Motorcycle Industry Council

January 28, 2009

VIA FEDERAL EXPRESS

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway, Room 502
Bethesda, MD 20814-4408

Re: PETITION FOR TEMPORARY FINAL RULE TO EXCLUDE A CLASS OF MATERIALS UNDER SECTION 101(b) OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT

Dear Mr. Stevenson:

Attached please find an original and five copies of a petition for a temporary final rule to exclude a class of materials under Section 101(b) of the Consumer Product Safety Improvement Act.

The Motorcycle Industry Council respectfully urges your prompt attention to this petition.

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Irvine, CA 92618

Counsel for Motorcycle Industry Council

PETITION FOR TEMPORARY FINAL RULE TO EXCLUDE A CLASS OF MATERIALS UNDER SECTION 101(b) OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT

Relief from the CPSIA's lead content requirements for youth all-terrain vehicles (ATVs) and youth off-highway motorcycles (OHMs) should be granted because lead-containing components, parts and accessories pose no risk of causing measurable increase in blood lead levels in children ages 12 and younger.

The Motorcycle Industry Council (MIC) is a not-for-profit industry association representing over 300 manufacturers and distributors of motorcycles, scooters, parts and accessories for powersports vehicles, and members of allied trades. MIC's members include the major manufacturers and distributors of OHMs: Honda, Kawasaki, KTM, Suzuki and Yamaha. Scores of other MIC members – mostly small U.S.-based businesses – rely on the sale of parts and accessories and services related to OHMs and ATVs. Select youth model ATVs and OHMs, and parts and accessories for those vehicles, are or have been intended primarily for use by children ages 6 to 12, and thus are subject to the lead content limits specified in Section 101 of the Consumer Product Safety Improvement Act (CPSIA), Pub. L. No. 110-314. Some components of, and parts and accessories for, youth ATVs and OHMs unavoidably contain small quantities of lead in excess of the CPSIA limits – although not in excess of the lead limits set forth in various European Union Directives for electronic devices and motorized vehicles and motorcycles. The lead in these components, parts and accessories is unavoidable either because small amounts of lead are needed for safety (such as facilitating the machining of tire valves, critical to assuring air retention) or functionality (such as the lead used in battery terminals, which is needed to conduct electricity), or because lead cannot feasibly be removed from recycled materials. Because these small quantities of lead are unavoidable, MIC's member companies will need relief from the CPSIA requirements in order to continue to sell their products on or after February 10, 2009.

As indicated, such relief is appropriate because the best available evidence shows that lead-containing youth ATV and OHM components, parts and accessories – even those that would be considered accessible to children under the CPSC's proposed accessibility regulations – are nonetheless highly unlikely to be touched by children at all in most cases, and that any contact that does occur poses no risk to children ages 12 or younger.

The comment period for CPSC's proposed procedures for seeking an exclusion from the lead limits, however, does not close until February 17, 2009, and published reports indicate that the rulemaking for the adoption of such procedures may not be completed until sometime this summer. Thus, as a practical matter, it is impossible for the CPSC to complete rulemaking in time for affected manufacturers and distributors to seek and obtain new exclusions under the contemplated procedures before the February 10, 2009 effective date for the new CPSIA lead requirements. MIC's members cannot wait until the summer of 2009 to begin the process of seeking exclusions for the small but unavoidable (and harmless) quantities of lead in their youth ATV and OHM products.

Accordingly, through this petition, MIC joins some of its member companies in seeking emergency relief, in the form of a temporary final rule, granting a temporary exclusion from the lead limits for certain lead-containing materials (as specified below) in youth ATV and OHM components, parts and accessories. A grant of this petition will allow the CPSC's staff the time it needs for a thorough review of the public comments filed in response to its now-pending CPSIA regulatory proposals, and an orderly completion of the rulemakings, consistent with the Administrative Procedure Act. It also will allow MIC's member companies – and their thousands of dealers – to continue selling their products, while, at the same time, posing none of the risks to children that the CPSIA was enacted to prevent.

PETITION FOR A TEMPORARY FINAL RULE

Pursuant to Sections 3 and 101(b)(1) of the CPSIA, and this agency's proposed implementing regulations, MIC hereby petitions for a temporary final rule excluding from the lead limits established for children's products under the CPSIA the class of materials consisting of (i) lead battery terminals used in youth ATVs and youth OHMs and (ii) steel, aluminum, and copper alloys that are used in components of, and parts and accessories for, youth ATVs and youth OHMs and that contain lead in amounts not greater than those permitted by European standards for lead in motorized vehicles and motorcycles and electronic components and that are not otherwise inaccessible to children (and therefore exempt from the CPSIA). The grounds for this request are that the lead in such materials will not result in the absorption of any lead into the human body – taking into account normal and reasonably foreseeable use and abuse of such products by a child, as well as the aging of the products – nor have any other adverse impact on public health and safety. A proposed regulatory provision is included with this petition.[1]

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[1] This petition relates only to *accessible* lead in youth ATV and OHM components, parts and accessories. As the Commission has noted in its proposed interpretative rule on inaccessible component parts, "Section 101(b)(2) of the CPSIA provides that the lead limits will not apply to any component part of a children's product that is not accessible to a child through normal and reasonably foreseeable use and abuse." *See* Children's Products Containing Lead; Interpretative Rule on Inaccessible Component Parts, 74 Fed. Reg. 2439 (Jan. 15, 2009). In the proposed interpretative rule, the Commission has preliminarily determined that "an accessible component part of a children's product is one that a child may touch, and an inaccessible component part is one that is located inside the product and not capable of being touched by [a] child, whether or not such part is visible to a user of the product." *Id.* at 2440. For example, certain internal engine components that may consist of lead-containing alloys are inaccessible to children through normal and reasonably foreseeable use and abuse under this proposed standard, and, therefore, are excluded from compliance with the CPSIA's specified limits on lead levels. In addition, components of MIC's members' products that contain lead in amounts below the CPSIA's limits (and, therefore, that are in compliance with the CPSIA) are not addressed in this

Because the Commission has recently published proposed procedures for exclusion determinations, and comments on those procedures are not due until February 17, 2009 (*see* 74 Fed. Reg. 2428, 2429 (Jan. 15, 2009)), there is no reasonable prospect that a petition for a final exclusion could be acted upon by the Commission prior to February 10, 2009, when the lead content requirements of the CPSIA go into effect. As set forth below, the CPSIA's restrictions on lead in products primarily intended for use by children 12 or younger may preclude MIC's member companies from selling certain youth ATVs and OHMs and parts and accessories for those vehicles. A temporary Final Rule, however, will allow the CPSC's staff the time it needs for a thorough review of the public comments filed in response to its now-pending CPSIA regulatory proposals, resulting in an orderly completion of the rulemakings, consistent with the Administrative Procedure Act. It also will allow MIC's member companies – and their thousands of dealers – to continue selling their products (while, at the same time, posing none of the risks to children that the CPSIA was enacted to prevent) pending completion of a proceeding addressing a subsequent petition that MIC and some of its members anticipate filing for a permanent exclusion for their products.

The Administrative Procedure Act confers authority on agencies to issue interim and temporary final rules without prior notice and comment "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b). Here, the imminent compliance date for the lead limits in the CPSIA effectively precludes an opportunity for notice and comment on exclusion requests prior to the effective date of the CPSIA's lead content provisions. In similar circumstances, the

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petition. Replacement and aftermarket parts, as well as accessories, containing accessible lead in the amounts specified above are included in the scope of this petition.

Commission has previously exercised its authority to issue an immediately effective final rule under the CPSIA. *See* Final Rule, Certificates of Compliance, 73 Fed. Reg. 68328 (Nov. 18, 2008). In this matter, the need for immediately effective regulatory action is at least as compelling as it was with regard to certificates of compliance. Accordingly, the Commission should issue an immediately effective temporary final rule, granting MIC's request on an interim basis, for such period of time as the Commission requires to complete the procedural rule on exclusion petitions and process a petition for permanent exclusion through a final decision. MIC and some of its members intend to file a petition for a permanent exclusion promptly after the Commission adopts a final rule specifying the procedures and requirements for seeking such exclusions.

MIC's requests are amply supported by the best-available, objective scientific evidence. The class of materials for which an exclusion is being sought are (i) lead battery terminals and (ii) components and parts supplied as original equipment or available as replacement or aftermarket parts and accessories made with copper, aluminum, and steel alloys – such as tire valve stems, and fittings and connectors made with copper (and brass) alloys, brake and clutch levers and other brake components, throttle controls, engine housings, and carburetors made with aluminum alloys, steel fasteners, and frames and structural or engine components made with steel alloys, among other components – that contain lead in amounts not greater than those permitted under the European Union's RoHS and End-of-Life Vehicles ("ELV") Directives.[2]

The RoHS Directive (EU Directive 2002/95/EC (Jan. 27, 2003)) addresses "the restriction of the use of certain hazardous substances in electrical and electronic equipment." In

[2] In this petition, following the practice in the RoHS and ELV Directives, MIC uses the term "copper alloys" to refer generically to copper and brass alloys. The requested exclusion for copper alloys should, therefore, be construed to cover brass alloys, as well.

its proposed exemptions for certain electronic devices, the CPSC has recognized that the RoHS Directive's functionality-based exemptions from the RoHS lead prohibitions are sufficiently protective of children to comply with CPSIA. The lead limits and exemptions in the RoHS Directive were derived from the ELV Directive, EU Directive 2000/53/EC (Sept. 18, 2000). Both directives stem from the EU's ongoing efforts to establish an "Integrated Product Policy" to address environmental issues over the life cycle of products. *See generally* Communication from the Commission to the Council and the European Parliament: Integrated Product Policy: Building on Environmental Life-Cycle Thinking.

