



# PHTHALATES FREQUENTLY ASKED QUESTIONS

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## **What are phthalates?**

Phthalates are odorless, colorless chemicals that are added to plastic to make it soft and flexible. Phthalates are a family of chemicals that include diethyl phthalate (DEP), diethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), butyl benzyl phthalate (BBP), diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), di-n-octyl phthalate (DNOP), and many other distinct types. The polyvinyl chloride (PVC) plastics industry uses phthalates as additives to improve the flexibility of its products, including home vinyl siding, flooring, furniture, food packaging, toys, clothing, car interiors, and medical equipment, including IV bags. In addition, other manufacturers use phthalates in personal care products such as soap, shampoo, deodorant, hand lotion, nail polish, cosmetics, and perfume, as well as industrial products like solvents, lubricants, glue, paint, sealants, insecticides, and detergent.<sup>1,2</sup>

## **How long have we known about the problems phthalates can pose?**

Scientists began studying the toxicity of several phthalates as early as the 1950s and discovered significant evidence of environmental and human contamination in the early 1970s, including the leaching of phthalates into human blood from PVC bags used in hospitals.<sup>3</sup> As noted by the Worldwatch Institute,<sup>4</sup> NASA scientists warned against using PVC in the space program in 1971 because of poor physical properties and the presence of phthalates. They noted that “substitute polymers . . . are available and in many cases they have far superior physical properties at a small sacrifice in immediate cost.”<sup>5</sup> Nonetheless, phthalates remain in wide use today.

## **Why are phthalates such a problem?**

Phthalates are known endocrine disruptors and can affect normal hormonal processes. Phthalates don't stay in the plastics they soften or in the countless other products in which they are used. Instead, they migrate into the air,<sup>6</sup> into food, and into people, including babies and children. CDC scientists have found phthalates in the urine and blood of Americans of all ages.<sup>7</sup> Phthalate exposure has been linked to reduced testosterone levels,<sup>8</sup> lowered sperm counts,<sup>9</sup> early puberty in girls,<sup>10</sup> genital defects in baby boys.<sup>11</sup> Moreover, several studies in humans have shown some of these toxic effects at levels similar to what the average American is currently exposed to.<sup>12, 13</sup>

## **Isn't the dose of phthalates too low to make a difference in children?**

The theory associated with this myth assumes that a little bit of a toxic chemical is ok. It also assumes that exposure to one particular chemical through one particular route of exposure, in this case toys, is the only chemical to which a person will ever be exposed. This theory further assumes that all people have the same genetic responses to toxins and that children and infants have immune and endocrine system as mature as those of adults. These assumptions are scientifically outdated<sup>14,15</sup> and must be addressed.

In fact, children are exposed to hundreds if not thousands of chemicals every day. Some, like phthalates, are known toxicants, some are safe and some have little or no data to support any claim of safety or hazard. No one can tell you how all of these chemical interact with each other or what kind of effect they can have on a developing child. What we do know, though, is that phthalates often interact with each other to produce far more devastating impacts than they would acting alone. Recent studies coming out of the US Environmental Protection Agency have shown that when used in combination, certain phthalates, including those proposed to be banned by this measure, interact with each other to produce additive and sometimes synergistic effects.<sup>16</sup> In essence, it is like saying 1+1 doesn't equal 2 but rather 4 or 5. Even more alarming, new studies show that phthalates are interacting

with other types of chemicals to produce devastating impacts that don't appear when used alone.<sup>17,18</sup> It is unclear why this happens.

Additionally, evidence is mounting that, when it comes to chemicals and children, it's not just the dose that makes the poison. Timing of exposure is just as important.<sup>19,20</sup> Infants and children are not just smaller adults. They are still developing and are changing almost every day. A small dose of chemical can have a devastating impact one day whereas a few days or weeks later, the chemical would not have the same effect. This is because their endocrine systems are exquisitely sensitive and are sending signals to the brain and vice versa to direct growth and development. Phthalates interrupt these critical signals and, although the effects may not show up for many years, this interruption can set children on a path for later life diseases such as infertility or cancer of the prostate or breast.<sup>21</sup>

