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February 2, 2009

Via Electronic Mail and Hand Delivery

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

Re: Section 101 Request for Exclusion of a Material or Product: Request to Exempt Crystal Beads and Rhinestones

Dear Mr. Stevenson:

The Fashion Jewelry Trade Association ("FJTA"), Manufacturing Jewelers and Suppliers of America ("MJSA"), Footwear Distributors and Retailers of America (FDRA), National Retail Federation (NRF) and United Dance Merchants of America (UDMA) (hereafter collectively referred to as "Jewelry Producers and Retailers"), request an immediate emergency exemption for the following category of materials: crystal and glass beads, including rhinestones and cubic zirconium, used in children's products, including jewelry, apparel, accessories, footwear and other decorative applications, under the Consumer Product Safety Improvements Act of 2008 (CPSIA). We also ask that the exemption be extended to crystal decorative items to the extent any such item might be a children's product as defined in the CPSIA. Best available scientific evidence shows no link between wearing or handling crystal or glass beads and rhinestones and any health risk to children or increased blood lead levels from lead exposure based on reasonably foreseeable use and abuse scenarios.

The Administrative Procedure Act, 5 U.S.C. §553(b), authorizes the Commission to exclude rules from otherwise applicable notice and comment procedures where the agency, for good cause, finds such procedures to be impractical or contrary to the public interest. The impending February 10, 2009 deadline provides a compelling basis or "good cause" for emergency action. Further, Section 3 of the CPSIA gives the Commission authority to "issue regulations, as necessary, to implement this Act and the amendments made by this Act." The Commission should exercise its authority to immediately grant this request on an emergency basis, as failure to do so will amount to a ban on safe products, affecting millions of dollars of products and countless small businesses.

We urge the Commission to act promptly to recognize an exemption for crystal to avoid effectively banning this important, desirable and safe material effective February 10, 2009 by issuing a temporary final rule excluding from the total lead limits of 101(b)(1) a class of materials consisting of crystal or glass beads and rhinestones in children's products, and decorative uses of crystal and glass. Please feel free to contact me if you have questions about this request.

Respectfully Submitted,

Sheila A. Millar

Enclosures

cc: Michael Gale, Executive Director, Fashion Jewelry Trade Association
James K. McCarty, Chief Operating Officer, Manufacturing Jewelers and Suppliers of America, Inc.
Peter T. Mangione, President, Footwear Distributors and Retailers of America
Jonathan Gold, Vice President, Supply Chain and Customs Policy, National Retail Federation
Gina Costello, Executive Director, United Dance Merchants of America

Section 101 Request for Exclusion of a Material or Product: Request to Exempt Crystal Beads and Rhinestones

The Fashion Jewelry Trade Association (FJTA),[1] Manufacturing Jewelers and Suppliers of America (MJSA),[2] Footwear Distributors and Retailers of America (FDRA),[3] National Retail Federation (NRF)[4] and United Dance Merchants of America (UDMA)[5](hereafter collectively referred to as "Jewelry Producers and Retailers") request an immediate emergency exemption for the following category of materials: crystal and glass beads, including rhinestones and cubic zirconium,[6] used in jewelry, apparel, accessories, footwear and other decorative applications on children's products under the Consumer Product Safety Improvements Act of 2008 (CPSIA).[7] We also ask that the exemption be extended to any crystal decorative items primarily intended for children 12 and under.[8] Best available scientific evidence shows no link between wearing or handling crystal or glass beads and rhinestones and any health risk to children or increased blood lead levels from lead exposure based on reasonably foreseeable use and abuse scenarios.

Glass and crystal beads are critically important to the U.S. fashion industry. Crystal is used in both fashion and fine jewelry, for example. U.S. retail sales of jewelry, including fine jewelry, fashion jewelry and watches, is estimated at almost $66 billion in 2008.

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[1] FJTA members include approximately 255 suppliers and retailers of fashion or costume jewelry, many of whom are small businesses. FJTA does not represent the vending machine industry and its members do not make toy jewelry.

[2] MJSA has approximately 1800 members who make fine jewelry as well as parts and components used in fashion and fine jewelry. Many MJSA members are small businesses.

[3] FDRA is the trade association representing an estimated three-quarters of all U.S. footwear sales through its retailer, importer, distributor and manufacturer members.

[4] NRF is the world's largest retail trade association, with membership that comprises all retail formats and channels of distribution, including department, specialty, discount, catalog, Internet, independent stores, chain restaurants, drug stores and grocery stores, as well as the industry's key trading partners of retail goods and services. NRF represents an industry with more than 1.6 million U.S. retail companies, more than 25 million employees – about one in five American workers – and 2007 sales of $1.7 trillion. As the industry umbrella group NRF also represents over 100 state, national and international retail associations.

[5] UDMA represents approximately 89 members, most of whom are small businesses, that promote dance products and services.

[6] Throughout these comments any reference to "crystal" includes crystal, glass or rhinestones or cubic zirconium made of crystal or glass.

[7] Pub. L. No. 110-314, 122 Stat. 3016 (August 14, 2008).

[8] Decorative crystal products such as picture frames, lamps, figurines and the like are not designed or intended primarily for children 12 and under as a rule, but there may be rare occasions where such products would be intended for children. This request does not include crystal tableware (*e.g.*, wine and other glasses, decanters, etc.). These products are never designed or intended primarily for children 12 and under. Moreover, all tableware (including children's products) of any material must meet strict limits for leaching from food and beverage contact surfaces set by the federal Food and Drug Administration (FDA).

Approximately 62,000 people are employed in the jewelry industry; many are self-employed and most are small businesses. While we appreciate the extraordinary effort the Commission has made to provide guidance, clarity and sensible exclusions, the reality for a range of members of the fashion industry is that they will have to scrap potentially millions of dollars of safe products containing rhinestones and crystal unless you act immediately to exempt these materials from the total lead limits of the CPSIA.

The Commission has already proposed to recognize that certain materials – many used in jewelry – contain no or very low levels of lead and should be excluded from the CPSIA requirements.[9] The Jewelry Producers and Retailers strongly support those exemptions. Jewelry Producers and Retailers urge the Commission to also exempt glass and crystal beads and rhinestones used in jewelry, accessories, apparel and footwear from the total lead limits under Section 101(b)(1). While total lead content in glass and crystal beads or rhinestones may exceed the total lead limits under the CPSIA, these components do not pose a health risk to children based on best available scientific evidence.

The objective in giving the Commission authority to recognize exclusions from total lead limits specified in the CPSIA was to assure that such exclusions are based on best available, scientific evidence that foreseeable use or abuse of children's products would not expose a child to lead in such a way that it results in a meaningful increase in blood lead levels or otherwise poses a health risk. The best available scientific evidence supports a conclusion that crystal and glass beads and rhinestones should be exempt from the total lead limits established under the CPSIA. In addition to the absence of any published literature associating exposure to lead in crystal or glass beads and rhinestones with health risks to children, this evidence includes 1) CPSC's evaluation of total versus accessible lead in metal jewelry[10] as compared to accessible lead in crystal and glass beads and rhinestones, 2) a Proposition 65 settlement agreement that covered all materials used in jewelry and resulted in an exclusion from total lead limits or warning obligations for crystal,[11] and 3) existing accepted federal risk assessment standards for

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[9] *See* Children's Products Containing Lead: Proposed Determinations Regarding Lead Content Limits on Certain Materials or Products; Notice of Proposed Rulemaking. 74 Fed. Reg. 2433 (January 15, 2009).

[10] *See* Staff Briefing Package on Lead in Metal Jewelry, December 4, 2006, http://www.cpsc.gov/LIBRARY/FOIA/FOIA07/brief/LeadToyJewelry.pdf., Tab B (David Cobb, Memorandum to Kristina M. Hatelid "Summary of Test Results for Lead in Children's Metals Jewelry," , November 28, 2006) and C (Joanne Matheson, Memorandum to Kristina M. Hatelid, "Petition HP06-1 Lead in Jewelry Toxicity Review," November 28, 2006).

[11] *See People v. Burlington Coat Factory Warehouse Corporation, et al,* Case No. RG 04-162075 (Alameda Superior Court June 15, 2006). This agreement was subsequently enacted as legislation in California as A.B. 1681. *See* Cal. Health & Safety Code §§ 25214.1-.4. The California requirements were enacted legislatively in the State of Minnesota as well. *See* Minn. Stat. § 325E.389. The *Burlington* agreement and legislation were based on an assessment of total and accessible lead from materials used in jewelry for children (defined as children 6 and under) and all other consumers (those 7 and older). The *Burlington* proceeding recognized a distinction between younger children age 6 and younger and other consumers, setting material-specific limits on total lead in specific materials used in children's jewelry (for 6 and under) and other jewelry, and adopting numerous science-based exclusions for materials deemed safe. Crystal in jewelry for children 6 and younger was permitted subject to a 1 gram limit. We note that the State of California has asked the Commission to recognize as excluded from the scope of preemption

lead in, *e.g.*, foods.[12] This scientific evidence is summarized and analyzed in the attached report prepared by an independent expert scientific organization, Exponent.[13] *See* Attachment A.

The CPSC has recently proposed rules governing procedures for exemptions under Section 101(b)(1); however, comments on the proposed *process* are not due until February 17, 2009.[14] That is one week after the deadline by which all component parts of a children's product must meet the limits on total lead of 600 ppm. It is likely to be some months before rules on the process are finalized, and many more months before final action on exemption requests can be expected. The absence of a final rule will result in a ban on crystal and glass effective February 10, 2009, affecting an extensive array of products in the marketplace. Millions of dollars of inventory and thousands of business will be affected. We urge the Commission to act promptly to recognize an exemption for crystal to avoid effectively banning this important, desirable and safe material effective February 10 by issuing a temporary final rule excluding from the total lead limits of 101(b)(1) a class of materials consisting of crystal or glass beads and rhinestones in children's products, and decorative uses of crystal and glass.