In connection with a review of exemptions mandated by Annex II of the ELV Directive, the European Union has recently engaged in an exhaustive reexamination of the bases for exempting the various alloys and components, including those for which MIC seeks an exclusion here. That reexamination was conducted by an independent institute and involved a transparent process marked by extensive stakeholder participation and a thorough review of the state-of-the-art in materials properties, substitutability, and functionality. *See* Öko-Institut e.V., Final Report: Adaptation to Scientific and Technical Progress of Annex II, Directive 2000/53/EC (Jan. 16, 2008) ("Final ELV Report") (http://147.67.243.36/Public/irc/env/elv/library?l=/stakeholder_consultation/evaluation_procedure/reports/final_report/report_revision/_EN_1.0_&a=d).

The Final ELV Report recommended the retention of exemptions for lead in steel, aluminum, and copper alloys, and the exemption for lead batteries, noting the current lack of acceptable substitutes that do not contain lead for use in motorized vehicles and motorcycles. As set forth in greater detail below, the Final ELV Report exhaustively examined the uses of those alloys and components, the contribution that lead makes to such features as machinability, strength, and corrosion resistance; and the availability (or lack thereof) of substitute materials that do not contain lead. The Final ELV Report concluded that, at the present time, there are no adequate replacements for the class of materials at issue in this petition, although potentially acceptable replacement alloys may become available in the future. This conclusion comports with the CPSC's proposed exemption for certain electronic devices, in which the CPSC tentatively concludes that there are, at present, no suitable substitutes for these particular lead-containing alloys.

The lack of available substitutes for the lead battery terminals and for steel, aluminum, and copper alloys used by MIC's members companies in their youth ATV and OHM components, parts and accessories supports the reasonableness of the relief requested in this petition, which seeks only limited exclusions for lead battery terminals and for lead in certain alloys at levels not in excess of those permitted under the RoHS and ELV Directives.

In addition, MIC submits a report prepared by Dr. Barbara D. Beck, Ph.D., DABT, an expert in toxicology and health risk assessment for environmental chemicals, especially metals and air pollutants; former Fellow in the Interdisciplinary Programs in Health at the Harvard School of Public Health; current Lecturer in Toxicology at Harvard; and principal of Gradient Corporation. *See* Attachment A. In that report, which is based on a thorough literature review and analysis of existing data concerning the alloys at issue in this petition, Dr. Beck states that she has determined that the lead content in brass, aluminum, and steel alloys in certain components of youth ATVs and OHMs does not present an exposure concern for children and that an exclusion is appropriate for such components. She bases this conclusion on an analysis showing that – even in worst-case scenarios and using projected intakes of lead greater than those expected to result from exposure to MIC's members' products – no measurable increase in the blood lead levels of children ages 6 to 12 can be expected to result from their exposure to and contact with the materials for which this petition seeks an exemption.

Dr. Beck's focus on exposure effects on blood lead levels is consistent with the overall purposes of the lead level requirements of the CPSIA. As the House Report on the Act explained in connection with the exception to the lead standards for inaccessible parts, the legislation's focus was on ensuring "that any products granted an exception has no meaningful ability to expose a child to lead *in such a way that could raise blood lead level.*" H.R. Rep. 110-501, at 30 (2007) (emphasis added).

Finally, the relief requested here also is amply supported by available scientific evidence that children of the ages who are likely to use youth ATVs and OHMs do not typically engage in mouthing behaviors that are likely to involve youth ATV and OHM components, parts and accessories. *See* Stephen L. Young, Ph.D., Timothy P. Rhoades, Ph.D., P.E., CPE, & Julia K. Diebol, B.S.E., C.P.S.M., *Comments on Consumer Product Safety Improvement Act (CPSIA) Section 101 Lead in Children's Products: All-Terrain Vehicles and Off-Highway Motorcycles* at 4 (Applied Safety and Ergonomics, Inc. Oct. 31, 2008) (Attachment B). In addition, although the class of materials for which an exclusion is being sought by MIC includes components, parts and accessories that are accessible to children's hands, the best available scientific evidence shows that children between the ages of 6 and 12 – that is, the children for whom youth ATVs and youth OHMs are intended and marketed – do not engage in the hand-to-mouth behaviors commonly seen in younger children, and that, in the contexts in which MIC's members' products are generally used, hand-to-mouth activity could be expected to be minimal. *See* Stephen L. Young, Ph.D., CPE, Raina J. Shah, M.S.E, C.P.S.M., CPE, Timothy P. Rhoades, Ph.D., P.E., CPE, & Julia K. Diebol, B.S.E., C.P.S.M., *Report in Support of Petition for Temporary Final*

Exclusion Rule Under Consumer Product Safety Improvement Act (CPSIA) Section 101 Lead in Children's Products: All-Terrain Vehicles and Off-Highway Motorcycles at 4, 7 (Applied Safety and Ergonomics Jan. 27, 2009) (Attachment C).

In accordance with the Commission's proposed procedures and requirements for a Commission determination or exclusion, we are submitting the following information.

1. Requester's Identifying Information.

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2. Description of Class of Materials

The class of materials for which this petition seeks an exclusion are (i) lead battery terminals and (ii) steel, aluminum, and copper alloys containing lead in amounts up to those permitted under the RoHS and ELV Directives' exemptions.[3] Such alloys are used in various original equipment, replacement and aftermarket components, parts and accessories, including, but not limited to, fittings and connectors, engine housings, chassis parts, frames, drive lines, spoke nipples, tire valve stems, cables and hoses, brake levers and other brake system components, clutch levers, and throttle controls.

3. Lead Content

The lead content of the battery terminals can be as much as 100%, although some battery terminals may have less lead. The lead content of the alloys for which an exclusion is being sought varies because the diverse applications of the alloys in MIC's members' products may

[3] As noted above (at note 2), in this petition, following the practice in the RoHS and ELV Directives, MIC uses the term "copper alloys" to refer generically to copper and brass alloys.

require different lead levels for machinability, corrosion resistance, or other functional reasons. In addition, the lead content of the alloys also necessarily varies because, in some cases, the lead content results from the use of recycled aluminum and steel. In no case, however, does the lead content of products within the scope of this petition exceed the permissible lead content permitted under the exemptions set forth in the pertinent annexes to the RoHS and ELV Directives – that is, 0.35% lead by weight for steel alloys, 0.4% lead by weight for aluminum alloys, and 4% lead by weight for copper alloys.

4. Introduction of Lead in the Manufacturing Process

Lead is deliberately introduced into some members of the class of materials for which an exclusion is being sought in this petition in the process of preparing them according to precise standards and specifications that set forth the amounts of lead to be used for various applications and performance requirements. Lead also appears as an unavoidable result of the use of recycled materials.

5. Other Information Relevant to Lead Content

The Final ELV Report contains exhaustive discussions establishing that, in the current state of the art, lead is necessary in batteries and in the alloys for which an exclusion is being sought in order to assure safety, durability, and machinability.

Thus, for lead in steel, the report explains, "[l]ead is used in steel for improved machinability. By the addition of lead better chip fracturing, automation of the productive process, high cutting speed (low cycle times), longer tool life, better surface finish and more accurate dimension control can be achieved." Final ELV Report at 11. In galvanized steel, lead "has important functions in the galvanizing process" itself. *Id.* at 12.

As the report also makes clear, although attempts have been made to develop alternatives to lead as a machinability enhancer in steel, none of the possible substitutes has performed as well as leaded steel. Thus, for instance, leaded steels have been shown to outperform bismuth, increased sulfur, tin, phosphorous, and calcium as additives to steel. *Id.* at 14. These "non-leaded alternative grades generally gave poorer chip form and surface finish."

Bismuth provides some substitutability for lead under certain circumstances, but "the hot workability of bismuth steels is reduced compared to leaded steels. Hot workability is a fundamental requirement for steel production." *Id.* As a result, "it is significantly harder for a steel roller to produce a bar with the same machining properties and surface integrity if the steel obtains its machining properties through bismuth rather than lead." *Id.* Calcium also showed significant drawbacks as compared to lead (*id.* at 15), and "[s]teels containing tin generally did not show good performance in the machinability tests and thus, [were] not considered as a suitable replacement for lead in steel." *Id.*

Similarly, although there are ongoing efforts to develop alternatives to lead for galvanized steel, there is currently a lack of adequate supplies of potential alternatives (for instance, bismuth), and technical problems with regard to drainage of excess zinc from the galvanized product and the quality of the surface finish remain. *Id.* at 16-17.

As a result, the Final ELV Report concludes that because of the lack of available alternatives, "the use of lead in steel for machining purposes and in galvanized steel at the current state of the art is unavoidable." *Id.* at 18.

With regard to aluminum, the Final ELV Report explains that lead is found in aluminum either because it has been deliberately added for improved machinability or because the aluminum alloys contain lead as an impurity as a result of the production of the alloys from scrap. *Id* at 21. With regard to the deliberately added lead, the Final ELV Report concludes that leaded aluminum alloys are necessary for use in brake and clutch systems for safety-related reasons. Lead in aluminum alloys increases corrosion and wear resistance. Compared to tin- or bismuth-containing aluminum alloys, leaded aluminum alloys show higher resistance "against pitting corrosion in brake and clutch systems: at higher temperatures (>120 C) the adhesion of the anodised coating to the base material of lead-free alloys (e.g. tin and/or bismuth alloys) is stated to be negatively impaired in the presence of certain media like brake fluid." *Id.* at 19; *see also id.* at 20 (stating that test results were submitted showing that, for aluminum parts in brake and clutch systems, tin and bismuth are not as resistant to pitting corrosion by contact with brake fluid as leaded aluminum parts). The Final ELV Report concludes that the exemption for leaded aluminum alloys in brake and clutch systems "seems to be justified especially since safety related parts are concerned." *Id.* at 21.

As for recycled aluminum alloys – that is, "[a]luminum produced from recycled scrap metal" (*see id.*) – the Final ELV Report concludes that the removal or dilution of lead impurities in aluminum is not technically feasible on the scale needed for industrial purposes. *See id.* at 24-25.

