Concentrations and Potential Health Risks of Metals in Lip Products

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BACKGROUND: Metal content in lip products has been an issue of concern.

OBJECTIVES: We measured lead and eight other metals in a convenience sample of 32 lip products used by young Asian women in Oakland, California, and assessed potential health risks related to estimated intakes of these metals.

METHODS: We analyzed lip products by inductively coupled plasma optical emission spectrometry and used previous estimates of lip product usage rates to determine daily oral intakes. We derived acceptable daily intakes (ADIs) based on information used to determine public health goals for exposure, and compared ADIs with estimated intakes to assess potential risks.

RESULTS: Most of the tested lip products contained high concentrations of titanium and aluminum. All examined products had detectable manganese. Lead was detected in 24 products (75%), with an average concentration of 0.36 ± 0.39 ppm, including one sample with 1.32 ppm. When used at the estimated average daily rate, estimated intakes were >20% of ADIs derived for aluminum, cadmium, chromium, and manganese. In addition, average daily use of 10 products tested would result in chromium intake exceeding our estimated ADI for chromium. For high rates of product use (above the 95th percentile), the percentages of samples with estimated metal intakes exceeding ADIs were 3% for aluminum, 68% for chromium, and 22% for manganese. Estimated intakes of lead were <20% of ADIs for average and high use.

CONCLUSIONS: Cosmetics safety should be assessed not only by the presence of hazardous contents, but also by comparing estimated exposures with health-based standards. In addition to lead, metals such as aluminum, cadmium, chromium, and manganese require further investigation.

KEY WORDS: cosmetic safety, health risk, lipstick, metal, susceptible populations. Environ Health Perspect 121:705–710 (2013). http://dx.doi.org/10.1289/ehp.1205518 [Online 2 May 2013]

Cosmetic products contain thousands of chemicals, some of which have been associated with reproductive, developmental, or other health effects based on human or animal studies, including phthalates, formaldehyde, methylène chloride, acetone, acetonitrile, methacrylates, toluene, xylene, ethyl ether, and lead (Pb) (De Cock et al. 2012; Dodson et al. 2012; Ferret et al. 2012; Heisterberg 2012; Leefebvre et al. 2012; Moyer and Nixon 2012; Ulker et al. 2012). Lip products have been suggested as a particular concern because of the potential for exposure through ingestion (Loretz et al. 2005).

In October 2007, the Campaign for Safe Cosmetics tested 33 popular brands of lipsticks and reported that 61% contained Pb, with levels up to 0.65 parts per million, indicating a cause for concern (Campaign for Safe Cosmetics 2007). Although the Campaign for Safe Cosmetics report was not peer reviewed, it brought attention to the issue of chemicals in cosmetic and personal care products and their safety. Since then, two other studies evaluated Pb in eye shadows and lipsticks: a U.S. Food and Drug Administration (FDA) study that detected Pb in all tested lipsticks (Hepp et al. 2009) and a study (Al-Saleh et al. 2009) that identified several cosmetic products containing Pb >20 ppm, the FDA limit of Pb as an impurity in color additives for cosmetics (FDA 2011). Studies conducted in other countries have also detected Pb and cadmium (Cd) in some lipstick samples (Adepoju-Bello et al. 2012; Brandao et al. 2012; Gondal et al. 2010; Solidum and Peji 2011).

In the present study we extended the FDA study and the Campaign for Safe Cosmetics by testing for Pb, aluminum (Al), Cd, cobalt (Co), chromium (Cr), copper (Cu), manganese (Mn), nickel (Ni), and titanium (Ti) in lipsticks and lip glosses used by young women, estimating potential daily intakes, and comparing the estimates to existing health guidelines.

Method

Sample collection. A convenience sample of lipsticks and lip glosses was selected based on information provided by 12 members of the Asian Communities for Reproductive Justice (ACRJ) Youth Program, a group of Asian girls 14–19 years of age who lived in low-income neighborhoods in Oakland, California. Specifically, the girls were asked to record the brand and product names of the lipsticks and lip glosses they were carrying and had in their bathrooms at home, which represented products used by their sisters as well. The reported products were then purchased by researchers at a chain drug store (26 products), a major department store (4 products), and a chain specialty store (2 products).

All methods were approved by the University of California, Berkeley, Institutional Review Board (IRB). The young women who provided information on the lip products they used, and their parents or guardians, signed an informed consent form approved by the University of California, Berkeley, IRB before the study. We have complied with all applicable IRB regulations and requirements.

