

Original Article



Risk Assessment of Probable Lead and Mercury Residue in Lipsticks Sold in the Iran Markets

Hadi Rahimzadeh-Barzoki^{1,2}, Saeed Aghebat-Bekheir³, Parisa Sadighara⁴, Mahdi Jahanbakhsh^{4,5}, Amin Reyhani⁶, Amir Sasan Mozaffari Nejad^{7,8}, Ali Shahryari^{1,2}, Marziyeh Karami⁴, Dileep Kumar Yeruva⁹

¹Environmental Health Research Center, Golestan University of Medical Sciences, Gorgan, Iran

²School of Health, Golestan University of Medical Sciences, Gorgan, Iran

³Department of Toxicology and Pharmacology, School of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran

⁴Department of Environmental Health, Food Safety Division, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran

⁵Department of Drug and Food Association, Faculty of Pharmacy, Alborz University of Medical Sciences, Karaj, Iran

⁶Department of Toxicology and Pharmacology, Faculty of Pharmacy, Mazandaran University of Medical Sciences, Sari, Iran

⁷Infectious Disease and Tropical Medicine Research Center, Isfahan University of Medical Sciences, Isfahan, Iran

⁸Bio Environmental Health Hazards Research Center, Jiroft University of Medical Sciences, Jiroft, Iran

⁹Department of Chemical and Biochemical Engineering, Denmark Technical University-DTU, Kongens Lyngby, Denmark

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***Corresponding author:**

Amir Sasan Mozaffari Nejad,
Email: asmnejad@res.mui.ac.ir

Abstract

Introduction: The increasing use of cosmetic products has raised concerns about toxic metal contamination, particularly lead (Pb) and mercury (Hg), which may pose health risks to regular consumers. This study investigated Pb and Hg concentrations in six lipstick brands available in the Tehran market to evaluate potential health risks.

Methods: The concentrations of Pb and Hg were measured in the lipstick samples using a furnace atomic absorption spectrometer (FAAS) and a hydride generator atomic absorption spectrometer (HGAAS), respectively. The samples were first digested in acid solutions. Consumer health risks were then assessed using the Systemic Exposure Dose (SED) and Margin of Safety (MOS) for both once-daily and twice-daily applications.

Results: The mean concentrations of Pb and Hg ranged from 0.14 to 1.7 mg/kg and 0 to 0.065 mg/kg, respectively. The levels of the both elements were found to be below the allowable international standards set by the FDA and WHO. While no risk was observed for Hg across any brand, a health risk for Pb was found in some brands with twice-daily application. Specifically, the MOS value for brand 4 was 1,312 with twice-daily application, which is less than the safe threshold (10,000).

Conclusion: Despite heavy metal levels being within international standards, frequent daily use of these lipsticks may contribute to chronic exposure. Hence, continuous monitoring of heavy metal levels in cosmetic products is essential to protect consumers and prevent potential long-term health effects.

Keywords: Cosmetic safety, Toxic metals, Mercury, Systemic Exposure Dose (SED), Margin of Safety (MOS), Tehran market

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Introduction

Skincare products are categorized within the cosmetics group. These products serve as a protective barrier, enhancing both the skin's appearance and its health. Lipstick is a staple of everyday cosmetics; however, its metallic content has become an international health concern.¹ Many heavy metals are present in lipsticks. Some of these metals act as coloring agents, while others form part of the core structure, and the rest are inadvertently

added from the environment.²

Assessing the skin absorption of heavy metals in cosmetics depends on factors such as concentration, product amount, duration of skin contact, and the presence of emollients and penetration enhancers. Determining the permissible limits of heavy metals in cosmetics based on their risk to human health remains a challenge.^{3,4} Heavy metals are absorbed into the body through various pathways. Once in the bloodstream, these toxic elements



can accumulate in different tissues and organs, leading to dysfunction. For example, lead (Pb) can cause significant damage to vital organs.⁵⁻⁹

