

<b>Product Responsibility Best Practices</b>	<b>SUBJECT</b> understanding Phthalates	<b>LAST UPDATE</b> July 2019
	<b>APPLIES TO</b> • Suppliers • Distributors	<b>FOCUS ON</b> understanding the laws that regulate phthalate use and how they affect your promotional products business.
	<b>QUICK LINKS</b> • PPAI Corporate Responsibility: <a href="http://ppai.org/corporate-responsibility">http://ppai.org/corporate-responsibility</a> • UL: <a href="http://industries.ul.com/premiums-promotional-and-licensed-goods">industries.ul.com/premiums-promotional-and-licensed-goods</a> • Consumer Product Safety Commission: <a href="http://www.cpsc.gov">www.cpsc.gov</a>	<b>Intended for beginner compliance programs</b>

*Italic grey text indicates a hyperlink listed in the Online Resources section of this document.*

## What Are Phthalates?

Phthalates are chemicals that are primarily used to soften plastics and make them flexible. They are most often found in soft or flexible plastics like PVC or vinyl (except polyolefins).

Examples include:

- Soft or flexible rubber, except silicone rubber and natural latex
- Foam rubber or foam plastic such as PU foam
- Surface coatings, non-slip coatings, finishes, decals, printed designs
- Elastic materials on apparel such as sleepwear
- Adhesives and sealants

## Phthalates And The Consumer Product Safety Improvement Act (CPSIA)

The *Consumer Product Safety Improvement Act* ("CPSIA") defines a "children's product" as a consumer product designed or intended primarily for children 12 years of age or younger. Products used by children 12 years of age or younger that have declining appeal for teenagers and/or adults are likely to be considered children's products.

In 2008, the CPSIA made it unlawful to manufacture for sale, offer for sale, distribute in commerce or import into the U.S. any *children's toy or child-care article that contains certain phthalates* over specific concentrations.

### Phthalate Limits

There are currently eight regulated phthalates. Three cannot be in any toy or childcare article in concentrations exceeding 0.1 percent. They are di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or benzyl butyl phthalate (BBP). Three additional types of phthalates cannot be in any mouthable toy or part of a toy or child-care article in amounts exceeding 0.1 percent. These are Diisononyl phthalate (DINP), Diisodecyl phthalate (DIDP), Di-n-octylphthalate (DnOP).

These second three phthalates are currently under an interim ban while the commission completes rulemaking based on the Chronic Health Advisory Panel (CHAP) proposal regarding future bans.

Regulated Phthalates	Regulated Products
(DEHP), (DBP), (BBP), (DINP), (DIBP), (DPENP), (DHEXP), (DCHP) not allowed in concentrations exceeding 0.1%	Any children's toy or childcare article
DINP not allowed in concentrations exceeding 0.1%	Any children's toy, or any part of the toy, that can be placed in a child's mouth or childcare article

On a federal level, the phthalate ban applies only to children's toys and childcare articles. This ban does not apply to all children's products. Inaccessible component parts are exempt.

### Testing And Certification

Third party testing and certification is required for the children's toys and child care articles. A full description of the covered products is included in the *CPSC's FAQs*. The effective enforcement date was January 1, 2012 and applies to products manufactured after December 31, 2011.

Testing for phthalates in children's toys and childcare articles is subject to section 108 of the CPSIA, *CPSC-CH-C1001-09.2*, which is published separately and in conjunction with Section 108 of the CPSIA Policy. The test method simplifies the testing process, eliminates the unnecessary testing of materials that simply would not contain phthalates, reduces the cost of testing, and harmonizes the CPSIA phthalates regulations with those enforced by the European Commission and by California.

## Product Definitions

**Childcare Article** – A consumer product designed or intended by the manufacturer to facilitate sleep for, or the feeding of, children ages three and younger, or to help such children with sucking or teething.

**Children's Product** - The CPSIA defines a children's product as designed and intended primarily for use by a child 12 years of age and younger. Recent clarifications stress not just the word "primarily" but also "for use." Manufacturers should refer to the CPSC's 10 Questions, *Final Interpretative Rule on the Definition of a Children's Product*.

**Children's Toy** - A consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.

## CPSIA Enforcement

A knowing violation of these requirements is punishable by a civil penalty. The maximum civil penalty is \$100,000 per violation, and the maximum penalty for any related series of violations is \$15 million. In some cases, violations may also be punishable by criminal penalties, which have been made more severe under the CPSIA.

## Applicable Regulations

The *Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Revision of Determinations Regarding Certain Plastics (16 CFR 1308)* prohibits five phthalates at more than 0.1 percent content in children's toys and child care articles. Previously, the Consumer Product Safety Improvement Act prohibited three phthalates from having the 0.1 percent concentration, and a 2017 ruling by the Consumer Product Safety Commission (CPSC) added five additional phthalates to the list. The rule became effective on July 23, 2018. Phthalates are chemicals that are used to make plastics flexible, and some phthalates can be harmful if ingested. The CPSC's ruling increases to eight the list of phthalates that are restricted from use in children's toys and childcare articles at concentrations of greater than 0.1 percent. The five phthalates identified in the recent ruling are diisononyl phthalate (DINP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP), dicyclohexyl phthalate (DCHP); and diisobutyl phthalate (DIBP), and the three already prohibited prior to the recent ruling are di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) and benzyl butyl phthalate (BBP).

