Blankenfelde-Mahlow, Germany; phone: 49 0 33–7086–1883; fax: 49 0 33–7086–3276, for a copy of this service information.

(i) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on February 5, 2013.

Robert J. Ganley,
Acting Manager, Engine & Propeller Directorate, Aircraft Certification Service.

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0040]

16 CFR Part 1199

Children’s Toys and Child Care Articles Containing Phthalates; Final Guidance on Inaccessible Component Parts

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: On August 14, 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA). Public Law 110–314, Section 108 of the CPSIA, as amended by Public Law 112–28, provides that the prohibition on specified products containing phthalates does not apply to any component part of children’s toys or child care articles that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product. In this document, the Consumer Product Safety Commission (CPSC or Commission) issues guidance on inaccessible component parts in children’s toys or child care articles subject to section 108 of the CPSIA.

DATES: This rule is effective February 14, 2013.

FOR FURTHER INFORMATION CONTACT: Kristina M. Hathlete, Ph.D., M.P.H., Toxicologist, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987–2558; khatlelid@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

On August 14, 2008, Congress enacted the CPSIA (Pub. L. 110–314), as amended on August 12, 2011, by Public Law 112–28. Section 108 of the CPSIA, titled, “Prohibition on Sale of Certain Products Containing Specified Phthalates,” permanently prohibits the sale of any “children’s toy or child care article” containing more than 0.1 percent of three specified phthalates (di-2-ethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). These prohibitions became effective on February 10, 2009. 15 U.S.C. 2057c(a), (b). The terms or phrases “children’s toy,” “toy that can be placed in a child’s mouth,” and “child care article,” are defined in section 108(g) of the CPSIA. A “children’s toy” is defined as a “consumer product designed or intended by the manufacturer to facilitate sleep of a child 12 years of age or younger for use by the child when the child plays.” A toy can be placed in a child’s mouth “if any part of the 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 toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth.” The term “child care article” means “a consumer product designed or intended by the manufacturer to facilitate sleep of the feeding of children age 3 years and younger, or to help such children with sucking or teething.” 15 U.S.C. 2057c(g).

Section 108(d) of the CPSIA provides that the prohibitions for the specified phthalates shall not apply to any component part of a children’s toy or child care article that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. The Commission further provides that a component part is not accessible, if such component 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 includes swallowing, mouthing, breaking, or other children’s activities, and the aging of the product. 15 U.S.C. 2057c(d)(1).

The CPSC directs the Commission to: (A) Promulgate a rule providing guidance with respect to what product components, or classes of components, will be considered to be inaccessible; or (B) adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child’s mouth. 15 U.S.C. 2057c(d)(3).

Section 108 of the CPSIA also directed the Commission, not earlier than 180 days after the date of enactment of this Act (enacted Aug. 14, 2008), to appoint a Chronic Hazard Advisory Panel (CHAP), pursuant to the procedures of section 28 of the CPSA (15 U.S.C. 2077), to study the effects on children’s health of all phthalates and phthalate alternatives as used in children’s toys and child care articles. 15 U.S.C. 2057c(b)(2). The Commission appointed the CHAP on April 14, 2010, to study the effects on children’s health of all phthalates and phthalate alternatives, as used in children’s toys and child care articles. The CHAP currently is working on a report, including recommendations, to be sent to the Commission.

Under section 108(d)(2) of the CPSIA, the Commission may revoke any or all exclusions granted based on the inaccessible component parts provision of section 108 of the CPSIA, at any time, and require that any or all component parts manufactured after such exclusion is revoked, comply with the prohibitions of phthalates, if the Commission finds, based on scientific evidence, that such compliance is necessary to protect the public health or safety. 15 U.S.C. 2057c(d)(2).

