UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

VOTE SHEET

DATE: OCT - 7 2009

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Maruta Budetti, Executive Director MB

FROM: Philip Chao, Assistant General Counsel PC
Hyun S. Kim, Attorney, OGC HSK

SUBJECT: Request from Learning Curve Brands Inc. for Exclusion from Lead Content Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA)

Attached are the staff memoranda on the request from Learning Curve Brands Inc. (Learning Curve) for exclusion of brass and mechanical components in replica and toy die-cast items under section 101(b)(1) of the CPSIA.

Please indicate your vote on the following options.

I. Deny Learning Curve's request for exclusion.

_____ _____
(Signature) (Date)

II. Grant Learning Curve's request for exclusion and direct staff to draft a *Federal Register* notice for comment.

_____ _____
(Signature) (Date)

CPSA 6(b)(1) CLEARED for PUBLIC
✓ NO MFRS/PRVTLBLRS OR PRODUCTS IDENTIFIED 10/7/09 RH
__ EXCEPTED BY: PETITION RULEMAKING ADMIN. PRCDG
__ WITH PORTIONS REMOVED: _____

Note: This document has not been reviewed or accepted by the Commission.
Initials RH Date 10/7/09

III. Take other action.
(Please specify.)

_____

_____

_____

_____ _____

(Signature) (Date)

EXHR Staff Memorandum: Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from Learning Curve Brands Inc. dated October, 2009.

Human Factors Response to a CPSIA Section 101(b)(1) Request for a Lead Content Exclusion for Brass in Toys and Children's Products dated October, 2009.

UNITED STATES
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4330 EAST WEST HIGHWAY
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Memorandum

Date: OCT - 7 2009

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel CAF
Maruta Budetti, Executive Director MB

FROM : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction RJH
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences KH

SUBJECT : Request for Exclusion from Lead Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act from Learning Curve Brands, Inc.

Introduction

The Consumer Product Safety Improvement Act provides for specific lead limits in children's products. Section 101(a) of the CPSIA provides that by February 10, 2009, products designed or intended primarily for children 12 years of age or younger may not contain more than 600 ppm of lead. After August 14, 2009, products designed or intended primarily for children 12 years of age or younger cannot contain more than 300 ppm of lead. On August 14, 2011, the limit will be further reduced to 100 ppm, unless the Commission determines that this lower limit is not technologically feasible. Paint, coatings or electroplating may not be considered a barrier that would make the lead content of a product inaccessible to a child or prevent the absorption of any lead in the human body through normal and reasonably foreseeable use and abuse of the product.

Section 101(b)(1) of the CPSIA provides that the Commission may exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither: (a) result in the absorption[1] of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

[1] In toxicology, absorption refers to the transfer of a chemical into the systemic circulation from the site of exposure, primarily through the skin, respiratory tract and gastrointestinal tract [Gregus Z (2008) Mechanisms of Toxicity In: C. Klaassen, (Ed.) Casarett & Doull's Toxicology, The Basic Science of Poisons. (p. 46) New York: McGraw Hill Medical]. In this memorandum, the term exposure is used to refer to the amount of lead a child comes into contact with, as well as the amount taken into the body through ingestion. A portion of ingested lead will be absorbed into the body, depending on factors such as the child's age, fasting and nutritional status, and chemical and physical form of the lead.

60(X)) CLEARED
X MFRS/PRVTLBLRS OR 10/7/09 RH
PRODUCTS IDENTIFIED

CERTIFIED BY: PETITION
TRACKING ADMIN. PRCDG

Note: This document has not been reviewed or accepted by the Commission.
Initials RH Date 10/7/09

By rule[2], the Commission has established procedures by which interested people may request an exclusion from the lead limits of section 101 of the CPSIA. This rule states that upon receipt of a request for an exclusion, the Office of Hazard Identification and Reduction (EXHR) will assess the request to determine whether, on the basis of its review of the submitted materials, the normal and reasonably foreseeable use and abuse activity by a child (including swallowing, mouthing, breaking, or other children's activities) and the aging of the material or product for which exclusion is sought, will not result in the absorption of any lead into the human body nor have any other adverse impact on health or safety.

This memorandum provides the EXHR staff review of materials submitted by Learning Curve Brands, Inc. in their request for exclusion for lead-containing certain components of replica and toy die-cast items.

Product

Learning Curve Brands, Inc. requests that brass and other mechanical components of replica and toy die-cast items be exempted from the lead limits of section 101 of the CPSIA. The specific component discussed in the request is the brass collar that secures each wheel of the product (a toy tractor in this case) to the axles.

