylidene)bisphenol</i>		NTP, 2008

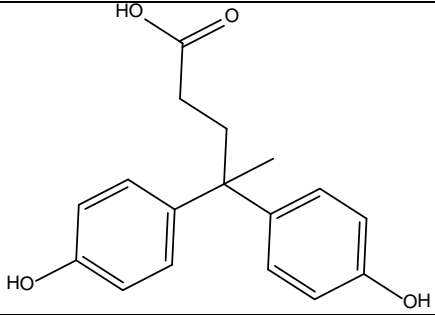
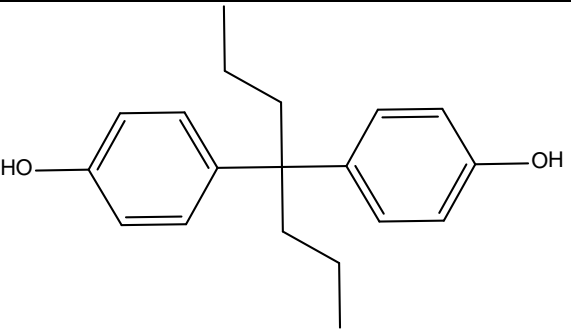
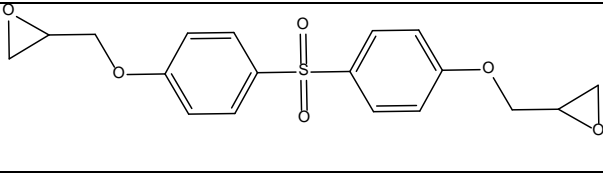
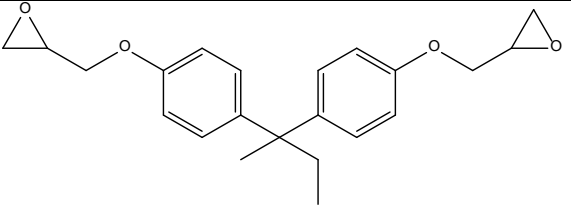
p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
6807-17-6	<p>2,2-Bis(4-hydroxyphenyl)-4-methylpentane (Bis-MP)</p> <p><i>4,4'-(1,3-dimethylbutylidene)bisphenol</i> <i>Bis MIBK</i></p>		NTP, 2008; Yamasaki 2003a
2081-08-5	<p>Bisphenol AD (BPAD) or Bisphenol E (BPE)</p> <p><i>4,4'-Ethylidenebisphenol</i> <i>1,1-Bis(4-hydroxyphenyl)ethane</i></p>		Okada et al. 2008; Okuda et al. 2011; Sui et al 2012; Kitamura et al. 2005; NTP, 2008; Hashimoto et al. 2001; Ike et al. 2002; Chen et al. 2002; Sakai et al. 2007; Zhang et al. 2010a
843-55-0	<p>Bisphenol Z (BPZ)</p> <p><i>4,4'-cyclohexylidenebisphenol</i> <i>1,1-Bis(p-hydroxyphenyl)cyclohexane</i></p>		NTP, 2008; Kitamura et al. 2005; Liao et al. 2012b; Okuda et al. 2011; Sakai et al. 2007; Yamasaki et al. 2004; Zhang et al. 2010a

p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
611-99-4	Bis(4-hydroxyphenyl) methanone 4,4'-Dihydroxybenzophenone (HBP) Bis(4-hydroxyphenyl) ketone		NTP, 2008; Chen et al. 2002; Hashimoto et al. 2001; Ike et al. 2006; METI, 2002; Perez et al., 1998; Yamasaki et al. 2003a
127-54-8	Bisphenol G (BPG) <i>2,2-Bis(4-hydroxy-3-isopropylphenyl)propane</i>		
1745-89-7	4,4'-(1-methylethylidene)bis[2-(2-propen-1-yl)phenol]		METI, 2002; Letcher et al. 2005
5384-21-4	4,4'-Methylenebis(2,6-dimethylphenol)		METI, 2002

p,p'-Bisphenols and their diglycidyl ethers

CAS No.	Chemical	Structure	Selected references that mention the chemical
126-00-1	4,4-Bis(4-hydroxyphenyl) valeric acid		METI (2002)
7425-79-8	4,4-Bis(4-hydroxyphenyl)heptane		Perez et al., 1998
3878-43-1	Bisphenol S diglycidyl ether (BSDGE) <i>Bis[p-(2,3-epoxypropoxy)phenyl]sulfone</i>		Park et al. 2004; Cerda et al. 2009 patent application
	Bisphenol B diglycidyl ether		Cerda et al. 2009 patent application