I. Background on Lead in Crystal and Glass

Glass and crystal beads and rhinestones have provided shine and sparkle to jewelry, apparel, accessories, shoes and other items popular with girls, teens and women for decades. Literally millions of glass and crystal beads and rhinestones in thousands of SKUs are used safely in these applications. There is no evidence whatsoever that glass and crystal beads and rhinestones have been associated with elevated blood lead levels in children.

A. Use of Lead in Crystal and Glass Beads, Rhinestones and Decorative Articles: Lead Content, Manufacturing Process, and Tests

As discussed below, lead is often used in making glass and crystal. Lead is intentionally added to impart brilliance and facilitate glass cutting, but is bound into the physical matrix of the crystal such that it is difficult for it to be released. Different types and

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California legislation under which crystal is exempt from lead limits. While science supports a complete exemption for crystal beads and rhinestones from size or weight limits, the jewelry industry has supported the California requirements and does not object to a 1 gram limit applied to crystal in products for children 6 and under.

[12] *See* 16 C.F.R. §1500.230. *See also* Michael Kastock, "FDA regulation of lead in food. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition," presented at ACPS-CP Meeting, July 22, 2008

[13] The report was prepared by Ms. Renee Kalmes, M.S.P.H., C.I.H., a Senior Managing Scientist at Exponent. Ms. Kalmes' professional profile is available at: http://www.exponent.com/renee_kalmes/#tab_profile.

[14] 74 Fed. Reg. 2428, January 15, 2009.

grades of glass and crystal exist, with varying lead content, but the total lead content may significantly exceed the limits specified in the CPSIA.[15] *See* Attachment A. Lead in crystal and glass is generally not accessible due to the physical properties and molecular makeup, in contrast to lead in other materials where the physical and chemical matrix of the material is different. "Lead bound in crystal glass" is also exempt from the Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the RoHS Directive pursuant to Commission decision 2006/690/EC. The description of this exception – "lead bound in crystal glass" - reflects recognition that lead is physically bound into the crystal matrix.

B. Tests for Lead Content

It is widely known that the total lead content in glass or crystal may be well in excess of 600 ppm. Laboratory tests for total lead in glass or crystal are difficult and potentially dangerous due to the fact that lead is physically bound in the material matrix. Glass and crystal materials do not dissolve under normal laboratory conditions for acid digestion used to test other materials. To fully dissolve the glass matrix, hydrofluoric acid (HF) must be used. Hydrofluoric acid is extremely difficult to work with because it is aggressive and can damage both human skin and various instruments necessary to analyze the resulting solutions. Thus, this type of dangerous acid is not typically used for safety reasons in most laboratories. The CPSC has not yet adopted a test method for testing total lead in crystal or glass.

In contrast, nitric acid and hydrochloric acid are used to evaluate total lead in metal children's products per CPSC's Standard Operating Procedure (SOP).[16] This method has been used for benchmark purposes but is viewed to potentially underestimate total lead content. X-ray fluorescence (XRF) technology may be used to test for total lead in glass or crystal if the sample is large enough, but for very small glass or crystal beads or rhinestones XRF technology may not provide an accurate measure of total lead content.

C. Tests for Accessible Lead

Tests for accessible lead reflecting mouthing and ingestion scenarios were conducted on beads and rhinestones made of glass and crystal. Methods and results are summarized in Attachment A.

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[15] In Europe, lead crystal is subject to Directive 69/493/EEC, which establishes requirements on the total quantity of lead in crystal, including minimum lead content. "Lead crystal" must have a minimum lead content of at least 24%; "full lead crystal" must have a minimum lead content of at least 30%. Other grades of crystal and glass beads or rhinestones may have lower lead content but total lead in many types of crystal beads or rhinestones used in jewelry or other fashion applications is likely to exceed the total lead limits specified in the CPSIA. Some lower lead glass and crystal is available, but purchasers of commodity beads and rhinestones are unable to distinguish between glass and crystals with varying levels of lead.

[16] *See* Test Method CPSC-CH-E1001-08, Standard Operating Procedure for Determining Total Lead (Pb) in Children's Metal (Including Children's Metal Jewelry), December 4, 2008, available at http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08.pdf.

II. The Commission Has Authority to Exclude Materials that Do Not Pose a Health Risk

The Commission has authority to exclude specific products or materials from the total lead limits of Section 101 if it determines that lead in such product or material will neither result in the absorption of any lead into the body, taking into account normal and reasonably foreseeable use and abuse conditions, nor have any other adverse impact on public health or safety.[17] Section 101 of the CPSIA adopts limits on total lead in "any part" of a children's product that phase down over time. It established limits on total lead in substrate materials used in children's products of 600 ppm effective February 10, 2009, dropping to 300 ppm by August, 2009. A further phasedown to 100 ppm must be implemented, but only if feasible. Congress recognized that zero lead was not technically achievable, and that children might be exposed to some accessible, ingestible lead in handling children's products that meet total lead limits under reasonable use and abuse scenarios, but in amounts that would not pose a health risk.

Congress did not and could not have meant that to satisfy the exemption criteria only materials with zero lead or zero accessible lead under laboratory test conditions could qualify for an exemption since it concluded that it could not and should not seek to mandate zero total lead in substrate materials. Common sense indicates that Congress expected that excluded materials, components and products should not have a meaningful ability to raise children's blood lead levels based on reasonably foreseeable use and abuse conditions specific to such products or materials. In other words, Congress intended that the Commission exercise its authority and judgment to exclude products or materials that would not result in meaningful exposure to accessible lead.

In this regard, data on potentially accessible lead in metal jewelry components that meet total lead limits set by the CPSIA (600 ppm and under) has been developed by the CPSC as part of its investigation of metal jewelry. The CPSC determined, based on laboratory testing, that metal jewelry components that contain total lead of less than 600 ppm will have accessible lead in the range of 20.27 μg, ± 7.81 μg.[18] A review of that data indicates that for metal jewelry components with total lead content of 300 ppm or less, the average accessible lead value was 15.4 μg.[19] Materials that, under reasonably foreseeable use and abuse conditions, do not release accessible lead in amounts greater

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[17] CPSIA § 101(b)(1). The finding is to be based on "best-available, objective, peer-reviewed, scientific evidence that lead in such product or material will neither – (A) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor (B) have any other adverse impact on public health or safety." No peer-reviewed studies of the impact of foreseeable use and abuse of crystal or glass beads or rhinestones on blood lead levels in children have been identified.

[18] *See* Staff Briefing Package on Lead in Metal Jewelry, http://www.cpsc.gov/LIBRARY/FOIA/FOIA07/brief/LeadToyJewelry.pdf., Tab B (David Cobb, CPSC Memorandum to Kristina M. Hatelid, November 28, 2006. "Summary of Test Results for Lead in Children's Metals Jewelry").

[19] *Id.*

than accessible lead released by materials that meet total lead content limits set forth in the CPSIA must logically be exempt from total lead limits on grounds that they meet the statutory criteria for exemption. Crystal and glass beads and rhinestones with total lead in excess of 24% meet this test. Congress cannot have intended to ban materials that release less accessible lead than compliant materials.

As we also demonstrate below and in Attachment A, crystal is exempt from health-protective warning requirements related to lead content under California law. Exposure to lead in crystal and glass beads or rhinestones is within background dietary exposures and is not likely to result in analytically discernible blood lead level changes.

While Section 101(b)(1) establishes that exemptions should be based on notice and a hearing, the Administrative Procedure Act, 5 U.S.C. §553(b), authorizes the Commission to exclude rules from otherwise applicable notice and comment procedures where the agency, for good cause, finds such procedures are impractical or contrary to the public interest. The impending February 10 deadline provides a compelling basis or "good cause" for emergency action. Further, Section 3 of the CPSIA gives the Commission has authority to "issue regulations, as necessary, to implement this Act and the amendments made by this Act." The Commission should exercise its authority to immediately grant this request on an emergency basis, as failure to do so will amount to a ban on safe products, affecting millions of dollars of products and countless small businesses.

III. Risk Assessment Criteria for §101(b)(1) Exemptions

In adopting the phaseout of lead in children's products, Congress looked principally at limits on total lead as a surrogate for evaluating accessible lead.[20] Congress recognized that adopting a standard of zero total lead content in consumer products was not feasible. Consequently it left it to the Commission to establish risk-based criteria for exemptions for materials under §101(b)(1) that, like crystal, might exceed the total lead limits but do not pose a health risk to children.

In evaluating the potential hazards of lead-containing materials in children's jewelry, the Commission has focused on metal.[21] The Commission's own assessment of the amount of accessible lead potentially available in metal that contains less than 600 ppm total lead provides a scientific basis on which to analyze exemptions for other products based on accessible lead under reasonably foreseeable use and abuse conditions.

Importantly, the CPSC staff determined after substantial testing that metal jewelry containing less than 600 ppm lead (some containing less than 100 ppm) would, under test conditions representing ingestion scenarios, result in average exposure to around 20 μg of

[20] Based on widespread scientific recognition that it is the accessibility of lead – the ability of lead to be potentially released under foreseeable use and abuse conditions – that is the primary measure of risk, many safety standards around the world test measure accessible lead. *See, e.g.*, ASTM F 963; DIN EN 71.

