

COLORANTS FOR FOODS

1. Introduction

Colorants have been added to foods, drugs, and cosmetics for centuries (1–3). Until the middle of the nineteenth century, the colorants added were materials easily obtainable from natural sources such as animals, plants, and minerals. In 1856, Sir William Henry Perkin discovered the first synthetic organic dyestuff, mauve, and soon a host of new and different colorants became available (4). The use of some of these in foods began in Europe almost immediately and their use was soon extended to drugs and cosmetics. French wines, for example, were colored with fuchsine, a triphenylmethane dye, as early as 1860. The United States first legalized the use of synthetic organic dyes in foods by an act of Congress that authorized the addition of coloring matter to butter in 1886; the second instance came in 1896, with the recognition of coloring matter as a legitimate constituent of cheese. By 1900, Americans were eating a wide variety of artificially colored products, including ketchup, jellies, cordials, butter, cheese, ice cream, candy, sausage, noodles, and wine. The use of the new synthetic colorants in drug and cosmetic products was also increasing rapidly.

This proliferation in the use of color additives was soon recognized as a threat to the public's health. Of particular concern were the practices of adding poisonous colorants to food, and of using dyes to hide poor quality or to add weight or bulk to certain items. References 5–14 provide additional information on the history of food colorants and their regulation. Reference 15 provides more information regarding the applications, properties, specifications, and analysis of color additives, as well as methods for the determination of colorants in products.

2. History of Regulation

Because of increasing public worry over such practices, some measures were eventually taken by American food manufacturers to police their own industry, but the effect was marginal, and it was clear that some form of government control was necessary if the public was to be protected. The first effective step taken by the U.S. government was the Appropriations Act of 1900 for the Department of Agriculture, the Bureau of Chemistry which provided funds to investigate the relationship of coloring matters to health and to establish principles that should be followed to govern their use (16). This resulted in the issuance by the Secretary of Agriculture of a series of Food Inspection Decisions (FID). One decision (FID 39, issued May 1, 1906) contained the first direct statement by the department concerning a coal-tar dye considered unsafe in foods. In effect, it stopped importation of macaroni colored with Martius Yellow.

At about the same time a thorough study was undertaken by the Department of Agriculture to determine which dyes, if any, were safe for use in foods and what restrictions should be placed on their use. This monumental task eventually included a study of the chemistry and physiology of the then nearly 700 extant coal-tar dyes as well as the laws of various countries and states regarding their use in food products. Most of this investigation was done under the guidance of Dr. Bernard C. Hesse, a German dye expert (17).

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Of the 80 colorants offered for use in foods in the United States in 1907, Hesse learned from the literature that 30 of them had never been tested at all and that their safety was therefore simply unknown, 26 had been tested but the results were contradictory, 8 were considered by most experts to be unsafe, and the remaining 16 were deemed more or less harmless. These 16 colorants were then tested physiologically by determining their acute short-range effects in dogs, rabbits, and human beings. Hesse then recommended the following seven colorants for use in food in the United States: Amaranth, Ponceau 3R, Orange I, Erythrosine (FD&C Red No. 3), Naphthol Yellow S (Ext. D&C Yellow No. 7), Light Green SF Yellowish, and Indigo Disulfo Acid, Sodium Salt (FD&C Blue No. 2).

Much of what Hesse uncovered during his study was used in formulating the Food and Drug Act of 1906. This act, plus FID No. 76 (July 13, 1907) put an end to the indiscriminate use of dangerous and impure coloring matters in foods. This new legislation required that only colors of known composition, examined physiologically and showing no unfavorable results, could be used. The new regulations also established a system for the voluntary certification of synthetic organic food colors by the Department of Agriculture.

During the next three decades there was a continual growth in the use and number of color additives, and using Hesse's rules, the list of colors certifiable for use in foods was expanded.

In 1938 a new law, the Federal Food, Drug, and Cosmetic Act of 1938 (18), which instituted several new and important practices, was enacted. First, it clearly stated that, henceforth, the use of any uncertified coal-tar color in any food, drug, or cosmetic shipped in interstate commerce was strictly forbidden. This restriction applied regardless of the inherent toxicity of the colorant. In effect, the colorants that could be used were limited, certification became mandatory, and governmental control was extended to the coloring of drugs and cosmetics. Next, it created three categories of coal-tar colors:

- *FD&C colors.* Those certifiable for use in coloring foods, drugs, and cosmetics.
- *D&C colors.* Dyes and pigments considered safe in drugs and cosmetics when in contact with mucous membranes or when ingested.
- *Ext. D&C colors.* Those colorants that, because of their oral toxicity, were not certifiable for use in products intended for ingestion, but were considered safe for use in products externally applied.

Passage of the 1938 Act launched a new series of scientific investigations and public hearings regarding the safety of the colorants then on the market. These efforts culminated in the publication in 1940 of Service and Regulatory Announcement, Food, Drug, and Cosmetics No. 3, which listed specific colorants that could be used along with specifications and regulations relating to their manufacture, labeling, certification, and sale.

In the early 1950s, a number of cases of sickness occurred in children who had reportedly eaten candy and popcorn colored with excessive amounts of dye. As a result of these illnesses, new animal feeding studies were undertaken by the FDA. These studies were conducted at higher levels and for longer test periods

than any experiments previously conducted and resulted in unfavorable findings for FD&C Orange No. 1, FD&C Orange No. 2, and FD&C Red No. 32.

The disputes that followed these events centered around interpretation of the 1938 act, which states that “The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food. . .” The FDA felt that harmless meant that a colorant must be safe regardless of the amount used, that is, harmless per se and on this basis delisted the colorants in question. The food-color manufacturers argued that the FDA interpretation of the law was too strict, that a color additive need only be harmless when properly used, and that the FDA should establish safe limits. They also contended that the conditions used for the new animal feeding tests were too severe.

In 1958 the Supreme Court ruled that under the 1938 law, the FDA did not have the authority to establish limits of use for colorants and that they were obligated to decertify or delist a color if any quantity of it caused harm even though lesser amounts were perfectly safe (19). The FDA’s hands were tied (20). A review of the remaining colors was started and soon several more were delisted, including FD&C Yellow Nos. 1–4. It became obvious that the existing law on certifiable colors was unworkable.

Through the efforts of the Certified Color Industry and the FDA, a new law was formulated, the Color Additives Amendments of 1960 (Public Law 86-618) (21). The amendments provided a breathing spell by allowing the continued use of existing color additives pending the completion of investigations needed to ascertain their suitability for listing as permanent colorants, and authorizing the establishment of limits of use by the Secretary of Health, Education, and Welfare, thus eliminating the controversial “harmless per se” interpretation formerly employed. A special proviso, the Delaney clause, directed the Secretary not to list a color additive for any use if that colorant could be shown to induce cancer in humans or animals (22). Other features eliminated any distinction under the law between coal-tar colors and other color additives and empowered the Secretary to decide which colors must be certified and which could be exempted from certification based on their relationship to public health. Under the new law, producers and consumers of color additives were obliged to provide the necessary scientific data to obtain permanent listing of a color additive.

