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# Regulation for safety and quality of cosmetics vis-a-vis colourants in India compared with other nations

Sujit Kumar\* and Roop Narayan Gupta

Department of Pharmaceutical Sciences, Birla Institute of Technology, Mesra, Ranchi, Jharkhand, India

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## ABSTRACT

*Cosmetics market has been increasing tremendously in the world and colourants are one of the most popular ingredients in cosmetic products providing a way in which a person can change his or her appearance and make the product instantly noticeable and attractable for purchase. Labelling, nomenclature and safety of colourants vary in different countries. Robust legislation exists in the European Union (EU) and the United States of America (USA) to regulate their use for cosmetic products. Variations in regulations affect safety assessments of cosmetic products. Indian regulation requires improvement and harmonization with international regulations. In the present article, we examine and establish the need for harmonisation of regulations for colourants.*

**Key words:** Colourants, legislation, regulation, labelling, nomenclature, safety

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## INTRODUCTION

In both the United States of America (USA) and the European Union (EU) cosmetics manufacturers ensure product safety prior to marketing. All the ingredients are listed on the product label and comply with any restrictions that are established for cosmetic ingredients and products. Colour additives are subject to more regulatory scrutiny in the US than they are in Europe. In USA, the Cosmetic Ingredient Review (CIR) expert panel conducts independent safety reviews of ingredients as a part of the cosmetics safety process, with the results published in the International Journal of Toxicology and on the CIR website. The EU Scientific Committee on Consumer safety is responsible for reviewing all special and active ingredients and assessing conditions for safe use. The results are subsequently published in the Committee's website [1]. Europe and USA are the largest markets in the world for cosmetic products. In the end user segments, decorative cosmetics (that modify the appearance of the area to which they are applied, usually by the use of colour, examples are: lipstick, eye shadow, blusher, eye pencil, liquid foundation, powder, mascara, nail polish etc.) have the highest average annual growth rate. The cosmetics market in India is growing at 15-20% annually, twice as fast as the USA and EU

market. Indian cosmetic industries continue to be a beautiful blend of traditional and modern like kajal, sindoor, kum-kum, herbal cosmetics, lipsticks, nail polishes etc. The aim of the present article is to compare the regulations in EU, USA, Canada, ASEAN nations and India for cosmetic colourants with respect to labelling, nomenclature, safety and thereby quality of the products to the end users and includes the following aspects.

## **COSMETICS COLOUR LABELLING**

### **EU**

In the EU, the regulatory framework is provided by the Cosmetics Directive (76/768/EEC) and its subsequent amendments. Colouring agents may be listed in any order after the other ingredients using the Colour Index Number or denomination adopted in Annex IV. For decorative cosmetics marketed in several colour shades, all colouring agents used in the range may be listed preceded by the words “may contain” or the symbol “+/-” [2, 3].

The Regulations make provision for the listing of all colouring agents used in a decorative cosmetics although each product would only contain a selection of those colours. The intention is to simplify manufacture by allowing all of the colouring agents to be listed on one label in a market where fashions and colours change frequently. Ingredient listing is required on the outer packaging only or, in its absence, on the primary container. Where it is impossible for practical reasons for the list to appear on the packaging (or container), it is required to be given on a leaflet, label, tag, tape or card enclosed with the product or attached to it. Colour ingredients which do not have a CI number, and not listed in the above Regulations, but are closely associated with colour might only be present in some products within the decorative range. These items are mentioned under the +/- (may contain) section of the ingredient listing like mica and tin oxide, both used as opacifiers.

### **US**

The cosmetic product ingredients labelling are regulated by the Federal Food, Drug and Cosmetic Act, as amended (FFDCA) and its implementing regulations. The Fair Packaging and labelling Act, as amended (FPLA) and its implementing regulations are also considered. Ingredients other than colours present at a concentration exceeding 1% in descending order or predominance, followed by ingredients other than colours present at 1% or less in any order, followed by colours present at any concentration listed in any order. The colour additives common to all shades must be listed before “May contain”, and only those not found in all shade formulations may be listed after “May contain” [4].

