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Do lead (Pb) content of lipsticks expose a health risk to children? A risk assessment study

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ABSTRACT

Background Lead (Pb) content in lipsticks and potential life-long exposure of which might cause severe effects in consumers are an important concern for public. Thus, studies emphasize that lead exposure has no safe levels.

Methods From 10 different brands, in total, 25 solid, gloss and creamy lipsticks are deployed from Turkish markets that are also categorized in two different price ranges. In order to evaluate the blood Pb levels in children, the United States Environmental Protection Agency's 'Exposure Uptake Biokinetic Model' is utilized. To assess the health risk of chronic usage both for children and adults, oral daily systemic exposure levels are calculated with the worst-case scenario and are compared with Maximum Allowable Dose Level for lipsticks. For lifetime risk assessment, exposure is assumed to start by age 7, and four different exposure scenarios have been deployed.

Results The mean lead content of lipsticks shows significant statistical differences between the high- and low-priced lipstick groups. Daily level and total risk for lifetime Pb exposure from deployed lipsticks are below the acceptable risk levels but long-worn usage of products with routine monitoring of metal content is crucial for sensitive and unintended exposure groups.

Keywords cancer risk, children health, computer modelling, lead exposure, risk assessment, safety testing

Introduction

Lipstick, a commonly used cosmetic for daily face makeup, has gained global attention due to concerns about its metal content.[1] It contains a combination of natural and synthetic chemicals, including emollients, colouring agents, antioxidants, stabilizers and fragrances.[2] While lead carbonate was previously used in cosmetics, it has been replaced by titanium dioxide due to its toxic effects.[3] However, lead contamination still exists in cosmetics.[4]

Despite efforts to reduce lead exposure through measures such as lead-free paints and fuel, environmental lead exposure remains a significant concern.[5] Cosmetics, including lipsticks, have been identified as a major source of lead exposure.[1,5–7]

Although cosmetics contribute less to heavy metal exposure compared to diet and dust, their repeated and prolonged use on sensitive areas raises concerns about potential toxicities and chronic effects.[8] Ingestion of lipsticks also provides an additional route of exposure, particularly when consumers eat and drink while wearing them. Additionally, lipsticks are used by children, despite not being intended for their age group.

Numerous studies have highlighted the presence of lead in lipsticks. In the USA, detectable levels of lead ranging from 0.03 to 0.65 ppm were found in 61% of tested lipsticks.[9] Although specific limits for lead in lipsticks have not been established by the US FDA, one-third of the tested lipsticks exceeded the lead limit set for candy, which is 0.1 ppm.[10] Cosmetic companies are responsible for testing the safety of their products, while the FDA conducts research to address safety concerns.[11]

In Europe, lead compounds in cosmetics have been banned since 1976, with trace quantities subject to good manufacturing practices.[12] Turkey has aligned its legislation with EU laws and has set an upper limit of 20 ppm for lead in cosmetic products, except toothpaste.[13]

Developing countries with inadequate safety regulations for cosmetics pose a greater risk to consumer health, as

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unregulated and affordable lipsticks are widely used, including by children.

Lead has well-documented detrimental effects on various organs and systems. Establishing a causal relationship between lead exposure and negative effects requires a multidimensional assessment due to lead's accumulation in the body over time. Lead is slowly absorbed through the skin, with adults orally digesting 5–15% of exposed lead, while children can digest up to 50%.[13] Separate assessments are needed for intended (adults) and unintended (children) health risks.

Exposure assessments for lead consider concentration levels in food, water, dust/air, bioavailability and source impacts, which can vary significantly.[14] Recent studies suggest that there is no safe level of lead exposure, emphasizing the need for exposure studies and population risk assessments.[15]

Despite the global concern about lead content in lipsticks, comprehensive research on the potential health risks associated with heavy metal ingestion in lipsticks is lacking in Turkey. This study aims to determine lead concentrations in lipsticks available in the Turkish market, investigate if lead content varies based on lipstick type and price range, and evaluate the potential health risks associated with daily lead ingestion in lipsticks. The study analyzes different types and price ranges of lipstick samples purchased from various stores to provide a risk assessment for public health safety.

