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Lead Testing Wipes Contain Measurable Background Levels of Lead

James. J. Keenan · Matthew H. Le · Dennis J. Paustenbach · Shannon H. Gaffney

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Abstract Lead is registered under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) as both a carcinogen and a reproductive hazard. As part of the process to determine if consumer products satisfy Proposition 65 with respect to lead, various wipe sampling strategies have been utilized. Four commonly used wipe materials (cotton gauze, cotton balls, ashless filter paper, and Ghost™ Wipes) were tested for background lead levels. Ghost™ Wipe material was found to have 0.43 ± 0.11 µg lead/sample (0.14 µg/wipe). Wipe testing for lead using Ghost™ Wipes may therefore result in measurable concentrations of lead, regardless of whether or not the consumer product actually contains leachable lead.

Keywords Accessible lead testing · Consumer products

Inorganic lead is a blue-to-white or silvery gray metal that is dense, soft, and pliable. Lead is widely used in the manufacturing of many consumer products, including ceramic glazes, paints, and plastics because of its qualities as a stabilizing material. In general, as the amount of leachable lead in a product increases, the likelihood of human lead exposure increases; thus a product's quantity of leachable or accessible lead is a critical parameter when evaluating potential exposures to lead-containing products. Lead can accumulate in the body, and is known to cause health effects following chronic exposure, including neurological, digestive, kidney, blood, and immune system effects (Gosselin 1984). Children are particularly susceptible to lead exposures, which can cause learning disabilities, as well as behavioral and emotional problems (Gosselin 1984; Lanphear et al. 2005). Several studies have examined the dermal absorption of lead in both humans and animals, indicating that inorganic lead salts and lead metal can dissolve in sweat and subsequently be absorbed through the skin, although in far smaller quantities than may become bioavailable via either inhalation or hand-to-mouth ingestion (Florence et al. 1996; U.S. EPA 1997).

James. J. Keenan (✉) · M. H. Le · D. J. Paustenbach · S. H. Gaffney
ChemRisk, LLC, 25 Jessie St. Suite 1800, San Francisco, CA 94105, USA
e-mail: jkeenan@chemrisk.com

A product's quantity of accessible lead is a critical parameter when evaluating potential exposures to lead-containing products. Although many regulations, such as the Consumer Product Safety and Improvement Act, do not address exposure, but instead establish maximum concentrations allowed in the product (Table 1), California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) does address exposure. Under Proposition 65, all products containing chemicals listed on the State of California's annually published register of chemicals believed to be carcinogenic, cause birth defects, or cause reproductive harm, must be accompanied by a warning to those who may be exposed to doses above those considered allowable by the Act (California Office of Environmental Health Hazard Assessment (OEHHA) 1986) A product is exempted from the warning requirements if a risk assessment demonstrates that an exposure "poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant

Table 1 Selected industry standards for lead in consumer products

Governing Body	System	Limit	References
State of California	Lead in jewelry	≤0.06% or 600 ppm total lead for each individual component of a product	Proposition 65 and California Health and Safety Code, Sect. 25214.1, et seq.
State of California	Lead exposure	0.5 μg/day	Proposition 65 Maximum Allowable Dose Level (MADL)
U.S. CPSC	Lead in coatings for toys, furniture etc.	<600 mg/kg (ppm)	CPSC (2008)
U.S. CPSC	Lead in consumer products	≤0.06% or 600 ppm (total ≤175 μg (extractable)	CPSC (2008)
U.S. CPSC	Lead in children's products	Phased, initially set at <600 mg/kg total	CPSC (2008)

The California environmental protection agency (CalEPA) office of environmental hazard

to subdivision (a) of Sect. 25249.8" (California Office of Environmental Health Hazard Assessment (OEHHA) 1986). The California Code of Regulations defines a consumer product exposure as an "exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service" (California Office of Environmental Health Hazard Assessment (OEHHA) 1986).