With regard to copper alloys, the Final ELV Report notes that "[t]he lead that is embedded as tiny nodules in the matrix of these alloys has the function of a chip breaker and machinability enhancer. The formation of small chips, which can be removed automatically, is facilitated." *Id.* at 26; *see also id.* at 28. The Final ELV Report notes, however, that there are potential substitutes for leaded copper alloys. At present, however, these alternatives to lead have a number of drawbacks. Thus, bismuth alloys are more susceptible to stress corrosion cracking, unfavorable chip form, and missing self-lubricating effects that result in higher tool wear. *Id.* at 29. As a result, the enhanced machinability of leaded copper alloys, which, for instance, permits the creation of deep grooves in threaded parts such as valve stems that are needed to ensure secure cap and air valve fitment for safety reasons, supports an exclusion for leaded copper alloys, in accordance with the conclusion of the Final ELV Report.

With regard to lead battery terminal posts, the Final ELV Report discussion of lead-acid batteries is pertinent. It states that "[t]he stakeholder presented plausible information showing the technological superiority of lead-acid batteries. Their substitution by lead-free alternatives would reduce the functionality and reliability of vehicles, the use of lead in this function hence is unavoidable at the time being and in the near future." *Id.* at 38.

The Final ELV Report's conclusions strongly support the relief sought by MIC. Although technological feasibility is not the statutory touchstone for exclusions of the class of materials for which MIC is petitioning, it is clear that Congress intended the Commission to consider issues of technological feasibility in implementing the CPSIA. Thus, in explaining Section 101, the Conference Report on the CPSIA states that the CPSC is ultimately required to "lower the permissible lead level in children's products to the lowest amount that is *technologically feasible.*" H.R. Rep. 110-787, at 66 (2008) (Conf. Rep.), *as reprinted in* 2008 U.S.C.C.A.N. 1112, 1113. The Final ELV Report supports the conclusion that, at the present time, feasible alternative materials are not available to substitute for the class of materials for which this petition seeks an exclusion. In the event that adequate, equally safe, functional, and machinable non-leaded substitutes become available, MIC member companies could explore their use. But in the present state of the art, if the petition were denied, the safety of youth ATVs and youth OHMs could be compromised, and MIC's members could be forced to suspend or terminate their production and sale of such products.

6. Methods for Testing Lead Content

Standards-setting organizations, such as ASTM International and the International Standards Organization, set forth precise standards for the composition of metallic alloys for various purposes, as well as methods for determining the content of such alloys. These standards are used by suppliers of alloys used by MIC's member companies and their suppliers. Materials engineers use highly sophisticated preparation and quality control procedures to assure uniformity and consistency in the preparation of alloys for industrial and commercial uses.

7. Assessment of Manufacturing Processes

Lead is introduced into MIC's members' products through the use of steel, copper, and aluminum alloys into which lead is introduced deliberately according to precise specifications by the suppliers of the alloys, or through the use of recycled materials. Accordingly, this category is not applicable to this petition.

8. Lead In The Product, Lead Coming Out of the Product, Conditions Under Which Lead Comes Out of the Product, and Information Relating to a Child's Interaction With the Product.

A. Lead in the Product

As noted above, MIC seeks an exclusion for battery terminals, as well as for lead in steel, aluminum, and copper alloys only up to the amount permitted by the RoHS and ELV Directives.

B. Lead Coming Out of the Products: Amounts and Conditions

In her report (Attachment A), toxicology and health risk assessment expert, Dr. Barbara D. Beck, provides a comprehensive analysis of the amounts of lead that can be dislodged from the pertinent components of youth ATVs and youth OHMs via direct contact, which is the only relevant condition for lead to emanate from MIC's members' products. *See* Attachment A at 3-

9. Dr. Beck and her team focused principally on two components – the brake lever and the tire valve stem. The former was selected for analysis because it likely is the component, part or accessory with which children would have the most frequent and prolonged contact. The valve stem was selected not because contact is likely, but because it is a copper (or brass) component that, under the RoHS and ELV directives, is permitted higher concentrations of lead than are aluminum or steel alloys. Dr. Beck's analysis concluded that the "estimated lead intake from brake levers and valve stems ranges from 0.015 to 0.050 μg/day." *Id.* at 8.[4] As Dr. Beck points out, "the default lead intake for diet used in the US EPA's Integrated Uptake Biokinetic Model (IEUBK) . . . is 2.22 μg/day for a 6 year old, and the default lead intake from water is 0.6 μg/day. The estimated intake from the [MIC's members'] components is well below these background exposures to lead in food and soil." *Id.* Dr. Beck goes on to show that a lead intake of "***ten times higher*** than the maximum estimated intake from motorized recreational vehicle components"—that is, 0.5 μg/day—"would have no discernable impact on blood levels in children." *Id.* at 9 (emphasis added); *see also id.* ("estimated lead intakes from motorized recreational vehicle components are well below background intakes of lead from food and water" and "will not result in a measurable impact on blood levels in children"). In short, the impact on blood lead levels of the *de minimis* intake of lead that could foreseeably result from contact with MIC's members' products is simply *not detectable*. *See id.*

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[4] Preliminary wipe test data conducted for MIC member, American Honda Motor Co., on exemplar components show that the estimates relied upon by Dr. Beck are very conservative and may overstate the actual presence of lead in these components by a substantial degree. MIC and its members will continue to work on expanded data in connection with preparation of a petition for a permanent exemption.

C. Children's Interactions with the Products

MIC's members' youth ATV and OHM products are not intended for use by children under 6. Analyses of children's likely interactions with these vehicles have been prepared by Applied Safety and Ergonomics, Inc. and are attached at Attachments B and C. These analyses, which were performed by teams led by Stephen L. Young, Ph.D., CPE, a Senior Consultant at Applied Safety and Ergonomics, Inc., conclude that the children for whom these products are intended (those in the 6-12 age group) are highly unlikely to engage in the "mouthing" behavior common in children 3 years and younger. *See* Attachment B at 4. Moreover, these products and their components, parts and accessories are not the sort of objects typically subject to children's mouthing behaviors. *See id.*

Other contacts by children with the class of materials for which an exclusion is sought in this petition are possible, however. Although MIC warns against operating these vehicles without wearing protective gloves, it is possible that such contacts may on occasion include touching with bare hands. Nonetheless children ages 6 to 12 are similarly unlikely to engage in hand-to-mouth behaviors, such as thumb-sucking, that are characteristic of younger children, and also are unlikely to engage in other hand-to-mouth behaviors, such as nail biting, while engaged in activities involving youth ATVs and OHMs. *See* Attachment C at 2-4, 7.

In addition, as noted above, Dr. Beck's toxicological analysis demonstrates that any contacts foreseeably resulting from children's interactions with MIC's members' products would result in no detectable increases in blood level levels.

9. Best Available Evidence Unfavorable to the Petition

MIC is not aware of any objective, peer-reviewed, scientific evidence that is unfavorable to the request.

PROPOSED REGULATORY PROVISION

Part 1500 – HAZARDOUS SUBSTANCES AND ARTICLES: ADMINISTRATION AND ENFORCEMENT REGULATIONS

Add a new section 1500.__ to read as follows:

§ 1500.__ Exemptions from Lead Limits under section 101 of the Consumer Product Safety Improvement Act for lead battery terminals and certain alloys used in children's motorized products.

(a) Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA) provides that "[t]he Commission may, by regulation, exclude a specific product or material from the prohibition in subsection (a) if the Commission, after notice and 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."

(b) The CPSIA provisions on lead limits in products designed or intended primarily for children 12 and younger go into effect on February 10, 2009. The Commission will not complete the promulgation of a final rule setting forth procedures for requesting exclusions under Section 101(b) of the CPSIA prior to that date. The motorcycle industry association has established that the CPSIA's restrictions on lead in products intended for use by children may preclude companies in that industry from selling certain children's motorized products. It also has shown that the imminent compliance date for the CPSIA's lead limits effectively precludes an opportunity for notice and comment on its request for the issuance of a final rule excluding a certain class of materials used in youth products from those lead limits. For this reason, as well as for the other reasons shown in its petition for a temporary final rule to exclude a class of materials under Section 101(b) of the CPSIA, the Commission finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest," 5 U.S.C. § 553(b), and that, therefore, good cause exists to promulgate a temporary final rule without prior notice and comment.

(c) The following class of materials used in connection with children's motorized products is hereby temporarily excluded from the prohibitions of Section 101(a) of the CPSIA: (i) lead battery terminals and (ii) steel, aluminum, and copper alloys that contain lead in amounts not greater than the amounts that are granted exemptions published in the Annex to the European Union Directive 2002/95/EC, as amended through European Union Decision on January 24, 2008, provided that the exemption is based on a functional requirement both for the use of a lead-containing component and for the use of the lead in such component, and does not include an exemption for decorative or non-functional uses of lead. This exclusion encompasses original equipment, replacement and aftermarket components, parts and accessories.

(d) This exclusion shall remain in effect until ________________ or until a final determination is made on a petition submitted pursuant to the procedures adopted by the Commission for exclusion petitions.

ATTACHMENT A

Exposure Evaluation of Manufactured Components in Consideration for Exclusion from the Consumer Product Safety Improvement Act (CPSIA)

Prepared for
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Prepared by
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January 26, 2009

1 Introduction

This report presents a scientific evaluation of certain youth All-Terrain Vehicle (ATV), youth off-road motorcycle, and youth snowmobile (hereinafter, "motorized recreational vehicle") components manufactured from certain lead-containing alloys in consideration of possible exclusion from the Consumer Product Safety Improvement Act of 2008 (CPSIA). Using scientifically accepted exposure assessment procedures and reasonable and foreseeable exposure scenarios, we have determined that the lead content in brass, aluminum, and steel alloys in certain motorized recreational vehicle components does not present any risk of a measurable increase in blood lead levels in children and that an exclusion is therefore appropriate for such components. Our detailed analysis follows.

2 Background

The Consumer Product Safety Improvement Act (CPSIA) of 2008 stipulates that, by February 10, 2009, children's products that contain more than 600 ppm (mg/kg) lead may no longer be sold in the United States (US Congress 2008, Pub. L. No. 110-314, § 101(a)(2)). The limit will be reduced to 300 ppm after August 14, 2009 and then to 100 ppm on August 14, 2011 unless the Commission determines that this lower limit is not technically feasible. Section 101(b) of the Act also allows for an exclusion for certain products or materials that exceed this limit, based on evidence that reasonably foreseeable use and abuse of the product will not "result in the absorption of any lead into the human body". In addition, a recent rulemaking notice has proposed procedures and guidance as to how an exclusion may be formally considered by the Consumer Product Safety Commission (CPSC) (74 Fed. Reg. 2428, 2429 (Jan. 15, 2009).