FFDCA defines a colour additive as a material which –(a) is a dye, pigment or other substance made by a process of synthesis or similar artifice, or extracted, isolated or otherwise derived, with or without immediate or final change of identity, from a vegetable, animal, mineral or other source, and (b) when added or applied to a food, drug or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting colour thereto.....The term colour includes black, white and intermediate grays.

### **ASEAN**

ASEAN (Association of South East Asian Nations) nations, a group of ten countries, follow ASEAN Cosmetic Directive which defines “colour” as a substance used as an ingredient of cosmetic product solely to give tonality to the product. Variants are defined (a range of cosmetic products) as similar in composition but differs in colours, flavours etc. - produced by the same manufacturer, and are intended for the same use but are available in different shades of colour (e.g. lipsticks, eye shadows or nail polish but not composite packs of different types). These are

considered as different types of products. Member States adopt the Cosmetic Ingredient Listings of the EU Cosmetic Directive 76/768/EEC including the latest amendments [5].

### **CANADA**

The basis for the regulatory authority for the Cosmetics Program comes from the Food and Drugs Act and Cosmetic Regulations [10]. Ingredient is defined as any substance that is one of the components of a cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the cosmetic but that are not present in the final product as a result of the chemical process [6].

All colouring agents, regardless of their concentration, may be listed in random order after the ingredients that are present at a concentration of more than 1% (as described in section 21.4(2) of the Cosmetic Regulations). It is also acceptable to list colouring agents in descending order of predominance.

For make-up products (e.g. lipstick, blush, eye shadow), nail polish and nail enamel, which are sold in a range of colour shades, all colouring agents used in the range may be listed if they are preceded by the symbol "+/-" or "±" or the phrase "may contain/peut contenir" (as described in section 21.2(2) of the Cosmetic Regulations). It is unacceptable to use this notation for other cosmetic products, such as hair dyes [7].

### **INDIA**

Cosmetics products in India is regulated under the Drugs and cosmetics Act 1940 and Rules 1945. BIS (Bureau of Indian standards) sets the standards for cosmetics for the products listed under Schedule 'S' of the Drugs and cosmetics Rules 1945.

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 60ml of liquids and 30gm of solid and semisolid [8].

## **NOMENCLATURE OF COLOURS**

Identification of the colour additives on cosmetic product labels has been a discussion item for many years between different regulatory bodies and the industry. There should be a simpler and uniform system of identifying these colour additives, one that could be used world-wide so that all cosmetic products use the same terminology for the same basic ingredients.

### **EU**

For colouring agents use of INCI names is recommended. EEC directive mentions that colouring agents may be listed in any order after the other ingredients using the Colour Index (CI) Number or denomination adopted in annex IV [3].

### **US**

The official names for colour additives in the USA are designated by FDA [9]. Colours subject to batch certification are designated as food, drugs and cosmetics (FD&C), drugs and cosmetics (D&C) or external drugs and cosmetics (Ext. D&C). This is followed by a colour designation, such as blue or red, and by No. (for number), and by a numeral. An example of such a name is FD&C Red No. 40. Colours made by combining these "straight" colours with "substrates"

(sodium, potassium, aluminium, barium, calcium strontium, or zirconium) are known as "lakes" and are named using the same convention, but with the addition of the word *lake* and the substrate, for example: *FD&C Red No. 40 Aluminium Lake*. Cosmetic colours that are not subject to batch certification are known by more common names, for example: Caramel *or* Henna. The important thing to note is that all of these colours, both those that are subject to batch certification and those that are not, must be pre-approved, and have specifications set, before being used in cosmetic products in the USA. FDA also allows companies marketing their products internationally to use dual labelling for colours, listing names acceptable to the FDA as well as Colour Index (CI) numbers that are required for labelling colours in the European Union and other countries in the world. Thus, for example, a cosmetic product in the USA may bear ingredient labelling for colours such as Yellow 5/CI 19140 or FD&C Yellow No. 5/CI 19140 [9]. The FDA has granted permission for the cosmetic industry to use abbreviated names on the labels of products containing the certifiable colours or lakes. For example, FD&C Blue No. 1 now may be listed as Blue 1, and FD&C Red No. 40 Aluminium Lake may now be listed as Red 40 Lake. The original colour names also may still be used.

