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Cosmetic Coloration: A Review

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Synopsis

Colorants for cosmetics appear to be more strictly regulated than any other cosmetic ingredients. Most countries have adopted a positive regulatory system for colorants used in cosmetics. Although there have been many reports on colorants that are used in food products from regulatory perspectives, reports on colorants used in cosmetic products have been limited. The objective of this report is to provide different countries' regulatory requirements and to encourage the cosmetic industry to export products in compliance with global regulations through a comparative analysis of cosmetic colorant regulatory systems in major countries. We first provide an overview of cosmetic colorant regulatory frameworks of the European Union, the United States, China, and Korea. Then the cosmetic colorants were divided into three sectors: synthetic, inorganic, and natural. Each chapter describes the colorants' general characteristics and explains the regulatory differences. Additionally, synthetic colorant labeling with a different nomenclature system is discussed.

INTRODUCTION

Colorants have been used since prehistoric times in cosmetics, foods, and fabrics (1). Colors influence people's moods and feeling as well as the appearance of the products to others. It has been reported that when people have their first interaction with a person or a product, 62–90% of their assessments are based on colors alone (2). When consumers select cosmetic products, color is a decisive factor in their purchases (3).

Recently, the cosmetic industry in Korea has developed at a very fast speed, and increased its global exports. Thanks to the growing popularity of K-beauty around the world, Korea has become the world's fourth largest cosmetic exporter after France, the United States, and Germany (4). When exporting products to various countries, understanding the differences in cosmetic regulatory systems between countries is crucial. Specially, cosmetic colorants follow a positive system in most countries. Because all countries have different approaches to these regulations, they are perceived as the biggest barrier to exports to the international market. Therefore, we have compared Korea's cosmetic regulations with those of other world leaders.

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There have been many reports (5–10) on colorants used in food products from regulatory perspectives, but reports (11,12) on colorants used in cosmetic products have been somewhat limited. In addition, the general properties of cosmetic colorants have not been discussed before. To use cosmetic colorants properly, it is essential to completely understand their regulation, which are based on the colorants' chemical properties. The objective of this report is to provide the general properties of cosmetic colorants and describe different countries' regulatory requirements. Ultimately, it is hoped that this report will serve as a useful reference document for those exporting cosmetics. The research described in this report was conducted using the following steps. First, we targeted the European Union (EU), United States, which have the world's leading markets and regulatory initiatives on cosmetics, and China, as it is the one of the fastest growing markets in the world. Japan was excluded because its regulatory system is similar to Korea's system. Second, the colorants were categorized as synthetic, inorganic, and natural according to their chemical characteristics. Then, we determined the colorants' general features and compared the key features of regulatory systems between countries. Third, the cosmetic labeling regulations for synthetic colorants in each country were studied.

OVERVIEW OF COSMETIC COLORANT REGULATORY FRAMEWORKS

In the EU, cosmetic products must comply with the requirements of European Regulation (EC) No 1223/2009, which replaced Council Directive 76/768/EEC (13). It defines colorants as substances that are exclusively or mainly intended to color the cosmetic product, the body as a whole, or certain parts thereof, by absorption or reflection of visible light (13). It does not include colorants colored through photoluminescence, interference, or chemical reactions. Substances intended to be used as a colorant should be listed in Annex IV of European Regulation (EC) No 1223/2009. Annex IV includes substance identification, product type and body parts to which it is applied, and maximum concentrations. Colorants assigned with an E number have been proven safe for use in food by the member states. Each E number has a separate specification for purity criteria that are defined in Commission Regulation (EU) No 231/2012, and cosmetic colorants follow the same specifications. Colorants labeling is determined according to the nomenclature listed in Annex IV of the European Regulation.

In the United States, cosmetic products are regulated by the US Food and Drug Administration (FDA) under the Federal Food, Drugs, and Cosmetic (FD&C) Act and its implementing regulations (14). The FD&C Act defines a colorant as any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body (14). Colorants approved for use are named in the US Code of Federal Regulation (CFR) Title 21, Parts 70–82. Colorants derived from petroleum and synthetically produced organic colorants are subject to certification. If a manufacturer sends a sample, FDA personnel evaluate the purity, impurities, heavy metals, and so on, and assign a certified lot number. Colorants obtained from minerals, plants, or animal sources are not subject to batch certification requirements. However, they must comply with the identity, specifications, uses, and restrictions in Regulation 21 CFR 73. If the colorant subject to batch certification requirements is not certified, the cosmetics including that colorant are considered adulterated. Colorant labeling is determined according to the nomenclature listed in 21 CFR Parts 73, 74, and 82, and it is acceptable to use a colorant name with a Color Index (CI) number in parentheses.

In China, the cosmetic regulatory system is founded on Regulations Concerning the Hygiene Supervision Over Cosmetics (1989) supervised by the National Medicinal Products Administration, previously called the China Food and Drug Administration. Cosmetic ingredients should be listed in the Inventory of Existing Cosmetic Ingredients in China (15) and comply with the Safety and Technical Standard for Cosmetics-2015 regulation (16). Ingredients not listed in the Inventory of Existing Cosmetic Ingredients in China are required to undergo a registration procedure. The Safety and Technical Standards for Cosmetics regulation includes the lists of banned, allowed, and restricted ingredients. It defines a coloring agent as an ingredient added to cosmetics to create certain colors by absorbing and reflecting light (16). The list of colorants approved for use in cosmetic products can be found in Table 6 of the regulation along with the field of application, limitations, and requirements. The Chinese regulatory framework is similar to that of the EU. For this paper, we compared cosmetic color regulations in China to those of the other entities but did not analyze them in depth.

In Korea, cosmetic products are regulated by the Ministry of Food and Drug Safety under the Cosmetics Act and its amendments (17). A colorant is defined as an ingredient for which the main purpose is to make the color appear in cosmetic products or on skin (17). The Ministry of Food and Drug Safety's Colorant Specifications and Test methods notice laid out the types of colorants permitted in cosmetic products, their specifications, and the test methods. The types, usage areas, and usage of permitted colorants are specified in Annex 1. The particular specification and test method for each colorant are described in Annex 2. Although the acceptable criteria may be equivalent to those of other countries, it is mandatory to verify that manufacturer is using the same method detailed in Annex 2 of the regulation. Korean cosmetic regulations are similar to the Japanese cosmetic regulations, which have considerable differences from those of the EU and the United States.

In the next section, cosmetic colorants as mentioned before were grouped into three categories (synthetic, inorganic, and natural), and comparative studies are conducted. Although the regulations of each country are constantly changing, the current number of colorants permitted in cosmetics in each country is shown in Table I, as are provided the permitted number of colorants in the three categories. The numbers were tabulated based on the numbers in Appendix 1. Colorants used as hair dyes or cosmetic soaps are not discussed in this report. Throughout the paper, colorants will be referred to by the common names. The nomenclature for colorants from each country can be found in Appendix 1.

Table I
Comparison of the Number of Permitted Colorants in Cosmetics

	Total	Synthetic Colorants	Inorganic Colorants	Natural Colorants
EU[a]	153	110	29	14
United States[b]	65	37	20	8
China[c]	157	110	31	16
Korea[d]	102	59	30	13

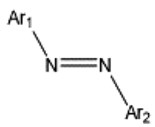
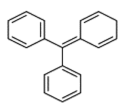
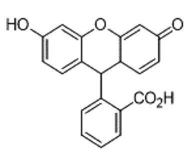
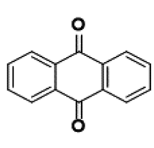
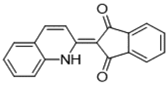
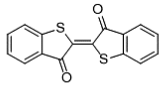
[a]FDA 21 CFR Parts 73 and 74.
[b]Annex IV, Regulation (EC) No 1223/2009.
[c]Table 6, Chap.3, Safety and Technical Standards for Cosmetics 2015.'
[d]Annex 1, MFDS Notification 'Colorants specification and test methods.'

COMPARISONS OF COSMETIC COLORANT REGULATIONS

SYNTHETIC COLORANTS

Synthetic colorants provide superior technical properties in tinctorial strength, hue, and stability compared to natural colorants (18). The use of synthetic colorants in cosmetic products has dominated the market globally because of the limitations of current technologies regarding natural colorants. Synthetic colorants present uniform quality and stability. Synthetic colorants do not appear in nature, are produced only by a chemical synthesis, and can be categorized based on their solubility and chemical structure. Depending on the solubility in the medium in which it is dispersed, one is soluble as a dye and the other is insoluble as a pigment (19). Additionally, synthetic colorants can be classified according to their common chemical structural features (Table II) (20–22).

Table II
Classification of Synthetic Colorants (US permitted colorants) by Structure

Classification	Chromophore	Examples [Common Name (CI No, US Name)]
Azo dye		Permaton Red (**CI 12085**, D&C Red No. 36), Ponceau SX (CI 14700, FD&C Red No. 4),Orange II (CI **15510**, D&C Orange No. 4), Brilliant Lake Red R (CI **15800**, D&C Red No. 31), Lithol Rubine B (**CI 15850**, D&C Red No. 6), Lithol Rubine BCA (**CI 15850**, D&C Red No. 7), Deep Maroon (**CI 15880**, D&C Red No. 34), Sunset Yellow FCF (**CI 15985**, FD&C Yellow No. 6), Allura Red AC (**CI 16035**, FD&C Red No. 40), Fast Acid Magenta (**CI 17200**, D&C Red No. 33), Tartrazine (**CI 19140**, FD&C Yellow No. 5), Resorcin Brown (**CI 20170**, D&C Brown No. 1), Sudan III (**CI 26100**, D&C Red No. 17)
Triarylcarbonium dye		Fast Green FCF (**CI 42053**, FD&C Green No. 3), Brilliant Blue FCF (**CI 42090**, FD&C Blue No. 1), Alphazurine FG (**CI 42090**, D&C Blue No. 4)
Xanthene dye		Uranine (**CI 45350**, D&C Yellow No. 8), Fluorescein (**CI 45350**, D&C Yellow No. 7), Dibromofluorescein (**CI 45370**, D&C Orange No. 5), Eosine YS (**CI 45380**, D&C Red No. 22), Tetrabromofluorescein (**CI 45380**, D&C Red No. 21), Tetrachlorotetrabromofluorescein (**CI 45410**, D&C Red No. 27), Phloxine B (**CI 45410**, D&C Red No. 28), Diiodofluorescein (**CI 45425**, D&C Orange No. 10), Erythrosine Yellowish NA (**CI 45425**, D&C Orange No. 11)
Anthraquinone dye		Pyranine Conc (**CI 59040**, D&C Green No. 8), Alizurine Purple SS (**CI 60725**, D&C Violet No. 2), Alizurol Purple (**CI 60730**, Ext. D&C Violet No. 2), Quinizarine Green SS (**CI 61565**, D&C Green No. 6), Alizarine Cyanine Green F (**CI 61570**, D&C Green No. 5)
Quinophthalone dye (Quonoline)		Quinoline Yellow SS (**CI 47000**, D&C Yellow No. 11), Quinoline Yellow WS (**CI 47005**, D&C Yellow No. 10)
Thioindigo dye (Indigos)		Helindone Pink CN (**CI 73360**, D&C Red No. 30)
Nitro dye	$Ar-NO_2$	Naphthol Yellow S (**CI 10316**, Ext. D&C Yellow No. 7)

Ar stands for Aryl group

Synthetic colorants have established specifications for impurities that can be generated through an analysis of synthetic processes and degradation products that may occur during further processing. Each country has set purity requirements for colorants to protect its consumers against unsafe products, adulteration, and fraud. During the synthesis of synthetic colorants, organic and inorganic impurities are determined by the degree of purity of the starting materials, reactants, and solvent. Therefore, it is important to use pure substances during the synthesis to reduce side reactions. Residual starting materials, intermediate products, by-products, and decomposed products are considered organic impurities. Metals included in the substances or used as a catalyst during the synthesis are considered inorganic impurities. Specially, impurities known to damage human health must meet the acceptance criteria or they are banned. Because certain levels of impurities may remain in a product, the manufacturing process should be fully understood to recognize the diverse sources of impurities.

Authorities in each country have established the quality requirements in the specifications for synthetic colorants to ensure consumers' safety. Specially, the EU and the United States have exemplary criteria for purity tests. The specifications can be broadly categorized as either identification tests or purity tests. Identification tests are experiments to prove the presence of the desired compound. Usually, organic structures are determined quickly by spectrophotometric tests that compare the absorption value of infrared (IR) and/or ultraviolet (UV) radiation with that of reference standards. In contrast, purity tests are experiments to determine the purity of the desired compound. To satisfy the purity tests, impurities must be carefully controlled during the synthesis of synthetic colorants.

In the next section, synthetic colorants are classified in terms of their chemical structure, and we discuss a representative group of useful dyes. First, azo dyes represent the largest share of the dye industry today. The advantage of this dye is that it is synthesized in only two steps, and various shades of colors can be expressed by simply changing the substituents. Second, xanthene dyes are important for their brilliant shades between greenish yellow and purple (23). They are also known to be the most abundant, widely distributed class of fluorescent molecules (24). Third, quinophthalone dyes were chosen because the EU and the United States have different definitions of the colorant. The distinct difference between each country's specifications also are described.

Azo Dyes.

Azo dyes, which are characterized by the presence of an azo bond (-N = N-), are the most important colorant and comprise over 50% of world dyestuff production (21). "Azo" group refers to two nitrogen atoms joined by a double bond. Azo dyes can have one or more azo groups in the compound. Azo dyes are simply synthesized in the sequential reaction of diazotization and azo coupling. The diazotization of an aromatic amine starts when it is treated with nitrous acid made from sodium nitrite ($NaNO_2$) and hydrogen chloride (HCl) at 0–5°C. Diazonium salt (a compound containing the N_2^+ group) reacts with other nucleophiles such as phenols or amines to yield azo colorants. The greatest advantage of this scheme is that it can produce a wide range of shades by only coupling readily available aromatic amines with phenols or naphthols. Another advantage of this process is that the reaction is carried out in water, which offers economic and environmentally friendly benefits. When an azo dye contains a group such as carboxylic acid ($-CO_2^-$) or sulfonic acid ($-SO_3^-$) in a molecule, it improves the dye's solubility. It has been

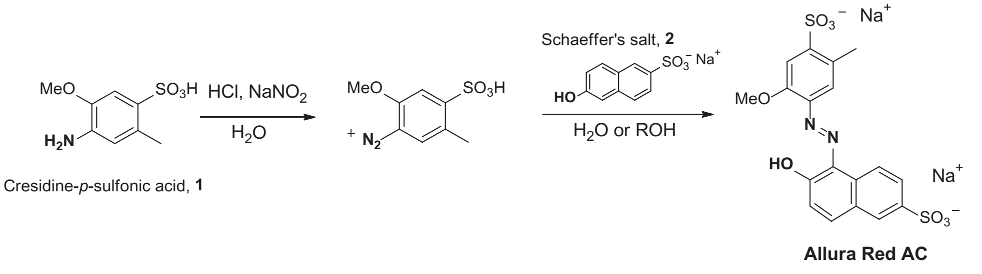


Figure 1. Synthesis of Allura red AC.

reported that azo dyes may be degraded by the cleavage of the azo bond to form aromatic amines (e.g., aniline, o-toluidine, and benzidine) in the presence of reducing species at higher temperatures (25).

Here, we discuss in more detail the different types of specifications applied in each country. Allura Red AC (AR; CI 16035, FD&C Red No. 40) is a red dye that is authorized for use in cosmetics in the four entities. It is prepared by coupling diazotized cresidine-*p*-sulfonic acid 1 with Schaeffer's salt 2 as shown (Figure 1) (20).

