
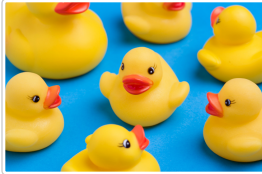




United States CONSUMER PRODUCT SAFETY COMMISSION

Phthalates

 简体中文



Six types of phthalates are currently banned for use in children's toys and certain child care articles in the amounts described on this page. An example of a product that may have phthalates is a product like a children's rubber duck – the flexible plastic feel may be from the use of phthalates in the manufacturing process. This page provides information for businesses seeking guidance on how to comply with the federal consumer product safety rules on phthalates.

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Overview

What are phthalates?

Phthalates are chemical plasticizers that are often used in the production of many types of plastics. Phthalates most often, but not always, are used to make plastics softer and/or more pliable.

What is the ban on phthalates?

Congress has permanently banned three types of phthalates: DEHP, DBP, and BBP[1] in any amount greater than 0.1 percent (computed for *each* phthalate individually) in: (1) children's toys, and (2) any child care article that is designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help children age 3 and younger with sucking or teething.

Congress has also banned on an interim basis three additional phthalates: DINP, DIDP, and DnOP[2] in any amount greater than 0.1 percent (computed for *each* phthalate individually) in: (1) any children's toy *that can be placed in a child's mouth*, and (2) any child care article that is designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help children age 3 and younger with sucking or teething.

Note that the "interim banned" phthalates limits apply to children's toys *that can be placed in a child's mouth* whereas the permanent ban applies to any children's toy. A discussion of the definitions of children's toys and child care articles is covered below. This document refers to both bans as the "ban on phthalates." Congress also directed the U.S. Consumer Product Safety Commission (CPSC or the Commission) to convene a chronic hazard advisory panel (CHAP) on phthalates, which is discussed in more detail below.

Where can I find the law describing the ban on phthalates?

The law that makes children's toys and certain child care articles subject to the ban on certain phthalates can be found in section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) (pdf), Pub. L. No. 110-314, 122 Stat. 3016 (August 14, 2008). Additional requirements on the ban on phthalates were added in section 5 of Public Law No. 112-28 (August 12, 2011), which amended the CPSIA.

May a manufacturer use a phthalate that is not banned or an alternative plasticizer in a children's toy or child care article?

The CPSIA has permanently banned DEHP, DBP, and BBP, while DINP, DIDP and DnOP are banned on an interim basis. However, an unbanned phthalate or an alternative plasticizer that is not one of the above banned phthalates may be used in a children's toy or child care article. During the CHAP's Congressionally mandated study of phthalates, an assessment of the interim banned phthalates (DINP, DIDP and DnOP) was conducted, as well as an assessment of the full range of other phthalates and phthalate alternatives for potential health effects.

Manufacturers are still responsible for ensuring that children's products are not considered "hazardous" under the general requirements of the Federal Hazardous Substances Act (FHSA). It is the manufacturer's obligation to ensure that any alternative plasticizer that is used be adequately tested such that the manufacturer is confident it does not pose a risk of injury under normal use or reasonably foreseeable misuse. Children's products that are hazardous or contain a hazardous substance are automatically banned. The Commission has issued chronic hazard guidelines to assist manufacturers in complying with the requirements of the FHSA.

Types of Products Subject to Phthalates Ban

What child care articles are covered by the ban on phthalates?

Covered child care articles are those which are designed or intended by the manufacturer for a child age three years old or younger to facilitate sleeping or feeding or to help the child in sucking or teething. The definition was provided by Congress in the CPSIA and, at this time, the Commission has not issued further interpretive guidance.

However, the staff has interpreted items such as children's sleepwear, infant and toddler bottles, sippy cups, utensils, bibs, pacifiers, and teethingers to be child care articles covered by the ban on phthalates. The staff determinations have not been approved by the Commission and the Commission may review and/or supersede the staff guidance and determinations.

What children's toys are covered by the ban on phthalates?

For purposes of the ban on phthalates, a "children's toy" is 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."

