

U.S. CONSUMER PRODUCT SAFETY COMMISSION WASHINGTON, D.C. 20207

May 10, 2007

Ms. Kathie Morgan ASTM International 100 Barr Harbor Drive West Conshohocken, PA 19428-2959

Dear Kathie:

On behalf of the U.S. Consumer Product Safety Commission (CPSC) staff, I am writing to request that ASTM coordinate the development of a new ASTM consumer product safety standard for lead in children's vinyl products.* The purpose of the standard would be to eliminate or significantly reduce children's exposure to lead in some consumer products. The development of standardized test methods for exposure to and total lead content of lead in vinyl products would also be an important aspect of this work.

The adverse health effects of lead poisoning in children are well documented and may have long-lasting or permanent consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Young children are most commonly exposed to lead in consumer products from the direct mouthing of objects, or from handling such objects and subsequent hand-to-mouth activity. The specific type and frequency of behavior that a child will exhibit depends on the age of the child and the characteristics and pattern of use of the product.

CPSC staff suggests that a new ASTM national consensus safety standard be developed under the oversight of the ASTM F-15 Committee on Consumer Products. The ASTM F-15 Committee seems well suited to oversee the development of such a standard since the ASTM F-15 has numerous subcommittees which for a number of years have been developing and maintaining safety standards for various children's products.

^{*} These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission

Examples of CPSC press releases on lead in vinyl children's products can be found at:

http://www.cpsc.gov/cpscpub/prerel/prhtml07/07175.html http://www.cpsc.gov/cpscpub/prerel/prhtml07/07107.html

Enclosed are: (1) a recent CPSC warning about the potential lead exposure from worn vinyl baby bibs, (2) a copy of the CPSC guidance for lead in consumer products in general as codified at 16 CFR §1500.230, and (3) a list of potentially interested parties who may wish to participate in the development of such a standard. Please contact me at 301-504-7245 if you have any questions.

Sincerely

Colin B. Church

Voluntary Standards Coordinator

Enclosures

ce: Ms. Kitty Pilarz, Chairman, ASTM F15 Committee Mr. John Blair, Vice Chairman New Projects, ASTM F15 Committee



NEWS from CPSC

U.S. Consumer Product Safety Commission

Office of Information and Public Affairs

Washington, DC 20207

FOR IMMEDIATE RELEASE May 2, 2007 Release #07-175

CPSC Hotline: (800) 638-2772 CPSC Media Contact: (301) 504-7908

CPSC Warns About Worn Vinyl Baby Bibs

WASHINGTON, D.C. – The U.S Consumer Product Safety Commission (CPSC) staff today warned that there is a potential risk of lead exposure from baby bibs with cracked or peeling vinyl surfaces. This consumer alert applies only to used bibs that are worn or have deteriorated. Pieces of vinyl containing lead could pose a hazard to infants if they are swallowed. CPSC staff recommends that parents and caregivers discard bibs that are in poor condition to avoid any potential exposure to lead from swallowed vinyl.

Some vinyl materials, including those used as the front or back of baby bibs, contain lead (Pb) compounds as part of their formulation. Acting on information provided by and in cooperation with the New York and Illinois Attorney Generals' Offices, CPSC recently tested a wide range of bibs from various retailers nationwide.

The CPSC staff's risk assessment concludes that none of the bibs that were tested at CPSC's laboratory would pose a risk of substantial illness to children from mouthing. However, if the condition of a vinyl bib deteriorates to the point that a baby could pull or bite off and swallow a piece of vinyl containing lead, then the amounts of lead consumed could approach levels of concern.

CPSC staff therefore advises parents and caregivers to stop using vinyl bibs in such condition. In the CPSC staff's view, this step could effectively prevent any significant risk of exposure to lead from these products. This precaution would also protect infants from the risk of choking on loose pieces of vinyl.

CPSC takes the issue of lead exposure very seriously, as lead is toxic and if ingested by young children can cause adverse health effects, such as learning disabilities, behavioral problems, growth retardation and hearing problems. There have been no reported injuries involving these bibs.

Vinyl baby bibs have been sold through major retailers since at least 2004. They range in price from \$2 to \$7 and come in packs of up to ten. The bibs come in colorful designs and have either a vinyl front with a cloth backing or a cloth front with vinyl backing.

Manufacturers and retailers, in cooperation with the CPSC and the New York and Illinois Attorneys General, plan to develop clear and effective guidelines addressing the use of vinyl in children's products.

Send the link for this page to a friend! The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of serious injury or death from more than 15,000 types of consumer products under the agency's jurisdiction. Deaths, injuries and property damage from consumer product incidents cost the nation more than \$700 billion annually. The CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical, or mechanical hazard or can injure children. The CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters, and household chemicals - contributed significantly to the 30 percent decline in the rate of deaths and injuries associated with consumer products over the past 30 years.

