

G. Phthalates

The following phthalates are discussed in this document:

Chemical Name	Chemical Abstract Service (CAS) number
Butyl benzyl phthalate (BBP)	85-68-7
Dibutyl phthalate (DBP)	84-74-2
Di (2 – ethylhexyl) phthalate (DEHP)	117-81-7

1. Overview

Phthalates are manufactured chemicals added to polyvinyl chloride (PVC), plastics, paints, cosmetics, wood varnish, and medical supplies to increase flexibility or improve other characteristics, such as durability. In addition to being in consumer products, phthalates are pervasive in the environment and have been found in food, drinking water, household dust, and indoor air (Agency for Toxic Substances and Disease Registry [ATSDR], 2002; Centers for Disease Control and Prevention [CDC], 2010d; Consumer Products Safety Commission [CPSC], 2010a). It is likely that children’s mouthing, chewing and crawling behaviors result in greater relative exposure to phthalates when compared to adults. Phthalate exposure can occur through ingestion, inhalation, and direct contact (ATSDR, 2002; Environmental Protection Agency [EPA], 2009).

Laboratory tests have shown that phthalates can cause developmental and reproductive effects, kidney and liver damage, as well as mortality (ATSDR, 2002; CPSC 2010a; EPA, 2009). Some studies have also reported adverse effects of phthalate exposure on human reproductive and developmental outcomes (EPA, 2009; Swan et. al, 2005). Surveys of human populations are currently being completed in effort to further investigate this possibility.

Recently, interest in the possible health effects from exposure to several phthalates in combination has risen. An evaluation of phthalates and anti-androgen exposure has been proposed and is scheduled to be conducted by the CPSC Chronic Hazard Advisory Panel (CHAP) (EPA, 2009; National Academy of Sciences, 2008). Information about this work is available at <http://www.cpsc.gov/about/cpsia/chapmain.html>

Di (2–ethylhexyl) phthalate (DEHP) has been named a probable human carcinogen by EPA in the Integrated Risk Information System (IRIS). The classification of DEHP as a carcinogen varies by agency, however. The National Toxicology Program has categorized DEHP as “reasonably anticipated to be a human carcinogen,” while the International Agency for Research on Cancer (IARC) has categorized DEHP as “Group 3: not classifiable as to human carcinogenicity” (ATSDR, 2002; EPA, 1991; International Agency for Research on Cancer [IARC], 2000). The other two phthalates, butyl benzyl phthalate (BBP), and dibutyl phthalate (DBP), are not considered to be carcinogens by these agencies.

As described below, there are already regulations in place that attempt to limit a child’s exposure to phthalates. However, compliance with regulations may vary. In addition, phthalates are still in many consumer products. While these products may not be specifically designed for children,



many of the products are in the home environment where there are pathways of exposure for children. In addition, women who are pregnant could have exposure to items containing phthalates, possibly resulting in fetal exposure.

2. Brief chemical profiles

a. Butyl benzyl phthalate (BBP)

CAS Number 85-68-7

2006 U.S. production volume (manufacturer or imported): 50-100 million pounds (EPA, 2010a)

Use: BBP is used in polyvinyl chloride (PVC) as a stain-resistant plasticizer, specifically in vinyl tiles. The Household Products Database lists BBP in several products used in home maintenance, such as tile mastic, caulk, and sealants, as well as some paints and adhesives (National Library of Medicine [NLM], 2010a).

EPA Toxic Release Inventory (TRI): Reporting releases of this chemical is not currently required by EPA under TRI. Reporting was required from 1993-1998, where TRI data show BBP was reported released in Minnesota in quantities ranging from 875 pounds (1993) to 4,591 pounds (1992). The largest release amount in 1992 was reported by a cabinet maker conducting on-site disposal of the chemical (EPA, 2010b). Because of recent interest in this chemical, EPA is considering proposing rules that would once again require reporting of BBP releases to the TRI (EPA, 2009).

NHANES: Biomonitoring data from NHANES show that metabolites of this chemical are found in urine samples from all population groups (children 6-11 years and 12-19 years, adults, males, females and in people of the sampled ethnicities) (CDC, 2010a).

Other biomonitoring data:

BBP was reported in human adipose tissue in the U.S. (Hazardous Substances Data Bank [HSDB], 2010a).

Environmental disposition of the chemical: (Note: this information is not intended to be comprehensive.) BBP has been found in indoor air, fish, drinking water, surface water, groundwater, plants, animals, runoff water (HSDB, 2010a).