## INDIA

Rule 127 clause (2) of the Drugs and Cosmetics Rules 1945 mentions that the label on the container of a *drug* containing a permitted colour shall indicate the common name of the colour, for example: Quinazarine Green SS, Tartrazine, Erythrosine etc. But, the same is not true with cosmetics. No direction is given in the D&C Act and Rules regarding the nomenclature of a colouring agent.

*Pond's White Beauty cream* (Hindustan Unilever Ltd.) mentions CI 14700 on the label. *Garnier Wrinkle Lift anti-ageing cream* (Loreal India Pvt. Ltd.) does not mention any colour. *Lactocalamine* (Nicholas Piramal India Ltd.) mentions the colour on the label as "permitted colour". *New Ever Youth Orange Peel Off Skin Vitalizer* (Cadila Healthcare Ltd.) does not mention any colour. *Artistry essentials polishing scrub* (imported by Amway India Enterprises Pvt. Ltd.) mentions the colour as ultramarines. *Glister toothpaste* (manufactured by Sarvottam Care, India for Amway India Enterprises Pvt. Ltd.) mentions the colour as FD&C Blue No 1 (CI 42090). These examples prove that there is no harmonization in the nomenclature of colourants in India. Table I, compares the names of the colour additives used by USA and Indian regulation.

## SAFETY ISSUES

### EU

In EU the safety of cosmetics is covered by the EC Cosmetics Directive (76/768/EEC) as amended. Annex IV to Cosmetics Directive 76/768/EEC provides for a "list of colouring agents allowed for use in cosmetic products". The allowed use refers to different fields of applications [10]. This is implemented in UK by the Cosmetic Products (Safety) Regulations 2008 [11]. Mica is not considered a colourant in EU and Japan. Aluminium colourants are approved for all cosmetic applications in EU and Japan. Ferric ferrocyanide may be used in externally applied cosmetics in addition to the lip area use in EU and Japan.

**Table I**

Colour Index No.	Colour	
	USA	INDIA
10316	Ext yellow 7	Yellow
12085	Red 36	Red
20170	Brown 1	Orange
40800	$\beta$ -carotene	Orange
60730	Ext violet 2	Violet
75120	Annatto	Orange
75130	$\beta$ -carotene	Orange
75170	Guanine	White
75470	Carmines	Red
75810	Chlorophyllin-copper complex	Green
77000	Aluminium powder	White
77007	Ultramarines	Blue
77163	Bismuth oxychloride	White
77288	Chromium oxide	Green
77400	Bronze powder	Brown
77489	Iron oxides	Orange
77491		Red
77492		Yellow
77499		Black
77742		Manganese violet
77820	Silver	White
77891	Titanium dioxide	White
77947	Zinc oxide	White

## US

US Food and Drug Administration (USFDA) requires that all colour additives must be tested for safety and approved for their intended use by the FDA before they can be marketed in the USA. In addition, batch certification (testing by FDA) is required for most colour additives (except one class of hair dyes) to assure that they meet the specifications of the regulations. Use of an unapproved colour additive in a cosmetic product, or of an approved colour additive, but in an unapproved manner, makes the product illegal and adulterated. All colour additives must meet the requirements for identity and specifications stated in the Code of Federal Regulations (CFR). Colour additives may be used only for the intended uses stated in the regulations that pertain to them. The regulations also specify other restrictions for certain colours, such as the maximum permissible concentration in the finished product [9]. Inorganic and natural colours are exempt from this certification. FDA has approved 64 colour additives for cosmetic use either with or without batch certification [12].

