

Quality Concerns of Lip Care Cosmetics and Applicable Regulatory Framework: Need for a Harmonized Cosmetovigilance Programme

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ABSTRACT

Cosmetics still have a glitzy attraction, but the public is increasingly concerned about their toxicity. Since 2500 BC, one way of enhancing the beauty of lips has been using lipstick compositions. Lip care cosmetic product usually contains emollients, waxes, texturing agents, preservatives, and oils. Women apply lipstick two to several times per day, according to the researchers. In terms of substance exposure, that translates as consuming or holding onto approximately 87 mg of lipstick every day. It has been shown to contain trace amounts of heavy metals such as Cd, Cr, Cu, Co, Ni and Pb. Cosmetics either contain trace levels of these harmful metals on purpose or as impurities in the raw materials. Long-term exposure to these chemicals can pose serious risks to human health, most notably skin cancer. Mineral pigments, which are frequently used to make lipstick, cause products to get contaminated with heavy metals. So, there is necessity for stringent regulation of cosmetics in a harmonized way. It is crucial to regulate this business to safeguard consumers and society. This review article provides an overview of the many regulations that apply to cosmetics across the world as well as suggestions regarding the same.

Keywords: Lipstick, Lip care, Adulterants, Regulations, Toxicity, Cosmetovigilance.

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INTRODUCTION

Cosmetics that are routinely applied directly to human skin, mucous membranes, hair, and nails, should be safe for health, and there has been growing concerns in recent years regarding this issue.¹ As we know, cosmetics are a woman's best friend, and they're popular with males too. Cosmetics are crucial not only for improving one's appearance but also for boosting one's self-esteem.² Cosmetics in India are defined by the Section 3(AAA) of the Drugs and Cosmetics Act 1940.³ The manufacture of cosmetics is governed by a system of inspection and licencing by the State Licensing Authorities appointed by the respective State Governments, while the import of cosmetics is governed by a system of registration by the Central Licensing Authority appointed by the Central Government, in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under. In accordance with the terms of the 1940 Drugs and Cosmetics Act, the Drugs Controller General (India) serves as

the Central Licensing Authority, granting the Import Registration Certificate and controlling the import of cosmetics into India.³ According to the Food and Drug Administration (FDA), which regulates cosmetics in the United States.⁴ Cosmetics are products "intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions."⁵ Cosmetics retain their glitzy allure, but public worry over their toxicity has become a hot topic. Toxic metal traces can be purposely introduced to cosmetics or present as contaminants in raw materials. To control this, The Food, Drug, and Cosmetic Act (FDCA) establishes a comprehensive regulatory framework for all pharmaceuticals/cosmetics that enter interstate commerce.⁶ These laws help to safeguard customers from tainted or Misbranded Foods, Pharmaceuticals, Cosmetics, or Medical devices.⁷

Evolution of lipsticks is depicted in Figure 1. Modern fashion could not be what it is today without the presence of lipsticks.⁸

Regulatory Requirements of Cosmetics

The major goal of cosmetics regulation in all countries is to assure the safety of cosmetics while avoiding negative health impacts on consumers.⁹



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In USA

The FDA defines cosmetics as "items intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for washing, beautifying, enhancing attractiveness, or altering the look". The Federal Food, Drug, and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA) are the two most important laws governing cosmetics sold in the United States. These laws give the FDA jurisdiction to regulate cosmetics. The FDCA prohibits the interstate commerce of adulterated or misbranded cosmetics.¹⁰ Here, product composition violations, whether caused by ingredients, contaminants, manufacturing, packaging, or shipping and handling, are referred to as "Adulteration" whereas Violations involving products that are improperly labelled or packaged in a deceptive manner is referred to as "Misbranding".