Lipstick is one of the products that is applied directly to the skin (lips). These metals can enter the body and have dangerous effects on internal organs. Heavy metals from cosmetics are a key environmental pollutant. Cosmetics pose a significant risk for causing allergies due to their daily use and application on sensitive skin regions, such as the lips, which have a high potential for absorption.^{4,10} The evaluation of heavy metals in lipstick is important because not only do they lack effective biological functions in the body, but they can also be highly toxic even at very low concentrations.¹¹⁻¹³ It is important to acknowledge that prolonged cosmetic use can result in heavy metal deposition in the body. In addition, mixtures of Pb, cadmium (Cd), arsenic (As), and mercury (Hg) might produce synergistic effects.¹¹⁻¹⁴ It is worth noting that prolonged cosmetic use can result in heavy metal deposition in the body. In addition, a mixture of Pb, Cd, As, and Hg might produce a synergistic outcome.¹⁴⁻¹⁶

Pb is a naturally occurring silver-gray metallic element with an atomic number of 82, an atomic weight of 207.19, and a specific gravity of 11.34. It has become a major health concern due to its potential to increase the risk of various cancers, including colorectal and colon cancer.^{17,18} Over the past two decades, Pb poisoning has been identified as having dangerous effects on human health.¹⁹ Pb affects all body systems, such as the reproductive system, renal system, and liver. Complications of poisoning are divided into two categories: acute and chronic poisoning. These include stomach pain, nausea, anemia, infertility, nervous system disorders, behavioral disorders, and learning and hearing disorders.^{20,21} One of the concerns regarding lipstick is its contamination with high levels of Pb. These contaminants originate from contaminated raw materials or through the use of pigments containing Pb.^{22,23}

Among the heavy metals in cosmetics, Hg is usually present at very low levels.⁴ After being absorbed through the skin, Hg exposure may result in a wide range of symptoms, including vomiting, nausea, kidney damage, malformations, and effects on the central nervous system, such as tremors, weakness, fatigue, and memory loss. High Hg content can be fatal.²⁴⁻²⁶ Therefore, it is necessary to screen raw materials for contamination.²⁷⁻²⁹ It has been reported that the highest consumption of cosmetics occurs in the Asian region, which necessitates accurate and regular assessments regarding heavy metal levels.^{9,30-34}

This study aimed to quantify Pb and Hg levels in six lipstick brands using atomic absorption spectrometry and to conduct a risk assessment to evaluate the associated health risks.

Materials and Methods

Chemicals

Every chemical employed in the experiments was pure and did not require any further purification. The two types of acid used for heavy metal analysis, HNO₃ (67%), and

HClO₄ (60%), were of the highest purity and were supplied by Merck Company. The stock solutions of Pb and Hg ions were also bought from Merck Company. To prepare the working standard solutions, the stock solutions were gradually diluted using deionized water.

Instrument of the measurement

To measure the levels of Pb, a GBC Atomic Absorption Spectrometer (Avanta PM, Australia) equipped with a GF 3000 graphite furnace atomizer and an autosampler (Pal 3000) was utilized. Deuterium background correction was applied to account for non-specific absorbance. The hollow cathode lamp for Pb operated at 10 mA with a spectral bandwidth of 1 nm, and a wavelength of 217.0 nm was selected for Pb analysis. Argon of >99.999% purity was utilized as the inert purging gas. Table 1 summarizes the temperature schedule of the graphite furnace used to determine Pb. Also, the GBC Atomic Absorption Spectrometer (Avanta PM, Australia), in conjunction with a cold vapor system (Hydride generator HG3000) and a Hg hollow cathode lamp, was employed to measure the concentrations of Hg. The absorption wavelength was a device at 253.7 nm. For maintaining the background correction, a deuterium lamp was used. The experiments utilized 99.999 % Argon as the protective and purge gas, 3.0 N hydrochloric acid (HCl) solution, and sodium borohydride (NaBH₄) as the reducing agent.

