Risk Assessment of Metals in Consumer Products Intended for Children

Wade, M., Sciullo, E., Day, K., Sarala, R., Chand, D., DeGuzman, M., Garcha, J., Hussain, F., Snider, M., Behrsing, T.

Department of Toxic Substances Control, CalEPA, Sacramento, CA, USA.

ABSTRACT

Recently concerns have been raised about toxic chemicals, especially metals, found in consumer products (CPs). An example is lead (Pb) in children's toys and jewelry. We encountered numerous challenges and uncertainties in attempting to perform risk assessments on CPs containing toxic metals. Risk assessment protocols, and toxicity and toxicokinetic (TK) data developed for evaluating chronic exposure are often inadequate for assessing short-term exposure to CPs; and, risk assessments for some CPs were developed years ago. We developed a general framework for CP risk assessment by evaluating risk and identifying uncertainties on a product-specific basis. Potential hazards from multi-component CPs designed for children and advertised as lead-free were evaluated by testing metal content, and extractability in saline and dilute acid solutions mimicking mouthing and swallowing, respectively. Two separate CPs contained up to 47000 ppm (4.7%) total Pb and 700,000 ppm (70%) total cadmium (Cd). Simulated ingestion extracted 67 µg Cd, which exceeds the US EPA one-day drinking water advisory dose-equivalent of 60 µg/day for a 15 kg child. Simulated mouthing extracted a total of 3.6 µg Cd, compared to the Agency for Toxic Substances and Disease Registry intermediate duration Minimum Risk Level of 7.5 µg/day. While total Pb contents were high, the amounts extracted from simulated ingestion were well below the threshold set by US Consumer Product Safety Commission for evaluating acute exposures and no Pb was detected via saline extraction. Major uncertainties exist. CPs can be made by a dozen different manufacturers and metal composition among CP samples varies, which could indicate poor quality control during manufacturing and impact chemical properties of metals such as solubility. Other key uncertainties include use of in vitro simulations, and lack of relevant TK data and acute toxicity criteria. Given the potential for leaching toxic metals from CPs, and lack of data for assessing short-term exposures, more information is needed for assessing risk from CPs.

INTRODUCTION

- Consumer product (CP) safety is currently the focus of much attention – particularly children's products.
- Major uncertainties in CP risk assessment exist. Public awareness is great, making the need for risk assessments which are predictive of real-life exposures even more critical.
- Recent legislation aimed at addressing concerns for metals such as lead. Exposure to toxic metals (e.g. cadmium) used as substitutes for lead is an emerging concern.
- This poster discusses considerations for CP risk assessment, presents an example risk evaluation, and identifies key uncertainties and information needed for assessing CP risk.

Regulations & Standards for Lead, Cadmium, and Antimony in Products Intended for Children[6]

	Federal		European	California	
	CPSIA[7]	ASTM F963-07 16 CFR 1303	EN 71:Part 3: 1994	CA Health and Safety Code[1]	Lead Containing Jewelry Law[2]
Regulated Item	Child's products including jewelry	Toys	Toys	Toys	Jewelry
Lead (Pb)	300 ppm[3] (content limit) 90 ppm (paint limit)	90 ppm SS[4]	90 ppm SS[4]	600 ppm	
Cadmium (Cd)		75 ppm SS[4]	75 ppm SS[4]	> 0.1% SS[5]	
Antimony (Sb)		60 ppm SS[4]	60 ppm SS[4]	> 0.1% SS[5]	

[1]California Health & Safety Code sections 108550-108585. [2]California Health & Safety Code sections 25214.1-25214.4.2. [3]The limit will decrease to 100 ppm on August 14, 2011 unless CPSC determines the lower limit is not technologically feasible. [4]SS = Soluble in 0.07% HCL, particle size 500 µm. [5]SS = Components are considered soluble if quantities of Cd and Sb exceed 0.1% when dissolved in 5% HCL. [6]The regulations & standards presented for Cd, Pb & Sb is not an all-inclusive list and only represents a fraction of the regulations & standards for metals in products intended for children's use. [7]Consumer Product Safety Improvement Act.