With the passage of the Medical Device Amendments of 1976 (Public Law 94-295) Congress created a new category of color additive by mandating the separate listing of colorants for use in medical devices if the color additive in them comes in direct contact with the body for a significant period of time.

Colorants currently in use and their status are shown in Tables 1. This list is accurate as of June 2007 but are subject to change. Such changes as well as any changes in the regulation of color additives are routinely published in the *Federal Register*. The FDA, Division of Colors and Cosmetics also provides additional regulatory information (14).

3. Coloring Food

Table 1 lists various colorants permitted for use in foods.

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Most staple foods such as meat, white bread, potatoes and other vegetables, and most fruits are not artificially colored since their natural appearance is perfectly acceptable. Foods are usually colored because they have no natural color of their own, because their natural color was destroyed or drastically altered as a result of processing or storage, or because their color varies greatly with the season of the year or their geographic origin. Thus, colorants are added to foods to make them appear the way the customer wants and expects them to appear.

Consumers' expectations depend on several factors including cultural background, past experiences, desire for color coordination, esthetic appeal, local customs, fads, etc. Thus, eg, a Texas red hot sold in the South is often colored quite differently than one sold in the North, Midwesterners prefer butter with a deep yellow color, and on birthdays the decoration on a boy's cake are often blue and those on a girl's are often pink.

Color expectation in food depends also on how well established the color of that food is and how closely its color is associated with its quality. Black cabbage, green rice, or purple milk, for example, do not meet standards of identity for these foods. Also, because of color, green grapefruit and bananas are perceived as immature, anything but the most brilliant red beef is suspect, and excessively brown or spotted produce is shunned in favor of the brightest, most uniformly colored products available. The colors of some foods, in fact, are so well fixed that they serve as reference standards when speaking of certain hues; ie, lemon yellow, eggshell white, cherry red, chocolate brown, and pea green.

3.1. Colorless Foods. The principal use of color additives in food is in products containing little or no color of their own. These include many liquid and powdered beverages, gelatin desserts, candies, ice creams, sherbets, icings, jams, jellies, and snack foods. Without the addition of color to some of these, eg, gelatin desserts and soft drinks, all flavors of the particular product would be colorless, unidentifiable, and probably unappealing to the consumer.

3.2. Process and Storage Difficulties. Often the process used to prepare a food results in the formation of a color in the product, the depth of which depends largely on the time, temperature, pH, air exposure, and other parameters experienced during processing. It is deemed necessary to supplement the color of the product to ensure its uniformity from batch to batch. Items that fall into this category include certain beers, blended whiskies, brown sugars, table syrups, toasted cereals, and baked goods.

During storage, natural pigments often deteriorate with time because of exposure to light, heat, air, and moisture or because of interaction of the components of the food with each other or with the packaging material. The color of maraschino cherries, for example, fares so poorly with storage that they are routinely bleached then artificially colored.

3.3. Regional and Seasonal Problems. The problems of the dairy and citrus fruit industries are typical of those encountered with products produced in different areas of the country or at different times of the year.

In many parts of the United States, the soil and weather conditions are such that chlorophyll continuously forms in the fruit of orange trees as well as in the leaves of the trees; the result is mature oranges that are substantially greener than the same variety of orange produced in regions of the country with different growing conditions. Most varieties of Florida oranges tend to be

green, suggesting immaturity, even though they contain the proper ratio of solids to acid for fully nutritious, mature fruit. The necessity of coloring these oranges to make them comparable in appearance and thus as commercially acceptable as naturally orange-colored fruit was recognized years ago and began on a commercial scale about 1934.

In milk approximately 90% of the yellow color is because of the presence of β -carotene, a fat-soluble carotenoid extracted from feed by cows. Summer milk is more yellow than winter milk because cows grazing on lush green pastures in the spring and summer months consume much higher levels of carotenoids than do cows barn-fed on hay and grain in the fall and winter. Various breeds of cows and even individual animals differ in the efficiency with which they extract β -carotene from feed and in the degree to which they convert it into colorless vitamin A. The differences in the color of milk are more obvious in products made from milk fat, since here the yellow color is concentrated. Thus, unless standardized through the addition of colorant, products like butter and cheese show a wide variation in shade and in many cases appear unsatisfactory to the consumer.

Other products having natural color that varies enough to make standardization of their color desirable include the shells of certain kinds of nuts, the skins of red and sweet potatoes, and ripe olives.

3.4. Miscellaneous Uses. Inks used by inspectors to stamp the grade or quality on meat must, by law, be made from food-grade colors. Dyes used in packaging materials that come in direct contact with a food must also be food-grade or, if not, it must be established that no part of the colorant used migrates into the food product. Pet foods, too, if colored, must contain only those colorants recognized by the FDA as suitable for the purpose.

References 23–31 cover various aspects of food coloring technology in the United States and internationally.

4. Regulations Governing Use

4.1. Listed and Provisionally Listed Colorants. Colorants can be divided into two groups: those listed for use and those provisionally listed. Listed additives are colors that have been sufficiently evaluated to convince FDA of their safety for the applications intended. These colorants are also known popularly as permanently listed colorants; however, they in fact can be delisted for sufficient cause. Provisionally listed colorants, on the other hand, are dyes and pigments that are not considered unsafe but that have not undergone all the tests required by the Color Additives Amendments of 1960 to establish their eligibility for permanent listing. Currently, these colors can still be used in those applications in which they were used prior to enactment of the 1960 amendments, unless newer temporary regulations restrict their use further. The status of these colorants is reviewed about once each year and, if sufficient reason exists and if the manufacturers or consumers of these colors request it, their provisional listing status is extended pending completion of the required scientific investigations.

4.2. Certification of Colorants. A further distinction between color additives is made relative to whether there is requirement for FDA certification. In general, only synthetic organic colorants are now subject to certification,

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whereas natural organic and inorganic colorants, such as turmeric and titanium dioxide, are not. The exemption from certification for a particular colorant holds whether the colorant is obtained from natural sources or is synthetically produced, as in the case of natural and synthetic β -carotene.

If a color requires certification prior to its sale, an appropriate size representative sample of each batch, along with a request for certification must be submitted to the FDA, Color Certification Branch, to see if it conforms to the specifications and other conditions established for it. The charge for certification of a straight colorant, a lake of a straight colorant, or a repack of either, is \$0.55/kg of the batch, with a minimum charge of \$160. The charge for the certification of other repacks is \$25 minimum, plus \$0.13/kg for each kg over 45.5 kg (100 pounds), for batches weighing less than 455 kg. If the batch is found satisfactory, a lot number is assigned to it and a certificate of certification is issued. These certificates are valid so long as the regulations pertaining to the storage, packaging, labeling, distribution, and use of the lot are strictly adhered to.