### **Isn't DINP the only phthalate used in toys and hasn't it been proven safe?**

Studies done at the US EPA have shown that DiNP causes harm to the male reproductive tract similar to the changes seen after exposure to the phthalates DEHP and DBP.<sup>22</sup> Furthermore, independent studies done by the San Francisco Chronicle<sup>23</sup> and Environment California<sup>24</sup> have found other phthalates in children's toys including DEHP, DNOP, BBP and DBP. These phthalates were found in levels that would violate European and California standards for these phthalates in children's toys. Furthermore, the phthalates that have been shown to cause harm to the male reproductive tract seem to be able to act in an additive manner – so exposure to DEHP and DBP can cause a cumulative harm larger than exposure to one of these chemicals alone.

### **Why is the Consumer Product Safety Commission<sup>25</sup> review of phthalates flawed?**

The CPSC considered only one phthalate DiNP, when determining the safety of phthalates in children's toys. They have not evaluated other phthalates either individually or in combination in children's toys. Yet, we know there are many different types of phthalates in children's toys. Exposure to just one phthalate does not represent real world situations and a risk assessment of just one phthalate isn't going to accurately predict safe exposure levels.

As mentioned previously, the dose as well as the timing of exposure are very important when considering the toxic outcome. The CPSC study of DiNP used outdated science and did not include carefully designed studies that would find reproductive toxicity during critical windows of exposure. Instead, the CPSC study considered liver toxicity when determining the safety of DiNP, an end point that is not nearly as sensitive as reproductive toxicity.

Furthermore, there were many limitations to the CPSC analysis in that they did not consider other routes of exposure to phthalates other than mouthing behavior (ie they didn't consider dermal exposures or ingestion from contaminated food sources) and they didn't consider the evidence that phthalates act in an additive manner.

Even taking all of the flaws of this study into account, the CPSC concluded that phthalate exposure may be a risk to children who mouth phthalate laden products for more than 75 minutes per day. Many children mouth many different phthalate laden products for more than 75 minutes per day and many are also exposed to phthalates through their shampoo, soap and food containers.<sup>26</sup>

### **Won't the removal of phthalates from our children's products make them more brittle and cause a choking hazard?**

There are many viable alternatives to phthalates. Many countries have banned the use of these chemicals; yet their children have soft toys and there have been no reports of increased choking from brittle toys. This is simply a scare tactic to distract us from the real problem.

### **Hasn't the EU Chemicals Bureau said that phthalates are safe?**

The European Union has banned all of the phthalates listed in this measure and they have upheld their decision time and again. While the European Chemicals Bureau did release a report minimizing the risk of two phthalates, this report was contradictory to other EU and scientific, peer-reviewed studies and the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment overturned this report in 2004<sup>27</sup>. The EU upheld their ban on these

phthalates because of the overwhelming evidence that shows that phthalates are unsafe for children. Studies that have been released since that report continue to reaffirm the toxic effects of phthalates and the effects of phthalate mixtures.

### **Aren't the phthalate alternatives more dangerous and untested?**

There are many potential alternatives to phthalates and while it may be true that some of them are as toxic, it is also true that there are other, safer alternatives. Phthalates are used primarily with polyvinyl chloride (PVC), a plastic that does not need to be used to make toys. There are many other types of plastic that manufacturers can use such as polyethylene or polypropylene that are considered to be safer plastics that do not require the use of phthalates.<sup>28</sup>

### **Will taking phthalates out of toys hurt businesses?**

No. In fact, since the EU banned phthalates from toys, toy sales have increased, at a pace that exceeds their growth in the United States.<sup>29</sup>

*For more information, please contact the Breast Cancer Fund:*

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<sup>1</sup> Phthalate Esters Panel. (2007). Phthalates—the basics Retrieved May 2, 2008 from <http://www.phthalates.org/whatare/index.asp>

<sup>2</sup> Centers for Disease Control (CDC) (2005). Third national report on human exposure to environmental chemicals, p. 253.

<sup>3</sup> Carpenter CP, et al (1953). Chronic Oral Toxicity of Di-(2-ethylhexyl) Phthalate of Rats, Guinea Pigs, and Dogs. *AMA Archives of Industrial, Hygiene and Occupational Medicine* 8: 219-226.

