U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

October 19, 2010

Ms. Joan Lawrence
Chairman, ASTM F15.22 Subcommittee on Toy Safety
c/o Toy Industry Association, Inc.
1115 Broadway, Suite 400
New York, NY 10010

Dear Ms. Lawrence:

I am writing on behalf of the U.S. Consumer Product Safety Commission (CPSC) staff[1] to encourage the work of the ASTM Subcommittee on Toy Safety to revise the toy safety standard to eliminate the potential hazard of cadmium in some toys. I am enclosing a copy of the CPSC's "Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials," dated August 2010, and a copy of the CPSC's "Staff Report: Cadmium in Children's Metal Jewelry," dated October 2010, for the Subcommittee's information. Please circulate this information to members of the Subcommittee.

Recently CPSC staff completed a report on testing lead- or cadmium- containing jewelry and metal alloy samples. The testing was done to evaluate the potential for chemical exposure if an item is swallowed by a child. CPSC staff concluded that a test method for chemicals that can migrate from small items if swallowed—especially metal items—should be based on measuring solubility in an acidic solution over a 24 hour period. This conclusion is based on the results of testing hundreds of jewelry and metal alloy samples, as well as information about the length of time an ingested foreign object could be present in the digestive tract of a child. It is hoped that this information, as well as that contained in the CPSC "Staff Report: Cadmium in Children's Metal Jewelry," will be helpful to members of the ASTM F15.22 Subcommittee.

[1] This letter was prepared by CPSC staff and has not been reviewed or approved by and may not necessarily reflect the views of the Commission.

Please let me know if there is any further technical support CPSC staff can provide to expedite the completion of an effective, revised ASTM F963 safety standard that addresses the potential cadmium hazard. Please call me at 301-504-7245 if you have any questions.

Sincerely,

Colin Church
Voluntary Standards Coordinator

Enclosures

cc Mr. Len Morrissey
Staff Manager, ASTM F15 Committee

Ms. Kristina Hatlelid, Ph.D., M.P.H.
Toxicologist, U.S. Consumer Product Safety Commission

Mr. Jason Howe
Chemist, U.S. Consumer Product Safety Commission

Staff Report

Cadmium in Children's Metal Jewelry
October 2010

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Staff Report

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

Memorandum

Date: October 14, 2010

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences

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

SUBJECT : Children's Cadmium-Containing Metal Jewelry[1,2]

Introduction

The U.S. Consumer Product Safety Commission (CPSC) administers federal laws concerning children's products and other consumer products. Federal laws and CPSC regulations apply nationwide to the consumer products in interstate commerce that are within its jurisdiction. Since its inception, the CPSC has played a prominent role in protecting the public, especially children, from the hazards of exposure to toxic chemicals. While the CPSC and other federal agencies, as well as local, state, and other organizations, have paid close attention to the potential for exposure to lead, many other chemicals may be found in products that, if exposure occurs, could result in adverse health effects in the users of those products.

Young children may be exposed to chemicals in consumer products from the direct mouthing of objects, from handling such objects and subsequent hand-to-mouth activity, or from swallowing a small object or a small part of a product. The specific types and frequency of behavior that a child will engage in depends on the age of the child and the characteristics and pattern of use of the product.

Recently, CPSC staff identified a number of products, particularly jewelry intended for use by children that presented a risk of adverse health effects from exposure to cadmium.

Regulatory framework

The CPSC protects children, and consumers in general, from hazardous exposure to substances, such as cadmium in consumer products, under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. §§ 1261–1278). The Federal Hazardous Substances Act requires that certain hazardous household products ("hazardous substances") bear cautionary labeling to alert

[1] These comments are those of the CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

[2] A draft of this document was disseminated for external peer review. A summary of the peer review comments and the staff responses to the comments may be found in Tab A.

consumers to the potential hazards that those products present and to inform them of the measures they need to take to protect themselves from those hazards. Any product that is toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or that generates pressure through decomposition, heat, or other means requires labeling, if the product may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

The FHSA gives the Commission authority to ban by regulation a hazardous substance if it determines that the product is so hazardous that the cautionary labeling required by the act is inadequate to protect the public. Any toy or other article that is intended for use by children and that contains a hazardous substance is also banned under the FHSA if a child can gain access to the substance.

Regulating products under the FHSA generally requires assessment of exposure and risk. Assessments are generally conducted on a case-by-case basis, considering the specific characteristics of the product, the intended consumers of the product, and the interaction between the consumer and the product.

This document provides the staff's approach to assessing products under the FHSA, summarizes the relevant toxicology of cadmium, derives limits for exposure that, if exceeded, could result in adverse health effects, and discusses the results from analytical tests that could result in further scrutiny of products that may cause excessive exposure to cadmium in children who use the products.

Cadmium Toxicology

This section includes a brief overview of cadmium toxicology. The staff prepared a separate toxicity review that includes a broader discussion of the available data,[3] which may be found in Tab B.

The adverse health effects of cadmium exposure in humans have been documented largely in occupational settings, and mostly through inhalation, although nonworker populations have been studied as well. The principal effects of long-term exposures are chronic obstructive pulmonary disease and emphysema from inhalation of cadmium and cadmium compounds, and chronic renal tubular disease from inhalation and oral exposures. Depending on the dose and duration of exposure, effects have been observed in multiple organ systems and tissues, including kidney, liver, and bone. Although cadmium exposure in workers through inhalation is associated with lung cancer, there is insufficient evidence in humans or experimental animals to determine whether cadmium is carcinogenic from oral exposure.

Cadmium and cadmium compounds are poorly absorbed following ingestion, unless the levels are high enough to cause damage to the gastrointestinal tract. Absorbed cadmium accumulates largely in the kidney and liver, with a very long half-life, which is measured in decades. Only a small portion of the absorbed cadmium is excreted in the urine or in feces. Consequently, cadmium exposures are cumulative.

[3] "Toxicity Review of Cadmium." CPSC Memorandum from Dominique J. Williams and Kristina M. Hatlelid, Ph.D., M.P.H. to Mary Ann Danello, Ph.D. August 2010.

The forms of cadmium in consumer products vary from cadmium metal in certain metal alloys, including materials used in soldering and electroplating, to cadmium salts and other compounds used in materials such as paints and plastics. Cadmium is found widely in the environment, in foods, and in tobacco. Diet is the major source of cadmium exposure for most people.

Exposure to cadmium also may occur through contact with some consumer products. 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. Staff identified information relating to ingestion of cadmium and cadmium compounds as most relevant to the assessment of cadmium exposures from consumer products.

Existing Exposure Limits

Several limits for exposure to cadmium have been established for regulatory or other purposes. For example, the World Health Organization (WHO) has developed a Provisional Tolerable Monthly Intake level (PTMI) of 25 micrograms per kilogram body weight per month[4] (25 µg/kg/month) (or 0.8 µg/kg/day) (JECFA, 2010). The U.S. Environmental Protection Agency (EPA) developed an oral reference dose (RfD[5]) of 1 µg/kg/day for food intake and 0.5 µg/kg/day for cadmium in drinking water (different levels of absorption of cadmium from food or from water account for the different RfD values) (EPA, 1994). The Agency for Toxic Substances and Disease Registry (ATSDR) developed a minimal risk level (MRL[6]) for chronic[7] oral exposure of 0.1 µg/kg/day (ATSDR, 2008). These limits were based on studies of kidney effects in humans.

The ATSDR's 2008 draft toxicological profile also includes an MRL for intermediate length exposure of 0.5 µg/kg/day based on effects on bone in experimental animals. Due to inadequacies in the acute oral exposure database, the ATSDR has not derived an acute duration MRL.

The preceding exposure limits are for general use (*e.g.*, PTMI, MRL) or apply to specific exposure media (*e.g.*, RfD for food or water). A child-specific standard for cadmium exposure exists in the form of the European toy safety standard EN 71-3 (European Standard EN 71-3, 1994). Under this standard, the limit for exposure to cadmium from toys for young children is 0.6 µg per day, based on information concerning normal background cadmium intake levels and a policy decision to limit cadmium exposure from toys to 5 percent of the assumed background exposure. Recently, the EC toy safety directive (Council Directive, 2009) established new health-based exposure limits for toys, using recent data on kidney effects in humans, including studies considered by the ATSDR (2008) and CPSC staff in the current evaluation. Effective July 20, 2013, the European toy safety standard for cadmium exposure from toys is based on an exposure limit of about 0.2 µg per day. Note that these toy safety standard daily limits are not

[4] Exposure limits are generally expressed in terms of milligrams of exposure per kilogram body weight. Since 1 mg = 1,000 µg, 1 µg/kg/day is equivalent to 0.001 mg/kg/day.

[5] The EPA's RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

[6] The ATSDR's MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

[7] As defined in the ATSDR toxicological profiles, chronic exposure is exposure to a chemical for 365 days or more; intermediate exposure is 15 through 364 days; acute exposure is 1 through 14 days.

expressed in terms of body weight, but are daily limits for cadmium exposure that have been adjusted to account for the weight of a young child (7.5 kilograms for the revised standard—about 16.5 pounds).

Long-Term Exposure

A number of additional chronic exposure studies are now available that allow for dose-response analysis, and can be used to estimate an acceptable daily intake level (ADI). The staff's calculations generally are based on the study reporting the lowest exposure levels associated with adverse effects (lowest observed adverse effect level or LOAEL) or a dose that was not associated with an adverse effect (no observed adverse effect level or NOAEL). A number of high quality studies have considered cadmium-related adverse effects in the kidney and bone, reporting quantitative estimates for the level of cadmium intake that is associated with adverse effects ranging across about one order of magnitude (i.e., the high end of the range is about 10 times the low end of the range).

Staff chose the analysis of an epidemiological study by Suwazono *et al.* (2006) as the key study for a number of reasons, including that the study was based on a large, well-characterized population without any identified source of environmental or occupational exposure; the modeling included multiple covariates to account for potential confounders; and the estimated cadmium exposures associated with adverse health effects were among the lowest of several studies. Suwazono *et al.* (2006) used a benchmark dose[8] approach to analyze the data from a study of 820 Swedish women. The analysis estimated the concentration of cadmium in urine associated with urinary protein markers for adverse effects in the kidney. These researchers reported 0.5 micrograms cadmium per gram creatinine[9] in the urine (0.5 µg/g creat.) as the lower confidence limit of the cadmium concentration benchmark dose level (*i.e.*, BMDL associated with a 5 percent excess risk of protein in the urine). Similar results were reported by Uno *et al*. (2005) and Järup *et al*. (2000).

Because the BMDL is a measure of cadmium excreted in urine, additional analysis is required to estimate the corresponding level of cadmium intake into the body. This can be done using modeling techniques. The derivation of the MRL presented in the draft ATSDR Toxicological Profile for Cadmium (ATSDR, 2008) has applied such an analysis using the results of several studies of European populations, including Suwazono *et al.* (2006). For a 0.5 µg/g creat. urinary concentration, the analysis published by the ATSDR (2008) estimated a level of cadmium intake of 0.33 µg/kg/day. This is the intake level chosen by CPSC staff as the critical exposure level.

The scientific community generally addresses uncertainty in the comprehension of toxicology and dose-response through the use of uncertainty factors. CPSC staff also uses an uncertainty factor approach in evaluating exposure levels to account for a lack of robust data from animal studies or a lack of information from human exposures (CPSC, 1992). CPSC staff may apply up to three uncertainty factors, depending on the completeness and relevance of the available data. An uncertainty factor may be used if data are available only in studies of animals and not in humans. An uncertainty factor is applied if the available studies do not identify a dose or

[8] A benchmark dose approach uses mathematical modeling to characterize exposure-response relationships.

[9] Urinary cadmium concentrations were normalized to the amount of creatinine also present in the urine, a common method that accounts for the variations in excretion of urine and that allows comparison of urinary measurements over time, between subjects, or from different studies.

exposure level that is not associated with an adverse effect (NOAEL). When a benchmark dose approach is used, the BMDL is treated as a NOAEL. The third type of uncertainty factor is applied to account for sensitive populations if the available studies do not adequately address such concerns.

In this case, only one uncertainty factor is needed, which is intended to account for the possibility of sensitive members of the population. The staff has chosen to apply a reduced uncertainty factor of 3, rather than the factor of 10 that is more typically used because of lack of knowledge of effects throughout a population. The reduced uncertainty factor is appropriate in this case because of the strength of the data that supports the identified critical exposure level, which is based on multiple studies of large numbers of people in different parts of the world. Therefore, an uncertainly factor of 3 applied to the intake level of 0.33 µg/kg/day results in an acceptable daily intake (ADI) of 0.1 µg/kg/day. This is the level of chronic exposure that should not be exceeded to avoid adverse health effects.

The key study used to estimate the ADI (Suwazono *et al.*, 2006) was based on data from adult women in a population that had no particular source of exposure to cadmium. Because the study participants likely experienced exposures to cadmium throughout their lives, such as through normal dietary sources, staff believes that the ADI may be applied to various scenarios involving exposures from consumer products during childhood and later in life.

Another issue to consider is the use of toxicokinetic modeling to relate intake of cadmium to absorption into the body, distribution within the tissues and organs of the body, and elimination from the body. Recent data indicate that children ages 6 through 11 years and females show increased urinary excretion of cadmium (Ruiz *et al*. 2010). This finding could indicate important differences in exposure and uptake of cadmium in these populations. Again, the epidemiological study that was used to estimate the acceptable daily intake level was conducted in women who likely experienced exposures to cadmium throughout their lives, including childhood. Although uncertainty remains on the implications of possible differences among various groups, the relatively large body of literature concerning long-term exposure and effects of cadmium supports the staff's approach.

Intermediate and Acute Duration Exposure

Documented acute[10] exposures in humans generally have involved exposure to relatively large amounts of cadmium compounds, resulting in severe adverse effects, including death. One report of a nonfatal exposure in humans was published by Nordberg *et al.* (1973). This case involved gastrointestinal symptoms in boys 13 through15 years old following ingestion of a beverage containing cadmium from a soda machine. Investigation of this case included analysis of a sample of water from the machine that contained 16 milligrams of cadmium per liter (16 mg/L). It is not clear from the report when the water sample was collected or how it was handled prior to testing for cadmium content. Based on information collected from the boys about five months after the incident, symptoms began within 15 minutes of consumption of the drink, and included headache, nausea, vomiting, abdominal pain, and diarrhea. All symptoms resolved within seven hours, and most of the boys returned to school when classes resumed after the weekend three days later. The children reported consuming 0.5 to 2.5 glasses of the drink,

[10]Acute exposures, 14 days or less, 16 C.F.R. §1500.3(c)(2)(i). Intermediate exposure duration is not defined within CPSC regulations, but generally means longer than acute exposure, but less than chronic; this term is defined in the ATSDR toxicological profiles as 15 to 364 days.

with an average of about one glass. Although the volume of beverage consumed was not reported, information in the publication's discussion suggests that the investigators considered a glass to be about 0.15 L. Using this estimate for the average intake, the toxic dose of cadmium was about 2.4 mg. Because of the high level of uncertainty in this quantitative estimate and inadequate documentation of the case, staff finds this study unacceptable for further quantitative analysis or derivation of an exposure limit. Staff has not located other studies or reports of health effects from short-term oral exposure in humans at doses that are not associated with severe adverse health effects or death. Nor has staff located any reports of persistent effects after a brief exposure has ended, or studies that measured long-term effects resulting from an acute exposure to cadmium.

Several studies in animals have been conducted involving single exposures or short-term dosing, usually at relatively high doses. Adverse effects have been reported for multiple tissues and organ systems, including death, and effects in the liver, kidney, and bones. Most of the studies are not suitable for use in dose-response analysis for deriving exposure limits because of the severity of the adverse effects associated with the dose levels chosen for the studies. Of the studies that are appropriate for use in extrapolating to an acceptable intake level for humans, the staff chose as the key study, the evaluation of short-term exposure in rats through drinking water by Borzelleca *et al.* (1989).

This study involved groups of male and female rats that were exposed to cadmium chloride in drinking water for 10 days. Cadmium exposure was calculated at 1.1, 7.8, and 11.1 mg/kg/day in males, and 1.1, 8.1, and 13.8 mg/kg/day in females, based on the concentration of cadmium chloride in the water and the animals' water intake. The authors noted a dose-dependent decrease in body weight gain among males. The summary data also appear to show reduced body weight in the highest dose group in males, and dose-related reduced body weight gain in females, but statistical analyses were not presented.

Because of the disagreeable taste of water containing cadmium chloride, reduction in body weight or reduction in body weight gain may be due to the tendency of the animals to reduce their water intake with a concomitant reduction in food intake. However, the same publication (Borzelleca *et al.*, 1989) included a study in which dosing through gavage (*i.e.*, delivery of the dose directly into the stomach through a feeding tube) also resulted in reduced body weight and reduced body weight gain. This latter study suggests that cadmium exposure affects body weight through means other than the effect on the taste of the drinking water, and, therefore, changes in the body weight endpoints should be considered related to the exposure. The results of this study are supported by findings of body weight effects in two other animal studies involving dosing through gavage (Baranksi, 1985; Machemer and Lorke, 1981).

For exposures through both gavage and drinking water, Borzelleca *et al.* (1989) also noted significant changes in certain clinical chemistry measures, suggesting systemic effects in addition to the effects on body weight. Therefore, staff concludes that short-term exposure to cadmium is associated with adverse effects in animals. The lowest dose administered in the drinking water study (1.1 mg/kg/day) (Borzelleca *et al.*, 1989) can be considered the no observed adverse effect level (NOAEL) and is appropriate for extrapolating to an acceptable intake level for humans.

As with the estimation of a longer term ADI, for an acute duration exposure limit, staff identifies the LOAEL or NOAEL and applies up to three uncertainty factors to account for sensitive

individuals, the use of a LOAEL instead of a NOAEL if that is the case, and for the use of data from studies in animals instead of in humans if that is also applicable. Consequently, the acute ADI for cadmium is 11 µg/kg/day, based on the NOAEL of 1.1 mg/kg/day, and the use of an uncertainty factor of 10 for the use of data from animals rather than humans, and another factor of 10 to account for sensitive individuals in human populations.

No information was located for human oral exposures of intermediate length duration. However, recent studies in young rats demonstrate dose-related effects on bone metabolism and bone biomechanical properties for exposures up to 12 months (Brzóska and Moniuszko-Jakoniuk 2005). Based on a number of effects reported at the lowest dose tested, the LOAEL for the intermediate duration study is approximately 0.2 mg/kg/day. The intermediate exposure MRL of 0.5 µg/kg/day presented in the recent draft toxicological profile (ATSDR 2008) was derived using a benchmark dose approach to analysis of this data.

In general, the animal studies conducted in acute exposure scenarios and intermediate duration scenarios indicate a very wide range of LOAELs and NOAELs (*i.e.*, orders of magnitude difference between lowest and highest reported values) including, in some cases, adverse effect dose levels that are comparable to the LOAELs and NOAELs reported in longer-term studies (see summary in Table 3.6, ATSDR 2008). As discussed above, ADIs, MRLs, and RfDs derived from chronic and intermediate duration studies range across about one order of magnitude. No acute exposure limits have been derived previously for oral exposure to cadmium.

Because cadmium is found in the environment, in foods, and in tobacco, most people experience some level of exposure to cadmium. Any additional exposure to cadmium from consumer products will add to the overall risk of adverse health effects that might be associated with other sources of cadmium.

Evaluation

Children's jewelry is not a distinct, easily-defined product for a specific group of consumers. Rather, this category of products could encompass a large variety of jewelry products suitable for children of specific ages or for children of all ages. Because exposure to substances is the focus of staff's assessment, the assessment will focus on a group of children likely to participate in the behaviors that could result in excess exposure to the substances, and who are also the most vulnerable to the effect of the possible exposures. In this case, staff has chosen to consider young children ages 2 through 6 years old. Children in this age group still have significant mouthing behaviors, and occasionally may swallow—accidentally or intentionally—small objects. This age group may also be of special concern because of the potential health effects of cadmium exposure in people at early stages of development, similar to the concern about lead exposure in young children. However, data currently do not exist that clearly show adverse health effects specifically associated with exposures in early childhood.

Children are not expected to use certain pieces of jewelry, such as a charm bracelet, throughout their daily life. Some jewelry, such as jewelry with seasonal themes, may be used for a few weeks, and pieces that are especially valued by the child or by their parents, may be worn only occasionally. However, some jewelry, such as inexpensive items, may be used frequently or until the item is no longer favored by the child or is lost. For this evaluation, staff assumes that a child will use a jewelry item frequently over weeks, months, or years.

Exposure to cadmium from metal jewelry items or similar objects could occur during handling or mouthing the product, or from swallowing a pendant, bead, or other small component part of jewelry.

An ingested product could result in an acute or short-term exposure, because ingested objects are usually eliminated from the body within a few days or possibly weeks. Therefore, data on the effects of acute or short-term cadmium exposure would be most relevant for an assessment of swallowed jewelry items.

As discussed above, acute exposure in humans and experimental animals causes a number of adverse effects. Because of the uncertainty regarding the circumstances and quantitative details of human exposure cases, staff has chosen to evaluate short-term exposures using the study in experimental animals by Borzelleca *et al.* (1989) to derive an ADI for acute exposure of 11 µg/kg/day.

To assess children's cadmium-containing jewelry, staff assumes that the vulnerable group of children is 2 to 6 years old, with an average weight of 18.2 kg (40 pounds) (Ogden *et al.* 2004). Given the 11 µg/kg/day acute ADI, **the maximum allowable acute exposure for a young child is about 200 µg/day**.

Handling or mouthing a product could result in a longer-term exposure because use of the product could occur over many weeks, months, or years. In contrast to acute exposure, long-term exposure to cadmium has been studied extensively and is well characterized. Given data from multiple studies, staff prefers to use studies in humans for characterization of human risks. Thus, because of the strength of the evidence in studies of human populations, staff has chosen to use epidemiological information (Suwazono *et al.* 2006) in the assessment of exposure to cadmium from children's jewelry. As discussed above, staff derived an acceptable daily intake level (ADI) for cadmium of 0.1 µg/kg/day for chronic exposure. Given the 18.2 kg body weight for children ages 2 to 6 years, and the 0.1 µg/kg/day ADI, **the maximum allowable chronic exposure for young children is about 1.8 µg/day**.

Ingestion of foreign bodies

As discussed in the staff's briefing package on lead-containing children's metal jewelry, several cases show that excessive exposure to lead resulted from children swallowing lead-containing metal jewelry items (CPSC 2006a).

Further, as documented in the briefing package, jewelry items are among the most commonly ingested items by young children (CPSC 2006b). Staff analyzed data from the National Electronic Injury Surveillance System (NEISS) database on emergency room-treated injuries associated with ingestion of consumer products by children. For 2000–2005, the staff estimated 302,587 emergency room-treated injuries, nearly 80 percent of which were children under age 7 years. The objects most commonly swallowed were coins (accounting for nearly half of ingestions); jewelry; toys not elsewhere classified; and nails, screws, tacks, or bolts.

Additional data on ingestion of objects are found in a 1998 study that evaluated 100 children ages 9 months to 13 years, who ingested various foreign bodies, including coins, ball bearings, pins, marbles, screws, buttons, a light bulb, a novelty nail file, and a clothespin (Macgregor and Ferguson, 1998). This study evaluated how long an ingested object might remain within the gastrointestinal tract. The total transit time for passage (from ingestion to elimination through

the rectum) of the items ranged from 1 to 46 days. The peak time of passage was 2 days, with a median time of 6 days. The authors noted that the mean transit time for an ingested object increased with age; it was greater than 15 days for 13 year olds, while it was typically 5 days for 4 through 10 year olds.

Thus, the available information shows that children may swallow items such as jewelry, and that ingested items can cause excessive exposure to chemicals from the swallowed items.

Assessment

Exposure to cadmium from children's metal jewelry could occur as children use and interact with a product. This exposure might occur from activities such as mouthing a product or handling the product with subsequent hand-to-mouth transfer of cadmium that might be removed from the surface of the product. This exposure could occur over the many days or months that a child uses a product such as metal jewelry. Exposure to cadmium also might occur if a child swallows a small item or a part of an item. In the case of ingestion of a product, the exposure would occur during the usually short time that the item remains in the gastrointestinal tract, notwithstanding the possibility that an ingested object sometimes is retained in the body for several weeks.

Staff evaluates possible exposures to cadmium or other chemicals from children's products by measuring leaching of the cadmium from the item using a saline solution to mimic the effects of mouthing, and a dilute hydrochloric acid solution to simulate the gastric effects on a swallowed item. The staff's standard laboratory procedure is to immerse an item in the saline solution for a period of six hours. Because of the data showing that ingested items sometimes remain in the stomach for several days, for products such as metal jewelry, staff conducts the dilute acid leaching test for 24 hours. Data generated by the staff indicates that 24 hours is generally sufficient time to identify products that could leach large amounts of chemicals.

Mouthed object

For the case of mouthing, staff assumes that each minute of extraction in the saline solution represents a minute of mouthing of the object by a child. A CPSC study of mouthing behaviors of young children estimated an average daily mouthing time of 37 minutes for all objects (excluding pacifiers) for children ages 24–36 months (CPSC 2001).

Using the saline extraction to simulate the effects of mouthing a jewelry item, with the assumption that mouthing a children's product for 37 minutes per day represents an excess exposure, and that the ADI for chronic exposure to cadmium is 1.8 micrograms per day for a young child, the ADI would be exceeded if the results of the saline extraction of the item exceeds 18 micrograms total cadmium extracted during the 6-hour saline extraction (Eq. 1).

$$(1.8\ \mu g/day)/(37\ min/day) \times (6\ hours \times 60\ min/hour) = 18\ \mu g \qquad (Eq.1)$$

where

1.8 µg/day is the chronic acceptable daily intake level (ADI) for children 2–6 years old,
37 min/day represents the daily mouthing time of jewelry, and
6 hours x 60 min/hour is the number of minutes each jewelry item is tested for leaching of cadmium into the saline solution in the laboratory evaluation.

Therefore, a test result for saline extraction of a mouthable product that exceeds 18 µg indicates that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance.

Swallowed object

Swallowing a cadmium-containing object is an acute exposure situation, for which the available toxicology database is limited. However, the need to evaluate products for the potential for acute exposure to cadmium prompted staff to choose data from acute studies in experimental animals to derive an acute exposure limit of 200 µg/day.

In contrast to repeated exposures to small amounts of a chemical over time, ingestion of an item results in the total exposure from the item occurring within a short time (*i.e.*, an acute exposure). The acute ADI would be exceeded if the result of the acid extraction of the item exceeds 200 micrograms total cadmium extracted during the 24-hour acid extraction.

Therefore, based on the available data on acute exposures, a test result for acid extraction of a swallowable product that exceeds 200 µg would indicate that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance.

Conclusion

Given the available information on cadmium toxicity and the assumptions about children's interactions with cadmium-containing products, staff has estimated limits for testing that may be used for evaluating children's jewelry under the FHSA. For a product that may be mouthed by a child, staff concludes that a result from the 6-hour saline extraction test that exceeds 18 µg would indicate that the product may meet the criteria established in the FHSA for a product to be considered a hazardous substance based on chronic toxicity. For a product or part of a product that may be swallowed by a child, the staff concludes that a result for the 24-hour acid extraction test that exceeds 200 µg would indicate that the product may be considered a hazardous substance based on acute toxicity.

In order for a substance to be considered a hazard under the FHSA, both exposure and the risk of adverse health effects associated with handling and use of the substance must be taken into account. Therefore, the characteristics of the product and a child's behaviors and interactions with the product must be considered along with the information on toxicity.

Discussion

This evaluation provides an approach to assessing cadmium-containing children's metal jewelry that takes into account both acute exposure (*e.g.* from swallowing) and longer term exposures (*e.g.* from repeated mouthing behaviors over time).

A key consideration in the toxicology of cadmium is that once absorption of cadmium occurs, it remains in the body, particularly in the kidneys and liver, for many years. Given the very long half-life of cadmium in the body, exposures that occur from swallowing an object or from mouthing an object over time could have significant impacts on the overall exposure to cadmium from all sources and contribute to the risk of adverse health effects from cadmium exposures.

The evaluation is based on a number of assumptions about children's behaviors, product characteristics, and relevant testing methods, and the existing knowledge base for cadmium toxicology. Because of the known hazards associated with human exposure to cadmium, staff has taken a conservative approach by using an estimated acceptable daily intake level (ADI) for

chronic exposure and assuming a relatively high level of mouthing activity. The acute exposure scenario was evaluated using data on adverse health effects from short-term exposure to cadmium in animals because that data is most relevant to the possible scenario in which a child swallows a cadmium-containing item.

The approach in this assessment to longer term exposure from mouthing items is conservative, largely because of the assumptions about the behaviors expected in very young children. Staff used data from an observation study for mouthing of all objects during a day, which would overestimate exposure that might occur from a particular product. Furthermore, the staff's assessment of mouthing behaviors that occur over time is based on an acceptable daily intake level that is not expected to cause adverse effects if the exposure occurred over many years.

