



# FOR CHILDREN ONLY

A PROPOSED CPSC RULE EXPANDS THE PHTHALATE BAN IN KID'S TOYS AND CARE ITEMS

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**T**HE U.S. CONSUMER PRODUCT Safety Commission (CPSC) has recently proposed a new rule that may affect you and your customers. It is the “Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates.” While the rule is targeted at a specific area, it potentially affects a number of consumer products you may import or distribute. Knowing what may be banned or restricted will allow you to stay ahead of the regulatory curve and help ensure the effective and efficient flow of your products to the market.

## Phthalates In Children’s Toys And Child Care Articles

The proposed CPSC rule changes how certain chemical plasticizers in children’s toys and child care articles are regulated. This rule on phthalates would create a new federal standard that specifies exactly which phthalates are barred from use in children’s toys and child care articles. The commission approved the phthalate Notice of Proposed Rulemaking on December 17, 2014, and recently extended the deadline for public comment until April 15, 2015.

## What Are Phthalates?

Phthalates are a group of chemicals often used to soften plastics such as polyvinyl chloride (PVC) and to make them more flexible. They are also used as solvents and stabilizers for fragrances. Phthalates have been used in numerous consumer products such as baby teethingers, plastic toys, home furnishings, air fresheners, car interiors, cosmetics, drugs, medical equipment and many other products. While phthalates are also found in food, indoor air, household dust and even soil, the CPSC regulates specific phthalates used in the manufacture of particular consumer products. It is important to understand not all phthalates are regulated the same way by the CPSC. The identity of a

chemical phthalate makes a great difference whether it is barred from use or not. The exact phthalate chemical names and their acronyms are therefore included in this article.

### Current CPSC Phthalate Rules

In February 2009, section 108(a) of the Consumer Product Safety Improvement Act (CPSIA) went into effect and 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 more than 0.1 percent of di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP) or butyl benzyl phthalate (BBP).

These three phthalates were permanently prohibited under the CPSIA and are also banned under the proposed rule.

Section 108(b)(1), on an interim basis, prohibited the manufacture for sale, offer for sale, distribution in commerce or importation into the U.S. of “any toy that can be placed in a

child’s mouth” or “child care article” which has a concentration of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP) or di-n-octyl phthalate (DNOP).

A “children’s toy” is defined in the CPSIA as “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.”—Section 108(g)(1)(B).

A “child care article” is “a consumer product designed or intended by the manufacturer

Phthalate	Current CPSC Rule	Proposed CPSC Rule
DEHP - (di(2-ethylhexyl) phthalate)	Permanently banned under CPSIA	No change - remains banned for all children’s toys and child care articles
DBP - (dibutyl phthalate )	Permanently banned under CPSIA	No change - remains banned for all children’s toys and child care articles
BBP - (butyl benzyl phthalate)	Permanently banned under CPSIA	No change - remains banned for all children’s toys and child care articles
DINP - (diisononyl phthalate)	Banned, on interim basis under CPSIA, only for toys that can be mouthed or child care articles	Interim ban changed to permanent ban — expanded to all children’s toys and child care articles
DIDP - (diisodecyl phthalate)	Banned, on interim basis under CPSIA, only for toys that can be mouthed or child care articles	Not banned
DNOP - (di-n-octyl phthalate)	Banned, on interim basis under CPSIA, only for toys that can be mouthed or child care articles	Not banned
DIBP - (diisobutyl phthalate)	Not banned under CPSIA	Banned for all children’s toys and child care articles
DPENP - (di-n-pentyl phthalate)	Not banned under CPSIA	Banned for all children’s toys and child care articles
DHEXP - (di-n-hexyl phthalate)	Not banned under CPSIA	Banned for all children’s toys and child care articles
DCHP - (dicyclohexyl phthalate)	Not banned under CPSIA	Banned for all children’s toys and child care articles
DIOP - (diisooctyl phthalate)	Not banned under CPSIA	Not banned
DMP - (dimethyl phthalate)	Not banned under CPSIA	Not banned
DEP - (diethyl phthalate)	Not banned under CPSIA	Not banned
DPHP - (di(2-propyl) heptyl phthalate)	Not banned under CPSIA	Not banned

to facilitate sleep or the feeding of children age three and younger, or to help such children with sucking or teething.”—Section 108 (g)(1)(C).

Children’s toys or child care articles that violate CPSC regulations can be stopped at U.S. ports and refused entry. Similarly, such unlawful products cannot be sold or distributed and could be subject to a “voluntary” recall.