2. Notice of Proposed Guidance

In the Federal Register notice of July 31, 2012 (77 FR 45297), the Commission published a proposed guidance on inaccessible phthalate-containing component parts. As stated in the preamble to the proposed guidance (77 FR 45299), the Commission proposed to adopt the lead guidance for determining inaccessible component parts for phthalates, with the exception of polyvinyl chloride (PVC or vinyl) or other plasticized materials covering mattresses and other sleep surfaces designed or intended by the manufacturer to facilitate sleep of children age 3 and younger. Both the lead guidance and proposed phthalate guidance specified that a children’s product, toy, or child care article that is completely enclosed or covered by fabric is considered inaccessible to a child, unless the product or part of the product in one dimension is smaller
than 5 centimeters. However, the lead guidance did not exclude vinyl or other plasticized materials covering mattresses and other sleep surfaces. The proposed phthalate guidance found that while lead is unlikely to leach through fabric except in the case of mouthing or swallowing an item, sheets or mattress pads that cover a vinyl sleep or other plasticized sleep surface should not serve as a barrier to the potential exposure of phthalates for young children. A child’s skin comes into close contact with mattresses and similar products for large portions of a day, and a mattress cover could be dampened with a spilled beverage, saliva, sweat, urine, or other liquid, which could facilitate phthalate migration through a fabric covering. 74 FR 39539 (August 7, 2009).

In addition, although section 108 did not specifically disqualify paint, coatings, or electroplating as barriers that would render phthalates inaccessible, the Commission proposed to adopt the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to inaccessibility of lead. The proposed phthalates guidance stated that paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. The proposed phthalates guidance also noted that in some applications, phthalates are added to paint, printing inks, or coatings. 77 FR 45299.

In addition, the Commission determined preliminarily that:

- An accessible component part is one that is capable of being touched or mouthed by a child;
- An inaccessible component part is one that is located inside the product and not capable of being touched or mouthed by a child, whether or not such part is visible to a user of the product;
- An inaccessible part is one that may be enclosed in any type of material, e.g., hard or soft plastic, rubber, or metal (with the exception of vinyl or other plasticized materials covering mattresses or other sleep surfaces for children age 3 and younger);
- To assess whether a part is inaccessible, the accessibility probes defined in the Commission’s existing regulations for evaluating accessibility of sharp points or sharp metal or glass edges (16 CFR 1500.48 and 1500.49) are appropriate. An “accessible phthalate-containing component part” would be considered one that contacts any portion of the specified segment of the accessibility probe. An “inaccessible phthalate-containing component part” would be considered as one that cannot be contacted by any portion of the specified segment of the accessibility probe; and
- Use and abuse tests are appropriate for evaluating whether phthalate-containing component parts of a product become accessible to a child during normal and reasonably foreseeable use and abuse of the product by a child (with the exception of the bite test). The purpose of the tests is to simulate use and damage or abuse of a product by children and to expose potential hazards that might result from use and abuse. 16 CFR 1500.50–1500.53.

B. Discussion of Comments to the Proposed Guidance and CPSC’s Responses

Five comments were received on the proposed guidance. Two of the comments were from industry and three from consumers or nonprofit consumer and public health organizations. Most comments express general support for the guidance.

1. Fabric Materials as a Barrier to Accessibility of Component Parts

Comment: One commenter states that fabric should not be considered a barrier, regardless of the size of the component, because children could be exposed to phthalates through the fabric.

Response: As provided in CPSC staff’s briefing memo “Guidance for Evaluating Accessibility of Phthalate-Containing Component Parts” dated July 13, 2012, CPSC staff is not aware of any studies that show the propensity for phthalates to move from a phthalate-containing material through an intact, non-phthalate-containing material, such as an outside covering, where it could eventually reach the outside of a product. Furthermore, CPSC staff’s review showed that the non-vapor passive movement of phthalates within a product, if it existed, would be exceedingly slow and would never account for any more than a small, negligible fraction of the original phthalate content of the inaccessible phthalate-containing part. Based on CPSC staff’s analysis, the Commission finds that, in most cases, phthalates that are inaccessible would not result in physical exposure to phthalates, unless it is reasonably foreseeable that a component part will become physically exposed through mouthing, swallowing, breaking, or other children’s activities, and aging of the product. Accordingly, a child’s toy or child care article that is, or contains, a phthalate-containing part that is enclosed, encased, or covered by fabric and passes the appropriate use and abuse tests on such covers, is considered inaccessible to a child, unless the product, or part of the product, in one dimension, is smaller than 5 centimeters; i.e., a fabric-covered component part is not inaccessible if the product, or part of the product, can be placed in a child’s mouth.