Linearity was identified in the range of 10.0 – 80.0 µg/L with a coefficient of determination (r^2) of 0.9941 for Pb, and 1.0 – 20.0 µg/L with a coefficient of determination (r^2) of 0.9912 for Hg. The Limit of Detection (LOD) and Limit of Quantification (LOQ) were 2.84 and 9.45 µg/L for Pb and 0.18 and 0.59 µg/L for Hg. For LOD and LOQ, calculation the blank samples were read 10 times and the average and standard deviation (SD) were calculated.³⁵ The LOD was calculated at a signal-to-noise ratio (S/N) of 3 while the LOQ was measured at S/N = 10.

Sample collection

In this cross-sectional, descriptive–analytical study, conducted over a six-month period, six best-selling lipstick brands from the Tehran market (Iran) were selected. From each brand, six samples were collected, resulting in a total of 36 lipstick samples for analysis. To maintain brand confidentiality, the samples were coded with numbers 1

Table 1. Instrumental parameters for Pb determination

Argon flow rate (L/min)	Hold Time (s)	Ramp Time (s)	Final Temp (°C)	Step
3.0	2.0	1.0	50	Pre-warming
3.0	-	-		Inject sample Inject step
3.0	15.0	10.0	90	Drying
3.0	10.0	15.0	120	Ashing
3.0	5.0	10.0	800	Pyrolysis
0.0	1.0	0.0	800	Gas stop step
0.0	1.2	0.7	2100	Atomization
3.0	2.0	1.0	2100	Cleaning

through 6.

Preparation of Samples

The lipstick samples were dried in an oven at 105 °C for 4 h and then kept in a desiccator for 24 h until a constant weight was achieved. The dried samples were ground into a fine powder using a porcelain mortar and pestle. Next, each sample was precisely weighed to 1 g using a laboratory balance. The wet digestion method was employed to digest the lipstick samples by repeatedly adding nitric acid (HNO₃) and perchloric acid (HClO₄) at atmospheric pressure in an open system on a hot plate at 100 °C. Afterwards, the samples were heated until white fumes appeared, indicating the completion of the digestion process. The resulting digestate was evaporated to a volume of approximately 1 mL. The digestate was then filtered using 0.45 µm Whatman filter paper. Doubly distilled deionized water was added to bring the final volume of each sample up to 10 mL. Finally, the samples were stored in clean, labeled bottles until analysis.³⁶

Risk Assessment of Heavy Metals in Cosmetic Products

Equations 1 and 2 were applied to evaluate the risk of heavy metals in cosmetic products.^{16, 36} Table 2 provides the definitions of the equations used to assess the risk of heavy metals in cosmetic products variables involved.

$$\text{MOS} = \text{BMDL}_{10} / \text{SED} \quad (1)$$

$$\text{SED} = A \times C (\%) \times \text{DA}_p (\%) \quad (2)$$

BMDL₁₀ is based on carcinogenicity studies in animals. BMDL₁₀ is calculated for Pb 0.00063 mg/kg/d. BMDL₁₀

Table 2. Definitions of variables for heavy metals in cosmetic products

Formula	Definition
$\text{MOS} = \text{BMDL}_{10} / \text{SED}$	Margin of Safety
BMDL ₁₀	Benchmark Dose Lower Limit
$\text{SED} = A \times C (\%) \times \text{DA}_p (\%)$	Systematic Exposure Dose (mg/kg b.w/day)
A	Daily Exposure/kg body weight
C (%)	Concentration of Elements
DA _p (%)	Dermal Absorption

for Hg is calculated 0.0011 mg/kg/d.¹⁶ The dermal absorption percentages for Pb and Hg are 0.3% and <1%, respectively.³⁶ The estimated daily exposure was calculated for two scenarios: once with the assumption of once-daily application and once with the assumption of twice-daily application.