In this analysis, we provide technical evidence that certain lead-containing components of motorized recreational vehicles primarily intended for use by children ages 12 and under should be considered for exclusions under the language of the CPSIA statute.

3 Metal Alloys and Motorized Recreational Vehicle Components

Certain motorized recreational vehicle components are made of metal alloys, which, as part of their functionality, contain lead. The alloys are:

- Copper brass alloys that may contain up to 4% lead (40,000 ppm)
- Aluminum alloys that may contain up to 0.4% lead (4000 ppm)
- Steel alloys that may contain up to 0.35% lead (3500 ppm)

In addition, exposed battery terminals contain unalloyed lead.

For the purpose of this analysis we have focused on specific components; however, this should not be taken to indicate that other alloys exceeding the CPSIA limits may not also merit exemptions. Rather, timing constraints prevent an analysis of all components individually. We have, as an upper bound case, focused on components where the concentrations of lead are relatively high and/or the exposure potential appears to be greatest.

The components of interest and their alloys (or lead composition) are:

- Valve stem (copper brass)
- Brake lever (aluminum)
- Steel frame (steel)
- Ignition key (copper brass)
- Battery terminals (unalloyed lead)

In our analysis, we will focus only on the brake lever and valve stem, as, together, these are believed to present the worst-case scenario – brake levers are the components with which a child will likely have the most contact in an exposure scenario, and the valve stem, while unlikely to be contacted by a child on a regular basis, has the highest permissible lead concentration of the components of interest that are foreseeably likely to be contacted by children.

4 Methodology

Our approach is based on generally accepted principles and approaches of exposure assessment, as applied to lead-containing materials (US EPA, 1994; 1997). There are three main components of the analysis:

- Estimation of amount of lead released from the component, leading to a potential for contact by a child
- Estimation of the amount of lead potentially taken up into the body by a child, considering reasonable use and abuse of the component

- Interpretation of the amount potentially taken up into the body, in the context of the statutory language

Details on each of these components is provided in the subsequent sections.

4.1 Estimation of Amount of Lead Released from the Component, Leading to a Potential for Contact by a Child

We employed two methods to quantify the potential amount of lead released from the component. While the preferred data would be actual lead measurements from wipe methods mimicking hand contact, such data are not available. Therefore, we extrapolated from the best-available existing data, using conservative assumptions where appropriate. For example, we assumed that lead released from copper brass products into water reflected the amount of lead on the surface of a component and that all of this lead could be transferred to fingers and hands; however, it is more plausible that only some lead on the surface of a product would be transferred to hands and fingers.

The two methods to estimate release of lead from motorized recreational vehicle components are:

- Extrapolation from studies of lead release from jewelry onto fingers by direct contact
- Extrapolation from studies of release of lead from brass faucets into water, normalizing to mass of lead released as a function of surface area

We focused our modeling effort on the brake lever and the valve stem. Our approach was to use worst case examples, either in terms of the nature of the contact or in terms of lead concentrations. Thus, the results of the analysis would be applicable to other components, which involve lesser contact or have lower lead concentrations. For example, the lead content in the steel frame (0.35%, or 3500 μg/g) is more or less comparable to that of the brake lever (0.4% lead, or 4000 μg/g), and it is reasonable to assume that a motorized recreational vehicle rider will have more frequent contact with the brake levers than with the frame of their vehicle. Likewise, the spoke nipple is composed of the same brass alloy (4% or 40000 μg/g lead content) as the valve stem. An older child is more likely to make adjustments to tire pressure using the valve stem than to touch the spoke nipple. Additionally, it is highly unlikely that a younger child (*i.e.* less than 6-years old, the population of greater concern for lead exposure) would ever adjust tire pressure at all. Therefore, estimating lead released from these components will result in a worst-case estimate of lead intake for the infrequently contacted components.

Details on the specific estimation methods are as follows.

4.1.1 Literature Review

We reviewed the literature for relevant, peer-reviewed studies that quantitatively evaluate the amount of lead that can be dislodged *via* direct contact with metallic surfaces. A study by Druhan (2004) of metallic jewelry is the only study that we identified that measured direct contact between hands and metallic surfaces; because the type of metal used in the jewelry was nonspecific, this study was used to evaluate both aluminum brake levers and brass valve stems. We also reviewed several faucet leaching studies. A study performed by Maas *et al.* (1997) was selected to evaluate brass components because of the large sample size (22 faucets), and because the size of each faucet tested was reported, which allowed us to estimate surface area.

In order to extrapolate the results of the jewelry and brass faucet studies to motorized recreational vehicle components, we developed a value called the Handling Transfer Coefficient (HTC). For both studies, we determined the amount of lead removed per surface area of test material, then divided this value by the lead concentration in the test material:

$$HTC\left[\frac{g}{cm^2}\right] = \frac{\dfrac{lead\ removed\ from\ test\ material\ [\mu g]}{surface\ area\ of\ test\ material\ [cm^2]}}{lead\ concentration\ in\ test\ material\ \left[\dfrac{\mu g}{g}\right]}$$

The HTC is an estimate of the amount of test material removed per surface area handled. Using this information, we derived average HTCs for both the jewelry study and the faucet study. Our approach is described in detail below.

4.1.2 Druhan (2004)

The jewelry study performed by Druhan (2004) involved volunteers briefly handling (with a portion of two fingers and the thumb) 20 pieces of metal jewelry. Following handling of each piece of jewelry, the fingers and thumb of the volunteers were rinsed with water, and the rinsate was then analyzed to determine the mass of lead (μg) transferred from the jewelry to the hand.[1]

For each piece of jewelry, Druhan reported the associated lead concentration (range of 11,000 μg/g to 893,700 μg/g), as well as the amount of lead removed from each piece of jewelry per square centimeter of surface area (range of 0.0028 $\mu g/cm^2$ to 0.80 $\mu g/cm^2$, excluding one outlier that was over 20 times greater than the next highest value). We calculated the HTC for each piece of jewelry, and the 95% upper confidence limit on the mean (UCLM) of all jewelry samples (excluding the outlier) is 1×10^{-6} g/cm^2. Because the lead concentration in the majority of the jewelry pieces was much higher than that of motorized recreational vehicle components, we chose to average the HTC for a total of three jewelry pieces containing less than 100,000 μg/g of lead; the concentrations in these three samples more closely resembled the concentrations in the motorized recreational vehicle components and are thus considered more representative. The maximum HTC for these samples is 2×10^{-6} g/cm^2 (the maximum value was used in this case because there were not enough samples to calculate a UCLM).

[1] Note that it appears Druhan (2004) may not have adequately controlled for cutting or scraping of individual jewelry pieces during an earlier analysis for total lead content. This would result in a bias towards overpredicting the amount of lead transferred to the hand.

4.1.3 Maas *et al.* (1997)

Maas *et al.* (1997) conducted a study of 22 faucets that were connected to a pressurized supply of a leaching solution prepared according to the NSF 61 protocol for faucet evaluation (pH of 8, 0 mg/L available chlorine, and 100 mg/L hardness) (NSF, 2000). Over the course of the study, faucets were "aged" by periodically flushing them with 100 mL of test solution. Prior to taking 200 mL leachate samples, each faucet was flushed, then allowed to stand for 30 minutes. Faucets were sampled three times at one-week intervals and analyzed for lead. Maas *et al.* reported the volume (cm^3) of each faucet tested and the concentration of lead in the associated leachate samples (µg/L). Using this volume, we were able to estimate the surface area (SA) of each faucet by assuming a uniform radius (r) of 1 cm for all faucets where:

$$SA = 2\pi r^2 + 2\frac{Volume}{r}$$

We determined the mass of lead removed from the faucet in the leaching test by multiplying the lead concentration (average of three samples) by the volume of leachate collected. We estimated the lead concentration of the brass faucets by assuming that faucets were composed of a brass alloy with 60,000 µg/g lead (6 % lead).[2] Using the mass of lead removed after 30 minutes of leaching, the estimated surface area of the faucet, and the estimated lead content in brass, we calculated the HTC for each faucet. The 95% UCLM of the HTC over all faucets is 6×10^{-7} g/cm^2.

4.2 Estimation of Amount of Lead Released from the Component and Subsequently Taken into the Body

There are several factors involved in transferring lead from the surface of the component into the body of the child. These include the surface area of the hand/fingers touching the component, the transfer of that amount of lead to the hand/fingers, the frequency and duration of the contact, the transfer of lead from hand/fingers to mouth, and subsequent intake of the lead into the body. This may be represented as the following equation:

$$Intake\left(\frac{ug}{day}\right) = HTC \times CA \times PbC \times TE \times \frac{EF}{7\ days/week}$$

where:

HTC = Handling transfer coefficient, g/(cm^2 ride)
CA = Area of component contacted, cm^2
PbC = Lead concentration in component, µg/g (ppm)
HTE = Hand transfer efficiency, unitless
EF = Exposure frequency, rides/week

[2] According to a study by Dresher (1992), the two most common brass alloys used in plumbing contain between 5.57% and 7% lead. We selected 6% as a value in the middle of this range. Use of this percentage is considered to be conservative since the brass components in motorized recreational vehicles contain less than 6% lead (brass motorized recreational vehicle components contain up to 4% lead).

Each of these parameters is explained in more detail below, and the exposure assumptions used for the component scenarios are provided in Table 1.

