

AN ASSESSMENT OF CHILDREN'S EXPOSURE TO CADMIUM UNDER ASTM F2923-14

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EXECUTIVE SUMMARY

Because cadmium exposure can be toxic to the kidneys, it is important to identify the relationship between an accurate estimate of the dose of cadmium exposure and the level at which this creates an adverse response in the human body. The U.S. Consumer Product Safety Commission (CPSC) conducted a standard rigorous analysis, and determined the likeliest route of exposure and the maximum safe acute and chronic exposure in connection with wearing and handling of jewelry by children. This analysis informed the development of ASTM F2923-14, the Standard Safety Specification for Consumer Product Safety for Children's Jewelry. The CPSC's analysis and the Children's Jewelry Standard's requirements are based on scientific principles of physiological conditions after CPSC staff conducted an analysis of the toxicological literature, and test data on actual jewelry samples analyzed for the propensity to release cadmium. The CPSC's analysis, and the standard which is based on that analysis, are conservative and health-protective.

BACKGROUND

Exposure to cadmium is a cause for concern, particularly with respect to accumulation in the kidneys. Accordingly, the U.S. Consumer Product Safety Commission (CPSC), which is the federal agency with jurisdiction over the safety of consumer products, prepared a report on the testing of jewelry and metal alloy samples to evaluate the potential for cadmium exposure if a

¹ Williams College, B.A., 1971 (Chemistry); Princeton University, M.A., 1975 (Chemistry); Princeton University, Ph.D., 1977 (Chemistry with an emphasis in inorganic chemistry).

child swallowed an item.² Finding the then-existing standards and tests inadequate to protect against cadmium exposure, the CPSC asked the jewelry industry to adopt a safety standard based on its tests. Specifically, the CPSC found the two-hour extraction test used in the American and European toy standards at the time (the American toy standard was ASTM F963-08, and the European toy standard was EN 71-3:1994) inadequate for metal components. The result is ASTM F2923-14, the Standard Specification for Consumer Product Safety for Children's Jewelry (Children's Jewelry Standard), which specifies tests to determine whether jewelry contains and will release cadmium above maximum safe levels.

CADMIUM TOXICOLOGY

Cadmium occurs naturally in the environment and is found widely in soil, water, living organisms, tobacco, and foods. Diet is the major source of cadmium exposure for most people. Exposure to cadmium also may occur through contact with some consumer products that contain cadmium, although is considered to be a much lower potential risk than dietary exposure. Exposures from products, especially in children, are most likely from handling objects and then transferring material from the hands to the mouth, through direct mouthing of objects, and from swallowing small objects or parts of products, such as children's jewelry.

Cadmium is poorly absorbed in the body following exposure by ingestion (about 1-10%).³ Cadmium that is absorbed can be found largely in the liver and kidney and the effects in the kidney are considered the most sensitive endpoint. Cadmium is excreted slowly; with a very long half-life measured in decades. The available data in the literature are sufficient for cadmium to be considered toxic.

Chronic Exposure Limits

Handling or mouthing children's jewelry could result in a longer-term exposure because use of the product could occur over time and therefore, is considered as a chronic exposure situation. The CPSC estimated an acceptable daily intake (ADI) level of 0.1 µg/kg/day, that is, a dietary exposure of 0.1 µg of cadmium per kg of body weight per day, for chronic exposure to cadmium to avoid adverse health effects by applying an uncertainty factor of 3 to data from an

² CPSC, *Children's Cadmium-Containing Jewelry* (Oct. 14, 2010), <http://www.cpsc.gov/PageFiles/115615/cadmiumjewelry.pdf>.

³ ATSDR (2008) Toxicological Profile for Cadmium (Draft). Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services.

<http://www.atsdr.cdc.gov/toxprofiles/tp5.html>.

epidemiological study.⁴ The targeted population for children's jewelry identified by the CPSC for this purpose is children ages 2 to 6 years, with an average body weight of 18.2 kg (40 pounds).⁵ This yields a maximum allowable chronic exposure for young children of 1.8 µg/day (0.1 µg/kg/day x 18.2 kg body weight = 1.8 µg/day).

Derivation of Acute Exposure Limits and Test Methods

Swallowing children's jewelry could result in an acute exposure while the item works its way through the digestive system before being eliminated from the body, usually within a few days. An acute maximum intake level of 11 µg/kg/day is estimated for cadmium based on a level of 1.1 mg/kg/day from a short-term oral exposure in rats by Borzelleca, et al. (1989), reduced by a safety factor of 100.⁶ Given the average body weight of a child of 18.2 kg, the maximum allowable acute exposure for a young child is about 200 µg/day (11 µg/kg/day x 18.2 kg bodyweight ≈ 200 µg/day).

