

Total Lead Content Business Guidance & Small Entity Compliance Guide



The limits on lead content in children's products have contributed to a successful effort by all federal health and safety agencies to lower the blood lead level in children. This page provides information for businesses seeking guidance on how to comply with the federal consumer product safety rules on lead.

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Overview

What are the federal requirements limiting the total lead content in children's products?

There are two distinct requirements concerning lead in children's products. One requirement concerns the total lead content

of the children's product (discussed on this page), while the other requirement deals specifically with the levels of lead contained in the paint or surface coating of a children's product. Please see our webpage on <u>lead in paint and similar surface coatings</u> for information on this requirement.

Total Lead Content

With a few limited exceptions explained below, all <u>children's products</u> manufactured in or imported into the United States must not contain more than 100 parts per million (ppm) of total lead content in accessible parts.

Lead in Paint and Similar Surface Coatings

All <u>children's products</u>, and some furniture, for adults and children, must not contain a concentration of lead greater than 0.009 percent (90 parts per million) in paint or any similar surface coatings.

Household paints must also meet this requirement.

Where can I find the law that limits total lead content in children's products?

You can find the law in section 101 of
the <u>Consumer Product Safety Improvement Act of 2008 (CPSIA)</u> (pdf)
(Public Law 110-314), as modified by H.R. 2715 (Public Law No. 112-28,
August 12, 2011) and in section 2(q)(1) of the
<u>Federal Hazardous Substances Act</u> (pdf), 15 U.S.C. § 1261(q)(1) (FHSA).

What parts of the children's product must comply with the total lead content limits requirement?

All accessible component parts of the <u>children's product</u> must comply with the total lead limits requirement.

The total lead content limits do not apply to component parts of a children's product that are not accessible to a child through normal and reasonably foreseeable use and abuse of the product. In addition to passing all applicable use and abuse testing, children's products or component parts of children's products which are enclosed, encased, or covered by fabric must measure 5 centimeters or greater in all dimensions to be considered inaccessible. Please see 16 CFR 1500.87 and our section below on Inaccessible Component Parts for more information.

What do I have to do to ensure that my product complies with the total lead content limits?

Manufacturers and importers of <u>children's products</u>
must <u>third party test</u> their product using a <u>CPSC-accepted laboratory</u>.

There are, however, a limited number of exemptions and exceptions to the third party testing requirement discussed further below.

Can I rely on assurances from my component supplier that the testing they have performed on a product satisfies regulatory requirements and thereby avoid testing the same component part twice?

Yes, provided that certain conditions are satisfied. The Commission has issued a rule regarding testing component parts. 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 at a CPSC-accepted laboratory.

Once I test my product at a CPSC-accepted laboratory, what else do I need to do?

Manufacturers and importers must certify, based on the results of the third party testing, that your children's product complies with the requirement limiting the total lead content.

Your certification must contain all of the required elements of a Children's Product Certificate (CPC).

The correct citation to include in the CPC for this total lead content requirement is: <u>15 U.S.C. 1278a</u>.

Test Methods and Procedures

What are the test methods for the ban on total lead content accepted by the Commission?

The applicable test methods for the ban on total lead content are:

- Lead Content in Children's Metal Products: Standard
 Operating Procedure for Determining Total Lead (Pb) in
 Metal Children's Products (including Children's Metal
 Jewelry), Revision November 15,

 2012, <u>Test Method CPSC-CH-E1001-08.3</u> (pdf).
- Lead Content in Children's Non-Metal Products:
 Standard Operating Procedure for Determining Total
 Lead (Pb) in Non-Metal Children's Products, Revision

November 15, 2012, <u>Test Method CPSC-CH-E1002-08.3</u> (pdf).

Note: Following development of the initial versions of the test methods for measuring lead in metal and nonmetal products,

Test Method CPSC-CH-E1001-08.1 (pdf) and

<u>Test Method CPSC-CH-E1002-08.1</u> (pdf), respectively, CPSC staff developed <u>Test Method CPSC-CH-E1001-08.2</u> (pdf)

and <u>Test Method CPSC-CH-E1002-08.2</u> (pdf) with expanded options for the use of X-ray Fluorescence (XRF). CPSC staff further expanded the options for the use of XRF in the current test

methods: <u>Test Method CPSC-CH-E1001-08.3</u> (pdf) and <u>Test Method CPSC-CH-E1002-08.3</u> (pdf).

