

CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products



21 November 1997

**U.S. Consumer Product Safety Commission
Washington, D.C. 20207**

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I. Introduction

Since its inception, the U.S. Consumer Product Safety Commission (CPSC) has played a prominent role in protecting the public, especially children, from the hazards of exposure to lead and other toxic chemicals. The CPSC has a strong record of removing products from the marketplace that contain lead and result in exposures that are hazardous to children. Just this past year, Commission action resulted in manufacturers eliminating the use of lead as a stabilizer in vinyl miniblinds, stopping the production of children's jewelry containing lead, and developing and distributing guidance to state health officials and others about lead paint on public playground equipment. Several years ago, CPSC recalled crayons that contained hazardous levels of lead. The Commission is continually screening toys for the presence of lead paint and has recalled many toys that violated the Commission's lead paint standard.

In 1996, CPSC found that children could be exposed to hazardous levels of lead in imported non-glossy vinyl (polyvinyl chloride, PVC) miniblinds. Following this discovery, CPSC staff collected and tested a number of children's plastic products that they believed might be repeatedly exposed to sunlight and heat such as the vinyl miniblinds. This type of exposure was shown by CPSC staff to promote the deterioration of the lead-containing PVC miniblind slats and result in the formation of lead dust on the slats' surface. The children's products collected and tested included wading pools, riding toys, basketball hoops, slides, and character toys. Testing revealed that many of these items were not PVC, but rather other types of plastic that do not contain lead. In those items that were PVC, CPSC staff did not detect lead.

In October 1997, Greenpeace released a study alleging that hazardous levels of lead and cadmium are present in many popular vinyl children's products. The CPSC staff tested a number of the same products for lead and cadmium that were tested by Greenpeace to evaluate the potential for exposure to children, and the risk created by that exposure. CPSC testing and evaluation indicated that the products tested are NOT hazardous. Because the products do not present a risk of lead or cadmium poisoning to children, CPSC did not seek corrective action. Health Canada released a report on October 30, 1997, of its investigation into lead and cadmium in certain vinyl consumer products and reached similar conclusions.

This document: 1) describes CPSC's regulatory authorities, 2) reports the results of CPSC staff testing, 3) describes the testing methods used and assessments made by the CPSC staff in reaching its conclusions, and 4) provides answers to some commonly asked questions.

II. CPSC's Regulatory Authorities

CPSC protects children from hazardous exposures to lead and cadmium (and any other substance) in consumer products under the Consumer Product Safety Act (CPSA) 15 U.S.C. § 2051-2084 and the Federal Hazardous Substances Act (FHSA) 15 U.S.C. § 1261-1278. In 1978, the CPSC banned paint containing in excess of 0.06% lead by weight intended for consumer use. At the same time, it also banned toys and other articles intended for use by children that use paint with a lead content in excess of 0.06% because they present a risk of lead poisoning to young children, 16 C.F.R. Part 1303. Lead may also be available to children from sources other than paint.

The Commission can take action against a product that contains lead or cadmium or any other toxic substance under the FHSA, but it must find that the product is a "hazardous substance" as that term is defined in section 2(f) of the FHSA, 15 U.S.C. § 1261(f). For a substance to be considered a hazard under the FHSA, the Commission must be able to demonstrate that persons are exposed to the substance during customary or reasonably foreseeable handling or use and the exposure may cause substantial personal injury or illness.

A toy or other article intended for use by children which contains a hazardous substance that is accessible to children is a banned hazardous substance, 15 U.S.C. § 1261(q)(1)(a). A product containing a toxic chemical that is not specifically intended for use by children but which creates a risk of substantial personal injury or illness due to customary or reasonably foreseeable handling or use, requires precautionary labeling, 15 U.S.C. § 1261(p).

III. Test Methods and Staff Assessments

The following discussion briefly describes the laboratory test methods and the technical rationale used by the CPSC staff in evaluating the potential hazard posed by the vinyl products identified in the October 1997, report by Greenpeace ("Lead and Cadmium in Vinyl Children's Products"). The laboratory test results and the staff's evaluation are found in the Appendix.

CPSC's Human Factors staff examined the list of products identified by Greenpeace (Table 1 of the Greenpeace report) to determine the intended age of the user and the likelihood of children handling, directly mouthing, or chewing the products.

If a product was identified as likely to be handled (touched), mouthed, or chewed by young children, CPSC staff obtained samples of the products from retailers in the Chicago, IL or Washington, D.C. areas. When the identical product listed by Greenpeace was unavailable, CPSC staff collected a sample of a similar product from the retailer, where available. If a product was unlikely to be touched, mouthed, or chewed by young children, then no lead or cadmium hazard would be likely and CPSC did not obtain these products for testing.

The CPSC Laboratory staff screened the products for lead and cadmium by determining total lead and cadmium concentrations in the PVC parts of the products. The staff followed the procedures described in the Association of Official Analytical Chemists 974.02 and used inductively coupled plasma emission spectrometry for analysis.