Usually, the requirements for synthetic colorants' purity are much greater than those of natural colorants. A comparison of the four entities specifications is shown in Table III. Concerning purity, AR must contain more than 85% of the total coloring matter. Specified impurities include *subsidiary coloring matters* and *organic compounds other than coloring matters*. Subsidiary coloring matters are compounds produced during the manufacturing process in addition to principal coloring matters (26). Organic compounds other than coloring matters are uncolored impurities such as uncombined intermediate starting materials (26). Subsidiary coloring matters are restricted in the EU by their total concentration and are restricted in three specified sections in the United States' regulatory framework (27). The higher/lower degree of sulfonation products (*tri*- and *mono*sulfonated components of AR) are included in the subsidiary coloring matters. Generally, impurities from the residual starting material in the raw material are restricted except in Korea. During the synthesis of AR dye, the starting material, cresidine-*p*-sulfonic acid (4-amino-5-methoxy-o-toluenesulfonic acid) and the coupling reagent of 6-hydroxy-2-naphthalene sulfonic acid, sodium salt (Schaeffer's salt) are regulated to 0.2% and 0.3%, respectively. Schaeffer's salt may react with another Schaeffer's salt to produce another by-product—6,6-oxybis(2-naphthalene-sulfonic acid)—which has a maximum content limitation of 1.0%. Moreover, the EU and China require the primary aromatic amine content to be less than 0.01%.

Xanthene Dye.

German von Bayer first synthesized xanthene dye in 1871 by condensing resorcinol and phthalic anhydride (28). Fluorescein (CI 45350, D&C Yellow No. 7) is one of the typical xanthene dyes. Xanthene 3 is a tricyclic compound of two benzene rings connected by a central pyran (oxygen-containing) ring. Fluorescein consists of a hydroxyl substituted xanthene ring connected to a benzene ring. The main characteristic of fluorescein is that it displays significant fluorescence. The fluorescence is widely seen in colorants in

Table III
Purity Specification Comparison of Allura Red AC

Purity Specification	EU	United States	China	Korea
Name	CI 16035	FD&C Red No. 40	CI 16035	Red 40
Loss on drying	—	≤ 14.0% (135° C)	—	≤ 10.0%(135° C)
Chlorides and sulfates	—		—	≤ 5.0%
Water insoluble matter	≤ 0.2%	≤ 0.2%	—	≤ 0.2%
Subsidiary coloring matters	≤ 3.0%			
Higher sulfonated subsidiary colors	—	≤ 1.0%	—	—
Lower sulfonated subsidiary colors	—	≤ 1.0%	—	—
Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid	—	≤ 1.0%	—	—
Organic compounds other than coloring matters				
6,6-oxybis (2-naphthalene sulfonic acid) disodium salt	≤ 1.0%	≤ 1.0%	≤ 1.0%	—
6-hydroxy-2-naphthalene sulfonic acid, sodium salt	≤ 0.3%	≤ 0.3%	≤ 0.3%	—
4-amino-5-methoxy-2-methylbenezene sulfonic acid (4-Amino-5-methoxy-o-toluenesulfonic acid)	≤ 0.2%	≤ 0.2%	≤ 0.2%	—
Unsulfonated primary aromatic amines	≤ 0.01%	—	≤ 0.01%	—
Ether extractable matter	≤ 0.2%			
Heavy metals				≤ 20 ppm
Arsenic	≤ 3 mg/kg	≤ 3 ppm	—	≤ 2 ppm
Lead	≤ 2 mg/kg	≤ 10 ppm	—	—
Mercury	≤ 1 mg/kg	—	—	—
Cadmium	≤ 1 mg/kg	—	—	—
Pure dye content	≥ 85%	≥ 85.0%	—	(85.0–101.0)%

Abbreviation: '—' : does not have a criteria
EU: European Union.
"—": does not have a criteria.

cosmetics, ink for highlighters, and fluorescent probes for biological research. To increase the maximum absorption of fluorescein dye, xanthene dyes have been halogenated to shift their spectral properties (29). Xanthene dyes have poor photostability, which means they may be fade from exposure to sunlight. For instance, the Dutch artist van Gogh enjoyed using bright xanthene dyes in his paintings, but they have faded after years of exposure to light (30). Furthermore, xanthene dyes are very sensitive to changes in their chemical environment, such as in their pH and in the solvent. Depending upon the pH of the solution, fluorescein appears in different forms: cation, neutral, monoanion, dianion (Figure 2) (31,32). Anions, a strongly fluorescent species, are formed by the deprotonation of mainly carboxylic acid (pKa 4.31) or/and phenol (pKa 6.43) protons in sequence (31). Neutral species of fluorescein are in equilibrium with the open quinoid

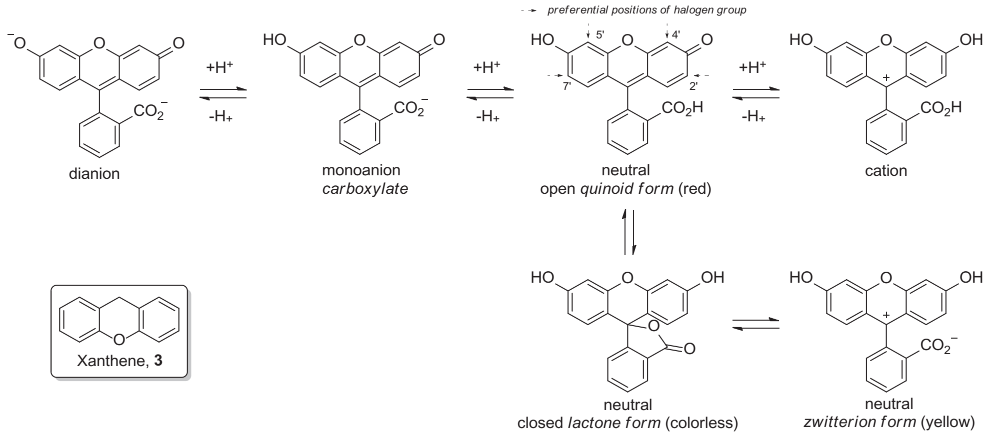


Figure 2. Structures of fluorescein by the pH of the medium. Adapted from Sjoback et al. (31)

form (major), closed lactone form, and zwitterion form. Importantly, each compound exhibits a different color red, colorless, and yellow, respectively. The lactone form prevails in an organic aprotic solvent, and the quinoid form prevails in a protic solvent such as water or alcohol (31). The equilibrium of the tautomers is affected by the solvent's polarity.

By the amount and source of halogen substituents, there are various xanthene dyes. Halogenation occurs in positions 4' and 5' followed by positions 2' and 7'. Dibromofluorescein (CI 45370, D&C Orange No. 5) has two bromine substituents, tetrabromofluorescein/eosine YS (CI 45380, D&C Red No. 21/22) has four bromine substituents, and tetrachlorotetrabromofluorescein/phloxine B (CI 45410, D&C Red No. 27/28) has four bromine and four chlorine substituents.

We will focus on discussing more details regarding tetrabromfluorescein (TBF; CI 45380, D&C Red No. 21) which has a yellowish-red color with green fluorescence (32). TBF is prepared by condensing phthalic acid or its anhydride 4 with two moles of resorcinol 5 in the presence of zinc chloride or concentrated sulfuric acid (Figure 3) (33). The resulting fluorescein 6 is then brominated in ethanol.

As a derivative of fluorescein, TBF exists in the following four possible structural forms in a medium depending on the pH of the solution: cation, neutral, monoanion, and dianion (Figure 4). Unlike the fluorescein, a phenol proton (pKa 2.85) that has

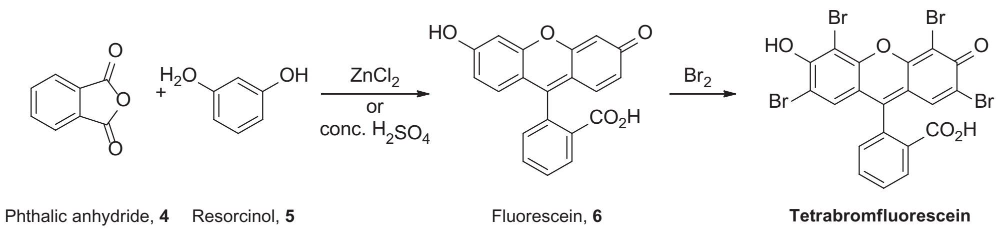


Figure 3. Synthesis of tetrabromfluorescein.

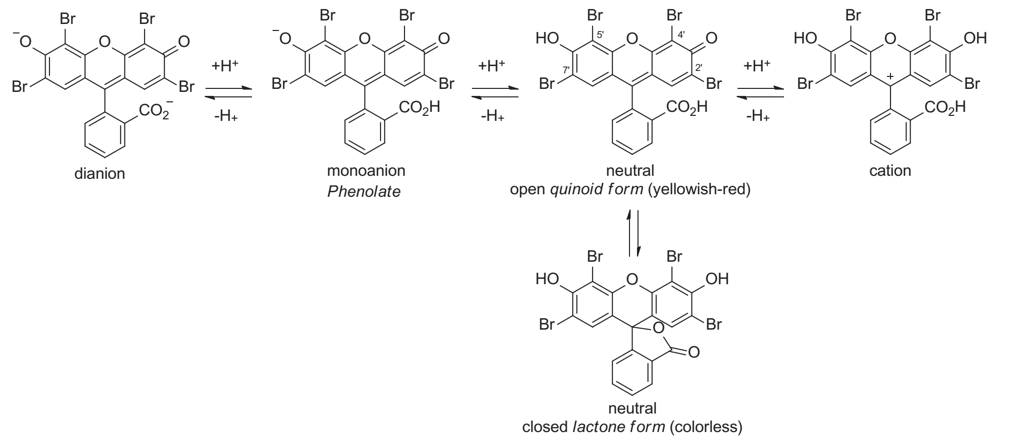


Figure 4. Structures of tetrabromfluorescein by the pH of the medium. Adapted from Cooksey et al. (30)

electron-withdrawing groups (halogen) nearby is more acidic than the carboxylic acid (pKa 4.95) (32). As the acidity of the molecules increases because of halogen substitution, the zwitterionic form seems highly implausible (30).

TBF exists in two tautomeric forms in a neutral solution: an open quinoid form, which has a yellowish-red color and fluorescence, and a closed lactone form, which is colorless with no fluorescence (30). A comparison of the four entities' specifications is shown in Table IV. TBF may contain lower halogenated subsidiary coloring matters as an impurity. In the specifications, the EU and China control the limits of fluorescein and *mono*brominated fluorescein to 1% and 2%, respectively. The United States has more intense standard limits: fluorescein, sum of *mono*- and *di*fluorescein, and *tris*bromofluorescein are restricted to 0.2%, 2%, and 11%, respectively. However, the four entities' legislation does not specify the exact position of the halogens on the substituted molecule. In the United States, the criteria for residual starting materials must be satisfied as well.

Quinophthalone Dye. Quinophthalone dye is made from quinaldine and phthalic anhydride and was first synthesized by Jacobsen in 1882 (34). It has a yellow to red shade and shows good lightfastness (35). It is typically synthesized by the condensation of quinolone with phthalic anhydride or phthalic acid in the presence of zinc chloride (22). Condensation products are sulfonated to produce a water-soluble dye. Quinoline Yellow SS (CI 47000, D&C Yellow No. 11) and Quinoline Yellow WS (QY; CI 47005, D&C Yellow No. 10) fall into the category of nonsulfonated and sulfonated products. When being sulfonated, oil-soluble Quinoline Yellow SS converts to water-soluble QY. Quinophthalone dye may exist as three tautomers: enaminone, keto-enol, and zwitterion forms (a compound containing both positive and negative charges; Figure 5). The enaminone form has been shown to be the most stable (36). Despite the quinophthalone structure's having been clarified, the conventional chemical structure [2-(2-quinolyl) indan-1,3-dione] is still widely used (Figure 5) (37). As for the sulfonation, it favors substitution in positions 6'- and 8'- positions in the quinoline ring and 4- and 5- positions in the indandione ring (37). Because current regulations simply name *mono*- and *di*sulfonates of quinophthalones,

Table IV
Purity Specification Comparison of Tetrabromfluorescein

Purity Specification	EU	United States	China	Korea
Name	CI 45380	D&C Red No. 21	CI 45380	Red 223
Solubility	—	—	—	Clear in EtOH
Insoluble matter	—	—	—	≤ 1.0%
Soluble matter	—	—	—	≤ 0.5%
Chlorides and sulfates	—	—	—	≤ 3.0%
Loss on drying	—	—	—	≤ 7.0%
Organic compounds other than coloring matter				
2-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid	—	≤ 0.5%	—	—
Phthalic acid	—	≤ 1%	—	—
Brominated resorcinol	—	≤ 0.4%	—	—
Heavy metals				≤ 20 ppm
Arsenic	—	≤ 3 ppm	—	≤ 2 ppm
Lead	—	≤ 20 ppm	—	—
Mercury	—	≤ 1 ppm	—	≤ 1 ppm
Zinc	—	—	—	≤ 200 ppm
Total color	—	≥ 90%	—	—
Disodium salt of 2′,4′,5′,7′-tetrabromofluorescein	—	≥ 87%	—	(90.0–101.0)%
Subsidiary coloring matters				
Fluorescein 2-(6-hydroxy-3-oxo-3H-xanthen-9-y1) benzoic acid	≤ 1%	≤ 0.2%	≤ 1%	—
Monobromofluorescein (2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid)	≤ 2%	≤ 2%	≤ 2%	—
Dibromofluoresceins	—		—	—
Tribromofluoresceins	—	≤ 11%	—	—
2′,4′,5′,7′-Tetrabromoflurorescein, ethyl ester	—	≤ 1%	—	—

Abbreviation : '—' : does not have a criteria

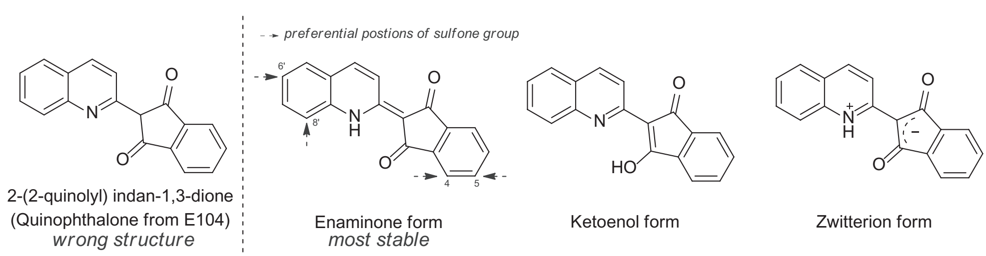
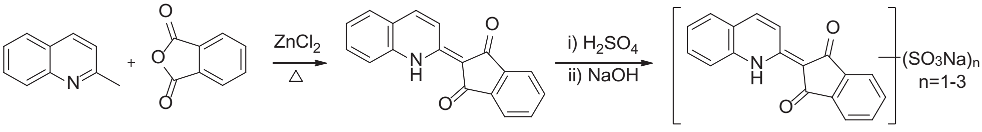


Figure 5. Structures of Quinophthalone.
Adapted from Han et al. (36) and Weisz et al. (37).



Quinaldine, **7** Phthalic anhydride, **4** 2-(2-Quinolyl)-1,3-indandione, **8** **Quinoline Yellow WS**

Figure 6. Synthesis of Quinoline Yellow WS.

they need clarification of the specific substitution sites for *mono*- and *di*sulfonates (e.g., 6'4-disulfonate, 8',5-disulfonate).

QY is a bright yellow dye with a green shade. It is prepared by condensing quinaldine 7 with phthalic anhydride 4, then sulfonating 2-(2-quinolyl)-1,3-indandione 8 (Figure 6) (37,38). The proportion of *mono*-, *di*-, and *tri*sulfonated compounds varies considerably according to the extent of sulfonation (37–39).

