



**ADVERSE REACTIONS OF COSMETIC PRODUCTS:  
REGULATORY CHALLENGES IN INDIA**

**SUJIT KUMAR\*<sup>1</sup> AND ROOP NARAYAN GUPTA<sup>2</sup>**

<sup>1</sup> *State Drugs Control Directorate, Government of Jharkhand, Namkum, Ranchi, Jharkhand, India.*

<sup>2</sup> *Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi, Jharkhand, India.*

**ABSTRACT**

Cosmetics have been in use since ages for improving the appearance of the person wearing them. These are generally regarded as safe but adverse reactions are often reported in different countries of the world. Adverse reactions are mainly due to hazardous and unsafe ingredients present in the product. Spurious or adulterated cosmetics are also responsible for adverse reactions. Cosmetics adverse reactions generally go unnoticed due to its slow action, ignorance and lack of proper reporting. In the present article we highlighted the adverse reactions and toxic effects of commonly used cosmetic products on the consumers. Regulation in India is inadequate and requires stringent measures to control such issues.

**KEY WORDS:** Cosmetics, Adverse reactions, Restricted or Prohibited substances, Regulations



**SUJIT KUMAR**

State Drugs Control Directorate, Government of Jharkhand,  
Namkum, Ranchi, Jharkhand, India.

## INTRODUCTION

Cosmetics have been used since ages. Decorating the face and body is an activity that is among the oldest, most widespread, and persistent of human behaviours. The word cosmetic derives from the Greek "*Kosm tikos*" meaning having the power, arrange, skilled in decorating<sup>1</sup>. Romans used the word "*cosmetae*"<sup>2, 3</sup> to describe slaves whose function was to bathe men and women in perfume. Around 10,000 B.C. Egyptians used scented oils to mask body odour, and dyes and paints to colour their body and hair. They believed "to smell beautifully was a sign of holiness" and only perfect-smelling persons would be received by the gods when they die. Different materials were used in those times. Women painted the undersides of the eyes with green colour made from malachite, a copper carbonate ore and lids, eye lashes were painted with black colour called kohl. Egyptian women (around 4000 BC) applied galena-mesdemet (made of copper and lead ore) and malachite (bright green paste of copper minerals) to their faces for color and definition. Romans used fat from a sheep, mixed with blood, for nail polish<sup>4, 5, 6,7</sup>. Chinese people used to stain their fingernails with gum arabic, gelatin, beeswax and egg around 3000 BC. The colours used to represent the social class in China. In India, henna was in use even around 300-400 AD as a hair dye and in mehndi, an art form in which complex designs are painted on to the hands and feet, especially before a Hindu wedding. Henna was also used in some North African cultures. Hindus used betel juice to darken the lips and teeth and aromatics for wedding and birth rituals<sup>8</sup>. In middle ages, various kinds of products were used together with white lead paint that probably consisted of arsenic. This arsenic poisoned women and many were killed as a result<sup>9</sup>. Mixtures of lead and copper were used as facial powder. One such mixture, Ceruse, made from white lead, is later discovered to be toxic and blamed for physical problems including facial tremors, muscle paralysis, and even death. During excavations lipsalves have been found believed to have been used by the Queen around 3200 BC. Both Nero and Poppaea

used cosmetics. They used white lead and chalk to whiten the skin; kohl to make up their eyes, eye –brows and lashes; focus, a red colour for cheeks and lips; psilotrum, a depilatory; barley flour and butter as a cure for pimples; and pumice stone for whitening their teeth<sup>10,11</sup>.

Cosmetics were unregulated 80 years ago in USA. 16 cases of blindness associated with the use of Lash lure Eye Lash aniline dye in 1930 impelled the US Congress to take action to protect American Republic. Age Intervention Eye lash used for eye lash improvement was withdrawn from US market as this product contained bimatoprost (prostaglandin analogue)<sup>12</sup>. Thallium-containing depilatory products caused severe and lethal intoxications in the year 1930<sup>13</sup>. In the 1950/60s, Zirconium-containing deodorants resulted in an outbreak of long-lasting allergic inflammatory skin reactions in consumers in Europe and the US<sup>14</sup>. In one disaster in France, more than 30 babies died owing to respiratory arrest when 6% of hexachlorophene was accidentally added to batches of baby talcum powder<sup>15</sup>. Different hazardous inorganic and organic materials were used for cosmetic purpose in the past. Unregulated ingredients and compositions in cosmetics caused severe adverse reactions all over the world. These remained unnoticed due to the lack of proper knowledge.