EPA Integrated Risk Management System Oral Reference Dose:

2×10^{-1} mg/kg/day (Liver-to-body weight and liver-to-brain weight ratios in rats)
Uncertainty factor: 1000 (EPA, 1993)

EPA Integrated Risk Management System Inhalation Reference Concentration:

None

Action in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits BBP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains BBP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of BBP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

b. Dibutyl phthalate (DBP)

CAS Number: 84-74-2

2006 U.S. production volume (manufactured or imported): 10-50 million pounds (EPA, 2010c)

Uses: DBP is used for manufacture of plastics, paints, wood varnishes, and lacquers. It has also been used in textiles, propellants, paper, printing inks, and cosmetics such as nail polish (ATSDR, 2001; CDC, 2010c; U.S. Food and Drug Administration [FDA], 2010). The Household Products Database shows that DBP is found in home maintenance products like joint compound and crack filler, as well as floor finishers and cosmetics (NLM, 2010b). It appears that DBP was used in food packaging in the past. In recent years, industry representatives from the American Plastics Council and the American Chemistry Council have stated that food packaging in the U.S. no longer contains phthalates (Enneking, 2006). It is unclear if phthalates are no longer in *any* food packaging, including food packaging manufactured outside of the U.S. (Note: Minn. Stat. 2010 116.9405 exempts food packaging from consideration for Priority Chemicals, except for packaging used for baby food or infant formula.)

EPA Toxic Release Inventory (TRI) data: According to the TRI, the amount of DBP that has been reported released to air, water or land in Minnesota from 1991-2009 has been zero for most years, except 1991, 1992, 1993, and 2001. In 2001, there were 400 pounds reported released, with no further releases reported since that time (EPA, 2010c).

NHANES: Biomonitoring information from NHANES shows that metabolites of this phthalate are found in all population groups tested. There were reportedly age-related differences in levels among the children tested, with toddlers showing the highest median levels of urinary metabolites from the 1999-2004 data (CDC, 2010c). From the 1999-2000 data, children age 6-11 years showed higher median level concentrations than adults and adolescents (CDC, 2010c).

Other biomonitoring data:

DBP has been found in human adipose tissue, tissue, blood, breast milk, and serum (HSDB, 2010b).

Environmental disposition: (Note: This list is not intended to be comprehensive.)

This chemical has been reported in drinking water, groundwater, surface water, seawater, precipitation, wastewater treatment plant leachate, landfill leachate, soil, sediment, indoor air, rural area air, urban area air, fish, seafood, birds, and household dust (HSDB, 2010b).

EPA Integrated Risk Management System Oral Reference Dose:

1×10^{-1} mg/kg/day (Increased mortality in rat studies)

Uncertainty factor: 1000 (EPA, 1990).

EPA Integrated Risk Management System Reference Concentration:

None

Action in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits DBP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains DBP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of DBP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

c. Di (2-ethylhexyl) phthalate (DEHP)

CAS Number 117-81-7

2006 U.S. production volume (manufactured or imported): 100-500 million pounds (EPA, 2010a).

Uses: DEHP is used as a plasticizer to soften plastic and polyvinyl chloride (PVC) products (CDC, 2010b; HSDB, 2010c). It is widely used in medical devices (intravenous tubing and blood bags), as well as in a variety of consumer products and industrial products. Example of products containing DEHP from ATSDR are “wall coverings, tablecloths, floor tiles, furniture upholstery, shower curtains, garden hoses, swimming pool liners, rainwear, baby pants, dolls, some toys, shoes, automobile upholstery and tops, packaging film and sheets, sheathing for wire and cable, medical tubing, and blood storage bags” (ATSDR, 2002). CDC notes that DEHP has been removed from most toys and packaging in the U.S. (CDC, 2010b). DEHP was used in baby

teethers and rattles in the past, but it is no longer used in these products produced domestically (ATSDR, 2002; CPSC, 2010d).

EPA Toxic Release Inventory (TRI): During the past 10 years, the amount of DEHP reported released in Minnesota in the TRI has decreased to nearly zero. Since 2006, no releases to land, air or water have been reported. In 2009, one company reported 250 pounds of DEHP shipped off-site for treatment. The peak amount of DEHP released was in 1995, when over 42,000 pounds were reported released, mostly by a rubber roller manufacturer. Thereafter, the reported releases of DEHP from the manufacturing processes appear to have decreased in the state (EPA, 2010d).

NHANES: The four metabolites of DEHP surveyed through NHANES were Mono-2-ethylhexyl phthalate (MEHP), Mono-(2-ethyl-5-hydroxyhexyl) phthalate (MEHHP), Mono-(2-ethyl-5-oxohexyl) phthalate (MEOHP) and Mono-(2-ethyl-5-carboxypentyl) phthalate (MECPP). All of the metabolites were detected in all population groups. NHANES reports relatively higher levels in children when compared to adults, and higher levels in females when compared to males (CDC, 2010b).