Materials and methods

Samples and reagents

A total of 25 lipstick samples were collected from 10 different brands available in Turkish markets. The lipsticks were categorized into three types: solid (classical hard type), gloss and creamy. They were further classified into two price ranges: Low Price and High Price. High-Price lipsticks were defined as being at least 2.5 times more expensive than the Low-Price lipsticks. It should be noted that there were no creamy lipsticks available in the Low-Price range at the time of sampling.

Instrumental analysis methods

The lead content in the lipstick samples was determined using continuous flow hydride generation atomic absorption spectrometry (CF-HG-AAS) with an ATI UNICAM 939 AAS instrument (UK) equipped with a UNICAM data coded Pb hollow cathode lamp.[16,17] Approximately 0.200–0.400 g of each lipstick sample ($n = 3$) was wet digested using a mixture of HNO_3 and HF (7,2, v,v)[18] in a Teflon beaker placed on a hot plate at 100 °C. The digested sample was evaporated to dryness, and the residue was dissolved in deionized water. A portion of the dissolved sample was diluted with HCl and $K_3Fe(CN)_6$ as an oxidizing agent. A reducing agent consisting of $NaBH_4$ in NaOH was pumped into the system, and a carrier solution of $K_3Fe(CN)_6$ in HCl was used. The lead hydride generated was swept with Ar gas to an atomizer for analysis. Standard Pb solutions were prepared for calibration. The lead standard was added to the lipstick sample, digested and analyzed using CF-HG-AAS.

Statistical analysis

The results are presented as means ± SD. Unpaired *t*-tests were performed using GraphPad InStat version 3.05 software. The exposure assessment was conducted using the Integrated Exposure Uptake Biokinetic (IEUBK) model, version 1.1 build 11 of the EPA's IEUBK for Windows software package.

Results

Lead concentration in lipstick samples:

Lead concentrations in the 25 lipstick samples ranged from 1.68 ± 0.72 mg/kg (95% confidence interval). The detection limit was determined as 3.3 Sb/m, where Sb represents the standard deviation of the blank signal ($n = 11$) and m is the slope of the calibration curve. The characteristic sensitivity, defined as the concentration resulting in an absorbance of 0.044, was found to be 0.56 μg/L. The limit of quantitation was calculated as 1.70 μg/L (10 χ Sb/m). The linear calibration range for lead in aqueous media at 283.3 nm was 2.5–100 μg/L, with an r^2 value of 0.9987. The recovery rate was determined as 98.14 ± 1.88 (95% confidence interval).

Lead concentration by lipstick type and price range

The mean lead concentrations (mg/kg) in solid, gloss and creamy lipsticks were 2.45, 1.28 and 0.95, respectively, irrespective of the price range. When considering price, high-priced solid lipsticks had a mean lead concentration of 2.17 mg/kg, while low-priced solid lipsticks had a mean lead concentration of 2.73 mg/kg. Among gloss lipsticks, high-priced ones had a mean lead concentration of 1.12 mg/kg, compared to 1.44 mg/kg for low-priced ones. Creamy lipsticks had the lowest lead content of 0.95 mg/kg. A statistically significant difference in mean lead content was found when comparing high-priced lipsticks ($n = 15$) to low-priced lipsticks ($n = 10$), regardless of the lipstick type ($P = 0.0212$). The mean lead concentration was 1.41 mg/kg in high-priced lipsticks and 2.085 mg/kg in low-priced lipsticks.

Lead concentration by lipstick colour

The lipstick samples included three main colours: brown, pink/red and nude. The mean lead concentrations (mg/kg) in brown, pink/red, and nude lipsticks were 2.17, 1.70

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and 0.95, respectively. Statistical analysis using an unpaired *t*-test revealed significant differences in mean lead content between the brown and nude-coloured groups ($P = 0.0073$) and between the pink/red and nude-coloured groups ($P = 0.0010$). However, no significant differences were observed between the brown and pink/red groups ($P > 0.05$).