### ADVERSE REACTIONS

EU defines an adverse health effect caused by cosmetic product as a harmful reaction that occurs from normal or reasonably foreseeable use of the product. Examples of common adverse reactions are allergic/irritative contact dermatitis, photo-allergic/toxic contact dermatitis, anaphylactic shock, conjunctivitis, urticaria, cosmetic acne, hypo/hyper pigmentation, itching, corrosive scalp injury, acute hair loss, loosening of nails from the nail bed and irritation of the mucous membrane of the oral cavity. Most common allergic reactions are caused by "stay-on" or "leave-on" products which includes moisturisers, hair dyes, nail cosmetics, deodorants, perfumes, facial and eye make-up products. Less

common adverse reactions are caused by the "rinse-off" or "wash-off" products which are removed from the skin after a short period ex. Soaps, shampoo, shaving creams etc<sup>16</sup>. Foley et al has reported that Cosmetics frequently cause adverse reactions<sup>17</sup>. A recent study found that an average adult uses nine cosmetic products daily. A survey report from USA reveals that more than 25% of women use 15 or more cosmetics daily<sup>18</sup>. It is estimated that about 1-3% of the population are allergic to a cosmetic or cosmetic ingredient<sup>19</sup>. In one American survey comprising 30,000 consumers, 700 allergic reactions occurred during 1-year period<sup>20</sup>. Systemic Contact Dermatitis are caused by the cosmetics when exposed orally or by inhalation which includes eczema, generalized rash, sometimes fever, malaise etc. reported<sup>21</sup>. In Britain, Commonest single reason for hospital referrals is attributed to allergic contact dermatitis<sup>22</sup>.

Dogra et al has reported contacts allergic dermatitis with various cosmetics in 3.3% of the consumers. Most common type of adverse reaction to cosmetics was contact allergic dermatitis in 59.2% mainly to hair dyes, shaving creams and lipsticks<sup>23</sup>. Mutagenicity and ochronosis has been reported by the use of skin lightening/depigmenting agents, such as hydroquinone<sup>24</sup>. In a study in India, fairness creams, kumkum powder (applied on forehead and scalp) is reported to cause depigmentation in 10% and hyperpigmentation in 7.5% of the consumers<sup>25</sup>. Cosmetic products containing fragrances, sunscreen chemicals, preservatives etc are matter of concern all over the globe. A brief overview is given in this article. Fragrances and preservatives- are the most common causative ingredients<sup>26</sup>. Fragrance can enter the body through the lungs, skin, ingestion, and via pathways from the nose directly to the brain and can cause headaches, irritation to eyes, nose, and throat, dizziness, fatigue, forgetfulness, and other symptoms. Fragrance is the number one cause of skin allergic reactions to cosmetics<sup>27</sup>. Sunscreens/ UV filters are products that are placed in contact with human skin with the intention of absorbing, scattering, or reflecting

solar UV radiation. Many recent reports from Europe and other western countries have highlighted increasing cases of allergic and photo allergic reactions to sunscreen products<sup>28,29</sup>. Almost 20% of photo allergic dermatitis or cosmetic allergy is attributed to sunscreen agents<sup>30</sup>. Benzophenone-3 (BZ3) found in sunscreen moisturizers, lip balm and children's sunscreen has been reported to be very hazardous. The chemical is absorbable through the skin and causes endocrine disruption. A study has revealed that mothers with high levels of BZ3 in their bodies were more likely to give birth to underweight baby girls<sup>31</sup>. CDC published results that BZ3 readily absorbs into the body and is present in 97% of Americans tested<sup>32</sup>. BZ3 and its metabolites cause weak estrogenic<sup>33, 34,35</sup> and anti-androgenic effects<sup>36</sup>. Para-aminobenzoic acid (PABA) was once a popular sunscreen ingredient. Its metabolites were detected in the urine of consumers when tested on consumers applying PABA-based sunscreens<sup>37</sup>. Its use has declined because of problems with allergic dermatitis photosensitivity and carcinogenicity. ASEAN nations and Canada have banned PABA containing sunscreens. Indian regulation allows up to 5% in cosmetics<sup>38</sup>. Padimate O (Octyl dimethyl PABA) releases free radicals and in turn causes DNA damage, estrogenic activity and allergic reactions<sup>39</sup>. It is allowed up to 8% in cosmetics in India<sup>38</sup>. Menthyl anthranilate (meradimate) has the ability to produce damaging reactive oxygen species when it is exposed to sunlight. Testes weight and testosterone levels were significantly reduced in male rats<sup>40</sup>. It is prohibited for use in sunscreen products within Europe and Japan but is still in use within the United States.