Any determination as to whether a particular product is designed or intended for use by a child 12 years of age or younger during play will be made after consideration of the following factors:

- Whether the intended use of the product is for play, including a label on the product if such statement is reasonable.
- Whether the product is represented in its packaging, display, promotion or advertising as appropriate for use by the ages specified.
- Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.
- The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

In addition, as part of the staff's proposed approach, the CPSC staff looks to the definition of "children's toy" in the ASTM F963 children's toy safety standard for guidance. The CPSIA made ASTM F963 a mandatory CPSC standard on February 10, 2009. ASTM F963 excludes certain types of children's toys. For further guidance on the types of children's toys that are covered by the ban on phthalates, you may review the Commission's draft guidance (pdf).

What is a children's toy that can be placed in a child's mouth?

Congress has stated that a "children's toy" means 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.

A children's toy can be placed in a child's mouth if any part of the children's toy can actually be brought to the mouth and kept in the mouth by a child so that it can be sucked and chewed. If the children's product can only be licked, it is not regarded as able to be placed in the mouth. If a children's toy or part of a children's toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth. At present, the Commission has not issued any additional information on interpreting these definitions. The definitions provided in the statute are found in section 108(e) of the CPSIA. For further guidance on the types of children's toys that can be placed in a child's mouth, you may review the Commission's draft guidance (pdf).

Component Parts and Inaccessibility

Does the ban on phthalates apply to inaccessible parts?

No. Inaccessible component parts are excluded from the ban on phthalates. Presently, a component part is not accessible if that part is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product. (Reasonably foreseeable use and abuse of the product includes swallowing, mouthing, breaking, or other children's activities, and the aging of the product.) The Commission has issued guidance on how to interpret "inaccessibility" found at 16 CFR 1199. For future updates on this issue and other regulatory issues that may affect you, it is recommended that you sign up for the CPSC Regulatory Updates email list.

Does every component part of every children's toy and child care article need to be tested?

No. The Commission has stated that it is unnecessary to test and certify materials that are known not to contain phthalates or to certify that phthalates are absent from materials that are known not to contain phthalates.

The following materials do not require testing for compliance with the ban on phthalates, provided that they have not been treated or adulterated by a substance that may contain phthalates:

- Untreated/unfinished wood;
- Metal;
- Natural fibers; and
- Natural latex and mineral products.

Additional examples of materials that do not require testing and certification include paper products (paper, paperboard, linerboard and medium, and pulp). See the Commission's Notice of Requirements (footnote 2) and the Commission's draft guidance (pdf).

Can I rely upon a supplier that certifies that its component parts comply with the ban on phthalates?

Yes, provided that certain conditions are satisfied. First, not all children's products are required to be tested for phthalates. The Commission has issued a statement of policy (pdf) on the testing of component parts with respect to the ban on phthalates which provides guidance on what types of materials used in a children's product must be tested.

Second, the Commission has issued a rule regarding testing component parts. To the extent that a children's product is required to be third party tested for phthalates, you can rely upon the test results or a certification from a component part supplier if the requirements in our regulation at 16 CFR part 1109 are met. That rule requires that in order to rely upon test results or a certification from a supplier, you must use due care to ensure that the tests results or the certificate is valid, and be given access to the underlying documentation, such as test results and attestations regarding how the testing was conducted and by whom. Generally, certifications of a component part must satisfy the requirement for a children's product certificate, and must be based on the results of testing from a laboratory whose accreditation has been accepted by the CPSC.

More information is available about component part testing

Third Party Testing and Certification

Is third party testing and certification required for the ban on phthalates?

Compliance with the ban on phthalates for children's toys and certain child care articles:

If you are a manufacturer, importer, or private labeler of children's toys and certain child care articles, **you must comply** with the ban on phthalates.

Third Party Testing:

If you are a manufacturer, importer, or private labeler of children's toys and certain child care articles, you **must test your products** at a CPSC-accepted Laboratory for compliance with the ban on phthalates. As explained more fully below, third party testing is required for all plasticized component parts in a children's toy or child care article and is not required for certain materials known not to contain phthalates. Third party testing is also not required for inaccessible component parts of a children's toy or child care article.