Where lead was present at concentrations exceeding 200 parts per million (ppm) or cadmium was present at concentrations exceeding 100 ppm, further testing was conducted to determine if the lead or cadmium would be released from the product in amounts that would pose a hazard to children during reasonably foreseeable handling or use.

Depending on Human Factors' assessment of the likely type of exposure by children, CPSC's Laboratory staff conducted wiping and/or extraction studies of the plastic. Wiping with moist filter papers was indicated if children were likely to handle the plastic containing lead or cadmium. Wiping analysis is done to determine the amount of accessible lead or cadmium on the surface of the product. The amount of lead or cadmium that can be extracted from the product was determined using saline or mild acid, according to a procedure similar to the ASTM toy safety standard F 963. Extraction with saline represents mouthing behaviors and mild acid extraction serves as a surrogate for chewing/ingestion. If a product did not have a detectable level of lead or cadmium, then the foreseeable consumer exposure would be insignificant and the product would not present a lead or cadmium hazard.

CPSC staff did not "weather" any of the products as Greenpeace did. The CPSC staff concluded that the children's products that were collected and tested would not have prolonged exposures to sunlight and heat in the course of their reasonably foreseeable handling or use. Therefore, CPSC staff anticipated that the products would not degrade in a way that would result in hazardous amounts of lead and cadmium becoming accessible to young children.

CPSC's Health Sciences staff evaluated the laboratory test results to determine if the products tested posed a lead or cadmium hazard. The adverse health effects of lead poisoning in young children are well documented and can have long-lasting or permanent consequences. The health effects include deficits in neurobehavioral function and intellectual performance, developmental delays, decreased stature, and diminished hearing acuity. The scientific community generally recognizes a blood lead level of 10 micrograms per deciliter (ug/dl) of blood as a level of concern and recommends various lead poisoning prevention activities. To prevent young children from exceeding the 10 ug/dl blood lead level, CPSC staff seeks to limit chronic ingestion of lead to not more than 15 ug of lead per day from consumer products.

Chronic cadmium ingestion results in kidney damage which is indicated by the presence of specific proteins in the urine. Using the EPA reference dose of 1 microgram per kilogram of body weight per day (ug/kg/day), CPSC staff suggests that chronic ingestion of cadmium not exceed 9.2 ug/day for a 1 year old, 13.5 ug/day for a 3 year old, and 20.2 ug/day for a 6 year old.

In evaluating the potential for a lead or cadmium hazard, the staff considered the laboratory data, the age of the child using the product, the type of exposure (handling, mouthing, chewing), the frequency and period of exposure, accessibility, extent of exposure (area handled, mouthed, or chewed), use environment (any exposure to heat and sunlight), and the staff's toxicity limits for lead and cadmium.

The health hazard evaluation determined whether reasonably foreseeable handling or use of the product would exceed the exposure limits for lead (15 ug per day) or cadmium (9.2 ug per day). Alternatively, the evaluation determined if the estimated use of the product was reasonable for given exposures at the exposure limits for lead or cadmium.

IV. Conclusions

Greenpeace released a study alleging that hazardous levels of lead and cadmium are present in many popular vinyl children's products. The CPSC staff tested a number of the same products for lead and cadmium that were tested by Greenpeace to evaluate the potential for exposure to children, and the risk created by that exposure. CPSC testing and evaluation indicated that the products tested are NOT hazardous. Although some of the vinyl products identified by Greenpeace and tested by CPSC staff contained lead or cadmium, further CPSC testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. Thus, children would NOT be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner.

The Commission takes very seriously any claim that children are being harmed by consumer products that contain lead or any other hazardous substance. After the release of the Greenpeace report and the CPSC staff's testing and evaluation, the staff met with Greenpeace representatives to explain the methods that CPSC used to test for lead and cadmium and to evaluate the potential for exposure by children, and the risk created by that exposure.

The Commission staff will continue to seek out and assess information about any potential risk to children from exposures to consumer products, and collect and test children's articles.

Appendix

Summary of CPSC Staff Assessment of Lead and Cadmium in Polyvinyl Chloride Products Identified in the October 1997 Greenpeace Report

November 1997

The following narrative discusses the CPSC staff's assessment of the potential hazard posed by lead and cadmium in children's polyvinyl chloride (PVC) products. The data and the hazard assessment are presented in the attached tables.

Table 1. "U.S. Consumer Product Safety Commission Laboratory Analysis Lead and Cadmium in Children's Plastic Products, 23 October 1997"

This table summarizes the CPSC laboratory analysis for total, dislodgeable, and extractable lead and cadmium, for the products and colors of plastic tested. The products tested by CPSC were those identified in the Greenpeace report¹. The total metal content is in parts per million (ppm) by weight of the plastic, as analyzed by the AOAC 974.02 procedure and inductively coupled plasma emission spectrometry (100 ppm = 0.01% by weight).

To determine the amount of available metal on the surface of the product, each product was wiped with moist filter papers according to the CPSC 30-stroke procedure. This procedure consisted of using 3 separate filter papers moistened with distilled water and lightly wiping each filter 10 times over the surface of the item being tested. The filter papers are individually digested in concentrated nitric acid and the amount of metal present is determined for each digest. The dislodgeable metal results are expressed in micrograms (ug) wiped from the surface.