Mica is on the approval list of the FDA. Aluminium colourants are approved for all cosmetic applications except for lip products. Ferric ferrocyanide may be used in externally applied cosmetics in the USA. CI 45425 (D & C Orange No.10 and 11) is banned and henna is listed for hair colour only.

## ASEAN

ASEAN PIF (Product Information File) requires signed assessment report of the safety for human health of the finished product based on its ingredients, their chemical structure and level of exposure along with the Curriculum Vitae of the safety assessor [13]. Marketing of cosmetic products containing the colouring agents other than those listed under Annex IV, Part 1 of ASEAN Cosmetic Directive (except cosmetic products containing colouring agents intended

solely to colour hair) is prohibited. This Directive does not mention about the EEC directive for the purity requirements of the colours.

### **INDIA**

IS 4707(part 1): 2001 under clause 4.1 mentions a list of 158 colouring agents. These colouring agents are generally recognised as safe (GRAS), their maximum concentration in finished products is prescribed and for many of them the requirement suggest that they must fulfil the purity requirements as laid down in the EEC directive of 1962. Henna is not listed as colour [14].

### **HEAVY METALS**

Heavy metals are found naturally in the environment in rocks, soil and water, and therefore exist in the manufacture of pigments and other raw materials in all industries including the cosmetics industry. Some of these metals have been used as cosmetic ingredients in the past. Examples include the preservative thiomerosal (contains mercury), the progressive hair dye lead acetate and a number of tattoo pigments such as red cinnabar (mercuric sulphide).

The metals of most concern are arsenic, cadmium, lead, and mercury. Oral exposure can occur for cosmetics used in and around the mouth, as well as from hand-to-mouth contact after exposure to cosmetics containing heavy metal impurities. Though heavy metals might not cause immediate health problems but its cumulative effect due to repeated application cannot be ruled out. As we know, lead builds up in the body over time and lead containing lipstick whether applied a number of times a day or on daily basis can contribute to significant lead exposure levels. Different heavy metals build up in the body over time and are known to cause varied health problems, which include: cancer, reproductive and developmental disorders, neurological problems; memory loss; mood swings; nerve, joint and muscle disorders; cardiovascular, skeletal, blood, immune system, renal problems; headaches; vomiting, nausea, and diarrhoea; lung damage; contact dermatitis; brittle hair and hair loss. Many are suspected hormone disruptors and respiratory toxins, and for some like lead, there is no known safe blood level. One study with contact dermatitis found 88 eye shadow colours from 49 different products revealed that 75 per cent of the colours contained more than five parts per million of at least one of lead, cobalt, nickel, chromium, and arsenic, and that 100 per cent of the products contained more than one part per million of at least one of those substances [15]. Testing conducted in the United States by the Campaign for Safe Cosmetics revealed that 61 per cent of the 33 brands of lipsticks contained lead, with levels of up to 0.65 parts per million. The higher-priced brands were not immune [16].

The US Food and Drug Administration also found lead in all the samples of lipstick that it tested, with levels ranging from 0.09 to 3.06 parts per million [17]. Health Canada found that 81 per cent of the samples of lipstick tested for lead had levels ranging from 0.079 to 0.84 parts per million, and that one lipstick contained 6.3 parts per million [18].

Significant concentrations of heavy metals have been found in a number of cosmetics in Asia. Some samples of Surma were found to have a lead content as high as 86%. A London-based toxicology unit published a case series of adverse events associated with traditional medicines that were reported to them between 1991 and 1995. Out of 12 cases of poisoning with lead, arsenic or mercury, nine cases were associated with herbal remedies from India and the remainder was due to traditional Indian cosmetics e.g. *surma* [19]. 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 [20].