Analytical method. Sample analysis followed National Institute for Occupational Safety and Health (NIOSH) standard method for metals (Method 7303: Hot Block/HCl/HNO3 Digestion) with slight modifications (NIOSH 2005). Approximately 0.5 g of each sample was transferred into a clean, 50-mL hot block digestion tube and digested with 2.0 mL concentrated nitric acid (HNO3) on a block digester (LACHAT Instruments, Loveland, CO) at 130°C for 15 h, with the tubes covered with glass funnels to allow for nitric acid reflux during the digestion. Samples were diluted to 12.5 mL with distilled, deionized water and then filtered to remove material that did not completely dissolve, including waxy material floating on the top of the digest and white or light yellow precipitates that were most likely silicates. Solutions were analyzed by inductively coupled plasma optical emission spectrometry (ICP/OES) (Optima 5300DV; PerkinElmer, Waltham, MA). Metals examined included Al, Cd, Co, Cr, Cu, Mn, Pb, Ni, and Ti. Reagent blanks and mail blanks were also analyzed.

Data analysis. Measured metal concentrations (parts per million, weight/weight) were

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*Asian Communities for Reproductive Justice is now known as Forward Together.

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converted to estimated daily metal intakes (micrograms per day) based on lip product use data from a study of cosmetic product use among 360 women (ages 19–65 years) from ten different U.S. geographical regions (Loretz et al. 2005). The investigators reported that on average the women used lipsticks 2.35 times per day (range, 0–20 times) and applied 10 mg of product at each use (range, 0–214 mg), resulting in average daily use of 24 mg of lip products (range, 0–214 mg; 95th percentile = 87 mg/day). We assumed that all applied lip products were ingested, and thus estimated metal intakes for average use (24 mg/day) and high use (87 mg/day) of lip products.

Metals in cosmetic products are not currently regulated in the United States. Therefore, as a point of comparison for potential health risks, we estimated acceptable daily intakes (ADIs) for Al, Cd, Cu, Ni, and Pb based on information used by the California Environmental Protection Agency (Cal/EPA) to determine Public Health Goals (PHGs) for drinking water (Cal/EPA 2001a, 2001b, 2006, 2008b, 2009) (Table 1). Specifically, we derived ADIs based on the following no observed adverse effect levels (NOAELs) or lowest observed adverse effect levels (LOAELs) and uncertainty factors (UF) used to determine PHGs: Al NOAEL/LOAEL = 125 mg/day and UF = 100 (for duration of study, 10 for individual variation and sensitive subgroups) (Cal/EPA 2001a); Cd NOAEL = 19 μg/day and UF = 50 (for protecting sensitive individuals, 10 for cancer risk due to oral exposure to Cd) (Cal/EPA 2006); Cu NOAEL = 426 μg/kg-day and UF = 3 for uncertainties in study data (Cal/EPA 2008b); Ni NOAEL = 1.12 mg/kg-day and UF = 1,000 (for interspecies extrapolation, 10 for intraspecies variability, and 10 for potential carcinogenicity of oral exposure) (Cal/EPA 2001b); Pb NOAEL/LOAEL = 2.86 μg/day and UF = 3 for uncertainty in protectiveness of this level and small sample size (Cal/EPA 2009). For NOAEL/LOAEL reported according to body weight per day (micrograms per kilogram per day) we assumed a body weight of 50 kg for young Asian women to determine the ADI.

Our ADI for Cr was based on the PHG derived by the Cal/EPA for carcinogenic risks associated with hexavalent Cr according to the standard risk calculation [concentration = risk/(potency × dose)] (Cal/EPA 2011b), such that ADI = risk/UF, where risk = a default risk level of 1 in 1 million, or 10−6, and UF = 0.5/mg/kg-day, the oral cancer potency for hexavalent Cr, resulting in an estimated ADI of 0.1 μg/day for a 50-kg woman. Mn does not have a PHG, so we used the California Reference Exposure Level (REL) for systemic effects of Mn via inhalation of 20 m³ of air per day (Cal/EPA 2008b), assuming that toxicokinetic differences between oral and inhalational routes of exposure were not significant. Co and Ti have no PHGs or RELs because they are not regulated by California or federal standards; therefore we did not derive ADIs for these metals.

Finally, we compared estimated metal intakes via lip products to the derived acceptable daily intakes. We derived relative intake indices (RIIs) for metals via lip products as a percentage of the ADI:

relative intake index (RII) % =

(estimated daily intake/ADI) × 100%

Hence, for each metal, intake at the ADI would yield an RII of 100%. RIIs were calculated assuming average use of lip products (intake of 24 mg of product/day) and high use (87 mg/day).