[21] Interim Enforcement Policy for Children's Metal Jewelry Containing Lead – 2/3/3005. http://www.cpsc.gov/businfo/pbjewelgd.pdf.

accessible lead.[22] Because Congress has determined that products with total lead of less than 600 ppm are deemed to be compliant with the CPSIA, the CPSC's own test data provides a measure of accessible lead for compliant products. Other products that meet those same accessibility parameters based on reasonably foreseeable use and abuse scenarios must be presumptively deemed safe for purposes of exclusions under 101(b)(1). Congress cannot have intended to ban materials that result in less accessible lead potentially available for absorption into the body than materials that meet the applicable total lead limits.

The Proposition 65 jewelry settlement agreement also evaluated lead in jewelry components, and resulted in an exclusion of crystal in jewelry as well (subject to a 1 gram limit on products for children 6 and under). This was based on a determination that chronic exposure to lead in crystal and rhinestone beads used in jewelry would be well below the Proposition 65 Maximum Allowable Dose Level (MADL) warning level for lead.[23] In other words, warnings related to lead in crystal beads and rhinestones used in jewelry are *not* required under this law. The data generated during that proceeding was deemed adequately representative to support the exclusion. Additionally, based on the data developed as part of the Proposition 65 proceeding on jewelry, and acid leach test data, the levels of lead in crystal and glass beads and rhinestones will not result in exposures that exceed health-protective limits set by federal agencies, and indeed are within the same range as background food intake levels and will not raise blood lead levels.

As outlined below and in Attachment A, the best available scientific evidence demonstrates that crystal and glass beads and rhinestones meet the criteria for exemption under the Act.

IV. Use of Crystal and Glass Beads and Rhinestones in Children's Jewelry

Crystal and glass beads and rhinestones can come in varying sizes. A popular stone for jewelry is size 10PP, for example. This stone measures 1.6-1.7 mm or 0.063-0.067 inches. It takes 333 of these 10 PP stones to equal one gram. The 1 gram weight

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[22] These tests were conducted in accordance with the CPSC Standard Operating Procedure (SOP) for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry 2/3/2005. *See* Staff Briefing Package on Lead in Metal Jewelry, December 4, 2006, http://www.cpsc.gov/LIBRARY/FOIA/FOIA07/brief/LeadToyJewelry.pdf., Tab B, David Cobb, CPSC Memorandum to Kristina M. Hatelid, November 29, 2006. "Summary of Test Results for Lead in Children's Metal Jewelry."

[23] The limits on total lead and exemptions developed pursuant to the settlement negotiations underwent a thorough evaluation by all the litigants. Excluded materials, including crystal, were determined to result in exposures from lead in jewelry to below 0.5 µg/day, the Maximum Allowable Dose Level (MADL) under Proposition 65. The MADL is the level at which chemicals or substances listed for reproductive toxicity have no observable effect, assuming exposure at 1,000 times that level. We note that the Proposition 65 MADL is not a suitable limit for general adoption by the CPSC because it is based on workplace exposures. It is a chronic exposure limit, not an acute toxicity limit.

reference is important both because standard tests often use 1 gram samples,[24] and because the Proposition 65 agreement excludes crystal from total lead limits, subject to a 1 gram limit in jewelry for children 6 and under.

Jewelry for children 6 and under using 1 gram of this size stone will typically will have no more than 10-15 size 10PP stones. One of the largest sizes used in designs for children 6 and under is 30 PP. It takes 27 size 30 PP stones to equal one gram. Jewelry for children 6 and under designed with this size stone typically will use 5 stones. In the 2 mm size, one gram contains 105 beads. In the 4 mm size, 11 beads equal one gram. Jewelry designs for younger children 6 and under typically would use 10-12 2mm beads or 4-6 4mm beads.

Table 1 provides a comparison of the number of beads or stones to make up 1 gram of crystal or glass:

Table 1

Description/Size	Number of Stones/Beads Required to Equal 1 gram	Typical Number of Stones/Beads in Jewelry for Children 6 and Younger
10-pp crystal stone/1.6–1.7 mm glued into cavity	333	10–15
30-pp crystal stone/larger stone glued into cavity	27	5
2-mm crystal beads	105	10–12
4-mm crystal beads	11	4–6

V. Crystal Beads and Decorative Articles Meet Criteria for Exemption Because They Do Not Pose a Health Risk to Children

As noted above, crystal and glass beads (including crystal and glass rhinestones or cubic zirconium) are widely used in jewelry, apparel, footwear, accessories and other applications. Lead is bound in the matrix of crystal and glass and thus lead in crystal or glass jewelry will not be absorbed into the body or create health risks under reasonably foreseeable use and abuse conditions. The physical makeup of lead in crystal and glass is thus vastly different from lead in other materials, where lead will be released more readily than it will from materials in which it is physically bound. Lead in crystal is not inhalable and lead does not easily penetrate skin. *See* Attachment A.

[24] The CPSC's acid leaching test procedure set forth in the Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry (2/3/2005), tests intact samples using hydrochloric acid. *See* http://www.cpsc.gov/BUSINFO/pbjeweltest.pdf. For crystal, a 1 gram sample is often used because of the small size and limits of detection; results for single crystals were calculated arithmetically.

As with all chemicals in the environment, the potential for lead to harm one's health depends on the form of the lead present, the amount taken into the body, and whether the lead is inhaled, touched, or ingested. Lead contained in crystal beads and rhinestones used in jewelry does not vaporize or become airborne as particles. Therefore, inhalation of lead from the jewelry products is not possible. In addition, skin contact with lead is not known to affect the health of people, because lead does not easily penetrate the skin under normal conditions. *See* Attachment A. Mouthing and ingestion represent worst-case potentially foreseeable use and abuse conditions for crystal beads and rhinestones in jewelry and apparel. (Mouthing and ingestion are very unlikely in accessories, footwear and other decorative applications.) Because of the physical make-up of crystal, even under aggressive acid test conditions, only minute amounts of lead – amounts less than accessible lead in materials that meet applicable total lead limits or in foods that we eat daily – will be released.

Indeed, these tests results show that while lead may be present at levels in the 23 % range and up, tests replicating direct mouthing and ingestion conditions illustrate that exposure to lead in crystal or glass beads and rhinestone will not result in any adverse health risk to children, and will not exceed levels of accessible lead associated with compliant materials. In addition, crystal is exempt from the Proposition 65 limits because lead in crystal, as indicated above, is not deemed to result in exposures that exceed levels set under that law. There is no indication in the published literature that wearing or handling children's products with crystal or glass beads or rhinestones is associated with an increase in blood lead levels in children.

A. Crystal Beads in Jewelry, Apparel, Accessories and Other Applications Will Not Result in Harmful Levels of Potentially Accessible Lead

Crystal and glass beads and rhinestones are often used in jewelry, apparel, hair accessories, belts, shoes, sunglasses, and even in crystallized mobile phones or other electronic applications.[25] The CPSC has recently proposed to define an "inaccessible" component part to mean only components that cannot be touched by a child. Crystal will thus be touchable or "accessible" (as defined by the CPSC) to children 12 and under in fashion and other applications. Jewelry Producers and Retailers are unaware of any reported instances where accidental ingestion of crystal beads has been associated with an increase in blood lead levels in children. The peer-reviewed literature does not indicate a single instance where exposure to crystal beads in jewelry, apparel, accessories or decorative items has resulted in an increase in blood lead levels in children.

[25] While lead bound in crystal is exempt under the EU RoHS Directive, the CPSC has not proposed to recognize this exclusion in its proposal on lead in electronics products on grounds that the lead does not perform a technical function for the electronics device. *See* 74 Fed. Reg. 3425 (January 15, 2009). The Jewelry Producers and Retailers respectfully ask the Commission to recognize an exclusion for decorative crystal, including in electronics products.

The absence of any health risk to children is supported by test data and analyses. As indicated in Attachment A, inhalation and dermal contact are not viewed to present any exposure risk to children from lead in crystal. Foreseeable abuse may include mouthing, or more rarely still, ingestion. Ingestion of jewelry pieces has been reported, primarily associated with metal components, but test data reflecting potential mouthing or ingestion scenarios – likely reflecting an unreasonable worst case exposure situation rather than reasonably anticipated use and abuse conditions - confirms the safety of glass and crystal beads and rhinestones.

Table 2 below summarizes information reported in Attachment A and compares extractable lead from CPSC tests on metal jewelry components that contained less than 600 ppm with industry test data on accessible lead from crystals that exceed 600 ppm. Saline test data was developed in connection with the Proposition 65 jewelry proceeding and was deemed representative of jewelry for purposes of the exclusion for glass and crystal in that proceeding. The CPSC's test data was deemed representative by the Commission of total and accessible lead in metal jewelry components for purposes of adopting the Interim Metal Jewelry Standard for lead in metal jewelry.[26] The tests on crystal reviewed in Attachment A reflect both saline (reflecting mouthing) and acid leach (reflecting ingestion) tests; acid leach tests were almost uniformly conducted on crystals that exceeded 23% lead and are representative of anticipated worst-case exposure scenarios associated with crystal and glass beads and rhinestones that contain higher total lead.

Table 2

Material	Total Lead	Saline Test Results (Average Per Item)	Acid Extraction Test Results (Average Per Item)
Metal components (weight unknown)	< 600 ppm	Not Summarized	20.27 μg $\pm$ 7.8 μg (for all metal components
Metal component (weight unknown)	< 300 ppm	Not summarized	15.4 μg (for all metal components
Crystal (1 g)	> 600 ppm	0.15 μg	0.52 μg[27]

Other federal agencies, such as the Food and Drug Administration (FDA), have evaluated lead exposures and developed safety assessments that also provide guidance on levels of lead that will not elevate blood lead levels in children. FDA established provisional

[26] Interim Enforcement Policy for Children's Metal Jewelry Containing Lead – 2/3/2005, available at http://www.cpsc.gov/BUSINFO/pbjewelgd.pdf.