4.3. Specifications. Most colorants in use today have specifications that must be met before they can be sold. In the case of the provisionally listed colors, these specifications may be revised if and when the colorants are removed from the provisional lists. Typical specifications for a synthetic aromatic organic dye, a synthetically produced natural colorant and an inorganic pigment, are given as examples. Many other examples can be found in Reference 15.

FD&C Red No. 40. This monoazo dye (5) is manufactured by coupling diazotized 5-amino-4-methoxy-2-toluenesulfonic with 6-hydroxy-2-naphthalenesulfonic acid. FD&C Red No. 40 is also known as Allura Red or CI Food Red 17. Its chemical identity is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid, which has the formula $C_{18}H_{14}N_2O_8S_2Na_2$, and mol wt 496.43.

FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts)—not more than 14.0%

Water-insoluble matter—not more than 0.2%

Higher sulfonated subsidiary colors (as sodium salts)—not more than 1.0%

Lower sulfonated subsidiary colors (as sodium salts)—not more than 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—not more than 1.0%

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt)—not more than 0.3%

4-Amino-5-methoxy-*o*-toluenesulfonic acid—not more than 0.2%

Disodium salt of 6,6'-oxybis(2-naphthalenesulfonic acid)—not more than 1.0%

Lead (as Pb)—not more than 10 ppm

Arsenic (as As)—not more than 3 ppm

Total color—not less than 85.0%

β-Apo-8'-carotenal. This colorant, C₃₀H₄₀O (CI Food Orange 6), EEC No. E 160e), is an aldehydic carotenoid (10) widely distributed in nature: it is isolated from numerous items, including spinach, oranges, grass, tangerines, and marigolds. It is synthetically produced as the crystalline all-trans stereoisomer, which is a purplish black powder that melts (with decomposition) in the range 136–140°C (corrected). Its mol wt is 416.65.

β-Apo-8'-carotenal shall conform to the following specifications:

Physical state—solid

One percent solution in chloroform—clear

Melting point (decomposition)—136–140°C (corrected)

Loss of weight on drying—not more than 0.2%

Residue on ignition—not more than 0.2%

Lead (as Pb)—not more than 10 ppm

Arsenic (as As)—not more than 1 ppm

Assay (spectrophotometric)—96–101%

4.4. Titanium Dioxide. Titanium dioxide [13463-67-7], TiO₂, mol wt 79.90, Titanic Earth, CI Pigment White 6, CI No. 77891, EEC No. E 171, is the whitest, brightest pigment known today, with a hiding power four to five times greater than that of its closest rival, zinc oxide (32).

Titanium dioxide shall conform to the following specifications:

Lead (as Pb)—not more than 10 ppm

Arsenic (as As)—not more than 1 ppm

Antimony (as Sb)—not more than 2 ppm

Mercury (as Hg)—not more than 1 ppm

Loss on ignition at 800°C (after drying for 3 h at 105°C)—not more than 0.5%

Water-soluble substances—not more than 0.3%

Acid-soluble substances—not more than 0.5%

Titanium dioxide—not less than 99.0% after drying for 3 h at 105°C

Lead, arsenic, and antimony—determined in the solution obtained by boiling 10 g of the titanium dioxide for 15 min in 50 mL of 0.5 N hydrochloric acid

In addition to individual specifications, general specifications have been written for provisionally listed certifiable colors:

	FD& colors, % max	D&C and Ext. D&C colors, % max
lead	0.001	0.002
arsenic (as As ₂ O ₃)	0.00014	0.0002
heavy metals (except lead and arsenic) (precipitated as sulfides)	trace	0.003
mercury	0.0001	
colors that are barium salts—soluble barium in dilute HCl (as BaCl ₂)		0.05

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The limit of 1 ppm mercury placed on colors intended for use in foods was established by a letter from the Acting Director of the Division of Colors and Cosmetics to the certified color manufacturers in 1970. This action was the first step taken to replace the somewhat nebulous heavy metals specifications previously used with concrete limits for specific metals.

4.5. Use Restrictions. There are numerous restrictions on the use of color additives. They cannot, for example, be employed to deceive the public by adding weight or bulk to a product or by hiding quality. In addition, special permission is needed to use colorants or products containing them in the area of the eyes, in injections, in surgical sutures, and in foods for which standards of identity have been promulgated under Section 401 of the Federal Food, Drug, and Cosmetic Act.

Other restrictions pertaining to the areas of use and the quantities of colorants allowed in products are specified in regulations for particular additives. Citrus Red No. 2, for example, can only be used to color the skins of oranges not intended for processing, whereas pyrophyllite can be used only to color drugs that are to be externally applied. A special case of the restricted use of a colorant is that of FD&C Red No. 4. Although it is designated as an FD&C colorant (implying that it can be generally used in foods), its use is now limited to coloring externally applied drugs and cosmetics only. FD&C Red No. 4 can no longer be used to color foods and ingested drugs. So many limitations have crept into the system that the designations FD&C, D&C, and Ext. D&C no longer have their original meaning.

The amount of a color additive allowed in a product depends on both the colorant and the article being colored. For example, TiO_2 when used to color foods cannot exceed 1% by weight of the food product. On the other hand, there is no numerical limit set on its use in the coloring of ingested or externally applied drugs. Similarly, ultramarine blue may be used to color salt intended for animal feed, but not in amounts exceeding 0.5% by weight of the salt. When numerical limits for the use of colorants are not specified, the amount allowed is controlled by "good manufacturing practice," an ill-defined term that in effect says that you cannot use more of a colorant in a product than is needed to achieve the desired effect. Today, the excessive use of colorants is rarely a problem since manufacturers are not likely to waste costly additives and, at the same time, run the risk of making their products appear unnatural.

5. Certified Colors

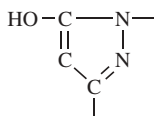
Presently, all certified colors are factory-prepared materials belonging to one of several different chemical classes. Although a few such as D&C Blue No. 6 (indigo) are known to exist in nature, certified colors owe their commercial importance to their synthetic production. Because of the starting materials used in their manufacture in the past, certified colors were once known as coal-tar dyes. Today, since most of the raw materials used in their preparation are obtained from petroleum, this term no longer applies.

Compared to noncertified color additives, certified colors are a cheaper, brighter, more uniform, and better characterized group of dyestuffs with higher

tinctorial strengths and a wider range of hues. They are available singly (primary colors) and in admixture with other certified colors (secondary mixes). By properly blending the available primary colorants, a nearly infinite number of shades can be prepared. Most are sold in various forms, including powders, granules, pastes, solutions and dispersions, and as lakes. Most are also available as is, or mixed with salt or sugar or some other approved solvent or diluent, depending on the colorant and its intended use.