Extractable metal results are expressed in micrograms per gram (ug/g) of plastic, using a 0.07N hydrochloric acid or normal saline extraction procedure similar to the ASTM toy safety standard F 963. Extraction with saline represents mouthing behaviors and mild acid extraction serves as a surrogate for chewing/ingestion. In the CPSC testing, a sample is extracted three times at 37 degrees Centigrade with 50 volumes of saline or mild acid for 1, 2, and 3 hours. After each time interval, the extractant is decanted and fresh extractant added. The product is thus exposed to a maximum of 6 hours of extraction.

Table 2. "Stages of the CPSC Hazard Assessment for Pb and Cd in Vinyl Children's Products, 30 Oct 1997"

The columns from left to right represent stages of the CPSC staff hazard assessment for lead (Pb) and cadmium (Cd) in the polyvinyl chloride products.

Column 1- Products from Greenpeace Table 1

This column contains information on the 26 of 28 products identified in Table 1 of Greenpeace's report that have already been cleared for public release under Section 6(b) of the Consumer Product Safety Act. The release process for the remaining two is not yet complete.

Column 2- Likely handling or mouthing by young children

Human Factors use evaluations were conducted on each of the 26 products on the Greenpeace list. The staff determined if handling or direct mouthing/chewing of the product was likely by young children. An affirmative determination for 18 of the 26 products prompted the staff to look for samples of the products in retail stores. If it was determined by the staff that a product was unlikely to be handled, mouthed, or chewed by young children, then no lead or cadmium hazard would be likely and products were not collected for testing. Staff concluded that none of the products are likely to be exposed to the conditions (repeated sunlight and heat) that vinyl miniblinds are and therefore, did not perform any weathering tests.

Column 3- Obtained by CPSC

CPSC staff obtained a total of 12 of the 18 products likely to be handled, mouthed, or chewed by children. Ten products were obtained from retailers in the Chicago, IL or Washington, D.C. areas. When the exact product listed by Greenpeace was unavailable, CPSC staff collected a sample of a similar product from the same retailer identified by Greenpeace. CPSC staff collected two products in this manner. CPSC staff was unable to find the remaining six products in the retail stores.

Column 4- Total Pb, Cd screening

CPSC staff screened the 12 products obtained for total lead and cadmium. In CPSC's experience, products containing less than 200 ppm lead and 100 ppm cadmium do not release appreciable amounts of dislodgeable or extractable metals, and would not be a lead or cadmium health hazard as a result of reasonably foreseeable consumer handling or use. Eight of the 12 products tested exhibited levels of lead above the screening levels (200 ppm lead and 100 ppm cadmium).

Column 5- Wiped or extracted Pb, Cd detected

CPSC staff conducted wiping and/or extraction studies for lead or cadmium depending on the staff's assessment on the age of the child that would be expected to play with the product and the type of behavior expected (hand-to-mouth, direct mouthing, or chewing). Wiping was indicated if children were likely to touch or handle the plastic that contained lead or cadmium. The filter paper 30-stroke CPSC laboratory procedure is a surrogate for handling by a typical, young child. Extraction with saline represents only the mouthing behavior. If chewing/ingestion of the plastic was likely, then the mild hydrochloric acid extraction served as a surrogate for the bioavailable metal. Four of the 8 products were above the detectable levels for dislodgeable or extractable lead or cadmium. If a product did not have a detectable level, then the foreseeable consumer exposure would be insignificant and the product would not be a lead or cadmium health hazard.

Column 6- Pb, Cd health hazard evaluation

The four products were then assessed for lead or cadmium health hazards based on the CPSC laboratory data, expected use characteristics, exposure assessments, and CPSC toxicity-related exposure limits of 15 ug/day for lead and 1 ug/kg body weight/day for cadmium. The health hazard evaluation determined whether reasonably foreseeable use of the product would exceed the exposure limits for lead or cadmium. Alternatively, the evaluation determined if the estimated use of a product was reasonable for given exposures occurring at the limits for lead or cadmium.

Conservative assumptions were used for assessing exposure when data did not exist, such as 1 stroke of the filter paper being equivalent to 1 stroke by a child's hand, 50% transfer efficiency of the dislodgeable lead or cadmium from the surface onto the hands and then ingestion of the lead or cadmium, and 10% of a food toy consumed in 30 days.

The critical health effect for lead is retarded mental development. The risk of this effect increases when the blood lead level exceeds 10 ug/dl. To prevent children 6 years of age and younger from exceeding the 10 ug/dl blood lead level, the CPSC staff suggests that chronic ingestion of lead be limited to 15 ug lead per day.

The critical health effect for cadmium is kidney damage which is indicated by certain proteins in the urine, including B2 microglobulin, cadmium-metallothionein, and retinol-binding protein. The chronic ingestion reference dose developed by the

US Environmental Protection Agency is 1 ug/kilogram body weight/day. CPSC staff suggests that chronic ingestion of cadmium not exceed 9.2, 13.5, and 20.2 ug per day for 1, 3, and 6-yr old children, respectively.