Health Canada's "Draft guidance on heavy metal impurities in cosmetics,(2009)" has acknowledged that heavy metal impurities in cosmetic products are unavoidable due to the ubiquitous nature of these elements, but should be removed wherever technically feasible. Heavy metal concentrations in cosmetic products are seen to be technically avoidable when they exceed these limits: Lead: 10 ppm; Arsenic: 3 ppm; Cadmium: 3 ppm; Mercury: 3 ppm; Antimony: 5 ppm [21].

### **Lead**

Lead affects almost every system in the body such as the reproductive, neurological, hematopoietic, hepatic and renal systems [22]. Pregnant women and young children are particularly vulnerable to lead exposure. Children absorb about 50% of ingested lead [23]. 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 [24]. 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 as that could be contaminated with lead [25].

The Drinking Water Guidelines in Canada limit the lead content to a Maximum Acceptable Concentration (MAC) of 0.010 milligrams per litre (0.010 ppm) of water [26]. Acceptable oral intake of lead impurities include 0.1 ppm (US FDA for candy) to 10 ppm (USP for nutritional supplements). The World Health Organization (WHO) has established 25 micrograms of lead per kilogram of body weight per week as a provisional tolerable weekly intake (PTWI) for children. Health Canada's Natural Health Products Directorate (NHPD) limits lead in products applied to the skin to 10 ppm (NHPD Compendium of Monographs).

### **Arsenic**

Arsenic exerts adverse effects on the skin and keratinizing structures including the hair and nails. Therefore, symptoms of acute overexposure include a variety of skin eruptions, alopecia and characteristic striation of the nails [27]. Children could ingest arsenic-containing cosmetics from hand-to-mouth contact (e.g. by rubbing their hands over the mouth and/or eating after rubbing the face). Arsenic and its inorganic compounds, and cadmium and its compounds are considered human carcinogens [28].

The maximum acceptable concentration (MAC) for arsenic in drinking water is 0.010 mg/L (10 mcg/L = 10 ppb) in Canada [29]. Acceptable limits of oral ingestion of arsenic impurities include 0.1 ppm in foods (Health Canada) to 3 ppm in nutritional supplements (USP). The US FDA limit for arsenic in certain colourants is <3 ppm [30]. The WHO provisional tolerable daily intake (PTDI) for inorganic arsenic is 2 mcg/kg bw/day.

### **Cadmium**

National Institute for Occupational Safety and Health (NIOSH) classifies cadmium as a human carcinogen. Cadmium binds to epidermal keratin when applied topically, thus explaining the limited dermal absorption observed *in vitro*. However, significant dermal exposure, as could occur in an occupational setting, can cause irritant dermatitis [31].

The Canadian Drinking Water Guideline, maximum acceptable concentration (MAC) for cadmium is 0.005 mg/L (0.5 ppb) [32]. Acceptable oral limits of cadmium include 0.09 mcg/kg bw/day to 3 ppm (USP for nutritional supplements). The WHO has established a Provisional Tolerable Daily intake for cadmium of 1 mcg/kg bw/day [33].

### **Mercury**

Various forms of mercury are toxic. Organic (methyl) mercury is of greater concern than inorganic mercury. However, all forms of mercury are absorbed through the skin and mucosa and dermal exposure can result in systemic toxicity. For the general population, the major route of mercury exposure is dietary intake [27]. Mercury compounds may cause allergic reactions, skin irritation, or adverse effects on the nervous system [34]. Clinical symptoms of overexposure to mercury include tremors, weakness, memory loss, dermatitis and impaired kidney function [35].

WHO has established a provisional tolerable daily intake of 2 mcg/kg bw/day for total mercury and a provisional tolerable weekly intake of 0.0016 mcg/kg for methyl mercury [36]. A limit of 3 ppm has been established for nutritional supplements (USP nutritional supplements). The US FDA limits mercury impurities in some colourants to <1 ppm. Thimerosal, a mercury salt, is acceptable for use as a preservative in eye cosmetics in the US, with a limit of 65 ppm mercury.