To withdraw adulterated and misbranded cosmetics from the market, the FDA can file a lawsuit in federal court through the Department of Justice.¹⁰

In India

India's cosmetics sector is rapidly expanding and the cosmetics industry requires tight regulation.¹¹ Cosmetic items in India are governed by the Drugs and Cosmetics Act 1940 and Rules 1945 as depicted in this article in Table 1, as well as Labelling Declarations issued by the Bureau of Indian Standards (BIS). BIS establishes cosmetics standards for products covered by Schedule "S" of the Drugs and Cosmetics Rules 1945. Cosmetics such as lipsticks and lip gloss are included in Schedule M-II.^{11,12} Parts XIII (cosmetic import and registration), XIV (cosmetic manufacturing for sale or distribution), and XV (cosmetic manufacturing for sale or distribution) (regulates labelling, packing and standards of cosmetics).¹²

On first conviction, imprisonment of up to one year or a fine of up to Rs. 1000 or both can be imposed if any of the Act's provisions or rules relating to cosmetics are not followed; on subsequent convictions, imprisonment of up to two years and a fine of up to Rs. 2000 can be imposed.¹¹

Skin Creams and Lipstick are specified in Indian Standards (IS) 6608:2004 and 9875:1990, respectively, by the Bureau of Indian Standards (BIS). According to IS 6608:2004, if all of the raw materials that require heavy metal testing have been tested and meet the standards, the manufacturer is not required to test the finished cosmetics for heavy Metals and Arsenic. If used in the manufacture of skin creams and lipstick, dye colours (pigments lakes) must comply with IS 4707 (Part I), subject to the provisions of Schedule Q of the Government of India's Drugs and Cosmetics Act and Rules, as amended from time to time. Other substances must adhere to the requirements of IS 4707 (Part 2). Cosmetics

comprising Dyes, Colours, and Pigments other than those specified by the Bureau of Indian Standards (IS: 4707 Part 1 as amended) and Schedule Q is prohibited under Rule 134 of the Drugs and Cosmetics Rules.

The maximum amount of Synthetic Organic Colours and Natural Organic Colours allowed in the Cosmetics is:

- Arsenic Trioxide at a concentration of 2 ppm (parts per million).
- Lead at a concentration of 20 parts per million (ppm) calculated as lead.
- 100 parts per million (ppm) of heavy metals other than lead, computed as the sum of the metals.

The use of lead and arsenic compounds in cosmetics for colouring is prohibited by Rule 145 of the Drugs and Cosmetics Rules. Importation of cosmetics that have been coloured with a lead or arsenic component is prohibited under Rule 135. Cosmetics containing mercury compounds are prohibited by rules 145 D and 135 A, respectively.¹⁴

In a study published in The Pollution Monitoring Lab (PML) of the Centre for Science and Environment (CSE), New Delhi, on January 15, 2014 it was seen that chromium was found in 50% of the lipstick samples tested, while nickel was found in 43%. The lab also tested for lead and cadmium, but found none. In the range of 0.45 ppm to 17.83 ppm, chromium was discovered in 15 of the 30 lipsticks tested. Nickel was discovered in 13 of the 30 items tested in concentrations ranging from 0.57 to 9.18 ppm.¹⁵

IN ASEAN Countries

ASEAN countries have the most recent cosmetics regulation, the ASEAN Cosmetic Directive (ACD).¹⁶ The ASEAN Cosmetic Committee (ACC) has coordinated, reviewed, and kept an eye on the ASEAN Cosmetic Directive's implementation (ACD), which includes the ASEAN National Cosmetic Regulatory and ASEAN Cosmetic Association, authorities (ACA). Through the harmonization of technical requirements, the ACD seeks to remove technical obstacles to the trade of cosmetics without compromising public health and safety for the ASEAN populace. Customers can now select from a greater range of cosmetic goods due to this.¹⁷

In European Union

Cosmetics are regulated in the European Union by Directive 76/768/EEC. The Directive's primary goal is to ensure consumer product safety while also enabling cosmetics trade within the EU.⁹ This regulation, which was initially enacted in 1976, states that cosmetics should not harm human health when used in normal or predictable circumstances. Later, Regulation (EC) No. 1223/2009 established the foundation for cosmetics regulation and cosmetovigilance consistency.¹⁸

ADULTERANTS

A chemical that is introduced to a product but isn't labelled as an ingredient, or a substance that accidentally makes its way into a product during manufacturing is said to be an adulterant.¹⁹ An

adulterant can make a product unsafe, less expensive to create, or fail to function properly.²⁰ When heavy metals like mercury or Scheduled Poison compounds like hydroquinone, tretinoin, antibiotics, or steroids are discovered in a cosmetic product, it