Examples of calculations of exposure assessments are shown in Table 3, "Consumer Product Health Hazard Evaluation, 28 October 1997". Using these types of calculations, the staff found none of the four products with detectable dislodgeable or extractable lead or cadmium were hazardous.

Table 4. "Dislodgeable Pb and Cd from Greenpeace Tables 6, 7, 8; 20 Oct 1997"

CPSC staff considered the type of weathering conditions used by Greenpeace to be unlikely for the products listed in the Greenpeace report (1). Nevertheless, CPSC staff evaluated "dust" wipe data from Tables 6, 7, and 8 in the Greenpeace report to determine if a lead or cadmium hazard would result from such weathering. Greenpeace Table 6 lists micrograms of lead and cadmium wiped from seven new, unweathered products. Greenpeace Table 7 is similar except that the products underwent an artificially accelerated weathering protocol. Greenpeace Table 8 is a 90th percentile estimate of the weathered product data and would be considered their worst-case maximum levels.

The lead or cadmium level per in² was calculated using the surface areas of the products listed in the Greenpeace report. A 50% hand-to-mouth transfer efficiency of the dust was assumed by CPSC staff.

The estimated surface areas that a child must regularly handle to ingest lead at 15 ug/day or cadmium at 9.2 ug/day for a 1-year old are shown in the boxes. Although the surface area of the weathered Barbie tent pole that would need to be touched on a regular basis to reach the limit of 15 ug/day lead or 9.2 ug/day cadmium was small (lead: 3.6 in²/day, Greenpeace Table 7 and lead: 2.2 in²/day, Greenpeace Table 8), the CPSC staff concluded that the tent pole was not a hazard for children because: (1) the pole pieces are covered by the tent sheet and the poles would not be repeatedly exposed to heat and sunlight; (2) the poles would only be handled during setup and takedown; and (3) it is likely that adults would be engaged in the main part of the handling. Thus, none of the six products in these tables would be a lead or cadmium hazard.

Conclusions

None of the vinyl children's products evaluated by CPSC staff are lead or cadmium consumer product hazards.

References

(1) Di Gangi, J. 1997. "Lead and cadmium in vinyl children's products; a Greenpeace expose." Greenpeace USA, Washington DC. October.

TABLE 1
 U.S. CONSUMER PRODUCT SAFETY COMMISSION
 LABORATORY ANALYSIS
 LEAD AND CADMIUM IN CHILDREN'S PLASTIC PRODUCTS
 23 October 1997

Product Name	Lead ¹ (ppm)	Cadmium ¹ (ppm)	Wipe Results		Extraction Results	
			Lead (ug)	Cadmium (ug)	Lead (ug/g)	Cadmium (ug/g)
Barbie Backpack, Pyramid Handbags, Inc.						
Pink Plastic	ND ²	ND ²	----	----	----	----
Purple Plastic	ND ²	ND ²	----	----	----	----
Blue Plastic	ND ²	ND ²	----	----	----	----
Purple Plastic Heart	ND ²	290	----	----	----	ND ^{2,5} ----
Modular Phone Cord, Gemini Industries, Inc.						
Ivory Color	910	ND ²	21 ⁴	----	97.8 ⁵	----
Purse, Pacific Kids						
Black Plastic	ND ²	ND ²	----	----	----	----
Phone Cord, not named						
Ivory Color	110	ND ²	----	----	----	----
White Color	30	ND ²	ND ²		----	----
Gray Color	ND ²	ND ²	----	----	----	----

Product Name	Lead ¹ (ppm)	Cadmium ¹ (ppm)	Wipe Results		Extraction Results	
			Lead (ug)	Cadmium (ug)	Lead (ug/g)	Cadmium (ug/g)
Kentucky Fried Chicken, Henry Gordy, Int'l.						
Brown Plastic Drumstick	20	510	----	0.4 ⁷	----	0.72 ⁸ , 18.6 ⁵
Yellow Plastic	ND ²	40	----	----	----	----
Yellow Paint	20	40	----	----	----	----
Barbie Slumber Tent, Ero Industries, Inc.						
Purple Plastic	ND ²	90	----	----	----	----
Pink Plastic	ND ²	100	----	----	----	----
Ivory Plastic Pole	5,920	ND ²	23.2 ⁶	----	NA ³	----
White Plastic Connector	ND ²	ND ²	----	----	----	----
Totebag, Tweety						
Yellow Plastic	20	160	----	ND ^{2,5}	----	----
Orange glitter	ND	ND				ND ⁵
Blue glitter	ND	ND				ND ⁵
Hackey Sack, Good Stuff Corp.						
Pink Plastic	50	ND ²	----	----	----	----
Green Plastic	3270	ND ²	ND ²	----	0.676 ⁸ , 28.85 ⁵	----
Orange Plastic	6300	ND ²	ND ²	----	0.968 ⁸	----
Blue Plastic	70	ND ²	----	----	----	----