5.1. Chemical Classifications. Azo colors comprise that largest group of certified colorants. They are characterized by the presence of one or more azo bonds ($-N=N-$) and are synthesized by the coupling of a diazotized primary aromatic amine to a coupling component, usually a naphthol. Certifiable azo colors can be subdivided into four groups: insoluble unsulfonated pigments, soluble unsulfonated dyes, insoluble sulfonated pigments, and soluble sulfonated dyes.

Three dyes are triaryl- or triphenylmethanes. Each, like FD&C Blue No. 1, consists of three aromatic rings attached to a central carbon atom. All are water-soluble, anionic, sulfonated compounds. FD&C Blue No. 1 has the structure (1) shown in Figure 1. FD&C Yellow No. 5 (6) and Orange B (9) are pyrazolones that contain the following common group:



The pyrazolones may also be classified as azo dyes since each contains an $-N=N-$ group.

5.2. Lakes. Lakes are a special kind of color additive prepared by precipitating a soluble dye onto an approved insoluble base or substratum. In the case of D&C and Ext. D&C lakes, this substratum may be alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these materials. Currently, alumina is the only substratum approved for manufacturing FD&C lakes.

FD&C lakes were first approved for use in 1959. Today, they are the most widely used type of lake. To make a lake, an alumina substrate is first prepared by adding sodium carbonate or sodium hydroxide to a solution of aluminum sulfate. Next, a solution of certified colorant is added to the resulting slurry, then aluminum chloride is added to convert the colorant to an aluminum salt, which then adsorbs onto the surface of the alumina. The slurry is then filtered, and the cake is washed, dried, and ground to an appropriate fineness, typically 0.1–4.0 μm .

Lakes are available with pure dye contents ranging from less than 1% to more than 40% and with moisture contents of 6–25%. Typical FD&C lakes contain 10–40% pure dye and 15–25% moisture. Typical use levels are 0.1–0.3%. Lakes are marketed as is, or mixed with other lakes or approved diluents, or dispersed in various edible vehicles such as hydrogenated vegetable oil, coconut oil, propylene glycol, glycerol, or sucrose syrup, or dispersed in other approved media that make the mixtures appropriate for printing food wrappings, for marking

capsules, for incorporating into health products that come into direct contact with the skin, and so on.

Lakes are insoluble in most solvents, although some bleeding or leaching may be observed in solvents in which the unlaked dye is soluble. FD&C lakes are insoluble in water in the pH range of 3.5–9.0, but outside this range, the lake substrate tends to dissolve releasing the captive dye.

Properties of lakes that enhance their usefulness include their opacity, their ability to be incorporated into products in the dry state, their relative insolubility, and their superior stability toward heat and light. Such properties have made possible the more effective and more efficient preparation of candy and tablet coatings, and often eliminate the need to remove moisture from dry products before coloring them. Lakes have also made possible the coloring of certain products that, because of their nature, method of preparation, or method of storage, cannot be colored with ordinary color additives.

Since there are no solvent-soluble FD&C colors, FD&C lakes have proven particularly valuable for coloring water-repelling foods such as fats, gums, waxes, and oils, and for coloring food-packaging materials including lacquers, containers, plastic films, and inks from which soluble dyes would be quickly leached. Similarly useful applications have been found for D&C and Ext. D&C lakes in their respective areas of application.

Unlike dyes that color objects through their adsorption or attachment from solution to the material being colored, lakes, like other pigments, impart color by dispersing them in the medium to be colored. As a consequence of this pigment-like character, both the shade and the tinctorial strength of lakes are highly dependent on the conditions used in their manufacture as well as their physical properties, including their particle size and crystal structure.

Some specific products in which lakes are used include icings, fondant coatings, sandwich cookie fillings, cake and doughnut mixes, decorative sugar crystals, coated and compression tablets (candy or pharmaceutical), hard candy, candy wafers, chewing gums, wax coatings for cheeses, yogurts, dry beverage bases, dessert powders, snack foods, spice mixes, canned and semimoist burger-type pet foods.

5.3. Properties of Colorants. Properties of a number of colorants are shown in Tables 2–6. For other properties see Reference 15. Most values are from the literature and, in general, refer to commercial colorants and not pure compounds. The composition of certified colorants can vary substantially with regard to the amounts of pure dye, salt, moisture, subsidiary dyes, trace metals, etc. that they contain, and of course the properties of color additives are affected by their composition.

Based on maximum color concentrations and the total annual production of food in each food category, the total certified food color that might be ingested per person per year is estimated to be 19.5 g. Based on recent annual colorant production figures and current total population, this figure is closer to 11 g/yr.

5.4. Permitted Colorants. The colorants listed in Table 1 appear in the *Code of Federal Regulations* (21 CFR 70-82). The structures shown in Figure 1 are, in general, taken from the *Colour Index* (CI) and represent each colorant's principal component.

6. Colorants Exempt from Certification

The Commissioner of Food and Drug has the authority to exempt particular color additives from the batch-certification procedure when it is believed that, because of their nature, certification is not needed to protect the public health. Although exempt colorants need not be certified prior to their sale, they are subject to surveillance by FDA to ensure that they meet current government specifications and that they are used in accordance with the law.

With the passage of the 1960 amendments, all exempt colorants then in use were provisionally listed pending completion of the studies needed to obtain their permanent listing. Since that time, most of them as well as several completely new colors have achieved this status. Exempt color additives now in use and their status are shown in Table 1.

Exempt colorants are made up of a wide variety of organic and inorganic compounds representing the animal, vegetable, and mineral kingdoms. Some, like β -carotene and zinc oxide, are essentially pure factory-produced chemicals of definite and known composition. Others, including annatto extract, cochineal extract, caramel, and beet powder are mixtures obtained from natural sources and have somewhat indefinite compositions.

6.1. Production and Use. In general, exempt colorants have less coloring power than certified colorants and thus have to be used at higher concentrations. Some, particularly those of plant origin, tend to be less stable, more variable in shade, and therefore more complicated to use than certified colorants, and are more likely to introduce undesirable flavors and odors into the products in which they are incorporated. Also, depending on their nature and origin, exempt colorants can vary substantially in composition from batch to batch, are more likely to be contaminated with undesirable trace metals, insecticides, herbicides, and bacteria such as *Salmonella*, and can be more difficult to obtain in steady supply compared with certified colorants.