While staff has taken a conservative approach, exposure to cadmium is associated with significant health effects, and any exposure from consumer products, such as jewelry, is in addition to exposures that most people experience from food, water, and other sources.

References

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TAB A: Staff Responses to Peer Review Comments

TAB A

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

Memorandum

Date: October 14, 2010

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences

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

SUBJECT : Staff Responses to Peer Review Comments on "Children's Cadmium–Containing Metal Jewelry" [1]

In June 2010, Consumer Product Safety Commission (CPSC) staff sought external scientific peer review of staff's draft document, "Children's Cadmium-Containing Metal Jewelry." Comments from the three reviewers were received by staff in July 2010. Staff revised the draft document based on the peer reviewers' comments and provides brief responses to the comments here. Similar comments or comments pertaining to specific topics are grouped and addressed together.

Comment

There were several specific observations related to sentence structure, wording, or clarity of the text, and a general comment that the document should contain more background on the purpose of the document and the regulatory approach.

Response: Staff revised the text accordingly to address both the specific and general comments about the document.

Comment

Among the three reviewers' comments were somewhat conflicting conclusions that the ADI approaches and data used are appropriate, or that there are deficiencies in the approach and discussion.

Response: The staff carefully considered each comment and revised the draft document to best address the comments and present an appropriate evaluation of the available data and information.

[1] The responses to the peer review comments are those of the CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Comment

A comment concluded that the review is incomplete, specifying that the form of cadmium and dose route in the toxicology studies should be included, as well as the form of cadmium expected from exposure to children's products. The review should include discussion of the renal cortex concentration threshold concept and database.

Response: The staff document was revised to include additional material and a greater level of detail to address the reviewers' concerns, although this document is not intended to be a standalone toxicity review. Staff's toxicity review of cadmium, a document produced separately from the reviewed evaluation, also addresses some of the reviewers' comments.

Comment

Consider the bone effects in the derivation of the ADI.

Response: While adverse effects on bone are important outcomes from exposure to cadmium, published analyses of epidemiological data show that for long-term exposure, effects in kidney are more sensitive endpoints. Thus, staff chose the study of effects in kidney for the dose-response analysis and derivation of the chronic duration ADI.

Comment

If long-term and intermediate-term LOAELs and NOAELs are similar, what does this mean for the minimum exposure period needed to produce a long-term effect?

Response: The available information indicates that the relationship between cadmium exposure and adverse health effects is complex, with considerable variability in responses, depending on dose, route of administration or exposure, and species or strain of animal or human population. Further, there are a variety of endpoints for cadmium toxicity, each with its own dose-response relationship. Many effects of cadmium are observed only at relatively high exposure levels, regardless of duration of exposure. Other effects have been seen following longer term exposures at lower levels, such as the adverse effects in kidney and bone that are the most significant and most sensitive endpoints for chronic exposures. The results of studies in experimental animals that show, in some cases, similar LOAELs and NOAELs in intermediate or longer term studies may be due to the specific endpoints considered in the studies, or the specific conditions of the studies, such as choice of species. However, the data do not provide for a clear conclusion to be made about the minimum exposure period needed to produce a long-term effect.

Comment

The application of the default uncertainty factor in the derivation of the chronic ADI could be reconsidered. Based on the large size of the populations included in the epidemiological studies, a factor of 3 would be appropriate. However, some remaining uncertainty, such as the possibility of effects of childhood exposure to cadmium, should be discussed.

Response: Staff agrees that the database for chronic exposure to cadmium is robust, and that uncertainty can be characterized using a factor of 3, rather than the default value of 10, to account for effects in sensitive subpopulations. Although children have not been specifically studied with respect to adverse effects from long-term exposure to cadmium, the epidemiological studies included populations with general environmental exposures to cadmium that likely occurred throughout their lives, including during childhood. Therefore, the results of those studies would, in part, reflect childhood exposure.

Comment

CPSC staff should model short-term exposure and derive ADI based on effects on cadmium concentration in the kidney.

Response: At this time, the staff does not believe that such an analysis, using available information, would significantly reduce the uncertainties related to data on short-term exposures. However, staff agrees that the approach to the short-term exposure data in the draft document is inadequate, and has revised the evaluation using information from published studies of acute exposure in experimental animals.

Comment

The approach to the swallowing scenario does not make sense and is not appropriate.

Response: Staff's approach to evaluating the acute exposure scenario was developed because of the lack of data specific to acute exposure to cadmium, particularly from foreign body ingestion, such as swallowing jewelry. Staff has reconsidered this approach and made appropriate changes to the report. Staff is now using published studies of acute exposure in experimental animals for the swallowing scenario assessment.

Comment

An acute exposure limit is needed. Reevaluate the available acute data or use an intermediate duration limit. Provide more details about the acute exposure data, including GI effects.

Response: Staff agrees that an acute exposure limit is needed. While staff still considers the available database on effects from acute exposures to be limited, this section of the report was revised to include information from published acute exposure studies in experimental animals.

Comment

How might the acute and chronic mechanisms of action differ?

Response: The toxicological effects of cadmium are many, and depend on dose, form, and route of exposure, whether the effect is observed in humans, and the species and strain of animal used in experimental studies. Systemic effects (multiple organs and tissues) are observed from both acute and chronic exposures. Acute exposures often involve higher exposure levels, which may result in effects that are not observed with lower dose, longer term exposures (*e.g.*, effects directly on gastrointestinal tissue that are related to high doses). Some actions of cadmium would be expected to occur regardless of the duration of exposure; some effects involving certain biological systems or processes may occur only after longer term exposures because repeated exposures over time are required to perturb the systems. Thus, acute and chronic toxicity may share certain mechanisms, depending on dose and other factors of exposure, while some mechanisms are relevant only with longer-duration exposure.

Comment

A commenter suggested that staff consider recent data that show increased urinary excretion of cadmium in children ages 6 through 11 years, as well as for females, which could indicate important differences in exposure and uptake of cadmium in these populations.

Response: Staff added discussion to the report, but because staff's analysis is based on a study in women who likely also had been exposed in childhood, the conclusions have not changed.

Although uncertainty remains on the implications of possible differences among various groups of people, the relatively large body of literature concerning long-term exposure and effects of cadmium supports the approach taken by staff.

Comment

It appears that the CPSC is deriving a different (higher) ADI than the ATSDR chronic MRL or USEPA RfD.

Response: As described in the draft document, CPSC staff derived an oral, chronic ADI that is lower than either the existing or draft MRL derived by the ATSDR, or the existing RfD derived by the EPA. The difference between the CPSC staff's draft ADI and the EPA's RfD stems from using different epidemiological studies as the basis for the analysis. Similar data were used to estimate the ADI in CPSC staff's draft analysis and the ATSDR's draft, but CPSC staff applied an uncertainty factor of 10 to account for sensitive members of the population, while the ATSDR used a factor of 3. ADI estimates are divided by uncertainty factors, so that using a factor of 10 results in a lower estimated ADI. Based on the peer review comments and additional consideration of this issue, the revised CPSC staff analysis includes an uncertainty factor of 3 rather than the default value of 10 (to account for effects in sensitive subpopulations) because of the strength of the numerous epidemiological studies. Therefore, staff's revised ADI is the same as the ATSDR's draft chronic MRL.

Comment

Are there data specifically on ingestion of jewelry regarding GI transit time?

Response: The CPSC databases allow estimates of the number of cases involving ingestion of jewelry, but few cases, if any, provide details about the incidents, such as GI transit time. The scientific literature discusses cases of foreign body ingestions, but jewelry ingestions have not been considered specifically, and the cases that have been reported are not well-described.

Comment

The dose associated with emesis should not be normalized to body weight; volume of stomach contents would be a more appropriate measure for extrapolation to different ages.

Response: The staff agrees with this comment, and revised the description of the data accordingly.

Comment

For the mouthing scenario, an intermediate duration exposure limit would be more appropriate.

Response: The staff used data from studies in humans to derive the exposure limit for longer term exposures. An intermediate duration study, conducted in animals, was not chosen for use in the assessment because data in humans, when available, is preferable to animal studies. In addition, in this case, the numerous, well-conducted studies in humans, lead to a higher level of confidence in the results than would occur using the study in animals.

TAB B: Toxicity Review of Cadmium

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: October 14, 2010

TO : Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences

THROUGH: Lori E. Saltzman, M.S., Director, Division of Health Sciences

FROM : Dominique J. Williams, Toxicologist, Division of Health Sciences
Kristina M. Hatlelid, Ph.D., M.P.H., Toxicologist, Directorate for Health Sciences

SUBJECT : Toxicity Review of Cadmium[1]

This memorandum provides the U.S. Consumer Product Safety Commission's (CPSC) Health Sciences staff assessment of the potential toxicity associated with cadmium and cadmium-containing compounds.

CPSC staff assesses a product's potential health effects to consumers under the Federal Hazardous Substances Act (FHSA). The FHSA is risk-based. To be considered a "hazardous substance" under the FHSA, a consumer product must satisfy a two-part definition. 15 U.S.C. §1262 (f)(1)(A). First, it must be toxic under the FHSA, or present one of the other hazards enumerated in the statute. Second, it must have the potential to cause "substantial illness or injury during or as a result of reasonably foreseeable handling or use." Therefore, exposure and risk must be considered in addition to toxicity when assessing potential hazards under the FHSA (CPSC, 1992; summarized at 16 C.F.R. §1500.135).

The FHSA addresses both acute and chronic hazards. While the FHSA does not require manufacturers to perform any specific battery of toxicological tests to assess the potential risk of chronic health hazards, the manufacturer is required to label a product appropriately according to the requirements of the FHSA. The first step in the risk assessment process is hazard identification, that is, a review of the available toxicity data for the chemical under consideration and a determination of whether the chemical is considered "toxic" under the FHSA. Chronic toxicity data (including carcinogenicity, neurotoxicity, and reproductive and developmental toxicity) are assessed by CPSC staff using guidelines issued by the Commission (CPSC, 1992). If it is concluded that a substance is toxic under the FHSA due to chronic toxicity, then a quantitative assessment of exposure and risk is performed to evaluate whether the chemical may be considered a "hazardous substance" under the FHSA.

[1] These comments are those of the CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

This memo represents the first parts of the risk assessment process, that is, the hazard identification and dose-response steps.

Staff's conclusion is that the data concerning the toxicity of cadmium, discussed below, are sufficient for cadmium to be considered toxic under the FHSA due to effects on multiple organ systems and toxic endpoints, including kidney dysfunction.

Staff has developed an acceptable daily intake level (ADI) for chronic exposure to cadmium by the oral route of 0.1 micrograms cadmium per kilogram body weight per day (0.1 μg/kg/day) based on studies in human populations. This is the level of chronic exposure that should not be exceeded in order to avoid health effects.

Introduction

Cadmium is a metal found in the earth's crust, and is known to be associated with zinc, lead, and copper ores. Pure cadmium is a soft, silvery-white metal that is insoluble in water; soluble forms include cadmium chloride and cadmium sulfate. Most cadmium used in the United States comes from the processing of other metals, such as lead, as well as recycling of nickel-cadmium batteries. According to Agency for Toxic Substances and disease Registry's Draft Toxicological Profile for Cadmium (ATSDR, 2008), approximately 83 percent of cadmium is used in batteries.

For nonsmokers, the primary source of cadmium is food. Those regularly consuming shellfish and organ meat have higher exposures. Leafy vegetables also contain high levels of cadmium. Tobacco leaves accumulate cadmium from the soil, leading to increased cadmium exposure among smokers (ATSDR, 2008).

Blood cadmium concentrations reflect recent and cumulative exposures; urinary cadmium levels reflect both cadmium exposure and the concentration of cadmium in the kidneys. As part of its National Health and Nutrition Examination Survey (NHANES), the Centers for Disease Control and Prevention (CDC) measured cadmium in the blood and urine of a representative sample of the U.S. population. From the 2003–2004 survey (CDC, 2009), the geometric mean blood and urine cadmium levels for the group 20 years of age and older was 0.378 micrograms per liter (μg/L) in blood and 0.260 μg/L in urine. Females (0.326 μg/L, blood; 0.216 μg/L, urine) had slightly higher levels than males (0.283 μg/L, blood; 0.206 μg/L, urine).

Several agencies have established recommendations or regulations for cadmium. The U.S. Environmental Protection Agency (EPA) developed an oral reference dose (RfD[2]) of 1 μg/kg/day for food intake and 0.5 μg/kg/day for cadmium in drinking water (different levels of absorption of cadmium from food or from water account for the different RfD values) (EPA, 1994) and has established limits for cadmium concentration in drinking water of 0.04 mg/L for exposures up to 10 days, or 0.005 mg/L for lifetime exposures (EPA, 2003). The U.S. Food and Drug Administration (FDA) established the limit for cadmium in bottled water at 0.005 mg/L (FDA, 2009). For exposure through inhalation in the workplace, the Occupational Safety and Health Administration (OSHA) established a limit of 5 micrograms per cubic meter of air (5 $\mu g/m^3$) for an 8-hour workday (OSHA, 2009).

[2] The EPA's RfD is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The ATSDR's 2008 draft toxicological profile includes a minimal risk level (MRL[3]) for chronic[4] oral exposure of 0.1 µg/kg/day, based on kidney effects in humans (ATSDR, 2008). The draft toxicological profile also includes an MRL for intermediate length exposure of 0.5 µg/kg/day based on effects on bone in experimental animals. Due to inadequacies in the acute oral exposure database, ATSDR has not derived an acute duration MRL.

Toxicokinetics

Cadmium is not well absorbed into the body, especially after ingestion or through the skin. After absorption, cadmium is widely distributed throughout the body, but is predominantly found in the liver and kidney. Excretion is very slow, with approximately 0.007 and 0.009 percent of the body burden being excreted in the urine and feces, respectively, per day (ATSDR, 2008).

Absorption

Based on a number of studies, the ATSDR (2008) reported that absorption from oral exposure likely ranges between 1 and 10 percent. While exposures through inhalation are important in the workplace, inhalation exposures are less likely from consumer products than exposures through ingestion of cadmium-containing substances and products.

All of the studies reviewed suggest that the absorption of cadmium via the dermal route is slow. Less than 1 percent of the administered dose is absorbed through the skin during dermal exposures. Dermal absorption generally would be a concern when solutions come into contact with the skin for several hours or more, such as in an occupational setting (ATSDR, 2008).

Distribution

Cadmium can be detected in all tissues, with the largest concentrations in the liver and the kidneys. Kjellström (1979) presented data from an international investigation of cadmium exposure. In this study, analysis of tissues from hundreds of people in Japan, Sweden, and the United States showed geometric mean concentrations in the kidneys and liver increased from less than 1 microgram per gram tissue weight (1 µg/g) in early childhood to a peak of 40–50 µg/g in the kidney, and 3–4 µg/g in the liver that occurs at around 50 to 60 years of age. After about age 60, tissue cadmium concentrations decrease over time.

Metabolism

After absorption, cadmium does not undergo direct metabolic conversion such as oxidation, reduction, or alkylation. However, the cadmium ion binds to proteins and other molecules, especially the proteins albumin and metallothionein (Nordberg, 1984). Cadmium in the blood is found primarily in protein complexes.

Elimination

Kjellström and Nordberg (1978, 1985) studied the available data and developed a human toxicokinetic model for cadmium to describe cadmium absorption, distribution, and excretion. Based on the available data, cadmium excreted from the body in feces is largely unabsorbed material from the gastrointestinal tract. Most of the cadmium that is absorbed into the body is

[3] The ATSDR's MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.

[4] As defined in the ATSDR toxicological profiles, chronic exposure is exposure to a chemical for 365 days or more; intermediate exposure is 15 through 364 days; acute exposure is through 14 days.

excreted slowly, with urinary and fecal excretion being approximately equal. Urinary excretion is dependent on blood and kidney concentrations, and the total excretion is assumed to be equal to the daily intake of cadmium at steady state.

From the model, these authors estimated that daily excretion in feces and urine is approximately 0.007 and 0.009 percent of body burden, respectively. The model also predicts that the half-life for cadmium in human tissue is in the range of 6 to 38 years in the kidney and 4 to 19 years in the liver.

Acute Toxicity

Investigation of suicide involving cadmium ingestion found that death occurred due to massive fluid loss, edema, and widespread organ destruction. Buckler *et al.* (1986) described a case of an estimated exposure of 1,840 mg/kg cadmium chloride that resulted in death within 33 hours. Wisniewska-Knypl *et al.* (1971) reported death within 7 days of ingestion of 25 mg/kg cadmium iodide.

In a less severe case of acute toxicity, Nordberg *et al.* (1973) reported gastrointestinal effects in children who ingested 16 mg/L cadmium from soft drinks. This case involved gastrointestinal symptoms in boys 13 to15 years old following ingestion of a beverage containing 16 milligrams cadmium per liter of beverage (16 mg/L). Based on information collected from the boys about five months after the incident, symptoms began within 15 minutes of consumption of the drink, and included headache, nausea, vomiting, abdominal pain, and diarrhea. All symptoms resolved within seven hours, and most of the boys returned to school when classes resumed three days later. The children reported consuming 0.5 to 2.5 glasses of the drink, with an average of about one glass. Although the volume of beverage consumed was not reported, information in the publication's discussion suggests that the investigators considered a glass to be about 0.15 L.

Studies in experimental animals show that the oral LD_{50}[5] ranges from approximately 100 to 300 mg/kg in rats and mice (Baer and Benson, 1987; Kostial *et al.*, 1978; Kostial *et al.*, 1979). The lowest dose of cadmium found to cause death (2 of 20 animals) was 15.3 mg/kg administered as cadmium chloride in water in a single dose by gavage in Sprague-Dawley rats (Borzelleca *et al.*, 1989). Other adverse effects from acute oral exposure include: reduced body weight or reduced body weight gain (cadmium doses greater than about 2 mg/kg/day); hemorrhages, ulcers, and reddening of the stomach and intestinal tract (61 mg/kg/day); testicular atrophy (66 mg/kg/day); and necrotic changes in the kidney (15.3 mg/kg/day) and liver (138 mg/kg/day) (Baranski, 1985; Borzelleca *et al.*, 1989; Machemer and Lorke, 1981).

Systemic Toxicity

Ingestion of cadmium is associated with numerous effects, primarily in the kidney and bone. The main effects and key studies are summarized below.

Kidney

The adverse effects of cadmium in the kidney are related to the concentration of cadmium within the kidney, particularly within the kidney cortex. Studies have been conducted using kidney cortex cadmium concentration as the measure of exposure. Because the concentration of cadmium in the kidney is associated with the concentration of cadmium in the urine, the latter

[5] LD_{50}, or lethal dose-50, is the dose that produces death in half of the group of test animals under specified conditions and test duration.

metric has been used in studies of living humans, in which kidney levels of cadmium cannot be directly measured.

Tubular dysfunction is considered one of the first signs of kidney damage, characterized by an increase in urinary, low-molecular-weight protein excretion, such as β2-microglobulin (β2M), human complex-forming glycoprotein (pHC) (also known as α1-microglobulin(α1M)), and retinol binding protein; or increased levels of intracellular enzymes, such as N-acetyl-β-glucosaminidase (NAG) in the urine (European Chemicals Bureau, 2007; Järup *et al.*, 1998).

Exposure at higher levels is associated with excretion of high-molecular-weight proteins, such as albumin, as demonstrated in studies of workers with exposure by inhalation (Bernard *et al.*, 1979, 1990; Chen *et al.*, 2006a, 2006b; Elinder *et al.*, 1985; Roels *et al.*, 1989, 1993; Thun *et al.*, 1989).

In workers exposed to high levels of cadmium, ending exposure does not usually lead to the reversal of the damage affecting the kidney. The increases in urinary levels of β2M, retinol binding protein, or total protein, or the decreases in glomerular filtration rate (GFR) have been seen years after the cadmium exposure in workers ended (Elinder *et al.*, 1985; Järup *et al.*, 1993; Mason *et al.*, 1999; Piscator, 1984; Roels *et al.*, 1989; Thun *et al.*, 1989). For workers with low exposure levels of cadmium, decreases or no change in urinary β2M levels were seen after exposure ended (McDiarmid *et al.*, 1997; van Sittert *et al.*, 1993). Roels *et al.* (1997) and Trzcinka-Ochocka *et al.* (2002) found that reversibility of cadmium-induced tubular dysfunction was dependent on the cadmium body burden and the severity of microproteinuria at the time cadmium exposure was reduced or stopped.

A number of large epidemiological studies have examined the effects of cadmium exposure on the kidney. A few such studies are summarized here.

Järup *et al.* (2000) examined 1,021 individuals living near a nickel-cadmium battery plant in Sweden for at least five years (n=799) or employed as battery workers (n=222). The mean urinary cadmium levels were 0.81 and 0.65 μg/g creatinine[6] in males and females, respectively. Urinary cadmium levels were significantly associated with urinary pHC levels, after adjustment for age, in the whole study population, or with the workers removed from the analysis. The prevalence of abnormal pHC values (defined as exceeding the 95th percentile in a Swedish reference population) was estimated to increase by 10 percent at urinary cadmium levels of 1 μg/g creatinine.

The European Chemicals Bureau (2007) recalculated the probability of pHC proteinuria (using the raw data from Järup *et al.*, 2000) to account for the differences in age of the reference population (mean of 40 years) and study population (mean of 53 years). Based on these recalculations, the urinary cadmium level associated with a 10 percent increased probability of abnormal pHC values (20 percent total probability) was 2.62 μg/g creatinine for the total population. In the nonworker subgroup, a urinary cadmium level of 0.5 μg/g creatinine was associated with a 13 percent probability (representing a doubling of the probability for the reference population) of abnormal pHC values.

[6] Measurement of creatinine levels in the urine or blood is used to evaluate kidney function. Urinary protein measurements are often normalized to creatinine to account for the variations in excretion of urine and allow comparison of urinary measurements over time, between subjects, or from different studies.

Noonan *et al.* (2002) examined 361 residents in Pennsylvania living near an old zinc smelting facility (geometric mean urinary cadmium level of 0.14 μg/g creatinine) and a reference community (without an identified exposure source) located 10 miles from the facility (geometric mean urinary cadmium levels of 0.12 μg/g creatinine). The data from the two communities were pooled because there were no differences in urinary cadmium levels between them. β2M, NAG, alanine aminopeptidase (AAP), and albumin (ALB) levels were measured as biomarkers of renal dysfunction. The geometric mean urinary cadmium levels were 0.07 and 0.08 μg/g creatinine in 88 males and 71 females ages 6 to17 years old, and 0.24 and 0.23 μg/g creatinine in 71 males and 80 females aged ≥18 years. No significant correlations between urinary cadmium levels and renal biomarkers were observed in the children, after adjustment for creatinine, age, and gender. In adults, significant correlations (after adjustment for creatinine, age, gender, smoking, and self-reported diabetes or thyroid disease) between urinary cadmium and NAG (partial correlation coefficient of 0.20, 95% CI of 0.05–0.36) and AAP (partial correlation coefficient of 0.21 and 95% CI of 0.05–0.36) were observed. Significant dose-effect relationships also were found for these two biomarkers. Urinary cadmium levels were not significantly associated with elevated levels of β2M or ALB.

Jin *et al.* (2002) examined three populations living various distances from a nonferrous metal smelter. The geometric mean levels of urinary cadmium were 11.18 and 12.86 μg/g creatinine in males (n=294) and females (n=171) in the highly polluted area, 3.55 and 4.45 μg/g creatinine in males (n=243) and females (n=162) in the moderately polluted area, and 1.83 and 1.79 μg/g creatinine in males (n=253) and females (n=155) in the control area. Significant correlations were found between urinary (and blood) cadmium levels and renal biomarkers (β2M, retinol binding protein, and ALB).

Dose-Response Relationships for Effects in Kidney

Several dose-response analyses have been done using a number of studies, including those summarized above, investigating the relationship between adverse effects in the kidney and urinary cadmium levels as a biomarker of cadmium concentration in the kidney.

Investigators analyzed data involving hundreds of people from studies in Europe (Järup *et al.*, 2000; Suwazono *et al.*, 2006), Japan (Kobayashi *et al.*, 2006; Shimizu *et al.*, 2006; Uno *et al.*,, 2005), and China (Jin *et al.*, 2004). The study populations lived in cadmium-polluted areas or had no particular source of cadmium exposure. Several studies used benchmark dose[7] approaches to estimate critical exposure levels. Most of these studies considered urinary excretion of pHC, NAG, β2M, retinol binding protein, ALB, or other proteins, and markers for changes in GFR as biomarkers of kidney injury. The analyses differed in choice of study population and also in the choice of model and parameters resulting in estimates of critical urinary cadmium concentrations (*i.e.*, the cadmium concentration associated with a specified level of risk for kidney dysfunction) ranging from about 0.3 to 15 micrograms cadmium excreted in urine per gram creatinine in urine (μg/g creat). These studies are summarized below.

In a population of workers and environmentally exposed people in Europe, Järup *et al.* (2000) found a 10 percent excess in urinary pHC at a cadmium concentration 1.0 μg/g creat.

Jin *et al.* (2004) examined a population living in a cadmium-contaminated area of China. Using a benchmark dose approach and cutoff value for defining abnormality for excretion of β2M of

[7] A benchmark dose approach uses mathematical modeling to characterize exposure-response relationships.

0.8 mg/g creat., these researchers estimated a critical cadmium concentration of about 4 to 15 μg/g creat. for a 5 percent excess risk.

In an analysis of data collected in a region of Japan without a source of cadmium pollution, Kobayashi *et al.* (2006) estimated a critical cadmium concentration for a 5 percent excess risk of about 2-4 μg/g creat.

Shimizu *et al.* (2006) analyzed people living in a cadmium-contaminated area of Japan. Using a benchmark dose approach and cutoff value for defining abnormality for excretion of β2M of 1 mg/g creat., these researchers estimated a critical concentration between 1 μg/g creat. and 4 μg/g creat.

Suwazono *et al.* (2006) used data from a study of Swedish women who had no particular environmental or occupational exposure to cadmium. Using a benchmark dose approach, and a cutoff based on the 95th percentile for urinary protein excretion estimated for a person with no cadmium exposure, the critical concentration was estimated at 0.6-1 μg cadmium/g creat. for a 5 percent excess risk based on excretion of NAG and pHC.

Another study in Japanese populations not exposed to a known source of cadmium resulted in an estimated critical concentration of 0.3-3 μg cadmium/g creat. (Uno *et al., 2*005).

Another analysis of several studies conducted mostly in Japanese populations was conducted by Gamo *et al.* (2006), with a focus on studying the effects of age and sex. Urinary cadmium was used as a biomarker of exposure and the prevalence of abnormal levels of β2M as an indicator of kidney dysfunction. The authors concluded that a significant increase in the prevalence of abnormal β2M levels would not result if the geometric mean urinary cadmium level in a nationwide population does not exceed 2 μg/g creat.

Diamond *et al.* (2003) considered data from 15 different epidemiological studies. These authors developed a pharmacokinetic/pharmacodynamic (PK/PD) model to determine the relationship of low molecular weight (LMW) proteinuria with cadmium exposure. The authors estimated tissue cadmium concentrations, rather than using cadmium excretion in the urine as a marker of dose, and estimated intake levels corresponding to the specified probabilities of observing LMW proteinuria in a model of a 55-year-old person. The analysis resulted in an estimate for 10 percent risk for LMW proteinuria with a median kidney cortex concentration of 153 μg cadmium per gram tissue, corresponding to a cadmium intake of 2 μg/kg/day in females and 4.3 μg/kg/day in males.

Liver

While liver tends to accumulate cadmium, it does not appear to be as sensitive to cadmium effects as the kidney.

The two cases involving death in humans discussed above (Buckler *et al.*, 1986; Wisniewska-Knypl *et al.*, 1971) included liver injury; but studies of lower doses in human have not shown significant liver-specific effects (Ikeda *et al.*, 1997, 2000).

In experimental animals, exposure in rats for 10 days to drinking water containing 13.9 mg/kg/day was not associated with liver effects, while a dose of 138 mg/kg/day caused severe effects, including necrosis of hepatocytes (Borzelleca *et al.*, 1989). Longer term studies have shown liver effects at lower doses. A 10-week study in male Rhesus monkeys at a dose of 4 mg/kg/day by gavage found decreased glutathione peroxidase and glutathione *S*-transferase

(GST) activity in the liver and other tissues (Sidhu *et al.*, 1993). A number of other studies have noted histopathologic changes in the liver and changes in liver-associated enzymes in other laboratory animals at doses as low as about 2 mg/kg/day (Groten *et al.*, 1990; Müller and Stacey, 1988; Schroeder *et al.*, 1965; Steibert *et al.*, 1984; Stowe *et al.*, 1972). Other studies with similar doses did not observe liver effects (Loeser and Lorke, 1977a; Kotsonis and Klaassen, 1978).

Musculoskeletal Toxicity

Cadmium effects on the bone in humans are evident in a cadmium-contaminated area in Japan, where some residents suffer from a disease known as *Itai-Itai* or "ouch-ouch" disease involving osteoporosis and osteomalacia.