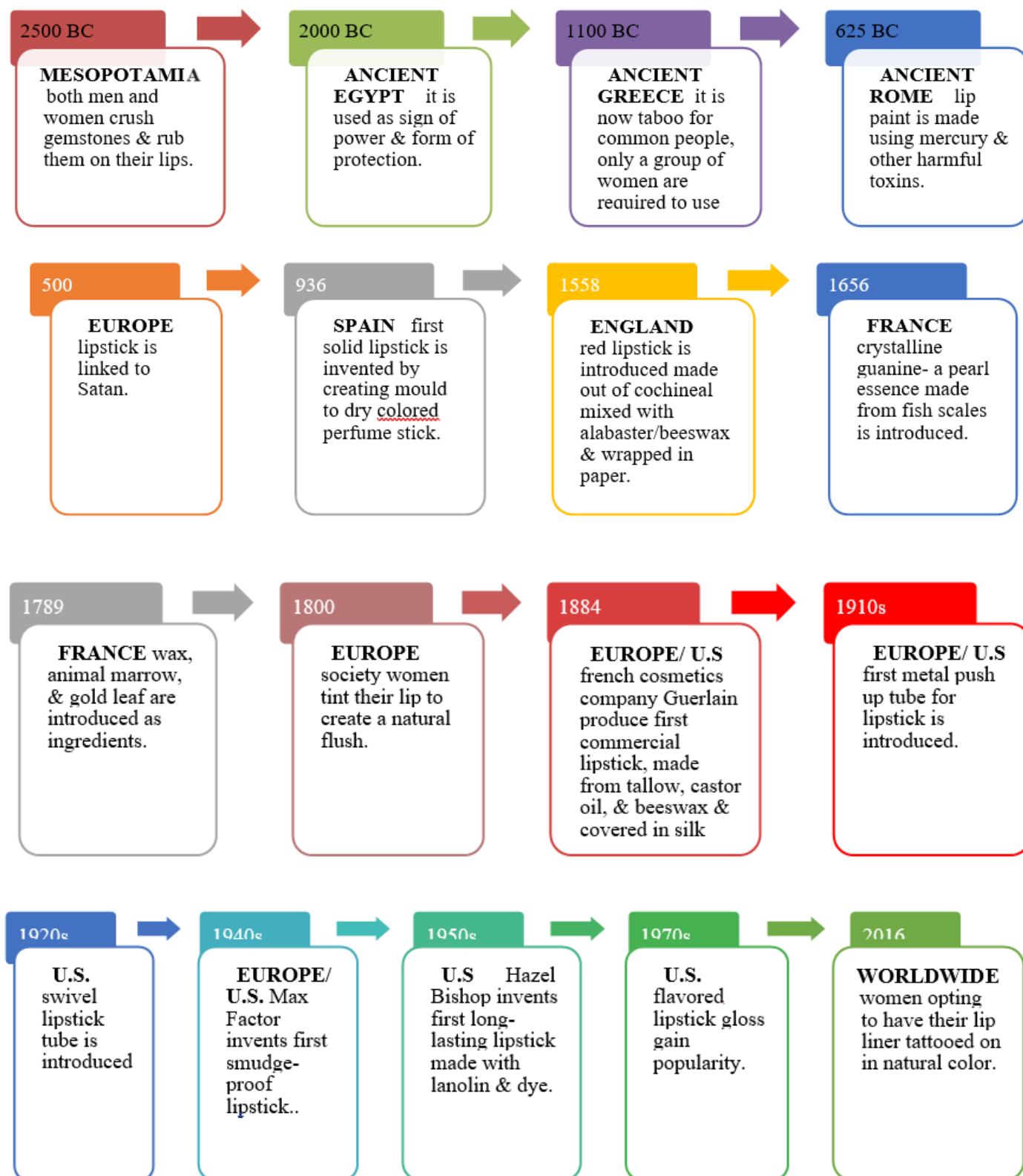


Figure 1: Evolution of lipsticks.⁶⁻⁸

is deemed to be adulterated.²¹ Vegetable oils offer skin-beneficial characteristics, thus they're increasingly being used as ingredients in cosmetics; yet, they're becoming targets of adulteration too in Brazil and around the world.²² Some cosmetics are administered using a spray, which poses the risk of inhaling. Lipsticks are also more likely to cause direct oral intake, exacerbating the detrimental effects of their contents.²³