Moreover, the Commission reiterates that vinyl or other plasticized materials covering mattresses and other sleep surfaces designed or intended by a manufacturer to facilitate sleep for children age 3 and younger should not be considered to be made inaccessible through the use of a fabric covering. As discussed in the preamble of the proposed guidance, the Commission reviewed phthalate-covered vinyl or other plasticized materials covering mattresses and sleep surfaces intended for young children. These mattresses or sleep surfaces are too large to be placed in a child’s mouth. Although such mattresses or sleep surfaces may be covered by fabric, such as sheets or mattress pads, additional consideration was given to whether children would become physically exposed to the vinyl or other plasticized materials covering the surface through reasonably foreseeable use and abuse of the products, including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product. The Commission determined there may be instances in which a child’s skin comes into close contact with a fabric covering over a phthalate-containing item for large portions of a day, such as a vinyl or other plasticized material covering a mattress or other sleep surface. Young children typically spend more than half of each day sleeping or resting, frequently on a mattress or similar item. While a mattress is typically covered with a sheet or mattress pad, such non-permanently affixed coverings that are either supplied with the mattress or provided by the consumer should not be considered to render the underlying material inaccessible. As with the potential transfer of phthalates by saliva during mouthing of an item, a mattress cover dampened with a spilled beverage, saliva, sweat, urine, or other liquid, could facilitate phthalate migration through the fabric. Furthermore, a nonpermanent covering cannot be assumed to be in use at all times; if it is not, the mattress could no longer be considered inaccessible. For these reasons, vinyl (or other plasticized material) covered sleep surfaces, which contain phthalates, designed or intended by a manufacturer...
to facilitate sleep for children age 3 and younger, should not be considered to be made inaccessible through the use of a fabric covering.

Comment: One commenter states that the proposed guidance “exempts components covered in fabric provided that the underlying component is not smaller than 5 centimeters in any one dimension.” According to the commenter, any exposure to phthalates-containing component parts within fabric coverings is very low and all phthalate-containing component parts covered by fabric should be exempt, irrespective of the size of the part. The commenter also suggests that a de minimis exception should be considered for accessible small plasticized parts.

Response: The commenter misinterprets the fabric covering restriction in the proposed guidance on inaccessible phthalate-containing component parts. The proposed guidance states that “a child’s product that is or contains a phthalate-containing component part which is enclosed, or covered by fabric and passes the appropriate use and abuse tests on such covers, is inaccessible to a child unless the product or part of the product in one dimension is smaller than 5 centimeters.” However, the 5 centimeter measure is applied to the fabric-covered part or product (i.e., a fabric covered plastic button), not to the size of the underlying phthalate-containing component part. If a toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in a child’s mouth (i.e., a fabric covered plastic ear on a stuffed animal). A phthalate-containing component part which is enclosed by a fabric covering is considered to be accessible to a child if the part or product is smaller than 5 centimeters in any dimension because such a part or product could be placed in a child’s mouth, and the fabric is not expected to perform as a barrier to saliva or other fluids or to prevent direct contact by the child with the saliva or other fluid after a fluid’s contact with the phthalate-containing part. Even if a fabric covering passes the applicable use and abuse tests, such a covering is not a barrier to the underlying material if the product can be placed in the mouth.

2. Exclusion of the “Bite Test” from Use and Abuse Testing

Comment: Two commenters question the exclusion of the “bite test” from the use and abuse testing and request that it be included in the guidance.

Response: Currently, the Commission does not use the bite test specified in 16 CFR 1500.51–1500.53, as a result of a court case (Clever Idea Co., Inc. v. Consumer Product Safety Commission, 385 F. Supp. 688 (E.D. N.Y. 1974)) that questioned the appropriateness of this test. Because the bite test currently is not applied as part of use and abuse testing for consumer products, it will not be applied for the purposes of evaluating products for accessibility of phthalate-containing component parts. However, this requirement may be modified in a future proceeding if the bite test is reevaluated.