To report a dangerous product or a product-related injury, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270, or visit CPSC's web site at www.cpsc.gov/talk.html. To join a CPSC email subscription list, please go to www.cpsc.gov/cpsclist.asp. Consumers can obtain this release and recall information at CPSC's Web site at www.cpsc.gov.

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PART 1500—[AMENDED]

 The authority citation for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261-1278.

2. A new § 1500.231 is added, to read as follows:

§ 1500.231 Guidance for hazardous liquid chemicals in children's products.

(a) Summary. The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from exposure to hazardous chemicals found in liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, keychains, liquid timers, and mazes.1 The Commission identifies the major factors that it considers when evaluating liquid-filled children's products that contain hazardous chemicals, and informs the public of its experience with exposure to these hazardous chemicals to children. To reduce the risk of exposure to hazardous chemicals, such as mercury, ethylene glycol, diethylene glycol, methanol, methylene chloride, petroleum distillates, toluene, xylene, and related chemicals, the Commission requests manufacturers to eliminate the use of such chemicals in children's products. The Commission also recommends that, before purchasing products for resale. importers, distributors, and retailers obtain assurances from manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

(b) Hazard. During reasonably foreseeable handling or use of liquidfilled children's products, hazardous chemicals may become accessible to young children in a manner that places children at risk. Young children are exposed to the chemicals from directly mouthing them or from handling such objects and subsequent hand-to-mouth or hand-to-eye activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of the product. The adverse health effects of these chemicals to children include chemical poisoning from ingestion of the chemicals, pneumonia from aspiration of the chemicals into the lungs, and skin and eye irritation from exposure to the chemicals. The chemicals may also be combustible.

(c) Guidance. (1) Under the Federal Hazardous Substances Act (FHSA),

products that are toxic or irritants and that may cause substantial injury or illness under reasonably foreseeable conditions of handling or use, including reasonably foreseeable ingestion by children, are "hazardous substances." 15 U.S.C. 1261(f)(1). A product that is not intended for children, but that creates a risk of substantial injury or illness because it contains hazardous chemicals, requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children that contains an accessible and harmful amount of a hazardous chemical is banned. 15 U.S.C. 1261(q)(1)(A). In evaluating the potential hazard associated with children's products that contain hazardous chemicals, the Commission's staff considers certain factors on a caseby-case basis, including: the total amount of the hazardous chemical in a product, the accessibility of the hazardous chemicals to children, the risk presented by that accessibility, the age and foreseeable behavior of the children exposed to the product, and the marketing, patterns of use, and life cycle of the product.

(2) The Commission's staff has identified a number of liquid-filled children's products, such as rolling balls, bubble watches, necklaces, pens, paperweights, maze toys, liquid timers, and keychains, that contain hazardous chemicals. In several of these cases, the staff determined that these products violated the FHSA because they presented a risk of chemical poisoning and/or chemical pneumonia from aspiration. This determination resulted in recalls or in the replacement of those products with substitutes, as well as in agreements with the manufacturers to discontinue the use of hazardous chemicals in liquid-filled children's products in future production. The Commission believes that these hazardous substances pose a risk to young children and, consequently, manufacturers should not have included them in the product design or manufacturing process.

(3) Therefore, the Commission considers the use of hazardous chemicals in children's products such as those described above to be illadvised and encourages manufacturers to avoid using them in such products. Further, the Commission recommends that, before purchasing such products for resale, importers, distributors, and retailers obtain assurances from the manufacturers that liquid-filled children's products do not contain hazardous liquid chemicals.

Dated: December 17, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 98-33865 Filed 12-21-98; 8:45 am] BILLING CODE 6355-01-U

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Codification of Guidance Policy on Lead in Consumer Products

AGENCY: Consumer Product Safety Commission.

ACTION: Final policy statement.

SUMMARY: The Commission codifies a policy statement, previously approved by the Commission and published in the Federal Register, that provides guidance for manufacturers, importers, distributors, and retailers of consumer products that may contain harmful amounts of the element lead. To protect children and other persons from the toxic effects of exposure to lead, the Commission recommends that such persons obtain sufficient tests and analyses to ensure that their products do not contain harmful levels of lead. DATES: This codification is effective December 22, 1998. This policy has been applicable since December 24,

FOR FURTHER INFORMATION CONTACT:

Mary Toro, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504-0608, ext. 1378.

SUPPLEMENTARY INFORMATION: On January 22, 1998, the Commission published in the Federal Register the text of a document that provides guidance for manufacturers, importers. distributors, and retailers of consumer products that may contain harmful amounts of the element lead. 63 FR 3310. To protect children and other persons from the toxic effects of exposure to lead, the Commission recommends that such persons obtain sufficient tests and analyses to ensure that their products do not contain harmful levels of lead.