California Lead Containing Jewelry Law[1]

Glass/Crystal Decorative Component	Up to 1 gm, excluding any glass or crystal decorative component that contains < 200 ppm lead by wt, and has not intentionally added lead
Printing Ink, Ceramic Glaze	<600 ppm lead by weight
Metallic Material	Either a Class I material or < 600 ppm lead by weight
[2]Nonmetallic Class 1 Material	Does not violate glass/crystal restrictions
[3]Nonmetallic Class 2 Material	Plastic or rubber materials <200 ppm lead by weight Dye or surface coating <600 ppm leady by weight
Class 3 Material	<200 ppm lead by weight

[1]California Health and Safety Code sections 25214.1-25214.4.2 [2]Class I Materials: stainless or surgical steel, karat gold, sterling silver, platinum, palladium, iridium, ruthenium, rhodium osmium, natural or cultured pearls, glass, ceramic, or crystal decorative components, gemstones, elastic, fabric, ribbon, rope, all natural decorative material, adhesive. [3]Class 2 Materials: electroplated and unplated metal, plastic or rubber, incl. acrylic, polyolefens, plastic beads and stones, and polyvinyl chloride (PVC); dye or surface coating. Not a class 1 or 2 material [4]Class 3 Materials: Not a class 1 or 2 material

Limited List of the Oral Toxicity Criteria

	Primary Health Effects[1]	Acute	Intermediate	Chronic	Cal/EPA Prop 65
Lead	-CNS-reduced IQ -Peripheral Nervous System -Anemia -Kidney	• **175 µg/day** (CPSC)		• **6 µg /day** (OEHHA[2] & PTTIL-US FDA) • **15 µg /day** (CPSC)	• **0.5 µg /day** (MADL/oral-OEHHA) • **15 µg /day** (NSRL/oral-OEHHA)
Cadmium	-Kidney – renal tubule -GI Tract (acute) -Skeletal Alterations – decrease in bone mineral density	• **0.04 mg/L** (1 & 10-Day HA-USEPA)[3]	• **5E-1 µg/kg-d** (MRL-ATSDR) • **2.7E-2 µg/kg-d** (DTSC)[4]	• **5E-1 µg/kg-d** (RfDo-IRIS) • **1E-1 µg/kg-d** (MRL-ATSDR) • **6.3E-3 µg /kg-d** (ADD-OEHHA)	• **4.1 µg /day** (MADL/oral-OEHHA)

[1] The primary health effects listed are for oral exposures.
[2] One µg/dl is the estimated incremental increase in children's PbB that would decrease IQ by up to one point. This corresponds to an increased daily intake of 6 µg of ingested bioavailable lead for a child. (http://www.oehha.ca.gov/public_info/public/kids/pdf/PbHQ43043007.pdf)
[3] USEPA One- and Ten-Day Health Advisory Levels for cadmium in drinking water are designed to protect a 10 kg child assumed to ingest 1L of water per day for up to one and ten days of exposure, respectively.
[4] The following parameters were used to derive this value for an intermediate exposure to cadmium in soil: NOAEL of 19 µg/day (from the OEHHA PHG Cadmium document), uncertainty factor of 10, and body weight 70 kg.

ADD – acceptable daily dose
ATSDR – Agency for Toxic Substances and Disease Registry
CPSC – Consumer Product Safety Commission
DTSC – Department of Toxic Substances Control
HA – Health Advisory (drinking water)
IRIS – Integrated Risk Information System
MRL – maximum risk level
MADL – maximum allowable dose level
NSRL – No Significant Risk Level
PTTIL – Provisional Total Tolerable Intake Level (value listed is for children)
OEHHA – Office of Environmental Health Hazard Assessment
RfDo – oral reference dose