Heavy Metals Adulteration in Lipsticks

Lipstick is consumed when the lips are licked while eating, drinking, or kissing, without intending to.²⁴ Lipsticks are known for their vast range of colours, which are usually obtained from additional Pigments that can be Organic or Mineral, and may contain heavy metals such as Cd, Cr, Cu, Co, Ni and Pb the health impacts of which are tabulated in Table 2.²⁵ The Long-term exposure to these compounds can pose a major threat to human health, notably skin cancer also depicted here in Table 3. The mineral pigments which are extensively employed in the production of coloured cosmetics result in the contamination of cosmetics with Heavy Metals (HMs). The HMs are purposely included to cosmetic products as colour, preservatives, UV filters, Anti-perspirant, Anti-fungal, and anti-bacterial agents.²⁶ Due to their potential toxicity, they could harm human health, especially the Neurological, Digestive, Reproductive, Respiratory, and integumentary systems.²⁴ Metal components are used in accordance with a country's regulatory laws. Heavy metals are also accidentally added to cosmetics as contaminants at various phases of manufacture¹ for example they might be released from medical devices during manufacturing.²⁷ The usage of metallic machinery throughout the manufacturing process is thought to be the cause of the presence of heavy metals in lipstick products. The components or contaminants in many lipstick products include heavy metals as Pb, Cd, Cr, As, Hg, Co, and Ni. Heavy metal contamination of lipstick preparations happens during production or as a result of improperly purified natural raw materials that are employed as ingredients.

Health Impacts of Heavy Metals and other Constituents of Lip Care Cosmetics

Lead-According to recent findings on the presence of lead (Pb) in lipsticks, the possible level of Pb exposure is dangerous under normal use.²⁸ Pb contamination in lipsticks might come from contaminated dust, Pb solder, leaded paint in production equipment, using natural Pb containing substances or under conditions that could introduce Pb into the ingredients.²⁹ According to the research studies, it is known that Pb enters the body through the gastrointestinal tract and lungs,³⁰ it destroys red blood cells and reduces their oxygen-carrying capacity to necessary tissues, resulting in anaemia.³¹ Cadmium Through research it is widely acknowledged that in the cosmetics Industry, Cd is used in colour pigments. It can be used in a variety of cosmetics, although it is most commonly found in lipstick, polluted air, cigarettes, and contaminated food. Even at modest levels of Cd, the cardiovascular system may get damaged. Its exposure is also linked to diabetes and hypertension.²⁷ It has been shown to reduce gonadotropin binding, altering the activity of steroidogenic enzymes.³¹ Furthermore, a synergistic impact between Pb, Cd, As, and Hg might result in cognitive impairment.²³ Chromium Cr levels were found to be highest in lipstick and eyeliner samples.²³ Even in extremely small amounts, chromium is toxic in nature. Its nature is genotoxic and hepatotoxic.³¹ Contact with certain chromium compounds also has been linked to the development of skin ulcers. It has also been recorded for those who are extremely sensitive to chromium redness and skin edema.²⁴ Mercury-The majority of Hg enters through the vapours of amalgam dental fillings, while seafood products constitute one of As and Hg's most important sources.³⁰ Mercury exposure can result in kidney damage, immunological decline, psychosis, anxiety, depression, and rashes on the skin. Arsenic- Arsenic impurities may be present in the raw material or detected during the manufacturing process in cosmetics.³⁰ Despite the fact that these are very small doses and there is no warning notice on the packaging, customers should be aware of the potential danger.³² Long-term arsenic exposure may cause skin irritation, circulatory and peripheral nervous system issues, as well as an increased risk of lung, gastrointestinal, and urinary tract cancer.³³ Phthalates- The endocrine system, which generates