In a study of a population of Swedish men and women living in an area with past sources of cadmium pollution, significant decreases in bone mineral density were observed in the group more than 60 years of age with the highest blood cadmium levels compared to lowest exposed group (Alfvén *et al.*, 2002). Åkesson *et al.* (2006), in a study of Swedish women without a particular exposure to cadmium, reported a significant negative relationship between urinary cadmium levels and bone mineral density. The median urinary cadmium concentration was 0.67 μg/g creat. in this population. These two study populations also were used to examine the relationship between cadmium exposure and kidney toxicity (see above).

A study in a group of Flemish women (Schutte *et al.*, 2008) showed effects on several measures of bone health in the absence of evidence of kidney dysfunction in most of the subjects.

In an analysis of women in the United States, Gallagher *et al.* (2008) used data from the Third U.S. National Health and Nutrition Examination Survey (NHANES) 1988–-1994, as well as NHANES 1999–-2004, to evaluate the association of urinary cadmium levels and osteoporosis. These researchers reported that women who were at least 50 years of age with urinary cadmium levels between 0.50 and 1.00 μg/g creat., were at 43 percent greater risk for osteoporosis, relative to those with levels less than or equal to 0.50 μg/g creat. Because smokers did not show a statistically increased risk, the authors concluded that dietary sources of cadmium, rather than cigarette smoke, are related to the osteoporosis risk. These authors also concluded that perhaps 21 percent of osteoporosis prevalence among women at least 50 years of age may be attributed to cadmium.

Recently, Suwazono *et al.* (2010), following their analysis of kidney effects in a population of Swedish women, looked at cadmium-induced bone effects. Using the benchmark dose approach, these researchers estimated the critical cadmium concentration of 1.8-3.7 μg/g creat. for a 5 percent excess risk of low bone mineral density. The lower confidence limit of the critical cadmium concentration (BMDL) is 1.0-2.1 μg/g creat.

Brzóska and colleagues published a series of studies demonstrating effects of cadmium on bone in experimental animals (Brzóska and Moniuszko-Jakoniuk, 2004a, 2004b, 2005a, 2005b, 2005c, 2005d; Brzóska *et al.*, 2004, 2005a, 2005b, 2005c). Osteopenia and osteoporosis were noted in male rats exposed for 12 months to cadmium at 0.5 mg/kg/day and 4 mg/kg/day, respectively. In female rates, osteopenia was reported after exposure at 0.08 mg/kg/day for 12 or 18 months, and osteoporosis was observed with exposed at 0.08 mg/kg/day for 24 months. Altered mechanical properties of bone also were observed by these researchers and others (Ogoshi *et al.*, 1989). A number of studies reported decreased bone calcium and increased urinary excretion of calcium in intermediate- and chronic-duration studies with doses of 0.2–8 mg/kg/day (Brzóska and

Moniuszko-Jakoniuk, 2005d; Kawamura *et al.*, 1978; Nogawa *et al.*, 1981; Pleasants *et al.*, 1992; Watanabe *et al.*, 1986).

Reproductive Toxicity

Several studies investigated the relationships between cadmium in blood, serum, or semen and hormone levels (testosterone, follicle stimulating hormone, luteinizing hormone, prolactin, estradiol) and measures of fertility. In a study of Eastern European men, Jurasović *et al.* (2004) reported a number of significant associations between reproductive health endpoints and cadmium blood concentrations, after adjusting for smoking status. Akinloye *et al.* (2006) also reported significant relationships between physical measures of decreased fertility and blood serum cadmium measurements. Seminal plasma cadmium concentration was not associated with the fertility outcomes. For hormone measurements, only seminal plasma cadmium concentration had a significant effect, and only for follicle stimulating hormone levels. In a study of men in the United States, using data from the third National Health and Nutrition Examination Survey (NHANES III), Menke *et al.* (2008) reported no association between urinary cadmium levels and serum testosterone and estradiol levels, after adjusting for smoking status.

No studies were found on reproductive effects in women after oral exposure to cadmium.

Several studies in experimental animals considered reproductive effects of cadmium exposure. Borzelleca *et al.* (1989) noted testicular atrophy in rats after exposure to 66 mg/kg/day by gavage for 10 days. A single dose of up to 25 mg/kg in rats had no effect (Dixon et al., 1976). Longer term studies (up to 17 weeks) in rats showed testicular effects with doses of about 5–12 mg/kg/day (Pleasants *et al.*, 1992; Pleasants *et al.*, 1993; Saxena *et al.*, 1989).

In studies of female animals, no effects on reproductive organs were noted in rats after exposure up to 138 mg/kg/day by gavage for 10 days (Borzelleca *et al.*, 1989). Baranski and Sitarek (1987) observed a significant increase in the duration of the estrous cycle in rats administered 40 mg/kg by gavage 5 days/week for 14 weeks.

A two-generation study involving male and female rats exposed to 2.5 mg/kg/day in drinking water for 180 days showed decreased litter size and increased interval between litters, and failure to breed in three of five second-generation pairs (Schroeder and Mitchener, 1971).

Developmental Toxicity

Several studies have considered the possible effects of cadmium exposure on pregnancy and offspring in humans. Salpietro *et al.* (2002) reported a significant association between cord blood cadmium levels and decreased newborn birth weight in a small study of women with relatively low cadmium exposures. Nishijo *et al.* (2002) reported decreased birth weight, probably secondary to early delivery, associated with maternal urinary cadmium levels. Zhang *et al.* (2004) reported an association between cord blood cadmium level and infant height, but not weight, or other pregnancy outcomes. These and other similar studies involved small numbers of participants, and did not control for confounding factors that might also be related to pregnancy outcomes, resulting in limited evidence of a causal relationship between cadmium exposure and pregnancy outcomes.

Numerous studies in experimental animals provide clearer evidence for developmental toxicity. Several studies reported reduced fetal or pup weight and increased incidence of skeletal malformations, missing internal organs or tissue, failure of testes to descend, and cleft palate in

offspring of mothers exposed to cadmium at doses of about 1–20 mg/kg/day (Ali *et al.*, 1986; Baranski, 1985; Baranski, 1987; Machemer and Lorke, 1981; Schroeder and Mitchener, 1971).

In multigenerational studies of rats, Nagymajtenyi and colleagues reported that cadmium administration of 7–14 mg/kg by gavage during pregnancy, lactation, and after weaning resulted in significant behavioral and electrophysiological effects in the offspring (Nagymajtenyi *et al.*, 1997; Desi *et al.*, 1998).

In a study in rats, Saxena *et al.* (1986) reported no developmental effects from exposure to either cadmium acetate (21 mg/kg/day as cadmium in drinking water) or lindane (20 mg lindane/kg by gavage), when administered alone during gestation. Coexposure to cadmium and lindane resulted in maternal toxicity and developmental toxicity. Effects in the dams included decreased weight gain; developmental effects included decreased fetal body weight, increased intrauterine death, and skeletal anomalies.

Neurologic Toxicity

A few studies have evaluated neurological effects from cadmium exposure. Based on analysis of metal content of hair, Thatcher *et al.* (1982) and Marlowe *et al.* (1985) reported associations between cadmium exposure and measures of intelligence or behavior. Because of shortcomings, including lack of control for confounding factors, such as exposure to lead, and inadequate assessment of cadmium exposure, the significance of these studies is unclear.

In studies in experimental animals, in both short-term and long-term studies with doses ranging from about 1 to 50 mg/kg/day, a number of neurologic endpoints, including decreased motor activity, weakness and muscle atrophy, increased aggressive behavior, increased passive avoidance behavior, and other changes in certain cells and enzyme levels have been observed (Baranski and Sitarek, 1987; Kotsonis and Klaassen, 1977; Kotsonis and Klaassen, 1978; Murthy *et al.*, 1989; Nation *et al.*, 1984; Nation *et al.*, 1990; Sato *et al.*, 1978; Valois and Webster, 1989).

Carcinogenicity

The carcinogenicity of cadmium and cadmium compounds has been evaluated largely in populations exposed through inhalation in workplace settings. Although deficiencies exist in the available information, the evidence supports the relationship between inhalation of cadmium and cancer (see ATSDR, 2008 for review of inhalation exposure studies). Cadmium and cadmium compounds are listed as "known to be human carcinogens" in the Report on Carcinogens, largely based on studies in workers (NTP, 2005).

A few investigations also have considered the relationship between cancer and oral exposure to cadmium in humans. Studies of populations in areas with known cadmium sources have not found significant associations with cancer (Bako *et al.*, 1982; Hardell *et al.*, 1994; Inskip *et al.*, 1982; Lauwerys and De Wals, 1981; Nakagawa *et al.*, 1987; Shigematsu, 1984). Some of these studies had methodological shortcomings or lacked statistical power to show effects, if such effects exist.

Studies in experimental animals and in vitro studies show that cadmium may have effects that could be associated with cancer. Kurokawa *et al.* (1989), in a study investigating whether certain metal compounds act as promoters of tumors initiated by other chemicals, reported that cadmium exposure at 61 ppm in drinking water did not affect the incidence of renal cell tumors, but was

associated with increased numbers of dysplastic foci in the kidney. These authors also reported that cadmium chloride did not act to increase tumors in the liver, stomach, pancreas, or skin.

In a study investigating cadmium carcinogenesis and dietary zinc deficiency in rats, Waalkes and Rehm (1992) reported a number of effects of exposure to cadmium in the diet at 0, 25, 50, 100, or 200 ppm for 77 weeks. The incidence of prostate tumors was slightly increased compared to controls at 50 ppm, but not the other dose groups. An increase in testicular tumors was noted only in the highest dose group that also received adequate levels of zinc, but not in groups that were fed the zinc-deficient diet. Leukemia incidence also was increased in the cadmium-exposed groups. The authors conclude that cadmium is associated with the incidence of tumors in exposed animals, and that dietary zinc deficiency has a complex, inhibitory relationship in cadmium carcinogenesis.

Although cadmium exposure carcinogenesis is not clearly shown in the human and animal studies, recent work *in vitro* provides evidence that cadmium exposure could be related to cancer. Benbrahim-Tallaa *et al.* (2009) showed that cadmium transformed normal human breast cells into cells that displayed characteristics of basal-like breast carcinoma. These cells, when injected into mice, produced invasive, metastatic cancer.

In a study of effects of cadmium on kidney cells, Chakraborty *et al.* (2010) reported that cadmium exposure caused changes in the cells related to proliferation and survival of preneoplastic cells, possibly providing a mechanism for cadmium-induced carcinogenicity.

Discussion

Cadmium is poorly absorbed in the body following exposure by inhalation (about 25 percent) or ingestion (about 1–10 percent). Cadmium that is absorbed can be found largely in the liver and kidney. Cadmium is excreted slowly; estimated half-lives of cadmium in tissues are 6–-38 years for the human kidney and 4–19 years for the human liver.

Cadmium has effects on numerous organ systems and cells within the body, principally the kidney and bone. Although cadmium exposure through inhalation in workers is associated with lung cancer, there is insufficient evidence in humans or experimental animals to determine whether cadmium is carcinogenic from oral exposure. CPSC staff concludes that the data are sufficient for cadmium to be considered toxic under the FHSA.

Based on a review of the data, the effects in the kidney can be considered the most sensitive endpoint. Cadmium exposure is associated with increased excretion of biomarkers for kidney dysfunction, including urinary N-acetyl-β-D-glucosaminidase (NAG), human complex-forming protein (pHC), β_2-microglobulin (β2M), and total protein, and decreased glomerular filtration rates (GFR).

CPSC staff identified the analysis of Suwazono *et al.* (2006) as the key study for an exposure-response analysis because this analysis was based on a large, well-characterized population of women who had no particular environmental or occupational exposure to cadmium; the study population excluded individuals such as those with diabetes, kidney cancer, or those who used certain medications; the analysis controlled for other potential confounders; and the estimated critical effect level was among the lowest estimated from the many published analyses.

Suwazono *et al.* (2006) used a benchmark dose approach to analyze the data from the study of 820 Swedish women. The analysis estimated the concentration of cadmium in urine associated with urinary protein markers (NAG and pHC) for adverse effects in the kidney. These

researchers reported a benchmark dose (BMD) for a 5 percent excess risk for each of the proteins excreted in the urine of 0.6 micrograms cadmium per gram creatinine in the urine (0.6 µg/g creat.). The lower confidence limit of the cadmium concentration BMD (*i.e.*, BMDL) was 0.5 µg/g creat. Similar results were reported by Uno *et al*. (2005) and Järup *et al*. (2000).

Because the BMDL is a measure of cadmium excreted in urine, additional analysis is required to estimate the corresponding level of cadmium intake into the body. This can be done using modeling techniques. The derivation of the MRL presented in the draft ATSDR Toxicological Profile for Cadmium (ATSDR, 2008) has applied such an analysis using the results of several studies of European populations, including Suwazono *et al.* (2006). For a 0.5 µg/g creat. urinary concentration, the analysis published by ATSDR (2008) estimated a level of cadmium intake of 0.33 µg/kg/day. This is the intake level chosen by CPSC staff as the critical exposure level.

The scientific community generally addresses uncertainty in the understanding of toxicology and dose-response through the use of uncertainty factors. CPSC staff also uses an uncertainty factor approach in evaluating exposure levels to account for a lack of robust data from animal studies, or a lack of information from human exposures (CPSC, 1992). CPSC staff may apply up to three uncertainty factors, depending on the completeness and relevance of the available data. An uncertainty factor may be used if data are available only in studies of animals and not in humans. An uncertainty factor is applied if the available studies do not identify a dose or exposure level that is not associated with an adverse effect (no observed adverse effect level or NOAEL). When a benchmark dose approach is used, the BMDL is treated as a NOAEL. The third type of uncertainty factor is applied to account for sensitive populations if the available studies do not adequately address such concerns.

In this case, only one uncertainty factor is needed, which is intended to account for the possibility of sensitive members of the population. Staff has chosen to apply a reduced uncertainty factor of 3, rather than the factor of 10 that is more typically used because of lack of knowledge of effects throughout a population. The reduced uncertainty factor is appropriate in this case because of the strength of the data that supports the identified critical exposure level, based on multiple studies of large numbers of people in different parts of the world. Therefore, an uncertainly factor of 3 applied to the intake level of 0.33 µg/kg/day results in an acceptable daily intake (ADI) of 0.1 µg/kg/day. This is the level of chronic exposure that should not be exceeded in order to avoid health effects.

Conclusion

The data concerning the toxicity of cadmium is sufficient for cadmium to be considered toxic under the FHSA due to effects on multiple organ systems and toxic endpoints, including kidney dysfunction. CPSC staff has developed an ADI for chronic exposure to cadmium by the oral route of 0.1 µg/kg/day, based on studies in human populations. Chronic exposures above the ADI of 0.1 µg/kg/day could cause adverse health effects.

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Staff Report on Toy Standard Test Methods with Data from Testing Metal Jewelry and Other Materials

August 2010

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Staff Report

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

Memorandum

Date: August 10, 2010

TO : Robert J. Howell, Assistant Executive Director, Office of Hazard Identification and Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director, Directorate for Health Sciences
Lori E. Saltzman, M.S., Director, Division of Health Sciences, Directorate for Health Sciences

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

SUBJECT : CPSC Staff Discussion of Toy Standard Test Methods[1]

Background

U.S. Consumer Product Safety Commission (CPSC) staff, as part of its work on possible hazards of children's jewelry and other products has considered the toy safety standards with respect to the requirements and test methods for certain chemical elements, such as cadmium. This discussion and the accompanying staff technical reports consider methods that CPSC staff has used to test and evaluate certain children's products, describe the current toy safety standards, and provide the staff's preliminary conclusion about testing methods for certain types of products.

Toxicological evaluation

Assessment of children's products for regulation under the Federal Hazardous Substances Act (FHSA) involves identification of possible hazards, including toxicity. Staff evaluates chemicals through toxicological review and quantitative dose-response analysis. With sufficient data on the chemical of interest, staff may estimate the level of exposure that if exceeded would be associated with adverse health effects, generally termed the acceptable daily intake level (ADI).

Exposure to elements from consumer products

To assess whether use of a product could result in excess exposure to a child, staff estimates possible chemical exposure through testing of products.

[1] These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Children may be exposed to chemicals in products from direct mouthing of objects, from handling such objects and subsequent hand-to-mouth activity, or from ingesting a small item or a portion of a product.

CPSC's Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff evaluates possible exposures to chemicals from children's products that may be mouthed or swallowed by measuring leaching of the chemical from the item using a saline solution to mimic the effects of mouthing, and a mild acid solution to simulate the effects of swallowing an item. In some cases in which exposure might occur from handling a product and subsequent hand-to-mouth activity, staff may use a procedure that simulates hand contact with a product through repeated swiping of the surface with a moistened wipe. Both the saline and acid leaching methods involve placing the item in the solution for specified time periods of at least six hours. For mouthing, the staff assumes that each minute of extraction in the saline solution represents a minute of mouthing of the object by a child. For the ingestion scenario, staff assumes that the leaching time represents the time the item is exposed to the acidic environment of the stomach.

Staff has used an acid extraction test carried out over six hours to reflect the length of time it takes for food to move through the stomach and small intestine, where the absorption of chemicals generally takes place. However, in the course of testing and evaluation of children's metal jewelry containing lead over the past several years, staff learned that these test conditions may not necessarily mimic the circumstances of ingestion of products.

As part of a previous staff project on lead in children's metal jewelry, the staff examined data from three cases in which ingestion of a lead-containing jewelry item was associated with prolonged exposure to an item. A four-year-old Oregon boy had a blood lead level (BLL)[2] of 123 µg/dL approximately three to four weeks after swallowing a pendant containing 38.8 percent lead (VanArsdale et al. 2004). The pendant was surgically removed from the child. A 4-year-old Minnesota boy died with a BLL of 180 µg/dL after ingesting a bracelet charm[3], determined by the state public health department laboratory as containing 99.1 percent lead (CDC 2006). A nine-year-old boy's BLL rose to 27 µg/dL four days after he swallowed a ring containing 90 percent lead. Three days later his BLL rose to 54 µg/dL, at which time endoscopy was performed to remove the ring (CPSC files).

Numerous other reports in published literature and CPSC databases demonstrate that children ranging in age from 9 months to 17 years have had exposure to lead from ingesting products such as jewelry, game pieces, crayons, chalk, lead weights/sinkers/pellets, lead shot/bullets, and curtain weights (Durback 1989, Fergusson 1997, Greensher 1974, Hugelmeyer 1988, Mowad 1998, Sprinkle 1995; CPSC databases).

As demonstrated by these cases, ingested foreign bodies may not be eliminated quickly from the body, but can be retained within the digestive tract for an extended period of time. This has been shown in a 1998 study of 100 children aged 9 months to 13 years who ingested various foreign bodies (objects included coins, ball bearings, pins, marbles, screws, buttons, a light bulb, a novelty nail file and a clothespin) (Macgregor and Ferguson 1998). The total transit time for

[2] BLL is a measure of recent exposure to lead. From a recent national survey, the geometric mean BLL in children aged 1-5 years was 1.9 µg/dL (CDC 2005). There is no known threshold for adverse effects of lead; CPSC staff has evaluated product exposures using 10 µg/dL as the level that should not be exceeded in order to avoid serious adverse health effects.

[3] The length of exposure in this case is unknown, but several days passed between initial presentation of illness and the discovery of the object in the gastrointestinal tract.

passage (from ingestion to elimination through the rectum) of these items ranged from 1 to 46 days. The peak time of passage was two days with a median time of six days. The authors noted that the mean transit time for an ingested object increased with age; it was greater than 15 days for 13-year-olds while it was typically five days for 4 through 10-year-olds.

Ingestion of items such as jewelry is not an infrequent occurrence for children of all ages. As presented in Tab D of the Briefing Package for Petition Requesting Ban of Lead in Toy Jewelry (Petition No. HP 06-1)[4], CPSC's Directorate for Epidemiology, Division of Hazard Analysis staff analyzed data from the National Electronic Injury Surveillance System (NEISS) database on emergency room-treated injuries associated with ingestion of consumer products by children. The staff searched the data for cases involving ingestion of foreign objects by children aged 18 years and younger and, because NEISS is a probability sample, established national estimates for ingestions by age group and product type. For 2000-2005, the staff estimated 302,587 emergency room-treated injuries, nearly 80 percent of which were children under seven years of age. The remaining 20 percent of the estimated injuries were reported in youths aged seven to 18 years. The objects most commonly swallowed were coins, accounting for nearly half of ingestions, followed by jewelry, toys not elsewhere classified, and nails, screws, tacks or bolts. Other major product categories included batteries, marbles, and non-electric Christmas decorations. Just considering cases involving jewelry, the staff estimated nearly 20,000 total emergency room-treated ingestions, about 62 percent of which were in children under age seven years, with the remaining 38 percent in children aged seven to 18 years.

Data: Lead in Jewelry

In 2004, CPSC staff increased efforts to protect children from lead in products. In particular, the staff focused on hazardous lead exposures from swallowing lead-containing metal jewelry. To avoid exceeding the 10 µg/dL blood lead level (BLL) of concern from acute exposure, the staff recommended that children not ingest more than 175 µg of accessible lead in a short period, such as might occur if a piece of jewelry were ingested. Therefore, children's metal jewelry samples that resulted in extraction of more than 175 µg of lead would be considered to be potentially associated with excess lead exposure if ingested by a child.

Staff analyzed hundreds of jewelry items such as beads, pendants, and other components of jewelry using the mild acid extraction test. The acid extraction test to simulate the effect of stomach acid on an ingested item was typically carried out for six hours to reflect the length of time it takes for food to move through the stomach and small intestine. Results of testing children's metal jewelry for lead content and lead solubility after six hours of extraction were presented in the staff briefing package for the petition on lead in toy jewelry (Tab B of the petition package).

Since CPSC staff was interested in the accessibility of lead from ingested items that might remain in the gastrointestinal tract for longer periods of time, an additional extraction period of 18 hours (for a total extraction time of 24 hours) was added to the extraction protocol. The staff's test protocol for each sample involved a one-hour extraction, followed by a two-hour extraction with fresh extraction solution, followed by a three-hour extraction with fresh solution, for a total of six hours. The latter time point was followed by an addition of fresh extraction

[4] Available at http://www.cpsc.gov/library/foia/foia07/brief/LeadToyJewelry.pdf.

solution for the remaining 18 hours of extraction. Results of testing using this revised protocol for samples collected in and tested in fiscal year 2007 are presented in Tab A.

Both the 2004 and 2007 data sets described above showed that, for most samples, the amount of lead that migrated from the item generally depended on the amount of lead present in the sample, with larger levels of extraction from samples with higher total lead content, although there is no strict relationship between content and solubility.

The 2007 report shows that migration of lead generally increases with increasing time in the acid extraction solution. However, in many cases, there is little change in the amount of lead migration over the first several time points. The staff also observed for many samples that low levels of lead extraction at the early time points were followed by large increases in lead release either at the six-hour point or the 24-hour point.

This report included acid extraction results for 378 metal jewelry items. For the 197 items that had more than 0.06 percent total lead that were tested for accessible lead, 110 (56%) had accessible lead greater than 175 µg after 6 hours, and 125 (63%) had accessible lead greater than 175 µg after 24 hours. Of the 218 metal items that had less than ten percent total lead, six had accessible lead greater than 175 µg after six hours, and ten had greater than 175 µg after 24 hours.

Thus, increasing the extraction time for metal items from six hours to 24 hours showed an increase in the proportion of product samples with accessible lead more than 175 µg, as well as levels of accessible lead that were much higher at the later time point. The average amount of accessible lead after 24 hours (8,200 µg) was about five times larger than the average after six hours (1,600 µg).

While the focus of the staff's jewelry analyses was on metal items, a number of non-metal samples were tested for lead accessibility. Of 71 non-metal items tested, 31 were crystal. Some of the crystal items had total lead content up to 25 percent, but none had extractable lead greater than 175 µg after testing for up to 48 hours. Plastic items accounted for most of the remainder of the items tested. Only polyvinyl chloride (PVC) types of plastics had significant lead content. As with the metal items, lead migration tended to increase with increasing length of extraction time. Of nine PVC plastic items, containing lead up to 0.8 percent, two had extractable lead results greater than 175 µg after 24 hours of testing, and an additional two samples exceeded 175 µg after 48 hours. All four of these samples were relatively large necklace cords or choke collar necklaces.

Data: Cadmium in Jewelry

Recently, staff has evaluated the potential for hazardous exposures to cadmium that might occur from mouthing or swallowing cadmium-containing children's metal jewelry (Tab B). At this time, the amount of data on cadmium-containing children's metal jewelry is limited compared to that for lead-containing children's metal jewelry. Also, the staff has not identified a specific total cadmium content level that might indicate a possible hazard, or a level of cadmium exposure that children should not exceed that would be used to identify products with the potential to cause excess exposure to cadmium or to define a cadmium extraction limit for certain products.

Staff evaluated 20 cadmium-containing jewelry items (*i.e.*, finished products of various sizes and designs, generally including electroplating or other surface finishes), several non-product metal

alloy samples in wire or powder form, and several non-product plastic samples. The extraction test methods used were the same methods used to evaluate lead content and lead extraction from children's metal jewelry.

The limited data on extraction of cadmium from jewelry items show that, like lead, there is no strict relationship between cadmium content and cadmium solubility. However, for many samples, those with higher total cadmium content generally had higher levels of extraction. The staff did not collect as much data for cadmium-containing jewelry as is available for the lead-containing samples. Thus, the staff does not have data on the extraction of cadmium over time from electroplated jewelry samples.

Data from testing cadmium-containing alloys that were not electroplated or coated show proportionally increasing extraction of cadmium over time. The staff would hypothesize that the presence of electroplating would have resulted in initially low levels of extraction, followed by increasingly higher amounts of extraction, but this cannot be shown at this time.

As with the testing of plastic for lead migration, cadmium extraction from plastics was considerably less than extraction from metals. Again, an extraction limit for cadmium from children's products has not been defined. Therefore, the staff cannot conclude whether cadmium leaching from plastic items would be excessive or not.

Toy Standards: ASTM F963, EN71-3

The ASTM International *Standard Consumer Safety Specification for Toy Safety* (ASTM F963) covers migratable (*i.e.,* soluble, leachable) elements from paints and coatings on toys, with a specific test method.

The current European *Standard Safety of Toys-Part 3: Migration of certain elements* (EN 71-3:1994) covers any toy material, clay, and finger paint, in addition to paints and coatings, with specified test methods. Thus, the materials included in the scope of EN 71-3 exceed the scope of ASTM F963. However, EN 71-3 does not apply to all toys. This standard is for toys that are likely to be sucked, licked, or swallowed, especially toys for children up to age six years, as well as cosmetic toys, writing instrument toys, and toys for food contact. Jewelry is not included in the scope of either the ASTM or EN standard, except for toy jewelry. Children's jewelry is generally not toy jewelry. Staff is not aware of a European standard for jewelry, except for the nickel directive[5], which restricts the amount of nickel that may contact skin due to the potential for health effects from sensitization.

Except for the differences in scope, the two standards have similarities. Both standards include requirements for migratable chemicals, not total chemical content. The test methods in both indicate that certain types of materials are to be ground or homogenized, such as paints and coatings. In EN 71-3, some materials are extracted whole, such as glass/ceramic/metallic materials, if the toy or component fits entirely within the small parts cylinder. Both standards indicate the amount of material to be tested, how the test material is to be prepared, the amount of acid to be used for the test, and other details for different materials; but generally, the test methods are similar, and the migration limits are the same.

[5] Directive 2004/96/EC of the European Parliament and of the Council of 27 September 2004 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of nickel for piercing post assemblies for the purpose of adapting its Annex I to technical progress.

A key aspect of the methods in both standards that differs significantly from the CPSC staff approach to evaluating certain products for the presence of a chemical hazard is that the extraction period in the toy standards is two hours. In contrast, CPSC staff typically uses an extraction period of at least six hours.

The basis of EN 71-3 is that a child is assumed to have an average daily intake (ingestion) of toy material of 8 milligrams (mg) per day. The standard acknowledges that in certain individual cases this figure might be exceeded. CPSC staff believes that the 8 mg/day assumption might be reasonable for paints and coatings, or materials that can be scraped off or that break up into small bits. As the language of the standard acknowledges, this level of ingestion could be exceeded in some cases.

To understand the implications of conditions of a test, consider the case of ingestion of small amounts of a toy material, such as paint or other scrapings or small bits. In this case, a two-hour extraction period may reasonably indicate whether excess leaching might occur. For such small bits, we might expect that ingestion would be followed by a relatively normal rate of elimination from the body as the small scrapings or pieces become mixed up in food and are transported through the gastrointestinal tract. Even if such small bits were not eliminated from the body within a day or two, as is the typical transit time for food, the exposure to chemicals that might migrate from the ingested materials is limited by the small size of the particles.