Results

Lip product information. We tested 32 individual products in this preliminary study, including 8 lipsticks and 24 lip glosses sold by a total of 7 distinct companies. Prices ranged from $5.59 to $24. The tested products were representative of those used by young women in the ACRJ Youth Program.

Metal concentrations in lip products. Mn, Ti, and Al were detected in all examined products, with Ti and Al present in the highest concentrations of the metals tested (Table 2 and Figure 1). Pb was detected in 75% of products, with an average concentration of 0.36 ± 0.39 ppm (median, 0.151 ppm; maximum, 1.32 ppm). Approximately half (47%) of the samples contained Pb at concentrations higher than the FDA-recommended maximum level of 0.1 ppm for Pb in candy likely to be consumed frequently by small children (FDA 2005). Co had the lowest average concentration among the examined metals (0.28 ± 0.31 ppm, mean ± SD). Metal concentrations varied substantially across the products (Table 2). For example, product L1014 had the highest Cr concentration (9.72 ppm) and the second highest concentrations of Cd, Mn, and Pb (2.16, 35.3, and 1.25 ppm, respectively). Products L1021 and L1029 had the highest concentrations of Pb (1.32 ppm) and Al (27.03 ppm), respectively, and both had high Cr and Mn levels. However, we did not observe clear patterns indicating that metal concentrations were related to specific brands, product type (lipstick vs. lip gloss), color, or cost.

Estimated daily intakes via use of lip products. We converted measured metal concentrations (parts per million) in the individual lip product samples to metal intakes (micrograms per day) based on usage patterns reported by Loretz et al. (2005), assuming average and high use (resulting in oral intake of 24 and 87 mg of product per day, respectively) (Table 3). RIIs comparing estimated metal intakes from lip products to the derived acceptable daily intake are presented in Figure 2. When used at the average daily rate (24 mg/day), estimated Cr intake from 10 products (31%) exceeded the ADI for Cr (RII > 100%). Estimates based on high use (87 mg/day) suggested exposures exceeding the ADI for Al in 1 sample (3% of the products tested), Cr in 22 samples (68%), and Mn in 7 samples (22%). Estimated intakes for Ni, Cu, and Pb were well below their ADIs even for high use. Estimated Pb intake for the product with the highest Pb concentration (product L1021) was 3% and 12% of the ADI assuming average and high use, respectively.

Discussion

This preliminary study of metal content in lip products suggests potential public health concerns. However, metals in cosmetic products are not currently regulated by the FDA. Although metal concentrations in lip products have been reported by studies both in the United States and in other countries (Adepoju-Bello et al. 2012; Al-Saleh and Al-Enazi 2011; Al-Saleh et al. 2009; Brandao et al. 2012; Gondal et al. 2010; Gunduz and Akman 2013; Hepp et al. 2009; Solidum and Peji 2011), interpreting how reported concentrations may be related to potential health risk is challenging. We used California Public Health Goals for drinking water contaminants to derive health-based standards for ingestion exposure from drinking water (Cal/EPA 2011a). In the calculation of PHG, a relative source contribution is applied to

Table 1. PHGs and ADIa derived for the present study.

| Metal intake guidelines | Al | Cd | Crb | Cu | Mn2 | Ni | Pb |
|-------------------------|----|----|-----|----|-----|----|----|
| PHG (μg/L)              |    |    | 0.04 | 0.02 | 300 | 0.09 | 12 | 0.2 |
| NOAEL/LOAEL (mg/day)    | 125| 19 | 0.05 | 426 | 3   | NA  | 1.12 | 2.86 |
| UF (mg/kg/day)          | 100| 50 | 0.5  | 3   | NA  | 1,000 | 3  |
| ADI (μg/day)           | 1,250| 0.38 | 0.1 | 7,100 | 1.8 | 56 | 0.95 |

Abbreviations: ADI, acceptable daily intake; NA, not applicable; PHGs, public health goals; UF, uncertainty factor.

See “Methods” for the calculation of ADI. For PHG, Cr(VI) potency factor was used instead of NOAEL/LOAEL. REL for manganese via inhalation was used instead of a PHG value (μg/m³).

