

Colorants for Cosmetic Products

T. Bombeli, MD BBA. **Cosmetic regulations in Europe, Japan, and the US do not contain lists of approved cosmetic ingredients except for preservatives, certain active ingredients, and colorants. For all other cosmetic ingredients the regulations allow for usage as long as the safety of the final cosmetic has been substantiated.**

Currently, the FDA has approved 64 color additives for cosmetic use either with or without batch certification (see: www.cfsan.fda.gov/~dms/opa-col2.html#table3A). It is notable that the regulations vary from region to region. For example micas, which are on the approval list of the FDA, are not considered a colorant in Europe or Japan. Also, regulations are specific to the type of cosmetic a colorant may be used in. Aluminum colorants, for example, are approved in the US, Europe and Japan as a cosmetic colorant for all cosmetic applications except for lip products in the US. Further, ferric ferrocyanide may be used in externally applied cosmetics in the US, while the EU and Japan also allow for lip area use. Due to these complexities, it is wise that appropriate use of each colorant be confirmed against each region's current cosmetic regulations.

Organic Colorants

Colorants are classified as either organic or inorganic depending on the chemistry. Organic colors were originally called „coal tar“ or „anilines“ because they were derived from coal sources. However, nowadays almost all organic colorants are synthetic and are available as either water soluble, oil soluble or insoluble (=Lakes) agents in all kinds of shades. In the US approved organic colors are designated as FD&C, D&C or Ext. D&C. This means:

- **FD&C:** certified for use in food, drugs & cosmetics
- **D&C:** certified for use in drugs & cosmetics including in those in contact with mucous membranes and those that are ingested
- **External D&C:** certified for use in drugs & cosmetics that do not come in contact with mucous membranes or those that are ingested.

In Europe and Japan color index numbers are employed for identification of organic colors. The following list shows examples of the seven

Organic Colorants

- Indigoid Group: e.g. D&C Red 30
- Xanthene Group: e.g. D&C Yellow 7 & D&C Yellow 8
- Azo Group: e.g. D&C Red 36, D&C Red 17, D&C Orange 4
- Nitro Group: Ext. D&C Yellow 7 (only one)
- Triphenylmethane Group: FD&C Blue 1, FD&C Green 3
- Quinoline Group: D&C Yellow 10 & D&C Yellow 11
- Anthraquinone Group: D&C Green 6, D&C Violet 2

Inorganic Colorants

Inorganic colorants are composed of insoluble metallic compounds which are either derived from natural sources (e.g. china clay, carbon deposits) or are synthesized. Inorganic colors do not have the same kinds of health risks as organic colors and, therefore do not require certification. Unfortunately, inorganic colorants are not available in the range of shades that the organic offers, and they are not water soluble which limits their range of applications. Below is a list of the different groups of inorganic colorants (suppliers offer various shades)

Inorganic Colorants & Their Use in Cosmetics

FDA Name	EU Color Index No.	Japan Name	Lip-sticks	Face Makeup	Nail Lacquers	Eye Makeup
Iron Oxide Black	77499	Iron Oxide	S	M	NR	M
Iron Oxide Red	77491	Iron Oxide	S	S	S	M
Iron Oxide Orange	77491/2	Iron Oxide	S	M	NR	M
Iron Oxide Yellow	77492	Iron Oxide	S	M	NR	M
Iron Oxide Brown	77491	Iron Oxide	S	M	NR	M
Chrome Oxide Green	77288	Anhydrous Chrome Oxide	X	NR	NR	M
Ultramarine Blue	77007	Ultramarine	X	S	NR	M
Ultramarine Pink	77007	Ultramarine	X	S	NR	M
Ultramarine Violet	77007	Ultramarine	X	S	NR	M
Manganese Violet	77742	Manganese	S	NR	NR	M
Ferric Ferrocyanide (Iron Blues)	77510	Ferric Ferrocyanide	X	NR	S	M

Key: S=Some Use, M=Major Use, NR=Not Recommended, X=Prohibited in US

Source: Whittaker, Clark & Daniels

Natural Colorants

In addition to the inorganic colors, there are other colorants that may be used in cosmetics that are exempt from certification. These are typically natural materials like:

- Caramel coloring and Carrot oil
- Beet extract
- Henna
- Fruit & vegetable juices

Selecting Colorants Based on Regulations

There are many factors that determine the appropriate colorant choice. Pay attention to the following before using a colorant:

- Products that do not come into contact with mucous membranes or the eye area (e.g. shampoo, conditioner, hand cream): use FD&C, D&C or Ext. D&C colors
 - Products that are used around the mouth (e.g. face cream, lipstick): use FD&C or specifically approved D&C colors
 - Products that are used around the eye (e.g. mascara, eyeshadow): use only inorganic or natural colors or specifically approved organic colors (e.g. FD&C Yellow 5)
- Note: there are natural colors that are not allowed like henna, silver, or lead acetate.

Selecting Colorants Based on Formulation

Color selection depends also on the properties of a formulation. As a rule of thumb:

- Liquid products (e.g. shampoo, lotion): use water-soluble D&C or FD&C colors.
- Solid products (e.g. powders): use inorganic or insoluble organic colors (Lakes)

Since many factors can affect the stability and activity of colorants (e.g. surfactants, pH value) please keep in mind that the same amount of a specific colorant may give a different shade in a different formulation.

Since colorants are extremely effective, only minute amounts are necessary to color a cosmetic product. For example, to color a shampoo only 0.0001% dye is necessary! - Therefore, colorants should be used in dilute stock solutions (such as 0.1%) either dissolved in water when water-soluble colorants are used or dispersed in oils or waxes when water-insoluble colorants are used.