Assessment

Learning Curve Brands, Inc. provided a number of reasons that they believe support their request. In brief, their stated reasons are: 1) CPSC has already granted an exemption for brass and other lead containing alloys in electronics where the material is necessary for the function of the product; 2) the brass is required to ensure that the products pass the necessary use and abuse tests by preventing the wheels from separating from the axles; 3) children are not likely to be exposed to the lead in the product; 4) other household products, including plumbing fixtures are allowed to contain lead at levels that exceed the CPSIA limits; and 5) a study conducted by RAM Engineering, a division of Intertek, determined that lead exposure to a child would be minimal, less than the amounts allowed in food.

The circumstances under which a specific product or material may be excluded from the CPSIA lead limits are narrow, based on whether reasonably foreseeable use and abuse of the product or material will result in the absorption of any lead into the human body. The previous Commission rulemaking for certain electronic products was conducted under the authority of a separate section of the law that specifically addresses electronic devices.

Consequently, the information relevant to this request is the evaluation conducted by RAM Engineering. This evaluation considered the possibility of exposure to lead from both mouthing (extraction with simulated saliva solution) and touching (wipe test). All simulated saliva extraction results were given as below the limit of detection, which was stated to be two micrograms (μg) of lead. The wipe testing, conducted using a method similar to the method used by CPSC staff, but using five wipes instead of three, resulted in a total of 0.8 μg lead removed from the surface of the component.

[2] "Children's Products Containing Lead; Final Rule; Procedures and Requirements for a Commission Determination or Exclusion," 74 Federal Register 10475 (11 March 2009), codified at 16 C.F.R. § 1500.90.

The report did not estimate the possible exposure to lead that might result from hand contact by a child. Instead, the authors looked to other regulatory paradigms for guidance. The authors cited a case involving the settlement of a California Proposition 65 action considering exposure to lead through handling of ceramicware and glassware. The settlement established safe harbor limits for lead, based on wipe testing, at one microgram for products intended for food use and at four micrograms of lead for products not intended for food use. The authors point out that the result of the wipe test of the brass component was well below the limit established for non-food contact.

Staff Conclusion and Recommendation

The staff believes that the assessment approach is generally sound, although it does not constitute a complete exposure assessment. That is, the requester's report did not quantitatively estimate the exposure to lead that might result from hand contact with the toy. Instead, the report authors compared the wipe results to another regulatory body's limit for wipe testing established for a different objective.

CPSC staff has conducted such analyses in the past for other products where exposure could occur through touching and handling. The staff generally considers that one wipe of a surface using the wipe testing procedure is the equivalent of one touching or handling event as a child interacts with a product. While the staff has not determined quantitatively how many times a child might touch the lead-containing component of a toy, some contact could occur[3]. The staff also assumes that some of the material that collects on children's fingers and hands is eventually transferred to their mouths, leading to ingestion and subsequent absorption of some of the lead. Therefore, given the wipe results presented in the request, the staff concludes that handling the toy would result in transfer of some lead to the mouth, leading to ingestion of some of the lead. The staff notes that, physiologically, if ingestion of lead occurs, some portion of the ingested lead will be absorbed into the body, whether or not the absorption results in a significant change in blood lead level. The amount of lead absorbed in this case is likely small.

As discussed above, the requester's report referred to a California Proposition 65 settlement that established safe harbor limits based on wipe testing. The staff is also aware that regulatory paradigms for lead in products exist within other federal regulatory agencies. For example, in 2006, the U.S. Food and Drug Administration (FDA) issued guidance[4] providing a recommended maximum lead level of 0.1 ppm in candy (equivalent to 0.1 μg/g). If, for example, a child consumed a piece of hard candy weighing 5 grams and containing lead at the recommended maximum level, the total intake of lead would be 0.5 μg.

Prior to enactment of the CPSIA, the staff's assessments of lead-containing children's products, under the Federal Hazardous Substances Act (FHSA), were based on estimates of lead intake and the subsequent effects of the exposure on the blood lead level, considering the toxicology of lead and the demonstrated health effects associated with increasing blood lead levels. Regulation of a consumer product as a "hazardous substance" under the FHSA requires assessment of exposure

[3] Memorandum from Jonathan D. Midgett to Kristina M. Hatlelid, "Human Factors Response to a CPSIA Section 101 Request for a Lead Content Exclusion for Brass in Toys and Children's Products," August 2009.

[4] Guidance for Industry: Lead in Candy Likely to Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), November 2006 (available at http://www.cfsan.fda.gov/guidance.html).

and risk from reasonably foreseeable use and abuse of the product. In this case, given the assessment provided by the requestors, the staff likely would have concluded that the estimated exposure to lead from children's contact with the die-cast toys would have little impact on the blood lead level. Accordingly, based on the staff's assessment, the staff would have recommended that the Commission not consider the product to be a hazardous substance to be regulated under the FHSA.