[27] All of the crystals tested for acid leaching contained more than 23% lead; one sample was tested using XRF and found to contain 38 ppm, but those results are deemed inaccurate.

tolerable daily intakes (PTDIs) of lead for various age and population groups. The PDTI corresponds to the daily lead intake that would theoretically result in a 1-microgram per deciliter (μg/dL) rise in blood lead levels in children and women of child-bearing age. The PDTI for lead for children under 7 years of age is 6 μg/day, and for children above 7 years of age, the PDTI is 15 μg/day. FDA has found that lead levels have significantly declined over the past few decades. Lead intake values for selected total diet studies (TDS) food categories based on mean lead levels range from 0.099 μg/day to 1.17 μg/day. The lead intake values based on maximum lead levels range from 0.23 μg/day to 3.52 μg/day. *See* Attachment A and Table 3 below.

Table 3

Ingested Food Item	Total Lead Per User (µg Pb/day)	
	Mean	Maximum
Food Product		
Peach, Canned in Light/Medium Syrup	1.174	3.522
Sweet Potatoes, Strained/Junior	0.917	1.882
Sweet Potatoes, Canned	0.777	1.658
Milk Chocolate Candy Bar, Plain	0.355	1.628
Dill Cucumber Pickles	0.375	1.335
Salad Dressing, Creamy/Buttermilk Type, Low Calorie	0.38	1.223
Raisin Bran cereal	0.147	1.057
Spinach, Fresh/Frozen, Boiled	0.202	0.963
Brownies, Commercial	0.238	0.693
Raisins, dried	0.122	0.474
Honey	0.143	0.338
Graham Crackers	0.136	0.353
Chocolate Chip Cookies, Commercial	0.137	0.298
Teething Biscuits	0.099	0.23
Total of All Foods	0.38	1.223

If a child ingested a crystal *every day* – an unforeseeable abuse situation - the exposure would be less than that associated with eating many common foods, and well below levels associated with acid extraction tests for accessible lead in metals that contain less than 600 or 300 ppm lead. Using the US Environmental Protection Agency's (EPA's) Integrated Exposure Uptake Biokinetic (IEUBK) model, these low intakes – representing in some instances exposures, such as daily ingestion, that are not reasonably foreseeable – nevertheless would not result in discernible changes in blood lead levels. *See* Attachment A.

Attachment A establishes that based on the best available scientific evidence, lead in crystal or glass beads and rhinestones will not pose a health risk to children or result in elevated blood lead levels. This conclusion would apply to all decorative uses of glass and crystal beads or rhinestones in jewelry, apparel, accessories, footwear or other

decorative applications, such as crystallized electronic devices such as mobile phones or other items.

B. Decorative Uses of Crystal Do Not Pose A Risk

In addition to excluding crystal and glass beads and rhinestones, we ask the Commission to also exclude decorative uses of crystal in the very few applications that might be intended primarily for children 12 and under. Crystal and glass decorative items, such as lamps, picture frames, collectible figurines, and other applications, are seldom designed or intended primarily for children 12 and under, but there may be occasional products that are intended for children in this age range. Fine decorative crystal items are not toys and indeed are generally not intended to be frequently handled. Mishandling is more likely to result in occasional cuts from broken glass than any type of lead exposure. There is no likelihood of accidental ingestion of these items; they are simply too large, and mouthing is deemed unlikely. Occasional dermal contact is the most likely exposure route. As noted above, there is no risk that children handling such items would be exposed to lead in amounts that would be absorbed or cause a health risk based on reasonably foreseeable use and abuse.

VI. Proposition 65 Jewelry Settlement

The State of California has asked the Commission to recognize as excluded from the scope of federal preemption its legislation applicable to jewelry.[28] This request necessarily includes the exemptions for crystal and glass enacted in the legislation. The exclusion for glass and crystal was adopted after a consensus based process involving various stakeholders, including the Attorney General, environmental groups and industry, with input from scientists. Because of the low potential for exposure to lead, the *Burlington* agreement and legislation codifying it excluded crystal and glass from limits on lead subject to a 1 gram limit in products intended for children 6 and under from the warning obligations under Proposition 65. Crystal and glass was entirely excluded in jewelry for consumers 7 and older. However, the Commission has not yet acted on the State's request, which, as noted above, necessarily encompasses a request to recognize all the exclusions.[29]

We have provided here and in Attachment A the scientific basis for a complete exclusion for crystal beads and rhinestones in children's products. However, Jewelry Producers and Retailers do not object to the 1 gram limit established under California law applicable to crystal and glass beads and rhinestones used in jewelry for children 6 and under in connection with granting a temporary final rule exempting glass and crystal as set forth

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[28] *See* Letter from Edmund G. Brown to CPSC Office of the Secretary, Filing Pursuant to Section 106(h)(2) of the Consumer Safety Improvements Act of 2008 (Public Law 110-314, 122 Stat. 3016), November 12, 2008. The request encompasses the *Burlington* agreement enacted as California's jewelry law, AB 1681, codified at Cal. Health & Safety Code §§ 25214.1-.4.

[29] The CPSC has proposed to exclude most of the materials excluded from AB 1681 in its recent proposal. *See* 74 Fed. Reg. 2433, January 15, 2009.

herein. As a practical matter, this limit is consistent with the amount of material typically used in jewelry for this age group. No limit should apply to crystal and glass beads and rhinestones used in products intended for children 7 – 12.

V. Best Available Evidence Unfavorable to the Request

The Jewelry Producers and Retailers are unaware of any objective, peer-reviewed scientific evidence related to the impact on blood lead levels of foreseeable use and abuse of crystal or glass beads in children's products unfavorable to this request.

VI. Organizations Requesting the Exemption

Organizations making this request for a categorical exclusion for crystal and glass beads and rhinestones and other decorative uses of crystal (to the extent the latter might be considered children's products as defined in the legislation)[30] include:

Fashion Jewelry Trade Association
1486 Stony Lane
Kingston, RI 02852
Att: Michael Gale, Executive Director
E-mail: fjta@aol.com

Manufacturing Jewelers and Suppliers of America, Inc.
45 Royal Little Drive
Providence, RI 02904
Att: James K. McCarty, Chief Operating Officer
E-mail: james.mccarty@mjsa.org

Footwear Distributors and Retailers of America
1319 F St. NW, Suite 700
Washington, DC 20004
Att: Peter T. Mangione, President
E-mail: ptmangione@fdra.org

National Retail Federation
325 7th St. NW, Suite 1100
Washington, DC 20004
Att: Jonathan Gold, Vice President, Supply Chain and Customs Policy
E-mail: goldj@nrf.com

United Dance Merchants of America
376 Main Rd.
Granville, MA 01034
Att: Gina Costello, Executive Director
E-mail: gina@udma.org

[30] As indicated above, most decorative applications of crystal would not qualify as a children's product. This request does not include crystal tableware as it is not designed or intended primarily for children 12 and under.

Conclusion

A review of the best available scientific information suggests several risk assessment approaches that all support an exclusion for crystal and glass beads and rhinestones. *See* Attachment A.

First, the CPSC's own analysis of the relationship between metal jewelry that contains total lead of less than 600 and 300 ppm and accessible lead from such items provides a framework for granting exemptions. Materials that, like crystal, generate less accessible lead in reasonably foreseeable use and abuse scenarios, including ingestion, than is likely to result from reasonably foreseeable use and abuse scenarios, including ingestion, of compliant materials, should be categorically excluded. Crystal and glass beads and rhinestones may exceed total lead limits but meet this standard.