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adjust intake of the contaminant from sources other than drinking water. Vulnerable populations such as infants and children are also considered by adjusting water consumption rate (dose) for the different age groups. PHGs provide information on concentrations of drinking-water contaminants that pose no significant health risks if the water is consumed for a lifetime. Although they are not regulatory standards, PHGs are considered more health based than Maximum Contaminant Levels, which are mandatory drinking-water standards that take into account not only health risks but also the feasibility and cost of monitoring and maintaining standards in drinking-water supplies. In deriving the ADIs we did not account for metal intakes from other sources, nor did we consider potential age- and sex-related vulnerabilities, although they may have been partially accounted for by the uncertainty factors used in deriving PHGs. We used 20% of RII as an additional comparison point because 20% is a typical relative source contribution value used in developing PHGs for

Table 2. Metal concentration in tested lip products and summary statistics (ppm w/w).

| Sample ID | Type     | Al  | Cd   | Co   | Cr   | Cu   | Mn   | Ni   | Pb   | Ti  |
|-----------|----------|-----|------|------|------|------|------|------|------|-----|
| L1001     | Lip gloss| 2.147| <0.002| 0.133| 0.584| 1.19 | 3.35 | 2.10 | 0.077| 125 |
| L1002     | Lip gloss| 4.413| 0.667| 0.887| 4.19 | 2.05 | 29.5 | 4.23 | 0.405| 663 |
| L1003     | Lip gloss| 4.559| <0.002| 0.302| 1.32 | 0.579| 5.39 | 9.14 | 0.149| 265 |
| L1004     | Lip gloss| 520  | 3.48 | 2.53 | 0.697| 0.889| 0.884| 9.73 | <0.025| 214 |
| L1005     | Lip gloss| 164  | 1.63 | <0.005| 0.386| 0.689| 0.700| 3.59 | 0.080| 329 |
| L1006     | Lip gloss| 10,536| <0.002| 0.200| 1.21 | 0.319| 6.83 | 0.651| 0.051| 454 |
| L1007     | Lip gloss| 547  | 0.333| 0.092| 0.205| 1.19 | 1.64 | 0.397| 0.042| 103 |
| L1008     | Lip gloss| 10,533| <0.002| 0.304| 1.20 | 1.03 | 6.78 | 1.85 | <0.025| 958 |
| L1009     | Lip gloss| 4,079| 0.953| 0.961| 4.94 | 0.197| 38.5 | 2.71 | 0.572| 1,418|
| L1010     | Lip gloss| 4,079| 0.953| 0.961| 4.94 | 0.197| 38.5 | 2.71 | 0.572| 1,418|
| L1011     | Lip gloss| 1,012| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1012     | Lip gloss| 1,012| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1013     | Lip gloss| 1,013| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1014     | Lip gloss| 1,014| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1015     | Lip gloss| 1,015| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1016     | Lip gloss| 1,016| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1017     | Lip gloss| 1,017| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1018     | Lip gloss| 1,018| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1019     | Lip gloss| 1,019| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1020     | Lip gloss| 1,020| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1021     | Lip gloss| 1,021| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1022     | Lip gloss| 1,022| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1023     | Lip gloss| 1,023| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1024     | Lip gloss| 1,024| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1025     | Lip gloss| 1,025| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1026     | Lip gloss| 1,026| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1027     | Lip gloss| 1,027| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1028     | Lip gloss| 1,028| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1029     | Lip gloss| 1,029| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1030     | Lip gloss| 1,030| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1031     | Lip gloss| 1,031| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |
| L1032     | Lip gloss| 1,032| 0.141| 1.28 | <0.010| 10.2| 0.299| 0.216| 60.0 | 178 |

For values > LOD

*LOD, limit of detection.*
the tested metals. We found that estimated intakes of Al, Cd, Cr, and Mn from some of the tested products were > 20% of their estimated ADIs, assuming average daily use of lip products. The proportion of samples with RII > 20% substantially increased assuming high use (corresponding to the 95th percentile of lip product use based on a previous study) (Loretz et al. 2005), including 63% of the products tested for Al, 31% for Cd, 91% for Cr, and 66% for Mn.

Cd and its compounds are known human carcinogens [International Agency for Research on Cancer (IARC) 1993]. Inhalation exposure of Cd has been associated with lung cancer and respiratory system damage (Chan et al. 1988; Davison et al. 1988; Nawrot et al. 2006; Smith et al. 1970; Stayer et al. 1992; Thun et al. 1985), and chronic oral exposure may lead to kidney and bone impairments (Åkesson et al. 2005; Nogawa et al. 1990). Animal studies indicate that young animals might absorb more Cd than adults and be more susceptible to bone impairments (Ogoshi et al. 1989). Animal studies also found that feeding rats and mice high levels of 

Figure 2. Box and whiskers plots showing distributions of RII values for each metal assuming average use or high use of lip products, defined as 24 and 87 mg of product/day, respectively. Corresponding numeric data are provided in Table 3 for all samples (n = 32). Boxes extend from the 25th to the 75th percentile, horizontal bars inside the boxes represent the median, diamonds represent the mean, whiskers extend to maximum and minimum observations within 1.5 times the length of the interquartile range above and below the 75th and 25th percentiles, respectively, and outliers are represented as circles. RII values represent the estimated daily intake for each metal as a percentage of the ADI values derived for this study. The horizontal line at RII = 100 indicates daily intakes that are equal to the ADI values for each metal; the horizontal line at RII = 20 indicates estimated daily intakes that are 20% of the ADI.