The definition of this colorant is significantly different between the EU and the United States. In the United States, the colorant has to contain more than 75% of the *mono*sulfonate, whereas in the EU, it has to contain more than 80% of the *di*sulfonate (Table V). Therefore, when QY is permitted by the US standard, it is banned in the EU and vice versa. In the EU, oversulfonated products, *tri*sulfonate, must be less than 7%. Particularly in the United States, the overall content of *di*sulfonates should be below 15%, and 6', 8'- in*di*sulfonates below 3%. In Korea, Yellow 203 is defined as a mixture of *mono*- and

Table V
Comparison of Purity Dye Content of Quinoline Yellow WS

Purity Specification	EU	United States	China	Korea
Name	CI 47005	D&C Yellow No. 10	CI 47005	Yellow 203
Pure dye content	≥ 70%	≥ 85%	—	(85.0–101.0)%
Monosulfonated quinophthalone 2-(2-quinolyl) indan-1,3- dione-monosulfonates [sodium salts of the monosulfonates of 2-(2-quinolinyl)-1H-indene-1,3 (2H)-dione]	≤ 15%	≥ 75%	—	—
Disulfoanted quiophthalone 2-(2-quinolyl) indan-1,3- dione-disulfonates (sodium salts of the disulfonates of 2-[2-quinolinyl]-1H-indene-1,3 [2H]-dione)	≥ 80%	≤ 15%	—	—
6′,8′-Disulfonated quinophthalone 2-(2,3-dihydro-1,3-dioxo-1H-indene-2-yl)-6, 8-quinoline disulfonic acid, disodium salt	—	≤ 3%	—	—
Trisulfonated quinophthalone 2-(2-quinolyl) indan-1,3- dione-trisulfonate	≤ 7.0%	—	—	—

Abbreviation: '—' : does not have a criteria
EU: European Union.
"—"′: does not have a criteria.

*di*sulfonates more than 85.0% ~ 101.0%. Therefore, any colorants imported from the EU and United States can be used.

In summary, we have discussed the general properties of synthetic colorants. It is important to understand the structural features of colorants as their visual characteristics are easily affected. Synthetic colorants have intense and uniform color, high stability, and economical value. However, increased concern over misuse synthetic colorants led to the establishment of the regulatory system. After an assessment of each colorant, each country introduced its positive list of colorants, then established its impurity acceptance criteria as part of its specifications. These impurities may pose potential health treats when present in finished products. A comparative analysis of the colorant specifications of four entities was performed. The main regulatory challenges were that all countries have established their own sets of positive lists, specifications, and definitions of each colorant. The differences in regulatory systems may lead to misuse or confusion among consumers.

INORGANIC COLORANTS

Inorganic colorants have been used since ancient times, for example, ancient Egyptians used iron oxides extensively in tomb wall paintings (40). They are generally stable coloring matters with a high heat stability, high chemical resistance, and low cost (41, 42). An inorganic colorant is defined as a dry, solid mineral that retains its color when ground to a fine powder (41). Inorganic colorants are chemically inert, insoluble compounds compared to organic colorants (42). They are classified as a pigment by definition because they are insoluble in the application medium.

World production of colorants is estimated to 10,000,000 tons annually, about 80% of which are inorganic pigments (43). Titanium dioxide (66%), iron oxides (approximately 15%), and carbon black (approximately 10%) make up more than 90% of the pigments (44,45). Inorganic pigments are either produced naturally mined and synthetically manufactured (analogous to naturally occurring minerals). Specially, to provide stable color consistency and better strength, some inorganic pigments–such as iron oxides–are obtained by chemical routes rather than directly from the naturally occurring minerals.

In the United States, colorants obtained primarily from mineral, plant, or animal sources are exempt from certification. Although they are exempt from certification, these colorants must conform to the identity, specification, restrictions, and labeling requirements in their individual listing regulations. Each country has its own positive list of inorganic pigments as well. For instance, mica is considered a colorant in the United States, but it is considered a general cosmetic ingredient rather than a colorant in the EU. The quality of inorganic pigments is also controlled through specifications. Heavy metal-based inorganic pigments such as lead, chromate, and cadmium pigments have limited or prohibited use in cosmetics. Other inorganic pigments may contain heavy metals a level that is not a threat to human health or the natural environment (46). In all four entities, the content of heavy metals (e.g., lead, arsenic, and mercury) in cosmetics is controlled by regulations.

Titanium Dioxides.

Titanium dioxide accounts for more than half of the worldwide use of inorganic pigments (45). Titanium dioxide is the whitest of all white pigments and is used extensively in the

Table VI
Comparison of Purity Specifications of Titanium Dioxide

Purity Specification	EU	United States	Korea
Name	CI 77891	Titanium dioxide	Titanium dioxide
Loss on drying	≤ 0.5%	—	≤ 0.5%
Loss on ignition	≤ 1.0%	≤ 0.5%	≤ 0.5%
Aluminium oxide and/or silicon dioxide	≤ 2.0%	—	≤ 2.0%
Acid soluble substances	≤ 0.5% (alumina, silica -free basis) or ≤ 1.5% (product containing alumina/silica)	≤ 0.5%	≤ 0.5%
Water soluble matter	≤ 0.5%	≤ 0.3%	≤ 0.25%
Cadmium	≤ 1 mg/kg	—	≤ 1.0ppm
Antimony	≤ 2 mg/kg	≤ 2ppm	≤ 2.0ppm
Arsenic	≤ 1 mg/kg	≤ 1ppm	≤ 1.3ppm
Lead	≤ 10 mg/kg	≤ 10ppm	≤ 10ppm
Mercury	≤ 1 mg/kg	≤ 1ppm	≤ 1.0ppm
Zinc	—	—	≤ 50ppm
Assay	≥ 99%	≥ 99.0%	≥ 99.0%

EU: European Union.
"—": does not have a criteria.
China has no specified specification.

cosmetic, paint, textile, plastic, and food industries (47). In the pigment industry, two crystallographic forms of titanium dioxide are used: rutile (the most common and more stable) and anatase (42). Titanium dioxide is produced synthetically because resources of the naturally occurring rutile form are limited (40). Generally, there are two types of titanium dioxide, pigment-grade and ultrafine-grade, according to their particle size and use. Pigment-grade titanium dioxide usually has a particle size greater than 100 nm to optimize the scattering of visible light. The ultrafine-grade titanium dioxide is used as a UV filter and has a primary particle size below 100 nm, which enhance its UV radiation absorption. The most important physical property of titanium dioxide is that it has high refractive index (2.70 for rutile and 2.55 for anatase), which are higher than that of diamond (2.42) (42). In a manner similar to that used for the regulations on synthetic colorants, the purity criteria for titanium dioxide were compared among countries (Table VI).

The standards of each country are well aligned with one another, except for a few tests. In addition, an international standard method is necessary for each test. In addition to its use as a white colorant, titanium dioxide is used as a component of pearlescent pigments. A pearlescent pigment consists of multiple layers; for example, mica is coated with metal oxides such as titanium dioxide or iron oxides (Figure 7). Multiple layers with a low refraction index (e.g., mica, synthetic mica, silica, alumina, and borosilicate) and high refractive index (e.g., titanium dioxide, iron oxides) produce interference or reflect light at the interface or surface of the layers causing a pearl-like luster. In the EU and the other countries, pearlescent pigments do not appear on the positive lists. Pearlescent pigments are rather considered as mixtures of mica, titanium

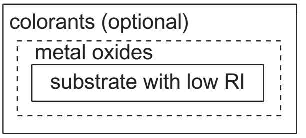


Figure 7. Structure of pearlescent pigments.

dioxide, and/or iron oxides and can be used if they meet each specification requirement (48,49).

Iron Oxides.

Iron oxides make up the second largest sales market of pigments after titanium dioxide. Generally, iron oxide is low-cost, inert to chemicals, insoluble in organic pigments, and of excellent durability, although it has low tinctorial strength and thermal stability (46). Even though iron oxides are common minerals found in nature (40), only synthetic iron oxide can be used in cosmetics because of its color consistency and purity. Synthetic iron oxides are produced with red (α-$Fe(III)_2O_3$), yellow (α-Fe(III)O(OH)), and black colors ($Fe(II)O \cdot Fe(III)_2O_3$) (50). The color can vary depending on the oxidation state of iron. Fe^{3+} represents yellow and red, and Fe^{2+} appears green and blue. In addition, the particle size of the iron oxides influences the hue of iron oxide pigments (50).

For iron oxides, the specifications in each country have limitations on maximum heavy metal (e.g., arsenic, lead) content (Table VII). Although "iron oxides" is used as the International Nomenclature Cosmetic Ingredients (INCI) name in the United States, the EU, and the other countries adopted distinct INCI names such as CI 77491 (red iron oxide), CI 77492 (yellow iron oxide), and CI 77499 (black iron oxide).

Table VII
Comparison of Purity Specifications of Iron Oxides

Purity Specification	EU	United States	Korea
Name	CI 77491	Iron oxides	Red iron oxide
Loss on drying	—	—	≤ 1.0%
Water soluble matter	≤ 1.0%	—	≤ 0.3%
Arsenic	≤ 3 mg/kg	≤ 3ppm	≤ 10ppm
Cadmium	≤ 1 mg/kg	—	—
Chromium	≤ 100 mg/kg	—	—
Copper	≤ 50 mg/kg	—	—
Lead	≤ 10 mg/kg	≤ 10ppm	≤ 10ppm
Mercury	≤ 1 mg/kg	≤ 3ppm	—
Nickel	≤ 200 mg/kg	—	—
Zinc	≤ 100 mg/kg	—	≤ 50ppm
Assay	≥ 68% (as iron)	—	≥ 90.0%(as Fe_2O_3)

EU: European Union.
"—": does not have a criteria.
China has no specified specification.

Carbon Black.

Carbon black is the most commonly used black pigment (46). Carbon black is pure elemental carbon produced by the partial combustion or thermal decomposition of gaseous or liquid hydrocarbons (42). Black pigments adsorb all wavelengths of visible light, and carbon black adsorbs up to 99.8% of visible light (42). The most important characteristic of carbon black is the small particle size and highly developed surface area of its particles, which gives it a high adsorption capacity. The tinting strength of carbon black is known to be determined chiefly by the particle size (51).

As the properties of carbon black align more with those of typical or general inorganic pigments than those of organic pigments (52), carbon black is considered an inorganic pigment in this report. Polycyclic aromatic hydrocarbons (PAHs) have been found to be adsorbed onto the surface of carbon black during manufacturing processes, and all four entities have established content limits for PAHs in the pigment (Table VIII) Carbon black consists of 95% pure carbon and other impurities adsorbed on the surface. The primary particle size of carbon black is between 5 and 500 nm, and those of its aggregates and agglomerates are 100–800 nm (53). To use carbon black as a pigment in the EU, the primary particle size must be greater than or equal to 20 nm, according to Annex VI (entry 126a). In the United States, carbon black is not exempt from certification, and the correct INCI name for carbon black after it has been certified by the FDA is D&C Black No. 2.

In summary, an inorganic pigment is a ground fine mineral powder with chemically inert and insoluble properties. The use of inorganic pigments dates back to ancient times. Still, there is a steadily increasing demand for inorganic pigments because of their low cost, stability, and lack of toxicity. In many countries, the heavy metal content in cosmetic colorants is strictly regulated. However, the variety and content of each heavy metal allowed may vary from country to country. In addition, uniform standards on pearlescent pigments that are widely used in the cosmetic industry are required.

Table VIII
Comparison of Purity Specifications of Carbon Black

Purity Specification	EU	United States	China	Korea
Name	CI 77266	D&C Black No. 2	CI 77266	Carbon black
Ash	≤ 4.0%	≤ 0.15%	Limit for polycyclic aromatic hydrocarbons: for 1g of Colorant samples, 10g of Cyclohexane is added, after continuous extraction in the extractor, the extraction liquid should be colorless, whose fluorescent intensity under ultraviolet rays shall not exceed that of control solution of quinine sulfate(0.1mg quinine sulfate dissolve in 1000mL 0.01mol/L sulfuric acid solution)	—
Arsenic	≤ 3 mg/kg	≤ 3 mg/kg		≤ 3ppm
Lead	≤ 2 mg/kg	≤ 10 mg/kg		≤ 10ppm
Mercury	≤ 1 mg/kg	≤ 1 mg/kg		—
Cadmium	≤ 1 mg/kg	—		—
Total Sulfur	—	≤ 0.65%		≤ 0.65%
PAH	—	≤ 0.5 mg/kg		≤ 0.5ppm
Benzo[*a*]pyrene	≤ 50 μg/kg	≤ 0.005 mg/kg		≤ 5ppb
Dibenz[*a,h*]anthracene	—	≤ 0.005 mg/kg		≤ 5ppb
Alkali soluble matter	Colorless	—		—
Assay	≥ 95%	≥ 95%		≥ 95.0%

EU: European Union.
"—": does not have a criteria.

NATURAL COLORANTS

Recently, the "clean beauty" trend has become increasingly popular in cosmetic markets around the world. The term "clean beauty" has no legal definition right now. Generally, it means a beauty product's manufacturer should consider human and environmental health, using nontoxic ingredients as a baseline and natural ingredients for active results (54). Clean beauty advocates natural products containing ingredients from plants and nature. Keeping pace with this trend, consumer demand is increasing for natural colorants instead of synthetic colorants.

In this report, natural colorants are colorants derived from natural sources. However, there is no widely accepted definition of natural colorants, and the term "natural colorant" is not used in four entities as it could mislead consumers. In this report, colorants from a natural origin (e.g., plants and insects) that are included on the positive lists in the regulations of each country (excluding the inorganic pigments discussed previously) are grouped as natural colorants regardless of their manufacturing process. Natural colorants can be classified based on their chemical structures (e.g., carotenoid, quinonoid, and flavonoid) and origin (e.g., plants and insects). Unlike synthetic colorants, natural colorants are expensive and easily affected by external factors such as pH, oxygen, heat, and light. In an effort to improve the stability of natural colorants, optimal extraction conditions and techniques for encapsulation matrices have been widely studied.

While synthetic colorants are tightly regulated because of their historical risks, natural colorants are defined ambiguously and relatively loosely, as currently regulated. For natural colorants, the specifications focus on a general test for residual solvents, an assay, and a test for heavy metals as these colorants are obtained mainly from plants. As the geographic origin and climate substantially influence their quality, the acceptance criteria of the assay test is relatively lower than those of synthetic colorants. There are no generally agreed upon maximum levels and types of residual solvents and heavy metals for natural colorants in cosmetic products. For instance, in the process of annatto extraction, isopropyl alcohol is allowed as an extraction solvent in the United States and Korea but not in the EU. In addition, the acceptable residual concentration of acetone varies from the United States and Korea (< 30 ppm) to the EU (< 50 ppm). The rest of this article encompasses general definitions, a comparison of regulatory requirements, and the practical limitations of natural colorants. As China has not established the specifications for natural colorants, this section will focus on the regulatory differences between the EU, the United States, and Korea.

Carotenoids: Annatto, Lycopene, β-Carotene, and Paprika Extract.