Formaldehyde and formaldehyde-releasing preservatives are used in many cosmetic products viz. shampoos, liquid body soaps, nail polishes, nail glues, eyelash glues, hair gels and hair-smoothing products<sup>41, 42</sup>. Canada restricts the concentration of formaldehyde<sup>43</sup>. It is banned by countries like Japan and Sweden for use in cosmetics<sup>44</sup>. Formaldehyde is considered a known human carcinogen<sup>45,46</sup>. The European Union and even India restricts the use of formaldehyde in

cosmetic products, and requires that products with formaldehyde or formaldehyde-releasing ingredients carry the label "contains formaldehyde"<sup>38</sup>. 1,4-dioxane is a frequent contaminant of common cosmetics ingredients<sup>47</sup>, but since it is present as contaminant; it is not listed among intentionally added ingredients. Ethylene oxide is added to the chemical which are harsher on the skin to make them less harsh. This ethoxylation process contaminate the chemical with 1,4-dioxane. It is considered as a probable human carcinogen by the U.S. Environmental Protection Agency<sup>48</sup> and listed as an animal carcinogen by the National Toxicology Program in USA<sup>49</sup>. Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi is raising the voice to remove formaldehyde or formaldehyde - releasing ingredients and 1, 4-dioxane from cosmetics<sup>50</sup>. Many manufacturers of cosmetic products containing herbal ingredients label the product as "Ayurvedic medicine" and try to bypass the specifications and evaluation Standards laid down by various regulatory agencies. Most of the toothpowders (Dant Manjans) are sold under this category. In Indian market Dantmanjans are labelled as Ayurvedic medicine. They are reported to fail tests prescribed in IS 5383-1978 (toothpowders) of the Bureau of Indian Standards, especially, presence of hard and sharp edged particles<sup>51, 52</sup>.

Hair dyes selling as Kali Mehandi (herbal) or herbal hair dye has been found to contain para-phenylenediamine (PPD) along with henna<sup>53</sup>. PPD is a well-known and extremely potent skin sensitizer<sup>54</sup>. PPD has been found to be very strong sensitizer and a common contact allergen in hair dyes in an approximated 35-42% of cases<sup>55</sup>. There have been several reports in the literature of immediate allergic (and also anaphylactic) reactions on using adulterated henna dyes<sup>56</sup>. Shampoos and conditioners are reported to cause eye irritation and matting of scalp hair due to the presence of formalin, parabens, hexachlorophene, triclosan, and fragrances<sup>57</sup>. Skin bleaching agents containing ammonium persulfate reported to cause types I and IV allergic contact reactions. Generalized

urticaria, asthma, syncope, and shock in reaction to the persulfate activator have been reported<sup>58</sup>. Baby products are often claimed as safe and gentle. Complaints were received about the development of blisters on the skin due the massage of the baby oil. FDA, Maharashtra investigated the baby products manufactured by a reputed company. It was reported that baby oil containing light liquid paraffin was an irritant. Baby products are basically targeted towards adult care as they claim for younger and softer skin by the use of the product. Since the baby soap did not contain coconut oil as ingredient, no claims can be made by the company as to the goodness of the coconut oil being available in the soap<sup>59</sup>.