Product Name	Lead ¹ (ppm)	Cadmium ¹ (ppm)	Wipe Results		Extraction Results	
			Lead (ug)	Cadmium (ug)	Lead (ug/g)	Cadmium (ug/g)
Umbrella A, Shaw Creations, Inc.						
Grey Plastic	ND ²	ND ²	----	----	----	----
White Plastic	20	ND ²	----	----	----	----
Orange Plastic	20	ND ²	----	----	----	----
Red Plastic	20	ND ²	----	----	----	----
Transparent Black Plastic	ND ²	ND ²	----	----	----	----
White Paint (Handle)	50	20	----	----	----	----
Orange and White Paint (Handle)	80	10	----	----	----	----
Umbrella B, Shaw Creations, Inc.						
Light Brown Plastic	810	ND ²	ND ²	----	----	----
Red Plastic	720	ND ²	ND ²	----	----	----
Orange Plastic	750	ND ²	ND ²	----	----	----
Dark Brown Plastic	690	ND ²	ND ²	----	----	----
Transparent Brown Plastic	20	ND ²	ND ²	----	----	----
Brown Paint (Handle)	50	ND ²	----	----	----	----
Dark Brown Paint	40	ND ²	----	----	----	----
Ivory Paint	50	ND ²	----	----	----	----
Black Plastic Handle	40	ND ²	----	----	----	----

Product Name	Lead ¹ (ppm)	Cadmium ¹ (ppm)	Wipe Results		Extraction Results	
			Lead (ug)	Cadmium (ug)	Lead (ug/g)	Cadmium (ug/g)
Minnie Mouse key bag, Disney Store						
pink strip	ND ²	ND ²	----	----	----	----
pink latch	ND ²	ND ²	----	----	----	----
pink bag	ND ²	40	----	0.9 ¹⁰ ----	----	----
Raincoat, Warner Bros.						
yellow plastic	ND ²	30	----	5.93 ⁹ ----	----	----
red composite	ND ²	50	----	----	----	----
ylow composite	ND ²	40	----	----	----	----
blue composite	ND ²	40	----	----	----	----
Space Jam placemat, Zak Designs						
white plastic	90	ND ²	----	----	----	----
ornge composite	120	ND ²	----	----	----	----
green composite	100	ND ²	----	----	----	----
Halloween placemat, Barth-Dreyfuss						
white plastic	150	10	----	----	----	----
ylow composite	190	10	----	----	----	----
blue composite	180	10	----	----	----	----
ornge composite	150	10	----	----	----	----
black composite	210	10	ND	----	----	----

Product Name	Lead ¹ (ppm)	Cadmium ¹ (ppm)	Wipe Results		Extraction Results	
			Lead (ug)	Cadmium (ug)	Lead (ug/g)	Cadmium (ug/g)
Blue vinyl placemat, not named						
Ivory vinyl placemat, not named	100	ND ²	-----	-----	-----	-----

NOTES:

¹ Determined by AOAC Method 974.2.

² Not detected (<10 ppm for lead or <50 ppm for cadmium).

³ Not applicable since mouthing is not anticipated.

⁴ Thirty wipes with water-moistened filter paper over 25.4 cm of the cord.

⁵ Six hour extraction with 0.07N HCl (based on ASTM F 963).

⁶ Thirty wipes with water-moistened filter paper over 52 cm of the pole.

⁷ Thirty wipes with water-moistened filter paper over 8 cm².

⁸ Six hour extraction with saline (based on ASTM F 963).

⁹ Thirty wipes with water-moistened filter paper over 90 cm² of the raincoat.

¹⁰ Thirty wipes with water-moistened filter paper over 41 cm² of the keyring bag.

TABLE 2

Stages of the CPSC Hazard Assessment for Pb and Cd in Vinyl Children's Products

30 Oct 1997

Products from Greenpeace Table 1	Likely handling or mouthing by young children	Obtained by CPSC	Total Pb, Cd screening	Wiped or extracted Pb, Cd detected	Pb, Cd health hazard evaluation
Minnie backpack	yes	not found			
101 Dalm backpack	yes	not found			
Barbie backpack	yes	yes	purple heart above- Cd	below extr	
barbell	no				
breast milk cooler	no				
Sega controller cable	no				
Gemini video coax cable	no				
Gemini phone cord	yes	yes	above- Pb	above wipe above extr	43 strokes/day 9.8 ug/day not hazardous
Philco in ear headphone	no				
Philco headph	no				
Gemini printer cable	no				
Minnie key ring	yes	yes	below		
pencil case	yes	not found			
Space Jam placemat	yes	yes	below		
Barth & Dreyfuss placemat	yes	yes	above- Pb	below wipe	
Pacific kids purse	yes	yes	below		
Tweety rain hat	yes	not found			