Accreditation to any of the previous versions of these test methods will remain acceptable unless the Commission provides a notice of phasing out previous versions.

Is X-ray fluorescence technology (XRF) approved for use by CPSC-accepted laboratories?

Some XRF technology is approved to test certain types of homogenous materials, with limitations, such as certain metal materials, polymers and plastics, and crystal, ceramic, and other siliceous materials, in CPSC-accepted laboratories. Approval of XRF technology has reduced

the price of third party testing for lead content. (Additionally, there is a specific XRF technology that is <u>approved</u> for use in testing to the separate <u>lead-in-paint</u> requirements).

The <u>applicable test methods</u> for the ban on total lead content are listed above.

International and State Level Lead Content Requirements

If I have tested my product for its soluble lead content for compliance with Europe's requirements, do I also need to test for total lead content with the CPSC's requirements?

Yes. All testing for lead content and other requirements must be performed by a <u>CPSC-accepted laboratory</u> using the methods approved by the Commission. Other countries have requirements and testing methods that differ from those of the CPSC.

Do individual states have other regulatory requirements concerning the amount of permissible total lead content?

Yes. Certain states, like Illinois and California, have other regulatory requirements concerning lead content. You may contact the attorney general or Department of Health in each state for further guidance on specific state laws and requirements.

Exceptions and Exemptions

Certain Products that Cannot Contain Lead

Has the Commission made a determination that certain products, by their nature, do not contain lead in excess of the legal limits?

Yes, the Commission has determined that certain classes of products do not exceed the lead content limits under section 101 of the CPSIA. The regulation includes determinations that certain 100 percent untreated, unadulterated products do not need to be tested by a third party laboratory.

Some determinations relied upon are those exempting products such as pure wood (not plywood or other composites); paper and other similar products made from cellulosic fiber; CMYK ink printing processes, certain precious and semi-precious gemstones and other minerals (provided that the mineral or material is not based on lead or lead compounds); natural or cultured pearls; certain natural and manufactured fibers, such as cotton, wool, and polyester, among others; certain plant-derived and animal-derived materials, such as animal glue, bee's wax, seeds, nut shells, flowers, sea shells, leather; and finally certain stainless steel and precious metals, as listed. The list above is a sampling of the determinations that the Commission has made. You can find the complete regulation, including the list of determinations, at 16 C.F.R. §1500.91.

Additionally, the Commission has determined that certain untreated and unfinished engineered wood products (EWPs), specifically, particleboard, hardwood plywood (without polyvinyl acetate), and medium-density fiberboard also do not exceed the total lead content limit and would not be required to have third party testing for compliance with the total lead content limit. You can read more about this determination at <u>83 FR 28983</u> and at 16 CFR Part 1252.

Does a third party laboratory have to test my product to ensure that it satisfies the lead determination?

No. You may rely on the assertions of your supplier or upon test results from a non-third party laboratory or certification body. However, you must keep records supporting your good faith assertion. In the event that you knowingly rely on a false assertion, then you may be subject to substantial civil and/or criminal penalties.

If all of the component parts of my product are inaccessible or else satisfy the lead determinations, am I still required to issue a children's product certificate?

Yes. If you are issuing a Children's Product Certificate certifying to another children's product safety rule (such as the lead in paint limit), you will need to ensure that all applicable children's product safety rules are certified to in Section 2 of the CPC.

I understand the determination that certain fabrics do not contain lead can be affected by printing or dyeing those fabrics. What do I need to do to ensure that my dyed fabrics fall under these determinations and do not require third party testing?

As discussed above, certain natural fiber and manufactured fiber textiles have been determined to not contain levels of lead in excess of the limits and do not need to be third party tested. Those fabrics are:

- Natural fibers (dyed or undyed) including, but not limited to: cotton, kapok, flax, linen, jute, ramie, hemp, kenaf, bamboo, coir, sisal, silk, wool (sheep), alpaca, llama, goat (mohair, cashmere), rabbit (angora), camel, horse, yak, vicuna, qiviut, guanaco; and
- Manufactured fibers (dyed or undyed) including, but not limited to: rayon, azlon, lyocell, acetate, triacetate, rubber, polyester, olefin, nylon, acrylic, modacrylic, aramid, and spandex.

To use this determination, you must ensure that the textiles are not treated or adulterated in any way with materials that could introduce lead into the material. (Dyes are not considered to be a material that may introduce lead into a material.)