3. Requirements for Labeling of Art Materials

Comment: One commenter requests consistency among the requirements for paints and other surface coatings for lead and phthalates and the requirements under ASTM D 4236 and ASTM F 963 that address art materials. This commenter specifically requests that bottles of paint available in retail stores should comply with all requirements because such paint could be used by children or on products for children.

Response: This comment is outside the scope of this guidance, which addresses the issue of when a phthalate-containing component part of a child’s toy or child care article is considered to be inaccessible to a child. The Standard Consumer Safety Specification for Toy Safety, ASTM F 963 requires that all art materials comply with the Labeling of Hazardous Art Materials Act. In addition to the LHAMA requirements discussed above, art materials that are designed or
intended primarily for children 12 years of age or younger, are also required, like all children’s products, to comply with the requirements of the CPSIA, including third party testing and certification.

C. Effective Date

Although guidance documents do not require a particular effective date under the Administrative Procedure Act, 5 U.S.C. 553(d)(2), the Commission recognizes the need for providing the guidance expeditiously. In addition, material published in the Code of Federal Regulations must have an effective date. Accordingly, the guidance will take effect upon publication in the Federal Register.

D. Final Guidance

The Commission is issuing the final guidance without substantive change from the proposed guidance.

List of Subjects in 16 CFR Part 1199

Business and industry, Infants and children, Consumer protection, Imports, Toys

For the reasons stated above, the Commission adds 16 CFR part 1199 to read as follows:

PART 1199—CHILDREN’S TOYS AND CHILD CARE ARTICLES CONTAINING PHTHALATES: GUIDANCE ON INACCESSIBLE COMPONENT PARTS


§1199.1 Children’s toys and child care articles: Phthalate-containing inaccessible component parts.

(a) Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits the sale of any “children’s toy or child care article” containing more than 0.1 percent of three specified phthalates (di-2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). Section 108 of the CPSIA also prohibits, on an interim basis, “toys that can be placed in a child’s mouth” or “child care article” containing more than 0.1 percent of three additional phthalates (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). A “children’s toy” is defined 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. A toy can be placed in a child’s mouth if any part of the 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 toy or part of a toy in one dimension is smaller than 5 centimeters, it can be placed in the mouth. The term “child care article” means a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 years and younger, or to help such children with sucking or teething.

(b) Section 108(d) of the CPSIA provides that the prohibitions in paragraph (a) of this section do not apply to component parts of a children’s toy or child care article that are not accessible to children through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission. A component part is not accessible if it 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, including swallowing, mouthing, breaking, or other children’s activities, and the aging of the product.

(c) Section 108(d)(3) of the CPSIA directs the Commission to promulgate a rule to provide guidance with respect to what product components or classes of components will be considered to be inaccessible for a children’s toy or child care article that contains phthalates or adopt the same guidance with respect to inaccessibility that was adopted by the Commission with regard to accessibility of lead under section 101(b)(2)(B) (15 U.S.C. 1278a(b)(2)(B)), with additional consideration, as appropriate, of whether such component can be placed in a child’s mouth. 15 U.S.C. 2057c(d)(3). 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.

(d) The accessibility probes specified for sharp points or edges under the Commission’s regulations at 16 CFR 1500.48–1500.49 should be used to assess the accessibility of phthalate-containing component parts of a children’s toy or child care article. A phthalate-containing component part would be considered accessible if it can be contacted by any portion of the specified segment of the accessibility probe. A phthalate-containing component part would be considered inaccessible if it cannot be contacted by any portion of the specified segment of the accessibility probe.

(e) For children’s toys or child care articles intended for children that are 18 months of age or younger, the use and abuse tests set forth under the Commission’s regulations at 16 CFR 1500.50 and 16 CFR 1500.51 (excluding the bite test of § 1500.51(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children’s toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(f) For children’s toys or child care articles intended for children that are over 18 months, but not over 36 months of age, the use and abuse tests set forth under the Commission’s regulations at 16 CFR 1500.50 and 16 CFR 1500.52 (excluding the bite test of § 1500.52(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children’s toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(g) For children’s toys intended for children that are over 36 months, but not over 96 months of age, the use and abuse tests set forth under the Commission’s regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of § 1500.53(c)), should be used to evaluate accessibility of phthalate-containing component parts of a children’s toy or child care article as a result of normal and reasonably foreseeable use and abuse of the product.