Products from Greenpeace Table 1	Likely handling or mouthing by young children	Obtained by CPSC	Total Pb, Cd screening	Wiped or extracted Pb, Cd detected	Pb, Cd health hazard evaluation
Columbia raincoat	yes	Warner Bros. raincoat	below		
shower curtain	no				
Barbie tent pole	yes	yes	above- Pb	above wipe	39 strokes/day not hazardous
Tweety totebag	yes	yes	above- Cd	below wipe	
Hackey Sack	yes	yes	above- Pb	below wipe above extr	1.92 ug/day green, 1.38 ug/day orange not hazardous
KFC	yes	yes	above- Cd	above wipe above extr	1416 strokes/day 3.8 ug/day not hazardous
cosmetics pouch	yes	not found			
doll stroller	yes	not found			
Looney Tunes umbrella	yes	2 Shaw umbrellas	1 umbrella above- Pb	below wipe	

Table 3

Consumer Product Health Hazard Evaluation

Brian C. Lee, PhD DABT

28 October 1997

Toxicity

Pb

Critical health effect- retarded mental development

Marker- blood Pb level. 10 ug/dL is the level of concern.

Chronic ingestion limit- 15 ug/day for 6 years of age and under.

Cd

Critical health effect- kidney damage

Markers- proteins in the urine (*B2*-microglobulin, Cd metallothionein, retinol binding protein)

Chronic ingestion limit- 9.2, 13.5, and 20.2 ug/day for 1, 3, and 6 yr-olds.

Laboratory analysis

Exposure

Product and age-dependent human use factors

Hand-to-mouth activities-

50% transfer efficiency

1 filter paper stroke is surrogate for 1 hand stroke by a child

Direct mouthing and chewing ingestion-

Saline extraction represents mouthing only

Mild HCl extraction is surrogate for bioavailability from chewing

ASTM F 963-96 and EN 71-3

Pb: 90 ug/g, Cd: 75 ug/g for surface coatings

Assessment

Given the number of strokes or surface area wiped, is the limit for Pb or Cd exposure exceeded? Or,
At the limit for Pb or Cd exposure, is the number of strokes or surface area wiped reasonable?

Given the amount of plastic mouthed, or chewed and ingested, is the limit for Pb or Cd exceeded? Or,
At the limit for Pb or Cd exposure, is the amount of plastic mouthed, or chewed and ingested reasonable?

Example calculations

1) A 10" length of phone cord yielded 0.7 ug Pb/stroke
To achieve the 15 ug/day limit for Pb, a child would need to conduct

$$15 \text{ ug/day} / 0.7 \text{ ug/stroke} / 0.5 \text{ efc} = 43 \text{ strokes/day,} \\ \text{or 1 stroke/day on a 430" length.}$$

2) A food toy yielded 18.6 ug Cd/g and weighed 61 g.
If a child ate 10% of the toy in 30 days, the exposure would be

$$18.6 \text{ ug/g} * 61 \text{ g} * 10\% / 30 \text{ days} = 3.8 \text{ ug/day.}$$

TABLE 4

Dislodgeable Pb and Cd from Greenpeace Table 6				20Oct1997			
new item	in2	Pb ug	Pb ug/in2	in2/day	Cd ug	Cd ug/in2	in2/day
Minnie backpack	96	1.984	0.021	1451.6	1.740	0.018	1015.2
101 Dal backpack	290	19.430	0.067	447.8	1.160	0.004	4600.0
Barbie backpack	290	14.210	0.049	612.2	nd		
Columbia raincoat	1700	235.733	0.139	216.3	nd		
Tweety rain hat	79	9.217	0.117	257.1	nd		
Barbie tent pole	36	13.404	0.372	80.6	nd		
Tweety totebag	240	0.240	0.001	30000.0	nd		

Dislodgeable Pb and Cd from Greenpeace Table 7				20Oct1997			
weathered item	in2	Pb ug	Pb ug/in2	in2/day	Cd ug	Cd ug/in2	in2/day
Minnie backpack	96	5.664	0.059	508.5	5.792	0.060	305.0
101 Dal backpack	290	19.430	0.067	447.8	14.307	0.049	373.0
Barbie backpack	290	35.380	0.122	245.9	23.393	0.081	228.1
Columbia raincoat	1700	336.033	0.198	151.8	nd		
Tweety rain hat	79	9.217	0.117	257.1	0.263	0.003	5527.0
Barbie tent pole	36	302.484	8.402	3.6	nd		
Tweety totebag	240	8.800	0.037	818.2	15.520	0.065	284.5

Dislodgeable Pb and Cd from Greenpeace Table 8				20Oct1997			
weather +10% item	in2	Pb ug	Pb ug/in2	in2/day	Cd ug	Cd ug/in2	in2/day
Minnie backpack	96	14.824	0.154	194.3	6.678	0.070	264.5
101 Dal backpack	290	24.284	0.084	358.3	15.852	0.055	336.6
Barbie backpack	290	83.692	0.289	104.0	35.840	0.124	148.9
Columbia raincoat	1700	590.554	0.347	86.4	nd		
Tweety rain hat	79	12.415	0.157	190.9	0.497	0.006	2924.7
Barbie tent pole	36	486.925	13.526	2.2	nd		
Tweety totebag	240	20.495	0.085	351.3	16.762	0.070	263.5