Carotenoids occur naturally in plants, algae, and fungi. There are over 600 known carotenoids. Carotenoids used in cosmetics are annatto, lycopene, β-carotene, and paprika extract. They exhibit different colors: red, orange, purple, and yellow. Carotenoids are categorized into two types: xanthophylls and carotenes. Xanthophylls contain hydrocarbon and oxygen (e.g., lutein, zeaxanthin, and astaxanthin), and carotenes contains hydrocarbon without the oxygen (e.g., α-carotene, β-carotene, γ-carotene, and lycopene) (55). Carotenoids typically contain eight isoprene units (Figure 8) (56). There have been reports of stability problems in carotenoids because of their extensive conjugated double bonds, which are referred to as the polyene chain (57–61). An unsaturated carotenoid is susceptible to oxidation and isomerization. The mechanism of carotenoid oxidation

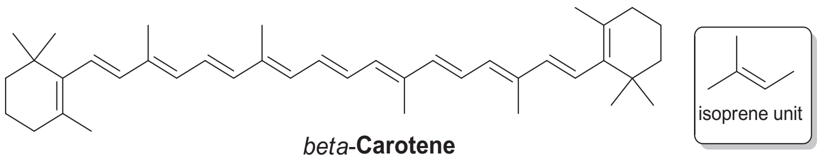


Figure 8. Structure of β-carotene.

has not been elucidated. However, the oxidation of alkenes leads to destruction of the chromophore of carotenoids, causing color loss (62). Isomerization can be caused by heat, acids, and light, but results in only a slight change in color (62).

To prevent the oxidation of carotenoids, the inactivation of the oxidative enzyme and the use of antioxidant agents (e.g., citric acid, α-tocopherol, and butylated hydroxytoluene) are recommended (62). Furthermore, to improve their solubility and chemical instability against environmental factors, such as light, temperature, and pH, spray drying and freeze-drying are used for encapsulating carotenoids (63,64). The most commonly used encapsulation technique is a method of enclosing active compounds in capsules with appropriate carrier matrices. Spray drying in a maltodextrin-based matrix is the most commonly used encapsulation technique in the cosmetic and food industries (64). In the next section, the definitions, production, and regulations of specific carotenoids will be discussed.

Annatto.

Annatto is an orange colorant prepared by extracting the outer coating of seeds from the annatto tree (*Bixa orellana* L.). The principal coloring matters of annatto seeds are bixin (oil soluble) and *nor*bixin (water soluble) (Figure 9) (56). In the manufacturing process, the extraction solvent influences the ratio of bixin and *nor*bixin and the amount of coloring matter. Heating in the extraction process converts the *cis*-bixin, or *cis-nor*bixin to a more stable isomer, *trans*-bixin or *trans-nor*bixin (65). Usually, organic solvent extraction provides higher extraction yields on both bixin and *nor*bixin. The bixin undergoes hydrolysis in hot alkaline solution to become *nor*bixin. The EU, the United States, and Korea permit the use of annatto as a cosmetic colorant. Specially, individual specification is determined separately according to the manufacturing process (e.g., solvent, alkali, or oil extraction) in the EU.

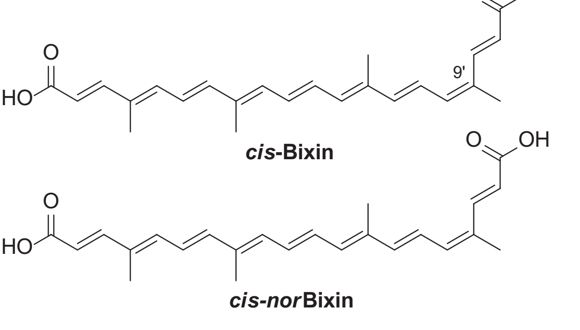


Figure 9. Structure of cis-bixin and cis-norbixin.

Lycopene.

Lycopene, the precursor of carotene, is a red colorant easily found in tomatoes. The principal coloring matter, lycopene, consists entirely of hydrocarbon and contains 13 trans-double bonds. Lycopene can be extracted from tomatoes and microorganisms (*B. trispora*) or synthesized chemically. Over 60% of lycopene production comes from plant extraction (66). Naturally occurring lycopene predominantly exists in an all-*trans*-configuration, but the *trans-cis* isomerization process can occur during processing and storage. Synthetic lycopene is synthesized via the double Wittig reaction using the strategy C15 + C10 + C10 (Figure 10) (67). Synthetic lycopene costs less than lycopene extraction from tomatoes and microorganisms (66). In the EU, synthetic lycopene is required to contain more than 70% *trans*-lycopene.

Alternatively, lycopene products derived from biomass have been developed as food and cosmetic additives. As an alternative and sustainable source for the production of lycopene, the *Blakeslea trispora* microorganism has been utilized (68,69).

β-Carotene.

β-carotene, known for its provitamin A activity, is a highly conjugated compound that makes carrots orange (Figure 8). It is obtained from various natural sources (plants, algae, and fungus) or prepared synthetically. In the EU regulation, four manufacturing methods are permitted to produce β-carotene as a colorant. Traditionally, β-carotene is obtained by solvent extraction from plants. The disadvantage of this process is that it requires high quantities of plants. For example, 2 g of α- and β-carotene requires 50 kg of carrots (70). Synthetically, the Grignard reaction or Wittig reaction is used as a key reaction for obtaining beta-carotene. In the first synthesis, two moles of C-19 aldehydes react with the Grignard reagent followed by dehydration and hydrogenation (71). The other synthesis uses the Wittig reaction of C-15 phosphonium salt and C-10 dialdehyde (71). Regarding the consumer demand for natural sources, β-carotene is also obtained from microorganisms such as the mold *B. trispora* and the algae *Dunaliella salina*. In the EU, assay values vary according to their sources: more than 96% for synthetic production, 5% for plant extraction. In the United States, regardless of its origin, raw material has to contain at least 96% total β-carotene.

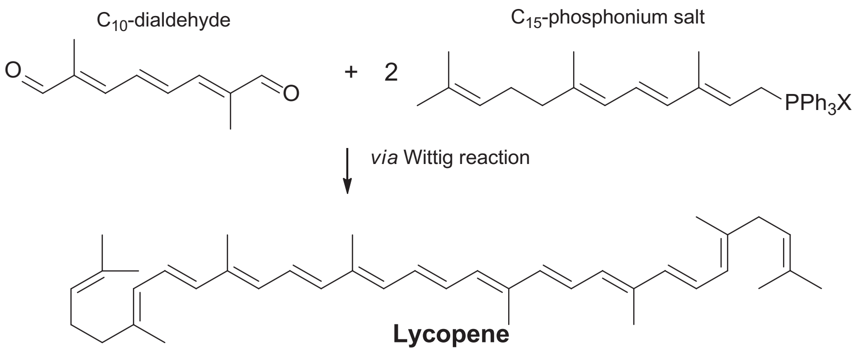


Figure 10. Synthesis of synthetic lycopene.
Adapted from Ernst et al. (67).

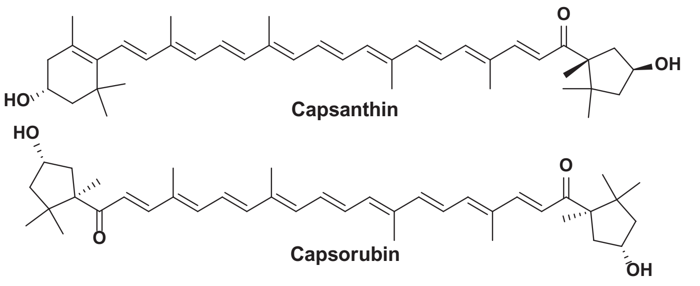


Figure 11. Structures of Capsanthin and Capsorubin.

Paprika Extract.

Paprika extract is a red colorant obtained from the solvent extraction of the dried pod of capsicum (*Capsicum annuum* L.). The carotenoid composition and content of the paprika extract can vary depending on the type of red pepper and geo-climatic conditions. The identified major coloring components of this major carotenoid are capsanthin and capsorubin (Figure 11).

In paprika extract, the pungent component, capsaicinoids, creates a serious limitation to its application (72). To use as paprika extracts as a colorant in cosmetics, they may undergo further purifications to remove the capsaicinoids. In the EU, the capsaicin concentration is limited to 0.025%.

Chlorophylls.

The greenness in plants is because of chlorophyll which is composed of pheophytin chelated with a magnesium ion. There are four types of chlorophylls: chlorophyll, chlorophyllin, and copper complexes of chlorophyll and chlorophyllin. Generally, chlorophylls can be extracted from green plants. Chlorophylls *a* and *b* are the two major types of this pigments, and they differ only in the functional groups [methyl (a) or aldehyde (b)] attached to the C-7 carbon (Figure 12) (56). Chlorophyllin is obtained through the saponification of chlorophyll. Saponification or alkaline hydrolysis produces a water-soluble compound by removing the phytyl and methyl ester groups. A copper complex of

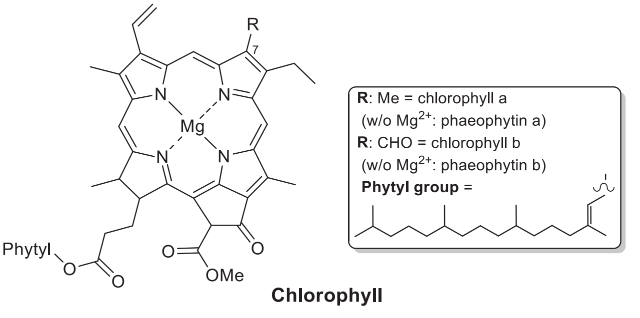


Figure 12. Structure of chlorophyll.

Table IX
Comparisons in Chlorophyll Characteristics

	Chlorophylls	Chlorophyllin	Chlorophyll-Cu complex	Chlorophyllin-Cu complex
Manufacturing process	Solvent extraction	Solvent extraction + saponification	Solvent extraction + addition of copper salts	Solvent extraction + saponification + addition of copper salts
Characteristics	· ester-phytol bond (lipid-soluble)	· product of saponification: → polarity↑ (water-soluble)	· ester-phytol bond (lipid-soluble)	· product of saponification: → polarity↑ (water-soluble)
Stability	Unstable		Stable	
Europe	Origin: edible plant material, grass, lucerne, nettle E 140 (i)	E 140 (ii)	E 141 (i)	E 141 (ii)
United States	Origin: dehydrated alfalfa · Not listed	· Not listed	· Not listed	§73.2125
Korea	Origin: green plants (e.g., Chlorella pyrenoidosa, spinach, comfrey, spirulina) 64. (1) Chlorophylls	· Not listed	64. (2) Chlorophyll-copper complex	64. (3) Chlorophyllin-copper complex

chlorophyll or chlorophyllin is obtained through the addition of copper ions to the plant extract or saponified plant extract.

The major cause of chlorophyll degradation is the loss of magnesium ions because of a change in pH (56,62,73,74). As magnesium is easily isolated from the chlorophyll structure, copper and zinc ions can replace the central magnesium ion. Copper is very effective for stabilizing the pheophytin and creates color consistency throughout the manufacturing process and storage (75). Therefore, copper chlorophyllin is the most commonly used colorant of the chlorophyll derivatives, and chlorophyll is rarely used because of its fragile nature. Copper chlorophyllin extracted from alfalfa is the only acceptable colorant made from chlorophyll derivatives in the United States (Table IX) (76).

The term "chlorophyllin" is not an accepted name. However, it has been used incorrectly by the food and cosmetic industry. Chlorophyllin contains a magnesium ion in its structure, so the term "copper-chlorophyll/chlorophyllin" is not adequate as copper replaces the central magnesium ion (75,77). Most importantly, the exact structure of the chlorophyllin-copper complex has not yet been elucidated fully. Copper chlorophyllin components differ in their origins, manufacturing processes, and storage conditions. The saponification process of chlorophyll is assumed to create diverse structures of copper chlorophyllins (e.g., Cu-chlorin e6, Cu-rhodin g7, Cu-chlorin e4, Cu-isochlorin e4, and Cu-chlorin P6; Figure 13). First, saponification hydrolyzes two ester groups to yield 13^2-carboxy pyropheophorbide *a*., and the β-ketoester of an isocyclic ring may be attacked again by the hydroxide ion to form Cu-chlorin e_6 (78–80). Oxidation at $C13^2$ or further decarboxylation has been attributed to the production of other copper chlorophyllin products (81,82). In the EU regulations, the Cu-chlorophyllin *a* is described as 13^2-carboxy pyropheophorbide *a*, although it has been reported as a minor product in copper chlorophyllin mixtures (75).

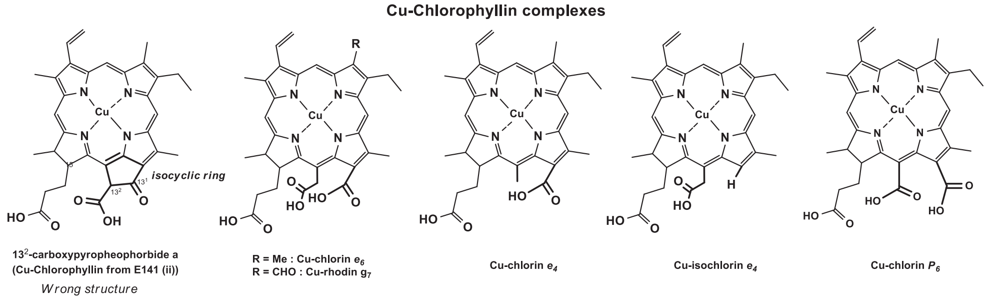


Figure 13. Possible structures of Cu-chlorophyllin complexes.

Carmines.

Carmine is a red colorant obtained by aqueous or alcoholic extraction from the dried bodies of the female cochineal insect (*Dactylopius coccus*). Three terms–cochineal, carminic acid, and carmines–are often used interchangeably. Strictly, a cochineal is the crude body of a cactus insect, carminic acid is the principal red colorant, and carmine is an aluminum lake of carminic acid (83). Carminic acid is an anthraquinone derivative possessing a *C*-glycoside (Figure 14). A C-glycosidic bond at C_7 offers stability against acid hydrolysis.

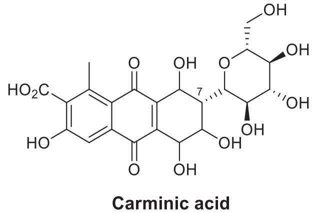


Figure 14. Structure of carminic acid.

According to the specification requirements for a carmine, the carminic acid content is required to be more than 50%. In the United States and Korea, cochineal extract is not permitted for use in cosmetics. Furthermore, carmines are required to be pasteurized or otherwise treated to destroy all viable salmonella microorganisms.

Compared to other natural colorants, carmines exhibit high stability against light, heat, and oxidation. For this reason, carmines have been extensively used in the cosmetic industry. However, numerous studies have reported allergic reactions to carmine colorants but not enough to harm the public (84). In addition, the use of insect bodies in cosmetics has been a controversial issue because it requires 80,000 to 100,000 insects to produce 1 kg of cochineal (56). Apart from the traditional manufacturing process using insects, alternatives such as microbial production are being developed (85).

Anthocyanins. Thousands of anthocyanins are found commonly in red-, purple-, and blue-colored vegetables and edible fruits (86). They consist of a sugar moiety and anthocyanidins (aglycone) from glycosylation (Figure 15). The sugar moiety includes glucose, rhamnose, xylose, galactose, arabinose, and fructose (87). According to the substituents (OH or OCH_3) in the B ring, there are six anthocyanidins used in the cosmetic and food colorants: cyanidin, delphinidin, pelargonidin, peonidin, malvidin, and petunidin (88).

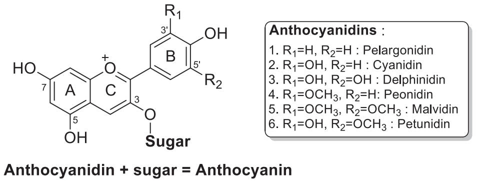


Figure 15. Structure of anthocyanin.

Anthocyanins are included on the colorant positive lists of the countries studied except in the United States. Only the EU has established specifications for anthocyanins. They clarify that the origin of anthocyanins should be vegetables and edible fruits. However, the sugar moiety of anthocyanins is not defined, but the permitted anthocyanidins are defined in the regulation.