This means that if you choose to print on your textile with after-treatment applications, including screen prints, transfers, decals, or other prints, you can no longer rely on the determination. You must have your inks or your final products tested by a CPSC-accepted laboratory or have the ink manufacturer provide you with a Children's Product Certificate certifying that the inks passed testing by a CPSC-accepted laboratory.

Certain types of printing on textiles use inks that effectively act like dyes. Those inks are absorbed into the fabric, and they become part of the fabric. If you are printing with a "dye-like ink," then, instead of ensuring compliance with the "lead in paint" requirements (a 90ppm limit), your garment is likely to be exempt from testing.

See 16 CFR 1500.91. If you intend to rely on this materials determination, you must conduct reasonable due diligence with your supplier or manufacturer to ensure the nature of the ink being used is in fact dye-like ink.

Generally, CPSC staff differentiates inks, paints, or pigments that effectively act like a dye by applying a scraping test. If the ink, paint, or pigment scrapes off then it is considered to be a surface coating (subject to the lead in paint limit of 90ppm); if it does not scrape off, then it is considered to be part of the textile itself (subject to the total lead content limit of 100ppm). For more information on the lead in paint requirements, please visit www.cpsc.gov/leadinpaint.

Inaccessible Component Parts

What does inaccessible mean?

A component part is not accessible if: (1) it is not physically exposed by reason of a sealed covering or casing; and (2) does not become physically exposed through reasonably foreseeable use and abuse of the product.

Do paints, coatings, and electroplating make a component part inaccessible?

No. Paints, coatings, and electroplating are not considered to be barriers that would make a component part inaccessible.

If a component part is covered or sealed is it inaccessible?

Yes. A component part of a children's product is inaccessible to a child if the part is not physically exposed by reason of a sealed covering or casing, and it does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product, as determined by the Commission.

In addition to passing all applicable use and abuse testing, children's products or component parts of children's products which are enclosed, encased, or covered by fabric must measure 5 centimeters or greater in all dimensions to be considered inaccessible.

How can I tell if the component part is inaccessible?

To assess whether a component will be considered inaccessible, you should review the technical requirements of the Commission's regulation at 16 C.F.R. §1500.87.

Certain Electronic Devices

Is there an exemption for electronic devices in children's products?

Yes. To the extent lead is used for the technological feasibility of certain electronic devices for children, such products may be allowed to have a higher lead content in certain component parts. Specific lead limits for such products may be found in our regulation 16 C.F.R. §1500.88.

In addition, components of electronic devices that are removable or replaceable, such as battery packs and light bulbs, that are inaccessible when the product is fully assembled, are not subject to the total lead limits.

Off-Highway Vehicles

Is there an exception for off-highway vehicles?

Yes. Off-highway vehicles are not subject to the total lead limits. An "off-highway vehicle" is any motorized vehicle that is manufactured primarily for use off of public streets, roads, and highways, is designed to travel on two, three, or four wheels, and has either a seat designed to be straddled by the operator and handlebars for steering control, or has a non-straddle seat, steering wheel, seat belts, and roll-over protective structure. The definition also includes snowmobiles.

This provision was enacted by Congress in H.R. 2715, <u>P.L. 112-28</u> (August 12, 2011).

Bicycles and Related Products

Is there a special provision for the metal components of bicycles and related products?

Yes. The metal components of bicycles and related products are permitted to contain up to 300 parts per million of lead. The list of metal component parts to which this exception applies is found in the

Notice of Stay of Enforcement Pertaining to Bicycles and R

Commission's Products

(pdf) published on June 30, 2009 (74 FR 31254).

This provision was enacted by Congress in H.R. 2715, <u>P.L. 112-28</u> (August 12, 2011).

Children's bicycles and related products must still be third party tested and certified as compliant with <u>16 CFR part 1512</u>. Please see our <u>Bicycle Requirements Business Guidance page</u> for additional information.

Ordinary Books and Paper-Based Printed Materials

Is there a testing exclusion for ordinary books and ordinary paperbased printed materials?

Yes. Ordinary books and paper-based printed materials are excluded from third party testing for lead content.

The term "ordinary book" means a book printed on paper or cardboard, printed with inks or toners, bound and finished using a conventional method, and that is intended to be read or has educational value. The term "ordinary paper-based printed materials" means materials printed on paper or cardboard, such as magazines, posters, greeting cards, and similar products, that are printed with inks or toners and bound and finished using a conventional method.