Table 1
Lead Intake Exposure Assumptions

Component	Material	HTC g/(cm^2 ride)	HTC basis[1]	CA cm^2	PbC µg/g	HTE unitless	EF rides/week
brake lever	aluminum alloy	1×10^{-6}	jewelry	56	4,000	0.25	2
valve stem	brass alloy	4×10^{-7}	jewelry	2.2	40,000	1	2
valve stem	brass alloy	6×10^{-7}	faucet study	2.2	40,000	1	2

Notes:

1. The Druhan (2004) jewelry study did not identify the metallic composition of the jewelry pieces; therefore, we applied the results to both aluminum and brass components. The Maas (1997) faucet study was specific to brass components; therefore, we have applied the results only to the brass valve stem.

Area of Component Contact (CA): This parameter represents the area of contact between a child's hand and the specific motorized recreational vehicle component (brake lever or valve stem).

The area of contact between the brake lever and hand is based on a brake lever with a 1.5 cm diameter (based on a reasonable approximation). We assume that the full perimeter of the lever is contacted across the width of a child's hand. We made a conservative assumption that a child's hand is 6 cm, which is an overestimate for younger children, but yields a larger contact area and therefore a higher, more conservative estimate of lead intake. With these assumptions, the contact area for each hand is 28 cm^2, and the total for two hands is 56 cm^2.

The area of contact between the valve stem and hand is equal to the exposed brass on the valve stem, which has a diameter of 0.7 cm and a length of 1 cm, for a total area of 2.2 cm^2 (based on measurement of a valve on a typical bicycle tube). We conservatively assume that one valve is handled per ride, which overstates exposure since a child is unlikely to touch the valve stem each time he or she rides a motorized recreational vehicle.

Lead Concentration in Component (PbC): This parameter is the concentration of lead in the motorized recreational vehicle component in µg/g (ppm).

The brake lever is made of an aluminum alloy that may contain up to 4,000 µg/g (0.4%) lead. Valve stems are made of a copper brass alloy that may contain up to 40,000 µg/g (4%) lead.

Hand Transfer Efficiency (HTE): The hand transfer efficiency parameter, or HTE, describes the fraction of soil on the hands that might be subsequently ingested via hand-to-mouth contact.

We used soil HTE factors developed by Dubé *et al.* (2004) to estimate HTE for the motorized recreational vehicle components. To develop the HTE factor, Dubé *et al.* (2004) reviewed data regarding children's incidental ingestion of soil, adherence of soil to the hands, and the skin surface area of the hands. The estimate of soil loading on the hands was combined with an estimated soil ingestion rate to derive the HTE factor, which is an estimate of the proportion of the mass of soil adhering to the hands that would need to be ingested to yield the estimated soil ingestion rate. Dubé *et al.* (2004) calculated a HTE factor of 0.25 for a child (ages 2-6 years), meaning that, on average, incidental ingestion of approximately one-fourth of the soil adhering to the palmar surface of a child's hands yields the typical estimated daily soil ingestion rate. For a child ages 7-12 years, Dubé *et al.* (2004) estimated the HTE would be approximately half of the HTE for a child (*i.e.*, 0.13), because available data indicates that, for older children and adults, incidental soil ingestion is less than that in younger children (less than 7 years old), and hand-to-mouth contacts are less frequent. For example, standard default soil ingestion rates for adults are typically about half of those for children ages of 2–6 years old (US EPA, 1997).

For scenarios involving contact with motorized recreational vehicle components, we extrapolated Dubé *et al.*'s soil HTE factors and have made the conservative assumptions that 1) one-fourth of all material that adheres to a child's hands from touching the brake lever is ingested (a lower value may be appropriate for older children) and 2) all of the material that adheres to a child's fingers from touching a valve stem is ingested.

Exposure Frequency (EF): The exposure frequency is the number of days per week that a child is expected to ride a motorized recreational vehicle.

We estimated an exposure frequency of 2 days/week for typical motorized recreational vehicle use.

4.3 Interpretation of Amount of Lead Taken into the Body

We recognize that the statute refers to no lead absorption in the body; however, we believe that, as a scientific matter, the concept of "no lead absorption" would be reasonably interpreted by the scientific community to mean no measurable impact on blood lead. This is consistent with the fact that, even at the permitted concentrations of lead in products, *i.e.*, 600 ppm at the first threshold, one cannot assume that the impact on lead intake is zero. Hence we have interpreted the intake and absorption of lead from the products in terms of an impact on blood lead, which would be so slight as to have no detectable impact in an individual). The specific intakes associated with these comparison points are described as follows in the results section.

5 Results

The results of our analyses were calculated using the above equations and assumptions, and are presented in Table 2. One can observe that the estimated lead intake from brake levers and valve stems ranges from 0.015 to 0.050 µg/day.

To place these values into context, the default lead intake for diet used in the US EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) (US EPA, 1994; 2001; 2009) is 2.22 µg/day for a 6 year old, and the default lead intake from water is 0.6 µg/day. The estimated intake from the components is well below these background exposures to lead in food and soil.

The IEUBK model will not register a detectable incremental increase to blood lead when modeling lead intakes as low as 0.015 to 0.050 μg/day for a child 6 years of age. Thus, in order to further evaluate the significance of intakes of 0.015 to 0.050 μg/day, we modeled the effect of an intake of 0.5 μg/day, which is ten times higher than the maximum estimated intake from motorized recreational vehicle components. We ran the IEUBK model with the assumption that the 6 year old child would be exposed to 0.5 μg of lead each day for a full year (US EPA, 1994; 2001; 2009).

With conservative default inputs for all exposure routes and without consideration of any lead intake from motorized recreational vehicle use, the IEUBK model predicts a blood lead level of 1.9 μg/dL for a 6-year-old child. Adding 0.50 μg/day of lead intake (which is higher than the intake amounts resulting from the modeling) starting at age 6 does not change the predicted blood lead level, yielding the same predicted blood lead level of 1.9 μg/dL. Thus, it is clear that an intake of 0.015 to 0.050 μg/day would have no discernable impact on blood lead levels. In other words, the predicted blood level would be 1.9 μg/dL even with an additional intake of 0.015 to 0.050 μg/day.

Table 2
Lead Intake Results

Component	Material	Basis of HTC	Lead Intake μg/day
brake lever	aluminum alloy	jewelry	0.032
valve stem	brass alloy	jewelry	0.050
valve stem	brass alloy	faucet	0.015

In conclusion, because estimated lead intakes from motorized recreational vehicle components are well below background intakes of lead from food and water, and because such intake will not result in a measurable impact on blood lead levels in children, we believe that exclusions are merited for the components noted.

References

Consumer Product Safety Commission (CPSC). 2009. "Children's Products Containing Lead; Notice of Proposed Procedures and Requirements for a Commission Determination or Exclusion." 16 CFR Part 1500. January 15.

Dresher, WH; Peters, DT. 1992. "Lead-free and reduced-lead copper-base cast plumbing alloys. Evaluation of candidate U.S. compositions. Part I." *Metals.* 46(11):1142-1146.

Druhan, JL. 2004. "Lead content of imitation jewelry products and their potential hazard to the consumer." *UNC Asheville J. Undergrad. Res.* 5p.

Dubé, EM; Petito Boyce, C; Beck, BD; Lewandowski, TA; Schettler, S. 2004. "Assessment of potential human health risks from arsenic in CCA-treated wood." *Hum. Ecol. Risk Assess.* 10:1019-1067.

Maas, RP; Patch, SC; Morgan, DM; Winfield, RL; Thornton, LR. 1997. "A Study of the Lead Leaching Characteristics of Twenty-Two New Water Faucets under Pressurized Conditions." University of North Carolina, Environmental Quality Institute, Asheville, NC. EQI Technical Report #97-036.NSF Joint Committee on Drinking Water Additives. 2000 (NSF). "Drinking Water System Components - Health Effects." NSF International. Ann Arbor, MI. ANSI/NSF 61-2000a. 166p.

US Congress. 2008. "Public Law 110-314: Consumer Product Safety Improvement Act of 2008." Accessed on January 21, 2009 at http://www.cpsc.gov/cpsia.pdf, August 14.

US EPA. 1994. "Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children." Technical Review Workgroup for Lead. OERR Publication 9285.7-15-1, EPA540-R-93-081, NTIS PB93-963510. February.

US EPA. 1997. "Exposure Factors Handbook." EPA/600/P-95/002Fa, EPA/600/P-95/002Fb, EPA/600/P-96/002Fc, NTIS PB98-124225, NTIS PB98-124233, NTIS PB98-124241, NTIS PB98-124217. August.

US EPA. 2001. "Integrated Exposure Uptake Biokinetic Model for Lead in Children." Version 1.0. Build 264.

US EPA. 2009. "Frequent Questions from Risk Assessors on the Integrated Exposure Uptake Biokinetic (IEUBK) Model." Accessed on January 22, 2009 at http://www.epa.gov/superfund/lead/ieubkfaq.htm.

ATTACHMENT B

Comments on Consumer Product Safety Improvement Act (CPSIA) Section 101 Lead in Children's Products: All-Terrain Vehicles and Off-Highway Motorcycles

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Introduction

Applied Safety and Ergonomics, Inc. (ASE) was contacted by counsel representing all-terrain vehicle (ATV) and off-highway motorcycle (OHM) manufacturers to consider normal and reasonably foreseeable use and abuse of youth ATVs and OHMs as part of an assessment related to Section 101 of the Consumer Product Safety Improvement Act ("the Act"). Specifically, we were asked to consider swallowing and mouthing behaviors as those activities are identified in Sections 101(b)(1)(A) and 101(b)(2)(A) of the Act. Contact with parts resulting from breakage is excluded from our analysis due to the durable nature and construction of these products, and the fact that they are not intended for children under age 6.

Our analysis considers mouthing and swallowing behaviors based on existing literature. This analysis clearly shows that an ATV or OHM is qualitatively different from the types of objects that have been identified in the literature as being a concern for child mouthing behaviors. In addition, the literature shows that children ages 6 through 12 do not mouth objects in the environment in the way or to the same degree as do children ages 3 years and younger.