Stability of anthocyanin is a major drawback of their use as a colorant. Temperature, pH, and light affect the color of anthocyanin. In a highly acidic aqueous solution, a flavylium cation that exhibits the typical red (or orange) color predominates. When the oxonium ion in the flavylium compound accepts the nucleophilic attack of water, the colorless form of carbinol, a pseudo-base, dominates (Figure 16 (1)) (56). Eventually, the ring-opened chalcone compounds are found in the basic solution. Moreover, a free hydroxyl group at position 7 or 4' in the flavylium cation facilitates a proton transfer to form blue quinoidal bases in weakly acidic or neutral solutions (Figure 16 (2)) (56). Additionally, the temperature influences anthocyanins' degradation. It was reported that the manufacturing and storage temperatures influence the pigment color (77). Storing the pigment at 4°C increases its half-life 8–10 months, which is six times longer than for storing it at room temperature (77,89). The mechanism of degradation from the heat is not fully elucidated. However, it has been suggested that the degradation starts with the hydrolytic opening of the pyrylium ring in the flavylium compound, which leads to chalcone (90).

There have been a number of studies on enhancing the stability of anthocyanin. The use of polymeric compounds (e.g., gum, pectin, and whey protein), phenolic compounds, and metallic ions have been shown to stabilize anthocyanins by forming molecular complexes (91).

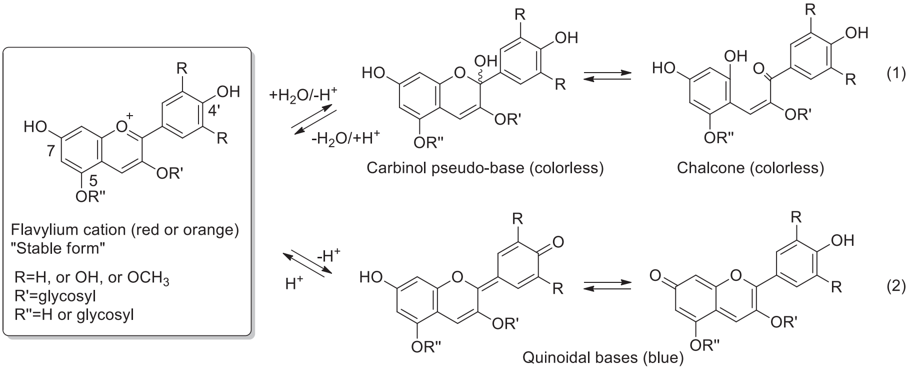


Figure 16. Structures of anthocyanins in aqueous solution.
Adapted from Delgado-Vargas et al. (56).

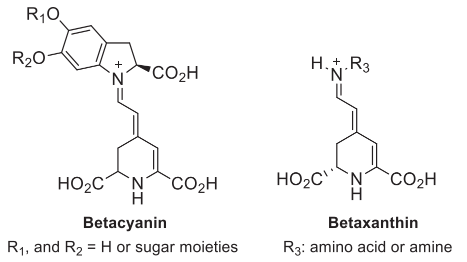


Figure 17. Structures of betalains.
Adapted from Rodriquez-Amaya et al. (92).

However, these stabilization methods were confine to particular cases (e.g., showing stability at a specific low pH or temperature) rather than general cases.

Beetroot Red.

Beetroot red is obtained from the roots of red beets (*Beta vulgaris*). Its coloring components are heterocyclic ring betalains consisting of betacyanins (red-purple) and betaxanthins (yellow) (Figure 17) (92). Betacyanins and betaxanthins are distinguished according to their chemical structure. The most well-known betacyanin is a betanin 9 that is a betanidin 5-O-β-glucoside (Figure 18). Beetroot red is obtained from the pressing of crushed beets or by aqueous or alcoholic extraction. Direct extraction includes a high-sugar content with a low betalain content. Consequently, the fermentation process may be included to reduce the sugar content and improve the color intensity (56).

Betanin is considered the main coloring component, and the raw material should contain more than 0.4% of betanin in the EU. In Korea, isobetanine and betanine are considered as the main coloring components and should contain more than the indicated content in raw materials. Two countries have set limits on nitrate which are high concentrated in beetroots.

Beetroot, like other natural colorants, is affected by several external factors: heat, pH, moisture, and metal ions (77,93). Hydrolysis–is known to be affected by several factors such as moisture, heat, and pH–is the most important factor affecting the color shift from red to yellow (77). Betanins (iminium ion) are readily hydrolyzed to betalamic acid (carbonyl compound) and *cyclo*-Dopa 5-O-β-glucoside (amine) to lose their color under the increased temperature and alkaline conditions (Figure 18) (92).

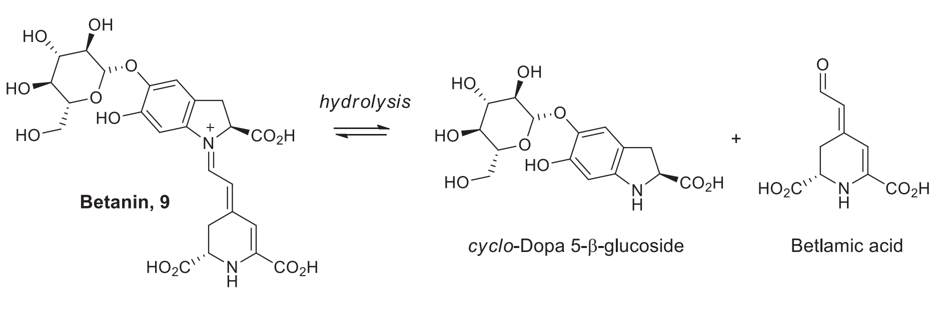


Figure 18. Hydrolysis of betanin.
Adapted from Rodriquez-Amaya et al. (92).

The fact that betanins are stable between pH 3 and 7 provides a strong advantage compared to anthocyanins (94). To protect betanins from external factors, encapsulation methods are being used. Maltodextrin and gum are used as encapsulating agents in freeze- or spray-drying techniques (95,96).

Curcumin.

Curcumin is obtained from the solvent extraction of turmeric (rhizomes of *Curcuma longa* L.). Curcumin produces bright yellow color close to Yellow No. 5. The major coloring components are curcumin, desmethoxy- and *bis*demethoxy curcumin (56). Curcumin consists of a mixture of tautomers: the enol form (more stable) and the keto form (Figure 19).

In the EU's specification, the content of curcumins should be more than 90%. To gain a concentrated content of curcumins, the extract may be purified further by crystallization. Residual solvents are limited in the EU and Korea. Curcumin has low water solubility; however, it dissolves in organic solvents such as acetone, methanol, and dichloromethane. It decomposes rapidly in alkaline solutions (pH > 7), although it shows stability in acidic conditions. In a previous report, 90% of curcumin decomposed within 30 min at pH 7.2 (98). The exact degradation mechanism has not been elucidated, however, curcumin is thought to degrade through an oxidation mechanism rather than hydrolysis (99). Moreover, curcumin has been found to decompose from visible light in both its solid and solution states. In a previous study, curcumin powder decomposed after exposure to sunlight for 120 h to colorless compounds: vanillin (34%), ferulic aldehyde, ferulic acid, and vanillic acid (0.5% each) (97). Again, to enhance curcumins' stability, encapsulation by freeze-drying and spray drying is the most used technique (100,101).

In summary, this report discussed colorants from natural origins that are included on the positive lists of cosmetic regulation. There is no widely accepted definition of natural colorants. The use of natural colorants has increased as the clean beauty trend has become more popular. Customers believe that compared to synthetic colorants, natural colorants have greater potential benefit to public health. However, the most important problem and main drawback of natural colorants are their instability issues. To overcome these limitations, the encapsulation technique using spray- or freeze-drying methods has been studied. Natural colorants are defined ambiguously and are relatively loosely regulated and studied compared to synthetic colorants. First, a correct definition of each natural colorant is required (e.g., Cu-chlorophyllin, anthocyanins). Second, permitted origins of

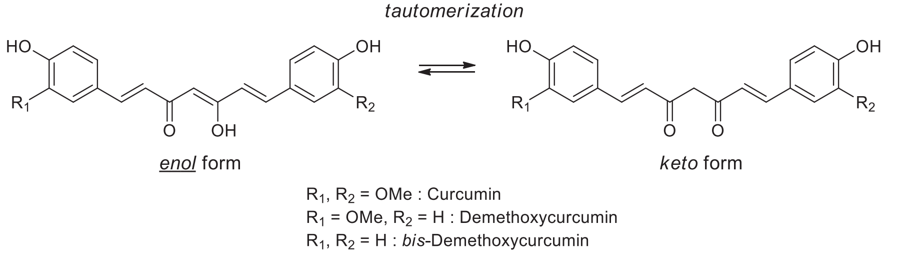


Figure 19. Tautomerization of curcumin.
Adapted from Jankun et al. (97) and Delgado-Vargas et al. (56).

raw materials and manufacturing processes need to be harmonized between countries. For example, chlorophylls should be obtained from alfalfa in the United States, and the permitted origin should be an edible plant in the European Union and a green plant in Korea. Third, restrictions on permitted extraction solvents and their residual solvent concentrations need to be harmonized in the specifications as well.

STANDARDIZATION CHALLENGES IN THE NOMENCLATURE OF SYNTHETIC COLORANTS

Each country has its own version of nomenclature for colorants. Confusion arises when labeling the salts or lakes of synthetic colorants. Here, we present the different labeling system developed by each country according to the rules of its nomenclature.

The list of official names for synthetic colorants are found in Regulation 21 CFR, Parts 74, and 82 for the United States and in Annex IV of Regulation (EC) No. 1223/2009 for the EU. Specifically, a CI number is used in the EU. This has a five- or six-digit number based on the chemical composition. In total, 34 categories of chemical groups have been identified (102). Among them, the nine categories shown in the Table X encompass the synthetic colorants used in cosmetics.

Some of the organic colorants have same dye and differ only in the metal used for salt formation. For example, Lithol Rubine B (CI 15850, D&C Red No. 6) is a sodium salt, and Lithol Rubine BCA (CI 15850, D&C Red No. 7) is a calcium salt. In the EU, these colorants with different metal ions for salt formation are not distinguished by the INCI name as they are assigned the same CI number (103). However, colorants with different metal ions are distinguished in their labeling in the United States and Korea (as discussed in the next section).

METAL SALT PIGMENTS

When sodium salt dye replaces a sodium cation in alkaline earth (e.g., calcium, strontium or barium) or transition metals (e.g., manganese), it leads to high insolubility, sometimes

Table X
CI Numbers Used in Synthetic Colorants by Chemical Group

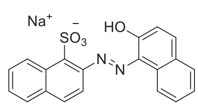
Chemical Group	CI Number
Nitroso	CI 10000–10299
Nitro	CI 10300–10999
Azo	CI 11000–19999 (mono) CI 20000–29999 (di)
Triarylmethane	CI 42000–44999
Xanthene	CI 45000–45999
Quinoline	CI 47000–47999
Anthraquinone	CI 58000–72999
Indigos	CI 73000–73999
Phthalocyanine	CI 74000–74999

Adapted from Society of Dyers and Colourists (102).

with different shades of colors (104). For this reason, the United States and Korea have assigned individual names to these colorants. Depending on each country's regulations, a particular salt form may not be permitted. Therefore, when a synthetic colorant is identified only by the CI number, it is necessary to confirm the metal ion of the dye. For instance, Lithol Reds (CI 15630) is known as the azo dye that has a different shade of red by the metal ion, from a yellowish red (sodium salt: Lithol Red) to a strong blue shade red (barium salt: Lithol Red BA; Figure 20) (104,105). If this colorant is imported from the EU to Korea, its labeling name is reassigned based on the metal ion: sodium salt for Red 205, barium salt for Red 207, calcium salt for Red 206, and strontium salt for Red 208. Lithol Rubine BCA (CI 15850), which is the calcium salt of Lithol Rubine B, is virtually insoluble in water, but Lithol Rubine B (sodium salt) has limited solubility in water. Another azo dye, Permanent Reds (CI 15865) is a red colorant ranging from bright orange (sodium salt: Permanent Red 2B) to bluish-red (calcium salt: Permanent Red F5R; Figure 20) (105). In Korea, only the calcium salt form, Red 405, is permitted. Triarylmethane dye has two salt forms: the blue sodium salt form Brilliant Blue FCF (CI 42090, FD&C Blue No. 1) and the greenish-blue ammonium salt form Alphazurine FG (CI 42090, FD&C Blue No. 4; Figure 20).

In addition, xanthene dyes that have different types of salt forms are distinguished by the nomenclature. Xanthene dyes are combined with alkali metal cations (e.g., sodium,

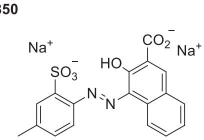
1) Azo dye : CI 15630



Red 205 (KR)

Salt Form (CI No; CAS RN)	Korea	US	EU, China
Na salt (CI 15630; 1248-18-6)	Red 205	Not listed	CI 15630
Ca salt (CI 15630:2; 1103-39-5)	Red 206		
Ba salt (CI 15630:1; 1103-38-4)	Red 207		
Sr salt (CI 15630:3; 6371-67-1)	Red 208		

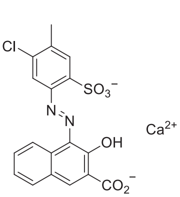
2) Azo dye : CI 15850



Red 6 (US)

Salt Form (CI No; CAS RN)	Korea	US	EU, China
Na salt (CI 15850; 5858-81-1)	Red 201	D&C Red No. 6	CI 15850
Ca salt (CI 15850:1; 5281-04-9)	Red 202	D&C Red No. 7	

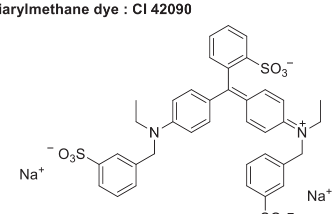
3) Azo dye : CI 15865



Red 405 (KR)

Salt Form (CI No; CAS RN)	Korea	US	EU, China
Na salt (CI 15865; 3564-21-4)	Not Approved	Not listed	CI 15865
Ca salt (CI 15865:2; 7023-61-2)	Red 405		

4) Triarylmethane dye : CI 42090



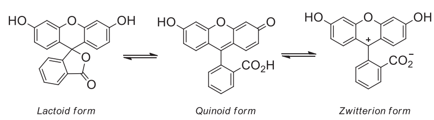
Blue 1 (US)

Salt Form (CI No; CAS RN)	Korea	US	EU, China
Na salt (CI 42090; 3844-45-9)	Blue 1	FD&C Blue No. 1	CI 42090
NH_4 salt (CI 42090; 2650-18-2)	Blue 205	D&C Blue No. 4	

Figure 20. Salt forms of azo and triarylmethane dyes.

Xanthene dyes :

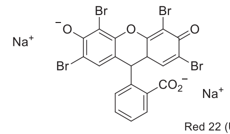
1) CI 45350



Yellow 7 (US), Yellow 201 (KR)

Salt Form (CI No; CAS RN)	**Korea**	**US**	**EU, China**
Fluorescein, Na salt (CI 45350; 518-47-8)	Yellow 202 (1)	D&C Yellow No. 8	CI 45350
Fluorescein, K salt (CI 45350; 6417-85-2)	Yellow 202 (2)	Not listed	
Fluorescein (CI 45350:1; 2321-07-5)	Yellow 201	D&C Yellow No. 7	

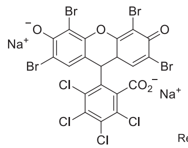
2) CI 45380



Red 22 (US), Red 103 (1) (KR)

Salt Form (CI No; CAS RN)	**Korea**	**US**	**EU, China**
Tetrabromofluorescein, Na salt (CI 45380; 17372-87-1)	Red 103 (1)	D&C Red No. 22	CI 45380
Tetrabromofluorescein (CI 45380:2; 15086-94-9)	Red 223	D&C Red No. 21	

3) CI 45410



Red 28 (US), Red 104(1) (KR)

Salt Form (CI No; CAS RN)	**Korea**	**US**	**EU, China**
fluorescein, Na salt (CI 45410; 18472-87-2)	Red 104 (1)	D&C Red No. 28	CI 45410
fluorescein, K salt (CI 45410; 75888-73-2)	Red 104 (2)	Not listed	
fluorescein (CI 45410:1; 13473-26-2)	Red 218	D&C Red No. 27	

Figure 21. Salt forms of xanthene dyes.

potassium) to make them more soluble in water. However, the insoluble pigments rendered after the addition of lead oxide or aluminum oxide to xanthene dye are not used as cosmetic pigments in the United States and Korea. Although salt forms of fluoresceins exist mainly in quinoid form, lactoid structures are still reported in the literature. However, fluoresceins (e.g., fluorescein, tetrabromofluorescein, and tetrachlorotetabromofluorescein) may exist in three tautomeric forms: lactoid, quinoid, and zwitterion (Figure 21).