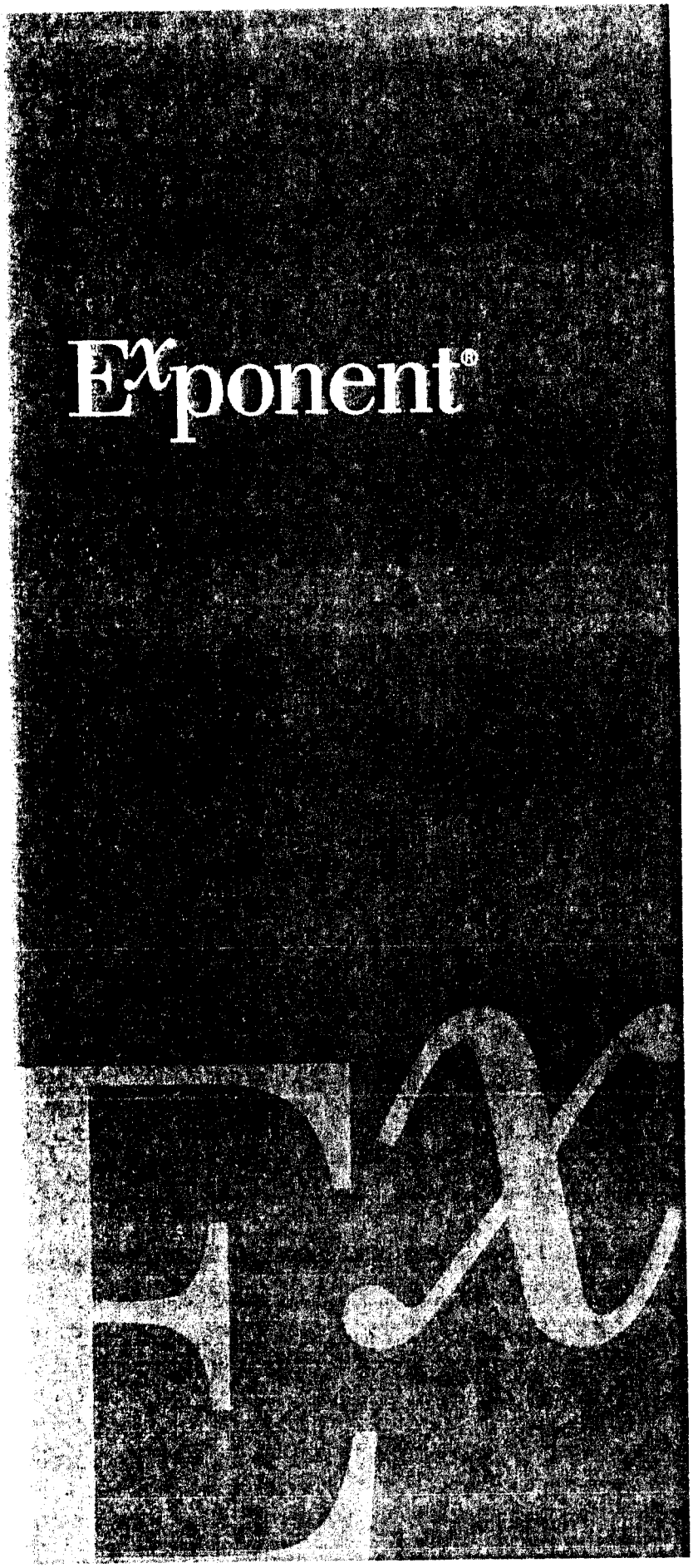
Second, a comprehensive process adopted under a Proposition 65 settlement, later enacted into law, established that crystal in crystal and glass beads and rhinestones met standards that obviated the need for warnings. For purposes of this request, while Jewelry Producers and Retailers believe the data presented in Attachment A supports a categorical exemption for crystal and glass, they do not object to an exemption that includes a 1 gram limit on use of crystal beads and rhinestones in products designed and intended primarily for children 6 and under, consistent with California law.

Third, potential exposure to lead from mouthing or ingesting crystal is less than lead contained in common foods, and is not likely to pose a health risk or cause an elevation in blood lead levels, based on EPA's IIEUBK model.

The Commission should immediately adopt an exclusion for glass and crystal beads and rhinestones in children's products and decorative uses of crystal in the form suggested in Attachment B. As indicated above, crystal is a critically important and safe material in a range of fashion-related industries. Millions of dollars worth of products use crystals. Because of the impending February 10 deadline after which products that contain any component that exceeds 600 ppm will effectively be banned, safe products are being returned and will be unsalable as a result of the ban. New children's products containing glass and crystal rhinestones cannot be sold. This issue affects thousands of producers and retailers, including many small businesses. Failure to act immediately to grant this emergency request will result in an enormous and unnecessary financial hardship on the jewelry, apparel, footwear, accessories and other industries, without enhancing children's safety. Reasonably foreseeable use and misuse will not result in an anticipated change in blood lead levels. These materials do not pose any risk likely to be greater than that posed by use or abuse of compliant products and materials. Congress cannot have intended to ban such products from the marketplace in enacting the CPSIA.

Enclosures: Attachment A
Attachment B

Attachment A



Health Sciences

Technical Report

Evaluation of Lead in Crystal Beads and Rhinestones

Exponent

Technical Report

Evaluation of Lead in Crystal Beads and Rhinestones

Prepared for

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February 2, 2009

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Contents

Introduction

This report describes an evaluation of potential exposure related to the lead content of crystal jewelry under reasonably foreseeable use and abuse situations. For purposes of this report, "crystal" refers to glass, including or rhinestones or cubic zirconium made of glass. Specifically, this report addresses the following items: (1) Description and use of crystal jewelry, (2) Potential exposure pathways, (3) Levels of extractable lead in crystal jewelry, and (4) Comparative analysis of lead exposure from crystal jewelry and technical evaluation

The primary focus of this evaluation pertains to the safety of crystal beads and stones in jewelry. However, the data and conclusions presented in this report could be applied to other uses of beads and stones, such as apparel, accessories, footwear and decorative items.

Assessing Lead Exposure

Analysis of lead exposure is primarily evaluated by changes in blood lead content. Blood lead levels are the amount of lead in micrograms (μg) in a deciliter (dL) of blood and may be used to indicate past or recent lead exposure. Prior to the 1980s, the largest sources of lead exposure in children were leaded gasoline emissions and lead-based paint[1]. As shown in Figure 1 below, it is encouraging to note that due to the phase out of these materials in the 1970's, average blood lead levels in the U.S. have declined from approximately 16 μg/dL in 1976 to less than 2 μg/dL in 1999. [2] Based on the most current assessment, the average blood lead level for children less than 7 years of age is 2.00 μg/dL and indicates a dramatic reduction in children's blood lead levels over the past decades. [3]

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[1] Center for Disease Control. 2004. Preventing Lead Exposure in young Children. A housing-based approach to primary prevention of lead poisoning. Recommendations from the advisory Committee on Childhood Lead Poisoning and Prevention. October

[2] Needham, LL. 2004. The NHANES Second National Report on Human Exposure to Environmental Chemicals. National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA. Downloaded from htt://www.envirohealthhouston.org/symposium04/NEEHAM%20revised.pdf.

[3] NHANES 2005-2006.

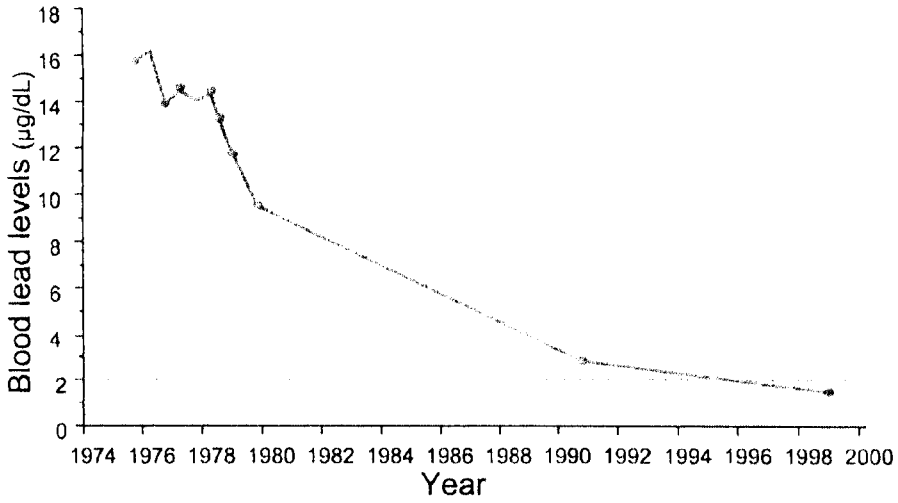

Figure 1-1 BLLs in the U.S. Population – 1976 to 2000

Description of Crystal Beads and Rhinestones

Crystal (including glass beads and rhinestones), is an amorphous solid made by thermally transforming several raw materials. Silicon oxide is the main component of crystal glass, but lead oxide (the source of lead in "lead" crystal), sodium oxide, potassium oxide and other oxides are used in the glass-making process. Lead is added to impart brilliance and to facilitate the glass cutting process. The glass melting process forms a unique matrix (network) from these oxides with new characteristics by chemical conversion. Lead, or any other chemical additive, is not easily available or accessible in crystal after manufacture because of the chemical conversion process. Ion exchange, a process by which substances such as lead might be released or migrate from the material, can happen only on the surface of glass crystal. Therefore, when crystal is exposed to an acidic environment, such as stomach acid, or an ionic environment, such as human saliva, acid protons and salt ions such as sodium, aluminum, and magnesium ions are exchanged for lead ions in the outer surface of the crystal, allowing only a very small amount of lead to migrate to the acidic or saline environment. The exchange reactions occur only at the surface of the articles.[4] Removing any component of a glass product by extraction (leaching) or any other means is very difficult and does not occur to a significant degree under normal or even abnormal circumstances.[5] Pure "leaded crystal" by definition must have a lead content of at least 24%. Other grades of crystal such as glass beads or rhinestones may have lower lead content. However, any type of crystal beads or stones used in jewelry or apparel is likely to exceed 600 ppm.

Concern arose several years ago about high lead content in metal jewelry, resulting in adoption of Interim Enforcement Guidelines for Metal Children's Jewelry by the Consumer Product Safety Commission (CPSC).[6] The CPSC addressed only metal components of children's jewelry. With regard to regulation of jewelry, the State of California adopted comprehensive limits on lead in jewelry, but agreed to exclude from regulation under the California's Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as Proposition 65) and California's Lead Containing Jewelry Law (AB1681), any crystal and glass elements in children's jewelry (defined as made for age six and under) that weighs less than one gram. Data reviewed by State of California scientists on the low levels of leachable lead was used to support this finding. No limits were applied to the use of glass or crystal beads or rhinestones in any jewelry for consumers 7 and older.

Jewelry primarily intended for young children (i.e., 6-7 years of age and under) is designed differently from non-children's products, in that children's jewelry contains fewer and smaller stones and beads. Data for typical stones/beads used in young children's jewelry products are summarized below.