On the other hand, items such as the glass/ceramic/metallic components that fit within the small parts cylinder and are tested intact, or any other item that is ingested as a piece rather than as a scraping or small bit, generally are considerably larger than 8 mg, with mass perhaps up to about 5 grams. These large items might remain in the stomach or GI tract for longer periods of time.

As we learned from the jewelry ingestion cases, and from a report in the literature on ingested foreign bodies (Mcgregor and Ferguson 1998), an object may remain in the body for days or weeks. For these larger objects, a two-hour test may not be adequate to determine whether excessive leaching might occur. On the other hand, for certain materials such as glass, a longer extraction time may not result in significantly more leaching than a shorter time. This is because some materials are not susceptible to dissolving under the test conditions of the standards, and only chemicals at the immediate surface of the product are available for leaching.

Another reason that the shorter test might not be appropriate for some products is that plating or coating, if present on the product or component, could initially block the migration of the elements. Again, from the staff's jewelry investigations, we know that such coatings will eventually weaken and allow the acid to reach the underlying material. In these cases, leaching would be evident only after several hours in the acid solution.

New EU standard

There is a new EU toy safety directive[6] that will result in significant changes in the EN 71-3 migration of elements standard. The new requirements for chemicals in toys are to go into effect in 2013. The exact form of the new standard is not known, since some of the details for implementing the new directive need to be worked out. However, the new standard will include a ban of certain fragrance chemicals and restrictions on chemicals that are carcinogenic, mutagenic, or reproductive toxicants; it adds more elements to the migration standard, sets

[6] Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

different migration limits for the elements that are in the current standard, and sets different migration limits for different types of materials. The staff has not yet evaluated the appropriateness of including the additional chemicals, or the revised migration limits, and cannot address methods that are not yet available. It is not clear to staff at this point if the scope of products or materials covered by the standard will change, or whether the test methods will be significantly revised. The staff does not know when the revised standard will be available.

Conclusion

Considering the available data on small swallowable metal jewelry items and the information about children's ingestion of small objects, including cases of serious adverse effects and death from the chemical content of some of the items, the staff has concerns about the appropriateness of the two-hour solubility test in both the ASTM F963 and EN 71-3 toy safety standards. Because an ingested foreign body may remain in the gastrointestinal tract for extended periods of time, and some materials are susceptible to excessive leaching of chemicals in the acid conditions of the stomach, the two-hour test may not identify products that could lead to excess exposure. As demonstrated with the results of the staff's testing of lead- or cadmium-containing jewelry and metal alloys, increasing the length of time in an acidic solution generally results in increasing solubility of the chemicals from products. Therefore, for small, swallowable items, especially metal items, the staff preliminarily recommends that the test procedure be carried out for 24 hours.

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TAB A: Summary of Test Results for Lead in Children's Metal Jewelry

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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Memorandum

Date: Aug 1, 2007

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THROUGH: Andrew G. Stadnik, P.E., Associate Executive Director, Directorate for Laboratory Sciences

Joel R. Recht, Ph.D., Director, Division of Chemistry, Directorate for Laboratory Sciences

FROM : David Cobb, Chemist, Division of Chemistry, Directorate for Laboratory Sciences

SUBJECT : Summary of Test Results for Lead in Children's Metal Jewelry[1,2]

Summary:

This memorandum provides a summary of the test results of U.S. Consumer Product Safety Commission (CPSC) staff testing for lead (Pb) in children's metal jewelry in fiscal year 2007. The CPSC Directorate for Laboratory Sciences (LS), Division of Chemistry (LSC) staff has analyzed 384 children's metal jewelry items from 104 official compliance samples and 73 non-metal items such as plastic and crystal from 27 official compliance samples. There were 198 metal items tested that had total lead of 0.06% or more. In general, the staff notes that by visual inspection or XRF (data not shown), the metal items and components were finished with non-lead metallic coatings or platings, *e.g.*, copper, nickel. While the integrity of such coatings was not specifically evaluated, the data show that coatings do not necessarily prevent accessibility of lead from the item.

Background:

Under the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261(f)(1), children's metal jewelry items that expose children to hazardous quantities of lead under reasonably foreseeable conditions of handling or use are banned hazardous substances. In 2005, CPSC's Office of Compliance issued an Interim Enforcement Policy for Children's Metal Jewelry

[1]These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

[2] Note this document was initially prepared in 2007 as part of a briefing package considering a ban on lead in children's metal jewelry, and does not reflect changes due to the enactment of the Consumer Product Safety Improvement Act of 2008 (CPSIA) and other later changes. Current testing methods and summaries of regulations for lead in children's products according to the CPSIA can be found at http://www.cpsc.gov/about/cpsia/sect101.html

Containing Lead for manufacturers, importers, and retailers.[3] The policy was accompanied by a two part testing procedure.[4] The procedure calls for the determination of the total lead content of a metal jewelry item by a specified method. Distinct metal component items within a jewelry sample, such as pendants, hooks, or beads are tested separately for total and accessible lead. If the total lead in a metal jewelry item is more than 0.06%, then an acid extraction for 6 hours is conducted by a second specified method. Metal jewelry with more than 175 µg of accessible lead by this method is subject to further review for age grading, and other risk factors and a risk assessment may result in enforcement action. Non-metal jewelry is not addressed in the Interim Enforcement Policy, but is subject to the FHSA.

Test Method:

Total Lead in Metal

The current test method[4] for total lead is based on methodology found in Canada Product Bureau Method C-02.4, and has been used for samples analyzed since December 2004. This method requires that the aliquots be ground into small particles to increase the rate of dissolution, and the procedure also contains a step for adding hydrochloric acid to assist in dissolving certain metal alloys.

Total Lead in Plastic

Plastic items were ashed in a muffle furnace at 600°C. 10-50 mg aliquots of the ashen item were dissolved in 2-3 ml of nitric acid on a hot plate. The digests were analyzed using inductively coupled plasma atomic emission spectroscopy (ICP) to determine lead content.

Total Lead in Crystal

Aliquots of crystal items were microwave digested with 2 ml of nitric acid and 1 ml of hydrofluoric acid. The digests were diluted with 4% boric acid to neutralize any free fluoride and analyzed by ICP to determine lead content.

Accessible Lead

The acid extraction test method[4] for accessible lead calls for an acid extraction that simulates exposure to metal that is ingested into the alimentary tract. The acid extraction involves placing an intact jewelry item in 0.07N hydrochloric acid (HCl) at 37°C for 6 hours. This procedure is based on methodology found in ASTM C927, C738, D5517, and F963. Extended acid extractions to 24 hours were performed on metal items. Plastic and crystal items were extracted with 0.07N HCl at 37°C for up to 48 hours.

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

[4]CPSC Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children's Metal Jewelry 2/3/05, http://www.cpsc.gov/businfo/pbjeweltest.pdf.

RESULTS AND DISCUSSION:

The test results for the samples are contained in Tables 1 and 2. The results showed that 197 out of 381 metal items tested (52%) had total lead of 0.06% or more. Acid extractions were done on 378 metal items; for the 197 items that had more than 0.06% total lead that were tested for accessible lead, 110 (56%) of those items had accessible lead greater than 175µg after 6 hours, and 125 (63%) had accessible lead greater than 175µg after 24 hours. Of the 218 metal items that had less than 10% total lead, 6 of those had accessible lead greater than 175µg after 6 hours, 10 had greater than 175µg after 24 hours. One item that had less than 0.06% total lead had accessible lead greater than 175µg after 24 hours.

Increasing the extraction time for metal items from 6 hours to 24 hours showed an increase in the proportion of products with accessible lead greater than 175 µg. The results also showed that the levels of accessible lead were much higher after 24 hours compared to 6 hours. The average 24 hour accessible lead (8183µg) was about 5 times as large as the average 6 hour accessible lead (1564µg).

There were 71 non metal items tested. Crystal accounted for 31 of those items. Some of the crystal items had total lead up to 25%, but none of the crystal items had extractable lead greater than 175µg. Plastic items accounted for most of the remainder of the items tested. Only polyvinyl chlorine (PVC) types of plastics had significant total lead. There were 9 PVC plastic items tested with lead levels up to 0.8%. Four of these items, with extractable lead results greater than 175µg after 48 hours of testing, were relatively large necklace cords or collars, weighing several grams.

Table 1. Metal Jewelry Results

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1.0	2.0	3.0	18		
06-810-3976	3	necklace	chain		0.015						
06-810-3976	3	necklace	teardrop pendant		96.2						
06-810-3976	3	necklace	hook		98.7						
06-810-3976	3	necklace	heart pendant		97.8						
06-810-3976	4	necklace	chain	0.38		2.5	0.4	0.0	0.9	2.9	3.8
06-810-3976	4	necklace	teardrop pendant	0.38(2)		494	684	659	8265	1838	10103
06-810-3976	4	necklace	hook	0.68		1207	1030	1203	7276	3440	10717
06-810-3976	4	necklace	heart pendant	5.04		5.0	12.6	47.9	3150	65.5	3216
06-810-3976	5	necklace	chain	0.38		2.3	0.8	0.6	1.1	3.7	4.8
06-810-3976	5	necklace	teardrop pendant	0.42(2)		466	735	1014	7476	2215	9691
06-810-3976	5	necklace	hook	0.66		544	1052	1065	1019	2663	3683
06-810-3976	5	necklace	heart pendant	5.18		12.9	5.2	20.7	1347	38.8	1386
06-810-3976	6	necklace	chain		0.002						
06-810-3976	6	necklace	teardrop pendant		99.2						
06-810-3976	6	necklace	hook		87.3						
06-810-3976	6	necklace	heart pendant		93.5						
06-840-7517	1	anklet	charm	3.3	87.6	892	1685	3143	23362	5720	29082
06-840-7517	2	anklet	charm	3.1	80.9	405	766	1279	17658	2450	20108
06-840-7642	3	bracelet	charm	2.69	0.44	7.7	0.5	0.4	9.0	8.6	17.6
06-840-7642	4	bracelet	charm	2.57	0.43	5.8	2.3	4.6	5.1	12.8	17.9
07-810-4655	3	Necklace	Charm back	6.615	95.3	31.8	65.9	98.3	7259	196	7455
07-810-4655	6	Necklace	Charm back	5.867	92.1	750	1202	3168	36372	5120	41492
07-302-0045	1	necklace	pendant	5.55	25.1	6936	14238	22312	104706	43486	148192
07-302-0046	1	necklace	cross pendant	4.64	44.2	559	988	1791	15776	3338	19114
07-302-0046	1	necklace	cross pendant clasp		3.5						
07-302-0046	1	necklace	star pendant	4.18	44.4	62.7	130	234	1521	426	1948
07-302-0046	1	necklace	star pendant clasp		42.5						
07-302-0075	1	key chain	pendant	20.32	0.023	0.0	0.0	0.0		0.0	
07-302-0075	2	key chain	pendant	20.38	0.068	17.4	0.0	0.0		0.0	
07-302-0075	3	key chain	pendant	20.10	0.025	43.0	0.0	0.0		0.0	
07-302-0075	4	key chain	pendant	20.89	4.27	226	284	356	1569	866	2435
07-302-0075	5	key chain	pendant	21.88	0.121	118	0.0	0.0		118	
07-302-0075	6	key chain	pendant	20.81	0.131	0.0	0.0	0.0		0.0	
07-302-0075	4	key chain	chain	3.50	0.235	2.0	0.0	0.0	1199	2.0	1201
07-302-0075	5	key chain	chain	3.47	0.009	2.7	2.0	0.0	407	4.7	412

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07-302-0075	4	key chain	key ring	3.92		10.8	2.6	0.0	236	13.4	249
07-302-0075	5	key chain	key ring	3.92		3.1	0.0	0.0	46.5	3.1	49.6
07-302-0075	6	key chain	key ring		0.008						
07-302-0075	6	key chain	key ring		0.002						
07-302-0093	1	Token	Token	16.208		0.0	0.0	8.3	11865	8.3	11874
07-302-0093	6	Token	Token	14.808		0.0	0.0	0.0	12.1	0.0	12.1
07-302-3734	1	Ring		0.576	76.9	253	418	758	2678	1429	4107
07-302-3734	2	Ring		0.622	55.5	587	1189	1523	7239	3299	10538
07-810-1371	1	necklace	hook	4.46	0.229	16.8	2.8	0.4	2.6	20.0	22.6
07-810-1371	1	necklace	Clasp	1.16	84.4	2820	1906	2834	18854	7560	26414
07-810-1371	1	necklace	pendant		0.011						
07-810-1371	2	necklace	hook	4.71	0.026	2.7	0.5	0.5	0.3	3.7	4.0
07-810-1371	2	necklace	Clasp	1.33	95.7	918	1471	2021	11990	4410	16401
07-810-1371	2	necklace	pendant		0.01						
07-810-1372	1	Ring		8.82	0.003	3.8	2.1	0.0	1.5	5.9	7.4
07-810-1372	2	Ring		5.6	0.001	1.8	1.5	0.5	0.0	3.8	3.8
07-810-4100	1	bracelet		4.02	0.01	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4100	2	bracelet		4.7	0.043	0.0	0.0	4.7	9.4	4.7	14.1
07-810-4126	1	key chain	charm	22.6	100	1021	2863	5396	92950	9280	102230
07-810-4126	2	key chain	charm	22	96.4	921	2245	3390	67779	6556	74335
07-810-4127	1	Ring		9.16		77.9	257	540	5083	875	5959
07-810-4127	2	Ring			88.5						
07-810-4127	4	Ring			90.5						
07-810-4127	5	ring		11.97		186	496	797	7727	1474	9201
07-810-4172	1	necklace	hook	0.4739	0.062	0.8	0.7	0.0	1.5	1.6	3.1
07-810-4172	1	necklace	pendant-lock	0.4279	0.008	0.2	0.0	0.0	0.0	0.2	0.3
07-810-4172	1	necklace	pendant-heart	0.7316	0.075	19.1	0.0	0.0	1.3	19.1	20.4
07-810-4172	2	necklace	hook	0.4222	0.107	9.1	1.3	0.7	2.1	11.1	13.2
07-810-4172	2	necklace	pendant-lock	0.4496	0.007	31.0	1.9	0.2	0.9	33.1	34.0
07-810-4172	2	necklace	pendant-heart	0.6730	0.038	0.2	0.0	0.0	0.0	0.2	0.2
07-810-4173	1	necklace	hook	0.4	0.062	15.9	31.6	0.7	0.6	48.2	48.8
07-810-4173	1	necklace	Pendant	1.815	0.004	8.0	0.2	0.0	0.0	8.1	8.1
07-810-4173	1	necklace	Pearl earring-setting	0.124	0.001	0.9	13.8	5.7	0.4	20.5	20.9
07-810-4173	2	necklace	hook	0.4631	0.072	20.5	1.4	0.9	1.1	22.9	23.9
07-810-4173	2	necklace	Pendant-metal	1.475	0.022	55.8	12.1	12.1	1.8	80.0	81.8
07-810-4173	2	necklace	“diamond” earring-setting	0.4082	0.032	15.9	0.2	0.0	0.1	16.1	16.2
07-810-4173	2	necklace	Pearl earring-setting	0.1762	0.015	39.2	22.8	10.6	4.0	72.7	76.7

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						1	2	3	18		
07-810-4294	1	Ring	dark blue stone	1.76		65.1	110	176	1548	351	1899
07-810-4294	2	Ring	dark blue stone		92.5						
07-810-4294	3	Ring	blue stone	2.09	81.2	18.9	108	288	4084	415	4499
07-810-4294	3	Ring	no stone	1.6	71.9	53.6	103	169	952	326	1278
07-810-4294	4	Ring	no stone	0.68	0.031	1.4	1.0	2.0	23.1	4.4	27.5
07-810-4294	5	Ring	green stone	1.19	68.9	6.0	0.0	3.6	49.2	9.6	58.8
07-810-4294	5	Ring	pink stone	1.79	80.5	0.0	0.0	9.0	388	9.0	397
07-810-4294	5	Ring	blue stone	1.92	73.7	82.6	280	720	5260	1083	6344
07-810-4294	6	Ring	no stone/thin ban	1.8	75.9	3.6	24.3	70.2	1863	98.1	1961
07-810-4470	1	necklace	pendant	13.36	0.004	0.0	0.0	0.0	7.3	0.0	7.3
07-810-4470	1	necklace	hook	0.49	0.009	0.7	0.0	0.0	1.2	0.7	1.9
07-810-4470	1	necklace	tear drop charm	0.17	4.15	0.1	0.1	0.1	86.4	0.3	86.7
07-810-4470	3	necklace	pendant	13.39	0.004	0.0	0.0	14.4	6.1	14.4	20.5
07-810-4470	3	necklace	hook	0.49	0.011	0.3	0.5	1.5	2.0	2.3	4.3
07-810-4470	3	necklace	tear drop charm	0.17	3.71	0.0	0.2	0.0	3.4	0.2	3.6
07-810-4471	1	zipper	pull	0.02	4.37	9.4	2.0	0.0	0.0	11.4	11.4
07-810-4471	1	zipper	hook	0.007	0.71	15.9	25.7	30.3	23.1	71.9	95.0
07-810-4471	4	zipper	pull	0.023	4.35	7.7	2.8	2.1	2.4	12.6	15.0
07-810-4471	4	zipper	hook	0.012	0.65	0.0	0.0	0.0	4.5	0.0	4.5
07-810-4471	5	zipper	pull	0.153	4.37	4.0	0.0	0.0	3.0	4.0	7.0
07-810-4471	5	zipper	hook	0.012	0.72	13.7	22.5	32.2	51.0	68.4	119
07-810-4502	3	necklace	charm	9.529	0.037	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4502	3		hook	0.477	0.022	0.2	0.0	0.0	0.0	0.2	0.2
07-810-4502	6		charm	9.626	0.01	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4502	6		hook		0.023	0.0	0.0	0.0	2.2	0.0	2.2
07-810-4502	3 and 6		tear drops	0.304	4.48	1.8	0.1	0.6	344	2.5	346
07-810-4519	1	bracelet	pendant	11.37		1829	2891	6248	77362	10968	88330
07-810-4519	1	bracelet	hook	1.11		957	2244	3481	22600	6682	29282
07-810-4519	2	bracelet	pendant	10.38		296	270	441	8874	1007	9882
07-810-4519	2	bracelet	hook	1.08		643	2214	4358	32098	7214	39312
07-810-4519	3	bracelet	pendant	10.98	102	115	225	1290		1631	
07-810-4519	3	bracelet	hook		83.6						
07-810-4519	4	bracelet	pendant	11.2	90.6	5.6	28.0	89.6		123	
07-810-4519	5	bracelet	pendant		97.4	475	520	6817		1676	
07-810-4519	5	bracelet	hook	11.43	92.4						
07-810-4519	6	bracelet	pendant	10.77	91.3	0.0	21.6	64.7		86.3	
07-810-4599	4	Ring		1.9	0.01	0.0	0.0	0.0	3.8	0.0	0.0
07-810-4599	5	Ring		0.31	0.001	1.1	0.0	0.0	0.0	1.1	0.0

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						1	2	3	18		
07-810-4600	1	Ring		1.799	0.063						
07-810-4600	3	Ring		1.557	0.076						
07-810-4601	3	Bracelet				0.0	0.0	0.0	0.0	0.0	0.0
07-810-4601	6	Bracelet				0.0	0.0	0.0	0.0	0.0	0.0
07-810-4654	1	ring		13.48		3321	4252	5042	28552	12622	41175
07-810-4654	2	ring			80.2						
07-810-4654	5	ring		12.71		1794	2620	2932	13546	7339	20886
07-810-4654	6	ring			85.5						
07-810-4655	3	necklace	charm	6.615	95.3	31.8	65.9	98.3	7259	196	7455
07-810-4655	6	necklace	charm	5.867	92.1	750	1202	5120	34419	7072	41491
07-810-4656	1	necklace	Clasp	0.4136	65.6						
07-810-4656	2	necklace	Clasp	0.439	68.0						
07-810-4656	3	necklace	Pendant (pink)		0.808						
07-810-4656	3	necklace	Clasp			536	758	1128	7242	2421	9664
07-810-4656	4	necklace	Pendant (pink)			4.9	1.5	0.3	0.9	6.7	7.6
07-810-4656	4	necklace	Clasp			459	623	1203	6730	2285	9015
07-810-4656	5	necklace	Pendant (blue)			1.9	0.6	0.4	2.2	2.9	5.1
07-810-4656	6	necklace	Pendant (blue)		0.192						
07-810-4674	1	necklace	pendant	1.82	0.05	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4674	1	necklace	hook	0.16	0.012	0.2	0.0	0.0	0.2	0.2	0.4
07-810-4674	2	necklace	pendant	1.84	0.068	0.9	0.0	0.0	0.0	0.9	0.9
07-810-4674	2	necklace	hook	0.16	0.017	0.2	0.0	0.0	0.5	0.2	0.7
07-810-4675	1	necklace	pendant	5.373		3.7	0.6	1.4	3.9	5.7	9.2
07-810-4675	1	necklace	hook	0.177		0.1	0.1	0.0	0.0	0.2	0.2
07-810-4675	2	necklace	pendant	5.333		1.7	1.4	0.0	2.6	3.1	8.2
07-810-4675	2	necklace	hook	0.171		0.0	0.1	0.0	0.0	0.1	0.2
07-810-4675	4	necklace	pendant	5.14	0.02						
07-810-4675	4	necklace	hook	0.174	0.015						
07-810-4675	5	necklace	pendant	5.28	0.198						
07-810-4675	5	necklace	hook	0.166	0.014						
07-810-4703	2	necklace	Hook	0.557	81.7	263	709	1180	11085	2152	13237
07-810-4703	2	necklace	pendant	3.274	77.6	616	1028	1634	16926	3278	20204
07-810-4703	3	necklace	Hook	0.537	72.2	979	2037	2485	20878	5501	26379
07-810-4703	3	necklace	pendant	3.037	75.5	1427	2544	4189	21535	8160	29695
07-810-4704	3	necklace	Hook	0.514	76.2	584	1446	2289	17316	4319	21635
07-810-4704	3	necklace	pendant	2.964	92.1	244	52.0	57.0	846	353	1199
07-810-4704	4	necklace	Hook	0.587	70.3	572	1629	2608	18961	4809	23770
07-810-4704	4	necklace	pendant	2.345	89.8	52.0	14.0	25.0	198	91.0	289
07-810-4705	1	necklace	Hook	0.572	91.6	572	1404	2228	17058	4204	21262
07-810-4705	1	necklace	pendant	2.471	86.9	14.0	42.0	24.0	2198	80.0	2278
07-810-4705	2	necklace	Hook	0.581	85.6	1189	2958	5352	22800	9499	32299

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07-810-4705	2	necklace	pendant	2.184	79.9	133	42.0	53.0	1853	228	2081
07-810-4711	4	earring	metal	1.058	0.049	8.4	3.3	2.5	2.5	14.2	16.7
07-810-4711	5	earring	metal	1.426	0.051	6.5	6.1	5.2	4.4	17.8	22.2
07-810-4724	6	hair clip, green			0.001						
07-810-4724	6	hair clip, purple			0.003						
07-810-4724	6	hair clip, red		0.529		0.3	0.0	0.0	0.5	0.3	0.8
07-810-4724	6	hair clip, yellow		0.547		0.0	0.0	0.0	0.5	0.0	0.5
07-810-4725	1	pin		11.02	88.4	334	1303	7660	90173	9297	99471
07-810-4725	3	pin		10.94	90.1	440	1142	3881	66501	5463	71964
07-810-4946	1	anklet	pendant	3.18	53.4	448	1217	3070	17505	4734	22240
07-810-4946	3	anklet	pendant	3.16	50.5	1821	3197	6849	35960	11867	47828
07-810-4946	5	anklet	pendant	2.58	16.5	90.7	166	377	7424	634	8058
07-810-4946	6	anklet	pendant	2.86	54.7	28.1	111.4	224.5	8375	364	8739
07-810-4947	3	Bracelet	Connector	0.1209	0.010	0.1	0.1	0.1	0.1	0.4	0.5
07-810-4947	3		Pendant 1	0.9423	0.201	0.5	0.3	0.4	1.0	1.2	2.2
07-810-4947	3		Pendant 2	1.1407	0.100	2.0	0.9	0.7	0.4	3.6	3.9
07-810-4947	5		Connector	0.1213	0.013	0.2	0.1	0.1	0.3	0.4	0.7
07-810-4947	5		Pendant 1	0.8961	0.481	0.4	0.3	0.4	0.8	1.2	2.0
07-810-4947	5		Pendant 2	1.3189	0.104	0.8	0.4	0.4	0.3	1.6	1.9
07-810-4948	2	Bracelet	charm, P	1.064	0.059	2.9	0.0	0.0	0.0	2.9	2.9
07-810-4948	2		charm, S	1.035	0.093	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4948	4		charm, P	1.081	0.077	0.0	0.0	0.0	0.0	0.0	0.0
07-810-4948	4		charm, S	1.151	0.046	4.7	0.0	0.0	0.0	4.7	4.7
07-810-5001	1	kit	chain	3.11	0.04	64.4	5.8	2.0	0.5	72.2	72.7
07-810-5001	1	kit	hook	0.495	0.017	1.1	0.3	0.2	0.3	1.6	1.9
07-810-5001	1	kit	charm-bag	0.872	0.019	0.2	0.2	1.5	0.2	1.9	2.1
07-810-5001	1	kit	charm-dog	0.997	0.017	0.2	0.2	0.3	0.0	0.6	0.7
07-810-5001	2	kit	chain	3.301	0.006	5.7	1.5	0.2	0.0	7.4	7.4
07-810-5001	2	kit	hook	0.485	0.024	0.5	0.4	0.5	0.5	1.3	1.8
07-810-5001	2	kit	charm-bag	0.758	0.013	0.4	3.0	0.6	0.1	3.9	4.1
07-810-5001	2	kit	charm-dog	0.933	0.009	1.2	0.3	0.2	0.3	1.7	2.0
07-810-5002	1	necklace	pendant	1.505	79.5	33.1	75.3	98.0	1625	206	1832
07-810-5002	1	necklace	hook	0.188	0.018	0.0	0.2	0.0	0.1	0.2	0.3
07-810-5002	5	necklace	pendant	1.37	74	161	227	302	1506	691	2197
07-810-5002	5	necklace	hook	0.186	0.255	0.0	0.0	0.0	0.5	0.0	0.5
07-810-5027	3	earring			0.024						
07-810-5027	4	necklace	chain	1.24	0.007	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	4	necklace	pendant	1.93	0.011	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	4	necklace	hook	0.27	0.016	0.0	0.0	0.0	0.3	0.0	0.3
07-810-5027	4	earring		0.44		0.2	0.0	0.0	0.0	0.2	0.2

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+18 =24
						1	2	3	18		
07-810-5027	6	necklace	pendant	1.79	0.023	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5027	6	necklace	hook	0.25	0	0.4	0.0	0.0	0.0	0.4	0.4
07-810-5027	6	earring		0.4	0.011	0.0	0.6	0.0	0.2	0.6	0.8
07-810-5028	1	necklace	charm		0.021						
07-810-5028	1	necklace	hook		85.5						
07-810-5028	2	necklace	charm		0.041						
07-810-5028	2	necklace	hook		0.021						
07-810-5028	4	necklace	charm	2.24	0.159	1.2	0.0	0.0	0.0	1.2	1.2
07-810-5028	4	necklace	hook	0.49	0.045	0.4	0.3	0.0	0.0	0.7	0.7
07-810-5028	5	necklace	hook	0.75	94.5	249	583	1105	9331	1937	11269
07-810-5028	6	necklace	charm	1.93	0.041	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5028	6	necklace	hook	0.49	0.027	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5032	1	spring bracelet		2.580	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5032	5	spring bracelet		2.618	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5033	2	metal ring		1.3285	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5033	5	metal ring		2.3045	0.015	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5035	3	necklace	charm	0.721	0.101	55.1	0.0	0.0	0.9	55.1	56.0
07-810-5035	6	necklace	charm	0.653	0.085	190.5	5.2	1.8	4.6	198	202
07-810-5121	4	necklace	pendant	7.1	81.92	32.0	5.3	17.4	73591	54.7	73646
07-810-5121	4	necklace	hook	0.77	85.7	947	2214	2566	23251	5727	28979
07-810-5121	6	necklace	pendant	7.36	84.67	475	310	379.4	40443	1164	41608
07-810-5121	6	necklace	hook	0.61	82.28	976	1879	1190	3128	4045	7174
07-810-5122	5	ring			0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5122	6	ring			0.008				0.0	33.0	33.0
07-810-5126	2	necklace	chain	3.62	0.005	0.0	0.0	1.9	9.4	1.9	11.3
07-810-5126	5	necklace	chain	2.81	0.012	0.0	0.0	1.5	6.9	1.5	8.4
07-810-5126	5	necklace	pendant	2	0.004	0.0	0.0	0.0	2.5	0.0	2.5
07-810-5127	1	ring		1.88	0.005	0.0	0.0	0.0	5.9	0.0	5.9
07-810-5127	6	ring		2.91	0.005	0.0	0.0	0.0	0.0	0.0	0.0
07-810-5128	2	necklace	pendant	0.996	0.017	0.0	0.8	0.5	1.3	1.3	
07-810-5128	3	necklace	pendant	1.081	0.004	2.6	2.6	1.7	4.8	6.9	11.7
07-810-5128	4	necklace	pendant	1.187	0.006	0.7	1.0	1.1	3.6	2.8	6.4
07-810-5128	5	necklace	pendant	0.872	0.008	0.0	0.4	0.7	1.9	1.1	3.0
07-810-5176	1	necklace	key shaped pendant		0.004						
07-810-5176	1	necklace	heart shaped pendant		0.001						
07-810-5176	1	necklace	crown shaped pendant		0.002						
07-810-5176	4	necklace	key shaped pendant	0.539	0.029	0.3	0.3	0.3	0.3	0.9	1.2