LAKE PIGMENTS

There is no current agreement regarding a universal definition of lake pigments. It is liable to cause confusion with other pigments; toners and true pigments. In the organic pigments, there are three types of pigments: lake, toner, and true pigment (106). However, as these pigments are mostly used with a diluent, the term "lake" is often used in some countries or industries for all three pigments (106,107). Historically, although the term "lake" refers to dyes adsorbed on the substratum, the current usage of this term may refer to the insoluble metal salt pigments (34).

Numerous definitions exist for lake pigments depending on their industrial use. The definition of a lake pigment in the cosmetic industry is a water-insoluble pigment composed of a water-soluble straight color strongly adsorbed onto an insoluble substratum by a precipitant (108). The straight color is adsorbed onto the substratum by means of various interactions including ionic bonds, hydrogen bonds, and van der Waals forces (108). The overall process of lake pigment formation consists of three steps: substratum

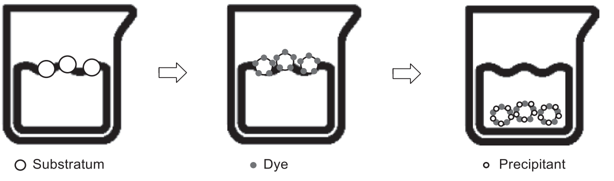


Figure 22. Preparation of lake pigments.

formation, dye adsorption, and dye precipitation. In more detail, a lake pigment is prepared by adding water-soluble dye into an aqueous slurry of inorganic substratum; then, it is precipitated with a metallic salt to make a lake pigment (Figure 22).

In the United States, lake pigments are named using a combination of the name of a dye and the cation of the precipitant. For instance, FD&C Yellow No. 5, which is precipitated with aluminum chloride, can be identified as FD&C Yellow No. 5 Aluminum Lake without the knowledge of what kind of substratum was used. From the name of the lake pigments, it is difficult to recognize what substratum was used. Previously, an alumina substratum was the only substratum used, so there was no need to put it into the nomenclature. Nowadays, substrata other than alumina–barium sulfate, and calcium carbonate–are used widely. Even though the substratum comprises of 56–89% of the lake pigment, it is difficult to notice which substratum was used with the current nomenclature (108). Although United States and China list lake pigments on product labels, the EU and Korea do not distinguish lake pigments from pure dyes on labels.

Toners are pigments made by replacing of sodium metals with metals of higher valence, such as barium and calcium, without using a substratum to achieve the desired high insolubility (104). A toner is distinguished from a lake pigment by the absence of a substratum. When a dye combines with higher valence metals to become a toner, it renders increased lightfastness, higher color strength, and modified shade (109). For example, a calcium cation substituted for the sodium ion in the pigments Deep Maroon (CI 15880, D&C Red No. 34) and Lithol Rubine BCA (CI 15850, D&C Red No. 7) are the most representative toner pigments.

True pigments are insoluble (water, oils, and other solvents) compounds that contain no salt-forming group (e.g., salt, acid, or lactone group) to promote their solubility (106). They have no metal ions or substrata. These pigments are known as the most stable organic pigments, although their existence is relatively rare (19,106). Helidone Pink CN (CI 73360, D&C Red No. 30) and Permaton Red (CI 12085, D&C Red No. 36) are true pigments.

Any certified colorants (toners or true pigments) mixed with a diluent are considered lake pigments in the United States (10,106,107). For instance, Japan does not permit lake pigment D&C Red No. 30 (CI 73360) to be used in cosmetics, but in the case of D&C Red No. 30 (CI 73360) being mixed with a diluent, it is regarded as a lake pigment in the United States, but a mixture produced by combining a true pigment and a diluent in Japan. Certain pigments like toners and true pigments can have different labels compared to those of the United States, based on its own regulations.

In summary, the use of a different type of metal salt results in different shades and solubility from pure dye colorants. It is essential to have a distinct nomenclature for colorants in which different cations are combined with pure dye. Moreover, a universal definition of a lake pigment is required for consistency in the cosmetic colorant labeling system between countries.

CONCLUSION

In this report, cosmetic colorants were categorized into three groups (synthetic, inorganic, and natural) and reviewed. It also presented an overview of the general properties of cosmetic colorants and a comparison of the differences in regulations between the EU, the United States, China, and Korea.

Narrowing regulatory system gaps between countries is a key challenge facing the cosmetic colorant industry. First, to ensure international consistency on safety and regulation, a positive list of cosmetic colorants should be harmonized between countries. Especially if one country has banned a colorant used in cosmetics but other countries still permit its use, it will cause confusion among consumers. Furthermore, the ingredients listed on the positive list should be identified by their INCI names. The ingredient list of natural colorants is somewhat vaguely identified compared to that of synthetic colorants. In addition, the naming of chemical compounds in the specifications should be written in exact chemical names rather than ambiguous terms (e.g., higher sulfonated subsidiary colors). Second, generally accepted uniform specifications, standards, and methods should be adopted. Although a cosmetic colorant is included on the positive list, it may have different structures because each country has set its own definition in its specification. The specification includes the definition, origin, manufacturing process, purity criteria, and so on. Additionally, it is recommended that the testing methods and procedures be harmonized to minimize the misinterpretation of test results. Lastly, natural colorants have presented stability concerns rather than safety issues before now. Rather than limiting the types of natural colorants and regulating their use, encouraging manufacturers to be responsible for ensuring the safety of their products could be an alternative approach.

This report ultimately aimed to provide a common understanding of cosmetic colorant regulations, and support manufacturers' trading of cosmetics around the world. National regulatory authorities and manufacturers in each country should continue to promote international regulatory collaboration to develop the harmonization of cosmetic colorants.

Appendix

List of colorants in cosmetic products

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
1		CI 10006			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
2	Naphthol Green B	CI 10020		Green 401	Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	§2. Green 401 (CI 10020) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
3	Naphthol Yellow S	CI 10316	Ext. Yellow 7	Yellow 403 (1)	Synthetic	· Not to be used in eye products	1-naphthol≤0.2%: 2,4-dinitro-1-naphthol≤ 0.3% · Not to be used in eye products	§74.2707a Ext. D&C Yellow No. 7 · Not to be used in eye and lip products	§18. Yellow 403 (1) (CI 10316) · Not to be used in eye and lip products
4	Hanza Yellow	CI 11680		Yellow 401	Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	§17. Yellow 401 (CI 11680) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
5		CI 11710			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
6	Orange no. 401	CI 11725		Orange 401	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§57. Orange 401 (CI 11725) · Not to be used in products applied on mucous membranes · Ba, Sr, Zr lake cannot be used
7		CI 11920			Synthetic	-	-	· Not listed	· Not listed
8		CI 12010			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed

Appendix
(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
9	Permaton Red	CI 12085	Red 36	Red 228	Synthetic	· 3%	· 3 % · 2-chloro-4-nitrobenzenamine ≤ 0.3%; 2-naphthalenol≤ 1%; 2,4-dinitrobenzenamine≤ 0.02%; 1-[(2,4-dinitrophenyl) azo]-2-naphthaleno l≤ 0.5%; 4-[(2-chloro-4-nitrophenyl) azo]-1-naphth alenol ≤ 0.5%; 1-[(4-nitrophenyl) azo]-2-naphthalenol≤ 0.3%; 1-[(4-chloro-2-nitrophenyl)azo]-2-naphthalenol)≤ 0.3%	§74.2336 D&C Red No. 36 · Not to be used in eye products · Lipstick products 3%	§39. Red 228 (CI 12085) · 3%
10	Toluidine Red	CI 12120		Red 221	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§52. Red 221 (CI 12120) · Wash-off products · Ba, Sr, Zr lake cannot be used
11		CI 12370			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
12		CI 12420			Synthetic	· Rinse-off products	· Maximum 4-chloro-o-toluidine concentration in the coloring agent: 5mg/kg · Rinse-off products	· Not listed	· Not listed
13		CI 12480			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
14	Pigment Red 5	CI 12490		Pigment Red 5	Synthetic	-	-	· Not listed	· Not listed
15		CI 12700			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
16		CI 13015			Synthetic	-	-	· Not listed	· Not listed
17		CI 14270			Synthetic	-	-	· Not listed	· Not listed

Appendix
(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
18	Ponceau SX	CI 14700	Red 4	Red 504	Synthetic	-	5-amino-2,4-dimethyl-1-benzenesulfonic acid and its sodium salt≤ 0.2%: 4-hydroxy-1-naphthalenesulfonic acid and its sodium salt≤ 0.2%	§74.2304 FD&C Red No. 4 · Not to be used in eye and lip products	§13. Red 504 (CI 14700) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
19		CI 14720			Synthetic	§E 122 AZORUBINE, CARMOISINE	the total quantity of 4-aminonaphthalene-1-sulfonic acid and 4-hydroxynaphthalene-1-sulfonic acid≤ 0.5%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	· Not listed
20		CI 14815			Synthetic	-	-	· Not listed	· Not listed
21	Orange II	CI 15510	Orange 4	Orange 205	Synthetic	· Not to be used in eye products	2-naphthol ≤ 0.4%; sulfanilic acid, sodium salt ≤ 0.2%; 4,4'-(Diazoamino)-dibenzenesulfonicacid ≤ 0.1% · Not to be used in eye products	§74.2254 D&C Orange No. 4 · Not to be used in eye and lip products	§19. Orange 205 (CI 15510) · Not to be used in eye products
22		CI 15525			Synthetic	-	-	· Not listed	· Not listed
23		CI 15580			Synthetic	-	-	· Not listed	· Not listed
24	Fast Red S	CI 15620		Red 506	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§ 54. Red 506 (CI 15620) · Wash-off products · Ba, Sr, Zr lake cannot be used
25	Lithol Red	CI 15630 (Na salt)		Red 205	Synthetic	· 3%	· 3%	· Not listed	§6. Red 205 (CI 15630) · 3% · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
26	Lithol Red BA	CI 15630 CI 15630:1 (Ba salt)		Red 207	Synthetic	· 3%	· 3%	· Not listed	§8. Red 207(CI 15630:1) · 3% · Not to be used in eye and lip products

Appendix
(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
27	Lithol Red CA	CI 15630 CI 15630:2 (Ca salt)		Red 206	Synthetic	· 3%	· 3%	· Not listed	§7. Red 206 (CI 15630:2) · 3% · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
28	Lithol Red SR	CI 15630 CI 15630:3 (Sr salt)		Red 208	Synthetic	· 3%	· 3%	· Not listed	§9. Red 208 (CI 15630:3) · 3% · Not to be used in eye and lip products
29	Brilliant Lake Red R	CI 15800	Red 31	Red 219	Synthetic	· Not to be used in products applied on mucous membranes	Aniline ≤ 0.2%; 3-hydroxy-2-naphthoic acid, calcium salt ≤ 0.4% · Not to be used in products applied on mucous membranes	§74.2331 D&C Red No. 31 · Not to be used in eye and lip products	§10. Red 219 (CI 15800) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
30	Lithol Rubine B	CI 15850 (Na salt)	Red 6	Red 201	Synthetic	§E 180 LITHOLRUBINE BK	2-amino-5-methylbenzensulfonic acid, calcium salt ≤ 0.2%; 3-hydroxy-2-naphthalene carboxylic acid, calcium salt≤ 0.4%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	§74.2306 D&C Red No. 6 · Not to be used in eye products	§32. Red 201 (CI 15850)
31	Lithol Rubine BCA	CI 15850 CI 15850:1 (Ca salt)	Red 7	Red 202	Synthetic	§E 180 LITHOLRUBINE BK	2-amino-5-methylbenzensulfonic acid, calcium salt ≤ 0.2%; 3-Hydroxy-2-naphthalene carboxylic acid, calcium salt≤ 0.4%; unsulfonated primary aromatic amines(calculated as aniline) ≤ 0.01%	§74.2307 D&C Red No. 7 · Not to be used in eye products	§33. Red 202 (CI 15850:1)
32		CI 15865 (Na salt)			Synthetic	—	—	· Not listed	· Not listed
33	Permanent Red F5R	CI 15865 CI 15865:2 (Ca salt)		Red 405	Synthetic	—	—	· Not listed	§12. Red 405 (CI 15865:2) · Not to be used in eye and lip products

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
34	Deep Maroon	CI 15880 CI 15880:1 (Ca salt)	Red 34	Red 220	Synthetic	-	2-amino-1- naphthalenesulfonic acid, calcium salt≤ 0.2%; 3-hydroxy-2-naphthoic acid≤ 0.4%	§74.2334 D&C Red No. 34 · Not to be used in eye and lip products	§35. Red 220 (CI 15880:1) · Ba, Sr, Zr lake cannot be used
35		CI 15980			Synthetic	-	-	· Not listed	· Not listed
36	Sunset Yellow FCF	CI 15985	Yellow 6	Yellow 5	Synthetic	§E 110 SUNSET YELLOW FCF	the total quantity of 4-aminobenzene-1-sulfonic acid, 3-hydroxynaphthalene-2,7-disulfonicacid, 6-hydroxynaphthalene-2-sulfonicacid, 7-hydroxynaphthalene-1,3-disulfonicacid and 4,4'-diazoaminodi (benezenesulfonic acid) ≤ 0.5%; 6,6'-oxydi(2-naphthalene sulfonic acid) disodium salt) ≤ 1.0%; unsulfonated primary aromatic amines(calculated as aniline) ≤ 0.01%	§74.2706 FD&C Yellow No. 6 · Not to be used in eye products	§ 47. Yellow 5 (CI 15985)
37	Allura Red AC	CI 16035	Red 40	Red 40	Synthetic	§E 129 ALLURA RED AC	6-hydroxy-2-naphthalene sulfonic acid,sodium salt ≤0.3%; 4-amino-5-methoxy-2-methylbenezenesulfonic acid≤ 0.2%; 6,6'-oxydi (2-naphthalene sulfonicacid) disodium salt ≤1.0%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	§74.2340 FD&C Red No. 40 · Also Al lake (eye area)	§ 27. Red 40 (CI 16035)

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
38	Amaranth	CI 16185		Red 2	Synthetic	§E 123 AMARANTH	the total quantity of 4-aminonaphthalene-1-sulfonic acid, 3-hydroxynaphthalene-2,7-disulfonicacid, 6-hydroxynaphthalene-2-sulfonicacid, 7-hydroxynaphthalene-1,3-disulfonicacid and 7-hydroxy naphthalene-1,3,6-trisulfonic acid ≤ 0.5%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	§ 26. Red 2 (CI 16185)
39		CI 16230			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
40	New Coccine (Ponceau 4R)	CI 16255		Red 102	Synthetic	§E 124 PONCEAU 4R, COCHINEAL RED A	the total quantity of 4-aminonaphthalene-1-sulfonic acid, 3-hydroxynaphthalene-2,7-disulfonic acid, 6-hydroxynaphthalene-2-sulfonic acid, 7-hydroxynaphthalene-1,3-disulfonicacid and 7-hydroxynaphthalene-1,3,6-trisulfonic acid ≤ 0.5%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	§28. Red 102 (CI 16255)
41		CI 16290			Synthetic	-	-	· Not listed	· Not listed