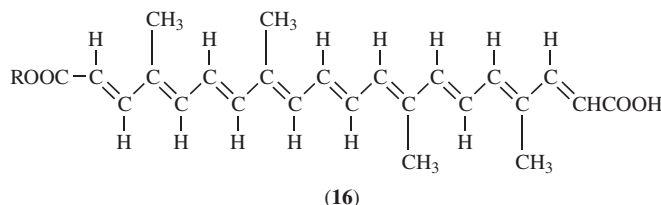
Exempt colorants are inherently neither more nor less safe than certified colorants. However, they are viewed as having been obtained from nature (natural) (33–35) and thus imagined as less of a health hazard than certified colorants. In fact, like all color additives, they are fabricated products.

6.2. Annatto Extract. The annatto tree (*Bixa orellana*) is a large, fast-growing shrub cultivated in tropical climates, including parts of South America, India, East Africa, and the Caribbean. The tree produces large clusters of brown or crimson capsular fruit containing seeds coated with a thin, highly colored resinous coating or marc that serves as the raw material for preparation of the colorant known As annatto extract [8015-67-6].

The colorant is prepared by leaching the annatto seeds with an extractant prepared from one or more approved, food-grade materials taken from a list that includes various solvents, edible vegetable oils and fats, and alkaline aqueous and alcoholic solutions (36, 37). Depending on the use intended, the alkaline extracts are often treated with food-grade acids to precipitate the annatto pigments, which in turn may or may not be further purified by recrystallization from an approved solvent. Annatto extract is one of the oldest known dyes, used since antiquity for the coloring of food, textiles, and cosmetics. It has been used in the United States and Europe for over 100 years as a color additive for butter and cheese (38, 39).

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The chief coloring principle found in the oil or fat extracts of annatto seeds is the carotenoid bixin (**17**, $R = \text{CH}_3$) (CI Natural Orange 4, [6983-79-5] EEC No. E 160b), which is the monomethyl ester of the dicarboxylic acid norbixin. The principal colorant in alkaline aqueous extracts is norbixin [542-40-5] (**16** $R = \text{H}$) (40, 41).



Annatto extract is sold in several physical forms, including dry powders, propylene glycol/monoglyceride emulsions, oil solutions and suspensions, and alkaline aqueous solutions containing anywhere from 0.1–30% active colorant calculated as bixin, $\text{C}_{25}\text{H}_{30}\text{O}_4$, or norbixin, $\text{C}_{24}\text{H}_{28}\text{O}_4$, as appropriate. It is used in products at 0.5–10 ppm as pure color, resulting in hues ranging from butter yellow to peach, depending on the type of color preparations employed and the product colored. Annatto extract's chief use is in foods such as butter, margarine, processed cheeses, nondairy creamers, cooking oils, salad dressings, cereals, ice cream, ice cream cones, sausage casings (42), bakery goods, snack foods, and spices. It is often used in combination with turmeric.

The chemistry and performance of annatto extract is essentially that of bixin, a brownish red crystalline material that melts at 198°C . It is moderately stable toward light and has good stability toward oxidation, change in pH, and microbiological attack. Bixin is very stable toward heat up to 100°C , fairly stable at 100 – 125°C , and unstable above 125°C , where it tends to form 13-carbomethoxy-4,8-dimethyltridecahexanoic acid.

6.3. β -Carotene. β -Carotene (**12**) [7235-40-7] is an isomer of the naturally occurring carotenoid, carotene (CI Food Orange 5, CI Natural Yellow 26, EEC No. E 160a). It is the pigment largely responsible for the color of various products obtained from nature including butter, cheese, carrots, alfalfa, and certain cereal grains. The colorant is synthetically produced from acetone, using the process developed in the 1950s by Hoffmann-LaRoche Inc., which results in the formation of the optically inactive all-trans form (Fig. 2). This synthesis made β -carotene very important in the history of the use of color additives because it was one of the first natural colorants synthetically produced on a commercial scale and the one that eventually raised the question as to whether factory-produced analogues of natural colorants should require certification by the FDA such as coal-tar dyes do, and whether such compounds could continue to be referred to as natural colors. This controversy eventually led to the creation of the category of colorants called colorants exempt from certification.

β -Carotene forms reddish violet platelets that melt in the range 176 – 182°C . It is insoluble in water, ethanol, glycerol, and propylene glycol, and only slightly soluble in boiling organic solvents such as ether (0.05%), benzene (0.2%), carbon disulfide (1%), and methylene chloride (0.5%). Its solubility in edible oils is about 0.08% at room temperature, 0.2% at 60°C , and 0.8% at 100°C . β -Carotene is sensitive to

alkali and very sensitive to air and light, particularly at high temperatures (43, 44). Pure crystalline β -carotene remains unchanged for long periods of time when stored under CO_2 below 20°C but is almost completely destroyed after only six weeks when stored in air at 45°C . Vegetable fat and oil solutions and suspensions are quite stable under normal handling conditions. β -Carotene is one of the rare color additives with nutritional value; it is converted biologically by humans into vitamin A; 1 g of β -carotene = 1,666,666 USP units of vitamin A.

β -Carotene is marketed as dry crystals packed under nitrogen, as a dry water-dispersible powder containing about 1% β -carotene, dextrin, gum acacia, partially hydrogenated vegetable oil, sucrose, sodium ascorbate, and dl- α -tocopherol, as liquid and semisolid suspensions in edible oils including vegetable, peanut, and butter oils, as water-dispersible beadlets composed of colorant plus vegetable oil, sugar, gelatin, and carbohydrate, and as emulsions (45, 46).

The colorant is used at 2–50 ppm as pure color to shade margarine, shortening, butter, cheese (4'), baked goods, confections, ice cream, eggnog, macaroni products, soups, juices, and beverages (47). Its chief advantages over other colorants are its nutritional value and its ability to duplicate natural yellow to orange shades.

6.4. β -Apo-8'-carotenal. The specifications of this colorant (13) were discussed earlier. β -Apo-8'-carotenal has provitamin activity with 1 g of the colorant equal to 1,200,000 IU of vitamin A. Like all crystalline carotenoids, it slowly decomposes in air through oxidation of its conjugated double bonds and thus must be stored in sealed containers under an atmosphere of inert gas, preferably under refrigeration. Also like other carotenoids β -apo-8'-carotenal readily isomerizes to a mixture of its *cis* and *trans* stereoisomers when its solutions are heated to about 60°C or exposed to ultraviolet light (48).

In general, its solubility characteristics are similar to those of β -carotene except that it is slightly more soluble in the usual solvents. In addition, because of its aldehydic group, β -apo-8'-carotenal is slightly soluble in polar solvents such as ethanol. Vegetable oil solutions of the colorant are orange to red, depending on their concentration. Aqueous dispersions range in hue from orange to orange-red.

β -Apo-8'-carotenal is sold as a dry powder, as 1–1.5% vegetable oil solutions, as 20% suspensions in vegetable oil, as 2–4% solutions in a mixture of monoglycerides and dl- α -tocopherol, and as 10% dry beadlets. The vegetable-oil suspensions are purplish black fluids at room temperatures that set to thick pastes when refrigerated. The dry beadlets are colloidal dispersions of colorant in a matrix of gelatin, vegetable oil, sugar, starch, and antioxidants (44, 45).