## The CPSIA And The CHAP

The CPSIA required the establishment of a Chronic Hazard Advisory Panel (CHAP) of scientists to study the potential health effects of certain phthalates (and alternatives). The CPSIA focused on phthalates in products children can put in their mouths and chew or suck. The basic concern is that phthalates can have negative health effects including so-called endocrine-disrupting effects. The CHAP was required to make recommendations to the CPSC including whether to continue an interim ban on specific phthalates and whether to ban other phthalates.

The CHAP reported its findings and recommendations to the commission in July 2014. In its report, the CHAP found exposure to some phthalates was associated with harmful changes to male reproductive development (“antiandrogenic” effects). The CHAP essentially recommended that certain phthalates be permanently banned, other phthalates not be banned and others studied further or banned on an interim basis. The CPSC staff reviewed the CHAP report extensively and used it to create the pending rule.

## Proposed CPSC Phthalate Rule

The CPSC’s proposed rule adopts almost all of the CHAP’s recommendations concerning phthalates and phthalate alternatives. They include:

1. Three phthalates were already *permanently* banned under the CPSIA in 2008: DEHP, DBP and BBP. Those three phthalates remain banned without any change under the proposed rule.
2. The proposed rule makes changes to three phthalates previously subject to the CPSIA’s interim ban:
  - First, the interim ban on DINP should be made permanent and extended to all children’s toys and child care articles—

no longer just for children’s toys that can be mouthed.

- Second, the interim ban on DNOP and DIDP should be lifted because they do not appear to have antiandrogenic effects.
3. Four other phthalates should also be banned: diisobutyl phthalate (DIBP), di-n-pentyl phthalate (DPENP), di-n-hexyl phthalate (DHEXP) and dicyclohexyl phthalate (DCHP). These would be prohibited for use in children’s toys and child care articles.
  4. The CHAP recommended an interim ban on diisooctyl phthalate (DIOP) because it found insufficient evidence to support a permanent prohibition. However, the CPSC took no action on this phthalate because it could not prohibit DIOP on an interim basis. As a result, DIOP is *not* prohibited on any basis under the proposed rule.
  5. The CPSC did not take any action on other phthalate alternatives that the CHAP reviewed, but had insufficient information on which to act. The CHAP did not recommend any prohibitions on dimethyl phthalate (DMP), diethyl phthalate (DEP) or di(2-propyl) heptyl phthalate (DPHP). It did recommend additional study on DEP and DPHP.
  6. The CPSC is not recommending a change to the 0.1 percent (1,000 parts per million) concentration level. It agreed with the CHAP that found no compelling reason to support raising or lowering the limit. The CPSC said, “The limit is based on practical considerations, that is, the desire to prohibit intentional phthalate use while allowing trace levels.”

## Scope Of The Proposed Rule

Importantly, the CPSC decided *not to recommend* expanding the scope of the proposed rule to include “any children’s product” containing any phthalates. Although the CPSC had the authority to do so under the CPSIA, it chose to limit the phthalate rule only to “any children’s toy or child care article.” This is significant because had the rule been expanded, it would have limited phthalates in children’s rainwear, footwear, backpacks, certain school supplies, apparel containing elastic waistbands, and printed t-shirts and sweatshirts. As the rule stands now, not all children’s products are barred

from containing phthalates—only “children’s toys” or “child care articles” are included in the proposed rule.

## Current Status Of Proposed Rule

As mentioned earlier, the CPSC formally approved the notice of proposed rule in mid-December 2014 and issued it for publication and comment. The rule has been subject to strong criticism by several groups, including the American Council on Science and Health, who cited an earlier blue ribbon panel study that contradicts certain key CHAP and CPSC recommendations. The American Chemistry Council and Exxon Mobil also criticized the CHAP report and its methodology. It seems unlikely, however, that the CPSC commissioners will significantly change their positions. The Commission’s 3-2 vote to publish the notice of proposed rulemaking was along strict party lines and most likely will not change appreciably at the time of the final vote on the rule.

## Looking Ahead

If this proposed rule is finalized and made into a formal regulation, manufacturers, importers, distributors and sellers of children’s toys and child care articles will need to make sure their products are in compliance with this final regulation. If a product contains the wrong type and amount of a particular phthalate, it will be illegal to import it or sell it in the U.S. Now is the time to review your product specifications, testing and certification procedures if you deal with children’s toys or child care articles. Once the proposed rule is finally adopted, businesses will have 180 days to comply with the new requirements following its formal publication in the Federal Register. Getting ahead now will keep you from being caught short later. 

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