## State Of Washington Children's Safe Products Act

Washington State's Children's Safe Products Act (CSPA), includes a "Prohibition on the Manufacturing and Sale of Children's Products Containing Lead, Cadmium and Phthalates" (RCW 70.240.020) as well as the Reporting Rule (Chapter 173-334 WAC) which requires manufacturers to report certain Chemicals of High Concern to Children (CHCC) to the *Department of Ecology (DOE)*.

While focus to date has been on the Reporting Rule, DOE has advised that they are also *enforcing the lead, cadmium and phthalates prohibition*. It is important to note that while lead, cadmium and phthalates are restricted under the CPSIA, Washington's limits may be more stringent and apply to a broader range of children's products.

Where federal law provides limits on the same consumer product and for the same risk of injury, the state "refers the matter to the CPSC to ensure compliance." When children's products are covered by the state law and not the CPSIA, the state will enforce the state law. An example of this is toys which have federal requirements for lead, cadmium and phthalates.

- Lead restriction is similar to CPSIA although it does cover a broader range of products.
- Cadmium restriction is more stringent both in limit and scope of products. From a federal standpoint, cadmium is restricted to 75 ppm in children's toys per ASTM F963-11, the standard consumer safety specification for toy safety. Washington's limit is 40 ppm and applies to a broader range of children's products including clothing and footwear, jewelry, childcare articles and others.
- Phthalates are restricted by federal law in children's toys and childcare articles. As with cadmium, Washington's CSPA covers a broader range of children's products such as clothing and footwear and cosmetics.

Children's products are defined in RCW 70.240.010 and include any of the following: toys, children's cosmetics, children's jewelry, products that help a child with sucking or teething, products that facilitate sleep, relaxation or feeding of child, clothing (including footwear), and car seats.

## California Proposition 65

Also known as the *Safe Drinking Water and Toxic Enforcement Act of 1986*, California Proposition 65 requires businesses to notify Californians via warning labels about significant amounts of

chemicals known to the State of California to cause cancer, birth defects or other reproductive harm contained in the products they purchase, in their homes or workplaces, or that are released into the environment.

### CPSIA vs. PROP 65

Side-By-Side Comparison Of CPSIA, California Phthalates Ban And Proposition 65			
	CPSIA	CA Phthalate Ban	CA Prop 65
<b>Covered Phthalates</b>	DEHP, DBP, BBP, DINP, DIBP, DPENP, DHEXP, DCHP, 0.1% (1,000 ppm)	Same as CPSIA	DEHP, DBP, BBP, DIDP and DnHP
<b>Level</b>	0.1% (1,000 ppm)	Same as CPSIA	Regulates exposures not concentrations, but recent Proposition 65 settlements involving phthalates generally range from 200 ppm to 1,000 ppm for concentration limits.
<b>Toys</b>	For children 12 years of age or less  For DINP, DIDP and DNOP, only those toys that can be placed in the mouth  CPSC is considering the exclusions in ASTM F963-07	Age limit not defined for DEHP, DBP or BBP  For DINP, DIDP and DNOP toys for children less than three years of age, and only those toys that can be placed in the mouth	All ages and all products that can result in an exposure to listed phthalate(s)
<b>Child-care Articles</b>	For children three years of age or less  To facilitate sleeping, feeding, sucking or teething	Age limit not defined for DEHP, DBP or BBP  Child-care articles for children three years of age or less, and only those toys that can be placed in the mouth for DINP, DIDP and DNOP  Includes products designed to facilitate relaxation	All ages and all products that can result in an exposure to listed phthalate(s)
<b>Using Alternative Chemicals</b>	Certain alternative chemicals may be banned based on findings of Chronic Hazard Advisory Panel	Must use least-toxic alternative and not carcinogens or reproductive toxicants identified by EPA or California agencies	Using alternative chemicals that are listed under Proposition 65 may require warnings

Source: Arnold & Porter LLP

The California Office of Environmental Health Hazard Assessment (OEHHA) maintains a list of more than 900 chemicals considered to cause harm, including cadmium, lead, mercury and polychlorinated biphenyls (PCBs), and phthalates.

Many of the compounds identified on the *Prop 65 list*, while permissible under federal regulations, are prohibited or are

restricted to lower levels than those imposed by the federal government. So while the same products may be safely shipped and received in other states, doing so in California without the *proper warnings* carry significant penalties for the violators. Where products violate the regulation, all parties involved in the chain of distribution—suppliers, distributors, and end buyers—are potentially liable.