Table 1: Provisions under Drug and Cosmetics Act.¹³

Sl. No.	Rules No. (Drug and Cosmetics Act)	Purpose
1.	134	Cosmetics containing dyes, colours, and pigments other than those specified by the Bureau of Indian Standards (IS: 4707 Part 1 as amended) and Schedule Q is prohibited.
2.	145	The use of lead and arsenic compounds in cosmetics for the purpose of colouring is prohibited by this rule.
3.	135	Rule 135 prohibits the import of cosmetics that have been coloured with lead or arsenic ingredient.
4.	145 D and 135 A	Cosmetics containing mercury compounds are prohibited from being manufactured or imported under this rule.

Table 2: Various heavy metal types and their health impact.^{28-44,46}

Sl. No.	Heavy metal	Health impact
1.	Lead	Anemia
2.	Cadmium	Cardiovascular damage, diabetes, hypertension and cognitive impairment.
3.	Chromium	Skin ulcer, skin redness and skin edema.
4.	Mercury	Neurological disease-Minamata disease.
5.	Arsenic	Skin irritation, lung and gastrointestinal ulcer.
6.	Phthalates	Gestational diabetes.
7.	Parabens	Breast Cancer
8.	Mineral Oil (If not refined)	Cancer
9.	Retinyl palmitate	Genetic abnormalities.
10.	Bisphenol-A	Polycystic ovarian syndrome.

Table 3: Carcinogenic components of lip care cosmetics with their related health concerns.⁵²

Carcinogenic component	Related health concerns
Mineral oils	Mineral oils as a known human carcinogen. Mineral oils can target organs including eyes, skin, and respiratory system through inhalation, or skin and eye contact. ⁵³
Chromium	Chromium can also lead to developmental problems in both females and males. ⁵⁴
Cadmium and its compounds	In addition to its carcinogenic properties, cadmium targets the cardiovascular, renal, neurological, reproductive and respiratory systems through inhalation and ingestion. ⁵⁵
Arsenic	It may result in keratosis, hyperpigmentation, and potential vascular problems. The Endocrine Disruption Exchange contends that arsenic can lead to endocrine disruption; the EPA identifies arsenic as a priority pollutant and controls arsenic emissions. Arsenic can target organs like the liver, kidneys, skin, lungs, and lymphatic system through inhalation, skin absorption, skin and eye contact, and ingestion, exposure to arsenic causes lung and lymphatic cancer. ⁵⁶
Formaldehyde	Formaldehyde leads to irritation of the eyes, nose, throat and respiratory system. ⁵⁷

hormones, can be harmed by phthalates. Exposure to phthalates may cause developmental, neurological, and reproductive harm.³⁴ According to two recent Harvard researchers, phthalates may raise the risk of miscarriage and gestational diabetes in pregnant women. The National Research Council claimed in a 2008 risk assessment report that they have been linked to reproductive and genital Malformations, reduced sperm count, disturbed hormones, and infertility in several animal studies.³⁵ The CDC's (Centre for Disease Controls) National Biomonitoring Program identified DEP (Diethyl Phthalate) metabolites in 2,540 samples and DBP (Dibutyl Phthalate) metabolites in 99 percent of them.³⁶ DEP metabolites were found in higher concentrations in non-Hispanic blacks, possibly as a result of their frequent and continuous use of items marketed primarily to girls and women of colour.³⁷ Parabens-Preservatives such as parabens are commonly used in cosmetics and can easily permeate the skin. These are notorious for producing psychological effects.³⁴ coughing, irritation on skin vomiting, and diarrhoea.³⁸ Parabens have been researched for their potential to cause breast cancer due to their ability to Mimic Oestrogen in the body. However,