Statistical Analysis

Analysis of variance (ANOVA) and Tukey post-hoc tests were conducted on each lipstick brand to determine if there were significant variations in the heavy metal concentrations in different of each brand. A statistically significant was determined as 0.05 ($P < 0.05$). Statistical software package SPSS 15.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analyses. All concentrations for each sample are mean value of duplicate experiments.

Results and Discussion

Figure 1 displays the mean concentrations of Pb and Hg (mg/kg dry weight) for six different lipstick brands. There was no significant difference between the samples in Hg content. The amount of Pb in brand 4 differed significantly from the other brands ($P \leq 0.05$). The amount of this element in brand 4 was higher than in other brands. The risk evaluation was performed using MOS; the average concentration of each element was determined for factor C, and a mean body weight of 60 kg was assumed. The results of this evaluation have been shown in Tables 3 and 4. The health risks of using lipstick twice a day are more than once.

Cosmetics are recognized as an important source of heavy metals in both the environment and the human body. Several heavy metals such as Pb and Hg have a cumulative effect on the body, particularly in fatty tissue. Due to this accumulation, they may cause various long-term health consequences. Therefore, it is necessary to examine the levels of harmful metals in commonly used cosmetic products to address this concern. While the toxicity of Pb and Hg is well-documented, a major concern is that prolonged exposure to even relatively low levels of these toxic metals in cosmetics poses a potential hazard to human health.^{16,26,37,38} Hence, the primary aim of this study was to assess the potential health hazards associated

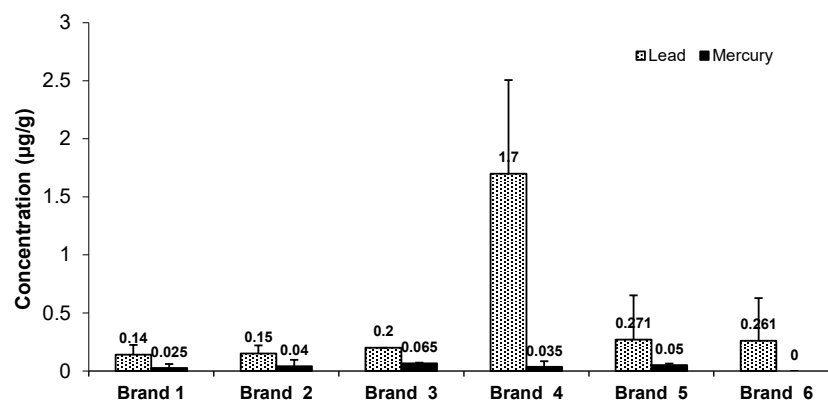


Figure 1. Mean concentration (mg/kg of dry weight) of Pb and Hg contents in different brands of lipsticks

Table 3. The calculated MOS values for Pb and Hg in lipstick (once application per day)

Element	Brand 1	Brand 2	Brand 3	Brand 4	Brand 5	Brand 6
Pb	33,000	30,000	22,500	2,600	16,000	17,000
Hg	1,000,000	570,000	360,000	680,000	470,000	-

Table 4. The calculated MOS values for Pb and Hg in lipstick (twice application per day)

Element	Brand 1	Brand 2	Brand 3	Brand 4	Brand 5	Brand 6
Pb	15,789	15,000	11,052	1,312	8,289	8,513
Hg	130,400	78,947	49,180	90,909	63,829	-

with heavy metals in cosmetics in Iran. Table 5 shows the acceptable levels of heavy metals such as Pb and Hg in cosmetic products approved by various international and national organizations including the Food and Drug Administration,³⁹ World Health Organization (WHO), European Union (EU), German Federal Government and Health Canadian Regulatory. The results of this study have been compared with the limits established by these organizations.