Assessment (OEHHA) has developed "safe harbor levels" that are used to assess product compliance with Proposition 65. These concentrations are the anticipated absorbed doses which should not present an increased health risk to the consumer (including children). For chemicals believed to be carcinogens, established allowable daily intake levels are called "No Significant Risk Levels" (NSRLs), which are defined as the daily dose that, over a 70-year lifetime, may result in cancer risk of one excess case in 100,000 individuals. For chemicals listed as causing reproductive toxicity under Proposition 65 (Sect. 12805), Maximum Allowable Dose Levels (MADLs) were established, representing the No Observable Effect Level (NOEL) in animal models for the chemical, divided by an uncertainty factor of 1,000 to account for possible variance between animal models and humans (California Office of Environmental Health Hazard Assessment (OEHHA) 1986). Proposition 65 lists inorganic lead as both a carcinogen and as a reproductive hazard. The NSRL adopted for lead as a carcinogen is 15 micrograms per day (μg/day) for oral exposure. The MADL adopted for lead as a reproductive hazard is 0.5 μg/day (California Office of Environmental Health Hazard Assessment (OEHHA) 1986).

Wipe sampling, which is recommended by various governmental and non-governmental bodies because of its simplicity and accuracy, is the preferred method for accessible lead testing and subsequent exposure assessment, both in industrial and consumer settings (Bai et al. 2003; HUD 1996). Specific to lead sampling, various materials have been recommended, such as cotton swabs, cotton gauze, disposable toilettes, as well as commercially available Ghost™ Wipes, a product designed specifically for use in assessing accessible lead. However, if background lead concentrations exist within these materials, exposure calculations could be affected. The objective of this study was to determine background lead levels in commonly used wipe testing materials and to assess their affect on Proposition 65 exposure assessments.

Materials and Methods

Surface lead testing materials commonly used for consumer products were chosen following a review of published wipe testing methodologies. The U.S. Consumer Product Safety Commission (CPSC) published a draft methodology for testing accessible lead in consumer products (CPSC Undated) recommending the use of #2 filter paper, 55 mm in diameter, which has been moistened with the same weight (±10%) of distilled water or the use of commercially available pre-moistened wipes such as Ghost™ Wipes (CPSC Undated). The National Institute for Occupational Safety and Health (NIOSH) has also published a standardized sampling methodology designed for testing surface lead contamination (NIOSH 1994). The methodology requires the use of 2″ × 2″ sample pads, cotton gauze, or ashless quantitative filter paper as sampling material. It is noted in this methodology that pre-moistened toilettes such as Wash'n Dri™ may be used, although other commercially available wipe materials may not ash properly, or may contain measureable lead (National Institute for Occupational Safety, Health (NIOSH) 1994). According to both methods, the samples are to be analyzed using flame atomic absorption spectrometry (AAS) or inductively coupled mass spectrometry (ICP-MS) following surface wipe testing.

Twenty-four unused Ghost™ Wipe samples, three cotton ball samples, three cotton gauze samples, and three ashless quantitative filter paper samples were tested for lead. Ghost™ Wipes and ashless quantitative filter paper were obtained from SKC West Laboratories, and cotton balls and cotton gauze were obtained from local stores. Samples were collected by removing three units of each test material from their original packaging and placing them directly in the bottles to be shipped to the laboratory. TestAmerica Laboratories performed the digestion and analysis of all materials in accordance with U.S. EPA SW-846 Method 3050B (Acid Digestion of Sediments, Sludges, And Soils) and SW-846 Method 6020 (LOD = 0.1 µg/sample), respectively (U.S. EPA 2007a, b).

Results were reported in µg/sample and summary statistics, including the minimum, mean, maximum and 95th percentile values of the distribution were calculated when applicable. The 95th percentile of lead in the material was calculated using the nonparametric or distribution-free weighted averaging method (Helsel and Hirsch 1995) using the SYSTAT version 11 statistical program, and was used to correct for background concentrations of lead in the material.

To show the impact of background lead levels on assessing product compliance with Proposition 65, example exposure estimates were performed. These example exposure estimates assumed that a consumer product was tested for accessible lead using the U.S. CPSC recommended Ghost™ Wipes and a wipe testing methodology that included using three separate wipes over a 100 cm^2 area of the consumer product. It was assumed that the consumer product had 0.05 µg/cm^2 of accessible lead on the surface, and that the product was used for 4 h per day. For simplicity, the exposure estimate evaluates only the hand-to-mouth exposure route. This exposure route applies to lead that is ingested as a result of handling a product; lead is transferred from the product to the hand, and then transferred from the hand to the mouth, usually by touching the mouth or lips with the hand, by nail biting, or by finger or thumb sucking. The common assumptions used in the calculation of hand-to-mouth exposure are included in Table 2. The exposure calculation is as follows:

$$M_{\text{hand-mouth}} = L_{\text{hand}} \times A \times f_{\text{direct}} \times \lambda_D \times t,$$

where $M_{\text{hand-mouth}}$ is the mass of lead transferred to the mouth (µg), L_{hand} is the loading of lead on the hands (µg/cm^2), A is the surface area of the hand in contact with the mouth (cm^2), f_{direct} is the hand-to-mouth transfer factor, λ_D is the rate of hand-to-mouth contact (#/h), and t is the amount of time the hand remains loaded with lead.

Results and Discussion

A total of 33 samples were collected. Each sample included three units of wipe material that were removed from their packaging, digested together, and analyzed using ICP-MS (LOD = 0.1 µg/sample). Lead was not found in cotton ball (n = 3) or filter paper (n = 3) samples. One of three cotton gauze samples was found to have 0.2 µg of lead. Every Ghost™ Wipe sample (n = 24) contained measurable amounts of lead. On average, Ghost™ Wipe material was found to have 0.43 ± 0.11 µg lead/sample (0.14 µg/wipe; Fig. 1). The Ghost™ Wipe results were therefore used in the example exposure calculations.

The average total lead found in Ghost™ Wipe samples was 0.43 µg (Range: 0.27–0.63 µg). Thus, if average Ghost™ Wipes were used to test a consumer product containing 0.2 µg of accessible lead, using the standard hand-to-mouth equation above, the uncorrected lead exposure via hand-to-mouth activity of an adult female would be 1.77 µg/day (Fig. 2). If the maximum and minimum lead levels found in the Ghost™ Wipe samples were used (instead of the average value) to sample a consumer product with 0.2 µg of accessible lead, the uncorrected estimated exposure would be 2.38 and 1.28 µg/day, respectively (Fig. 2). All of these uncorrected example exposure estimates exceed the Proposition 65 MADL of 0.5 µg/day.

If a sufficient number of field blanks are included in the sampling plan (n ≥ 8), the 95th percentile of lead in the material can be calculated. By definition (US EPA 1989), the 95th percentile is "that value X such that 95% of the data have values less than X, and 5% have values exceeding X." The 95th percentile therefore represents an upper bound value for the mass of lead that would be expected to be present due only to the wipes themselves. In this study, the 95th percentile of lead found in Ghost™ Wipes was 0.55 µg. In order to illustrate the effect of correcting an exposure estimate using the 95th percentile of lead found in

Table 2 Exposure assumptions used in estimating dose

Parameter	Value	Unit	Note/References
Hand-to-mouth transfer factor for lead, f_{direct}	50%	(unitless)	Camann et al. (2000)
Rate of hand-to-mouth contact for adults, λl_D	9	# Contacts/h	Agency U.S. EPA 2002
Surface area of the hand that comes into contact with the mouth[a]	17	cm^2	California Office of Environmental Health Hazard Assessment (OEHHA) (2008)
Hours of use of the consumer product	4	h/day	U.S. Census Bureau (2004)

[a] OEHHA selected 17 cm^2 as the value for adult women (California Environmental Protection Agency (CalEPA), 2008)