a 2019 research of breast cancer survivors in Iran indicated that the amount of parabens taken increased the risk, particularly in those with hereditary breast cancer.³⁹ Mineral Oils-Mineral Oils, which are commonly included in Lipsticks, Clog skin pores and cause a variety of long-term negative effects.⁴⁰ but Mineral oils, when highly purified, have no negative consequences. However, if the petroleum is not highly refined, it may include carcinogenic polycyclic aromatic hydrocarbons (PAHs). This indicates that it may raise the risk of cancer. B. Chuberre *et al.*, 2019 in the article entitled "Mineral oils and waxes in cosmetics: an overview" mainly based on the current European regulations and the safety profile of these compounds says that mineral Oils are authorised to be used in cosmetics in Europe only if they meet strict Purity standards for PAHs. These rules and safety criteria ensure that Mineral Oils are refined to remove any Potentially Cancer-Causing Chemicals and to limit the amount of PAHs.⁴¹ Retinyl Palmitate-This is a synthetic version of vitamin A that is harmful to pregnant women and may cause other reproductive issues.⁴² When retinol compounds are exposed to UV radiation, they break down and form harmful radicals that can damage

DNA and cause genetic abnormalities, which may lead to cancer.⁴³ Dyes-Many lipsticks contain synthetic colours derived from Aluminium or Petroleum. Our bodies store these colours in organs and fatty tissues. One of the Petroleum products utilised coal tar is known to be Carcinogenic. Heavy Metals may even be present in some of the colours. Although some of them have not been approved for use as food colourants' they may be used in cosmetics.⁴³ Bisphenol-A (BPA) in Lipstick Containers-In the study published (in cosmeticobs)in 2010 "Bisphenol A: a risk through food", BPA was identified in nearly 95% of lipstick containers, including those that claimed to be organic and chemical-free, and the chemical easily penetrates into the actual lipstick that is applied to the lips and causes infertility and cancer.⁴⁴ A class of man-made organic chemicals known as bisphenols is used to make plastics, epoxy resins, and personal care items like lipstick, face cosmetics, and nail polish. Although bisphenols' health impacts have received a lot of attention, recent examples between these chemicals and reproductive health suggest that more study needs to be done on them.⁴⁵ Apoptosis, DNA damage, disruption of cell-to-cell communication, mitochondrial damage, disruption of tight junctions, and slowed proliferation are just a few of the effects that Bisphenols, particularly Bisphenol A, F, and S, have been shown to have on testicular cells. These effects pose a threat to the health of male reproductive organs. Additionally, because bisphenols interact agonistically or antagonistically with hormone receptors, they change the activities of organs and cells.⁴⁵ BPA is an endocrine disruptor that has been linked to fertility problems, birth defects, and cancer. It can also affect males who are kissed by lipstick users, resulting in a "Castrated kiss" in which the affected male absorbs BPA into his bloodstream, affecting his fertility and reproductive organs.⁴⁶ The female gamete appears to be particularly vulnerable to BPA exposure, which has been related to an increased risk of Breast Cancer as well as the role of Polycystic ovary syndrome.³⁸ The second most prevalent cancer to cause mortality in women worldwide and the fifth most common cause of Cancer death worldwide is breast cancer.⁴⁷

Challenges in Assuring Quality Lip Care Cosmetics

Lipstick is more than simply a cosmetic for women; it symbolises confidence, courage, and independence.⁴⁸ In the Indian market, there has been a lot of discussion about fake cosmetics. Cosmetics in branded bottles have been discovered being marketed to parlours and salons.¹² Many cosmetic products contain impurities such as high levels of Heavy Metals (Lead, Zinc, and Cadmium) in Lipsticks, Lip Glosses, Eye shadows, and Henna Hair Dye.⁴⁹

Counterfeit Manufacturing- Counterfeit manufacturing is exact or close reproductions of trademark product packaging, import, export, distribution and selling with hard-to-resist pricing to deceive customers.⁴⁴ Sometimes look alike of branded beauty products are sold for a fraction of their true value. But the truth is that these are Counterfeit/Fake products, not branded ones. They are created to seem identical to the genuine things in order

to deceive customers into believing they are the authentic thing. These are unlawful, which is why identifying and tracking down the producer is so difficult. At best, exposure to the harmful ingredients of such counterfeit lip care cosmetics may result in an allergic reaction, swelling, chemical burns, rashes, and pimples, which are quickly reversed as the user stops. Customers purchasing cosmetics online should be aware of the key indicators for counterfeits and assess the quality of products in person before using them.⁵⁰