Risk assessment

Risk assessment involves evaluating exposure data and potential effects. When considering lead in cosmetics, both cancer and non-cancer risks must be taken into account. Although there is insufficient human carcinogenicity data, lead is classified as a probable human carcinogen (B2) based on evidence from animal studies.[19] The International Agency for Research on Cancer has also determined that inorganic lead compounds are probably carcinogenic to humans (Group 2A) based on animal evidence.[20]

Estimated dietary lead intake varies across European countries, ranging from 7.0 to 293 μg/day.[21] The estimated daily lead intake from various sources in adults ranges from 14.4 to 28 μg/day, while in children, it is higher, ranging from 30.6 to 132 μg/day.[14] For Turkey, the adult daily intake was reported as 70 μg/day, with no available data for children.[14] Dust is not a significant source of lead for adults but is relevant for workers and children. Lead concentrations in indoor dust in Turkey range from 0.4 to 20 μg/g.[22] However, there is a lack of literature on children's exposure values and lifetime cancer risk assessment for lead in Turkey.

Lead exposure from lipsticks primarily occurs through ingestion, especially by licking lips or engaging in daily activities like eating and drinking. Children are more susceptible to lead exposure due to their hand-to-mouth behaviours. Lead absorption is higher in children (about 50%) compared to adults (about 10%).[13]

Lead distribution in the body can be described by a three-compartment model involving bone tissue, blood, and soft tissues. The effects of lead are typically associated with lead blood levels (BLL), which are correlated with concentrations in soft tissues.[23] Children's heightened sensitivity to environmental lead levels raises concerns about neurotoxicity and brain development[24], while 10 μg/dL BLL in children are associated with disturbance in early physical and mental growth and in later intellectual functioning and academic achievement.[25]

Non-cancer risk/BLL assessment

Non-cancer risk assessment involves assessing BLL resulting from lead exposure from various sources, including lipsticks. The EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model has been used to assess BLLs in children exposed to lead from lipsticks. The IEUBK model estimates the risk of elevated blood lead levels considering the environmental lead exposures of children[26] and The EPA recommends the use of the IEUBK model for predicting BLLs in children aged 0–7 years.[27] For modelling assumptions, the maximum allowable outdoor soil lead concentration based on the Turkish Regulation on Control of Soil Pollution[28] (300 mg/kg) was used. The indoor dust concentration was assumed to be constant at 20 μg/g, which represents the assessed maximum level in Turkish indoor settings.[22] The average atmospheric Pb metal concentration was considered as 0.23 ng/m^3 [29] and ventilation rates and lung absorption percentages were predefined (5 m^3/day for ages 2–5 and 7 m^3/day for ages 5–7, with lung absorptions 32%). No specific data on daily dietary lead intake for children in Turkey were available, so a worst-case scenario assumption of 9 μg/day was used for ages 2–7 (assumed from 5.6 $\pm$ 3.5 μg/day for Australia young children,[30] 5.82 $\pm$ 1.90 μg/day for Korean kindergarten children.[31] Water consumption was estimated at approximately 0.5 L/day, with a lead concentration in drinking water of 1 μg/L, based on the latest report from the Ankara Metropolitan Municipality.[32] The highest Pb concentration observed in the study (3.68 mg/kg) was selected as the worst-case scenario value for lipstick intake. Absorption fraction percentages were assumed as follows: soil 30%, dust 30%, water 50%, diet 50% and lipstick 50%. Baseline BLL of 3.6 μg/dL for children in central urban areas of Turkey was assumed.[33] The modelling results indicate that BLL values did not increase by more than 1 μg/dL.