β -Apo-8'-carotenal is used wherever an orange to reddish orange shade is desired. The dry beadlets are water-dispersible and can be used to color aqueous-based foods and beverages such as juices, fruit drinks, soups, jams, jellies, and gelatins. The vegetable-oil solutions and suspensions are most useful in fat base or fat-containing foods including processed cheese, margarine, salad dressings, fats, and oils. It is used in the range 1–20 ppm as pure color (43).

6.5. Canthaxanthin. The newest of the synthetically produced carotenoid color additives, canthaxanthin [514-78-3] (β -carotene-4-4'-dione), became commercially available about 1969 (49). Its CI designation is Food Orange 8, CI No. 40850. Its EEC designation is E 160g.

Unknown until 1950 when F. Haxo isolated it from an edible mushroom (*Cantharellus cinnabarinus*), canthaxanthin has since been identified in sea

trout, algae, daphnia, salmon, brine shrimp, and several species of flamingo. Crystalline canthaxanthin is prepared synthetically from acetone or β -ionone using procedures similar to those used for β -carotene and β -apo-8'-carotenal (44).

Canthaxanthin crystallizes from various solvents as brownish violet, shiny leaves that melt with decomposition at 210°C. As is the case with carotenoids in general, the crystals are sensitive to light and oxygen and, when heated in solution or exposed to ultraviolet light or iodine, form a mixture of cis and trans stereoisomers. Consequently, crystalline canthaxanthin should be stored under inert gas at low temperatures. Unlike the carotenoid colorants β -carotene and β -apo-8'-carotenal, canthaxanthin has no vitamin A activity. It is chemically stable at pH 2–8 (the range normally encountered in foods) and unaffected by heat in systems with a minimal oxygen content.

The solubility of canthaxanthin in most solvents is low compared with β -carotene and β -apo-8'-carotenal. Oil solutions of canthaxanthin are red at all concentrations. Aqueous dispersions are orange or red depending on the type of emulsion prepared.

Besides as a dry powder, canthaxanthin is commercially available as a water-dispersible, dry beadlet composed of 10% colorant, gelatin, vegetable oil, sugar, starch, antioxidants, and preservatives (56). Canthaxanthin is used at 5–60 ppm as pure color to produce a tomato red. The colorant is useful in coloring tomato products such as tomato soup, spaghetti sauce, and pizza sauce, Russian and French dressings, fruit drinks, sausage products, and baked goods (43).

6.6. Caramel. Officially, the color additive caramel is the dark brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates: dextrose, invert sugar, lactose, malt syrup, molasses, starch hydrolysates and fractions thereof, or sucrose. Practically speaking, caramel is burned sugar.

Caramel (CI Natural Brown 10, EEC No. E 150) is most often made from liquid corn syrup with a reducing sugar content of 60% or more, expressed as dextrose. Sucrose (cane sugar) is less frequently used because of its relatively high cost and because after inversion, dextrose and levulose react at different rates, making the burning process difficult to control, sometimes resulting in a product inferior to that made from corn sugar. In most cases a small amount of an approved acid, alkali, or salt is used to expedite the reaction and to obtain products with specific properties for specific applications.

To prepare caramel, corn syrup and the appropriate reactants are cooked at about 121°C for several hours or until the proper tinctorial power has been obtained. The product is then filtered and stored cool to minimize further caramelization. Often it is drum- or spray-dried to produce free-flowing powders containing 5% or less moisture (50, 51).

Because of the many variables in ingredients and process conditions involved in manufacture, caramel's exact chemical composition is unknown. Caramel coloring is freely soluble in water and insoluble in most organic solvents. Its solubility in solutions containing 50–70% alcohol varies with the type of caramel. In concentrated form the colorant has a distinctive burned taste that is unnoticeable at the typical levels of use. The specific gravity of caramel coloring syrups ranges from 1.25 to 1.38; the total solids content varies from 50 to 75%. The pH of the acid-proof caramels used for carbonated beverages and acidified solutions is

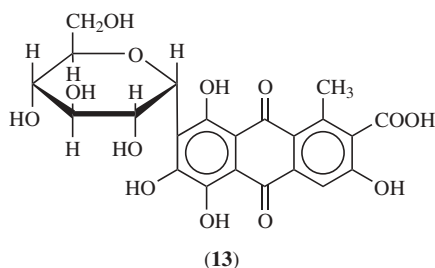
normally 2.8–3.5. Most bakers' caramels, which are a less refined grade of colorant used for cookies, cakes, bread, and so on, have a higher pH because of differences in their manufacturing processes (52).

In aqueous solution, caramel coloring exhibits colloidal properties; the particles carry small positive or negative electrical charges, depending on the method used in its manufacture and the pH of the product being colored. The nature of this charge is most important in using caramel since it must be the same as that of the product it is added to, or else mutual attraction will occur causing flocculation or precipitation. A good soft drink caramel should carry a strong negative charge and have an isoelectric point at pH 1.5 or less. Beer caramel usually has a positive charge.

Seventy-five to eighty-five percent of the caramel produced in the United States is used in soft drinks, particularly root beers and colas. Caramel is also used extensively to standardize the hue of blended whiskeys, liqueurs, wines, and beer. Other uses include the coloring of baked goods, syrups, preserves, candies, pet foods, gravies, canned meat products, soups, condiments, vinegars, and dark sugars (53). Where the use of liquid coloring is impractical, such as in cake mixes and other dry products, powdered caramel is added. Typical use levels are high (0.1–30%), but the colorant is relatively inexpensive and shows good stability in most products.

Shades that can be produced using caramel colorants range from delicate yellows to reds to the darkest browns.

6.7. Cochineal Extract. Cochineal extract (CI Natural Red 4, EEC No. E 120) is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal, which is the dried bodies of the female insect *Coccus cacti* (*Dactylopius coccus costa*), a variety of field louse. The coloring principle of the extract is believed to be carminic acid [1260-17-9] (**13**), an hydroxyanthraquinone linked to a glucose unit, comprising approximately 10% of cochineal and 2–4% of its extract.



Carminic acid [1390-65-4] is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principle (again, chiefly carminic acid) obtained by the aqueous extraction of cochineal. Carmine is normally 50% or more carminic acid.