(h) For children’s toys intended for children over 96 months through 12 years of age, the use and abuse tests set forth under the Commission’s regulations at 16 CFR 1500.50 and 16 CFR 1500.53 (excluding the bite test of § 1500.53(c)) intended for children ages 37–96 months should be used to evaluate accessibility of phthalate-containing component parts of a children’s toy as a result of normal and reasonably foreseeable use and abuse of the product.

(i) Because the Commission adopts the same guidance with respect to inaccessibility for phthalates that was adopted by the Commission with regard to accessibility of lead, paint, coatings, and electroplating may not be considered a barrier that would render phthalate-containing component parts of toys and child care articles inaccessible. A children’s toy or child care article that is or contains a phthalate-containing component part that is enclosed, encased, or covered by fabric and passes the appropriate use and
abuse tests on such covers, is considered inaccessible to a child, unless the product or part of the product, in one dimension, is smaller than 5 centimeters. 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.

(j) The intentional disassembly or destruction of products by children older than age 8 years, by means or knowledge not generally available to younger children, including use of tools, will not be considered in evaluating products for accessibility of phthalate-containing components.


Todd A. Stevenson, Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

Montana Regulatory Program
AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: We are issuing a final decision on an amendment to the Montana regulatory program (the Montana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). We are not approving the amendment. Montana proposes changes to the Montana Strip and Underground Mine Reclamation Act (MSUMRA) that differentiate between coal beneficiation and coal preparation plants. Montana revised its program to clarify ambiguities and improve operational efficiency.

DATES: Effective Date: February 14, 2013.

FOR FURTHER INFORMATION CONTACT: Jeffery Fleischman, Casper Field Office Director, Telephone: (307) 261–6550, Internet address: jfleischman@OSMRE.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Program
II. Submission of the Proposed Amendment
III. Office of Surface Mining Reclamation and Enforcement’s (OSMRE’s) Findings
IV. Summary and Disposition of Comments
V. OSMRE’s Decision
VI. Procedural Determinations

I. Background on the Montana Program

Section 503(a) of the Act permits a State to assume primary for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with policies and conditions of approval in the April 1, 1980, Federal Register (45 FR 21560). You can also find background information on the Montana program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the April 1, 1980, Federal Register (45 FR 21560). You can also find later actions concerning Montana’s program and program amendments at 30 CFR 926.15, 926.16, and 926.30.

II. Submission of the Proposed Amendment

By letter dated June 7, 2011, Montana sent us a proposed amendment to its program (SATS number: MT–032–FOR, Administrative Record Docket ID No. OSM–2011–0011) under SMCRA (30 U.S.C. 1201 et seq.). Montana submitted the amendment to include changes made to the MSUMRA as a result of the Montana Legislature’s 2011 passage of a Senate Bill (SB 297) relating to coal beneficiation. Montana sent the amendment to include changes made at its own initiative.

We announced receipt of the proposed amendment in the October 17, 2011, Federal Register (76 FR 64045). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment’s adequacy (Administrative Record No. MT–29–16; Administrative Record Document ID No. OSM–2011–0011–0010). As a result, Montana stated that it will not be submitting revised amendments or draft proposed changes in response to our February 14, 2012, letter. Therefore, we are proceeding with the final rule Federal Register document.

III. OSMRE’s Findings

30 CFR 732.17(b)(10) requires that State program amendments meet the criteria for approval of State programs set forth in 30 CFR 732.15, including that the State’s laws and regulations are in accordance with the provisions of the Act and consistent with the requirements of 30 CFR Part 700. In 30 CFR 730.5, OSMRE defines “consistent with” and “in accordance with” to mean (a) with regard to SMCRA, the State laws and regulations are no less stringent than, meet the minimum requirements of, and include all applicable provisions of the Act and (b) with regard to the Federal regulations, the State laws and regulations are no less effective than the Federal regulations in meeting the requirements of SMCRA.

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at