Cancer risk

For cancer risk assessment, the study used a worst-case scenario considering direct ingestion of lipstick by licking. The cancer slope factor established for lead, which is 8.5×10^{-3} [34] was used, and the Maximum Allowable Dose Level (MADL) for lead was set at 0.5 μg/day[35] was considered.

Daily lipstick usage data for adults with an average of 2.35 applications per day and per application of 10 mg[36] was obtained, and the same amounts were assumed for children. The absorption fraction percentages used were 50% for children and 10% for adults, as mentioned previously.

The highest measured concentration of lead in the study was 3.68 mg/kg, which was selected as the value for the worst-case scenario of lipstick intake. The oral intake for children was calculated as 0.034592 μg, while for adults, it was 0.008648 μg. Both the children and adult oral daily exposure levels were found to be lower than the MADL levels.

Lifetime risk assessment was conducted considering different exposure scenarios based on changes in body weight as individuals age. For ages 7–11, a body weight of 30 kg was

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Table 1 Assumptions for each age interval

Age	*Body weight (kg)*	*Oral absorption rate*	*Cancer slope factor*	*Frequency day/day*
≥7– < 11	30	50%	8.5×10^{-3}	90/365
11– < 15	40			180/365
15– < 18	50			360/365
≥18	60	10%		

assumed; for ages 11–15, it was 40 kg; for ages 15–18, it was 50 kg; and for adult females, it was 60 kg.

The cancer risk was calculated for each age interval using the formula:

$$Risk_i = C.((IR_i.EF_i.ED_i)/BW_i.AT).SF.ADAF_i$$

In this formula, 'i' for each age interval, C represents the concentration of lead in the exposure medium (μg/day), IRi is the intake rate of the exposure medium (mg/day), EFi is the exposure frequency (days/year), EDi is the exposure duration (years), BWi is the body weight of the exposed person (kg), AT is the averaging time (days), SF is the cancer slope factor (mg/kg/day) and ADAFi is the age-dependent adjustment factor. The total risk calculated for the individual is the sum of all the risks calculated for each age intervals (see Table 1).

Using the previously calculated oral intake values (0.034592 μg/day for < 18 and 0.008648 μg/day for adults), the cancer risk was calculated for each age interval. The total risk for lifetime lead exposure from lipstick usage was found to be 1.5087×10^{-9}, which is significantly below the acceptable risk level of 10^{-5}.

It should be noted that this study focused on lead exposure from lipstick usage and did not consider other potential routes of lead exposure.

Discussion

Main finding of the study

In our study, we investigated the lead content in lipstick samples, and our findings revealed a mean lead concentration of 1.68 ± 0.72 mg/kg, falling within the 95% confidence limits. These results align with previous studies and regulatory standards, indicating that the lead content in the tested lipsticks is below the acceptable limits set by regulatory authorities. When comparing different price range groups, our study revealed a significant difference in lead content ($P < 0.05$), suggesting factors other than chance are responsible for the observed results. Although, our study's findings demonstrate that the lead levels found in the analyzed lipsticks present daily and lifetime risks of exposure below acceptable thresholds.

What is already known on this topic

Previous studies have reported lead concentrations of approximately 2.08 ppm in the majority of tested cosmetics.[37] In their study, they conducted a subacute dermal toxicity study on albino rats, suggesting a proposed maximum allowable concentration of lead as 10 mg/kg in cosmetic products.[37]

Al-Saleh et al.[1] found lead levels ranging from 0.27 to 36.90 ppm in all tested lipstick samples. Only two samples exceeded the FDA's limit of 20 ppm for lead impurities in colour additives used in cosmetics. Excluding these two samples, the mean lead content dropped to 2.07 ppm, consistent with our study's finding of a mean lead content in lipsticks of 1.68 ppm.

In our study, the lead content in the samples ranged from 1.68 ± 0.72 mg/kg, within the 95% confidence limits. These results are consistent with the FDA's study on the US market,[10] with all samples achieving lead content below 10 ppm.