CONSUMER PRODUCTS IN THE NEWS

- **"Death of a Child After Ingestion of Metallic Charm --- Minnesota, 2006"** (Source: US Centers for Disease Control and Prevention, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d323a1.htm)

Photo: US CPSC

- Heart-shaped charm bracelet given as a free gift with shoe purchases
- Childs PbB elevated to 180 µg/dl
- Lead content of ingested charm was 99.1%

- **December 2009 – "…Antimony and Chromium Above Legal Limits in Some of Season's Most Popular Toys"** (Source: http://www.marketwire.com/press-release/Goodguide-1086308.html)

Photo: http://www.zemoticlor.com/Money/new-economy/2009/1206/could-a-consumer-groups-report-lead-to-a-shu-shu-pet-recall

- Toys reported to contain metals at levels exceeding federal standards
- CPSC confirmed that Zhu Zhu Pets do not exceed federal standards (Source: http://www.washingtonpost.com/wp-dyn/content/article/2009/12/07/AR2009120702243.html?wpisrc=rss_business)
- GoodGuide say they regret the error of comparing their X-ray fluorescence (XRF) data to federal standards which are based on solubility test (http://www.marketwire.com/press-release/GoodGuide-Issues-Correction-About-Its-Toy-Testing-Methodology-1086821.htm)

Emerging Concern for Children's Jewelry: Cadmium

- **"AP IMPACT: With lead use barred, tests reveal toxic cadmium in children's jewelry from China"** (Source: The Associated Press, http://ca.news.yahoo.com/s/capress/100110/business/us_cadmium_jewelry_1)

Photo: US CPSC

- **January 2010 - "Children's Necklaces Recalled Due to High Levels of Cadmium"** (Source: US CPSC, http://www.cpsc.gov/cpscpub/prerel/prhtml10/10127.html)
  - 55,000 children's necklaces recalled
  - First recall of children's jewelry in United States due to cadmium

- **January 2010 - "Cadmium New Fears in Kids' Trinkets" -** (Source: http://www.cbsnews.com/stories/2010/01/12/earlyshow/contributors/susankoeppen/main6086882.shtml)

Photo: http://wwwimage.cbsnews.com/images/2010/01/12/image6086881g.jpg

- Toxic metal found in high levels in jewelry for kids from China
- 91% cadmium
- International chain store Claire's, says it will no longer sell the Reindeer charm bracelet

CASE STUDIES – POTENTIAL HAZARD FROM LEAD AND CADMIUM IN TWO CPs

BACKGROUND

- Two separate, multi-component CPs (CP #1 and CP #2) designed for children
- Advertised as lead-free
- US CPSC testing methodology generally followed. Individual CP components tested for:
  - Total metal concentration
  - Extractability in saline – mimicking mouthing scenario
  - Extractability in dilute acid – mimicking ingestion scenario

METHODOLOGY

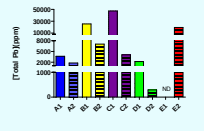
- Four duplicate samples of each CP evaluated (designated 1-4)
- Separate components of each CP tested individually
  - CP #1 components: A, B, and C
  - CP #2 components: D and E
- Total Metals: Samples digested with 1:1 HNO_3 (and 30% H_2O_2 and 1:1 HCl, if applicable) over a hot plate. Digests cooled, filtered, and made to final volume with deionized H_2O. Metal analysis of digests by inductively coupled plasma atomic emission spectroscopy (ICP-AES).
- Saline Extraction: Samples extracted with 0.9% saline soln (volume in mls equal to 50X weight of sample in gms) for 1 hr at 37ºC in a shaking water bath. After 1 hr, saline soln is taken out and replaced with same volume of fresh saline soln. Extraction is repeated for 2 hrs and then 3 hrs, with fresh saline soln used for each timed extraction. Each of the 3 extracted solns individually analyzed using ICP spectrometer.
- Weak Acid Extraction: Same as for saline extraction, except 0.07 N HCl used instead of saline.