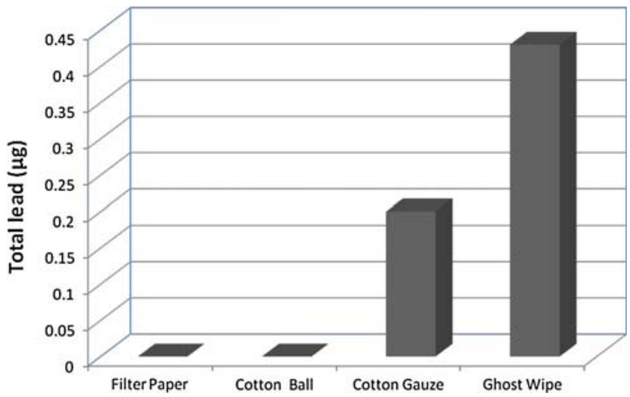

Fig. 1 Average total lead per sample

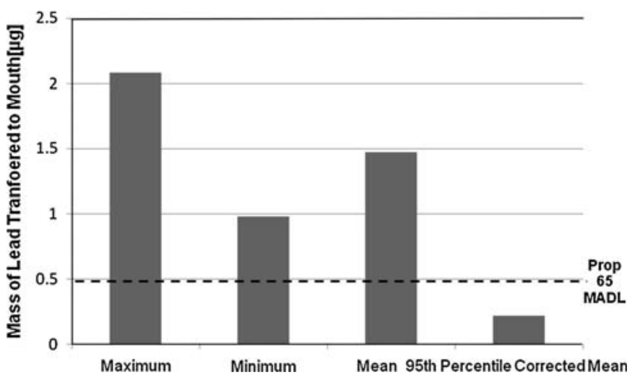

Fig. 2 Example hand-to-mouth exposure calculations

Ghost™ Wipes, the 95th percentile background lead level was subtracted from the uncorrected theoretical mean exposure estimate, resulting in a corrected exposure estimate of 0.10 µg/kg-day (Fig. 1).

Accurate testing of accessible lead in consumer products is of significant importance, particularly in California, where Proposition 65 mandates low consumer exposure. There are several regulations that specify allowable background lead concentrations in wipe sampling materials. Criteria set by ASTM International and the U.S. Department for Housing and Urban Development (HUD), for example, require that the background level of lead in a wipe must be 1.0 and 5.0 µg, respectively. These levels are 10- and 50-fold higher than the reporting limits in this study (0.1 µg), respectively. If analytical methods with low limits of detection are selected, then, wipe testing for lead using acceptable wipe materials according to ASTM and HUD criteria may therefore result in measurable concentrations of lead, even if the consumer product does not actually contain lead.

Lead testing methodologies often list several options for materials in addition to Ghost™ Wipes or other commercially available products that are designed specifically for lead testing. These include, but are not limited to, cotton gauze, cotton balls, or ashless filter paper. In this study, cotton balls, ashless filter paper, and cotton gauze were not found to have to have detectable levels of lead, with the exception of one of the cotton gauze samples, which had a low concentration of lead (Fig. 1). The concentration of lead in the one gauze sample was significantly less than that found in Ghost™ Wipe samples, and, because of the low number of cotton gauze samples tested, no conclusion can be made about its acceptability as a wipe testing material for assessing lead exposure from consumer products. The data suggest, however, that the use of cotton balls or ashless filter paper would avoid background concentration corrections in exposure estimates, although the sample size is insufficient to draw a firm conclusion. Additional testing of these alternative materials is necessary.

The Ghost™ Wipes tested in this study met ASTM and HUD criteria, and were recommended for use by several government agencies. With average lead concentrations of 0.43 µg (range 0.27–0.63 µg), however, Ghost Wipes used to test for accessible lead in consumer products may lead to an erroneous conclusion that a product causes lead exposures in excess of the Proposition 65 Safe Harbor Levels (Fig. 2). If one were to accept (adopt) that uncorrected example exposure calculations were accurate and representative, a consumer product tested with 0.2 µg of accessible lead on its surface would be required under Proposition 65 to have a warning label, even if the Ghost™ Wipes with the lowest background lead concentrations (0.27 µg/sample) were used in the testing. The addition of unnecessary warning labels to any product would likely have considerable negative impacts on a product's sales and use.

Careful consideration must therefore be given to choosing a wipe material for accessible lead testing and to the analysis of field blank controls. Unused wipe material ($n \geq 8$) should be analyzed in the same way as the samples in order to quantify the mass of lead associated with the wipe material itself. Because these field blanks represent the background lead mass in the wipe samples and not the mass of lead that may have contaminated the wipes during transport to the lab or during analysis, these data should be treated the same way that background concentration data are treated in other environmental media; the 95th percentile concentration is representative of the upper bound value. The 95th percentile concentration therefore represents an upper bound value for the mass of lead that would be expected to be present in the wipe material itself, and should be subtracted from the results.

Wipe testing for lead using Ghost™ Wipes and an analysis according to ICP-MS may therefore result in measurable concentrations of lead, regardless of whether or not the tested surface or product actually contains accessible lead. As demonstrated above, these results may falsely lead to a conclusion that a tested product may be responsible for human lead exposures in excess of the Proposition 65 Safe Harbor Levels. Special attention therefore needs to be paid to the choice of wipe material and the use of field blank controls.

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