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
42	Fast Acid Magenta	CI 17200	Red 33	Red 227	Synthetic	-	4-amino-5-hydroxy-2,7-naphthalenedisulfonic acid, disodium salt ≤ 0.3%; 4,5-dihydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt ≤ 3%; aniline ≤ 25mg/kg; 4-aminoazobenzene ≤100μg/kg; 1,3-diphenyltriazene≤ 125μg/kg; 4-aminobiphenyl≤ 275μg/kg; Azobenzene ≤ 1mg/kg; Benzidine ≤ 20μg/kg	§74.2333 D&C Red No. 33 · Not to be used in eye products · Lipstick products 3%; mouthwash, dentrifices	§38. Red 227 (CI 17200) · Lipsticks 3% · Ba, Sr, Zr lake cannot be used
43		CI 18050			Synthetic	· Not to be used in products applied on mucous membranes	the total quantity of 5-acetamido-4-hydroxynaphthalene-2,7-disulfonic acid and 5-amino-4-hydroxynaphthalene-2,7-disulfonic acid≤ 0.5%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01% · Not to be used in products applied on mucous membranes	· Not listed	· Not listed
44		CI 18130			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
45		CI 18690			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
46		CI 18736			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
47	Fast light Yellow 3G	CI 18820		Yellow 407	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§55. Yellow 407 (CI 18820) · Wash-off products · Ba, Sr, Zr lake cannot be used
48		CI 18965			Synthetic	-	-	· Not listed	· Not listed

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
49	Tartrazine	CI 19140	Yellow 5	Yellow 4	Synthetic	§E 102 TARTRAZINE	· The total quantity of 4-hydrazinobenzenesulfonic acid, 4-aminobenzene-1-sulfonic acid, 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid, 4,4'-diazoaminodi (benzene sulfonic acid) and tetrahydroxy succinic acid ≤ 0.5%; unsulfonated primary aromaticamines (calculated as aniline) ≤ 0.01%	§74.2705 FD&C Yellow No. 5 · Also Al lake (eye area)	§46. Yellow 4 (CI 19140)
50		CI 20040			Synthetic	Maximum 3,3'-dimethyl benzidine concentration in the coloring agent: 5 ppm · Rinse-off products	· Maximum 3,3›-dimethyl-benzidine concentration in the coloring agent: 5mg/kg · Rinse-off products	· Not listed	· Not listed
51		CI 20170	Brown 1		Synthetic	· Not listed	· Not listed	§74.2151 D&C Brown No. 1 · Not to be used in eye and lip products	· Not listed
52	Naphthol Blue Black	CI 20470		Black 401	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§56. Black 401 (CI 20470) · Wash-off products · Ba, Sr, Zr lake cannot be used
53		CI 21100		Orange 204	Synthetic	· Maximum 3,3›-dimethylbenzidine concentration in the coloring agent: 5 ppm · Rinse-off products	· Maximum 3,3-dimethyl-benzidine concentration in the coloring agent: 5mg/kg · Rinse-off products	· Not listed	§50. Orange 204 (CI 21100) · Wash-off products · Ba, Sr, Zr lake cannot be used
54		CI 21108			Synthetic	· Maximum 3,3›-dimethylbenzidine concentration in the coloring agent: 5 ppm · Rinse-off products	· Maximum 3,3-dimethyl-benzidine concentration in the coloring agent: 5mg/kg · Rinse-off products	· Not listed	· Not listed

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
55		CI 21230			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
56		CI 24790			Synthetic	· Rinse-off products Purity criteria: aniline ≤ 0,2 % 2-naphtol ≤ 0,2 % 4-aminoazobenzene ≤ 0,1 % 1-(phenylazo)-2-naphtol ≤ 3 % 1-[2-(phenylazo) phenylazo]- 2-napthalenol ≤ 2 % · Not to be used in products applied on mucous membranes	· Rinse-off products	· Not listed	· Not listed
57	Sudan III	CI 26100	Red 17	Red 225	Synthetic		· Not listed	§74.2317 D&C Red No. 17 · Not to be used in eye and lip products	§11. Red 225 (CI 26100) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
58		CI 27755			Synthetic	-	-	· Not listed	· Not listed
59		CI 28440			Synthetic	§E 151 BRILLIANT BLACK BN, BLACK PN	The total quantity of 4-acetamido-5-hydroxynaphthalene-1,7-disulfonic acid, 4-amino-5- hydroxy naphthalene-1,7-disulfonic acid, 8-aminonaphthalene-2-sulfonic acid and 4,4'-diazoaminodi-(benzenesulfonic acid) ≤ 0.8%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	· Not listed
60		CI 40215			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
61		CI 40820			Synthetic	§E 160 e BETA-APO-8′-CAROTENAL (C30)	-	· Not listed	· Not listed
62		CI 40825			Synthetic	-	-	· Not listed	· Not listed
63		CI 40850			Synthetic	§E 161g CANTHAXANTHIN	-	· Not listed	· Not listed

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
[illegible]		CI 42045			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
[illegible]		CI 42051			Synthetic	§E 131 PATENT BLUE V	· The total quantity of 3-hydroxy benzaldehyde, 3-hydroxy benzoic acid, 3-hydroxy-4-sulfobenzoic acid and N,N-diethylamino benzenesulfonic acid ≤ 0.5%; Leuco base ≤ 4.0%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	· Not listed
66	Fast Green FCF	CI 42053	Green 3	Green 3	Synthetic	-	· Leuco base ≤ 5%; the total quantity of 2-,3-,4-formylbenzenesulfonic acids and their sodium salts ≤ 0.5%; the total quantity of 3- and 4-[(ethyl(4-sulfophenyl) amino)methyl] benzenesulfonic acid and its disodium salts ≤ 0.3%; 2-formyl-5-hydroxybenzenesulfonic acid and its sodium salt ≤ 0.5%	§74.2203 FD&C Green No. 3 · Not to be used in eye products	§21. Green 3 (CI 42053)
67		CI 42080			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
68	Brilliant Blue FCF	CI 42090 (Na Salt)	Blue 1	Blue 1	Synthetic	§E 133 BRILLIANT BLUE FCF	· The total quantity of 2-,3- and 4-formyl benzene sulfonic acids ≤ 1.5%; 3-(ethyl(4-sulfophenyl) amino) methyl benzene sulfonic acid) ≤ 0.3%; leuco base ≤ 5.0%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	§74.2101 FD&C Blue No. 1 · Also Al lake (eye area)	§41. Blue 1 (CI 42090)

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
69	Alphazurine FG	CI 42090 (ammonium salt)	Blue 4	Blue 205	Synthetic	§E 133 BRILLIANT BLUE FCF	· The total quantity of 2-,3- and 4-formyl benzene sulfonic acids ≤ 1.5%; 3-(ethyl(4-sulfophenyl) amino) methyl benzene sulfonic acid) ≤ 0.3%; leuco base ≤ 5.0%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	§74.2104 D&C Blue No. 4 · Not to be used in eye and lip prodcuts	§45. Blue 205 (CI 42090) · Ba, Sr, Zr lake cannot be used
70		CI 42100			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
71		CI 42170			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
72		CI 42510			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
73		CI 42520			Synthetic	· 5ppm · Rinse-off products	· 5mg/kg · Rinse-off products	· Not listed	· Not listed
74		CI 42735			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
75	Solvent blues 4	CI 44045			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
76		CI 44090			Synthetic	§E 142 GREEN S	· 4,4'-bis(dimethylamino) benzhydryl alcohol ≤ 0.1%; 4,4'-bis(dimethylamino) benzophenone ≤ 0.1%; 3-hydroxynaphthalene-2,7-disulfonic acid) ≤ 0.2%; leuco base ≤ 5.0%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	· Not listed
77	Acid red	CI 45100		Red 106	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§51. Red 106 (CI 45100) · Wash-off products · Ba, Sr, Zr lake cannot be used

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
78	Violamine R	CI 45190		Red 401	Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	§53. Red 401 (CI 45190) · Wash-off products
79		CI 45220			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
80	Uranine	CI 45350 (Na salt)	Yellow 8	Yellow 202 (1)	Synthetic	· 6%	· 6% · Resorcinol ≤ 0.5%; phthalic acid≤ 1%; 2-(2,4-dihydroxybenzoyl) benzoic acid ≤ 0.5%	§74.2708 D&C Yellow No. 8 · Not to be used in eye and lip products	§49. Yellow 202 (1)(CI 45350) · 6% · Ba, Sr, Zr lake cannot be used
81	Uranine K	CI 45350 (K salt)		Yellow 202 (2)	Synthetic	· 6%	· 6% · Resorcinol ≤ 0.5%; phthalic acid ≤ 1%; 2-(2,4-dihydroxybenzoyl) benzoic acid ≤ 0.5%	· Not listed	§15. Yellow 202 (2)(CI 45350) · 6% · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
82	Fluorescein	CI 45350 CI 45350:1	Yellow7	Yellow 201	Synthetic	· 6%	· 6% · Resorcinol ≤ 0.5%; phthalic acid≤ 1%; 2-(2,4-dihydroxybenzoyl) benzoic acid ≤ 0.5%	§74.2707 D&C Yellow No. 7 · Not to be used in eye and lip products	§48. Yellow 201 (CI 45350:1) · 6% · Ba, Sr, Zr lake cannot be used
83	Dibromofluorescein	CI 45370 CI 45370:1	Orange 5	Orange 201	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H-xanthen- 9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)ben zoic acid)≤ 1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid) ≤ 2%	§74.2255 D&C Orange No. 5 · Not to be used in eye products · Mouthwashes, dentifrices; Lipsticks 5%	§24. Orange 201 (CI 45370:1) · Not to be used in eye products
84	Eosine YS	CI 45380 (Na salt)	Red 22	Red 103 (1)	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H-xanthen- 9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)ben zoic acid)≤ 1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid) ≤ 2%	§74.2322 D&C Red No. 22 · Not to be used in eye products	§29. Red 103 (1)(CI 45380) · Not to be used in eye products

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
85	Tetrabromofluorescein	CI 45380 CI 45380:2	Red 21	Red 223	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H-xanthen- 9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)ben zoic acid)≤ 1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid)≤ 2%	§74.2321 D&C Red No. 21 · Not to be used in eye products	§36. Red 223 (CI 45380:2) · Not to be used in eye products
86	Eosin(e) YSK	CI 45380 (K salt)		Red 230 (2)	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H-xanthen- 9-y1) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)ben zoic acid) ≤ 1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid) ≤ 2%	· Not listed	§40. Red 230 (2)(CI 45380)
87		CI 45396			Synthetic	· 1 %, when used in lip products Only in free acid form, when used in lip products	· 1 %, when used in lipstick, the coloring agent is allowed only in free acid form	· Not listed	· Not listed
88		CI 45405			Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H xanthen- 9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid · Not to be used in eye products	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)ben zoic acid≤ 1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid≤ 2% · Not to be used in eye products	· Not listed	· Not listed
89	Tetrachlorotetrabro-mofluorescein	CI 45410 CI 45410:1	Red 27	Red 218	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H xanthen- 9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid ≤1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid ≤ 2%	§74.2327 D&C Red No. 27 · Not to be used in eye products	§34. Red 218 (CI 45410:1) · Not to be used in eye products

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
90	Phloxine B	CI 45410 (Na salt)	Red 28	Red 104 (1)	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H xanthen- 9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid≤1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl)benzoic acid≤ 2%	§74.2328 D&C Red No. 28 · Not to be used in eye products	§30. Red 104 (1)(CI 45410) · Not to be used in eye products
91	Phloxine BK	CI 45410 (K salt)		Red 104 (2)	Synthetic	· Not more than 1 % 2-(6- hydroxy-3-oxo-3H xanthen- 9-yl) benzoic acid and 2 % 2-(bromo-6-hydroxy-3-oxo- 3H-xanthen-9-yl) benzoic acid	· 2-(6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid≤1%; 2-(bromo-6-hydroxy-3-oxo-3H-xanthen-9-yl) benzoic acid≤ 2%	· Not listed	§31. Red 104 (2) (CI 45410) · Not to be used in eye products
92	Diiodofluorescein	CI 45425 CI 45425:1	Orange 10	Orange 206	Synthetic	· Not listed	· Triiodoresorcinol≤ 0.2%; 2-(2,4-dihydroxy-3,5-dioxobenzoyl) benzoic acid ≤ 0.2%	§74.2260 D&C Orange No. 10 · Not to be used in eye and lip products	§3. Orange 206 (CI 45425:1) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
93	Erythrosine Yellowish NA	CI 45425 (Na salt)	Orange 11	Orange 207	Synthetic	· Not listed	· Triiodoresorcinol ≤ 0.2%; 2-(2,4-dihydroxy-3,5-dioxobenzoyl) benzoic acid≤ 0.2%	§74.2261 D&C Orange No. 11 · Not to be used in eye and lip products	§4. Orange 207 (CI 45425) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
94		CI 45430			Synthetic	§E 127 ERYTHROSINE	· Triiodoresorcinol ≤ 0.2%; 2-(2,4-dihydroxy-3,5-dioxobenzoyl) benzoic acid≤ 0.2%	· Not listed	· Not listed

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No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
95	Quinoline Yellow SS	CI 47000	Yellow 11	Yellow 204	Synthetic	· Not to be used in products applied on mucous membranes	Phthalic acid≤ 0.3%; 2-methylquinoline ≤ 0.2% · Not to be used in products applied on mucous membranes	§74.2711 D&C Yellow No. 11 · Not to be used in eye and lip products	§16. Yellow 204 (CI 47000) Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
96	Quinoline Yellow WS	CI 47005	Yellow 10	Yellow 203	Synthetic	§E 104 QUINOLINE YELLOW	· The total quantity of 2-methylquinoline, 2-methylquinoline sulfonic acid, phthalic acid, 2,6-dimethyl quinoline and 2,6-dimethyl quinoline sulfonic acid ≤ 0.5%; 2-(2-quinolyl)indan -1,3-dione ≤ 4 mg/kg; unsulfonated primary aromatic amines(calculated as aniline) ≤ 0.01%	§74.2710 D&C Yellow No. 10 · Not to be used in eye products	§20. Yellow 203 (CI 47005) · Not to be used in eye products
97		CI 50325			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
98		CI 50420			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
99	Pigment Violet 23	CI 51319			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
100		CI 58000			Synthetic	-	-	· Not listed	· Not listed
101	Pyranine Conc	CI 59040	Green 8	Green 204	Synthetic	· Not to be used in products applied on mucous membranes	· Trisodium salt of 1,3,6-pyrene trisulfonic acid ≤ 6%; Tetrasodium salt of 1,3,6,8-pyrene tetrasulfonic acid ≤ 1%; pyrene ≤ 0.2% · Not to be used in products applied on mucous membranes	§74.2208 D&C Green No. 8 · 0.01% · Not to be used in eye and lip products	§1. Green 204 (CI 59040) · 0.01% · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
102		CI 60724			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
103	Alizurine Purple SS	CI 60725	Violet 2	Violet 201	Synthetic	-	· p-Toluidine≤ 0.2%; 1-hydroxy-9,10- anthracenedione≤ 0.5%; 1,4-dihydroxy-9,10-anthracenedione ≤ 0.5%	§74.2602 D&C Violet No. 2 · Not to be used in eye and lip products	§25. Violet 201 (CI 60725) · Ba, Sr, Zr lake cannot be used