Mayer FL et al. (1972). Phthalate Esters as Environmental Contaminants. *Nature* 238: 411-413.

Singh AR, et al. (1972). Teratogenicity of Phthalate Esters in Rats. *Journal of Pharmacological Science* 61: 51-55

Jaeger RJ, Rubin RJ. (1972). Migration of a Phthalate Ester Plasticizer from Polyvinyl Chloride Blood Bags into Stored Human Blood and its Localization in Human Tissues. *New England Journal of Medicine* 287: 1114-1118.

<sup>4</sup> McGinn AP. (2000). *Why Poison Ourselves? A Precautionary Approach to Synthetic Chemicals*, Worldwatch Paper 153, November 2000. ISBN: 1-878071-55-6. Worldwatch Institute, Washington DC.

<sup>5</sup> Gross FC, Colony JA. (1973). The Ubiquitous Nature and Objectionable Characteristics of Phthalate Esters in Aerospace Technology. *Environmental Health Perspectives* 3:37-48.

<sup>6</sup> Rudel RA, Brody JG, Spengler JD, et al. (2001). Methods to detect selected potential mammary carcinogens and endocrine disruptors in commercial and residential air and dust samples. *Journal of Air and Waste Management Association* 51:499-513.

<sup>7</sup> Centers for Disease Control (CDC) (2005). Third national report on human exposure to environmental chemicals, p. 253.

<sup>8</sup> Main KM, Mortensen GK, et al. (2005). Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in three months old infants. *Environmental Health Perspectives* 114:270-276.

Wilson VS, Lambright C, et al. (2004). Phthalate ester-induced gubernacular lesions are associated with reduced Insl3 Gene Expression in the fetal rat testis. *Toxicology Letters* 146:207-215.

Parks LG, Ostby JS, et al. (2000). The plasticizer diethylhexyl phthalate induces malformations by decreasing fetal testosterone synthesis during sexual differentiation in the male rat. *Toxicology Science* 58:339-349.

<sup>9</sup> Duty SM, Singh NP, et al (2003). The relationship between environmental exposures to phthalates and DNA damage in human sperm using the neutral comet assay. *Environmental Health Perspectives* 111:1164-1169.

Duty SM, Silva MJ, et al. (2003). Phthalate exposure and human semen parameters. *Epidemiology* 14:269-277.

Rozati R, Reddy PP, et al. (2002). Role of environmental estrogens in the deterioration of male factor fertility. *Fertility and Sterility* 78:11887-1194.

<sup>10</sup> Colón I, Caro D, et al. (2000). Identification of phthalate esters in the serum of young Puerto Rican girls with premature breast development. *Environmental Health Perspectives* 108:8895-900.

<sup>11</sup> Swan SH, Main KM, et al. (2005). Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environmental Health Perspectives* 113:1056-1061.

Fisher JS, Macpherson S, et al. (2003). Human “testicular dysgenesis syndrome”: A possible model using *in-utero* exposure of the rat to dibutyl phthalate. *Human reproduction* 18:1383-1394.

Gray LE Jr, Ostby J, et al. (2000). Perinatal exposure to the phthalates DEHP, BBP, and DINP, but not DEP, DMP, or DOTOP, alters sexual differentiation of the male rat. *Toxicological Sciences* 58:350-365.