In order to make this policy more accessible to interested parties, the Commission is codifying the policy as 16 CFR 1500.230.

Since this is a statement of policy and interpretative rule, neither a general notice of proposed rulemaking or a delayed effective date is required. 5 U.S.C. 553(d)(2). A delayed effective date is not required for the additional reason that this policy is not a

This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

substantive rule. 5 U.S.C. 553(d)(3). Accordingly, this codification will become effective immediately upon its publication in the **Federal Register**.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and recordkeeping requirements, and Toys.

For the reasons given above, the Commission amends 16 CFR part 1500 as follows:

PART 1500-[AMENDED]

 The authority citation for part 1500 continues to read as follows:

Authority: 15 U.S.C. 1261-1278.

2. A new § 1500.230 is added, to read as follows:

§ 1500.230 Guidance for lead (Pb) in consumer products.

- (a) Summary. (1) The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in consumer products. The Commission identifies the major factors that it considers when evaluating products that contain lead, and informs the public of its experience with products that have exposed children to potentially hazardous amounts of lead.
- (2) To reduce the risk of hazardous exposure to lead, the Commission requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation. The Commission also recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children.
- (b) Hazard. Young children are most commonly exposed to lead in consumer products from the direct mouthing of objects, or from handling such objects and subsequent hand-to-mouth activity. The specific type and frequency of behavior that a child exposed to a product will exhibit depends on the age of the child and the characteristics and pattern of use of the product. The adverse health effects of lead poisoning in children are well-documented and may have long-lasting or permanent

consequences. These effects include neurological damage, delayed mental and physical development, attention and learning deficiencies, and hearing problems. Because lead accumulates in the body, even exposures to small amounts of lead can contribute to the overall level of lead in the blood and to the subsequent risk of adverse health effects. Therefore, any unnecessary exposure of children to lead should be avoided. The scientific community generally recognizes a level of 10 micrograms of lead per deciliter of blood as a threshold level of concern with respect to lead poisoning. To avoid exceeding that level, young children should not chronically ingest more than 15 micrograms of lead per day from consumer products.

(c) Guidance. (1) Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), household products that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are "hazardous substances." Ā household product that is not intended for children but which creates such a risk of injury because it contains lead requires precautionary labeling under the Act. 15 U.S.C. 1261(p). A toy or other article intended for use by children which contains a hazardous amount of lead that is accessible for children to ingest is a banned hazardous substance. 15 U.S.C. 1261(q)(1)(B). In evaluating the potential hazard associated with products that contain lead, the Commission staff considers these major factors on a case-by-case basis: the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.

(2) Paint and similar surface coatings containing lead have historically been the most commonly-recognized sources of lead poisoning among the products within the Commission's jurisdiction. The Commission has, by regulation, banned paint and other similar surface coatings that contain more than 0.06% lead ("lead-containing paint"), toys and other articles intended for use by children that bear lead-containing paint. and furniture articles for consumer use that bear lead-containing paint. 16 CFR Part 1303. In recent years, however, the Commission staff has identified a number of disparate products—some intended for use by children and others simply used in or around the household or in recreation—that presented a risk of

- lead poisoning from sources other than paint. These products included vinyl miniblinds, crayons, figurines used as game pieces, and children's jewelry.
- (3) In several of these cases, the staff's determination that the products presented a risk of lead poisoning resulted in recalls or in the replacement of those products with substitutes, in addition to an agreement to discontinue the use of lead in future production. The Commission believes that, had the manufacturers of these lead-containing products acted with prudence and foresight before introducing the products into commerce, they would not have used lead at all. This in turn would have eliminated both the risk to young children and the costs and other consequences associated with the corrective actions.
- (4) The Commission urges manufacturers to eliminate lead in consumer products to avoid similar occurrences in the future. However, to avoid the possibility of a Commission enforcement action, a manufacturer who believes it necessary to use lead in a consumer product should perform the requisite analysis before distribution to determine whether the exposure to lead causes the product to be a "hazardous substance." If the product is a hazardous substance and is also a children's product, it is banned. If it is a hazardous household substance but is not intended for use by children, it requires precautionary labeling. This same type of analysis also should be performed on materials substituted for
- (5) The Commission also notes that, under the FHSA, any firm that purchases a product for resale is responsible for determining whether that product contains lead and, if so, whether it is a "hazardous substance." The Commission, therefore, recommends that, prior to the acquisition or distribution of such products, importers, distributors, and retailers obtain information and data, such as analyses of chemical composition or accessibility, relevant to this determination from manufacturers, or have such evaluations conducted themselves.

Dated: December 17, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

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BILLING CODE 6355-01-U

This guidance is not a rule. It is intended to highlight certain obligations under the Federal Hazardous Substances Act. Companies should read that Act and the accompanying regulations in this part for more detailed information.

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Possible participants in an ASTM activity concerning lead in vinyl children's products:

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