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[4] A.A. Ahmed and I.M. Youssof, Glass Technology, 38(5), 171-178 (1997)

[5] Ahmed, A.A., and Youssof, I.M. (1997). Interaction between lead crystal glass (24% PbO) and acetic acid. Glass Sci. Technol., Vol.70 (6), pages 173-185.

[6] Interim Enforcement Policy for Children's Metal Jewelry Containing Lead 2/3/2005.

Description/Size	Number of Stones/beads Required to Equal 1 gram	Typical Number of Stones/beads in Jewelry for Children 6 and Younger
10-pp crystal stone/1.6–1.7 mm glued into cavity	333	10–15
30-pp crystal stone/larger stone glued into cavity	27	5
2-mm crystal beads	105	10–12
4-mm crystal beads	11	4–6

Potential Exposure Pathways

As with all chemicals in the environment, the potential for lead to harm one's health depends on the form of the lead present, the amount taken into the body, and whether the lead is inhaled, touched, or ingested. Lead contained in crystal beads and rhinestones used in jewelry does not vaporize or become airborne as particles. Therefore, inhalation of lead from the jewelry products is not possible. In addition, skin contact with lead is not known to affect the health of people, because lead does not easily penetrate the skin under normal conditions.[7] Therefore, the only reasonable route of potential exposure to lead in crystal beads or rhinestones associated with jewelry products is oral contact from incidental mouthing and to a much lesser degree, incidental oral contact via hand-to-mouth activities after handling the jewelry products. Accidental swallowing of a crystal jewelry bead is a potentially foreseeable although rare occurrence; however, repeated daily ingestion of crystals in jewelry is not reasonably foreseeable under normal use or repeated unintended use of the product. These pathways also apply to the use of crystal beads and stones in other applications, such as apparel, accessories and footwear. However, mouthing of these types of products is less likely.

[7] Agency for Toxic Substance and Disease Registry. ATSDR. 2007. Toxicological profile for lead. U.S. Department of Health and Human Services, Public Health Service. August

Levels of Extractable Lead from Glass and Crystal Beads and Rhinestones

We are not aware of any published literature regarding extractable levels of lead from crystal jewelry nor are we aware of any published, peer-reviewed data linking use or exposure of lead in crystal and rhinestone beads used in jewelry or other consumer products to any health effects.[8] Various tests have been conducted, some as part of the Proposition 65 jewelry agreement, to determine the leachable concentrations of lead from representative jewelry crystals under conditions reflecting mouthing. The Consumer Product Safety Commission (CPSC) has also conducted accessible-lead studies focusing on metal jewelry. Leaching-test results are typically presented in micrograms of lead leached per gram of material (μg/g) extracted by a certain extractant (e.g., "simulated saliva" or saline solution to mimic mouthing behavior, or acid to simulate interaction with stomach acid after accidental ingestion) over a certain time period.

For the purpose of this assessment, we assumed that the available saline extraction data provide a very conservative (*i.e.*, upper-bound) estimate of the amount of lead that a child might potentially ingest from sucking on or licking the crystals, and that the acid extraction data provide a conservative (*i.e.*, upper-bound) estimate of the amount of lead that might be liberated from the crystals following accidental ingestion of the crystals. These assumptions are consistent with the specifications of the methods used in generating the extraction data. We have also conservatively used the extraction data to represent potential daily intakes that could repeatedly occur day after day (i.e., frequency of potential mouthing or ingestion behavior is not considered, but rather assumed to occur daily).

Saline Extraction Proposition 65 Testing of Crystals

As part of Proposition 65 testing to simulate mouthing, samples were extracted in saline at 30 °C, 60 revolutions per minute (rpm), for 1 hour.[9] Saline extraction for one hour provides a conservative estimate of potentially accessible lead, in that average daily mouthing for non-pacifier objects is considerably less than one hour.[10, 11, 12] These assessments are consistent with the CPSC's assessment of mouthing behaviors.[13] Table 1 provides results for the amount

[8] Published reports have associated ingestion of metal jewelry components containing high total lead levels with elevated blood lead levels.

[9] This method was used as part of the Proposition 65 jewelry evaluation. During protocol development, shaking, no shaking, 22 °C and 30 °C 22 were evaluated with selection of 30° at 60 rpm.

[10] U.S. EPA.2008. Child-specific exposure factors handbook.

[11] Juberg DR, Alfano K, Coughlin RJ, Thomason KM. 2001. An observational study of object mouthing behavior by young children. Pediatrics 2001; 107:135-142.

[12] British Department of Trade Industry. 2002. Research into mouthing behavior of children up to 5 years old. Consumer and Competition Policy Directorate. Department of Trade and Industry, London UK.

[13] CPSC.1998. The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products, December.

of lead leached by saline extraction from a variety of approximately 1-gram samples of various crystal stones and beads.

As shown in Table 1, the total content of lead in the crystal samples ranges from 870 parts per million (ppm; equivalent to μg/g) to 23,320 ppm (0.087% to 2.3%).[14] However, the amount of lead leached per crystal is very low, ranging from 0.008 μg to 0.701 μg, with an average value of 0.12 μg lead per crystal. The amount of lead leached per gram is also very low, ranging from 0.041 μg/g to 0.779 μg/g, with an average of 0.27 μg/g. As indicated above, depending on the type of stone or crystal, 11 to 333 beads are required to equal a gram, whereas only 4 to 16 crystals are typically used in the jewelry product. Even under a very conservative assumption in which a child mouths 1 gram of crystal jewelry—which would entail in some instances many hundred crystals and numerous products—for an hour every day, on average, the amount of lead leached is significantly below any regulatory benchmark level of concern, and even below the Proposition 65 warning level of 0.5 μg/day.[15] Therefore, as was determined by the State of California, mouthing of crystal jewelry is not expected to result in adverse health effects to a child. As discussed previously, these data were reviewed by State of California scientists and supported the exemption of crystal and glass elements in children's jewelry that weighed less than one gram. No limits were applied to the use of glass or crystal beads or rhinestones in any jewelry for consumers 7 and older. Further evaluation of the relevance of leachable lead from crystal beads and rhinestones used in jewelry based on saline extraction is presented in the "comparative analysis" section.

Acid Extraction

Table 2 provides the amounts of lead leached from various 1-gram samples of crystal stones and beads using CPSC's acid extraction method for metal jewelry, which involves 6 hours of total acid leaching time.[16] The acid extraction data provide an estimate of the amount of lead that might be liberated from the crystals following accidental ingestion. The total lead content for some of the samples was measured using x-ray fluorescence (XRF), with values generally over 23% lead.[17] For these tests, a variety of 2-millimeter (mm) and 4-mm colored crystal beads were analyzed, as well as some larger crystals. The number of crystals required for a 1-gram sample ranges from 4 to 221. With the exception of one sample that was above 1 gram, the amount of lead leached per crystal ranges from 0.01 to 2.8 μg, with an average of 0.52 μg lead per crystal. Based on the average value, daily ingestion of a crystal would not exceed any

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[14] Total lead content was measured using standard digestion procedures (*i.e.*, nitric acid solution) using EPA 3050/6020a, similar to methods outlined in CPSC metal jewelry. Complete extraction of lead from crystal and glass is not possible without use of a more aggressive solution that dissolves the glass matrix, such as hydrofluoric acid (HF). HF has severe safety requirements and because of its aggressiveness toward human skin and instrument components is not routinely used in laboratories. Consequently, the reported total lead levels likely underestimate the total lead content in the beads tested. XRF measurements of glass and crystal have shown > 20% lead.

[15] FDA recognizes a provisional total daily intake (PTDI) level of 6 μg/day for children under 7 years of age, and 15 μg/day for children older than 7 years of age. CPSC has used a target value of 15 μg/day (15–30 days).

[16] CPSC Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry 2/3/2005. This procedure is based on methodology found in ASTM C927, C738, D5517 and F963.

[17] The XRF measurement for one crystal bead was reported as 38 ppm,

regulatory benchmark levels.[13] In interpreting this information, it is important to understand that this type of repeated daily ingestion of the jewelry crystals is not reasonably foreseeable under normal use or repeated unintended use of the product. Based on these data, if accidental ingestion occurs, the amount of lead that might be leached from crystal stones and be potentially available for absorption is low. Further evaluation of the relevance of leachable lead from crystal jewelry based on acid extraction is presented in the comparative analysis section below.

Comparative Analysis of Lead Exposure from Crystal Beads and Rhinestones

The Consumer Product Safety Improvement Act (CPSIA) establishes limits on total lead starting in 2009, stipulating that the limit for lead content in children's products will be set at 600 ppm initially, with lower limits to be phased in over the next 3 years, from 600 ppm to 300 ppm, and ultimately to 100 ppm (if feasible). At the lowest lead content of 100 ppm specified in the CPSIA, this means that 100 ppm would contain 100 μg of lead per gram (μg/g = ppm: 100 ppm = 100 μg/g). By stipulating the lowest value of 100 ppm (or 300 ppm if 100 ppm is not technologically feasible), CPSIA acknowledged that some amount of lead may still be present. Because some amount of lead will continue to be present (*i.e.*, 300 ppm), some "accessible" amount of lead (*i.e.*, more than zero and potentially up to 300 ppm) may be detected, depending on the analytical test conditions. Therefore although total content limits are mandated in the legislation, the primary intent is to ensure there is no meaningful exposure to children from the products. This has traditionally been measured by testing for accessible lead.