The cochineal insect lives on a species of cactus (*Nopalea coccinellifera*) and was once known only in Mexico. The Aztecs cultivated it for its color value and often exacted it as tribute. It is believed that Cortez found native Mexicans using cochineal in 1518 and at first believed it to be kermes, an ancient dyestuff widely used in Europe at the time. The eventual discovery that cochineal was in

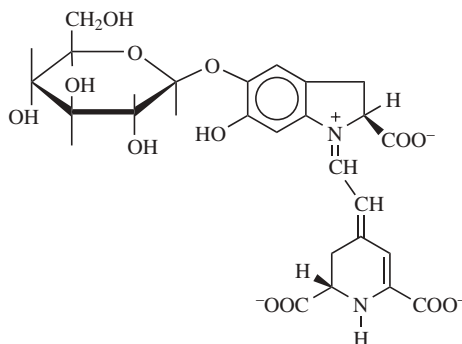
fact a new colorant, and one 10 times stronger than kermes, gave the Spaniards an exclusive on an important and lucrative article of commerce. By the end of the sixteenth century, as much as 230,000 kg of cochineal were being shipped from Mexico to Spain each year, a rather astounding figure considering that it requires over 150,000 hand-gathered insects to make a single kg of cochineal. Numerous attempts were made to raise the cochineal beetle in other areas of the world, but most failed partly because of the specialized climates needed for its cultivation and partly to the Spaniards' doggedness in guarding their monopoly. In spite of these obstacles, cochineal was eventually produced elsewhere, including the Canary Islands, Spain, the East and West Indies, Palestine, and parts of Central and South America. The cochineal trade peaked about 1870 then declined rapidly because of the introduction of synthetic colors in 1856.

Cochineal extract is typically acid (pH 5–5.3) and has a total solids content of about 6%. It frequently contains sodium benzoate as a preservative. Cochineal extract varies in shade from orange to red, depending on pH. It is insoluble in typical solvents including water, glycerol, and propylene glycol but can be dispersed in water. It exhibits good stability toward light and oxidation but poor stability toward pH and microbiological attack. Its tinctorial strength is only moderate. Use levels range from 25–1000 ppm.

Carmine is a pigment and thus exhibits little solubility in most solvents. Since it is also an aluminum lake, it can be solubilized by strong acids and bases that cause degradation of the substratum and release of the color. Both colorants are useful for producing pink shades in retorted meat products, candy, confections, aperitif alcoholic and soft drinks, cider, vinegar, yogurts, ice creams, baked goods, jams, jellies, rouge, eye shadow, and pill coatings (40).

6.8. Dehydrated Beets. This color additive is defined as a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

Beet roots contain both red pigments (betacyanins) and yellow pigments (betaxanthins), known collectively as betalains. Generally, the betacyanin content of beets far exceeds that of the betaxanthins. Of the betacyanins present, 75–95% is betanin [7659-95-2] (**17**) (EEC No. E 162), making it the principal pigment in beet colorant.



(17)

Although many factors influence the actual quantity of pigment present in beet tissue, the average amount has been estimated as 1000 mg/100 g of total solids, or 120 mg/100 g of fresh weight.

Beet extract is also used as a colorant. Extract is sold as either a concentrate prepared by evaporating beet juice under vacuum to a total solids content of 40–60%, or as a powder made by spray-drying the concentrate. Both products usually contain ascorbic or citric acid as a stabilizer, and a preservative such as sodium propionate. On a dry-weight basis, beet extract typically contains between 0.4 and 1.0% betanin, 80% sugar, 8% ash, and 10% crude protein.

Beet colorant readily dissolves in water and water-based products. It is reasonably stable when used from pH 4 to pH 7, and it is adequately light stable. However, beet colorant does degrade readily at temperatures as low as 50°C, particularly when exposed to air or light. It is most stable to heat in the range of pH 4.0–5.0. Because of the carbohydrates present in beet colorant, it tends to carry the natural flavor of beets.

Alone, beet colorant produces hues resembling raspberry or cherry. When used in combination with water-soluble annatto, strawberry shades result.

Beet colorant is best used in foods with short shelf lives that do not require high or prolonged heat treatment. When heat treatment is necessary, degradation of the colorant is minimized by adding it after the heat treatment, or as near the end of the heating cycle as possible. Beet colorant has been used successfully to color such products as hard candies, yogurts, ice creams, salad dressings, ready-made frostings, cake mixes, meat substitutes, powdered drink mixes, gravy mixes, marshmallow candies, soft drinks, and gelatin desserts. Typically, the colorant is added at 0.1–1%, based on the weight of the final product.

6.9. Grape Color Extract and Grape Skin Extract. Grape color extract (EEC No. E 163) is an aqueous solution of anthocyanin grape pigments made from Concord grapes or a dehydrated water-soluble powder prepared from the aqueous solution. The aqueous solution is prepared by extracting the pigments from precipitated less produced during the storage of Concord grape juice. It contains the common components of grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc, but not in the same proportion as found in grape juice. The dehydrated water-soluble powder is prepared by spray drying the aqueous solution containing added malto-dextrin.

The purple color of grape color extract is a result of the presence of water-soluble pigments, mainly the 3-mono- and 3,5-di-glucosides of malvidin, delphinidin, and cyanidin, and their acylated derivatives. Colorant stability is greatest below pH 4.5. Colorant intensity increases as pH falls. Grape color extract is stable to light and at temperatures adequate for canning most fruit. It is affected by oxygen, by SO₂ concentrations greater than 150 ppm, and by metal ions, especially tin, iron, and aluminum, which can complex with anthocyanins to produce a bluer color. Complexation can be controlled somewhat by the addition of metal sequestrants, such as pyrophosphates, EDTA, and citrate. Ascorbic acid appears to improve color stability by acting as an oxygen scavenger.

Grape color extract is used to color such products as bakers jams, non-standard jellies and preserves, sherbets, ices, pops, raspberry, grape and strawberry yogurts, gelatin desserts, canned fruit, fruit sauces, candy and confections, and bakery fillings and toppings. Typical use concentrations are 0.05 to 0.8%, based on the weight of the finished product.

Grape skin extract (enocianina) is a purplish red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes

have been pressed to produce grape juice or wine. It contains the common components of grape juice namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc, but not in the same proportions as found in grape juice. During the steeping process, sulfur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulfur dioxide may be present.

Typically, grape skin extract has a specific gravity of 1.13 g/mL at 20°C, a solids content of 28–32° Brix ($\pm 3^\circ$), a pH of 3.0, and a color strength as anthocyanin of about 1.25% (as measured at 520 nm in pH 3.0 citrate buffer). Grape skin extract is also available as spray-dried powders with color values three to four times those of the liquid. The properties and uses of grape skin extract are similar to those of grape color extract.

6.10. Paprika and Paprika Oleoresins. Paprika is the deep red, sweet, pungent powder prepared from the ground, dried pod of mild capsicum (*Capsicum annuum*). It is one of the two principal kinds of red pepper; the other is cayenne. Paprika is produced in large quantities in Hungary and is also available from many warm-climate areas, including Africa, Spain, and the American tropics. The chief classifications of paprika are Hungarian paprika, which has the pungency and flavor characteristics of that produced in Hungary (Rosenpaprika and Koenigspaprika), and Spanish paprika (pimenton, pimiento).