Review of Literature Regarding Child Swallowing and Mouthing

The general literature on child development shows that children instinctively exhibit rooting and sucking behaviors immediately after birth. Mouthing and sucking behaviors continue throughout childhood for both nutritive (e.g., breast-feeding) and non-nutritive (e.g., pacification) reasons (Turgeon-O'Brien, 1996). Because of this natural tendency for children to mouth objects in the environment, research has been conducted to identify the types of objects that children mouth and the potential risks associated with such behaviors. Research has also sought to identify the extent and pattern of mouthing behaviors of children across different ages. These studies support two general propositions as they relate to ATVs and OHMs:

1. An ATV or OHM is qualitatively different from the types of objects that have been identified in the literature as being a concern for child mouthing behaviors.
2. Children age 6 through 12 years do not mouth objects in the environment in the way or to the same degree as do children ages 3 years and younger.

These two propositions will be addressed individually in the following sections.

Types of Objects Mouthed by Children

Several studies have examined child mouthing behaviors (i.e., sucking, licking, chewing, etc.) with a view toward identifying risks to children from ingestion of objects. These studies have identified the types of objects that children mouth in naturalistic settings. For example, Norris and Smith (2002) identified a number of items that were mouthed by children ages 5 years and below (see Table 1). Similarly, Juberg et al. (2001) identified a similar list of objects mouthed by children ages three years and below (see Table 2).

Table 1. Items mouthed by children in Norris and Smith (2002)

Building block	Hair band/clip/scrunchie	Bath toy
Pen/pencil	Fork and toy fork	Brush/hairbrush
Spoon and toy spoon	Modeling clay	Buttons
Toy figures and accessories	Necklace and toy necklace	Toy car wheel
Play food	Straws	Dice/domino
Ball	Clothes peg	Hat bobbles
Remote control (TV, CD player)	Fridge magnet	Pencil sharpener
Toothbrush	Fur	Toy pliers
Paper	Bamboo cane/stick/ lollipop stick	Rope
Baby wipes/tissues	Cassette tape, reel of tape	Seashell
Crayon	Toy screwdriver/ screw	Soap
Jigsaw piece	Comb	Soil
Stacking cups/rings	Dressing gown belt	Tape measure
Balloons	Emery board/nail file/sandpaper	Cable tie
Doll accessories	Knife and toy knife	Cafetiere plunger
Sponge	Lip salve/lipstick/ make-up	Can
Cuddly toy	Pebble	Candle
Key and toy key	Scissors	Chalk
Pen top	String	Toy drill bit
Coin and toy coin	Zip	Toy fire engine ladder
Straps/cords	Ball bearings/ marbles	Toy fishing rod
Chocolate wrapper/crisp packet/cake cup/packet	Coat hanger	Gasket
Cables (electrical, telephone, games controllers)	Eraser	Pastry cutter
Bottle lids/tube lids/bottle tops e.g. shampoo, glue, toothpaste	Magnet	Radiator cap
Toy traffic lights	Badges	Rubber band
Cloth	Beads	Shredded paper
Ring and toy ring	Cotton thread/wool	Syringe
Bag	Laces	Toy bolt
	Whistle	Toy fire extinguisher

Table 2. Items mouthed by children in Juberg et al. (2001)

Animals	Christmas tree beads	Newspaper
Balls	Christmas tree ornament	Nickel
Barn	Christmas lights	Paper (ate it)
Beads	Coat zipper	Pen and top of pen cap
Blocks	Cordless phone antenna	Pencil
Candy dispenser	Cotton swab	Pencil holder
Car	Crayon	Penny
Cups	Cup handle	Picture frame
Doll house figures	Diaper rash ointment tube	Piece of rubber
Keys	Dog food	Pine needles
Fence	Dog biscuit	Plastic bag
Play food	Dog bone (ate it)	Plastic end to blind cord
Rattle	Doll house figures	Plastic spoon
Rubber ducky	Egg carton	Playing card
Shapes	Electrical cord	Play money
Stack rings	Empty baby food jar and lid	Ponytail holders
Toy figures	Empty vitamin bottle	Scissors
Toy phone	Eraser	Sister's necklace
Toy thermometer	Extension cord	Small play fork
Trucks	Eyeglasses	Soda pop can
Tub toy	Eye piece of binoculars	Stroller handle
Wand	Foil	Stuffed animals
Action figure sword	Frosting tube top	Styrofoam peanuts
Adult necklace	Hairbrush	TV Remote control
Bar of soap	Highchair strap	Telephone
Barretts	Keys and key chain	Tissue
Battery	Lint	Toy truck wheels
Blanket	Lip balm	Toothbrush
Blue chalk (ate it)	Magnet	Toy cars/fire trucks
Bobby pin	Make-up brush	Twistie
Books	Marble	Vacuum hose attachment
Bowl	Marker and cap	Vanity cabinet knobs
Button	Molding clay	Wash cloth
Candy dispenser	Nail file	Wooden spoon
Car keys (metal part)	Nail polish bottle	Wrapping paper, ribbon
Chalk	Nail clippers	

These studies indicate that children may exhibit mouthing behaviors toward a variety of objects in the household. However, ATVs and OHMs are not on any of these lists and they are not qualitatively similar to the types of objects that are commonly mouthed by children. Unlike many of the household items on these lists, ATVs and OHMs do not naturally "afford" (i.e., lend themselves to) mouthing behaviors.

Mouthing Behavior as a Function of Age

Most studies on child mouthing behaviors have examined children ages three years and younger because these ages are the most susceptible to compulsive and indiscriminant mouthing. For example, Juberg et al. (2001) examined mouthing behavior of children ages 0 to 36 months and found that mouthing time for non-pacifier objects was significantly greater for children 0-18 months than for children 19-36 months. These authors concluded that their findings were "consistent with patterns of child development, which show a peak period for mouthing activity that is positively correlated with teething and negatively correlated with increased mobility" (p. 140).

Other studies have examined mouthing behavior of children up to age five. Tulve et al. (2002) employed a recursive partitioning algorithm to divide children into two age groups with regard to mouthing frequency: ≤24 months and >24 months. At ages greater than 24 months, mouthing behaviors were significantly less frequent than they were for younger children. Also consistent with previous findings, this study showed that "toys and hands were preferentially mouthed as compared to other body parts and household surfaces" (p. 264). Similar findings have been observed in other studies of children's mouthing behaviors (see Norris & Smith, 2002; EPA, 2002).

These studies, taken as a whole, indicate that younger children (i.e., under age 3) are significantly more likely to mouth a wide variety of objects in the environment, but the frequency of mouthing behaviors decreases significantly for older children (>3) and they become more discriminating about the types of objects they mouth. While there can be variability in the nature and frequency of mouthing behaviors across different children, the available literature shows that children ages 6 through 12 are not part of the age demographic that is prone to compulsive and indiscriminant mouthing of objects in the environment. Coupled with the notion that ATVs and OHMs are not objects that are likely to be mouthed (see discussion above), this literature indicates that it is extremely unlikely that children ages 6 to 12 would mouth ATVs and OHMs.

Conclusions

The literature reviewed clearly shows that an ATV or OHM is qualitatively different from the types of objects that have been identified in the literature as being a concern for child mouthing behaviors. ATVs and OHMs do not naturally "afford" (i.e., lend themselves to) mouthing behaviors. In addition, the literature indicates that children ages 6 through 12 do not mouth objects in the environment in the way or to the same degree as do children ages 3 years and younger. Based on the literature reviewed, we believe it is extremely unlikely that children ages 6 though 12 would mouth ATVs or OHMs during reasonably foreseeable use and abuse.

References

Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment–Washington Office. (2002). *Child-specific exposure factors handbook*, EPA-600-P-00-002B. Washington, D.C.: Environmental Protection Agency.

Juberg, D.R., Alfano, K., Coughlin, R.J., and Thompson, K.M. (2001). An observational study of object mouthing behavior by young children, *Pediatrics, 107*, 135-142.

Norris, B. and Smith, S. (2002). *Research into the mouthing behaviour of children up to 5 years old.* London: Department of Trade and Industry.

Tulve, N.S., Suggs, J.C., McCurdy, T., Cohen Hubal, E.A., and Moya, J. (2002). Frequency of mouthing behavior in young children, *Journal of Exposure Analysis and Environmental Epidemiology, 12*, 259-264.

Turgeon-O'Brien, H. (1996). Non-nutritive sucking habits: A review, *Journal of Dentistry for Children, 63*(5), 321-326.

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ATTACHMENT C

Report in Support of Petition for Temporary Final Exclusion Rule Under Consumer Product Safety Improvement Act (CPSIA) Section 101 Lead in Children's Products: All-Terrain Vehicles and Off-Highway Motorcycles

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Introduction

Applied Safety and Ergonomics, Inc. (ASE) was contacted by counsel representing all-terrain vehicle (ATV) and off-highway motorcycle (OHM) manufacturers to consider normal and reasonably foreseeable use and abuse of youth ATVs and OHMs as part of an assessment related to Section 101 of the Consumer Product Safety Improvement Act ("the Act"). Specifically, we were asked to evaluate the potential for children to touch parts of youth ATVs and OHMs made of steel, aluminum, or copper alloys that may contain lead and then to put their hands into their mouths. Contact with parts resulting from breakage is excluded from our analysis due to the durable nature and construction of these products, and the fact that they are not intended for children under age 6.

As it relates to lead exposure risks, there are three modes of ingestion by children that are typically considered in the literature: direct ingestion of lead-containing objects or lead paint, direct mouthing of objects that contain lead or are contaminated by lead dust, and handling of lead-containing objects with subsequent hand-to-mouth activity. This report focuses on the last of these modes in the context of potential lead exposure from children's use of ATVs and OHMs.[1] This report addresses the potential for children to touch parts of youth ATVs and OHMs made of steel, aluminum, or copper alloys that may contain lead and then to put their hands into their mouths.

In evaluating the potential for children to be exposed to lead from youth ATVs and OHMs as a result of hand-to-mouth behaviors, we have addressed several factors that have been considered and deemed relevant by the Consumer Product Safety Commission (CPSC), including the age and foreseeable behavior of children using youth ATVs and OHMs (Section 1) as well as patterns of use for these products (Section 2).[2]

Section 1 – Age and Foreseeable Behavior

A child's age is an important consideration in lead-related hazard evaluations because young children are more sensitive to the effects of lead than are adults. In addition, non-nutritive mouthing (NNM) behaviors in children vary as a function of age, and such behaviors can contribute to the risks of lead exposure. This section addresses the relationship between NNM behaviors and the use of youth ATVs or OHMs as a function of age.