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07-810-5176	4	necklace	heart shaped pendant	0.394	0.003	0.2	0.2	0.2	0.5	0.6	1.1
07-810-5176	4	necklace	crown shaped pendant	1.099	0	0.5	1.0	0.3	0.6	1.8	2.4
07-810-5176	6	necklace	key shaped pendant	0.561		0.0	0.0	0.0	0.0	0.0	0.0
07-810-5176	6	necklace	heart shaped pendant	0.396		0.0	0.2	0.0	0.5	0.2	0.7
07-810-5176	6	necklace	crown shaped pendant	1.021		0.0	0.0	0.0	0.0	0.0	0.0
07-810-5177	2	Bracelet	key shaped cross pendant	1.465	86.5	7928	1649	8389	43384	17966	61350
07-810-5177	2	Bracelet	curved shape cross pendant	1.473	57.3	896	506	938	7560	2340	9900
07-810-5177	2	Bracelet	square cross	1.264	60.4	993	155	524	3166	1672	4838
07-810-5177	2	Bracelet	thick cross pendant	2.897	92.5	6840	2909	6944	34119	16693	50812
07-810-5177	2	Bracelet	Hook	0.922	81.3	657	199	3643	36763	4499	41262
07-810-5177	6	Bracelet	key shaped cross pendant	1.754	92.7	1460	348	2498	14250	4306	18556
07-810-5177	6	Bracelet	curved shape cross pendant	1.347	63.7	678	267	1071	3623	2016	5639
07-810-5177	6	Bracelet	square cross pendant	1.219	68.6	1452	374	2761	5051	4587	9638
07-810-5177	6	Bracelet	thick cross pendant	2.909	83.1	3450	1572	2262	44240	7284	51524
07-810-5177	6	Bracelet	Hook	1.096	80.6	700	34.2	4194	33726	4920	38646
07-810-5178	4	Choker	Large Butterfly charm	3.838	82.5	2083	774	4825	31284	7362	38986
07-810-5178	4	Choker	small butterfly charm	1.827	90.9	968	1028	2002	9746	3998	13744
07-810-5178	4	Choker	large heart charm	3.472	53.3	4447	2298	3591	35057	10336	45393
07-810-5178	4	Choker	Heart with crystal charm	2.197	91.6	2859	2716	3678	191066	9253	28359
07-810-5178	4	Choker	Hook	0.754	78.1	293	956	1820	7128	3069	10197
07-810-5178	6	Choker	Large Butterfly charm	4.254	88.6	1957	2189	5292	34428	9438	43866
07-810-5178	6	Choker	small butterfly charm	1.937	91	1418	1724	4385	23742	7527.0	31269

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07-810-5178	6	Choker	large heart charm	3.074	77.9	10158	2311	6428	34604	18897	53501
07-810-5178	6	Choker	Heart with crystal charm	2.094	97	2416	5191	1929	7602.	9536	17138
07-810-5178	6	Choker	Hook	0.753	86.4	153	617	1201	3145	1971	5116
07-810-5221	4	charm		2.677	0.007	0.0	0.0	0.0	1.6	0.0	1.6
07-810-5221	6	charm		2.684	0.008	1.4	0.0	0.0	1.5	1.4	2.9
07-810-5259	2	Ring	Pendant	0.8	4.18	2.4	0.4	0.4	0.4	3.2	3.6
07-810-5259	2	necklace	Pendant	0.88	2.2	1.3	0.0	0.4	0.4	1.7	2.1
07-810-5259	6	Ring	Pendant	0.84	0.5	1.3	0.0	0.4	0.8	1.7	2.5
07-810-5259	6	necklace	Pendant	0.8	0.59	0.4	0.0	0.0	0.4	0.4	0.8
07-810-5260	2	Ring	pendant	0.47	0.303	0.2	0.2	0.2	0.2	0.7	1.0
07-810-5260	2	necklace	pendant	2.01	0.166	1.0	0.0	1.0	0.0	2.0	2.0
07-810-5260	5	Ring	pendant	0.49	2.333	0.5	0.3	0.5	0.3	1.3	1.5
07-810-5260	5	necklace	pendant	2	0.363	0.0	0.0	1.0		1.0	2.0
07-810-5260	5	necklace	shoe pendant	1.64	0.118	0.8	0.0	0.8	1.6	1.6	3.3
07-810-5261	1	necklace	butterfly pendant	1.66	0.114	0.0	0.0	0.8	0.8	0.8	1.7
07-810-5261	1	necklace	ladybug pendant	1.36	1.922	0.0	0.0	0.0	0.7	0.0	0.7
07-810-5261	1	necklace	clover pendant	1.26	1.188	2.5	0.6	0.6	0.6	3.8	4.4
07-810-5261	4	necklace	butterfly pendant	1.62	1.305	4.9	0.8	0.8	0.8	6.5	7.3
07-810-5261	4	necklace	ladybug pendant	1.42	0.556	4.3	0.0	0.7	0.7	5.0	5.7
07-810-5261	4	necklace	clover pendant	1.2	0.435	0.0	0.0	0.0	0.6	0.0	0.6
07-810-5275	2	Bracelet	charm	1.135	0.015	26.0	0.9	1.4	2.1	28.4	30.4
07-810-5275	5	Bracelet	charm	1.154	0.007	0.4	0.0	0.0	1.2	0.4	1.5
07-810-5276	2	Bracelet	charm	0.494	0.013	116.1	4.7	1.8	2.9	122	125
07-810-5276	2	Bracelet		0.53	0.008	4.5	0.6	0.2	2.0	5.2	7.3
07-810-5276	5	Bracelet	charm	1.377	0.578	29.5	21.1	29.8	391	80.4	471
07-810-5276	5	Bracelet		0.476	0.008	1.0	0.4	0.2	1.7	1.7	3.3
07-810-5277	2	necklace	clasp	0.494	0.116	19.0	0.1	2.3	45.7	21.4	67.1
07-810-5277	2	necklace		0.53	0.385	5.5	3.1	2.0	12.8	10.6	23.4
07-810-5277	5	necklace	clasp	1.377	0.117	2.0	2.8	4.8	33.5	9.6	43.0
07-810-5277	5	necklace		0.476	0.24	4.7	2.0	1.5	12.6	8.2	20.8
07-810-5645	2	ring			0.086						
07-810-5645	3	ring			0.091						
07-810-5645	6	ring				4.6	2.3	4.4		11.3	
07-840-6040	2	ring		0.904	0.043	4.3	2.2	2.5	43.6	9.0	52.6
07-840-6040	3	ring		0.702	0.042	1.6	1.5	2.4	13.5	5.5	19.0

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07-840-6041	2	necklace	pendant	2.857	0.005	0.0	0.0	0.0	1.1	0.0	1.1
07-840-6041	2		chain	2.526	0.006	0.0	0.0	0.0	2.9	0.0	2.9
07-840-6041	6	ring		0.485	0.005	0.0	0.0	0.3	0.0	0.3	0.3
07-840-6042	1	body claps	charm	0.708	0.015	1.0	0.0	0.0	0.6	1.0	1.6
07-840-6042	4	body claps	charm	0.384	0.006	0.3	0.0	0.0	6.4	0.3	6.7
07-840-6042	5	body claps	charm	0.526	0.01	0.0	0.4	0.0	0.0	0.4	0.4
07-840-6137	2	necklace	pendant	2.51		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6137	2	necklace	hook	0.48		0.5	0.3	0.0	0.7	0.8	1.5
07-840-6137	4	necklace	pendant		0.012						
07-840-6137	4	necklace	hook		0.03						
07-840-6137	5	necklace	pendant	2.66		6.7	0.0	0.0	0.0	6.7	6.7
07-840-6137	5	necklace	hook	0.55		0.3	0.0	0.0	0.0	0.0	0.3
07-840-6137	6	necklace	pendant		0.058						
07-840-6137	6	necklace	hook		0.055						
07-840-6138	5	necklace	Pendant	5.3	0.036	10.4	0.0	0.0	0.0	10.4	10.4
07-840-6138	5	necklace	Hook	0.48	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6138	6	necklace	Pendant	5.26	0.036	11.5	0.0	0.0	0.0	11.5	11.5
07-840-6138	6	necklace	Hook	0.5	0.012	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6139	1	charm	charm		0.013						
07-840-6139	2	charm	charm		0.01						
07-840-6139	4	charm	charm	2.34		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6139	5	charm	charm	2.32		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6143	1	necklace	Clasp	0.99	0.009						
07-840-6143	2	necklace	Pendant	0.6342	0.031						
07-840-6143	3	necklace	Pendant			1.1	0.3	0.1		1.4	2.9
07-840-6143	4	necklace	Clasp	0.0985	0.012						
07-840-6143	5	necklace	Pendant	0.6301	0.008						
07-840-6143	7	necklace	Pendant			0.4	0.7	0.1		1.1	2.3
07-840-6143	3,7,2, 5	necklace	4 Clasps			1.0	0.2	0.0		1.1	2.3
07-840-6169	3	necklace	Pendant	2.6156	87.4	357	6054	8620	59429	15031	74461
07-840-6169	4	necklace	Pendant	1.9664	84.3	1610	3038	4132	52938	8780	61717
07-840-6170	3	necklace	Pendant	5.289	0.02	12.4	4.7	2.8	5.4	19.9	25.3
07-840-6170	4	necklace	Pendant	4.851	0.46	2.4	2.1	2.4	71.4	6.9	78.4
07-840-6187	1	necklace	pendant	3.14	0.867	0.0	0.0	0.0		0.0	0.0
07-840-6187	4	necklace	pendant		0.144						
07-840-6187	5	necklace	pendant	2.84		0.0	0.0	0.0		0.0	0.0
07-840-6187	6	necklace	pendant	2.1		4.1	0.9	0.0	0.0	5.0	5.0
07-840-6188	1	necklace	pendant		0.064						
07-840-6188	2	necklace	pendant	1.34		7.2	0.0	0.0	0.0	7.2	7.2
07-840-6188	3	necklace	pendant		0.045						
07-840-6188	4	necklace	pendant	1.64		2.3	0.0	0.0	1.2	2.3	3.5
07-840-6188	6	necklace	pendant	1.3		3.7	0.0	0.0	1.0	3.7	4.7

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07-840-6190	1	necklace	chain		0.007						
07-840-6190	4	necklace	chain		0.013						
07-840-6224	3	Ring necklace	Ring	2.969	0.002	0.0	0.4	0.6	0.0	1.0	1.0
07-840-6224	3	Ring necklace	pendant	2.800	0.008	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6224	5	Ring necklace	Ring	2.946	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6224	5	Ring necklace	pendant	2.885	0.004	0.3	0.0	0.0	0.0	0.3	0.3
07-840-6225	4	necklace	pendant	3.712	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	4	necklace	pendant	3.455	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	6	necklace	pendant	3.525	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6225	6	necklace	pendant	3.544	0.003	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6238	1	necklace	pendant	6.166	91.1	10.4	55.6	75.9	585	142	727
07-840-6238	1	necklace	tear drops	0.474	84.8	228	286	318.	1576	833	2409
07-840-6238	1	necklace	clasp	0.62	88.9	1210	1975	2806	15891	5990	21881
07-840-6238	2	necklace	pendant	5.702	52.5	38.3	75.5	98.7	647	212	859
07-840-6238	2	necklace	tear drops	0.474	84. 7	3.4	0.3	4.6	6921	8.2	6929
07-840-6238	2	necklace	clasp	0.636	85.2	1585	3110	5372	31218	10067	41285
07-840-6320	1	Bracelet	bracelet	5.73	0.128	0.0	0.4	1.0	2.6	1.4	3.9
07-840-6320	2	Bracelet	bracelet	5.57	0.021	0.0	0.0	1.8	3.2	1.8	5.0
07-840-6321	1	Ring	Ring	2.99	0.063	0.0	0.0	0.0	4.7	0.0	4.7
07-840-6321	2	Ring	Ring	3.26	0.063	0.0	0.3	5.5	0.0	5.9	5.9
07-840-6356	2	necklace	charm	3.184	0.021	2.0	1.5	10.0	14.2	13.5	27.7
07-840-6356	2	necklace	clasp	0.35	0.031	2.3	1.7	3.5	0.3	7.4	7.7
07-840-6356	5	necklace	charm	2.901	0.034	3.8	3.5	4.9	12.2	12.2	19.5
07-840-6356	5	necklace	clasp	0.35	0.03	86.1	4.7	3.1	93.9	93.9	94.9
07-840-6357	2	necklace	pendant	2.316	0.005	15.5	0.3	0.7	1.1	16.5	17.6
07-840-6357	5	necklace	pendant	2.281	0.006	1.7	0.0	0.6	0.3	2.3	2.5
07-840-6397	4	Bracelet	hook	0.0988	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	5	Bracelet	hook	0.0974	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	4	Bracelet	chain	0.5115	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6397	5	Bracelet	chain	0.529	0.006	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	chain	0.4098	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	hook	0.0826	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	4	Bracelet	charm	0.8434	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	chain	0.3988	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	hook	0.0919	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6398	6	Bracelet	charm	0.8075	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	chain	0.3781	0.000	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	hook	0.085	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	1	Bracelet	charm	0.5921	0.001	1.4	1.5	3.5	0.0	6.4	6.4
07-840-6399	2	Bracelet	chain	0.361	0.001	0.0	0.0	0.5	0.0	0.5	0.5

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6399	2	Bracelet	hook	0.095	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6399	2	Bracelet	charm	0.573	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	5	Bracelet	hook	0.0925	0.002	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	5	Bracelet	chain	0.542	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	6	Bracelet	hook	0.1001	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6400	6	Bracelet	chain	0.5167	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6401	2	ring	Ring	0.326	0.002	0.2	0.0	0.0	0.0	0.2	0.2
07-840-6401	3	ring	Ring	0.293	0.001	0.3	0.1	0.0	0.0	0.4	0.4
07-840-6402	2	ring	Ring	0.2545	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6402	6	ring	Ring	0.327	0.001	0.0	0.0	0.0	0.0	0.0	0.0
07-840-6411	2	necklace	pendant	1.432	0	0.6	0.2	0.1	0.3	0.8	1.1
07-840-6411	1	necklace	pendant	0.965	0	0.8	0.2	0.4	2.0	1.5	3.5
07-840-6412	1	necklace	pendant	6.958	0	1.6	0.5	0.5	0.7	2.6	3.3
07-840-6412	2	necklace	pendant	11.306	0	7.9	0.3	0.6	1.6	8.9	10.4
07-840-6428	4	ring set	ring 1	1.024	0.218	1.4	0.7	1.1	4.5	3.2	7.7
07-840-6428	4	ring set	ring 3	1.141	0.065	5.0	4.2	0.8	0.8	10.0	10.8
07-840-6428	6	ring set	ring 1	1.296	92.7	14.4	29.0	48.1	255	91.5	346
07-840-6428	6	ring set	ring 3	1.238	0.048	0.6	0.0	0.0	0.9	0.6	1.5
07-840-6429	3	necklace	Pendant	1.493	0.031	0.0	0.0	0.0	0.7	0.0	0.7
07-840-6429	4	necklace	Pendant	1.574	0.03	0.0	0.0	0.0	1.0	0.0	1.0
07-840-6465	1	necklace	Pendant			19.0	37.9	7.5	56.8	64.4	121
07-840-6465	2	necklace	Pendant			4.8	1.6	4.8	6.4	11.2	28.8
07-840-6465	5	necklace	Pendant	7.996	0.062						
07-840-6465	6	necklace	Pendant	8.0217	0.045						
07-840-6466	1	bracelet		850		8.5	0.0	0.0	0.0	8.5	8.5
07-840-6466	3	bracelet			0.006						
07-840-6466	4	bracelet			0.005						
07-840-6466	5	bracelet		867		0.0	0.0	0.0	0.0	0.0	0.0
07-840-6518	1	necklace	pendant	9.317	0.011	1.6	0.0	0.1	0.5	1.7	2.8
07-840-6518	1	necklace	pendant	2.891	0.01	1.1	0.2	0.0	0.2	1.3	1.5
07-840-6518	2	necklace	pendant	9.066	0.008	1.0	1.6	0.5	0.7	3.1	3.8
07-840-6518	2	necklace	pendant	2.845	0.01	0.8	0.3	0.6	0.3	1.7	2.0
07-840-6519	1	mixed	pendant	2.206	0.01	4.2	0.8	0.2	0.2	5.2	5.4
07-840-6519	2	mixed	pendant	2.265	0.01	1.3	0.6	0.2	0.1	2.1	2.2
07-840-6520	1	necklace	pendant	3.261	nd	2.4	0.5	0.6	0.3	3.5	3.8
07-840-6520	1	necklace	pendant	4.183	nd	1.6	0.2	0.0	0.0	1.7	1.7
07-840-6520	2	necklace	pendant	2.503	nd	0.6	0.7	0.0	0.3	1.3	1.6
07-840-6520	2	necklace	pendant	4.238	nd	2.7	0.0	0.2	1.6	2.8	4.4

Sample	Sub	Sample Type	Parts	Weight (grams)	% Pb	µg of Pb extracted				Total Extractable Pb, µg	
						Acid Extraction Time (hour)				1+2+3 = 6	1+2+3+ 18=24
						1	2	3	18		
07-840-6787	1	necklace	charm	10.08	0.023	8.5	0.0	0.0	37.1	8.5	45.6
07-840-6787	1	necklace	clasp	0.39	0.063	2.5	2.5	5.6	23.6	10.6	34.2
07-840-6787	2	necklace	charm	9	0.193	0.0	0.0	0.0	38.9	0.0	38.9
07-840-6787	2	necklace	clasp	0.42	0.066	1.0	1.9	4.0		6.9	6.9
07-840-6788	1	Bracelet	bracelet	4.48	0.028	1.6	0.0	0.0	2.1	1.6	3.6
07-840-6788	2	Bracelet	bracelet	4.54	0.047	0.7	0.0	0.0	1.1	0.7	1.8
07-840-6969	3	necklace	Hook	0.432	67.5	629	1392	3566	8954	5587	14541
07-840-6969	5	necklace	Hook	0.615	52.2	472	1608	3380	10029	5460	15489
07-840-7061	6	Bracelet	charm		88.7	353	734	1165	17474	2252	19726
07-840-7061	6	Bracelet	ring 1		87.2	234	549	1130	13529	1914	15443
07-840-7061	6	Bracelet	ring 2		87.1	63.4	51.8	53.9	2573	169	2742
07-840-7061	6	Bracelet	hook		84.8	874	1696	2291	29050	4860	33910
07-840-7061	6	Bracelet	tear drop		89.9	144	182	239	1277	565	1842
07-840-7061	8	Bracelet	charm		85.4	810	1210	1415	10858	3435	14293
07-840-7061	8	Bracelet	ring 1		89	806	1756	2757	27871	5320	33191
07-840-7061	8	Bracelet	ring 2		84.8	767	1459	1875	16097	4101	20198
07-840-7061	8	Bracelet	hook		86	737	1801	2495	18704	5032	23736
07-840-7061	8	Bracelet	tear drop charm		85.4	226	340	366	1955	931	2887
07-840-7064	21	Bracelet	charm	11.52	89.2	1931	4205	16685	137393	22822	160214
07-840-7064	21	Bracelet	link	2.597	89.3	2223	3300	3869	30166	9292.4	39459
07-840-7064	21	Bracelet	clasp	2.539	91.8	2220	3699	4799	38513	10612	49125
07-840-7064	22	Bracelet	charm	10.015	94.5	2412	6228	13298	109385	21938	131323
07-840-7064	22	Bracelet	link	2.701	87.0	2805	3591	3676	25696	10072	35768
07-840-7064	22	Bracelet	clasp	2.262	94.9	430	5675	7267	39761	13372	53134
07-840-7171	3	ring		5.78	11.9	85.0	114	167	968	366	1334
07-840-7171	5	ring		5.57	6.52	238	288	457	2923	983	3906
07-840-7172	4	necklace	pendant	9.57	1.37	5.8	0.0	0.0	33.3	5.8	39.1
07-840-7172	4	necklace	hook	0.55	88.9	274	459	673	2233	1406	3638
07-840-7172	7	necklace	pendant	8.14	0.50	0.00	0.00	0.00	0.00	0.00	0.00
07-840-7172	7	necklace	hook	0.54	89.3	663	931	1735	9702	3329	13030
07-840-7173	8	ring #1	solder	5.676	13.7	404	572	733	3175	1710	4885
07-840-7173	8	ring Crown	solder	5.626	1.65	130	85	39	230	254	484
07-840-7173	8	ring	ring metal		0.006						
07-840-7174	5	ring		1.559	0.266	764	1023	1572	4862	3358	8220
07-840-7174	5	chain		0.973	0.001	2.8	0.0	0.0	0.0	2.8	2.8
07-840-7174	8	ring		1.589	1.21	690	1198	1872	7281	3759	11041
07-840-7174	8	chain		0.99	0.006	0.7	1.0	0.0	0.0	1.7	1.7

Table 2. Non-Metal Jewelry Results

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-302-0045	1	necklace	cord	PVC	1.68	7.6	3.3	0.039	26.9	14	41
07-302-0046	1	necklace	crystal	crystal		116.9	107.6	23.5			
07-302-0046	1	necklace	crystal	crystal		88	101	17.3			
07-810-4076	2	bracelet		plastic (ABS)		nd	nd				
07-810-4076	2	ring		plastic(ABS)		nd	nd				
07-810-4076	2	hair clip		plastic (ABS)		nd	nd				
07-810-4076	3	false nails		plastic (ABS)		1.3	nd				
07-810-4076	3	ring		plastic (ABS)		nd	nd				
07-810-4076	6	false nails		plastic (ABS)		nd	nd				
07-810-4077	4, 5	Ring		plastic	0.7258	0.283/2.283	0/0.8	0.0013			
07-810-4173	1	necklace	Crystal from pendant	crystal		465	507	13.57			
07-810-4173	2	necklace	Crystal from “diamond” earring	crystal				13.68			
07-810-4294	1		beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	3		beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	5	Ring	beads/stone)	Epoxy Resin		ND	ND				
07-810-4294	5	Ring	beads/stone)	crystal				14.8			
07-810-4294	5	Ring	beads/stone)	Epoxy Resin		ND	ND				
07-810-4654	2	ring		plastic(methyl acrylate) gemstone		nd	nd				
07-810-4711	4	earring	crystal	crystal				0.015			
07-810-4711	5	earring	crystal	crystal				0.051			
07-810-4948	2		Beads(5x)	plastic (PVC)	0.4416	388	361	0.198	2.74	1.82	4.56
07-810-4948	4		Beads(5x)	plastic (PVC)	0.4428	388	361	0.202	4.80	0.24	5.04
07-810-5027	2	necklace	pendant	glass crystal				0.064			
07-810-5027	3	earring		glass crystal		92	65	0.549			
07-810-5027	3	necklace	pendant	glass crystal	0.083				2.6	1.3	3.9
07-810-5034	2	necklace	bead	plastic (ABS) with metal foil		3.5	ND	0.01	0.4	0.8	1.2
07-810-5034	4	necklace	bead	plastic (ABS) with metal foil		6.5	ND	0.014	0.6	0.3	0.9
07-810-5034	5	necklace	green bead	plastic (ABS) with metal foil		3.2	ND	0.014	0.2	0.4	0.6
07-810-5034	5	necklace	gold bead	plastic (ABS) with metal foil		2.8	ND	0.026	0.2	0.2	0.4
07-810-5222	3	necklace	cord	plastic (PVC)	2.45			0.596	85.2	105.1	190.3

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-810-5222	3	necklace	bead	plastic	0.4026				0	0	0
07-810-5222	4	necklace	cord	plastic (PVC)	2.58			0.604	81.1	101.2	182.3
07-810-5222	4	necklace	bead	plastic	0.4205				0	0	0
07-810-5178	4	Choker		crystal	0.0387			12			
07-810-5178	4	Choker	collar	plastic (PVC)		166	202	0.48	298	292	590
07-810-5178	6	Choker		crystal	0.0347			17.2			
07-810-5178	6	Choker	collar	plastic (PVC)				0.83	146	117	262
07-810-5259	2&6	Ring	Pendant	crystal				0			
07-810-5259	2&6	necklace	Pendant	crystal				0			
07-810-5260	2	Ring	bead	crystalline bead				0.035	6.5	1.2	7.7
07-810-5260	2	necklace	bead	crystalline bead				0	22.3	0.9	23.3
07-810-5260	5	Ring	bead	crystalline bead				0.041	22.2	12	34.2
07-810-5260	5	necklace	bead	crystalline bead				0	0	0	0
07-810-5260	2&5	necklace	pendant	crystal				0			
07-810-5261	1	necklace	beads	crystalline bead				0.01	0		0
07-810-5261	4	necklace	beads	crystalline bead				0.018	0		0
07-810-5261	1&4	necklace	butterfly pendant	crystal				0			
07-840-6137	4	necklace	crystal	glass crystal				5.9			
07-840-6137	6	necklace	crystal	glass crystal				7.54			
07-840-6137	**	necklace	crystal	glass crystal	0.0705				0.8	0.4	1.2
07-840-6171	4	necklace	charm	plastic	6.136			0.01	0	0	0
07-840-6171	4	necklace	chain	plastic	13.78			0.01	0	0	0
07-840-6171	8	necklace	charm	plastic	6.167			0.012	0	0	0
07-840-6171	8	necklace	chain	plastic	13.85			0.005	0	0	0
07-840-6172	5	bracelet	bead	plastic	0.474			0.001	0.4	0	0.4
07-840-6172	5	bracelet	battery holder	plastic	0.534			0.008	1.9	1.3	3.2
07-840-6172	8	bracelet	bead	plastic	0.432			0.0004	0.5	0	0.5
07-840-6172	8	bracelet	battery holder	plastic	0.527			0.005	1.2	0.3	1.5
07-840-6189	1	necklace	pendant	plastic PA		nd	nd				
07-840-6190	1	necklace	pendant	plastic PA		nd	nd				
07-840-6220	4	jeans	yellow rhinestone	crystal metal backing		483	360	3.34	30.6	19.8	50.4
07-840-6220	4	jeans	orange rhinestone	crystal metal backing				0.035	23.5	14.5	38
07-840-6220	4	jeans	silver rhinestone	crystal (metal backing)		933	970	10.4	0.5	11.7	12.2

Sample	Sub	Sample Type	Parts	Material	Weight g	* XRF		% Pb	µg Pb 1st 24 hours	µg Pb 2nd 24 hours	Total µg Pb 48 hours
						Pb Lα	Pb Lß				
07-840-6224	1	Ring necklace	Ring	crystal				0.147			
07-840-6224	2	Ring necklace	Ring	crystal				0.146			
07-840-6466	3	bracelet		glass crystal				22.8			
07-840-6466	4	bracelet		glass crystal				25.2			
07-840-6466	***	crystal		glass crystal	0.148				2.4	1.8	4.2
07-840-6519	1	mixed	plastic band	plastic (PVC)	0.787	30.26	28.36	0.102	24.38	5.43	29.81
07-840-6519	2	mixed	plastic band	plastic (PVC)	0.796			0.022	5.86	1.77	7.63
07-840-6970	1	necklace		painted wood		nd	nd				
07-840-7642	3	necklace	coated plastic beads	plastic				0.004	2.8	0	2.8
07-840-7642	4	necklace	coated plastic beads	plastic					11.6	0	11.6

*Note: XRF = x-ray fluorescence spectroscopy. Items were screened using XRF to determine presence of Pb. The analysis done was qualitative, not quantitative although intensity values for Pb La and Lb are related to amount of lead present. nd= not detected

** -4 subs used

***- 12 subs used

PA -Polystyrene Acetonitrile

TAB B: Assessment of Cadmium Migration from Materials

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

Memorandum

Date: June 3, 2010

TO : Kristina Hatlelid, Ph.D., M.P.H.
Toxicologist
Division of Health Sciences

THROUGH: Andrew G. Stadnik, P.E., Associate Executive Director, Directorate for Laboratory Sciences

Joel Recht, Ph.D.
Director, Laboratory Sciences, Division of Chemistry

FROM : Ian A. Elder, Ph.D.
Chemist, Laboratory Sciences, Division of Chemistry

SUBJECT : Assessment of Cadmium Migration from Materials[1]

1.0 EXECUTIVE SUMMARY

In response to concern about cadmium in children's consumer products, the primary goal of this study is to produce data that can be used in determining the public health and clinical significance of exposure to cadmium at levels that may migrate from metal and plastic materials. Study results may be useful with derived exposure limits for acute and chronic cadmium toxicity in the establishment of total cadmium content limits similar to regulations for lead. Products tested for cadmium under the Federal Hazardous Substances Act are currently evaluated for estimates of exposure levels using the time-consuming migration tests described in this memorandum.