However, the CPSIA establishes the standard by which the staff evaluates the materials submitted with a request for exclusions. The law states that an exclusion may be granted if lead in such product or material will neither: (a) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

The requester's report indicated that children's use of the toy could result in exposure to lead through hand contact with the lead-containing brass component. CPSC staff assumes that at least some of the material that collects on children's hands is eventually transferred to their mouths, leading to ingestion and subsequent absorption of some of the lead. Since contact with the toy could result in absorption of lead, however small the absorbed amount, the staff concludes that the statutory standard has not been met.

UNITED STATES
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4330 EAST WEST HIGHWAY
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Memorandum

Date: June 30, 2009

TO : Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

THROUGH: Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction
Hugh M. McLaurin, Associate Executive Director, Directorate for Engineering Sciences

FROM : Jonathan D. Midgett, Ph.D., Engineering Psychologist, Division of Human Factors

SUBJECT : Human Factors Response to a CPSIA Section 101 Request for a Lead Content Exclusion for Brass in Toys and Children's Products

Introduction

This memorandum provides the Human Factors staff response to the request by Learning Curve Brands, Inc. for an exclusion from the lead content limits set by the Consumer Product Safety Improvement Act of 2008 (CPSIA).

Product

The subject products are small vehicle toys, such as trucks and tractors. These die-cast metal toys are miniature replicas with high levels of detail intended for children 3 years of age and older. The manufacturer uses brass collars to secure the wheels to the axles. The brass collars are visible and accessible to children during play.

Assessment

Section 101(b)(1) of the CPSIA allows the Commission to exclude a specific product or material from the lead limits established for children's products under the CPSIA if the Commission, after notice and a hearing, determines on the basis of the best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither: (a) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (b) have any other adverse impact on public health or safety.

Human Factors staff looked at the reasonably foreseeable use and abuse of brass collars on the wheel axles of small vehicle toys to assess the likely interaction of the youth user and the parts.

Small Vehicle Play

According to the AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior (2002)[1], 3-year-old children "display a moderate degree of dexterity and fine-motor control, and low to moderately complex cause-and-effect functionality in their pretend play. They enjoy small vehicles that produce sounds or talking, lights, or movement by pushing buttons on the toy or on a remote control to produce basic actions. Small vehicle toys are attractive to this age because they are used increasingly in cooperative contexts that have a low to moderate level of social interactions, especially as they approach age 4. These children are attracted to both smaller (1 to 8 inches) and larger (12 to 24 inches) vehicles of more complexity and detail. They prefer vehicles in basic coordinated sets (for example, miniature die-cast cars and vehicles approximately 1:60 to 1:64 scale) and those with relevant figures and accessories. Boats, cars, motorcycles, fantasy vehicles, trucks, and flying machines begin to appeal to 3-year olds when they are more detailed, so they are attracted to materials like die-cast metal or plastics that capture more detail. They begin to prefer a moderate level of realistic detail like proportional design, loose parts, functionality, decorations, and printed words. They enjoy rich vibrant colors and bright pastel colors. They are attracted to simple remote devices that have easy to manipulate buttons or joysticks. Children in this age group also like to use pull-back-and-release mechanisms or simple, multiple-turn winding mechanisms that have a large key and low tension. They enjoy pretending with numerous movable parts, like doors, hoods, dumpers, hoses, sails, rudders, propellers, simple levers, with large workable parts for easy pincer grasp. Small vehicles that have licenses popularized by various media begin to appeal to these children. If the toy is designed to be picked up during use, lightweight vehicles (no more than 6 to 8 ounces) are more appropriate. Preferred trains have multiple cars that fasten and detach. As with the previous age group, large simple tracks with easy connections appeal to these children because they derive a sense of completion and accomplishment when putting objects together." (p. 109)

The subject products are detailed small vehicles that will interest this age group in pretend play. Since some children 3 and 4 years of age are still engaging in some hand-to-mouth behavior, it can be expected that some of these children will bring their hands to their mouths after touching the metal parts of the toys. While children 5 years of age and older do not typically engage in substantial hand-to-mouth behavior, it is not unreasonable to assume they may wipe their mouth or face with their hands during and after playing with their toy vehicles.

Human Factors staff is not aware of any scientific data that measured how many times a child using a small vehicle will contact the various metal parts of the vehicle, but it is reasonable to assume that they will come in contact with various parts during normal play events. Due to the recessed location of the brass collars, such parts are not easily accessible places for mouthing, like an edge or a protrusion would be.

Staff Conclusion

Human Factors staff believes that during normal play children 3 years of age and older will interact with the metal parts of their small vehicles. During reasonable foreseeable use and abuse, children may have incidental contact with the brass collars on the wheels of the subject small vehicles, but are unlikely to mouth that area of the toy for substantial periods of time.

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[1] Smith, T.S. (Ed.). (2002). AGE DETERMINATION GUIDELINES: Relating Children's Ages to Toy Characteristics and Play Behavior, U.S. Consumer Product Safety Commission, Bethesda, MD.