Colour cosmetics like lipstick, eye shadow, blusher, eye pencil, liquid foundation, powder, mascara, nail polish etc. have the highest average annual growth rate. Colorants are a good source of heavy metal poisoning. Though heavy metals might not cause immediate health problems but its cumulative effect due to repeated application cannot be ruled out. The metals of most concern are arsenic, cadmium, lead, and mercury. Lead affects almost every system in the body such as the reproductive, neurological, hematopoietic, hepatic and renal systems<sup>60</sup>. Children absorb about 50% of ingested lead<sup>61</sup>. The use of lead contaminated lipstick or eye shadows by pregnant or/and lactating women could expose the foetus and infants to the risk of lead poisoning. Latest study shows that there is no safe level of lead exposure<sup>62</sup>. Lipsticks manufactured in the United States and used daily by millions of American women also contain surprisingly high levels of lead, according to a test report released in 2007 by the Campaign for Safe Cosmetics. More than 16 branded lipsticks tested contained detectable levels of lead, with levels ranging from 0.03 to 0.65 parts per million (ppm). None of these lipsticks listed lead as an ingredient<sup>63</sup>. The Centre for Disease Control and Prevention (CDC) has even gone so far as to recommend that parents should avoid using cosmetics on their children that could be contaminated with lead<sup>64</sup>. Arsenic exerts adverse effects on the skin; arsenic has a pronounced affinity for skin and keratinizing

structures including the hair and nails. Therefore, symptoms of acute over exposure include a variety of skin eruptions, alopecia and characteristic striation of the nails<sup>65</sup>. Arsenic and its inorganic compounds, and cadmium and its compounds are considered human carcinogens<sup>66</sup>. Mercury compounds are reported to cause allergic reactions, skin irritation, or adverse effects on the nervous system<sup>67</sup>. Clinical symptoms of overexposure to mercury include tremors, weakness, memory loss, dermatitis and impaired kidney function<sup>68</sup>. Drugs and Cosmetics Rules 1945 mentions that the permitted synthetic organic colours and natural organic colours used in the cosmetic shall not contain more than 2 ppm of Arsenic calculated as Arsenic trioxide, 20 ppm of lead calculated as lead, 100 ppm of heavy metals other than lead calculated as the total of respective metals. A study conducted in India to estimate the presence of heavy metals (lead, arsenic etc.) in cosmetics viz. lipstick, shampoo, surma, hair colours, talcum etc. had showed alarming results. The issue was raised on the floor of the parliament.

### **REGULATORY PROVISIONS IN INDIA**

Cosmetics produce local (skin, eye) exposure and are used in the oral cavity, on the face, lips, eyes and mucosa. Therefore, systemic exposure to these ingredients cannot be excluded. Up to the 1960s it was generally believed that cosmetics remained on the surface of the human body. Therefore, only local effects were the concern for safety. Before 1962; there was no regulation to manufacture cosmetics in India. Government of India amended the Drugs Act 1940 by bringing the cosmetics also within the purview of the Act and the title of the Act was changed to the Drugs and Cosmetics Act. This amendment was carried out by the Act 21 of 1962. Cosmetics is defined as any article intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic<sup>69</sup>. For a long time standards for cosmetics in finished form were not under the Act and Rules. In early eighties,

the standards framed by the Indian Standards Institution (now called as Bureau of Indian Standards) were adopted for certain cosmetics. Now as many as 29 cosmetics are placed under Schedule S are required to comply with Indian standards. Sindoor, face pack and Kajal are also under consideration for inclusion into the list. Still a lot of cosmetic products are required to be placed under Schedule S<sup>70</sup>. Rules for import and manufacture were introduced under the Drugs and Cosmetic Rules in the year 1964. The Govt. of India as per vide GSR No 426(E) dated 19th May 2010 has enacted the "Import Registration of Cosmetics" rules with effect from 1st April 2013. Now, cosmetics can no longer be imported into India without obtaining the registration from the Government. BIS has classified raw materials in two groups – GRAS (Generally recognised as safe) and GNRAS (Generally not recognised as safe). BIS classify GNRAS as annex A, B, C, and D. Annex A provides a list of substances which must not form part of the composition of cosmetic products. Annex B provides a list of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down. Annex C mentions list of preservatives which cosmetic products may contain and Annex D provides list of UV filters which cosmetic sunscreen products may contain<sup>71</sup>.

List of restricted/ prohibited substances notified by the Government of India are:

- Prohibition of manufacture of cosmetics containing colours other than those prescribed: Dyes, colours and pigments other than the one specified by the BIS (IS:4707 part 1 as amended) and Schedule Q.[under rule 144].
- Permitted synthetic organic colours and natural organic colours used in the cosmetic shall not contain more than :2 ppm of Arsenic calculated as Arsenic trioxide, 20 ppm of lead calculated as lead, 100 ppm of heavy metals other than lead calculated as the total of respective metals. [under rule 144-A].
- Manufacture of cosmetic containing hexachlorophene. Soaps may contain hexachlorophene not exceeding 1% w/w. [under rule 144-A].