Certification:

After a product is tested for compliance with the ban on phthalates, the manufacturer, private labeler, or importer **must issue a Children's Product Certificate** in which it certifies that the children's toy or child care article complies with the ban on phthalates. Other details of testing and certification requirements are contained in the "notice of requirements" (pdf).

For which age groups (i.e., the product's intended users) is third party testing and certification required for the ban on phthalates?

All children's toys intended or designed primarily for children 12 years of age and younger must be subjected to third party testing for the three permanently banned phthalates (DEHP, DBP, and BBP) by a CPSC accepted laboratory.

Children's toys intended or designed primarily for children 12 years of age and younger that can be placed in a child's mouth must also be subjected to third party testing for the three interim banned phthalates (DINP, DIDP, and DnOP) by a CPSC accepted laboratory.

Child care articles intended or designed primarily for children 3 years of age and younger must be subjected to third party testing by a CPSC accepted laboratory.

The manufacturer, importer, or private labeler must issue a written certification based on the results of the third party testing, as described further here: www.cpsc.gov/CPC.

What are the test methods for the ban on phthalates accepted by the Commission?

The two test methods currently approved by the Commission are:

1. Test Method: CPSC-CH-C1001-09.3 - Standard Operating Procedure for Determination of Phthalates, April, 1, 2010 [PDF]
2. Alternate Phthalates Test Method: GB/T 22048-2008, children's toys and Children's Products-Determination of Phthalate Plasticizers in Polyvinyl Chloride Plastic, issued on June 16, 2008 ("Chinese Test Method").

Where should I purchase standard or certified reference materials for phthalates testing?

The National Institute for Standards and Technology (NIST) is working on a certified reference material containing a specified amount of phthalates in polyvinyl chloride (PVC). For liquid standards, there are many reputable dealers offering either phthalates in bulk, or phthalates in solvent.

My product failed a laboratory test, but phthalates were not purposefully added. Why did it fail the test?

A failed test could indicate contamination from a number of sources and requires a thorough assessment of the manufacturing and shipping processes. For example, contamination could arise from recycled plastics, poorly cleaned manufacturing equipment, or even alternative plasticizers that contain trace amounts of the prohibited phthalates.

It is possible that the test is a false positive. Testing lab errors could arise from confusion over plasticizer identification. Operators are reminded that test method CPSC-CH-C1001-09.3 calls for an extensive qualitative identification; this should include a retention time match and a mass spectrum match with a known standard material.

DINP and DIDP each have multiple formulations and chemical abstract service (CAS) numbers. Which ones are regulated?

Section 108 of the CPSIA does not distinguish between different formulations or CAS numbers. Therefore, all formulations of DINP and DIDP fall under the interim ban for mouthable children's products and child care articles. For testing purposes, laboratories should quantify DINP and DIDP with the appropriate formulation. The chromatographic results for the different compound formulations are distinct and should be identifiable by trained personnel.

Chronic Hazard Advisory Panel on Phthalates (CHAP)

What is the CHAP on phthalates?

Congress required the CPSC to convene a phthalates chronic hazard advisory panel (CHAP) composed of scientific experts to study the health effects of the three interim banned phthalates in addition to similar phthalates alternatives. The CHAP examined the possible health effects of phthalates as they act on the body individually and in combination with one another. A copy of the CHAP's final report and CPSC staff's executive summary is available here https://www.cpsc.gov/https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_CHAP-REPORT-With-Appendices.pdf.

Is there the possibility that the interim ban on phthalates may be lifted?

The Commission must issue a final rule, based on the CHAP's report, to determine whether to continue the ban of the three interim banned phthalates in addition to any phthalates alternatives examined by the CHAP. The Commission has issued a Notice of Proposed Rulemaking (NPR) as directed by Congress in the CPSIA that would establish a new regulation on the use of specified phthalates in children's toys and child care articles. More information about the status of this rulemaking is available here.

Is there the possibility that additional bans on phthalates and similar plasticizers may be imposed?