The content of heavy metals in cosmetics has been reported in several studies.^{22,25,27,30,34,38,40-42} In 2007, the FDA established the acceptable level of heavy metal content in cosmetics.³⁹ Specifically, Health Canada and the FDA set the limit for Pb in cosmetic products at 10 µg/g.²⁵ However, more recently, the Federal Office of Consumer Protection and Food Safety of Germany introduced stricter regulations to safeguard consumers. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) advised in 2017 that the level of Pb in cosmetics should not exceed 2 µg/g, and the maximum allowable amount of cadmium should be limited to 0.1 µg/g.⁴³

The results showed that Pb concentrations in all samples were lower than the permissible limit. According to the Environmental Protection Agency (EPA) standard, the safe level for Pb is 0.5 µg/g.⁴⁴ As shown in Figure 2, the Pb concentration in all samples was below the FDA limit. However, according to the EPA safety level, only four samples showed concentrations higher than the allowable range. In a study conducted in Bangladesh, the concentration of heavy metals in lipstick and eye pencil samples was measured. The findings indicated that the Pb concentrations were below the permissible limit.³² Similarly, a study by Li in China examined heavy metals in lipstick samples and found that the Pb concentration in all samples was lower than the standard.⁴⁵ A previous study conducted in the EU investigated Pb concentrations in 149 samples of lip products, including lip glosses and lipsticks.⁴¹ The results revealed that 49 samples contained more than 1 µg/g of Pb, with an average Pb content of 0.75 µg/g in lipsticks. These findings demonstrated that the Pb concentration in all samples was lower than the permissible limit set by the FDA.

In the current study, the Hg content of the samples was in the range of 0 to 0.065 µg/g (Figure 1). The Hg content of lipsticks in all samples was in accordance with the national standard. Among the samples, the highest concentration was related to Brand 3 (Figure 1). Hg was

Table 5. The maximum permissible limits set by regulatory agencies for Pb and Hg toxic elements in cosmetic products

Organization	Permissible limit Pb (µg/g)	Permissible limit Hg (µg/g)	References
FDA	<10	<1	42
WHO	<10	<1	43
EU	<0.5	NA	51
Canada	<10	<1	42
German Federal Government	<20	<1	42

NA not available

not detected in the Brand 6. Hg is usually present in very low concentrations in most cosmetics and is sometimes undetected due to its minimal amount.⁴

In a 2018 study conducted in South Korea, the concentration of heavy metals in cosmetics was measured using the ICP method. The researchers examined four lip products, including lip gloss, lip tint, lip balm, and lipstick. The results illustrated that the concentration of Hg in all samples was below the detection limit of the method (LOD=0.207 µg/g).¹⁶ In a similar report by Mostafa in Saudi Arabia, heavy metals (Cd, Pb, zinc, Hg, and nickel) were measured in 36 samples of cosmetics using the ICP-MS method. The results revealed that the concentrations of Cd, Pb, Zn, Hg, and Ni ranged from 0.03 to 0.53, 10.28 to 107.01, 14.49 to 867.12, 1.75 to 6.45, and 4.22 to 31.36 µg/g, respectively.⁴⁶ Although cadmium and Hg levels stayed within normal limits across all samples, the Pb concentration surpassed the WHO's recommended threshold. In several studies, the levels of Hg were found to be below the permissible limits set by the FDA and EU in lipsticks.⁴⁷⁻⁵⁰

The findings of the present study indicated that the levels of Pb in all tested lipstick samples were higher than the levels of Hg. The mean values for Pb and Hg were 0.453 ppm and 0.0358 ppm in all brands, respectively. According to the regulatory agencies of the FDA and WHO, the values for Pb and Hg were lower than the permissible limits.

The value for risk based on BMDL₁₀ is 10,000.⁴⁴ The value for Hg was more than 10,000 in all brands. The value for Pb in three brands after two applications, was less than 10,000. In the case of brand 4, this value was less than 10,000 after one application. In the case of two applications, this amount was reported to be less than 10,000 in three brands. Therefore, continuous monitoring and informing the target group is essential.