Other biomonitoring data: DEHP has been found in human adipose tissue, serum, breast milk, and cord blood (HSDB, 2010c).

Environmental disposition: (Note: This information is not intended to be comprehensive.) This chemical has been detected in drinking water, groundwater, surface water, seawater, precipitation, soil, sediment, indoor air, rural area air, urban area air, fish, animals, dairy milk, and house dust (HSDB, 2010c).

EPA Integrated Risk Management System Oral Reference Dose:
 2×10^{-2} mg/kg/day (Increase in relative weight in guinea pig study)
Uncertainty factor: 1000 (EPA, 1991)

Actions in U.S. states:

(Information taken from the Lowell Center for Sustainable Production States US Chemical Policy database at <http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php>.)

California: Prohibits DEHP and other phthalates in products intended for young children at quantities greater than 0.1% (California Health & Safety Code §§ 108935-108939).

Vermont: Restricts sale of a toy or childcare article that contains DEHP and other phthalates (18 V.S.A. § 1511).

Washington: Limits the amount of DEHP and other phthalates in children's products (RCW 70.240.020). This law was pre-empted by the Federal Consumer Product Safety Improvement Act.

(Lowell Center for Sustainable Production, 2010).

3. Statutory Requirements

The table and information summary below provide information about how the three phthalates meet the criteria of Minn. Stat. 2009 116.9401 – 116.9407.

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	<p>BBP: "Phthalate syndrome": birth defects at high doses, male reproductive organ development</p> <p>DBP: Birth defects, reproductive organ development</p> <p>DEHP: Birth defects, fetal death</p>	<p>CPSC 2010b NTP 1989</p> <p>CPSC 2010c EPA 2009 HSDB 2010b</p> <p>ATSDR 2002 CPSC 2010d NTP 1983</p>
Subd. (e)(2) cause cancer, genetic damage, or reproductive harm	<p>BBP: Decrease in sperm production in parent: effects extended to offspring</p> <p>DBP: Reproductive effects: decreased pregnancies, reduced fertility</p> <p>DEHP: Reproductive effects: changes to reproductive organ morphology</p> <p>DEHP: Cancer: B2 – probable human carcinogen</p> <p>DEHP: Cancer: Group 3: Not classifiable as to human carcinogenicity</p> <p>DEHP: Cancer: Reasonably anticipated to be a human carcinogen</p>	<p>CPSC 2010b HSDB 2010a</p> <p>CPSC 2010c</p> <p>ATSDR 2002 CPSC 2010d EPA 2009</p> <p>EPA 1991</p> <p>IARC 2000</p> <p>NTP 2005</p>
Subd. (e)(3) disrupt the endocrine or hormone system	<p>BBP: increases peroxisome proliferating activated receptor and pituitary-gonadal hormones, decreases thyroid hormones</p> <p>DBP: Possible hormonal effects</p> <p>DEHP: Estradiol metabolism and estrogen receptor function altered</p>	<p>CPSC 2010b</p> <p>CPSC 2010c</p> <p>CPSC 2010d</p>
Subd. (e)(4) damage the nervous system, immune system, or organs, or cause other systemic toxicity	<p>BBP: Decreased body weight, increased organ weights</p> <p>DBP: Increased mortality, toxic effects on liver and kidney</p> <p>DEHP: Toxic effects on kidney, liver, reproductive organs, thyroid</p>	<p>CPSC 2010b EPA 1993 HSDB 2010a</p> <p>CPSC 2010c EPA 1990</p> <p>ATSDR 2002 CPSC 2010d HSDB 2010c</p>

Statute	Information	References
Subd. (e)(5) be persistent, bioaccumulative, and toxic;	DEHP: Persistent in environment, can be bioaccumulative in some species, but often metabolized	ATSDR 2002 HSDB 2010c
Subd. (e)(6) be very persistent and very bioaccumulative		
Minn. Stat. 116.9403		
Subd. (a) (1): has been identified as a high-production volume chemical by the United States Environmental Protection Agency	BBP: 50 to 100 million pounds DBP: 10 to 50 million pounds DEHP: 100 to 500 million pounds	EPA 2010a
Subd (2) Meets any of the following criteria:		
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	BBP: Found in human adipose tissue, amniotic fluid, blood, breast milk, cord blood, urine DBP: Found in human adipose tissue, breast milk, serum, urine DEHP (or metabolites): Found in blood, human breast milk, lungs of newborns, urine, other tissues and fluids	CDC 2010b CPSC 2010b HSDB 2010a CPSC 2010c HSDB 2010b ATSDR 2002 CPSC 2010d HSDB 2010c
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	BBP: Indoor air in residences, household dust, drinking water DBP: Found in indoor air, household dust , drinking water, other products in the home environment DEHP: Found in indoor air, drinking water, household dust	CPSC 2010b HSDB 2010a ATSDR 2002 CPSC 2010c HSDB 2010b NLM 2010b ATSDR 2002 HSDB 2010c
Subd. (a)(2)(iii): the chemical has been found through monitoring to be present in fish, wildlife, or the natural environment	BBP: found in fish, animals, soil DBP: Found in fish, shellfish, groundwater DEHP: Found in fish, wildlife, surface waters, rainwater, groundwater	CPSC 2010b HSDB 2010a HSDB 2010b ATSDR 2002 HSDB 2010c