Overview of Non-Nutritive Mouthing Behaviors

Children are born with the ability and desire to mouth and suck objects in the environment. Initially, this behavior is instinctive, adaptive and beneficial as it allows the infant to ingest food. Later in infancy (at about 7 to 8 months of age), it also serves to soothe teething pain and allows the infant to explore and sample their environment. As

[1] The potential for direct ingestion and mouthing of ATV components are addressed in a previous report (Young et al., 2008).

[2] The CPSC considers a number of other factors when evaluating the potential hazard associated with products that contain lead, including: the total amount of lead in the product, the bioavailability of such lead, accessibility of the lead to children, the foreseeable duration of exposure, marketing, and the life cycle of the product (CPSC, 1998).

soon as infants gain sufficient control of their limbs, they start to exhibit mouthing behaviors toward non-nutritive objects in their environment. The most common form of NNM behaviors in young children is mouthing objects such as blankets, pacifiers, toys, etc. as well as sucking on fingers, thumbs and toes. Another common mouthing behavior in older children (e.g., ages 3 to 16) is nail biting. Thumb sucking and nail biting will be considered separately in the next two sections. Effects of age and situational factors on the likelihood of these behaviors are discussed.

Thumb Sucking

Thumb sucking is the most common form of NNM in children under age six—far more common than mouthing behaviors with any other object, including pacifiers (Friman, Byrd & Oksol, 2001). For the purposes of this discussion, thumb sucking includes mouthing behaviors toward other fingers, but the thumb is more commonly sucked than are other digits.

Thumb sucking is almost universal in newborns and its absence is sometimes interpreted as an indication of physical or developmental problems. Thumb sucking is a common childhood behavior that is estimated to occur in 23% to 46% of children aged 1 to 4 years (Infante, 1976; Larsson & Dahlin, 1985; Traisman & Traisman, 1958). Other estimates suggest that thumb sucking occurs in approximately 50% of children between ages 2 and 3 years (Klackenberg, 1949; Ozturk & Ozturk, 1977; Popovich & Thompson, 1974). The incidence of thumb sucking declines as children age, and on average thumb sucking typically ceases at 3.8 years of age (Traisman & Traisman, 1958). It is estimated that only 25% of five year olds suck their thumbs (Klackenberg, 1949; Mahalski & Stanton, 1992). Honzik and McKee (1962) showed that thumb sucking decreased in a near-linear fashion as age increased (see Figure 1):

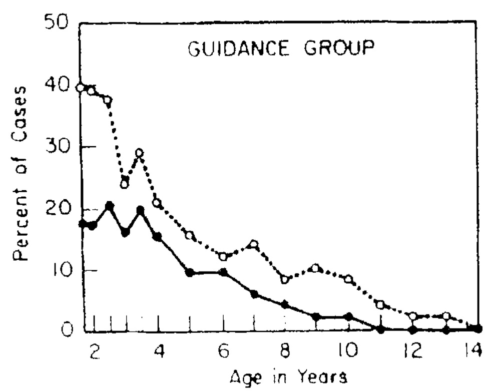

Figure 1. Thumb sucking as a function of age & gender (girls = dotted line; boys = solid line).

Most children cease sucking their thumb or fingers without intervention before they enter school (Friman & Schmitt, 1989; Traisman & Traisman, 1958). At the same time, children who continue to suck their thumbs after around age five often face discouragement and pressure from parents and their peers (Friman, McPherson, Warzak, & Evans, 1993; Sigelman & Begley, 1987). At about age five, doctors become concerned about a greater risk for dental malocclusion (Friman, 1987; Schmitt, 1987), digital deformities (Reid & Price, 1984), and speech difficulties (Luke & Howard, 1983). As a result, the incidence of thumb sucking in children age five and above is significantly lower than with younger children (Mahalski & Stanton, 1992) and thumb sucking occurs with variable duration and intensity and mostly only when the child is alone (Ellingson et al., 2000).

Thumb sucking is not considered a "disorder" (except in rare cases) and it is not considered chronic or problematic unless it occurs in two or more environments (e.g., home and school) after age five (Friman & Schmitt, 1989). Thumb sucking appears to be beneficial to younger children through its capacity to modulate arousal (i.e., it has a "pacifying" effect) and this primitive benefit of thumb sucking (and other NNM behaviors) is replaced as the child ages by more complex, mature, and productive responses satisfying the same function. While a child's internal desire for thumb sucking decreases with age, the negative pressure from parents and peers is additional motivation for them to discontinue the behavior. The weight of available evidence suggests rather strongly that ingestion of toxins or pollutants from the environment as a result of thumb sucking is increasingly remote as the child become older starting at around age five.

Nail Biting

Nail biting (*onychophagia*) is a habit involving repetitive biting and/or chewing of the fingernails and, to a lesser extent, the toenails. Unlike with thumb sucking, the literature on nail biting varies considerably in terms of methodology, definitions, and consistency. As such, it is difficult to quantify the incidence of nail biting as a function of age. For example, at age 13, one study estimated the incidence of nail biting to be as high as 44% (Wechsler, 1931) while another study estimated it to be 12% (Deardoff, Finch, & Royall, 1974). Friman, Byrd, and Oksol (2001) tried to estimate the occurrence of nail biting by age, while noting that these were necessarily broad and imperfect age ranges and estimates:

> *"Based on our collective impressions of all the research, we offer the following tentative estimates of the prevalence of nail biting. Although it is very rare in children younger than three years, there appears to be a marked and sudden rise in incidence after that age. Between 20% and 40% of preschool children over the age of three years bite their nails. The prevalence appears to peak between the ages of 8-12 years of age, with estimates ranging from 25% to 60%. Prevalence declines through the teen years with estimates between 20% and 30% for late teens. Prevalence in young adults ranges between 10% and 25 % and declines to below 10% for adults over 35." (p. 214).*

Several authors suggest that estimates like these are inflated because of their failure to differentiate between frequent and infrequent nail biting. For example, Brosh and Fuqua (2004) observed that about 53% of college students reported biting their nails, but this rate dropped to about 18% when a slightly more stringent criterion was used to define nail biting (i.e., five episodes or more per day). Thus, there may be many children who are reported to be nail biters when, in fact, they do not exhibit this behavior with any significant regularity or frequency.

It should also be noted that nail biting does not occur for the same reasons as thumb sucking. As mentioned above, thumb sucking occurs to "pacify" the child or to reduce anxiety. There is a good deal of evidence to suggest that nail biting is motivated by the reinforcement received by even minor motor activities when most, if not all, other motor actions are restricted (see Woods et al. 2001). Put another way, when children are "sitting still" or otherwise restricted in their movements, they may revert to non-purposeful, stereotypic behaviors (e.g., biting nails, chewing on hair, etc.). Freeman et al. (2001) stated "Most hand-to-mouth...activities were observed during the children's inactive periods, particularly when watching television." (p. 507). Thus, nail biting is less likely to occur in situations where other motor behaviors are allowed, recommended or required. Consistent with this conclusion, Xue et al. (2007) observed that mouthing behaviors were significantly more likely to occur when a child is indoors than when he or she is outdoors.

Conclusions

The available evidence suggests that one of the primary modes of hand/finger-to-mouth contact (thumb sucking) is not a behavior that 6 to 12 year old youth ATV or OHM operators are likely to engage in. Nail biting is more likely than thumb/finger mouthing in this age range. However, the available evidence suggests that published incidence rates (by age) are likely inflated to some degree. Moreover, nail-biting behavior is significantly less likely to occur in conditions of youth ATV or OHM use—when children are physically active and outdoors.

To the extent that hand-to-mouth behaviors have been a concern with respect to lead ingestion, there is reason to believe that this may be limited primarily to children younger than age six. For example, the CPSC's concern over hand-to-mouth ingestion of lead dust from vinyl miniblinds has been limited to homes with children ages six and younger (CPSC, 1996). In addition, the CPSC, in 1997, analyzed the potential for lead exposure from a number of vinyl-containing products. Part of the criteria for lead exposures included whether or not the products were expected to be handled or mouthed by "young" children (CPSC, 1997).

Section 2 – Patterns of Use

In evaluating potential patterns of youth ATV and OHM use, we consider both instructed behaviors and additional behaviors that may be expected from children age 6 through 12. Specifically, "instructed behaviors" refer to those child behaviors intended based on operator's manuals and training materials. "Additional behaviors" refer to those actions that are not explicitly prescribed in such materials but where ATV or OHM component contact may occur based on the nature of the component involved (e.g., storage compartment) or based on general child behavior (e.g., leaning or resting of hands on components while standing near the vehicle or sitting in the operator's position).

To determine components contacted during instructed behaviors, we reviewed product owner's manuals, as well as training manuals available from the ATV Safety Institute (ASI) and the Motorcycle Safety Foundation (MSF). These manuals instruct children to wear protective gear, including gloves (SVIA, 2008, p. 7; MSF, 2005, p. 11; Polaris, 2007, p. 29). However, it is reasonably foreseeable that children may, on occasion, choose not to wear gloves and may contact components with their bare hands.

Instructed behaviors for children include mounting and dismounting the vehicle, operating controls, and, in some cases, performing a pre-ride check. When mounting and dismounting the ATV or OHM, youth are instructed to place their hands on the handlebars and their feet on the footrests (SVIA, 2008, p. 8; MSF, 2005, p. 12). For ATVs or OHMs equipped with a wrist tether strap, youth are also instructed to attach the strap to their wrist and to the vehicle before riding (Polaris, 2007, p. 30). Youth are instructed to operate controls, including the parking brake, front and rear brakes, throttle control lever, engine stop switch, and shift lever if equipped (SVIA, 2008, pp. 10-11, 13-14, 18, 20-22; MSF, 2005, pp. 13-15, 17-18, 22-26; Polaris, 2007, pp. 19-23). Some manufacturers instruct youth to perform a pre-ride check, which includes testing controls, making sure the seat is locked in place, and having an adult check gas and oil (Polaris, 2007, pp. 25-7).