When comparing different price range groups, our study revealed a significant difference in lead content ($P < 0.05$), suggesting factors other than chance are responsible for the observed results. Manufacturing processes, techniques that limit lead content, and the ingredients used may contribute to this significant difference. Piccinini et al.[38] analyzed the lead content of lip products in various price ranges, including lipsticks and lip glosses. They found that lipsticks had nearly twice the mean Pb concentration (0.75 ± 0.64 mg/kg) compared to lip glosses (0.38 ± 0.33 mg/kg). Interestingly, their study also demonstrated that more expensive lipstick products had significantly lower lead content than cheaper ones. Our findings align with Piccinini et al.'s[38] study regarding the distribution of lead content according to price categories. In our study, cheaper lipstick products had higher lead content, resulting in average lead levels two to three times higher compared to their study. Variations in products, batch or year of production, and color choices may contribute to this disparity. However, the substantial sample size discrepancies between studies are not statistically meaningful for comparison. It is plausible that sellers/manufacturers prioritize meeting the

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target of less than 10 ppm lead content rather than minimizing lead content as much as possible.

Furthermore, recent studies question the acceptability of even low levels of lead in these products.[15] Gilbert and Weiss[39] emphasized the importance of lowering the CDC blood lead action limit to 2 mg/dL, citing scientific evidence showing that blood lead levels below 10 mg/dL may impair neurobehavioural development in children. Lead exposure has also been associated with infertility and miscarriage, with Mendola et al.[40] demonstrating its impact on the reproductive function of adult females. Although cosmetics may not be considered a major source of lead contamination, recent reports and studies highlight the risk of lead poisoning in children due to lead contamination in toys, jewelry, herbal remedies and candies.[41–43]

What this study adds

Our study provides updated data on lead content in lipstick samples, highlighting variations across different price ranges. A comprehensive risk assessment was conducted, including blood lead level evaluations and consideration of various age groups, enhancing the credibility of the findings. Utilizing the IEUBK model further strengthens the scientific validity of the study.

By analyzing different lipstick types, colors and price ranges, the manuscript offers a comprehensive understanding of lead contamination. The research contributes to addressing this public health concern while emphasizing the importance of continuous monitoring and regulation to mitigate health risks associated with lead exposure.

Limitations of this study

While our study provides valuable insights into lead content in lipsticks, it is essential to acknowledge certain limitations. Variations in product formulations, manufacturing processes, and batch or year of production may influence lead concentrations, warranting further investigation. Overall, our study underscores the need for continuous monitoring and regulation of lead content in cosmetic products, considering the potential health risks associated with lead exposure, even at low levels.

Conclusion and recommendations

The potential for lead exposure through cosmetics, in addition to other primary sources, raises significant concerns. Conducting risk assessments to evaluate the health effects of these additional exposures is crucial. The hazard identification process should identify intrinsic factors that may pose potential risks to human health, considering both daily usage patterns and prolonged exposure, especially among vulnerable and unintended exposure groups.

Our study's findings demonstrate that the lead levels found in the analyzed lipsticks present daily and lifetime risks of exposure below acceptable thresholds. Since removing lead from cosmetic products after manufacturing is not feasible, the focus should be on carefully selecting raw materials to ensure product quality and safety. While the regulation of cosmetovigilance systems may vary among countries, post-marketing surveillance plays a vital role in safeguarding public health. Therefore, routine monitoring of metal content, including lead, is essential to assess the safety of finished cosmetic products.

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Supplementary data

Supplementary data are available at the *Journal of Public Health* online.

Conflict of interest

None declared.

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Authors' contributions

D.M.Ö., O.K.U. and A.B. all contributed to the study conception and design. Material preparation, data collection and analysis were performed by D.M.Ö., O.K.U. and A.B. The risk assessment process is conducted by O.K.U. The first draft of the manuscript was written by O.K.U. and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Availability of data and materials

Data available on request from the authors.

Ethical approval/informed consent to participate and/or publish

Not applicable/there is no animal and/or human participant involved in this work. No ethical approval or informed consent needed.

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