Prop 65 limits the amount of certain phthalates in children's toys and childcare articles for companies doing business in California. It covers the same eight phthalates as the CPSIA, and **while restrictions are similar they are not identical.**

- For toys and childcare articles, the chemicals DEHP, DBP or BBP may not be present in concentrations exceeding 0.1 percent.
- For toys and childcare articles intended for use by a child less than three years of age and which can be placed in the child's mouth, the chemicals DINP, DIDP or DnOP may not be present in concentrations exceeding 0.1 percent.

Prop 65 defines a toy as a product designed or intended by the manufacturer to be used by children when they play. A childcare article is defined as a product designed or intended by the manufacturer to facilitate sleep, relaxation or the feeding of children, or to help children with sucking or teething.

These restrictions apply generally to **anyone manufacturing, selling, distributing or offering for sale** toys or childcare articles in California.

### Proposition 65 Enforcement

The California's ban on phthalates does not contain any specific enforcement provisions, nor does it assign enforcement to any particular state agency. Enforcement falls under California's main consumer protection statute, the Unfair Competition Law, which allows for a penalty of up to \$2,500 for each violation to be assessed. In addition, the courts may also impose injunctive relief, restitution and attorneys' fees. The most common enforcement comes in the form of public enforcers, as well as private enforcers acting with private attorneys who file suit under California's Unfair Competition Law.

Proposition 65 **applies to everyone in the distribution chain.** Unless proper testing has been performed, if a distributor or their customer sells or distributes a product without a required warning, the distributor and supplier can be liable.

### Product Concept and Sourcing Considerations

When selecting a product and a production partner, it is not enough to simply understand regulations and how they apply

to your product. It is essential that you evaluate your production partners to ensure they have proper chemical controls in their facilities. Consider asking:

- How are chemicals sourced?
- How are chemicals stored?
- How are chemicals mixed? What controls do you have in place?
- How do you label chemicals? What languages do you include on those labels?
- Do you have SDS on-site for all chemicals in use?
- Is your team trained to handle chemical spills/human exposure?
- Do you regularly inspect your facility to ensure compliance with chemical management procedures? When you find non-conformities, how do you put CAPs in place?

### Online Resources:

**CPSIA:** <http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/The-Consumer-Product-Safety-Improvement-Act/>

**CPSC Phthalate Opinion:** <http://www.ppai.org/media/1764/phthalatesop.pdf>

**CPSC Phthalate Overview:** <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information/>

**CPSC Statement of Policy: Testing Component Parts for Phthalates:** <http://www.ppai.org/media/1763/phthalates.pdf>

**CPSIA Testing of Component Parts:** <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Third-Party-Testing/Component-Part-Testing>

**CPSC Test Method CPSC-CH-C1001-09.3:** [https://www.cpsc.gov/s3fs-public/pdfs/blk\\_pdf\\_CPSC-CH-C1001-09.3.pdf](https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_CPSC-CH-C1001-09.3.pdf)

**CPSIA Children's Products:** <http://www.cpsc.gov/Business--Manufacturing/Business-Education/childrens-products/>

### **CPSIA Children's Toy's and Child Care Articles**

**Containing Phthalates:** <http://www.cpsc.gov/en/Regulations-Laws--Standards/Federal-Register-Notices/2013/Childrens-Toys-and-Child-Care-Articles-Containing-Phthalates-Final-Guidance-on-Inaccessible-Component-Parts-16-CFR-Part-1199-FINAL-RULE-February-14-2013/>

**CHAP on Phthalates:** <https://www.cpsc.gov/chap>

**CHAP Report:** <https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf>

**PPAI Product Responsibility Best Practices:** <http://www.ppai.org/corporate-responsibility/product-responsibility/product-responsibility-resources/>

**OEHHA:** <http://oehha.ca.gov>

**Prop 65:** <https://oehha.ca.gov/proposition-65>

**Prop 65 In Plain Language:** <https://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language>

**Prop 65 FAQs:** <https://oehha.ca.gov/proposition-65/proposition-65-faqs>

**Prop 65 Chemical List:** <https://oehha.ca.gov/proposition-65/proposition-65-list>

**Prop 65 Warnings:** <http://oehha.ca.gov/media/RegsArt6.pdf>

**PPAI Prop 65 Best Practice:** <http://www.ppai.org/media/1814/pr-bp-proposition-65.pdf>

**PPAI Prop 65 Overview:** <http://www.ppai.org/media/1854/pr-prop-65-guidebook-2007.pdf>

**PPAI Responsible Sourcing Webinars:** <https://onlineeducation.ppai.org/corporate-responsibility>

**Washington State Department of Ecology (DOE):** <http://www.ecy.wa.gov/>

**Children's Safe Product Act –RCW 70.240.020 Lead, Cadmium, and Phthalates:** <https://ecology.wa.gov/Waste-Toxics/Reducing-toxic-chemicals/Childrens-Safe-Products-Act>

**Washington State RCW 70.240.020:** <http://app.leg.wa.gov/RCW/default.aspx?cite=70.240.020>

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