**Questions and Answers
Lead and Cadmium in Children's
Polyvinyl Chloride (PVC) Products
Prepared by CPSC Staff**

November 1997

In 1996, the U.S. Consumer Product Safety Commission (CPSC) found that children could be exposed to hazardous levels of lead in imported non-glossy vinyl (polyvinyl chloride, PVC) miniblinds. Following this discovery, the CPSC staff collected and tested a number of children's products that they believed might be repeatedly exposed to sunlight and heat such as the vinyl miniblinds. This type of exposure was shown by CPSC staff to promote deterioration of the lead-containing PVC miniblind slats and result in the formation of lead dust on the slats' surface. The products collected and tested included wading pools, riding toys, basketball hoops, slides, and character toys. Testing revealed that many of these items were not PVC, but rather other types of plastic that do not contain lead. In those items that were PVC, CPSC staff did not detect lead.

In October 1997, Greenpeace released a study alleging that hazardous levels of lead and cadmium are present in many popular vinyl children's products. The CPSC staff tested a number of the same products for lead and cadmium that were tested by Greenpeace to evaluate the potential for exposure by children, and the risk created by that exposure. CPSC testing and evaluation indicated that the products tested are NOT hazardous. Because the products do not present a risk of lead or cadmium poisoning to children, CPSC did not seek corrective action. Health Canada released a report on October 30, 1997, of its investigation into lead and cadmium in certain vinyl consumer products and reached similar conclusions.

Below are answers to some commonly asked questions.

Is there a health hazard from lead or cadmium in the children's vinyl products tested by CPSC?

CPSC staff found no lead or cadmium hazard in the products it tested. Although some of the products identified by Greenpeace and tested by CPSC staff contained lead or cadmium, further CPSC testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. Thus, children would NOT be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner.

How did CPSC test and evaluate the potential lead or cadmium hazard posed by the vinyl products listed in the Greenpeace report?

Of the products identified in the Greenpeace report as containing "hazardous" levels of lead or cadmium, only 18 were considered by CPSC staff as likely to be handled, mouthed, or chewed by children. CPSC staff collected 12 of the 18 products from retailers in the Chicago, IL or Washington, D.C. areas.

The CPSC staff chemically analyzed these 12 products to determine the total amounts of lead and/or cadmium contained in the products. Where the chemical screening procedure revealed that lead was present in amounts greater than 200 parts per million or cadmium was present in amounts greater than 100 parts per million, the CPSC staff conducted further studies to determine if that lead or cadmium would be released from the product in amounts that would pose a hazard to children during reasonably foreseeable handling or use. Eight of the 12 products tested had levels of lead or cadmium above the screening levels (200 parts per million for lead and 100 parts per million for cadmium). None of the products tested by CPSC had both lead and cadmium.

Although eight of the vinyl products contained lead or cadmium, the mere presence of lead or cadmium in these products does not in and of itself, make the products hazardous. A hazard results if the chemicals are released from the products through reasonably foreseeable handling or use in amounts that can cause substantial personal injury or illness.

CPSC staff conducted wiping and/or extraction studies for lead or cadmium to determine if the lead or cadmium could be released from these eight products in hazardous amounts. Wiping and/or extraction studies were conducted depending on the staff's assessment on the age of the child that would be expected to play with or use the product and the type of behavior expected (handling, mouthing, or chewing).

CPSC staff conducted wiping tests using moistened filter papers if children were expected to handle the plastic containing lead or cadmium. CPSC staff performs this type of testing to determine the amount of lead or cadmium on the product's surface. Extraction studies were conducted with saline to simulate mouthing behaviors or with mild acid to simulate chewing and ingestion. CPSC staff performs this type of testing to determine the amount of lead or cadmium that can be extracted or released from the product. CPSC found four of the eight products tested to have detectable amounts of lead or cadmium by wiping and/or extraction testing.

CPSC staff did not "weather" any of the products as Greenpeace did. The CPSC staff concluded that the children's products would not be repeatedly exposed to sunlight and heat in the course of their reasonably foreseeable handling or use. Therefore, CPSC staff anticipated the products would not degrade in a way that would result in hazardous levels of lead or cadmium becoming accessible to young children.

CPSC staff then evaluated the four products with detectable amounts of lead or cadmium, as determined from the wiping or extraction studies, for their potential to present a lead or cadmium health hazard. Staff considered the laboratory test results, product use characteristics, and the levels at which adverse health effects are associated with exposures to lead and cadmium; and concluded that none of these products present a health hazard.

CPSC testing and evaluation indicated that the products it tested are NOT hazardous. Because the products do not present the risk of lead or cadmium poisoning to children, CPSC did not seek corrective action.

Why didn't CPSC subject the products to weathering conditions (sunlight or heat) during testing like Greenpeace did?

The CPSC staff concluded that none of the the products identified and weathered by Greenpeace would be repeatedly exposed to prolonged sunlight and heat in the course of their reasonably foreseeable handling or use. Therefore, CPSC staff anticipated that the products would not degrade in a way that would result in hazardous amounts of lead and cadmium becoming accessible to young children. However, even when CPSC staff used Greenpeace's weathering data in the exposure calculations, the data showed the products would not result in hazardous exposure to lead or cadmium.