The test procedures used in this study were designed to estimate exposure from products like children's jewelry. Migration of cadmium from material surfaces was characterized with solutions that simulate saliva and gastric acid. The study attempted to correlate total cadmium content levels with extractable cadmium within specific material types. For metal-based materials, the study found that product composition factors, such as element content and coatings, have a larger effect on cadmium migration than does total cadmium content. Alloys containing zinc were found to leach less cadmium than those that are free of zinc. Plastics did not leach detectable levels of cadmium.

[1] These comments are those of the CPSC staff, have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

The study plan was also designed to produce information on the accuracy and precision of analytical techniques used by the U.S. Consumer Product Safety Commission (CPSC) staff for measuring cadmium content and migration. The development of efficient concentration-based referral levels for metal products may be complicated by the effect of coatings on x-ray fluorescence (XRF) analyzer accuracy and the effects of coatings and zinc content on soluble cadmium migration.

2.0 SCOPE AND APPLICABILITY

Some children's jewelry products have been found to contain very high levels of cadmium (Ref. 1). There is concern that migration of cadmium from these products may result in exposure to toxic levels of cadmium for the children who use such products. The study described herein examines the accessibility of cadmium in metal and plastic materials containing different levels of cadmium. The cadmium-containing materials include reference standards and children's jewelry products. An understanding of cadmium leach rates may be useful when developing content regulations to ensure that exposures are less than health-based limits. The study also evaluates analytical techniques employed by CPSC staff for the identification of children's products that are likely to contain hazardous levels of accessible cadmium.

Since 2007, CPSC staff has tested a variety of jewelry items for cadmium content and cadmium solubility. Dilute hydrochloric acid (HCl) and saline are used to simulate the leaching expected during the digestion and mouthing of materials, respectively. As confirmed by Figures 1 and 2, staff perception has been that cadmium solubility is highly variable and not necessarily proportional to a material's cadmium concentration (data included in Table 1). It seems reasonable to expect reduced cadmium migration relative to total cadmium content when a base material is coated (e.g., painted or electroplated) with cadmium-free material. Likewise, a coating with cadmium or a cadmium-containing material without such a coating could represent a worst-case scenario. The primary issue this study sought to resolve was whether cadmium solubility is proportional to cadmium content in homogenous materials.

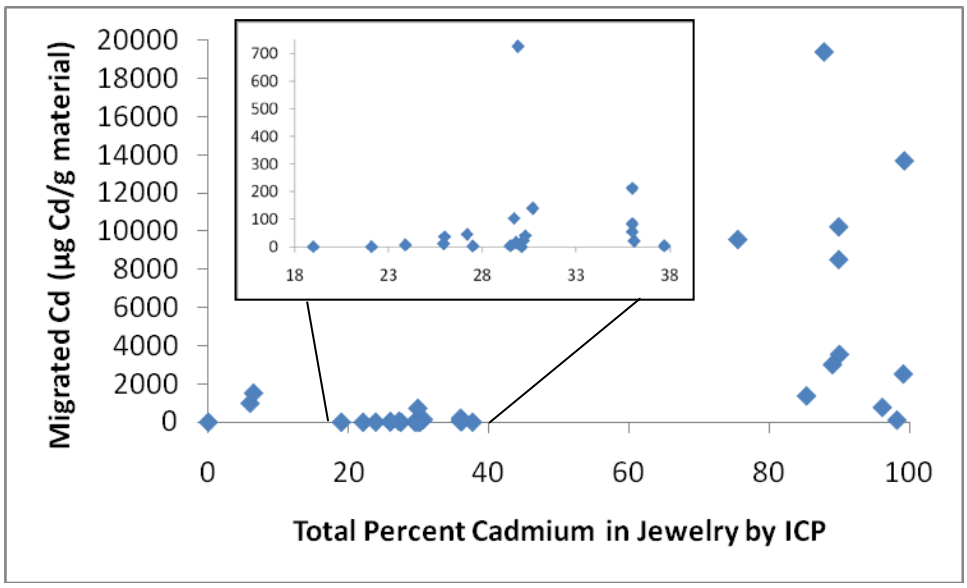

Figure 1. Soluble migrated cadmium from jewelry components with 24 hours of exposure to 0.07N HCl.

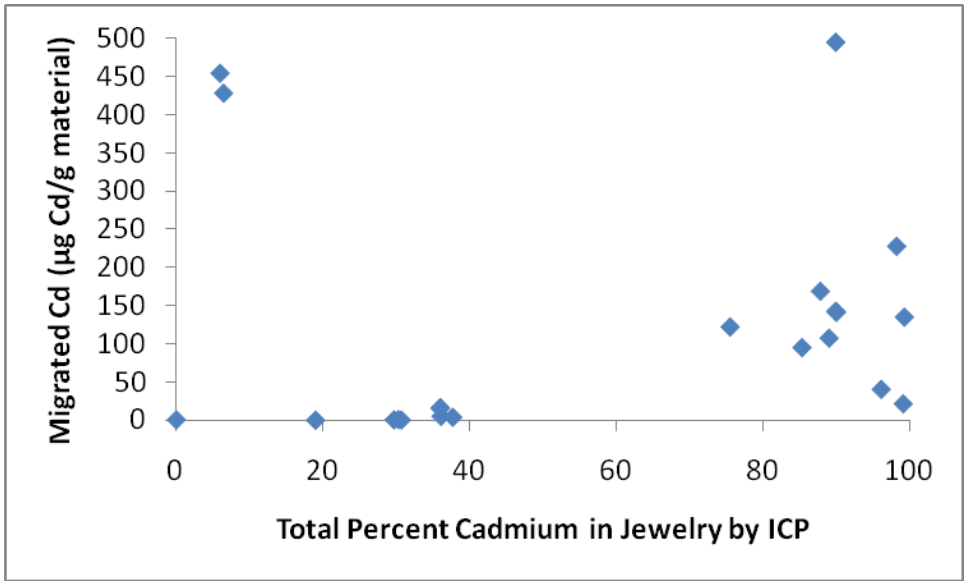

Figure 2. Soluble migrated cadmium from jewelry components with six hours of exposure to 0.9% NaCl.

Table 1. Cadmium Data from Jewelry Analysis

Component	Content by ICP-OES (%)	Content by XRF (%)	Migrated into 0.07N HCl, 24h (µg/g)	Migrated into 0.9% NaCl, 6h (µg/g)
08-302-2601 Charm	1.32	1.16	-	-
08-302-2600 Charm	1.02	0.923	-	-
08-302-2599 Charm	1.35	1.30	-	-
08-302-2598 Charm	1.32	1.04	-	-
08-810-5399 Ball	22.1	-	0.84	-
08-810-5399 Big Tree	23.9	-	7.20	-
08-810-5399 Tree	30.1	-	0.85	-
08-810-5399 Hat	27.5	-	3.04	-
08-810-5399 Stocking	29.5	-	4.08	-
08-840-7192 Globe	37.7	15.4	-	-
08-840-7192 Bird	43.6	13.8	-	-
08-840-7306 Charm	36.0	-	83.3	16.7
08-840-7306 Charm	36.0	-	212	15.5
08-840-7306 Charm	36.0	-	54.8	-
09-810-7596 Hook	33.4	11.3	-	-
09-810-7596 Link	36.2	12.1	-	-
10-302-2023 Clasp	5.98	1.20	988	455
10-302-2023 Flake	98.2	28.4	110	228
10-302-2023 Man	99.1	30.2	2519	21.6
10-302-2024 Clasp	6.47	1.50	1520	429
10-302-2024 Tree	85.3	34.1	1374	95.3
10-302-2024 Cane	96.1	31.7	773	40.6
10-302-2024 Deer	99.3	33.2	13668	135
10-302-2206 Heart	89.9	42.6	10215	495

Table 1 Continued. Cadmium Data from Jewelry Analysis

Component	Content by ICP-OES (%)	Content by XRF (%)	Migrated into 0.07N HCl, 24h (µg/g)	Migrated into 0.9% NaCl, 6h (µg/g)
10-302-2206 Key	0.0285	0.0248	1.21	0.67
10-304-3090 Flower	19.0	12.3	0.72	0.08
10-304-3415 Metal	75.5	27.1	9552	122
10-304-3415 Star	30.3	19.1	40.8	0.88
10-304-3416 Star	30.7	18.2	140	0.35
10-304-3417 Heart	36.1	17.2	21.6	5.23
10-304-3417 U	29.7	13.4	103	0.64
10-304-3418 Heart	37.7	14.7	3.76	3.90
10-304-3418 Crown	30.2	16.3	22.7	-
10-304-3419 Bracelet	87.8	23.7	19362	169
10-304-3420 Bracelet	90.0	34.2	3545	142
10-304-3421 Bracelet	89.9	29.7	8506	143
10-304-3422 Bracelet	89.0	25.4	3008	108
10-304-3815 Pendant	16.0	13.8	-	-
10-304-3816 Pendant	15.4	6.94	-	-
10-304-3817 Pendant	16.4	5.39	-	-
10-304-3818 Pendant	15.6	8.97	-	-
10-810-5600 Tag	29.8	8.11	16.4	-
10-810-5600 Pendant	29.9	15.5	726	-
10-810-5600 Clamp	26.0	9.17	12.3	-
10-810-5601 Tag	27.2	16.2	45.6	-
10-810-5601 Pendant	26.0	18.5	36.5	-

3.0 SUMMARY OF METHOD

3.1 Selection of Test Materials

A brief survey of 20 metal components from 14 children's jewelry products (submitted to the laboratory due to expected cadmium content) found that copper and zinc were the most prevalent metals (Figure 3). Other elements preliminarily identified by XRF include: tin, silver, bismuth, antimony, titanium, nickel, lead, and iron. These elements were present less frequently and at lower concentrations than copper and zinc. A variety of commercially available materials was acquired for use as standards in this study. Metal alloy and plastic standards include materials similar to the substrates and coatings used in the jewelry products described above. Study materials contain a range of cadmium concentrations and, unlike most children's jewelry, the study materials are homogenous. Certificates of chemical analysis are included in the Appendix[2].

A material's surface area is expected to affect its soluble cadmium. In an effort to standardize the exposed area between study alloys, materials were acquired in wire form with diameters of 2.36-2.39 mm whenever possible. Plastics and some alloys were not available with these dimensions, so extractions were also conducted using powdered material. Powdered materials represent a surface area limit that is significantly greater than what is expected for accessible areas on children's products.

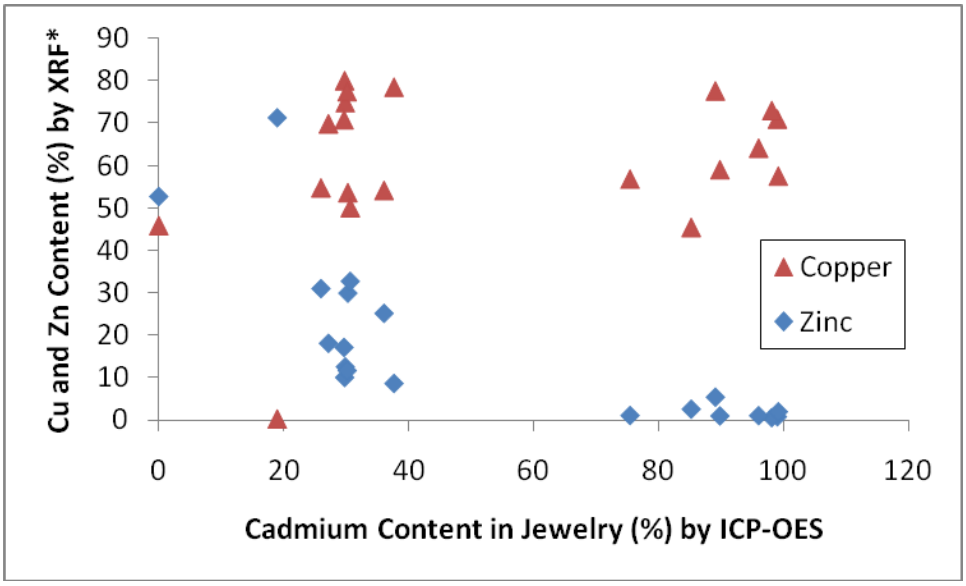

Figure 3. XRF estimates of copper and zinc content in jewelry components. Note, XRF accuracy for copper and zinc have not been determined at CPSC. The values presented above should be considered relative estimates only. As shown elsewhere in this memorandum, cadmium XRF measurements for real-world (inhomogeneous) metal samples generally have poor accuracy.

[2] Manufacturer specific information has been coded and certificates of analyses redacted pursuant to section 6 (b) of the Consumer Product Safety Act.

3.2 Test Material Preparation

Plastic materials and metals purchased in powder form were used without cleaning or sanding. Metal materials received in wire, disc, or bar form were cleaned using standard practices for the preparation of corrosion test specimens (Ref. 2). In brief, the materials were each washed in hexanes, and then sanded with 600-grit silicon carbide abrasive paper. Sanded materials were washed thoroughly with deionized water followed by acetone and then dried with hot air. Powdered metal material was made from cleaned bulk solids with a rotary grinding tool. Plastics purchased in pellet form were ground to powder with a cryogenic mill.

3.3 Data Collection and Handling

The instrumentation and procedures described in this report are routinely used (with adaptations as necessary) by CPSC staff and are similar to those that were used to evaluate the migration of lead from children's products (Ref. 3). Each of the study materials was tested for cadmium content by XRF and inductively coupled plasma-optical emission spectrometry (ICP-OES), and for cadmium migration in saline and dilute acid.

Twelve replicate measurements were made for each determination of cadmium content and for each soluble cadmium migration test of a reference alloy. Measurements that were outside of plus or minus three times the replicate set's standard deviation were not included in calculations of cadmium content, accuracy, and precision data. The final values include a minimum of ten replicate measurements. Measurement precision is illustrated in plots with error bars at plus and minus two times the standard deviation. For plastic materials, cadmium migration was found to be less than the method detection limits, so only six replicate measurements were made. Due to the difficulties involved in quantitatively transferring small portions of material, replicate XRF measurements were not performed for study materials in powder or pellet form.

3.4 Cadmium Screening by Portable X-ray Fluorescence Analysis

XRF measurements were made using a Thermo NITON XL3t XRF Analyzer in either TestAll mode or Alloy mode. Measurement duration was at least 60 seconds. XRF detection limits were estimated for plastics and metals by taking the average of individual detection limits from multiple non-detect measurements. The XRF limit of detection was 2 ppm for plastics and 48 ppm for metals. Non-detect results (i.e., less than the analyzer's limit of detection) are included in tables as "nd". Non-detect results are included in plots as half the limit of detection and are indicated with a black square (■).

3.5 Soluble Cadmium Migration in Saline

Extractions were performed on 0.49-0.51 g portions of plastic pellets, 0.148-0.152 g portions of powders, 3 cm segments of 2.4 mm diameter wires (~ 1 g), and 23 cm segments of 0.8 mm diameter wire (~ 1 g). Samples were weighed and then placed in a 0.9% sodium chloride (NaCl) solution with a volume equal to 50 times the sample weight (e.g., 50 mL saline solution per gram of sample). The extraction occurred over six hours at 37.5 ºC in a shaker bath. Extraction solutions were collected and analyzed by ICP-OES. Samples were diluted further and reanalyzed if cadmium values exceeded 1.5 times the concentration of the high calibration standard. The amount of migrated soluble cadmium was calculated by multiplying the measured concentration by the total dilution volume (e.g., 20 µg/mL x 50 mL = 1,000 µg).

3.6 Soluble Cadmium Migration in Dilute Acid

Extractions were performed on 0.49-0.51 g portions of plastic pellets, 0.148-0.152 g portions of powders, 3 cm segments of 2.4 mm diameter wires (~ 1 g), and 23 cm segments of 0.8 mm diameter wire (~ 1 g). Samples were weighed and then placed in a 0.07 N HCl solution with a volume equal to 50 times the sample weight (e.g., 50 mL acid solution per gram of sample). The extraction occurred at 37.5 ºC in a shaker bath. For wires and plastic pellets, extraction solutions were collected at 6, 24, and 48 hours after the extraction start time (i.e., samples were placed in fresh acid solutions at the 6 and 24 hour time points). For powders, separate sample portions were used for each time point. Extraction solutions were collected from powders using syringe filtration units (0.45 µm). Extraction solutions were analyzed by ICP-OES. Samples were diluted further and reanalyzed if cadmium values exceeded 1.5 times the concentration of the high calibration standard. The amount of migrated soluble cadmium was calculated by multiplying the measured concentration by the total dilution volume (e.g., 20 µg/mL x 50 mL = 1,000 µg). For metal wires and plastic pellets, the 24 hour-cumulative soluble cadmium was calculated by summing the cadmium extracted over the initial six hours and the subsequent 18 hours. The 48-hour value is the sum of measurements taken at the three time points.

3.7 Sample Preparation for Total Cadmium Content

Samples were digested following standard operating procedures for determining total lead in children's products (Ref. 3). Metals were digested by the hot block method and plastics were digested using a microwave digestion system.

3.8 ICP-OES Calibration and Analysis

Calibration standards were prepared at 0.00, 0.10, 0.25, 0.50, 1.00, 5.00, 10.0 and 20.0 µg/mL by the dilution of a 1,000 µg/mL cadmium standard (SCP Science, Champlain NY; Cat# 140-051-480). A quality control standard was prepared at 0.50 µg/mL by the dilution of a 100 µg/mL multi-element standard (SPEX CertiPrep, Metuchen NJ; Cat# CL-QC-21). An internal standard solution of 2 µg/mL yttrium in

2% nitric acid was prepared using a 1,000 µg/mL standard (SPEX CertiPrep, Metuchen NJ; Cat# PLY2-2Y). Standards, blanks, and samples were analyzed on a Varian VISTA-MPX CCD Simultaneous ICP-OES system (plasma flow: 15.0 L/min; nebulizer flow: 0.75 L/min; pump speed: 20 rpm; auxiliary gas flow: 1.5 L/min; cadmium wavelength: 214.439 nm; yttrium wavelength: 324.228 nm; power: 1.20 kW; and replicates: 3). The 0-20 µg/mL calibration curves had correlation coefficients greater than 0.9990 with less than 5% error for the quality control standard. Samples with on-instrument concentrations less than 5 µg/mL were measured using a calibration range of 0-5 µg/mL. All other samples were evaluated against the full calibration range.

ICP-OES instrument detection limits were determined for each method by multiplying three times the standard deviation of seven replicate measurements of reagent blanks. Method detection limits for ICP-OES were determined using reagent blanks fortified with 2-3 times the instrument detection limits. The method detection limits were calculated as follows: MDL = t x S, t=3.14 (99% confidence level for 7 replicates), S = standard deviation. The instrument and method detection limits are included in Table 2. Non-detection ICP-OES measurements (i.e., less than the method detection limit) are listed in tables as “nd”. Non-detect results are included in plots using estimated ICP values equal to half of the method detection limit. Non-detect data points are indicated in plots with a black square (■).

Table 2. Instrument and Method Detection Limits for ICP-OES

Method	**Instrument Detection Limit (µg/mL)**	**Method Detection Limit (µg/mL)**
Cadmium Content in Plastic	0.005	0.009
Total Cadmium in Metal	0.010	0.042
Acid Extraction of Cadmium	0.001	0.045
Saline Extraction of Cadmium	0.001	0.001

4.0 RESULTS AND DISCUSSION

4.1 Characterization of Materials and Analytical Techniques

Figure 4 compares XRF and ICP-OES measurements for cadmium content in jewelry samples tested at CPSC (data included in Table 1). XRF measurements for cadmium in jewelry have significantly greater error than what is seen with homogenous alloys (Figure 5-C). In general, the relative error was found to increase with cadmium content (Panel 4-B). Figures 5-A and B demonstrate agreement between manufacturer certificates of analysis for metals and cadmium content measurements made at CPSC by ICP-OES and XRF. Panel 5-C shows good correlation between ICP-OES and XRF. Figure 6-A shows moderate agreement between vendor-certified cadmium levels and ICP-OES measurements for plastic test materials. Panels 6-B and C indicate that XRF readings did not agree very well with either the certificates of analysis or ICP-OES measurements. XRF measurements of cadmium in polyvinyl chloride standards were significantly lower than expected.

Precision and accuracy information for cadmium measurements are included in Tables 3 and 4 for metals and plastics, respectively. Accuracy was evaluated with comparisons of XRF and ICP-OES cadmium content measurements to vendor-certified values (also see Figures 5 and 6). The precision of replicate measurements was determined as the relative standard deviation for each material available in wire or pellet form. Relatively good accuracy and precision was obtained with ICP-OES for most alloy materials. The precision of XRF readings for alloys was also good but the accuracy was off by more than 5% for half of the metals. While the accuracy and precision of ICP-OES analysis for plastic materials was acceptable, XRF measurements could be classified as having moderate to poor accuracy.

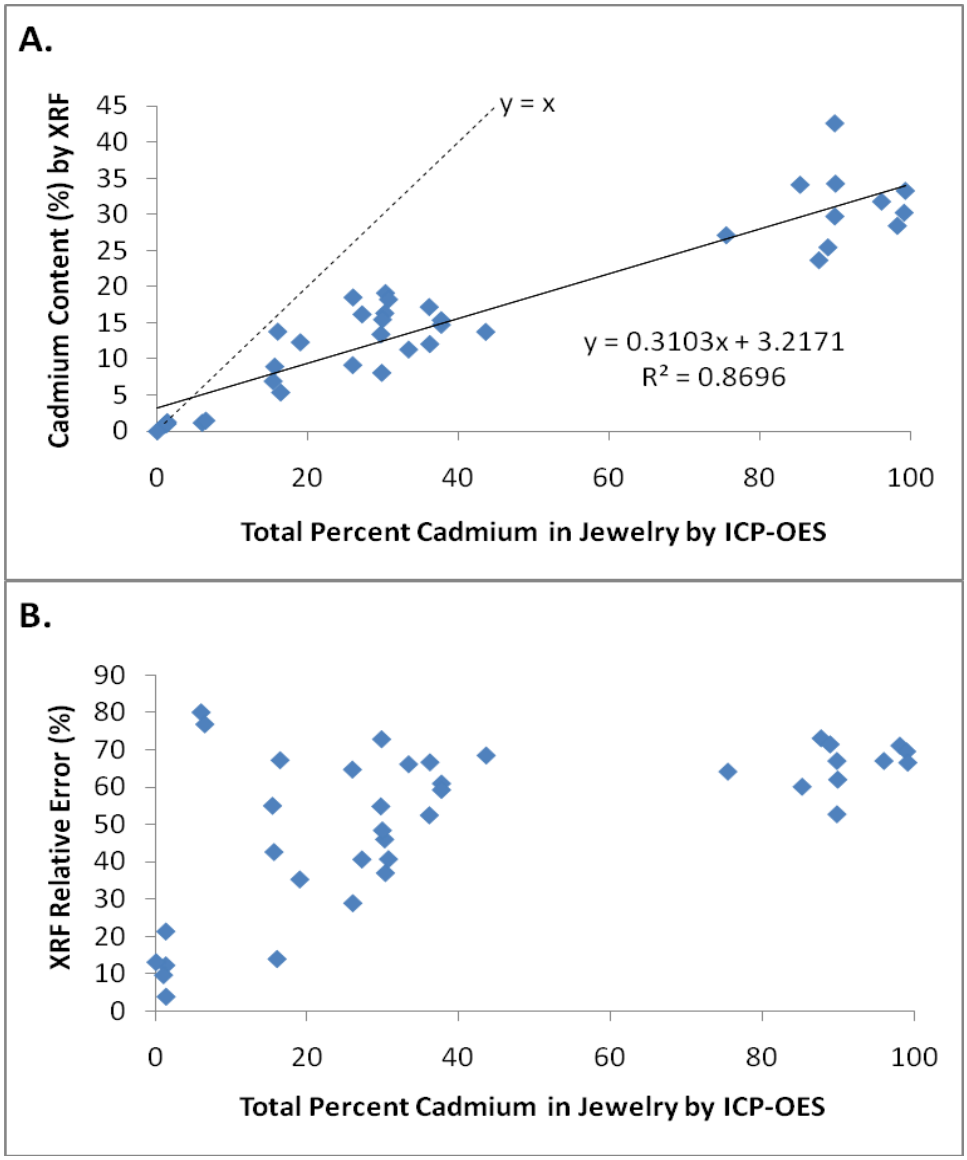

Figure 4. Effect of coatings on XRF accuracy (compare with Figure 5 for homogenous materials). Panel A: XRF and ICP-OES cadmium measurements for jewelry components. Panel B: Relative error of XRF measurements compared to ICP-OES measurements (relative error = -(XRF concentration-ICP concentration)/ICP concentration x 100).

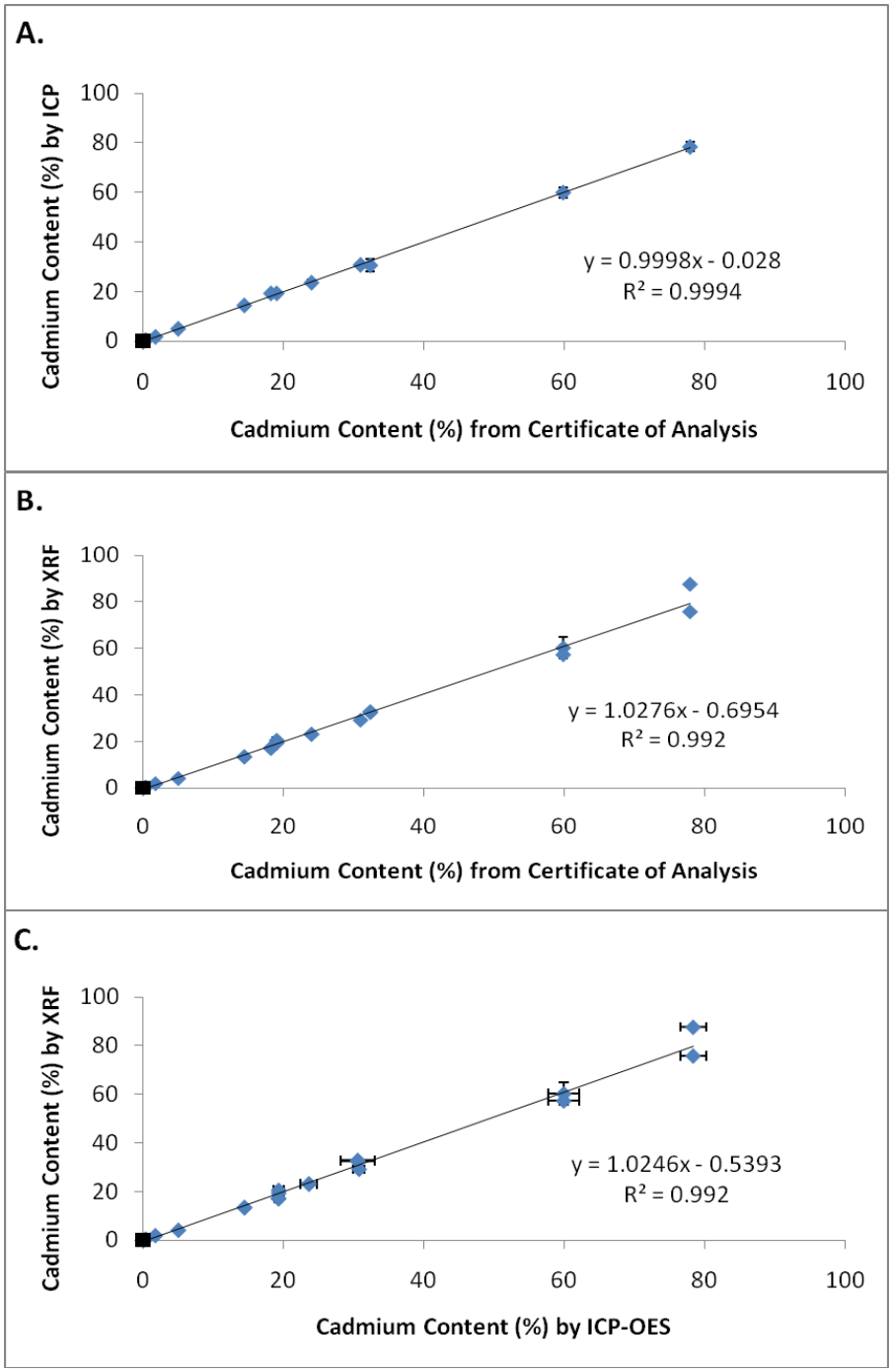

Figure 5. Confirmation of vendor-certified cadmium levels in metal test materials by ICP-OES (Panel A) and XRF (Panel B) analysis. Panel C shows a linear relationship between ICP-OES and XRF measurements. Note: plots contain XRF measurements for both wires and powders.