During these instructed behaviors, when children do not wear gloves, contact with the following metal alloy-containing components may be expected:

- Ignition key
- Ignition housing
- Wrist tether strap
- Brake lever
- Parking brake lever
- Throttle control lever
- Throttle control housing
- Shift lever

In addition to instructions directed to children, materials reviewed describe activities to be performed by adults. These include inspecting the vehicle before each use (SVIA, 2008, pp. 15-16; MSF, 2005, pp. 19-20), starting the vehicle (SVIA, 2008, pp. 16, 20; MSF, 2005, pp. 20, 24-5), refueling the vehicle (SVIA, 2008, p. 16; MSF, 2005, p. 20; Polaris, 2007, p. 26), operating speed limiters or other supervisor control features (MSF, 2005, p. 15; SVIA, 2008, p. 11), and maintaining the vehicle according to the owner's manual (SVIA, 2008, pp. 15-16; MSF, 2005, pp. 19-20). Although starting the vehicle is included as an adult and not a child activity, it is foreseeable that some older youth operators under age 12 may choose to start, or re-start, the engine themselves. This activity, if performed without gloves, may involve bare-hand contact with the following metal alloy-containing components:

- Fuel control valve
- Choke
- Kickstart lever or pull cord

In addition to the behaviors and components described above, other foreseeable behaviors include those that are not explicitly prescribed but where component contact may occur based on the nature of the component involved or general child behavior. Based on the nature of the component, we believe it is foreseeable that children age 6 through 12 may use the front or rear carry bars and access the under-seat storage area, if provided. During these behaviors, if not wearing gloves, children may, on occasion, contact the following metal alloy-containing components:

- The interior surface of the storage area
- Front and/or rear carry bars

Similarly, based on general child behaviors, we believe it is foreseeable that children may lean or rest their hands on the following metal alloy-containing components while standing near the vehicle or sitting in the operator's position:

- Brake fluid reservoir on handlebar

In addition, during these behaviors, children may, on occasion, come into contact with the following metal alloy-containing components:

- Taillight
- Reflectors

Although children may be instructed to perform a pre-ride check of controls (Polaris, 2007, pp. 25-27), the instructional materials reviewed direct adults, and not children, to perform maintenance and more comprehensive inspection activities, such as inspecting the vehicle before each use (SVIA, 2008, pp. 15-16; MSF, 2005, pp. 19-20; Polaris, 2007, pp. 84-86), adjusting speed limiters (SVIA, 2008, p. 11; MSF, 2005, p. 15), and maintaining the vehicle according to the owner's manual (SVIA, 2008, pp. 15-16; MSF, 2005, pp. 19-20). Given these instructions, the nature of these inspection and maintenance activities, and the age range of the children involved, metal alloy-containing components for which contact with bare hands is not reasonably foreseeable on a frequent and recurrent basis include (but are not limited to):

- Engine
- Transmission
- Drive train
- Frame nuts, bolts, and fasteners
- Axles
- Suspension
- Exhaust pipe
- Muffler

Summary and Conclusions

Our evaluation of potential patterns of youth ATV and OHM use shows that bare-hand contact with some components may occur during reasonably foreseeable use or abuse based on instructed behaviors. Some additional components have a lower probability or expected frequency of contact based on consideration of additional behaviors. For remaining components, we expect no reasonably foreseeable frequent and recurrent bare-hand contact.

In addition, hand-to-mouth behaviors are expected to be infrequent for children ages 6 to 12. Specifically, the available evidence suggests that one of the primary modes of hand/finger-to-mouth contact (thumb sucking) is not a behavior that 6 to 12 year old youth-ATV or -OHM operators are likely to engage in. Nail biting is more likely than thumb/finger mouthing in this age range. However, the available evidence suggests that published incidence rates (by age) are likely inflated to some degree. Moreover, nail-biting behavior is significantly less likely to occur in conditions of youth ATV or OHM use—when children are physically active and outdoors.

References

Brosh, S., & Fuqua, W. (2004). An experimental analysis of antecedents to habit behaviors. Paper presented at the *Association for Behavior Analysis*, Chicago, IL.

Consumer Product Safety Commission (CPSC). (1996, June 25). CPSC Finds Lead Poisoning Hazard for Young Children in Imported Vinyl Miniblinds [Press Release]. Retrieved from http://www.recalls.gov/CPSCPUB/PREREL/PRHTML96/96150.html.

Consumer Product Safety Commission (CPSC). (1997, November 21). CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products. Retrieved from http://www.cpsc.gov/cpscpub/pubs/lead/pbcdtoys.pdf

Consumer Product Safety Commission (CPSC). (1998, December 22). Codification of Guidance Policy on Lead in Consumer Products; Final Policy Statement, 63 Fed. Reg. 70648.

Deardoff, P.A., Finch, A.J., & Royall, L.R. (1974). Manifest anxiety and nail biting. *Journal of Clinical Psychology, 30*, 378.

Ellingson, S.A., Miltenberger, R.G., Stricker, J.M., Garliinghouse, M.A., Roberts, J., & Galensky, T.L. (2000). Analysis and treatment of finger sucking. *Journal of Applied Behavior Analysis, 33*, 41-52.

Freeman, N.C.G., Jimenez, M., Reed, K.J., Gurunathan, S., Edwards, R.D., Roy, A., Adgate, J.L., Pellizzari, E.D., Quackenboss, J., Sexton, K., & Lioy, P.J. (2001). Quantitative analysis of children's microactivity patterns: The Minnesota Children's Pesticide Exposure Study. *Journal of Exposure Analysis, 11*, 501-509.

Friman, P.C. (1987). Thumb sucking in childhood. *Feelings and Their Medical Significance, 29*, 11–14.

Friman, P.C., & Schmitt, B.D. (1989). Thumb sucking in childhood: Guidelines for the pediatrician. *Clinical Pediatrics, 28*, 438–440.

Friman, P.C., Byrd, M. R., & Oksol, E.M. (2001). Characteristics of oral-digital habits. In D. W. Woods & R. G. Miltenberger (Eds.), *Tic Disorders, Trichotillomania, and Other Repetitive Behavioral Disorders: Behavioral Approaches to Analysis and Teatment* (pp. 197-222). Norwell, ma: Kluwer.

Friman, P.C., McPherson, K.M., Warzak, W.J., & Evans, J. (1993). Influence of thumb sucking on peer social acceptance in first grade children. *Pediatrics, 91*, 784–786.

Honzik, M.P., & McKee, J.P. (1962). The sex difference in thumb-sucking. *The Journal of Pediatrics, 61*, 726-732.

Infante, P.F. (1976). An epidemiologic study of finger habits in preschool children, as related to malocclusion, socioeconomic status, race, sex, and size of community. *Journal of Dentistry for Children, 43*, 33–38.

Klackenberg, B. (1949). Thumb sucking: frequency and etiology. *Pediatrics, 4*, 418-424.

Larsson, E.F., & Dahlin, K.G. (1985). The prevalence and the etiology of the initial dummy and finger sucking habit. *American Journal of Orthodontics*, *87*, 432–435.

Luke, L.S., & Howard, L. (1983). The effects of thumb sucking on orofacial structures and speech: A review. *The Compendium of Continuing Education*, *4*, 575–579.

Mahalski, P.A., & Stanton, W.R. (1992). The relationship between digit sucking and behavior problems: A longitudinal study over 10 years. *Journal of Child Psychology and Psychiatry*, *33*, 913-923.

Motorcycle Safety Foundation (MSF), Dirt Bike School. (2005). Parents, Youngsters and Off-Highway Motorcycles.

Ozturk, M., & Ozturk, O.M. (1977). Thumb sucking and falling asleep. *British Journal of Medical Psychology*, *50*, 95-103.

Polaris. (2007). Predator 50 Owner's Manual.

Popovich, F., & Thompson, G.W. (1974). Thumb and finger sucking: Analysis of contributory factors in 1258 children. *Canadian Journal of Public Health*, *65*, 277-280.

Reid, D.A., & Price, A.H. (1984). Digital deformities and dental malocclusion due to finger sucking. *British Journal of Plastic Surgery*, *37*, 445–452.

Schmitt, B.D. (1987). *Your child's health*. Toronto: Bantam.

Sigelman, C.K., & Begley, N.L. (1987). The early development of reactions to peers with controllable and uncontrollable problems. *Journal of Pediatric Psychology*, *72*, 99-115.

Specialty Vehicle Institute of America (SVIA), ATV Safety Institute. (2008). Parents, Youngsters and All-Terrain Vehicles.

Traisman, A.S., & Traisman, H.S. (1958). Thumb and finger sucking: A study of 2650 infants and children. *The Journal of Pediatrics*, *52*, 566–572.Please let me know if there is any other information or issue you would like me to consider.

Tulve, N.S., Suggs, J.C., McCurdy, T., Cohen Hubal, E.A., & Moya, J. (2002). Frequency of mouthing behavior in young children. Journal of Exposure Analysis and Environmental Epidemiology, 12, 259-264.

Wechsler, D. (1931). The incidence and significance of fingernail biting in children. *Psychoanalyst*, *18*, 201-209.

Woods, D.W., Fuqua, R.W., Siah, A., Murray, L.K., Welch, M., Blackman, E., & Seif, T. (2001). *Education and Treatment of Children*, *24*, 199-216.

Young, S.L., Rhoades, T.P., & Diebol, J.K. (2008, October 31). *Comments on Consumer Product Safety Improvement Act (CPSIA) Section 101 Lead in Children's Products: All Terrain Vehicles and Off-Highway Motorcycles.*

Xue, J., Zartarian, V., Moya, J., Freeman, N., Beamer, P., Black, K., Tulve, N., & Shalat, S. (2007). A meta-analysis of children's hand-to-mouth frequency data for estimating nondietary ingestion exposure. *Risk Analysis*, *27*, 411-420.

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