Why didn't CPSC recall these products?

The mere presence of lead or cadmium in these products does not in and of itself, make the products hazardous. A hazard results

if the chemicals are released from the products through customary or reasonably foreseeable handling or use in amounts that can cause a substantial adverse health effect. Although some of the products tested by CPSC contained lead or cadmium, further CPSC testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. Thus, children would NOT be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner. Since CPSC found no hazard it did not seek a recall of the products.

What are the adverse health effects for lead and cadmium? Are there limits for exposure?

The adverse health effects of lead poisoning in young children are well documented and can have long-lasting or permanent consequences. The health effects include deficits in neurobehavioral function and intellectual performance, developmental delays, decreased stature, and diminished hearing acuity. The CPSC, the Centers for Disease Control and Prevention, the Environmental Protection Agency, the Department of Housing and Urban Development, and other Federal agencies, recognize blood lead levels above 10 micrograms per deciliter (ug/dl) as a health concern and recommend various lead poisoning prevention activities. To prevent young children from exceeding the 10 ug/dl blood lead level, CPSC staff seeks to limit chronic ingestion of lead to not more than 15 ug of lead per day from consumer products.

Chronic cadmium ingestion results in kidney damage which is indicated by the presence of certain proteins in the urine. Using the EPA reference dose of 1 microgram per kilogram of body weight per day (ug/kg/day), CPSC staff suggests that chronic ingestion of cadmium not exceed 9.2 ug/day for a 1 year old, 13.5 ug/day for a 3 year old, and 20.2 ug/day for a 6 year old.

What factors are considered by CPSC staff in its hazard assessment?

Determining the product-specific human use characteristics of a product is an essential component of a hazard assessment, especially for children's products. CPSC staff considers the reasonably foreseeable use of a product by determining the age of the child using the product, the type of exposure (hand-to-mouth, chewing, mouthing), the frequency and period of exposure, accessibility, extent of exposure (area handled, mouthed, or chewed), and use environment (any exposure to heat and sunlight). The relationship between exposure and adverse health effects are also considered for each chemical or substance.

Does CPSC have any regulations for lead or cadmium in children's vinyl products?

In 1978, the CPSC banned paint containing in excess of 0.06% lead by weight intended for consumer use. At the same time, it also banned toys and other articles intended for use by children that use paint with a lead content in excess of 0.06% because they present a risk of lead poisoning to young children.

Under the Federal Hazardous Substances Act (FHSA), the Commission has additional authority to protect children from hazardous exposures to lead and cadmium (and any other substance) in consumer products. To exercise this authority, the Commission must be able to demonstrate (a) that persons are exposed to the substance during customary or reasonably foreseeable handling or use, and (b) that exposure may cause substantial risk of adverse health effect(s). A toy or other article intended for use by children which contains a hazardous amount of a toxicant that is accessible to children is a banned hazardous substance. A product containing lead or cadmium (or any other substance) that is not specifically intended for use by children but which creates a risk of substantial personal injury or illness due to customary or reasonably foreseeable handling or use requires precautionary labeling under the FHSA, 15 U.S.C. § 1261(p).

Shouldn't companies stop using lead or cadmium even if the products don't release hazardous levels of lead or cadmium?

The Commission does not have the authority to require companies to stop using lead or cadmium in consumer products if the levels that are released are not hazardous under the Federal Hazardous Substances Act. However, the Commission staff encourages companies that do use lead or cadmium in any consumer product, to eliminate the use of lead or cadmium in that product if the lead or cadmium can be released or become accessible to children through customary or reasonably foreseeable handling or use.

Does the CPSC regularly test products?

CPSC staff continues to seek out and assess information about any potential risk to children from exposures to consumer products. CPSC staff regularly collects and tests children's articles and will take action to remove a product from the marketplace where it can be demonstrated that the product is hazardous.

Can the 0.02% lead specification limit developed by CPSC staff for miniblinds be applied to vinyl children's products?

CPSC staff developed a manufacturing guidance limit for lead of 0.02% by weight specifically for vinyl miniblinds in 1996. This limit was based on the staff's assessment of the health effects

associated with lead ingestion, the limit for lead derived from the likelihood of children ingesting leaded dust from degrading miniblinds, and the average surface area of a 2 to 6 years old child's hand. The staff believed that this limit would minimize the risk of lead poisoning from PVC miniblinds when manufacturers discontinued using leaded formulations during the manufacturing process and followed good manufacturing practices. The staff also believed that with no lead intentionally added and good manufacturing practices, much lower lead levels were feasible for miniblinds.

Caution should be taken in applying the 0.02% lead limit to vinyl products besides miniblinds. Differences in manufacturing processes, materials used, accessibility of lead-containing parts, product usage, and environmental conditions, could affect the appropriateness of this limit for other types of vinyl products.

For the recent tests conducted by the CPSC staff, the 0.02% lead level was used as a practical screening threshold to decide when further testing was needed.