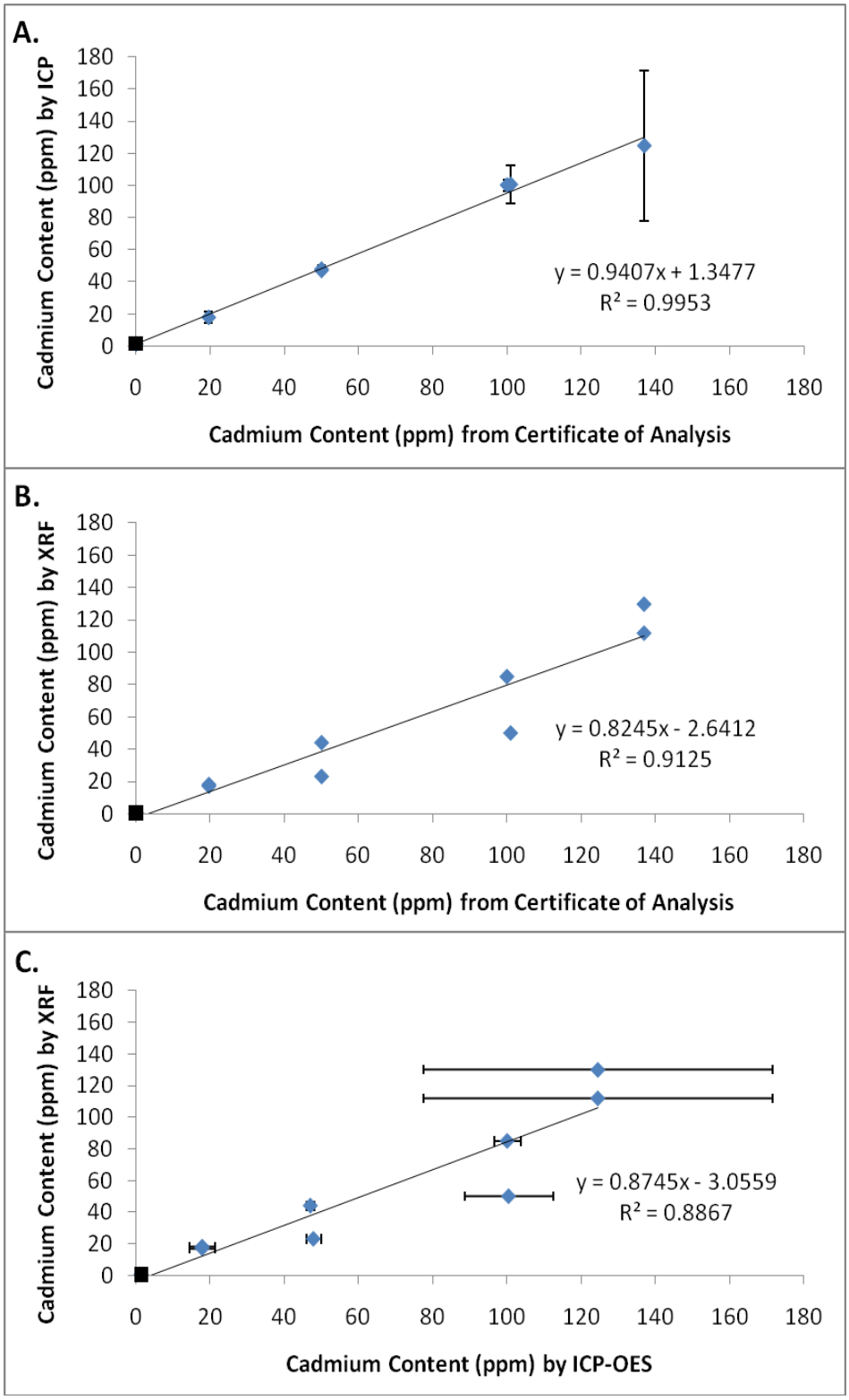

Figure 6. Confirmation of vendor-certified cadmium levels in plastic test materials by ICP-OES (Panel A). Panels B and C show XRF readings are low compared to certificates of analysis and ICP measurements. Note: plots contain XRF measurements for both pellets and powders.

Table 3. Analysis of Cadmium Content in Metal Test Materials.

		ICP-OES				XRF			
Material	**Certificate of Analysis (%)**	**Mean (%)**	**Standard Deviation (%)**	**RSD (%)**	**Recovery (%)***	**Mean (%)**	**Standard Deviation (%)****	**RSD (%)****	**Recovery (%)***
M001 Wire	32.398	30.601	1.213	4.0	94	32.456	0.047	0.1	100
M001 Powder	32.398	-	-	-	-	32.875	-	-	101
M002 Wire	59.92	59.99	1.09	1.8	100	60.27	2.27	3.8	100
M002 Powder	59.92	-	-	-	-	57.33	-	-	96
M003 Wire	19.042	19.322	0.382	2.0	101	20.588	0.507	2.5	108
M003 Powder	19.042	-	-	-	-	19.378	-	-	102
SRM 629 Powder	0.0155	0.0185	0.0028	15.1	119	nd***	-	-	N/A
SRM 683 Powder	0.00011	nd	N/A	N/A	N/A	nd	-	-	N/A
SRM 1129 Powder	0.006	0.006	0.000	0.9	100	nd	-	-	N/A
M004 Wire	14.42	14.44	0.10	0.7	100	13.36	0.18	1.4	93
M004 Powder	14.42	-	-	-	-	13.54	-	-	94
M005 Wire	18.22	19.30	0.26	1.3	106	17.02	0.36	2.1	93
M005 Powder	18.22	-	-	-	-	17.28	-	-	95
M006 Wire	24.01	23.63	0.56	2.4	98	23.13	0.19	0.8	96
M006 Powder	24.01	-	-	-	-	23.17	-	-	96
M007 Wire	78.01	78.44	0.95	1.2	100	87.65	0.38	0.4	112
M007 Powder	78.01	-	-	-	-	75.82	-	-	97
M008 Wire	< 0.01	0.02	0.00	3.9	N/A	nd	-	-	N/A
M008 Powder	< 0.01	-	-	-	-	nd	-	-	N/A
M009 Powder	31.0	30.8	0.40	1.3	99	29.2	-	-	94
M010Powder	1.75	1.73	0.02	1.3	99	1.90	-	-	108
M011Powder	4.99	5.02	0.04	0.9	101	4.10	-	-	82
M012 Powder	0.33	0.34	0.00	0.7	103	0.35	-	-	107
M013 Powder	0.37	0.38	0.00	0.5	103	0.40	-	-	108

* Percent recovery was calculated using cadmium concentrations reported in certificates of analysis.

** A single XRF measurement was taken for powders so standard deviation and relative standard deviation data are not available.

*** nd = non-detect.

Table 4. Analysis of Cadmium Content in Plastic Test Materials.

		ICP-OES				XRF	
Material	**Certificate of Analysis (ppm)**	**Mean (ppm)**	**Standard Deviation (ppm)**	**RSD (%)**	**Recovery (%)***	**Mean (ppm)**	**Recovery (%)***
PVC001 Sample 1	0	nd**	N/A	N/A	N/A	nd	N/A
PVC001 Sample 2	50	48	1	2.1	96	23	46
PVC001 Sample 3	101	100	6	6.0	99	50	50
PE001 Sample 1	0	nd	N/A	N/A	N/A	nd	N/A
PE001 Sample 2	50	47	0.5	1.1	94	44	88
PE001 Sample 3	100	100	2	1.8	100	85	85
ERM-EC680k Pellet	19.6	17.9	1.7	9.5	91	18	92
ERM-EC680k Powder	19.6	17.9	-	-	-	17	87
ERM-EC681k Pellet	137	125	24	19	91	130	95
ERM-EC681k Powder	137	125	-	-	-	112	82

* Percent recovery was calculated using cadmium concentrations reported in certificates of analysis.

** nd = non-detect.

4.2 Soluble Cadmium Migration

Tables 5 and 6 include data for soluble cadmium migration from metals into dilute acid and saline, respectively. All measurements of soluble cadmium migration from plastics were less than the method detection limits. Figures 7 and 8 illustrate the migration of cadmium over time from metal wires and powders, respectively. Substantially different behavior is seen for the materials, including comparisons between alloys. Interestingly, the amount of migrated cadmium decreased over time for some powdered alloys. This effect was not observed for any of the samples in wire form. The decrease in migrated cadmium over time seems to be more prevalent in powders containing high levels of zinc (32-93%), with the exception of NIST SRM 1129 which contains only 0.006% cadmium and no documented zinc. The observed effect could come from differences in the test procedures for wire and powder samples. For wires, extract solutions were removed at each time point and the samples were placed in fresh solution. Extract solutions were not filtered prior to analysis. The cumulative soluble migrated cadmium for the 24-hour time point is the sum of measurements from the initial 6-hour extraction and subsequent 18-hour extraction. The 48-hour value is the sum of measurements from all three time points. For powders, different sets of materials were used for each time point (i.e., test materials remained exposed to extract solutions for full 6, 24, and 48-hour periods). Extract solutions were filtered away from powder samples using 0.45 μm syringe filter units. Filtration may have removed suspended cadmium precipitates.

No soluble cadmium was detected in saline or acid extract solutions for plastic study materials. The plastics contained low cadmium concentrations compared to most of the metals examined in the study. Plastic standards with high cadmium content were not commercially available. The plastic cadmium content levels are comparable to those in the NIST alloy materials and M008. It may be worthwhile to survey cadmium-containing plastic products to ensure that cadmium content and migration data from study plastics are representative of real-world products.

Figures 9-A and B show the amount of cadmium leached from metal wires and powders containing different levels of cadmium after 48 hours of exposure to dilute acid. Migrated cadmium was not proportional to cadmium content. This suggests that alloy composition and/or other material properties play a role in accessible cadmium. Figures 10-A and B show measurements of cadmium leached from metal wires and powders using a saline solution. In general, materials that produce elevated levels of migrated cadmium in saline also produce elevated levels in dilute acid (Figure 11).

Figure 12 illustrates the apparent effect of zinc on soluble cadmium migration from alloys. Plotting levels of migrated cadmium against the concentration of elements present in many of the test materials indicates an apparent trend with respect to zinc content. Panel A shows that cadmium migration into dilute acid decreased rapidly as zinc content increased, regardless of cadmium content. Panels B and C separate alloy powders into groups based on elemental composition. Materials high in zinc had relatively low migrated cadmium. Alloy materials with intermediate levels of zinc

plus intermediate levels of silver and copper were found to produce moderate levels of migrated cadmium compared to materials with little or no zinc.

As seen in Figures 1, 2, 9, and 10, soluble cadmium migration is not proportional to total cadmium content. This is due to variable composition and the presence of coatings (e.g., paint, electroplating) on many commercial products. Since surface properties are important factors in both XRF measurements and soluble cadmium migration, plots were made to look for a relationship between the two parameters. A linear correlation would be useful for predicting cadmium exposure risk using only the XRF data collected in the field. However, as seen in Figure 13, the overall data pattern is much like that in Figures 1 and 2, with cadmium concentrations shifted to lower values. This result is not unexpected when one considers the moderately good correlation seen in Figure 4-A and the relative error shown in Figure 4-B.

Table 5. Migration of Soluble Cadmium from Metals into 0.07N Hydrochloric Acid.

	6h Migrated Cadmium			24h Migrated Cadmium			48h Migrated Cadmium		
Material	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**
M001 Wire	1449.8	101.46	7.00	5148.8	542.91	10.54	9944.6	1215.3	12.22
M001 Powder	17791	7754.8	43.59	47789	16538	34.61	59997	21940	36.57
M002 Wire	nd*	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M002 Powder	2807.4	2638.2	93.97	785.91	1316.0	167.45	76.25	128.01	167.90
M003 Wire	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M003 Powder	57.94	22.76	39.29	44.63	36.46	81.70	25.30	13.16	52.02
SRM 629 Powder	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
SRM 683 Powder	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
SRM 1129 Powder	24.51	0.53	2.18	23.64	5.12	21.65	24.68	0.22	0.91
M004 Wire	86.35	7.92	9.18	319.73	39.29	12.29	753.13	77.69	10.32
M004 Powder	1712.4	78.09	4.56	3065.1	324.65	10.59	3302.1	366.95	11.11
M005 Wire	25.59	2.18	8.53	84.54	4.82	5.71	160.79	7.42	4.62
M005 Powder	1267.1	119.27	9.41	2156.7	203.58	9.44	3311.0	263.29	7.95
M006 Wire	52.31	5.69	10.87	136.54	13.43	9.84	231.70	19.52	8.43
M006 Powder	1772.2	199.64	11.27	4481.4	217.03	4.84	7474.4	213.07	2.85
M007 Wire	1137.5	35.34	3.11	3493.2	195.60	5.60	5269.0	364.17	6.91
M007 Powder	13695	1964.8	14.35	12407	2852.0	22.99	17176	4487.4	26.13
M008 Wire	nd	N/A	N/A	nd	N/A	N/A	nd	N/A	N/A
M008 Powder	4.26	1.43	33.49	9.21	3.12	33.89	11.76	2.70	22.94
M009 Powder	606.09	130.99	21.61	425.95	80.48	18.89	469.76	149.78	31.88
M010Powder	8457.5	339.22	4.01	9669.4	184.08	1.90	9721.2	381.83	3.93
M011Powder	1593.2	451.52	28.34	3509.3	646.65	18.43	4859.4	1016.3	20.91
M012 Powder	532.58	82.08	15.41	1059.0	59.17	5.59	1355.2	54.35	4.01
M013 Powder	674.82	50.90	7.54	1326.1	82.04	6.19	1844.9	56.99	3.09

* nd = non-detect.

Table 6. Migration of Soluble Cadmium from Metals into 0.9% Saline.

	6h Migrated Cadmium		
Metal Material	**Mean (µg/g)**	**Standard Deviation (µg/g)**	**%RSD**
M001 Wire	55.21	4.40	7.96
M001 Powder	286.70	60.75	21.19
M002 Wire	nd*	N/A	N/A
M002 Powder	64.30	18.12	28.17
M003 Wire	nd	N/A	N/A
M003 Powder	59.29	17.53	29.57
SRM 629 Powder	nd	N/A	N/A
SRM 683 Powder	nd	N/A	N/A
SRM 1129 Powder	3.42	0.30	8.76
M004 Wire	25.47	1.92	7.53
M005 Powder	140.91	20.71	14.70
M006 Wire	4.08	1.20	29.44
M006 Powder	152.93	23.05	15.07
M007 Wire	168.83	23.44	13.88
M007 Powder	165.81	23.54	14.20
M008 Wire	nd	N/A	N/A
M008 Powder	0.59	0.56	94.97
M009 Powder	63.12	12.92	20.48
M010Powder	284.74	15.98	5.61
M011Powder	128.89	32.33	25.09
M012 Powder	11.28	1.31	11.59
M013 Powder	6.44	1.33	20.60

* nd=non-detect.

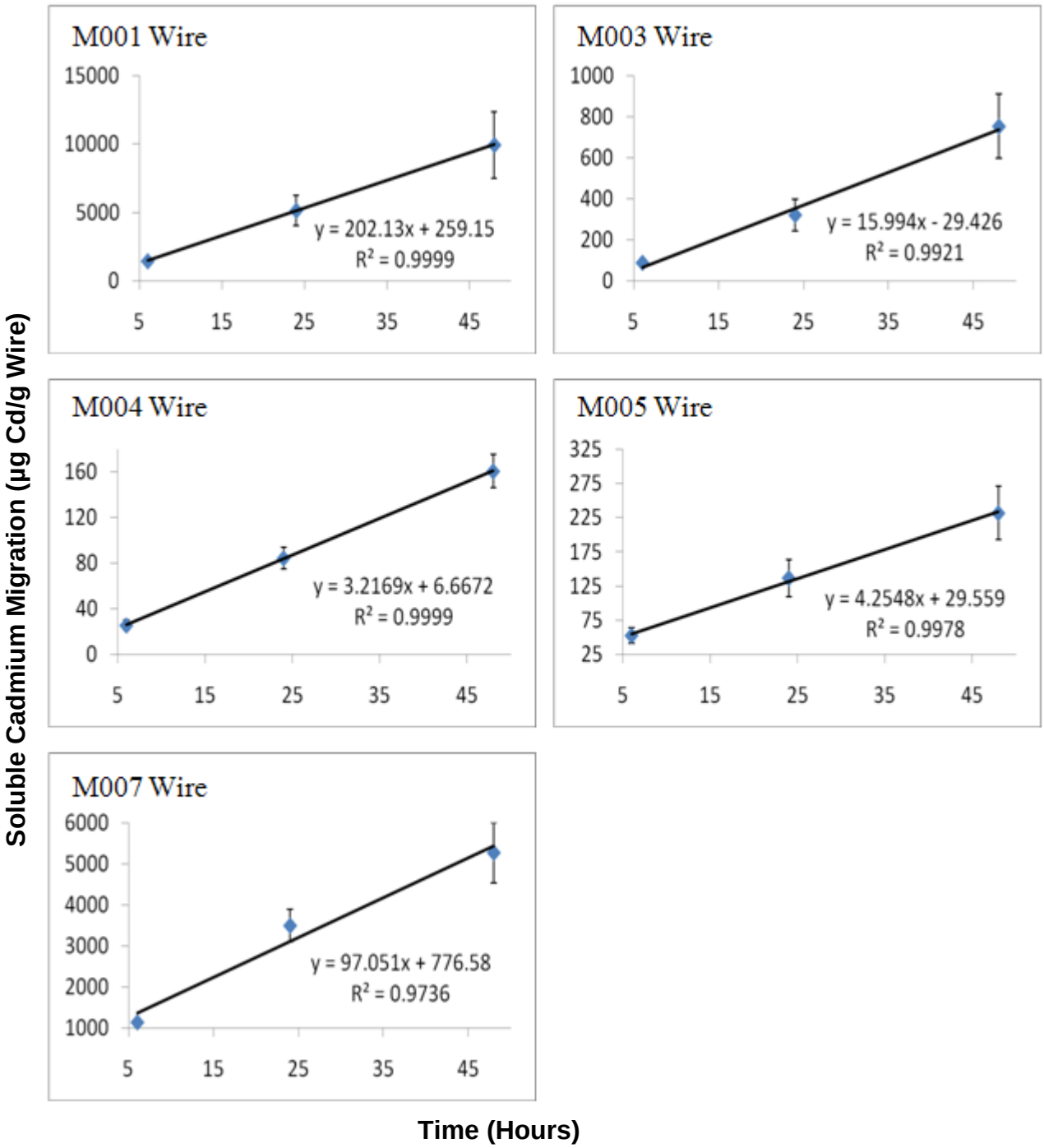

Figure 7. Cummulative cadmium migration from wires over 6, 24, and 48 hours. Measurements taken at the 24 and 48 hour timepoints were summed with values from previous timepoints.

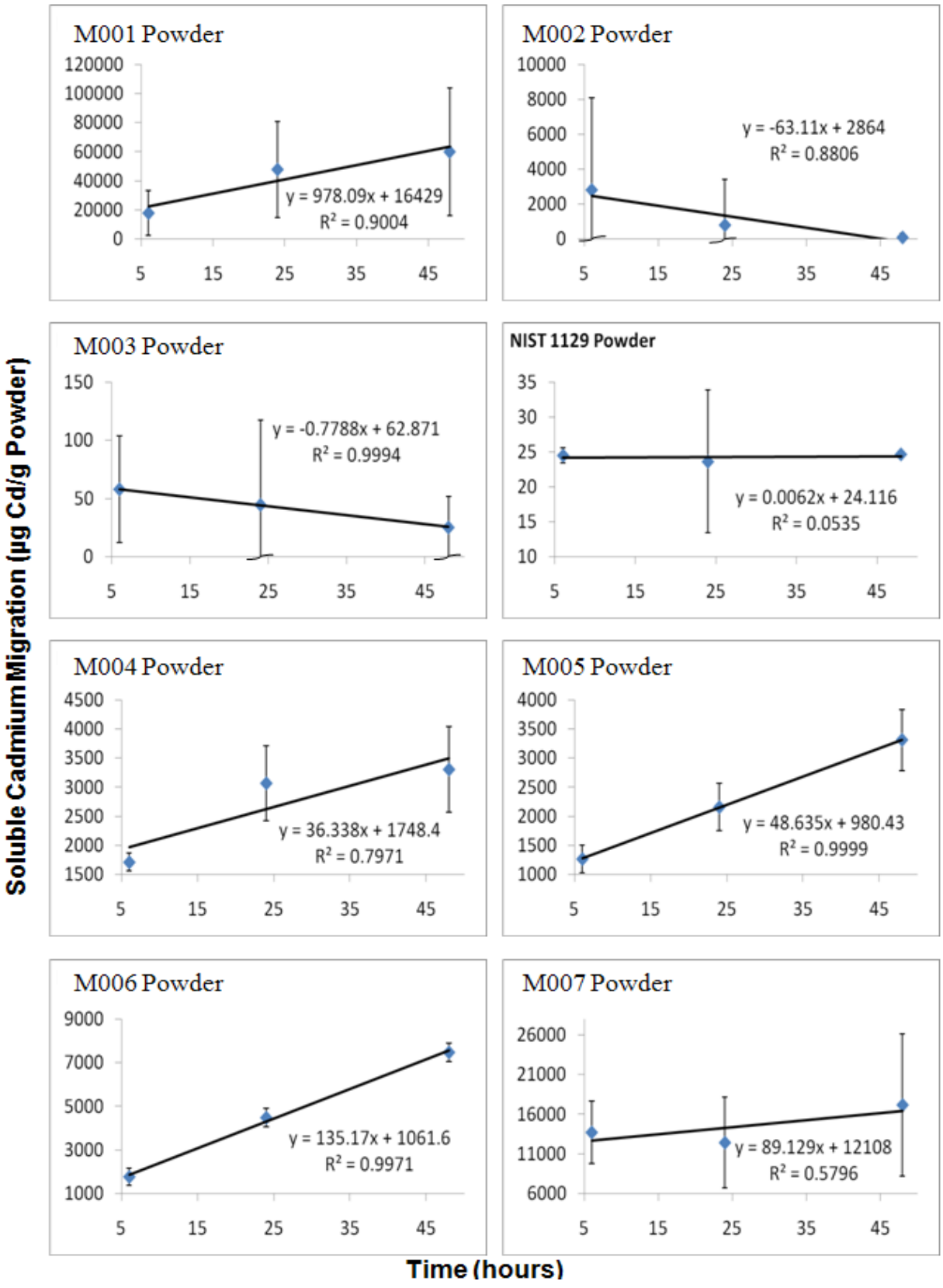

Figure 8. Cadmium migration from metal powder after 6, 24, and 48 hours. Each point is from a unique set of powders (i.e. values are not cummulative as with wires).

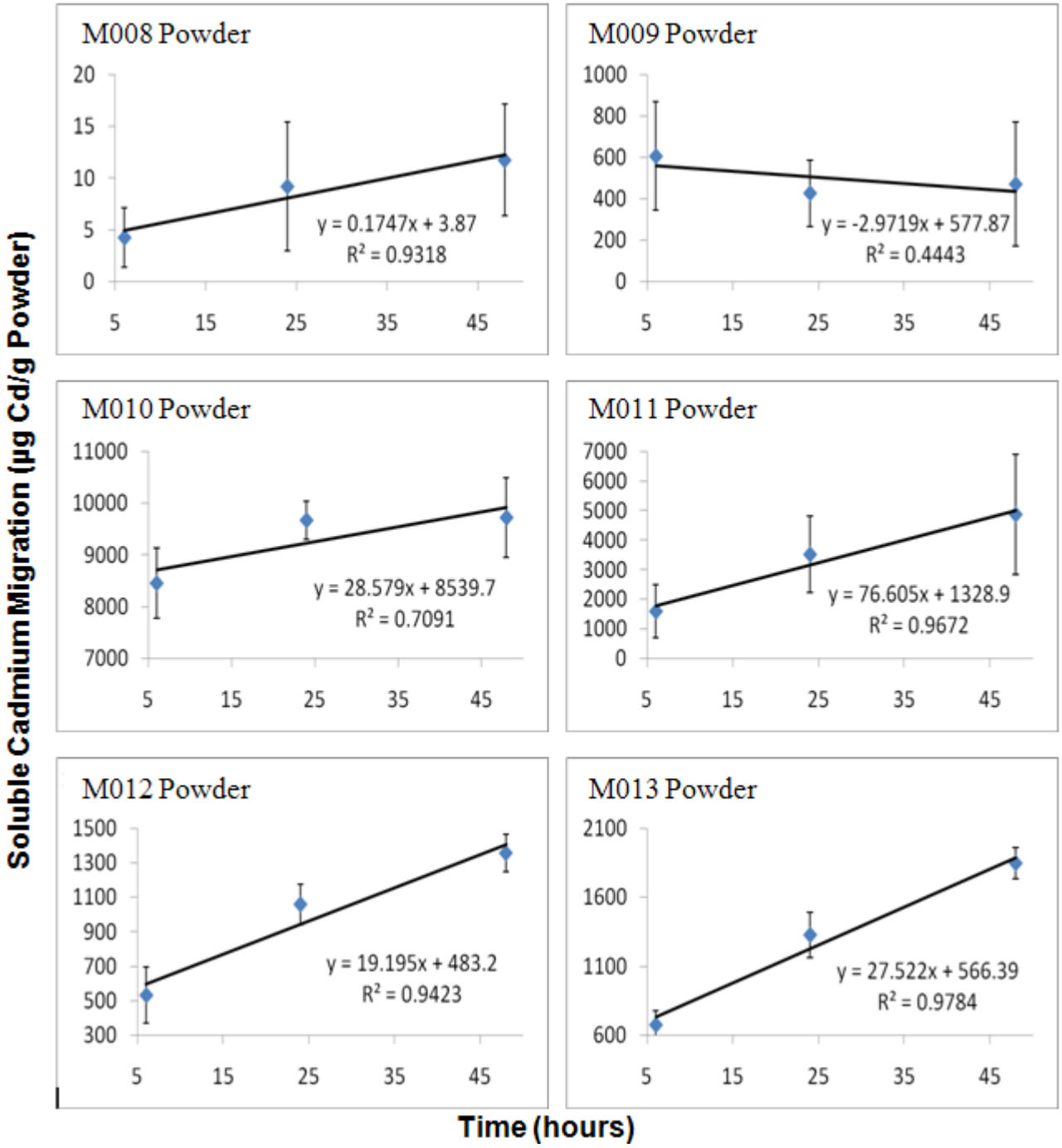

Figure 8 (Continued). Cadmium migration from metal powder after 6, 24, and 48 hours. Each point is from a unique set of powders (i.e. values are not cummulative as with wires).

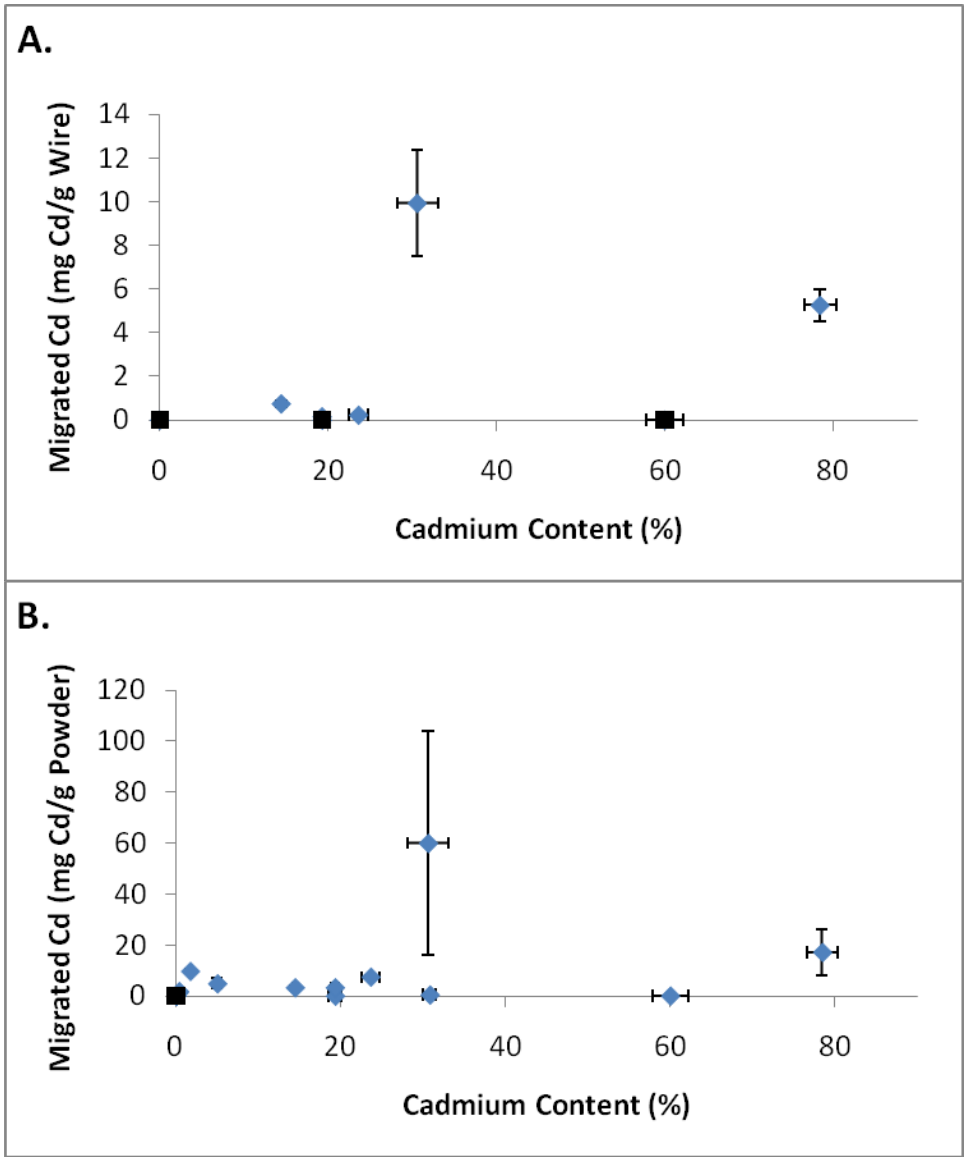

Figure 9. Cadmium leached from metal wires (Panel A) and powders (Panel B) containing different levels of cadmium after 48 hours of exposure to 0.07N HCl.