CPSC Test Results for Accessible Lead in Children's Metal Jewelry

As an example, CPSC staff evaluated accessible lead from children's metal jewelry.[18] The testing included data from 322 of 466 jewelry test items (primarily metal) in which both total lead content and acid extraction were measured.[19] The data are also summarized in Table 2 of a CPSC memorandum and demonstrates that, even at total lead content values of less than 600 ppm (some of the samples had total lead content value well below 100 ppm), the mean accessible lead value was 20.27 μg ±7.8 μg.[20] Our evaluation of the data indicates that even at total lead content of 300 ppm or less, the average accessible lead value was 15.4 μg. These data demonstrate that, even when meeting the 600-ppm, 300-ppm or ultimately, if adopted, the 100-ppm total lead content values, depending on the type of product and testing conditions, some accessible lead much greater than zero will be detected.

It is also noteworthy that, for crystal jewelry, the average accessible amount of 11.7 μg, based on acid extraction of a 1-g sample (which, as noted above, may include up to several hundred crystals) is lower than the CPSC mean accessible lead value of 20.27 μg for metal jewelry materials of less than 600 ppm total lead content and less than the average lead value of 15.4 μg for metal jewelry materials at or below 300 ppm. Additionally, it appears that the acid

[18] David Cobb, CPSC memorandum to Kristina M.Hatelid, November 29, 2006. Summary of test results for lead in children's metal jewelry.

[19] The Standard Operating Procedure (SOP) for acid extraction involves placing an intact jewelry item in 0.07 N hydrochloric acid at 37 degrees for 6 hours. This procedure is based on methodology found in ASTM C927, C738, D5517 and F963. *Id.*

[20] Joanne Matheson. Memorandum to Kristina Hatelid, November 28, 2006. Petition HP06-1 Lead in jewelry toxicity review.

extraction tests conducted by CPSC were not based on a 1-g sample, but rather, were conducted on an individual item of unknown total weight. Therefore, a more appropriate value for comparison to the CPSC 20-μg mean accessible value is the 0.52-μg average per-crystal leaching value. As summarized in Table 3 below, clearly the amount of potentially accessible lead from crystal based on acid extraction tests is well below accessible levels associated with products that meet the total lead content values of 600 ppm and 300 ppm mandated in the CPSIA.[21]

Table 3. Lead acid leaching results for crystal and other materials

Material	Weight	Total Lead Content (ppm)	Average 6-hour Acid Extraction Results (ug)
Metal jewelry components	unknown	≤600 ppm	20.27
Metal jewelry components	unknown	≤300 ppm	15.4
Crystal	1 gram	> 600 ppm	11.7 (max)
Crystal	1 gram	> 600 ppm	0.52 (avg)

Therefore, the issue at hand is not demonstrating that no accessible lead is detectable, but rather, ensuring that any trace amount of accessible lead that may be detected does not pose a health risk based on the specific applications of lead-containing material. As is the case with any chemical in the environment, the detection of accessible lead does not necessarily indicate a health risk.

Other agencies such as the U.S. Environmental Protection Agency and the U.S. Food and Drug Administration (FDA) have dealt with the issue of trace levels of lead and established benchmarks based on protection of health. In no case, was "zero" lead a reasonable or technologically achieve goal. For example, the CPSC applies a 15 μg of lead per day level for chronic exposure to lead in consumer products.[22] In the jewelry petition, CPSC staff evaluated the difference in lead absorption from acute lead exposure (accidental ingestion of metal jewelry) and estimated that children should not ingest more than 175 μg of accessible lead in a short period of time to remain within the daily exposure limit.[23] Data on crystal indicates that even under extreme ingestion exposure scenarios, the amount of potentially accessible lead is orders of magnitude below these benchmark values.

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[21] Saline extraction and wipe data are also presented in the CPSC staff report, but we have not statistically evaluated those date here. Similar to the data for acid extraction, extractable levels of lead under saline conditions were detected for those materials in which the total lead content values were below 600, 300, and 100 ppm.

[22] CPSC staff report on lead and cadmium in children's PVC products. U.S. Consumer Products Safety Council. November 21, 1997.

[23] Joanne Matheson. Memorandum to Kristina Hatelid, November 28, 2006. Petition HP06-1 Lead in jewelry toxicity review.

FDA Guidance on Lead Levels

The FDA has regulated lead in food for decades and has long recognized that it is a naturally occurring element. Thus, it is impossible for food to be absolutely free of lead. As a result, in the 1990s, FDA established provisional tolerable daily intakes (PTDIs) of lead for various age and population groups. The PDTI corresponds to the daily lead intake that would theoretically result in a 1-microgram per deciliter (μg/dL) rise in blood lead levels in children and women of child-bearing age. The PDTI for lead for children under 7 years of age is 6 μg/day, and for children above 7 years of age, the PDTI is 15 μg/day.

To evaluate the amount of lead exposure resulting from ingestion of food products, FDA has conducted total diet studies (TDSs) from the 1970s into the 1990s. These studies show a decline in the estimated daily lead intake, from 60–90 μg/day (1972–1982) to 4 μg/day (1991–1995). As stated by FDA, the most recent diet study[24] likely reflects the background presence of lead in food and is low with respect to PTDI.[25]

Table 4 summarizes lead intakes in μg/day for children younger than 12 years for selected TDS food categories. To estimate lead intake corresponding to a given TDS code, the mean and maximum lead concentrations associated with that TDS food were combined with the consumption data for all National Health and Nutrition Examination Survey (NHANES) foods that were mapped to that TDS food code. NHANES is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is a major program of the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) and has the responsibility for producing vital and health statistics for the Nation.[26]

As shown in Table 4, the lead intake values for selected TDS food categories based on mean lead levels range from 0.099 μg/day to 1.17 μg/day, and the lead intake values based on maximum lead levels range from 0.23 μg/day to 3.52 μg/day. This analysis indicates that the amount of lead intake from food is in the same range as the mass of lead leached from one gram of crystals under saline conditions or the amount of lead leached per crystal under acidic conditions. Therefore, the information indicates that a child would have to mouth 1 gram of

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[24] FDA Total Diet Study statistics on element results. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD. Revision 4.1 Market Basket 1991-3 through 2005. December 11, 2007.

[25] Michael Kastock. 2008. FDA regulation of lead in food. U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition. Presented at ACPS-CP Meeting July 22.

[26] Lead concentrations for selected foods were derived from the recent TDS, in which approximately 280 foods were sampled. Although there are many fewer TDS foods (~280) than NHANES foods (>6,000), the goal of the TDS diets is to account for representative total food consumption. To accomplish this, FDA grouped (or aggregated) the NHANES foods according to their similarity to TDS foods and created a "mapping" file in which each NHANES food was assigned to one of the TDS foods. For this analysis, to estimate lead intake corresponding to a given TDS code, the lead concentration associated with that TDS food was combined with the consumption data for all NHANES foods that were mapped to that TDS food code.

crystals per day or ingest one crystal every day, to achieve the same level of exposure to lead as is achieved from normal dietary sources. For example, based on saline leach-test data, the hypothetical maximum amount of lead leached if a child mouthed 1 gram of crystal every day is 0.779 μg. This value is less than the average lead intake of a child eating strained junior sweet potatoes. When considering a hypothetical situation in which a child accidentally swallows a crystal on a daily basis, the average amount of lead leached from the crystals is 0.52 μg. This value is less than the average lead intake of a child eating dill cucumbers, brownies, or chocolate chip cookies. Even for those few crystals that resulted in acid-leach levels of 1–2 μg per crystal, the hypothetical dose associated with daily accidental ingestion of those crystals is within the range of maximum intakes from children eating raisin bran cereal or milk chocolate bars.

An addition example includes FDA's establishment of a guidance value for Mexican candy. The guidance value was supported by a safety assessment which estimated that children would not exceed 1.3-2.3 μg/day of lead intake from Mexican style candy once it complied with the guidance level. Again, the FDA safety assessment acknowledges that some amount of lead intake occurs, however, the trace amounts of lead results in no meaningful exposure and does not pose a health risk.[27]

Furthermore, using the U.S. EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model, these low intakes in the range of 1–2 μg/day are predicted to result in very small changes in blood lead levels. For example, the addition of 1 μg of lead is predicted to result in a blood lead change of 0.17 μg/dL, which would be difficult, if not impossible, to discern analytically. Additionally, an intake of 0.52 μg (the mean accessible value per crystal for acid leaching) results in no change to the predicted IEUBK blood lead level.

Based on the available data for accessible amounts of lead from crystal and when compared to other regulatory and health values deemed to be insignificant, no measureable impacts to blood levels and no meaningful levels of lead exposure are anticipated even under the hypothetical assumption of daily mouthing and accidental ingestion of a crystal.

[27] U.S. FDA. Supporting document for recommended Maximum Level for Lead in Candy likely to be consumed frequently be small children. Docket No., 2005D-0481. U.S. Department of Health and Human Services.FDA Center for Food Safety and Applied Nutrition. December 2005.