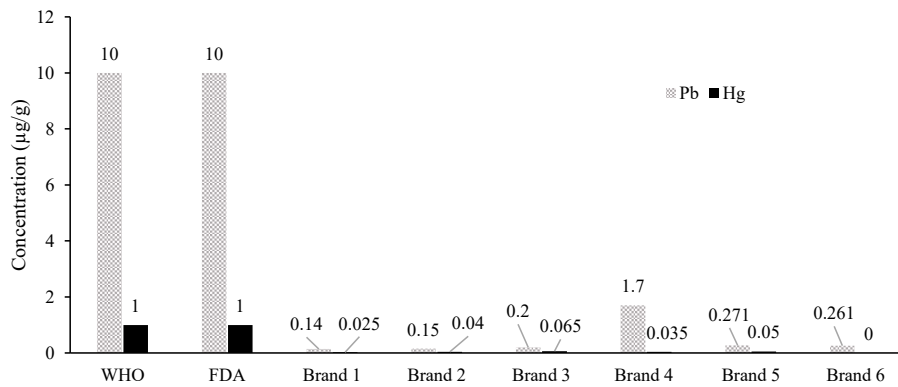


Figure 2. Comparison of Pb and Hg concentrations in various lipstick brands with international regulatory limits (WHO and FDA)

Conclusion

Although the heavy metal levels detected in the tested lipsticks were within acceptable limits, repeated application can lead to increased accumulation of these metals in the body through ingestion or dermal absorption. Further research is necessary to better identify the sources of heavy metals in cosmetics and prevent their contamination. To safeguard consumer health and raise awareness about the potential adverse effects of cosmetics, regular monitoring of toxic element concentrations is essential. Moreover, manufacturers should be encouraged to strictly adhere to FDA and other regulatory standards.

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Authors' Contribution

Conceptualization: Hadi Rahimzadeh-Barzoki, Parisa Sadighara, Amir Sasan Mozaffari Nejad.

Data Curation: Saeed Aghebat-Bekheir, Parisa Sadighara, Mahdi Jahanbakhsh, Amin Reyhani, Marziyeh Karami.

Formal Analysis: Hadi Rahimzadeh-Barzoki, Saeed Aghebat-Bekheir, Parisa Sadighara.

Funding Acquisition: Hadi Rahimzadeh-Barzoki.

Investigation: Hadi Rahimzadeh-Barzoki, Parisa Sadighara, Amir Sasan Mozaffari Nejad.

Methodology: Hadi Rahimzadeh-Barzoki, Parisa Sadighara.

Project Administration: Hadi Rahimzadeh-Barzoki, Saeed Aghebat-Bekheir, Parisa Sadighara, Amir Sasan Mozaffari Nejad.

Resources: Hadi Rahimzadeh-Barzoki.

Software: Mahdi Jahanbakhsh, Amin Reyhani, Marziyeh Karami.

Supervision: Hadi Rahimzadeh-Barzoki, Parisa Sadighara, Amir Sasan Mozaffari Nejad.

Validation: Hadi Rahimzadeh-Barzoki, Saeed Aghebat-Bekheir, Parisa Sadighara.

Visualization: Hadi Rahimzadeh-Barzoki, Saeed Aghebat-Bekheir, Parisa Sadighara, Amir Sasan Mozaffari Nejad, Ali Shahryari.

Writing–Review & Editing: Saeed Aghebat-Bekheir, Parisa Sadighara, Amir Sasan Mozaffari Nejad, Marziyeh Karami, Dileep. Yeruva.

Competing Interests

The authors declare no conflict of interest. groundwater or industrial effluents and include cost analysis to assess scalability.

Ethical Approval

IR.GOUMS.REC.1404.124

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Informed Consent Statement

Not applicable.

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