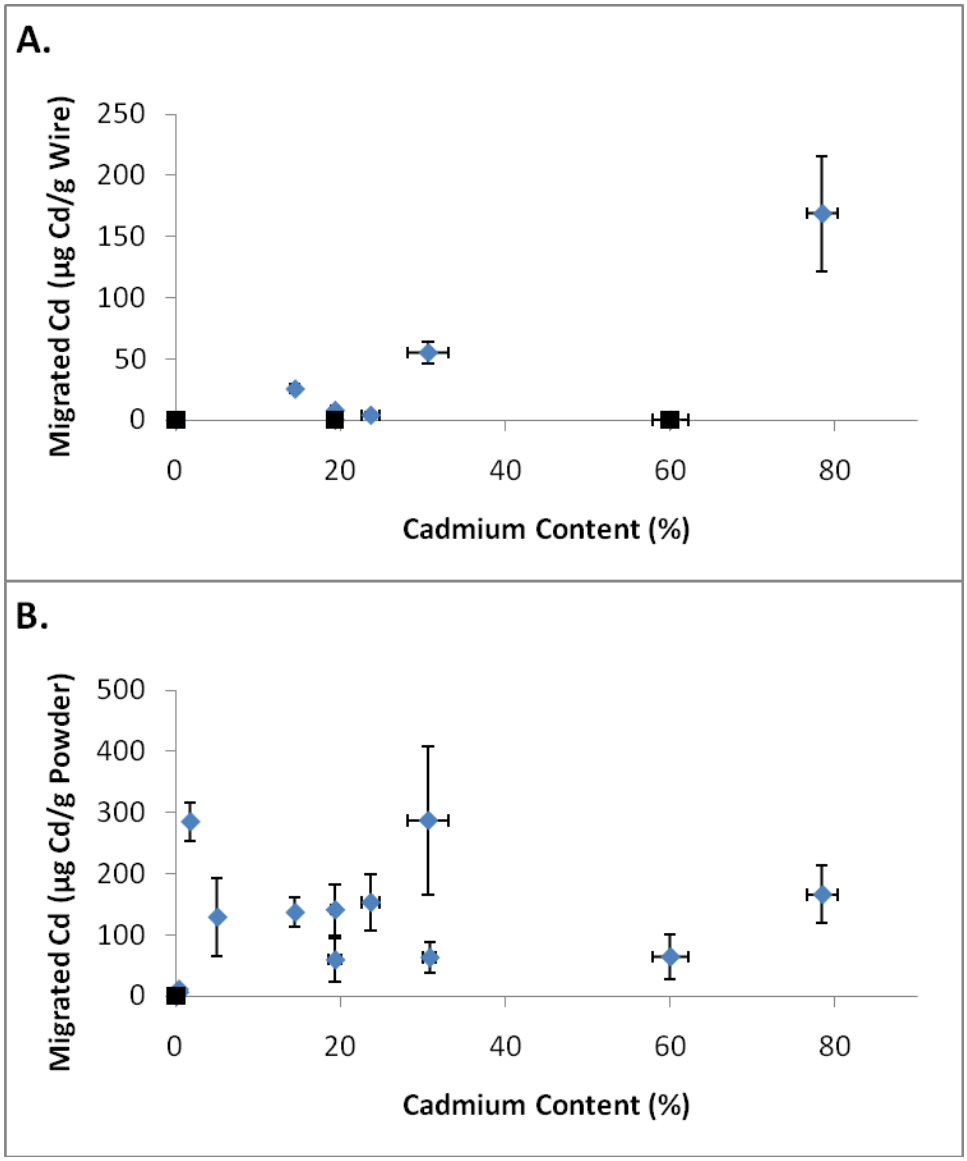

Figure 10. Cadmium leached from metal wires (Panel A) and powders (Panel B) containing different levels of cadmium after 6 hours of exposure to 0.9% NaCl.

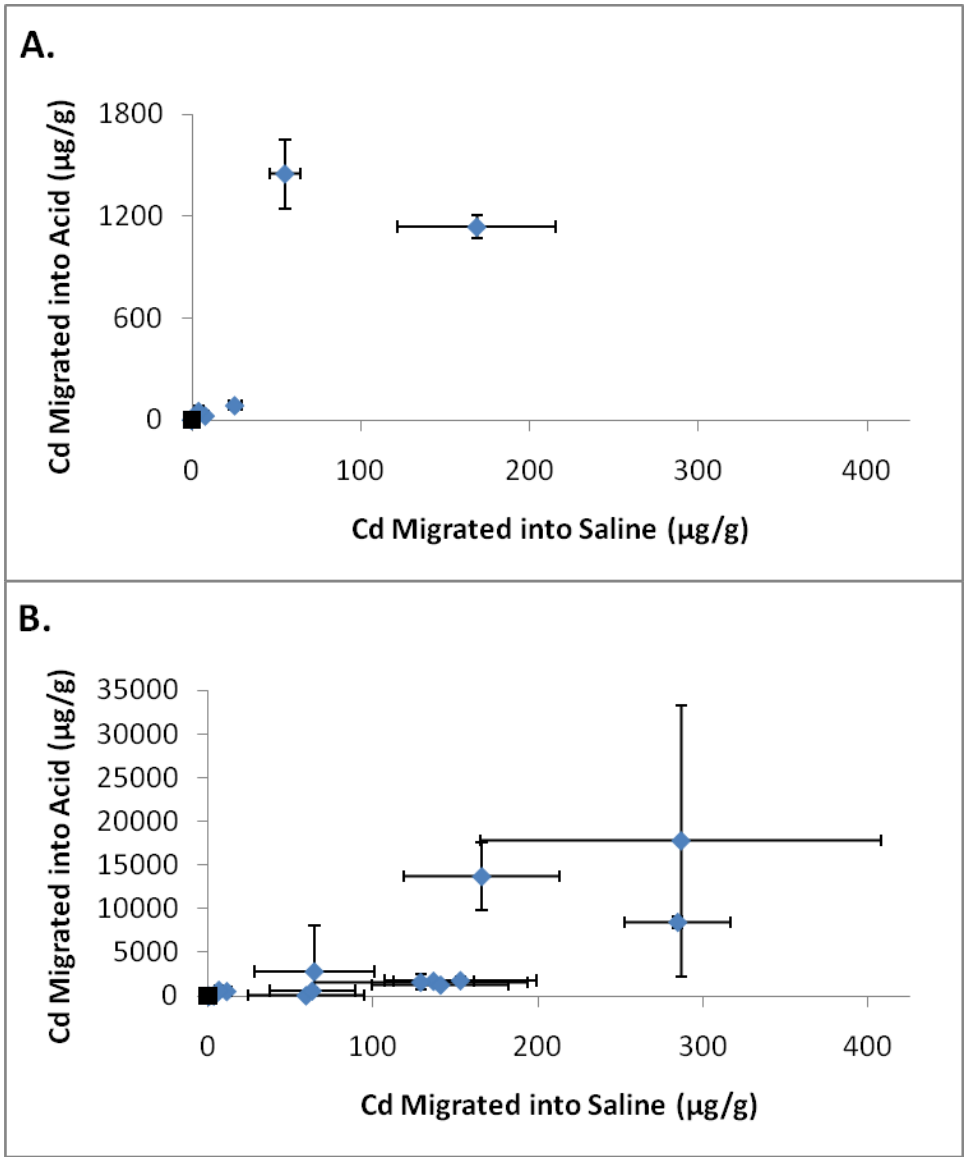

Figure 11. Comparisons of cadmium migration from alloys into dilute acid and saline over 6 hours. Panel A includes study wires and Panel B includes powder.

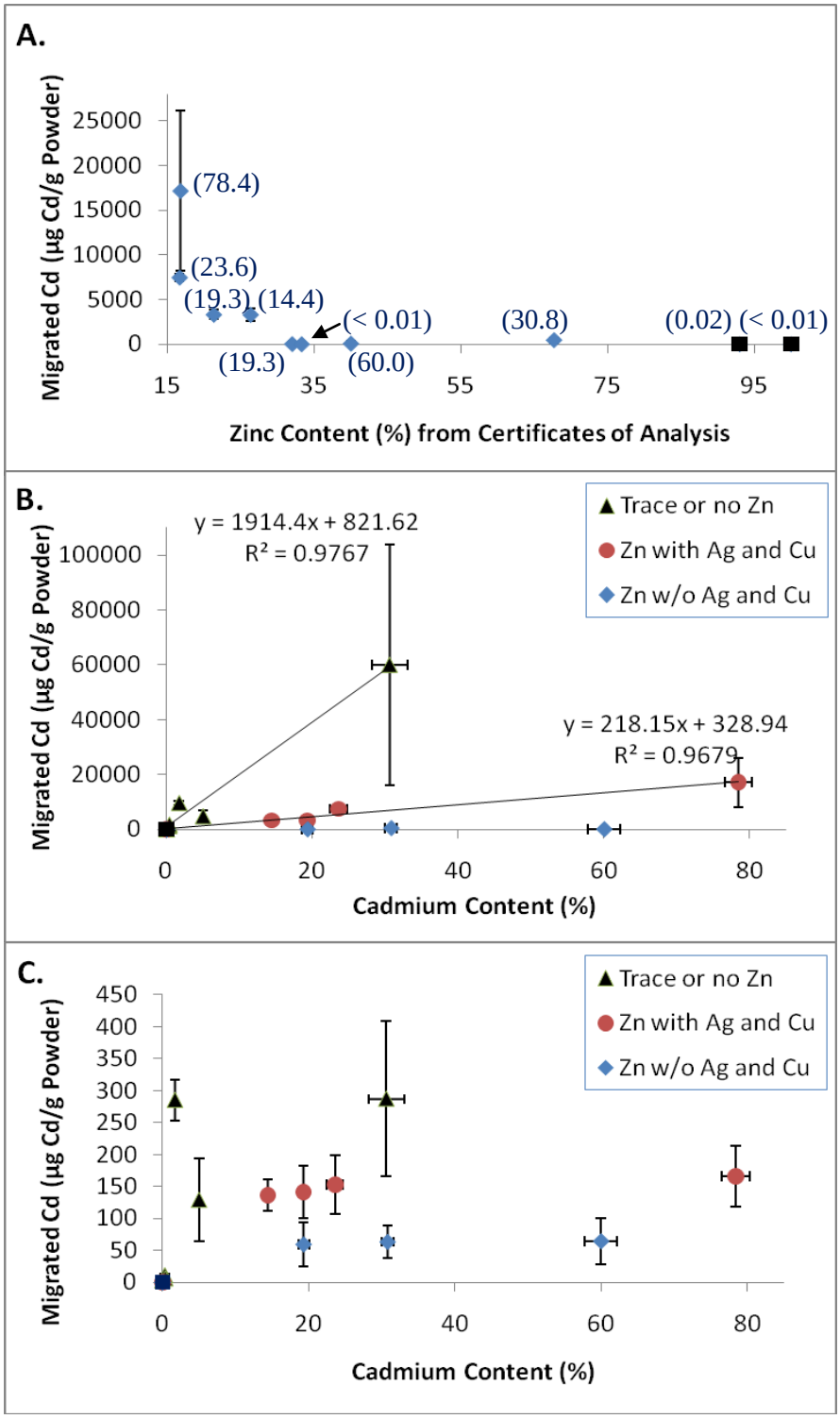

Figure 12. Effect of zinc on cadmium migration from alloy powders. Panel A: Cadmium migration into dilute acid (48h) as a function of zinc content. Cadmium content (%) is in parentheses. Panel B: Effect of alloy composition on 48h cadmium migration into dilute acid (-●-: 16-33% Zn with 5-67% Cu and/or Ag; -♦-: 32-93% Zn with ≤1.5% Cu and Ag). Panel C: Effect of alloy composition on cadmium migration into saline.

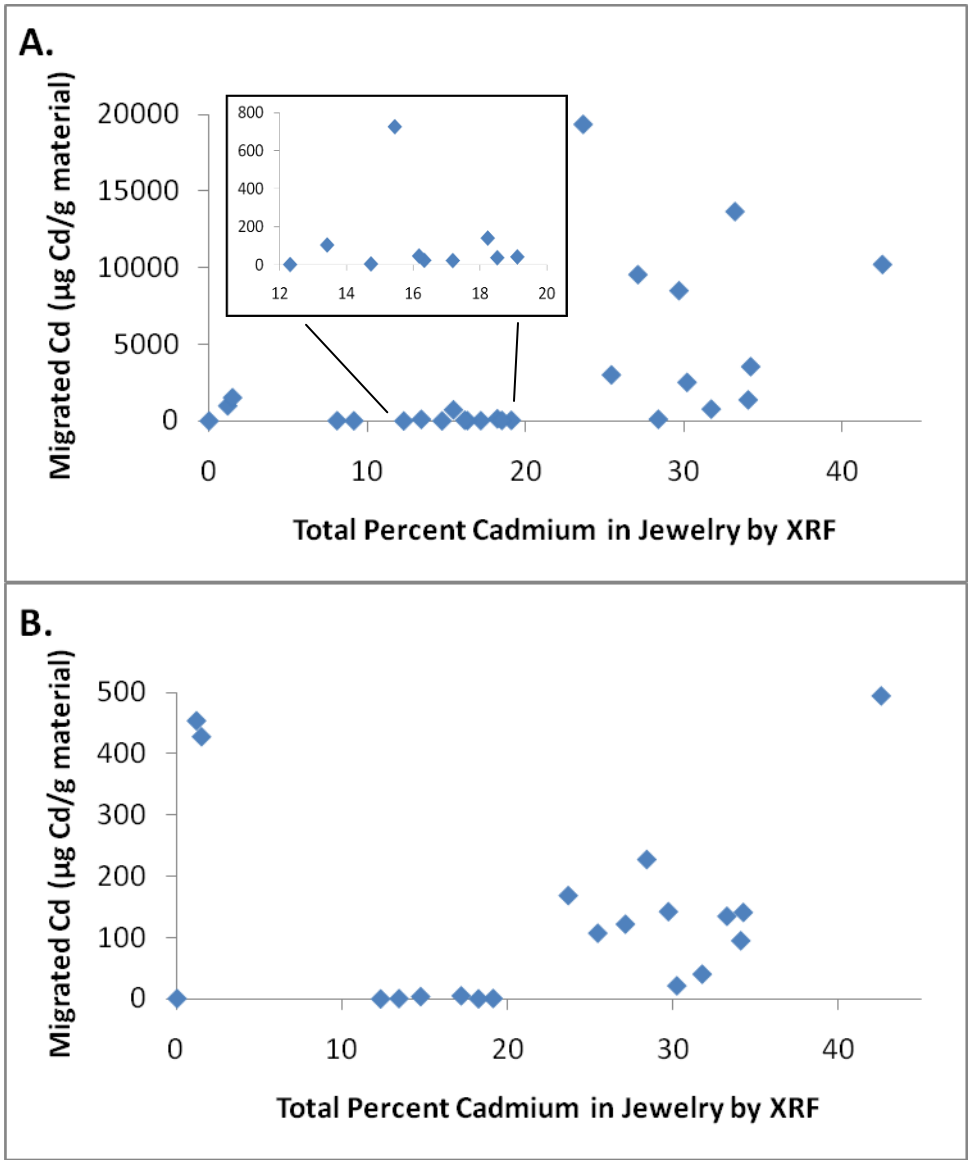

Figure 13. Soluble migrated cadmium from jewelry compared to cadmium content measurements by XRF. Panel A: Cadmium migrated into 0.07N HCl over 24 hours. Panel B: Cadmium migrated into 0.9% NaCl over 6 hours.

5.0 CONCLUSIONS

The primary goal of this study was to characterize the migration of cadmium from a variety of metal and plastic materials. The study found that soluble cadmium migration is not generally proportional to cadmium content. For alloys, product composition factors such as element content and coatings have a larger effect on cadmium migration than does total cadmium content. The presence of zinc reduces cadmium migration, and the addition of co-alloyed elements such as silver and copper, seems to mitigate zinc's effect. No detectable cadmium was found to migrate from plastic materials.

Efforts to define regulatory limits of total cadmium concentration based on cadmium migration tests may be complicated by coatings and the alloy effects associated with zinc. While one cadmium-containing metal (either as a coating or coating-free material) can have high cadmium migration, another metal with similar cadmium content may not yield hazardous levels of soluble cadmium for a variety of reasons (e.g., elemental content, coating type, coating thickness).

A secondary goal of this study was to provide accuracy and precision information for cadmium tests performed at CPSC. This information may be useful when adjusting field-XRF sample referral levels for products that require laboratory analysis. While agreement between XRF and ICP-OES cadmium content measurements for homogenous alloy materials was good (Figure 5-C), the relative error for XRF measurements in real-world (inhomogeneous) samples (Figure 4) ranged from -1 to -80%. As seen in Figure 4-A, a cadmium XRF reading of 20% could relate to a 30-85% total cadmium measurement by ICP-OES. This error can be attributed to the common use of coatings (e.g., paint, electroplating). No linear relationship was observed between XRF cadmium measurements and cadmium migration from jewelry samples. For these reasons, plus the apparent effect of zinc content on cadmium accessibility, the development of efficient concentration-based referral limits would be difficult. Even jewelry with relatively low XRF readings for cadmium can yield relatively high levels of soluble migrated cadmium (Figure 13).

6.0 REFERENCES

1. a) United States Consumer Product Safety Commission. “FAF Inc. Recalls Children's Necklaces Sold Exclusively at Walmart Stores Due to High Levels of Cadmium,” http://www.cpsc.gov/cpscpub/prerel/prhtml10/10127.html, 2010; b) United States Consumer Product Safety Commission. “CPSC Issues Warning on Children’s Winter and Holiday-Themed Charm Bracelets with High Levels of Cadmium,” http://www.cpsc.gov/cpscpub/prerel/prhtml10/10162.html, 2010; c) United States Consumer Product Safety Commission. “Claire's Recalls Children's Metal Charm Bracelets Due to High Levels of Cadmium,” http://www.cpsc.gov/cpscpub/prerel/prhtml10/10227.html, 2010.
2. a) “Standard Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens,” ASTM G 1 – 90, American Society for Testing and Materials, 1999; b) “Standard Guide for Conducting Corrosion Tests in Field Applications,” ASTM G 4 – 01, American Society for Testing and Materials, 2008.
3. a) United States Consumer Product Safety Commission. “Standard Operating Procedure for Determining Total Lead (Pb) in Children’s Metal Products (Including Children’s Metal Jewelry),” http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08.pdf, 2008; b) United States Consumer Product Safety Commission. “Standard Operating Procedure for Determining Total Lead (Pb) in Non-Metal Children’s Products,” http://www.cpsc.gov/about/cpsia/CPSC-CH-E1002-08.pdf, 2009; c) United States Consumer Product Safety Commission. “Standard Operating Procedure for Determining Lead (Pb) and Its Availability in Children’s Metal Jewelry,” http://www.cpsc.gov/businfo/pbjeweltest.pdf, 2005.

APPENDIX

Certificates of Analysis

Institute for Reference Materials and Measurements

ERM European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- EC680k

LOW DENSITY POLYETHYLENE		
	Mass Fraction	
	Certified value [1] [mg/kg]	Uncertainty [2] [mg/kg]
As	4.1	0.5
Br	96	4
Cd	19.6	1.4
Cl	102.2	3.0
Cr	20.2	1.1
Hg	4.64	0.20
Pb	13.6	0.5
S	76	4
Sb	10.1	1.6

1) Unweighted mean value of the means of 5-14 accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The value is traceable to the International System of Units (SI).
2) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) with a coverage factor k = 2.78 for Cr and k = 2 for all other elements, corresponding to a level of confidence of about 95 %.

This certificate is valid for one year after purchase.

Sales date:

The minimum amount of sample to be used is 150 mg.

NOTE

European Reference Material ERM®-EC680k was produced and certified under the responsibility of the IRMM according to the principles laid down in the technical guidelines of the European Reference Materials® co-operation agreement between BAM-IRMM-LGC. Information on these guidelines is available on the internet (http://www.erm-crm.org).

Accepted as an ERM®, Geel, May 2007

Signed:

Prof. Dr. Hendrik Emons
Unit for Reference Materials
EC-DG JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

Institute for Reference Materials and Measurements

ERM European Reference Materials

CERTIFICATE OF ANALYSIS

ERM®- EC681k

LOW DENSITY POLYETHYLENE			
	Mass Fraction		
	Certified value [1]	Uncertainty [2]	Unit
As	29.1	1.8	mg/kg
Br	0.77	0.04	g/kg
Cd	137	4	mg/kg
Cl	0.80	0.05	g/kg
Cr	100	5	mg/kg
Hg	23.7	0.8	mg/kg
Pb	98	6	mg/kg
S	0.63	0.04	g/kg
Sb	99	6	mg/kg

1) Unweighted mean value of the means of 5-14 accepted sets of data, each set being obtained in a different laboratory and/or with a different method of determination. The value is traceable to the International System of Units (SI).
2) The certified uncertainty is the expanded uncertainty estimated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) with a coverage factor k = 2.78 for Cr and k = 2 for all other elements, corresponding to a level of confidence of about 95 %.

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Accepted as an ERM®, Geel, May 2007

Signed:

Prof. Dr. Hendrik Emons
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EC-DG JRC-IRMM
Retieseweg 111
2440 Geel, Belgium

National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material® 629

Spectrographic Zinc-Base Die-Casting Alloy E

This Standard Reference Material (SRM) is intended primarily for evaluating chemical and instrumental methods of analysis of zinc-base die-casting alloys. SRM 629 is one of a series of reference materials (SRMs 625 through 630) for this purpose. A unit of SRM 629 consists of a bar segment approximately 44 mm square and 19 mm thick. The metallurgical condition is that resulting from a continuous chill casting process.

Certified Values: The certified values for 11 elements are listed in Table 1. The test methods used for certification are listed in Table 2. All values are reported as mass fractions [1] calculated as the unweighted mean of the mean values from the individual laboratories. The uncertainty listed with each value is an expanded uncertainty (approximately 95 % confidence level [2]) the standard deviation of the mean of means and calculated in accordance with the method in ISO and NIST Guides [3].

Table 1. Certified Values with Expanded Uncertainties

Element	Mass Fraction (%)	Element	Mass Fraction (%)
Aluminum	5.15 ± 0.05	Magnesium	0.094 ± 0.003
Cadmium	0.0155 ± 0.0021	Manganese	0.0017 ± 0.0002
Chromium	0.0008 ± 0.0003	Nickel	0.0075 ± 0.0004
Copper	1.50 ± 0.01	Silicon	0.078 ± 0.003
Iron	0.017 ± 0.004	Tin	0.012 ± 0.001
Lead	0.0135 ± 0.0014		

Expiration of Certification: The certification of this SRM is valid indefinitely provided the SRM is handled and stored in accordance with the instructions given in this certificate. However, the certification will be nullified if the SRM is damaged or otherwise altered. NIST will monitor this material and will report any significant changes in certification to the purchaser. Registration (see attached sheet) will facilitate notification.

The overall direction and coordination of the technical measurements leading to certification of this SRM were performed by R.E. Michaelis of the National Bureau of Standards (NBS) Spectrographic Standards Laboratory and R.K. Bell of the NBS Nonferrous Laboratory.

The support aspects involved in the issuance of this SRM were coordinated through the NIST Measurement Services Division.

Stephen A. Wise, Chief
Analytical Chemistry Division

Gaithersburg, MD 20899
Certificate Date: 20 September 2005
See Certificate Revision History on Last Page

Robert L. Watters, Jr., Chief
Measurement Services Division

National Bureau of Standards

Certificate of Analysis

Standard Reference Material 683

Zinc Metal

This Standard Reference Material (SRM) is intended for the calibration of instruments and the evaluation of chemical methods used in the analysis of zinc materials. SRM 683 is in the form of a semicircular bar segment, 57 mm diameter (2 1/4 inch), 25.4 mm (1 inch) deep at mid-diameter and 19 mm long (3/4 inch).

Element[1]	Recommended Value (ppm by wt.)	Range of Values Reported[2] (ppm by wt.)	Method of Analysis[3]
Lead	11.1	[9.6 - 11.3]	a,b
Copper	5.9	[5.3 - 6.1]	a,b
Iron	2.2	[1.7 - 3.1]	b,c
Silver	1.3	[1.0 - 1.4]	a,d
Cadmium	1.1	[1.0 - 1.2]	a,b
Thallium	(0.2)[4]	[0.17 - 0.18]	a
Tin	(0.02)	[0.013 - 0.023]	a

[1] Additional elements were sought by neutron activation. The following elements were not detected and are reported with an estimated upper limit of detection in parts per million by weight:

As (<0.002)	Mn (<0.2)	Sc (<0.003)
Ga (<.0002)	Mo (<.02)	V (<.005)
In (<.02)	Rh (<.3)	W (<.0001)

Potassium was not detected by either flame emission spectroscopy or by neutron activation at the 0.2 ppm level.

Aluminum, antimony, and sodium were detected by several techniques. The results were variable, but in no case are these elements present in concentrations greater than 3 ppm. Gold appears to be 0.02 ppm.

[2] The range of values reported is the extreme variation of the individual results reported by the methods of analysis used. The recommended value is based on considerations of the estimated systematic bias of each of the methods employed. From 7 to 13 individual determinations were made for each element certified.

[3] a. Spark-Source Mass Spectrometry - Isotope Dilution (R. Alvarez and P. Paulsen)
b. Polarography (E.J. Maienthal)
c. Spectrophotometry (E.R. Deardorff)
d. Neutron Activation Analysis (B.A. Thompson and D.A. Becker)

[4] Values in parentheses are not certified as only one method of analysis was used. They are provided for information only.

Gaithersburg, MD 20899
January 15, 1988
(Revision of certificates
dated 7-9-68 & 10-1-81)

Stanley D. Rasberry, Chief
Office of Standard Reference Materials

(over)

National Institute of Standards & Technology

Certificate of Analysis

Standard Reference Material 1129

Solder

(63Sn - 37Pb)

(In Cooperation with the American Society for Testing and Materials)

This Standard Reference Material (SRM) is in the form of atomized powder and sized between 75 and 45 micrometers (200 and 325 mesh size sieves) respectively. It is intended for use in chemical methods of analysis.

Element	Percent by Weight[1]	Estimated Uncertainty[2]
Tin	62.7	0.1
Antimony	0.13	.01
Arsenic	.055	.005
Bismuth	.13	.01
Cadmium	.006	.001
Copper	.16	.01
Nickel	.010	.002
Silver	.075	.005
Gold	.0175	.0005

[1] The certified value listed for a constituent is the present best estimate of the "true" value based on the results of the cooperative program for certification.

[2] The estimated uncertainty listed for a constituent is based on judgment and represents an evaluation of the combined effects of method imprecision, possible systematic errors among methods, and material variability. No attempt was made to derive exact statistical measures of imprecision because several methods were involved in the determination of most constituents.

The overall direction and coordination of the technical measurements leading to certification were performed under the direction of J.I. Shultz, Research Associate, ASTM/NIST Research Associate Program.

The technical and support aspects involved in the preparation, certification, and issuance of this Standard Reference Material were coordinated through the Office of Standard Reference Materials by W.P. Reed and R.L. McKenzie.

May 8, 1989
Gaithersburg, MD 20899

Stanley D. Rasberry, Chief
Office of Standard Reference Materials

(over)