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
104	Alizurol Purple	CI 60730	Ext. Violet 2	Violet 401	Synthetic	· Not to be used in products applied on mucous membranes	· 1-Hydroxy-9,10-anthracenedione ≤ 0.2%; 1,4-dihydroxy-9,10-anthracenedione ≤ 0.2%; p-toluidine ≤ 0.1%; p-toluidine sulfonic acids, sodium salts ≤ 0.2% · Not to be used in products applied on mucous membranes	§74.2602a Ext. D&C Violet No. 2. · Not to be used in eye and lip products	§5. Violet 401 (CI 60730) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
105	Quinizarine Green SS	CI 61565	Green 6	Green 202	Synthetic	-	· p-toluidine ≤ 0.1%; 1,4-dihydroxyanthraquinone≤ 0.2%; 1-hydroxy-4-[(4-methyl phenyl)amino]-9,10-anthracenedione≤ 5%	§74.2206 D&C Green No. 6 · Not to be used in eye and lip products	§23. Green 202 (CI 61565) · Ba, Sr, Zr lake cannot be used
106	Alizarine Cyanine Green F	CI 61570	Green 5	Green 201	Synthetic	-	· 1,4-dihydroxy anthraquinone ≤ 0.2%; 2-amino-m-toluene sulfonic acid ≤ 0.2%	§74.2205 D&C Green No. 5	§22. Green 201 (CI 61570) · Ba, Sr, Zr lake cannot be used
107		CI 61585			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
108		CI 62045			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
109		CI 69800			Synthetic	-	-	· Not listed	· Not listed
110	Carbanthrene Blue	CI 69825		Blue 204	Synthetic	-	-	· Not listed	§44. Blue 204 (CI 69825) · Ba, Sr, Zr lake cannot be used
111		CI 71105			Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
112	Indigo	CI 73000		Blue 201	Synthetic	-	-	· Not listed	§43. Blue 201 (CI 73000) · Ba, Sr, Zr lake cannot be used

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
113	Indigo Carmine	CI 73015		Blue 2	Synthetic	§E 132 INDIGOTINE, INDIGO CARMINE	· The total quantity of Isatin-5-sulfonic acid, 5-Sulfoanthranilic acid and anthranilic acid ≤ 0.5%; unsulfonated primary aromatic amines (calculated as aniline) ≤ 0.01%	· Not listed	§42. Blue 2 (CI 73015)
114	Helindone Pink CN	CI 73360	Red 30	Red 226	Synthetic	-	-	§74.2330 D&C Red No. 30 · Not to be used in eye products	§37. Red 226 (CI 73360) · Ba, Sr, Zr lake cannot be used
115		CI 73385			Synthetic	-	-	· Not listed	· Not listed
116		CI 73900			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
117		CI 73915			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
118		CI 74100			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
119	Phthalocyanine Blue	CI 74160		Blue 404	Synthetic	-	-	· Not listed	§14. Blue 404 (CI 74160) · Not to be used in eye and lip products · Ba, Sr, Zr lake cannot be used
120		CI 74180			Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
121	Pigment Green 7	CI 74260			Synthetic	· Not to be used in eye products	· Not to be used in eye products	· Not listed	· Not listed
122		CI 75100			Synthetic	-	-	· Not listed	· Not listed
123	Annatto	CI 75120	Annatto	Annatto	Natural	§E 160b ANNATTO, BIXIN, NORBIXIN	-	§73.2030 Annatto	§58. Annatto (CI 75120)
124	Lycopene	CI 75125		Lycopene	Natural	§E 160d LYCOPENE	-	· Not listed	§59. Lycopene (CI 75125)
125	Beta-Carotene	CI 75130 (or CI 40800)	Beta-Carotene	Beta-Carotene	Natural	§E 160 a (i) BETA-CAROTENE (ii) PLANT CAROTENES (iii) BETA-CAROTENE FROM Blakeslea trispora (iv) ALGAL CAROTENES	-	§73.2095 Beta-Carotene	§60. Beta-Carotene(CI 75130)
126		CI 75135			Natural	-	-	· Not listed	· Not listed

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
127	Guanine	CI 75170	Guanine	Guanine	Natural	-	-	§73.2329 Guanine	§61. Guanine (CI 75170)
128	Curcumin	CI 75300		Curcumin	Natural	§E 100 CURCUMIN	-	· Not listed	§62. Curcumin (CI 75300)
129	Carmine	CI 75470	Carmine	Carmine	Natural	§E 120 COCHINEAL, CARMINIC ACID, CARMINES	-	§73.2087 Carmine	§63. Carmines (CI 75470)
130	Chlorophylls	CI 75810	Chlorophyllin-Copper Complex or Potassium sodium copper chlorophyllin	Chlorophylls or Copper Chlorophyll or Chlorophyllin-Copper Complex	Natural	§E 140 (i) CHLOROPHYLLS (ii) CHLOROPHYLLINS §E 141 (i) COPPER COMPLEXES OF CHLOROPHYLLS (ii) COPPER COMPLEXES OF CHLOROPHYLLINS	-	§73.2125 Potassium sodium copper chlorophyllin · Not to be used in eye and lip products · Dentifrices; ≤ 0.1%	§64. Chlorophylls (CI 75810)
131	Aluminum	CI 77000	Aluminum Powder	Aluminum	Inorganic	§E 173 ALUMINIUM	-	§73.2645 Aluminum powder · Not to be used in lip products	§65. Aluminum (CI 77000)
132		CI 77002			Inorganic	-	-	· Not listed	· Not listed
133	Bentonite	CI 77004		Bentonite	Inorganic	-	-	· Not listed	§66. Bentonite (CI 77004)
134	Ultramarines	CI 77007	Ultramarines	Ultramarines	Inorganic	-	-	§73.2725 Ultramarines · Not to be used in lip products	§67. Ultramarines (CI 77007)
135		CI 77015			Inorganic	-	-	· Not listed	· Not listed
136	Mica	CI 77019	Mica	Mica	Inorganic	· Not listed	-	§73.2496 Mica	§101. Mica
137	Barium Sulfate	CI 77120		Barium Sulfate	Inorganic	-	-	· Not listed	§68. Barium sulfate (CI 77120)
138	Bismuth Oxychloride	CI 77163	Bismuth Oxychloride	Bismuth Oxychloride	Inorganic	-	-	§73.2162 Bismuth Oxychloride	§69. Bismuth oxychloride (CI 77163)
139	Calcium Carbonate	CI 77220		Calcium Carbonate	Inorganic	§E 170 CALCIUM CARBONATE	-	· Not listed	§70. Calcium carbonate (CI 77220)

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
140	Calcium Sulfate	CI 77231		Calcium Sulfate	Inorganic	-	-	· Not listed	§71. Calcium sulfate (CI 77231)
141	Carbon Black	CI 77266	Black 2	Carbon Black	Inorganic	· Purity > 97 %, with the following impurity profile: Ash content ≤ 0,15 %, total sulfur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a) pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, total Hg ≤ 1 ppm.	· Limit for polycyclic aromatic hydrocarbons: for 1 g of colorant samples, 1 g of cyclohexane is added, after continuous extraction in the extractor, the extraction liquid should be colorless, whose fluorescent intensity under ultraviolet rays shall not exceed that of control solution of quinine sulfate(0.1 mg quinine sulfate dissolve in 1 mL 0.1mol/L sulfuric acid solution)	§74.2052 D&C Black No. 2 · Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, nail enamel	§72. Carbon black (CI 77266)
142	Bone black, bone Charcoal	CI 77267	Black 3	Bone black, bone charcoal	Inorganic	-	-	§74.2053 D&C Black No. 3 · Not to be used in lip products · Eyeliner, eyeshadow, mascara, face powder	-
143	Vegetable Carbon	CI 77268:1		Vegetable carbon	Inorganic	-	-	· Not listed	-
144	Chromium Oxide Greens	CI 77288	Chromium Oxide Greens	Chromium Oxide Greens	Inorganic	· free from chromate ion	· Cr in 2% sodium hydroxide extraction solution, calculated as Cr_2O_3 ≤ 0.075%	§73.2327 Chromium Oxide Greens · Not to be used in lip products	§75. Chromium Oxide Greens (CI 77288)
145	Chromium Hydroxide Green	CI 77289	Chromium Hydroxide Green	Chromium Hydroxide Green	Inorganic	· free from chromate ion	· Cr in 2% sodium hydroxide extraction solution, calculated as Cr_2O_3 ≤ 0.1%	§73.2326 Chromium Hydroxide Green · Not to be used in lip products	§76. Chromium Hydroxide Green (CI 77289)
146	Cobalt Aluminum Oxide	CI 77346		Cobalt Aluminum Oxide	Inorganic	-	-	· Not listed	§77. Cobalt aluminum oxide (CI 77346)
147	Copper Powder	CI 77400	Copper Powder	Copper Powder	Inorganic	-	-	§73.2647 Copper powder	-

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
148	Bronze Powder	CI 77400	Bronze Powder	Bronze Powder	Inorganic	-	-	§73.2646 Bronze powder	-
149	Gold	CI 77480		Gold	Inorganic	§E 175 GOLD	-	· Not listed	§79. Gold (CI 77480)
150	Ferrous Oxide	CI 77489	Iron Oxides	Ferrous oxide	Inorganic	-	-	§73.2250 Iron oxides	-
151	Iron Oxide Red	CI 77491	Iron Oxides	Iron Oxide Red	Inorganic	§E 172 IRON OXIDES AND IRON HYDROXIDES	-	§73.2250 Iron oxides	§81. Iron oxide red (CI 77491)
152	Iron Oxide Yellow	CI 77492	Iron Oxides	Iron Oxide Yellow	Inorganic	§E 172 IRON OXIDES AND IRON HYDROXIDES	-	§73.2250 Iron oxides	§82. Iron oxide Yellow (CI 77492)
153	Iron Oxide Black	CI 77499	Iron Oxides	Iron Oxide Black	Inorganic	§E 172 IRON OXIDES AND IRON HYDROXIDES	-	§73.2250 Iron oxides	§83. Iron oxide black (CI 77499)
154	Ferric Ammonium Ferrocyanide	CI 77510	Ferric ammonium Ferrocyanide	Ferric ammonium Ferrocyanide	Inorganic	· free from cyanide ions	· Water-dissolved cyanide≤ 1 mg/kg	§73.2298 Ferric ammonium ferrocyanide · Not to be used in lip products	§84. Ferric ammonium ferrocyanide (CI 77510)
155	Ferric Ferrocyanide	CI 77510	Ferric Ferrocyanide	Ferric Ferrocyanide	Inorganic	· free from cyanide ions	· Water-dissolved cyanide≤ 1 mg/kg	§73.2299 Ferric ferrocyanide · Not to be used in lip products	§85. Ferric ferrocyanide (CI 77510)
156	Magnesium Carbonate	CI 77713		Magnesium Carbonate	Inorganic	-	-	· Not listed	§86. Magnesium carbonate (CI 77713)
157	Talc	CI 77718			Inorganic	· Not listed	-	· Not listed	· Not listed
158	Manganese Violet	CI 77742	Manganese Violet	Manganese Violet	Inorganic	-	-	§73.2775 Manganese Violet	§87. Manganese Violet (CI 77742)
159		CI 77745			Inorganic	-	-	· Not listed	· Not listed
160	Silver	CI 77820	Silver	Silver	Inorganic	§E 174 SILVER	-	§73.2500 Silver · Not to be used in eye and lip products · Fingernail polish ≤ 1%	-

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(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
161	Titanium Dioxide	CI 77891	Titanium Dioxide	Titanium Dioxide	Inorganic	§E 171 TITANIUM DIOXIDE · Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation.	-	§73.2575 Titanium dioxide	§89. Titanium dioxide (CI 77891)
162	Zinc Oxide	CI 77947	Zinc Oxide	Zinc Oxide	Inorganic		-	§73.2991 Zinc oxide	§90. Zinc oxide (CI 77947)
163	Lactoflavin, Riboflavin	-		Lactoflavin, Riboflavin	Natural	§E 101 (i) RIBOFLAVIN	-	· Not listed	§91. Riboflavin, Lactoflavin
164	Caramel	-	Caramel	Caramel	Natural	§E 150a-d PLAIN CARAMEL, CAUSTIC SULPHITE CARAMEL, AMMONIA CARAMEL, SULPHITE AMMONIA CARAMEL	-	§73.2085 Caramel	§92. Caramel
165	Capsanthin, capsorubin	-		Paprika Extract, Capsanthin, capsorubin	Natural	§E 160c PAPRIKA EXTRACT, CAPSANTHIN, CAPSORUBIN	-	· Not listed	§93. Paprika extract, Capsanthin/Capsorubin)
166	Beetroot Red	-		Beetroot Red	Natural	§E 162 BEETROOT RED, BETANIN	-	· Not listed	§94. Beetroot red
167	Anthocyanins	-		Anthocyanins	Natural	§E 163 ANTHOCYANINS	-	· Not listed	-
168	Aluminum Stearate Zinc Stearate Magnesium stearate Calcium Stearate	-		Aluminum stearate Zinc stearate Magnesium stearate Calcium stearate	Inorganic	-	-	· Not listed	§96. Aluminum stearate/ Zinc stearate/Magnesium stearate/Calcium stearate
169	Bromothymol Blue				Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed
170	Bromocresol Green				Synthetic	· Rinse-off products	· Rinse-off products	· Not listed	· Not listed

Appendix
(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
171	Acid Red 195				Synthetic	· Not to be used in products applied on mucous membranes	· Not to be used in products applied on mucous membranes	· Not listed	· Not listed
172	Bismuth Citrate		Bismuth citrate		Synthetic	· Not listed	· Not listed	§73.2110 Bismuth citrate · Not to be used in eye and lip products · Hair on the scalp	· Not listed
173	Disodium EDTA-copper		Disodium EDTA-copper	Disodium EDTA-copper	Synthetic	· Not listed	· Not listed	§73.2120 Disodium EDTA-copper · Not to be used in eye and lip products · Shampoos	-
174	Dihydroxyacetone		Dihydroxyacetone	Dihydroxyacetone	Synthetic	· Not listed	· Not listed	§73.2150 Dihydroxyacetone · Not to be used in eye and lip products · For use in tanning preparations	-
175	Guaiazulene		Guaiazulene	Guaiazulene	Natural	· Not listed	· Not listed	§73.2180 Guaiazulene · Not to be used in eye and lip products	§99. Guaiazulene
176	Henna		Henna		Natural	· Not listed	· Not listed	§73.2190 Henna · Not to be used in eye and lip products · Hair on the scalp	· Not listed
177	Lead acetate		Lead acetate		Inorganic	· Not listed	· Not listed	§73.2396 Lead Acetate · Not to be used in eye and lip products · Hair on the scalp; ≤0.6% lead	· Not listed

Appendix
(Continued)

No.	Common Name[a]	CI No. (salt form)[b]	US Name[c]	Korean Name[a]	Class	EU[b]	China[d]	United States[b]	Korea[a]
178	Pyrophyllite		Pyrophyllite	Pyrophyllite	Inorganic	· Not listed	· Not listed	§73.2400 Pyrophyllite · Not to be used in eye and lip products	§100. Pyrophyllite
179	Luminescent zinc sulfide		Luminescent zinc sulfide		Inorganic	· Not listed	· Not listed	§73.2995 Luminescent zinc sulfide · Not to be used in eye and lip products · Externally applied facial makeup and nail polish; <10%	· Not listed
180	Sorghum Red				Natural	· Not listed	· Not to be used in eye products	· Not listed	· Not listed
181	Galla Rhois Gallnut Extract				Natural	· Not listed	· When used with ferrous sulfate, only use in dye hair products	· Not listed	· Not listed

- colorants used as hair dyes and cosmetic soaps are not considered.
"—": Included on the positive list but does not have a specification
[a]Annex 1, MFDS Notification "Colorants specification and test methods."
[b]Annex Iv, Regulation (EC) No. 1223/2009.
[c]FDA 21 CFR Parts 73 and 74.
[d]Table 6, Chap. 3, Satefty and Technical Standards for Cosmetics 2015.

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