RESULTS AND COMPARISON TO REGULATORY LIMITS AND TOXICITY CRITERIA

Total Metals

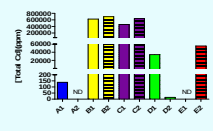
Lead

- Total [Pb] ranged from 0.0292 – 4.75%
- Total [Pb] per component as high as 62,920 µg
- Large variability among individual components of each CP, and between duplicates (up to more than 10-fold)



Cadmium

- Total [Cd] ranged from non-detect – 70%
- Total [Cd] per component as high as 3810 mg
- Similar to lead, large variability observed



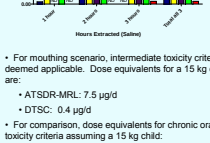
Saline Extraction
(intended to mimic mouthing scenario)

Lead

- All analyses non-detect with a method detection limit of 0.05 µg lead

Cadmium

- Estimated total amount of extractable cadmium over 6 hrs:
  - CP #1: 3.6 µg (0.5 + 1.2 + 1.9)
  - CP #2: 0.7 µg (0.65 + 0.05)

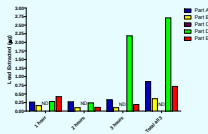


- For mouthing scenario, intermediate toxicity criteria deemed applicable. Dose equivalents for a 15 kg child are:
  - ATSDR-MRL: 7.5 µg/d
  - DTSC: 0.4 µg/d
- For comparison, dose equivalents for chronic oral toxicity criteria assuming a 15 kg child:
  - ATSDR-MRL: 1.5 µg/d
  - US EPA RfDo: 7.5 µg/d
  - OEHHA: 0.1 µg/d

Weak Acid Extraction
(intended to mimic ingestion scenario)

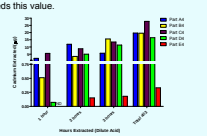
Lead

- Estimated total amount of extractable lead over 6 hrs:
  - CP #1: 1.3 µg (0.9 + 0.4 + below DL)
  - CP #2: 3.4 µg (2.7 + 0.7)
- Total amount extracted below CPSC's criterion for acute exposures and OEHHA, US FDA, and CPSC's chronic criteria



Cadmium

- Estimated total amount of extractable cadmium over 6 hrs:
  - CP #1: 67 µg (19.7 + 19.5 + 27.8)
  - CP #2: 16.8 µg (16.47 + 0.33)
- US EPA One- and Ten-Day HA level is equivalent to 4 µg/kg or 60 µg for 15 kg child. Total amount extracted for CP #1 exceeds this value.



GENERAL CONCLUSIONS

- **Evaluating risk from CPs remains uncertain.**
  - Analytical methodology selection for use in determining compliance with regulations and assessing risk is of critical importance.
    - The recent headlines regarding antimony and chromium clearly demonstrate this issue with respect to compliance.
    - Methodologies used for determining regulatory compliance may differ from those needed for use in assessing risk. Data collected for use in exposure assessment must consider product-specific exposure pathways.
  - Traditionally, risk assessments have been built on chronic studies of toxicity and may not be applicable to acute exposures to heavy metals in CPs.
    - Risk assessment protocols and toxicity criteria for acute and intermediate exposures to cadmium in CPs are lacking.
  - Relevant scientific data in current regulations may not reflect the current scientific data.
    - In the case of lead, the assessment utilizes the 10 µg/dl blood lead threshold as opposed to the more recently adopted criteria (increase of 1 µg/dl blood lead).
  - No standardization with regards to CPs.
    - Metal composition, manufacturing processes, and quality assurance protocols vary across CPs and manufacturers.
    - May affect chemical properties such as metal solubility which can impact toxicity.
- **It is our position that toxic metals should not be used in consumer products intended for children.**

REFERENCES

OEHHA, 2006. *Public Health Goals for Chemicals in Drinking Water, Cadmium*. December.

U.S. Consumer Product Safety Commission (CPSC), Consumer Product Safety Improvement Act. http://www.cpsc.gov/businfo/cpsa.pdf.

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