- Lead and Arsenic compounds for the purpose of colouring cosmetics. [under rule 145].
  - Manufacture of cosmetic containing mercury compounds. [under rule 145-D].
  - Fluoride content in tooth paste shall not be more than 1000 ppm. [under rule 149-A].
  - Manufacture and sale of all cosmetics licensed as tooth paste/tooth powders containing tobacco.
- Offences and penalties for imported cosmetics as prescribed in the Drugs and Cosmetics Act 1940 (as amended) are summarised in table 1.

**Table 1**  
**Offences and penalties for imported cosmetics.**

SI No.	Import of cosmetic	Maximum imprisonment	Maximum fine (Rs)
1	Spurious cosmetic	Three years	Five thousand
2	Containing ingredient which may render unsafe/harmful	Three years	Five thousand.
3	Other than in SI no. 1 & 2 and which is prohibited	Six months	Five thousand or with both.
4	Prohibited cosmetic	Three years	Five thousand or with both..
5	Repeated offence under SI no. 1,2 and 4	Five years	Ten thousand or with both.
6	Repeated offence under sl no. 3	One year	One thousand or both.

Offences and penalties for manufacture for sale or for distribution or sell, or stock or exhibit or offer for sale or distribute a cosmetic in India are summarised in table 2.

**Table 2**  
**Offences and penalties for cosmetics manufactured in India.**

SI No.	Type of offence	Maximum imprisonment	Maximum fine (Rs)
1	Not of standard quality	One year	Twenty thousand or with both
2	Misbranded	One year	Twenty thousand or with both
3	Containing ingredient which may render unsafe/harmful	One year	Twenty thousand or with both
4	Contravention of provisions of chapter IV	One year	Twenty thousand or with both
5	Contravention of provisions of the Act and Rules	One year	Twenty thousand or with both
6	Manufacture without licence	One year	Twenty thousand or with both
7	Restricted or prohibited cosmetics	Three years	Five thousand
8	Adulterated	Three years	Minimum fifty thousand or three times the value of cosmetics confiscated, whichever is more
9	Spurious	Three years	Minimum fifty thousand or three times the value of cosmetics confiscated, whichever is more

## DISCUSSION

- The punishment prescribed for manufacture for sale or for distribution or sell, or stock or exhibit or offer for sale or distribute a cosmetic which is containing any ingredient which may render it unsafe or harmful for use under the directions indicated is imprisonment for a term which may extend to one year or fine which may extend to twenty thousand rupees or with both. This punishment is not adequate to deal with this type of offence. It is a serious criminal offence for which more punishment must be prescribed. However, in the case of similar type of an imported cosmetics imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees is prescribed.
- Misbranded and Spurious cosmetics are defined u/s-9-C and 9-D respectively in the Drugs and Cosmetics Act for the purpose of import to India. However, adulterated cosmetics are not defined for the purpose of import. It means that if an imported cosmetic contains colourants other than those prescribed the maximum punishment one can get is one year imprisonment or with fine up to twenty thousand rupees. At

the same time, there is no statutory requirement to mention the colour on the product.