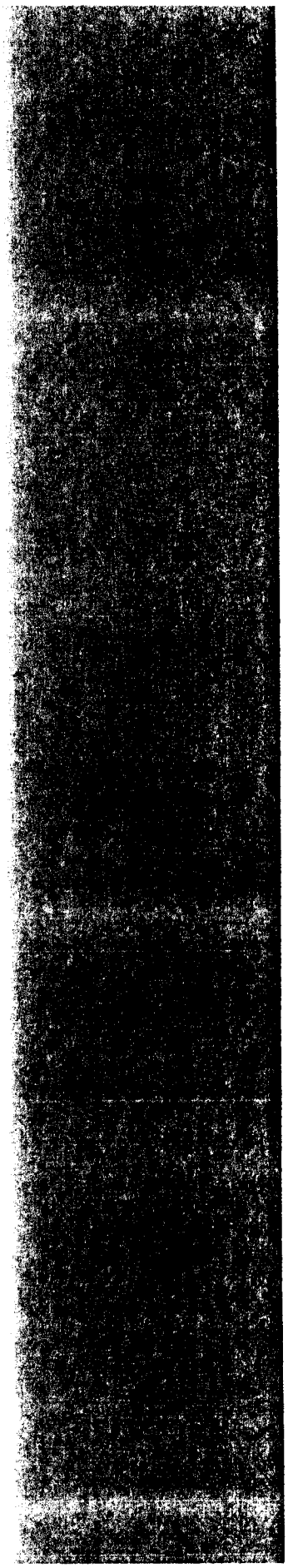
Conclusions

- Data from testing of other types of products (e.g., metal jewelry) demonstrates that, even when meeting the 600-ppm, 300-ppm, or 100-ppm total lead content standards, depending on the type of product and testing conditions, some accessible lead will be detected. Furthermore, under laboratory testing conditions, the amount of accessible lead from crystal stones and beads is significantly less than that from metal jewelry and below regulatory benchmarks.

- Testing of crystal stones and beads indicates that lead is not accessible to children in a manner that results in a health risk. This finding is consistent with Proposition 65 and California's Lead Containing Jewelry Law, in which these materials were exempted from lead limits based on evidence that crystal jewelry contained lead levels below health-protective warning thresholds.

- Evaluation of leachable lead concentrations from crystal jewelry under reasonably foreseeable use and abuse situations indicates that hypothetical doses from mouthing of a full gram of crystal or accidental ingestion of a crystal are within background food intake levels and any potential resultant impact on blood lead level is not analytically discernable.

Tables



Tale 1: Results of leachable lead for crystal beads and stones (Saline Extraction 30 C 60 rpm)

	Total lead ppm **	mass per stone	Sample weight (g)	Number of Stones per test	Lead leached (ug)	Lead leached (ug per gram)	leaching per crystal (ug)
tanzanite rhinestone	8325	0.202	1.21	6	0.05	0.041	0.008
blue zircon rhinestone	1,683	0.232	1.39	6	0.07	0.050	0.012
fuscia rhinestone	7650	0.387	1.16	3	0.06	0.052	0.020
emerald rhineston	5750	0.206	1.03	5	0.07	0.068	0.014
black rhinestone	7545	0.197	1.18	6	0.1	0.080	0.017
Montana rhinestone	10,090	0.357	1.07	3	0.09	0.084	0.030
light saph rhinestone	7715	0.380	1.14	3	0.1	0.088	0.033
peridot rhinestone	8845	0.177	1.06	6	0.1	0.094	0.017
saphire rhinestone	15,030	0.206	1.03	5	0.11	0.107	0.022
amethyst rhinestone	20,060	0.190	1.14	6	0.13	0.114	0.022
Ruby Rhinestone	6351	0.250	1	4	0.12	0.120	0.030
crystals	5415	0.015	1	68		0.130	0.000
light amethyst	870	0.010	0.48	50	0.063	0.131	0.001
rose Rhinestone	1867	0.009	0.46	51	0.062	0.135	0.001
rose rhinestone	4853	0.410	1.23	3	0.18	0.146	0.060
clear rhinestone	1723	0.009	0.47	50	0.077	0.163	0.002
cat's eye teal	946	1.030	1.03	1	0.19	0.184	0.190
lavendar (w/foil)	11,100	0.950	0.95	1	0.224	0.236	0.224
green glass	5650	0.247	0.74	3	0.281	0.380	0.094
Cat's eye blue	1021	0.810	0.81	1	0.312	0.385	0.312
CZ dark tear drop	6571	0.340	0.34	1	0.136	0.400	0.136
Cat's eye brown	1784	0.910	0.91	1	0.416	0.457	0.416
light sapphire	8053	0.012	0.6	50	0.278	0.463	0.006
lavendar (w/o foil)	6940	0.930	0.93	1	0.451	0.485	0.451
blue glass bead	7310	0.223	0.67	3	0.376	0.561	0.125
jet rhinestone	23,320	0.168	1.01	6	0.58	0.574	0.097
black rhinestone	4310	0.040	1	25	0.037	0.637	0.001
cat's eye brown	1432	0.880	0.88	1	0.563	0.640	0.563
Cat's eye rose	1352	0.900	0.9	1	0.701	0.779	0.701
				Average		0.27	0.12

*saline leaching based on one hour leaching tests

**Total content was measured using standard digestion procedures (i.e., nitric acid solution) as outlined in CPSC metal jewelry procedures. Complete extraction of lead from crystal and glass is not possible without use of a more aggressive solution that dissolves the glass matrix, such as hydrofluoric acid. HF has severe safety requirements and because of its aggressiveness toward human skin and instrument components is not routinely used in laboratories.

Table 2: Results of leachable lead for crystal beads and stones (CPSC acid Extraction /EPA 200.8)

	mass per stone (g)	number stones per test	total 6 hour leaching (ug/g) approx 1 gram sampled	leaching per crystal (ug)
Red (4mm)	0.031	32	0.36	0.01
Green (2mm)	0.00468	214	2.7	0.01
Red (2mm)	0.00478	210	3.38	0.02
Red (no foil)	0.196	6	0.139	0.02
purple (2 mm)	0.00461	217	9.49	0.04
black (2 m)	0.0054	186	8.14	0.04
Clear (2 mm)	0.00452	221	16.9	0.08
Green (no foil)	0.081	13	1.06	0.08
Green (4 mm)	0.039	26	3.19	0.12
blue (2 mm)	0.0071	141	25.5	0.18
Black (4 mm)	0.039	26	5.15	0.20
Purple (4 mm)	0.036	28	5.9	0.21
Blue (4mm)	0.038	27	13.7	0.51
Clear (4 mm)	0.037	27	23.4	0.87
clear 2 (no foil)	0.045	23	28	1.22
black 2 (no foil)	0.212	5	6.9	1.38
clear 1 (no foil)	0.045	23	35.9	1.56
Blue (no foil)	0.289	4	11.2	2.80
		Average	11.17	0.52

* one black bead with a weight of 1.47 grams resulted in a lead leaching value of 10.30 ug

Note: XRF measurements were conducted on some of these samples with values of > 23% lead. XRF measurements of the red bead showed 38 ppm lead. Usefulness of XRF measurements may be limited based on the size of the stone or bead.

Table 4. 2-Day Average Intake of Lead for Children < 12 years of age (mg/day); NHANES 2003-2004

TDS No.	TDS Category	Mean Levels Analyzed (mg/day) Per User	Mean Levels Analyzed (mg/day) Per user ug/day	Max Levels Analyzed (mg/day) Per User	Max Levels Analyzed (mg/day) Per user ug/day	Unweighted No. Users	No. NHANES Codes Mapped to TDS No.
74	Raisin Bran Cereal	0.000147	0.147	0.001057	1.057	45	36
95	Raisins, Dried	0.000122	0.122	0.000474	0.474	67	20
107	Spinach, Fresh/Frozen, Boiled	0.000202	0.202	0.000963	0.963	31	39
161	Dill Cucumber Pickles	0.000375	0.375	0.001335	1.335	122	26
172	Honey	0.000143	0.143	0.000338	0.338	39	1
183	Chocolate Chip Cookies, Commercial	0.000137	0.137	0.000298	0.298	385	20
187	Milk Chocolate Candy Bar, Plain	0.000355	0.355	0.001628	1.628	202	24
221	Sweet Potatoes, Strained/Junior	0.000917	0.917	0.001882	1.882	64	4
251	Graham Crackers	0.000136	0.136	0.000353	0.353	288	10
254	Peach, Canned In Light/Medium Syrup	0.001174	1.174	0.003522	3.522	92	9
291	Brownies, Commercial	0.000238	0.238	0.000693	0.693	77	13
317	Teething Biscuits	0.000099	0.099	0.00023	0.23	88	7
358	Sweet Potatoes, Canned	0.000777	0.777	0.001658	1.658	46	50
376	Salad Dressing, Creamy/Buttermilk Type, Low-Calorie	0.000161	0.161	0.000494	0.494	45	24
	Total of all foods	0.00038	0.38	0.001223	1.223	1161	283

Attachment B

Proposed Regulation

The Commission should issue a temporary final rule amending Part 1500 by adding a new provision as follows:

> §1500.___. Exemptions from total lead limits under Section 101 of the Consumer Product Safety Improvements Act for glass and crystal beads and rhinestones and glass and crystal decorative articles and objects.
>
> (a) The following class of materials used in children's products is excluded from the prohibitions of Section 101(a) of the Consumer Product Safety Improvements Act:
>
> (1) glass and crystal beads or rhinestones less than 1 gram in children's products primarily designed or intended for children age six (6) and younger;
> (2) glass and crystal beads or rhinestones in children's products primarily designed or intended for children 7 – 12; and
> (3) all decorative uses of glass and crystal such as picture frames, lamps, and figurines, in children's products.

Stevenson, Todd

From: Millar, Sheila A. [Millar@khlaw.com]
Sent: Monday, February 02, 2009 6:25 PM
To: CPSC-OS
Cc: Hatlelid, Kristina; Falvey, Cheryl; gmullan@cpsc.gov
Subject: Section 101 Request for Exclusion of a Material of Product: Crystal
Attachments: Final Petition Filing 2009_02_02.pdf

Attached please find an electronic copy of a Section 101 Request for Exclusion of a Material or Product: Request to Exempt Crystal Beads and Rhinestones. Copies will also be hand-delivered tomorrow. Please contact me if you have any questions.

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