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- Skakkebaek NE, et al. (2001). An increasingly common developmental disorder with environmental aspects. *Human Reproduction* 16:972-978.
- Paulozzi LJ. International trends in rates of hypospadias and cryptorchidism. *Environmental Health Perspectives* 107:297-302.
- <sup>12</sup> Swan SH, Main KM, et al. (2005). Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environmental Health Perspectives* 113:1056-1061.
- <sup>13</sup> Main KM, Mortensen GK, et al. (2005). Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in three months old infants. *Environmental Health Perspectives* 114:270-276.
- <sup>14</sup> Calabrese EJ. (2004). Hormesis: From marginalization to mainstream. A case for hormesis as the default dose-response model in risk assessment. *Toxicology and Applied Pharmacology* 197:125-136.
- <sup>15</sup> Koppe JG, et al. (2006). Exposure to multiple environmental agents and their effect. *Acta Paediatrica* 95 (Suppl 453):106-113.
- <sup>16</sup> Howdeshell KL, Furr J, et al. (2007). Cumulative effects of dibutyl phthalate and diethylhexyl phthalate on male rat reproductive tract development: Altered fetal steroid hormones and genes. *Toxicological Sciences* 99:190-202.
- Gray LE Jr, Wilson VS, et al. (2006). Adverse effects of environmental antiandrogens and androgens on reproductive development in mammals. *International Journal of Andrology* 29:96-104.
- <sup>17</sup> Hauser R., et al. (2005). Evidence of interaction between polychlorinated biphenyls and phthalates in relation to human sperm motility. *Environmental Health Perspectives* 113:425-430.
- <sup>18</sup> Rozati R, et al. (2002). Role of environmental estrogens in the deterioration of male factor fertility. *Fertility and Sterility* 78:1187-1194.
- <sup>19</sup> Grandjean P, et al. (2007). The Faroese Statement: Human health effects of developmental exposure to chemicals in our environment. *Basic and Clinical Pharmacology and Toxicology* 102:73-75
- <sup>20</sup> Shea K. (2003). Pediatric exposure and potential toxicity of phthalate plasticizers. *Pediatrics* 111:1467-1474.
- <sup>21</sup> Moral R, et al. (2007). The plasticizer butyl benzyl phthalate induces genomic changes in rat mammary gland after neonatal/prepubertal exposure. *BMC Genomics* 8:453.doi:10.1186/1471-2164-8-453
- Lee KY, Shibutani M, et al. (2004). Diverse developmental toxicity of di-n-butyl phthalate in both sexes of rata offspring after maternal exposure during the period from late gestation through lactation. *Toxicology* 203:221-238.
- <sup>22</sup> Gray LE Jr, Ostby J, et al. (2000). Perinatal exposure to the phthalates DEHP, BBP, and DINP, but not DEP, DMP, or DOTOP, alters sexual differentiation of the male rat. *Toxicological Sciences* 58:350-365.
- <sup>23</sup> Kay J. (2006). San Francisco prepares to ban certain chemicals in products for tots, but enforcement will be tough—and toymakers question necessity. *San Francisco Chronicle* November 19, p. A-1. Retrieved May 5, 2008 from <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2006/11/19/MNG2LMG0J1.DTL&hw=phthalates&sn=001&sc=1000>
- <sup>24</sup> Environment California (2005). The Right Start. Retrieved May 5, 2006 from <http://www.environmentcalifornia.org/center/improving-environmental-health/the-right-start>
- <sup>25</sup> Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP) (2001). Report to the U.S. Consumer Product Safety Commission. Retrieved May 2, 2008 from <http://www.cpsc.gov/library/foia/foia01/os/dinp.pdf>
- <sup>26</sup> Sathanarayana S, Karr CJ, et al. (2008). Baby care products: Possible sources of infant phthalate exposure. *Pediatrics* 121:e260-e268.
- <sup>27</sup> Phthalate-containing soft PVC toys and childcare articles. (2006) Europa: Activities of the European Union, Summaries of Legislation. Retrieved May 2, 2008 from <http://europa.eu/scadpluls/leg/en/lvb/l32033.htm>
- <sup>28</sup> Tickner J. (1999). A review of the availability of plastic substitutes for soft PVC in toys. Department of Work Environment, University of Massachusetts at Lowell, USA. Report commissioned by Greenpeace International.
- <sup>29</sup> Toy Industries of Europe (2006). Toy industry reports industry figures for 2005. Press release, Toy Industries of Europe. [http://www.tietoy.org/spaw2/uploads/files/152-TIE\\_FactFigures\\_2006.pdf](http://www.tietoy.org/spaw2/uploads/files/152-TIE_FactFigures_2006.pdf)
- International Trade Administration. (2006). U.S. Department of Commerce Industry Outlook: Dolls, Toys, Games, and Children's Vehicles NAICS Code 33993 Retrieved May 2, 2007 from [http://www.trade.gov/td/ocg/outlook06\\_toys.pdf](http://www.trade.gov/td/ocg/outlook06_toys.pdf)