- The minimum punishment prescribed under section 27-(c) for spurious drugs manufacture and sale in India is imprisonment for a term which shall not be less than seven years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees or three times the value of drugs confiscated, whichever is more. Although, cosmetic products have rarely been associated with serious health hazards, this does not mean that cosmetics are always safe to use, especially with regard to possible long-term effects as the products may be used extensively over a large part of the human lifespan. Oral exposure is inevitable.
- Cosmetics may contain ingredients whose safety is unclear or which are known to pose health risks. Testing of cosmetic products is voluntary and controlled by manufacturers. Many of them also contain "penetration enhancers" for increasing penetration through the skin. Therefore *spurious cosmetics* also require stringent punishment in tune with the punishment prescribed for spurious drugs.
- False or misleading claims in cosmetics to the intending user is prohibited under rule 148-B. Countries like Canada, Australia and ASEAN nations have issued guidelines for claims on cosmetic products. But in India no such guideline is issued so far<sup>72</sup>.
- Under Schedule M II of the Drugs and cosmetics Rules 1945 cosmetic products like face powder, cake make-up, compacts, face packs, masks, rouges, alcoholic fragrance solution etc are included. But since no standards of these cosmetics are prescribed by BIS it is virtually impossible to check the standard quality of these products.
- As per the Guidelines on Registration of Import of Cosmetics issued recently by the Central Drugs Standard Control Organization (CDSCO) about 80 brands of cosmetics are recognised for registration of import<sup>73</sup>. Not all these products are included in Schedule S of the Drugs and Cosmetics Rules. Therefore, without the standards for these cosmetic products, the quality of the product cannot be ascertained.
- A cosmetic product that has or is purported to have medicinal properties is termed as *cosmeceutical*. US FDA, Health Canada does not recognize this term. The product is regulated either as a cosmetic or a drug depending on the claims it makes and/or the composition of the product. In the absence of clear cut guidelines in India, companies deviate from the norms. This term is widely used by the industry to sell cosmetics by mixing drugs to make exaggerated claims though it has no legal sanctity.
- If any cosmetic is likely to involve any risk to human being, then in public interest the Central Government may, by notification in the official Gazette regulate, restrict or prohibit the manufacture sale or distribution of such cosmetic under section 26-A. Many substances prohibited in other countries are not yet prohibited in India. For example, formaldehyde is banned from use in cosmetics in both Japan and Sweden. Methyl anthranilate is prohibited for use in sunscreen products within Europe and Japan. PABA is banned in sunscreens in ASEAN nations and Canada.
- Where hazard exists there is provision to mention on the inner label of a cosmetic product; (a) adequate direction for safe use; (b) any warning, caution or special direction required to be observed by the consumer; and (c) a statement of the names and quantities of the ingredients that are hazardous or poisonous. Rule 149 only provides provision for the labelling of hair dyes, colours and pigments for para-phenylenediamine or other dyes, colours and pigments. It is up to the manufacturer to decide which are hazardous or poisonous
- Rule 148(7) of the Drugs and cosmetics Rules 1945 makes provision for listing of ingredients present in concentration of more than 1% shall be listed in the descending order of weight or volume at

the time they are added, followed by those in concentration of less than or equal to 1% in any order and preceded by word "ingredients".....provided that this statement need not appear for packs of less than 60 ml of liquids and 30gm of solid and semisolid. The purpose of cosmetic ingredient labelling is to enhance the safety of the consumers by making available to users valuable information concerning the composition of cosmetics. Listing on product labels provides the consumer with information that allows them to avoid products that contain an ingredient that may cause an adverse reaction. Most of the cosmetic manufacturers do not mention the colour on their products because they are added in less than 1% concentration and many cosmetic products are packed in less than 60ml of liquids and 30gm of solid and semisolid .None of the heavy metals are listed on the labels of the cosmetic products. Provision should be made in the act for compulsory disclosure of the heavy metal concentration on the cosmetic labels esp. on the colour cosmetics <sup>74</sup>.

## CONCLUSION

Not only ingredients containing unsafe, hazardous or poisonous substances but spurious and adulterated cosmetics are also responsible for adverse reactions due to their

use in consumers. Colorants, preservatives and sunscreen chemicals need to be used which are permitted and within the prescribed limits. Heavy metal content should be within the limit. Restricted and prohibited substances must not be used. Various adverse effects may occur in the form of acute toxicity, percutaneous absorption, skin irritation, eye irritation, skin sensitization and photosensitization, sub chronic toxicity, mutagenicity/genotoxicity, phototoxicity/photo irritation etc. by the use of cosmetics. At present there is no Cosmeto-vigilance programme running in India and hence there is no reporting of adverse events in cosmetics. Most of the adverse events go unnoticed. Countries like Italy and France have started separate Cosmeto-vigilance programme. Provision is required to be made in the Drugs and Cosmetics Act and Rules for the ingredients to be listed along with their percentage on the label of the cosmetic products so that the manufacturer's claims are not false and at the same time consumers can aware themselves of the allergens/toxicants present in the product and avoid them. Provision should be made in the act for compulsory disclosure of the heavy metal content on the cosmetics labels. Necessary amendments in the act are required. Furthermore, manufacturers and importers must ensure that products are safe and do not pose a risk to the users.

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