Neither term includes books or printed materials that contain components that are printed on material other than paper or cardboard or contain non-paper-based components, such as metal or plastic parts, or accessories that are not part of the binding and finishing materials used in a conventional method.

The definition does not include books with inherent play value, books designed or intended for a child 3 years of age or younger, and does not include any toy or other article that is not a book that is sold or packaged with an ordinary book.

This provision was enacted by Congress in H.R. 2715, <u>P.L. 112-28</u> (August 12, 2011).

Certain Used Children's Products

Is there an exclusion from the total lead requirements for used children's products?

Yes. Certain used children's products that were obtained by the seller for use (and not for the purpose of resale) or were obtained by the seller-directly or indirectly-from a person who obtained those products for use (and not for the purpose of resale) are excluded from the total lead content requirements. A "seller" includes a person who lends or donates a used children's product.

However, this exclusion does NOT apply to children's metal jewelry, any children's product for which the donating party or the seller has actual knowledge that the product is in violation of the lead limits, or any other product or product category that the Commission determines after a notice and hearing. Please see our <u>Resellers Guide</u> for more information.

This provision was enacted by Congress in H.R. 2715, <u>P.L. 112-28</u> (August 12, 2011).

Product-Specific FAQs

Product Packaging

Does packaging have to comply with the lead requirements? Does it matter if the packaging is intended to be reused (e.g., heavy gauge reusable bag with zipper closure to store a set of blocks)?

Packaging is generally not intended for use by children, given that most packaging is discarded and is not used or played with as a children's product. Also, disposable packaging is not subject to third party testing and certification requirements.

However, if the packaging is intended to be reused, or used in conjunction with the children's product, such as a heavy gauge reusable bag to hold blocks, the bag becomes a component or part of the product and would be subject to the lead requirements of CPSIA.

It should also be noted that many states have adopted their own packaging laws that address toxics in packaging or packaging components that have not been preempted by Commission action.

Arts, Craft, and Science Kits

Are chemistry sets, science education sets, and other educational materials excluded from the lead content limits for paint and surface coatings if they bear adequate labeling?

Certain articles that are intended for children for educational purposes are exempt for classification as a banned hazardous substance under the Federal Hazardous Substances Act (FHSA) (16 C.F.R. § 1500.85) and the lead limits under CPSIA if: (1) the *functional purpose* of the particular educational item requires inclusion of the hazardous substance (commonly referred to as the functional purpose exemption); (2) it bears labeling giving adequate directions and warnings for safe use; and (3) is intended for use by children who have attained sufficient maturity, and may reasonably be expected, to read and heed such directions and warnings.

Are children's art materials subject to the new lead limits?

Yes. To the extent that such art materials are designed or intended primarily for children 12 years of age or younger, they are subject to the lead limits under the CPSIA.

Moreover, all art materials, whether or not intended primarily for children, must comply with the Labeling of Hazardous Art Materials Act (LHAMA), codified at 16 C.F.R. § 1500.14(b)(8), which requires that art materials be labeled properly if they may present a chronic adverse health effect. Please see our Art Materials guidance page for more information.

Outdoor Playground Equipment

Are outdoor playground products required to comply with the total lead limits?

Yes, provided that the outdoor playground equipment is designed or intended primarily for use by children 12 years of age or younger.

Paper and Textile Printing Inks

Is ordinary printing on paper subject to compliance with the total lead content limit?

Yes. Ordinary printing on paper is subject to compliance with the total lead content requirement of 100 parts per million. However, the

Commission, in <u>16 CFR §1500.91</u>, has determined that paper and other similar materials and CMYK process printing inks commonly used in printing on paper do not require third party testing for compliance with the lead requirement.

In addition, Congress specifically exempted ordinary books and ordinary printed materials from third party testing for compliance with the total lead content requirement.

Are textile printing inks (screen-printing inks) considered to be part of the product's substrate or a surface coating?

It depends. Please see our additional FAQs on textile printing inks.

Where can I find additional information?

For more information, please contact the U.S. Consumer Product Safety Commission:

- First, please try our Regulatory Robot available online at https://business.cpsc.gov to find out the applicable requirements for your product.
- Office of Compliance (for specific enforcement inquires): e-mail: <u>section15@cpsc.gov</u>; telephone: (800) 638-2772.

3. Small Business Ombudsman (for general assistance understanding and complying with CPSC regulations): e-mail: Please use our <u>Contact Form</u>, which is the best way to get a fast response; telephone: (888) 531-9070.

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