## **DISCUSSION**

Different nations consider colourants as ingredient of cosmetic products. But no such provision exists in Indian legislation. In a country like Thailand there are five listings of cosmetic ingredients designated, namely prohibited substances, specially controlled substances, controlled substances, colorants and preservatives [37].

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 .

The use of INCI (International Nomenclature of Cosmetic ingredients) nomenclature provides uniform and consistent information to both health professionals and users. Majority of the countries require that the ingredients be listed using the INCI system. There are still some differences between the INCI system in Europe and the USA in the nomenclature of colours. This causes difficulties for importers and exporters.

Various brands of Herbal hair dyes manufactured by reputed firms are available in the Indian market which are claimed as a safe herbal product. The truth is that most of them are mixed with p-phenylenediamine (PPD). PPD and related compounds are used in permanent hair dyes, and more than two thirds of hair dyes currently used contain them. PPD is a well-known and extremely potent skin sensitizer [38].

IS: 4707 part I as amended has prescribed a list of colours to be used in cosmetics. No cosmetic shall be manufactured which contain dyes, colours and pigments other than the one specified by the BIS (IS: 4707 part I as amended) and Schedule Q. As per the Drugs and Cosmetics Rules 1945 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. There is no mention about the purity requirements of the colouring agents in the act.

Rule 145 of the Drugs and Cosmetics Rules 1945 prohibits use of lead and arsenic compounds in cosmetics for the purpose of colouring. Rule 135 prohibits import also of cosmetics containing lead or arsenic compounds for the purposes of colouring. Rule 145-D and 135-A prohibits manufacture and import respectively of cosmetics containing mercury compounds. If a cosmetic contains a colour which is not prescribed the product is deemed to be misbranded under section 17-C. Similarly, if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed it is declared adulterated under section 17-E. Manufacturing, selling, stocking or exhibiting adulterated cosmetic amounts to imprisonment up to three years and with fine which shall not be less than fifty thousand rupees or three times the value of cosmetics confiscated, whichever is more u/s-Section 27 A. Similarly for misbranded cosmetics provision of imprisonment for rupees or with a term which may extend to one year or with fine which may extend to twenty thousand rupees or both.

None of the heavy metals are listed on the cosmetic product label. People have the right to know what is in their products and to make their own decisions regarding safety.

Limit for lead and arsenic has been fixed for synthetic and natural organic colours in the Drugs and Cosmetics Rules 1945. No limit of these metals has been fixed for the Inorganic colours. [USFDA](#) has set a limit for lead in candy i.e., 0.1ppm. There is no limit set for heavy metals in the lipstick, nail polishes etc... This requires due consideration. At the same time necessary provision should be made in the Drugs and Cosmetics Act and subsequent Rules for the necessary disclosure of heavy metals (Pb, As etc.) content in the cosmetic products. Manufacturers should be required to disclose all substances including heavy metal content on their product labels and be freely available online before products hit the market. The proposed US Safe Cosmetics Act (2010) suggests that all ingredients, including those currently protected by trade secret laws (i.e. fragrance) unless protected as a trade secret by other laws, will have to be labelled on cosmetics [39]. It is recommended that India take a similar approach.

## CONCLUSION

The term “ingredient” for cosmetic products is not defined under Drugs and Cosmetics Act. For colourants to be treated as an ingredient, the term ingredient needs to be suitably defined and Purity requirement of colourants requires to be mentioned in the Drugs and Cosmetics Act. No guideline is given in the Drugs & Cosmetics Act and Rules regarding the nomenclature of colouring agents of cosmetics. For harmonization, INCI nomenclature is must and suitable provision is required to be made in the legislation. All types of herbal hair dyes should be free from PPD (colourant). Necessary provision is needed. 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. Furthermore, manufacturers and importers must ensure that products are safe and do not pose a risk to the users. 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. 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. Necessary amendments in the act are suggested. Limit for lead and arsenic needs to be provided for inorganic colours also in the Drugs and Cosmetics Rules.

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