The Commission staff has proposed the addition of certain phthalates to the list of the phthalate prohibitions. As of June 2015, the Commission is still analyzing the staff's proposal. Subscribe for e-mail updates to be informed if and when the Commission takes further action.

Children's Product-Specific FAQs

Does the packaging for child care articles and children's toys need to comply with the ban on phthalates?

Packaging is generally not intended for use by children when they play, given that most packaging is discarded and is not used or played with as a children's toy or child care article. However, if the packaging is intended to be reused, or used in conjunction with a child care article or with a children's toy while playing, such as a heavy gauge reusable bag used to hold blocks, it would be subject to the ban on phthalates.

Does the ban on phthalates apply to children's shoes or socks?

Shoes and socks are not considered to be children's toys or child care articles. See the Office of the General Counsel advisory opinion.

Does the ban on phthalates apply to items such as pool children's toys and beach balls?

Children's pool toys, beach balls, blow up rafts, and inner tubes designed or intended for children 12 years of age or younger would be considered children's toys. Those objects are used by children when playing in a swimming pool or at the beach. Therefore, they would be required to comply with the ban on phthalates.

If a cosmetic material is used in a children's toy set which has play value would it be classified as a part of the children's toy and therefore subject to the ban on phthalates?

Yes. If a cosmetic material is included in a children's toy set it is required to meet the requirements of the ban on phthalates. However, cosmetics in general when not packaged with a children's toy are not covered by the ban on phthalates and fall under the jurisdiction of the U.S. Food and Drug Administration (FDA).

Does the ban on phthalates apply to sporting goods?

The category of products known as "sporting goods" can include children's toys, but not all sporting goods are children's toys. Indeed, the mandatory ASTM F963 children's toy safety standard does not define sporting goods equipment to be a children's toy unless the product is a children's toy version of sporting goods equipment.

However, "children's toy" in section 108 of the CPSIA is defined broadly 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." Therefore, any determination as to whether a particular sporting goods product would be a children's toy as defined under section 108, and therefore, subject to the ban on phthalates, would be made on a case by case basis after consideration of the following factors:

- A statement by the manufacturer about the intended use of the product, including a label on the product if such statement is reasonable.
- Whether the product is represented in its packaging, display, promotion or advertising as appropriate for use by of the ages specified.
- Whether the product is commonly recognized by consumers as being intended for use by a child of the ages specified.
- The Age Determination Guidelines issued by the Commission staff in September 2002, and any successor to such guidelines.

Does the ban on phthalates apply to mattresses?

The Commission adopts the same guidance with respect to inaccessibility for the phthalates that was adopted by the Commission with regard to accessibility of lead, however, vinyl (or other plasticized material) covered mattresses/sleep surfaces, that contain phthalates that are designed or intended by the manufacturer to facilitate sleep of children age 3 and younger, are considered accessible and would not be considered inaccessible through the use of fabric coverings, including sheets and mattress pads.

Additional Resources and Information

Resources

- Statement of Policy: Testing of Component Parts with respect to Section 108 of the CPSIA, August 7, 2009 [PDF]
- Draft Guidance of Children's Products covered by Section 108, February 12, 2009 [PDF]
- 16 CFR Part 1199: Children's Toys and Child Care Articles Containing Phthalates: Guidance on Inaccessible Component Parts
- Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies to Assess Conformity with the Limits on Phthalates in Children's Toys and Child Care Articles [PDF]
- Information on the Chronic Hazards Advisory Panel on Phthalates (CHAP)

Unless otherwise noted, all policy guidance provided here is in effect regardless of the date or title of the relevant documents.

Where can I find additional information?

For more information on the requirements for phthalates, contact the U.S. Consumer Product Safety Commission:

- Office of Compliance (for specific enforcement inquiries): e-mail: sect15@cpsc.gov; telephone: (301) 504-7520.
- Small Business Ombudsman (for general assistance understanding and complying with CPSC regulations): e-mail: Please use our Contact Form, which is the best way to get a fast response; telephone: (888) 531-9070

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¹di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP).

²diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP)

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