4. Current Regulations

Concern about phthalates has prompted international, federal, and state level actions. BBP, DBP, and DEHP were prohibited by the European Commission in 1999 in soft toys intended for children age 3 or younger that were meant to be put into a child’s mouth. The ban was expanded and made permanent in 2005 by European Commission Directive 2005/84/EC, which prohibited use of BBP, DBP and DEHP in all toys and childcare articles. The phthalates diisodecyl phthalate (DIDP), di-iso nonyl phthalate (DINP) and di-n-octyl phthalate (DNOP) were restricted from use in toys that could be put into a child’s mouth (Europa, 2008).

The Australian government is currently studying phthalates DEHP, DIDP, BBP, DBP, and others. In a report on DEHP, the Australian government's Department of Health and Ageing stated that the reproductive risk to children and the general population from this chemical was unacceptable and called for restriction on this chemical in toys, childcare articles, and cosmetics (Australian Department of Health and Ageing, 2010).

In the U.S., the CPSC implemented a permanent ban on three phthalates, DEHP, BBP, and DBP, in children's products under the Consumer Product Safety Improvement Act of 2008. Children's product can contain no more than 0.1% of these phthalates individually (CPSC, 2008). An additional three chemicals, DINP, DIDP and DnOP were temporarily banned from children's products meant to be placed in a child's mouth. These three chemicals are being assessed by the CPSC CHAP. The CHAP will make recommendations about whether the temporary ban on the three chemicals should be extended (CPSC, 2010).

5. Planned Actions

a. Federal

(1) Consumer Product Safety Commission (CPSC)

As described above, the three phthalates, DINP, DIDP and DnOP, that are under a temporary ban in children's products will be evaluated by the CPSC CHAP. Decisions from the CHAP will guide future regulation of phthalates in consumer products. The work of the CHAP is expected to be completed in 2012.

(2) Environmental Protection Agency

The EPA has created a Chemical Action Plan for phthalates that describes the use of phthalates, associated health and environmental concerns, physical characteristics, risk management, and planned actions. Some of the planned actions for 2010-2012 include:

- Initiate rulemaking to add six of the eight phthalates addressed in EPA's Action Plan to the TRI: Diisobutyl phthalate (DIBP), BBP, Di-n-pentyl phthalate (DnPP), DnOP, DINP and DIDP.
- Consider implementing a significant new use provision for di-n-pentyl phthalate (DnPP) to require manufacturers or importers to notify EPA before using this chemical in any significant new use processes.
- Lay groundwork to consider initiating rulemaking under TSCA to regulate eight phthalates, after cooperating with CPSC and FDA to assess the use, exposure and substitutes available.
- Study the cumulative effect of exposure to several of the phthalates. Also, the EPA plans to look at the impacts of phthalates on children.
- Conduct a Design for the Environment and Green Chemistry alternatives assessment by 2012 (EPA, 2009).

b. States

As noted above, some states, specifically California, Vermont, and Washington, have implemented bans similar to the CPSC on children's toys or child care products containing phthalates in quantities of 0.1% or more. In the past four years, there has been other legislation introduced related to phthalates in an additional 17 states, including Minnesota. Many of the bills were not passed through the states' legislative body or were vetoed (Lowell Center for Sustainable Production, 2010). It is unknown if future actions are planned on the state level, though the trend in recent years has been for state action on chemicals of concern.

6. Conclusion

The ubiquity of phthalates and the current incomplete understanding of associated health effects in humans, especially from chronic and/or combined low dose exposures, raise concern. Currently, MDH has selected BBP, DBP, DEHP for the Priority Chemical list. All of these chemicals were high production volume chemicals in 2006 and in three or more of the remaining EPA IUR inventories since 1990. In addition, these chemicals meet relevant criteria of Minn. Stat. 2010 116.9401 – 116.9407, including exhibiting toxicity and being detected in human body fluids, the home environment, or the natural environment. There is a relatively new national ban on these three chemicals in children's toys and child care articles, but exposure will likely continue because of use in other consumer products that children and pregnant women contact.

7. References

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