Lipstick Dumping

Another issue that needs to be considered is lipstick dumping. In the United States, some 1,484 tubes of lipstick are sold every minute, and discarded lipstick tubes contribute to the 12% of solid waste made up of plastic. Not only do the plastic tubes harm the environment; most lipsticks also include petrochemicals and lead acetates. According to the Campaign for Safe Cosmetics, one-third of brand-name lipsticks have levels of lead that exceed the government safety standard, and incorrect disposal of those lipsticks pollutes landfills and groundwater.⁵¹ India has a large population, and its cosmetics business is similarly large. To protect the health of the Indian population, in addition to adequate regulation of these agents, a proper vigilance system is also essential.¹²

Low Durability

Inventory management is complicated by expiration dates, thus adopting flexible and agile acquisition strategies is essential. Preservers keep cosmetics from going bad in the cosmetics industry. However, employing these products is only transitory and is greatly impacted by their short shelf life. A poor inventory management strategy could result in significant waste rates.

Carcinogenicity

Another issue is carcinogenicity. Lipsticks have a lot of dangerous components including heavy metals like antimony, lead, cadmium, and mercury. Lipsticks may also contain formaldehyde, a preservative and proven carcinogen, mineral oil compounds, which are known to clog pores, and parabens, which are frequently employed as carcinogens. Additionally, hazardous petrochemicals are used by lipstick producers to create this lip formulations.⁵²

What Can Be Done by Users?

There is a solution to every difficulty. Negative effects on the health caused by lip care products can be mitigated by using safer alternatives. Those who use lipstick on a regular basis should keep the following suggestions in mind-

In the darker colours of lipsticks, heavy metal will undoubtedly be in abundance. As a result, lighter colours are recommended.

The detrimental effects of the chemicals in the lipstick can be mitigated by using a petroleum jelly base.

Users should not buy inexpensive products, no matter how appealing an untrusted brand lipstick appears to be, because they cause more harm than reputable brand lipsticks.

Lipsticks contain harsh chemicals that can harm the skin around them, so exfoliate at least twice a week.

Chemical lipsticks should not be worn during pregnancy since they can harm the baby in the mother's womb, instead, go for herbal alternatives.

Before going to bed, use an excellent makeup remover to remove and wipe away the lipstick.

To avoid the harmful effects of chemicals, choose for Homemade, Natural, and Organic Lipsticks.³⁴

CONCLUSION

Lipstick, in particular, has traditionally been considered a necessity for women. They boost women's confidence and looks. Even though it has a glamorous appeal, public worry about its toxicity has become a prominent topic. Some companies produce adulterated lipstick that contains prohibited substances and heavy metals like Cd, Cr, Cu, Co, Ni, and Pb that may be damaging to the user's health. So, to manage adulterants, several countries including India, USA, EU, and Canada, have created laws and regulations to assure the safety of cosmetics. The impact of adulterants on our health is also crucial factor to keep in consideration. Over the years, there have been concerns that lipstick contains dangerous levels of lead. The use of heavy metal-containing cosmetics and exposure to them can lead to organ malfunction, endanger human health and welfare worldwide, and have a significant detrimental effect on a country's economy. According to the assessment, ladies who have serious illnesses should examine the lipstick before using it to avoid aggravating their conditions. Heavy metals present in lipsticks not only pose a health risk but also provide difficulties in their manufacturing and marketing. Some of these difficulties are carcinogenicity, dumping, and low durability. Although manufacturing presents a myriad of challenges, one should abide by the laws and regulations established by their nation in order to provide the end customers with a high-quality product. There seems to be compelling urgency for developing harmonized cosmetovigilance programme so that all the global citizens get quality assured cosmetic products and any non-compliance breaching the quality may be detected with promptness and ease resulting in a timely action on such events.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DEP: Diethyl Phthalate; **DBP:** Dibutyl phthalate; **EU:** European Union; **FDA:** Food and Drug Administrative; **FDCA:** Federal Food, Drug, and Cosmetic Act; **FPLA:** Fair Packaging and Labelling Act; **PPM:** Parts Per Million.

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