Table 3. Estimated metal intakes via lip products for average (24 mg/day) and high (87 mg/day) daily use (μg/day).

| Sample ID | Average use | High use |
|-----------|-------------|----------|
| L1001     |             |          |
| L1002     |             |          |
| L1003     |             |          |
| L1004     |             |          |
| L1005     |             |          |
| L1006     |             |          |
| L1007     |             |          |
| L1008     |             |          |
| L1009     |             |          |
| L1010     |             |          |
| L1011     |             |          |
| L1012     |             |          |
| L1013     |             |          |
| L1014     |             |          |
| L1015     |             |          |
| L1016     |             |          |
| L1017     |             |          |
| L1018     |             |          |
| L1019     |             |          |
| L1020     |             |          |
| L1021     |             |          |
| L1022     |             |          |
| L1023     |             |          |
| L1024     |             |          |
| L1025     |             |          |
| L1026     |             |          |
| L1027     |             |          |
| L1028     |             |          |
| L1029     |             |          |
| L1030     |             |          |
| L1031     |             |          |
| L1032     |             |          |

For values > LOD

| Median    |             |          |
|-----------|-------------|----------|
| Mean      |             |          |
| SD        |             |          |
of Cd (1–20 mg/kg-day) during pregnancy resulted in low birth weight, affecting skeletal development, and behavior and learning problems [Agency for Toxic Substances and Disease Registry (ATSDR) 2008a]. Although less than half (47%) of the tested lip products had detectable levels of Cd, our results suggest that Cd intake could exceed 20% of our estimated ADI for Cd exposure via drinking water for one product assuming average use, and for 10 products assuming high use.

Cr(VI) is a known human carcinogen; inhalation causes lung cancer and oral exposure through drinking water has been linked with increased stomach tumors (ATSDR 2008b). Our measurements did not distinguish hexavalent Cr from less toxic forms, and the percentage of hexavalent Cr in the lip products is therefore unknown. However, high total estimated intakes of Cr from use of several lip products and the potential for additional exposure from other sources suggest that Cr intake from lip products should be a priority for additional research.

Our acceptable daily intake value for Mn was derived from the Cal/EPA reference exposure limit for inhalation exposure because a public health goal is not available for Mn in drinking water. Inhalational exposure to high levels of Mn in occupational settings causes neurological effects in humans (ATSDR 2008c; Cook et al. 1974; Crossgrove and Zheng 2004). Although the evidence is inconclusive, Mn in drinking water has been associated with neurological and neurobehavioral outcomes in children, which suggests that effects of oral exposure may be similar to effects associated with inhalational exposure (Bouchard et al. 2006; Kilburn 1987; Kondakis et al. 1989). Estimated Mn intake assuming high use of lip products exceeded our ADI value based on inhalational exposure for seven products (22% of tested products).

Although Pb was detected in 75% of the lip product samples, including 15 samples with concentrations higher than the FDA standard of 0.1 ppm for Pb in candy frequently consumed by children, RIs for estimated Pb intakes appeared to be low compared with RIs for Al, Cd, Cr, and Mn. Thus, although Pb in lip products has been intensively discussed (Al-Saleh et al. 2009), in contrast with an average Pb concentration of 0.36 ppm (range, 0.025–1.32 ppm) for our sample of 32 lip products. Differences between the studies may reflect variation in Pb content among the specific products tested, though incomplete digestion of our samples also may have reduced apparent concentrations relative to actual levels. Therefore, further studies should endeavor to measure total metal content to the degree possible.

Conclusion

Our data indicate the need for further studies to evaluate metal concentrations in lip products, as well as other cosmetics, and related potential health risks. In addition to Pb, metals such as Al, Cd, Cr, and Mn require further investigation. Cosmetics safety should be assessed not only by the presence of hazardous contents, but also by comparing estimated exposures with health based standards. This preliminary study of the metal content of 32 lip products suggests that toxic metals in cosmetics should be regulated to protect women’s health in the United States, as has already been undertaken by the European Union through their Cosmetics Directive.

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