THE BASIS OF THE CHILDREN'S JEWELRY STANDARD

CPSC's Conclusions

The Children's Jewelry Standard was developed based on the physiological profile of cadmium described above, after CPSC staff conducted an analysis of the toxicological literature and performed testing of actual components of jewelry and toys. CPSC staff concluded that acute accidental exposures were the key risk for pieces of children's jewelry and also for toys. They used 24-hour acid extraction test under constant agitation to simulate the stomach's digestive process. Applying the toxicological profile of cadmium, the CPSC staff concluded that the maximum allowable acute exposure to a young child is about 200 µg of cadmium.⁷ The CPSC also developed a standard for chronic exposures, wherein an item is placed in a saline solution for 6 hours to assess cadmium extraction: 18 µg of cadmium is the maximum safe amount that can be extracted to ensure that chronic overexposure does not occur. The staff identified ingestion – acute exposure – however, as the key route of exposure for consumer products, including children's jewelry.

⁴ Suwazono Y, Sand S, Vahter M, Filipsson AF, Skerfving S, Lidfeldt J, Akesson A (2006) Benchmark dose for cadmium-induced renal effects in humans. *Environ Health Perspect* 114:1072-1076.

⁵ Ogden CL, Fryar CD, Carroll MD, Flegal KM (2004) Mean bodyweight, height, and body mass index, United States 1960-2002. *Advance data from vital and health statistics*; no 347. Hyattsville, Maryland: National Center for Health Statistics.

⁶ Borzelleca J, Clarke E, and Condcie L (1989) Short-term toxicity (1 and 10 days) of cadmium chloride in male and female rats: Gavage and drinking water. *J Am Coll Toxicol* 8:377-404.

⁷ See *Cadmium in Children's Jewelry*, *supra* n.2.

In coming to this determination, the CPSC determined that the most likely, most concerning exposure to cadmium occurs when a child swallows a small part containing cadmium. The ingested item results in a potential for acute exposure to cadmium, not a daily exposure over a lifetime. Chronic exposures to cadmium in consumer products, by contrast, are in addition to the major sources of cadmium "exposures that most people experience from food, water, and other sources."⁸ Therefore, data on the effects of acute cadmium exposure are the most relevant information for assessing risk of exposure to cadmium for ingested jewelry items, using the maximum daily safe intake level of 11 µg/kg/day described above for acute exposure scenarios. To assess the potential hazard to children from children's cadmium-containing jewelry, CPSC considers the most vulnerable group of children is 2 to 6 years old with an average weight of 18.2 kg (40 pounds). CPSC calculates the maximum allowable acute exposure to a young child is about 200 µg (11 µg/kg/day x 18.2 kg = 200 µg per incidence).

Therefore, to be safe, the ingestion of a piece of jewelry should result in the release of no more than 200 µg of cadmium per swallowing occurrence. This value is not based on a reference dose (daily intake) value for cadmium, as ingestion is assumed to be a rare, generally single occurrence. Indeed, there is no evidence that any child is daily swallowing items of jewelry.

The Basis of the Children's Jewelry Standard

The CPSC recommended that both the toy and the jewelry industry incorporate its recommendations into separate standards under development at ASTM to address cadmium in metal components of these products. In particular, CPSC urged adoption of a migration test utilizing its 24-hour test method and a limit of 200 µg of cadmium. The Children's Jewelry Standard uses the above tests to assess the safety of children's jewelry, but incorporates a total content screening limit as an initial step. Where cadmium content is 300 ppm (mg/kg) or less, no further migration testing is required. If that limit is exceeded on any swallowable component (meaning a component that is a small part), additional extraction testing involving a 24 hour test in a heated 0.07 hydrochloric acid (HCl) solution with agitation to determine that the bioavailability of cadmium from a swallowed metal jewelry item is less than 200 µg, per the CPSC test protocol above.

The 300 ppm cadmium screening level is based on data about the portion of cadmium that migrated in testing of hundreds of pieces of metal jewelry. Analysis indicated that metal components that contain 1.35% (13,500 ppm) or less of cadmium are unlikely to yield more than a fraction of the 200 µg threshold. This observation is based on the low extraction of cadmium

⁸ See *id.*, Staff Report, at 11.

from a piece of metal jewelry: CPSC tests yielded an average migration of cadmium at 0.5%, and the highest migration observed was 2.349%. To add a factor safety, an exaggerative migration rate of 3% is assumed, yielding the screening limit of 300 ppm for components that weigh as much as 20 grams. This again represents an additional safety factor; components of children's jewelry seldom weigh more than 5 grams. A piece of jewelry with total of 300 ppm of cadmium is not expected to yield an extractable level of 200 µg of cadmium if ingested based on CPSC's tests of children's jewelry components. CPSC staff participated in the development of the ASTM F2923 standard and concurred with the inclusion of a screening limit as a way of minimizing costs of its recommended migration test procedure.

CONCLUSION

ASTM F2923-14, the Children's Jewelry Standard, establishes rigorous safety standards and testing methods to assess the potential hazard from cadmium in children's jewelry. It applies the authoritative risk assessment methodology of the CPSC on the acute cadmium exposure limit, and CPSC's recommended bioavailability test method to determine when such limit is met. Jewelry that meets the Children's Jewelry Standard's requirements is safe for children, and will not expose them to excess cadmium.