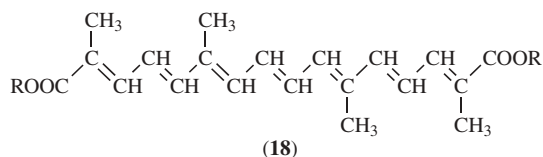
Paprika oleoresin (EEC No. E 160c) is the combination of flavor and color principles obtained by extracting paprika with any one or a combination of approved solvents: acetone, ethyl alcohol, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, and trichloroethylene. Depending on their source, paprika oleoresins are brown-red, slightly viscous, homogeneous liquids, pourable at room temperature, and containing 2–5% sediment.

The oleoresins are available in various standardized forms in which 1 kg of oleoresin is equal to 10–30 kg of paprika. Paprika oleoresins are typically standardized by dilution with vegetable oil or mono- or diglycerides.

Paprika and its oleoresin are approved for use in foods in general where its application as a color additive frequently overlaps its use as a spice. Both products have good tinctorial strength and are used at 0.2–100 ppm to produce orange to bright red shades.

6.11. Saffron. Saffron, known also as CI Natural Yellow 6, safran, crocine, crocétine, and crocus, is the dried stigma of *Crocus sativus*, a plant indigenous to the Orient but also grown in North Africa, Spain, Switzerland, Greece, Austria, and France. It is a reddish brown or golden yellow odoriferous powder having a slightly bitter taste. The stigmas of approximately 165,000 blossoms are required to make 1 kg of colorant (54).

The coloring principles of saffron are crocin [42553-65-1] and crocetin [27876-94-4]. Crocin is the gentiobiose diester of crocetin (18)



(18)

where R = H for crocetin and R = gentiobiose for crocin.

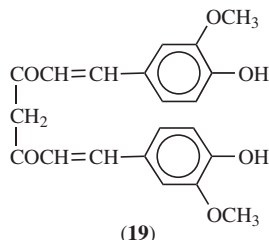
Crocin is a yellow–orange glycoside that is freely soluble in hot water, slightly soluble in absolute alcohol, glycerol, and propylene glycol, and insoluble in vegetable oils. Crocin melts with decomposition at about 186°C and has absorption maxima in methanol at about 464 nm and 434 nm.

Crocetin is a dicarboxylic acid that forms brick red rhombs from acetic anhydride that melt with decomposition at about 285°C. It is very sparingly soluble in water and most organic solvents but soluble in pyridine and similar organic bases as well as in dilute sodium hydroxide.

As a food colorant, saffron shows good overall performance (40). In general, it is stable toward light, oxidation, microbiological attack, and changes in pH. Its tinctorial strength is relatively high, resulting in use at 1–260 ppm.

6.12. Turmeric and Turmeric Oleoresin. Turmeric (CI Natural Yellow 3, EEC No. E 100) is the dried and ground rhizome or bulbous root of *Curcuma longa*, a perennial herb of the Zingiberaceae family native to southern Asia and cultivated in China, India, South America, and the East Indies. It is a yellow powder with a characteristic odor and a sharp taste.

Turmeric oleoresin is the combination of flavor and color principles obtained from turmeric by extracting it with one or a combination of the following solvents: acetone, ethyl alcohol, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, and trichloroethylene.



The principal coloring matter in turmeric and its oleoresin is curcumin [458-37-7] (1,6-heptadiene-3,5-dione, 1,7-bis[4-hydroxy-3-methoxy-phenyl] (19), an orange-yellow, crystalline powder, insoluble in water and ether but soluble in ethanol and glacial acetic acid. It has a reported melting point of 180–183°C.

Turmeric is available in various powdered forms, some containing as much as 90–95% curcumin, and as suspensions in a variety of carriers, including edible vegetable oils and fats, and mono- and diglycerides, most containing 2–6% curcumin. Turmeric oleoresin is most often sold as solutions in propylene glycol with or without added emulsifying agents, typically containing 20–25% curcumin. Both products exhibit poor to moderate stability to light, oxidation, and change in pH but good tinctorial strength. Turmeric is typically used at 0.2–60 ppm, whereas the oleoresin use is higher, 2–640 ppm. Both are used alone or in combination with other colorants such as annatto to shade pickles, mustard, spices, margarine, ice creams, cheeses, pies, cakes, candies, soups, cooking oils, and salad dressings (34). Turmeric and its oleoresin produce bright yellow to greenish yellow shades, and are often used as replacements for FD&C Yellow No. 5.

6.13. Synthetic Iron Oxide. This colorant is one or a combination of various synthetically prepared iron oxides, including the hydrated forms. The naturally occurring oxides are unacceptable as color additives because of the difficulties frequently encountered in purifying them.

Iron oxide (EEC No. E 172) is recognized under various names, including CI Pigment Black 11 and CI Pigment Browns 6 and 7 (CI No. 77499), CI Pigment Yellows 42 and 43 (CI No. 77492), and CI Pigment Reds 101 and 102 (CI No. 77491). The chemical composition and hence the empirical formula of the colorant varies greatly with the method of manufacture used but can generally be represented as $\text{FeO} \cdot x\text{H}_2\text{O}$, $\text{Fe}_2\text{O}_3 \cdot x\text{H}_2\text{O}$, or some combination thereof. Most are made from copperas (ferrous sulfate, $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$). The commonly used forms are the yellow hydrated oxides (ochre) and the brown, red, and black oxides.

The yellow oxides are prepared by precipitating hydrated ferric oxide from a ferrous salt using an alkali, followed by oxidation. The shades obtained range from light lemon yellow to orange, depending on the conditions used for the precipitation and oxidation. Yellow oxides contain about 85% Fe_2O_3 and 15% water of hydration.

Brown oxides are manufactured either by blending mixtures of the red, yellow, and black oxides or by precipitation of an iron salt with alkali followed by partial oxidation of the precipitate. The result is a mixture of red Fe_2O_3 [1309-37-1] and black Fe_3O_4 [1309-38-2], $\text{FeO} \cdot \text{Fe}_2\text{O}_3$.

Red iron oxides are usually prepared by calcining the yellow oxides to form Fe_2O_3 . The shade of the red oxide depends on the characteristics of the original yellow pigment, and the conditions of calcination and ranges from light to dark red. The product is 96–98.5% Fe_2O_3 .

The black oxides are prepared by the controlled precipitation of Fe_3O_4 (treat $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ with NaOH and O_2) to form a mixture of ferrous and ferric oxides.

Iron oxides are stable pigments insoluble in most solvents but usually soluble in hydrochloric acid. Those not soluble in HCl can be fused with potassium hydrogen sulfate, KHSO_4 , and then dissolved in water.

The principal use of iron oxide as a colorant is in cosmetics, particularly eye makeup and face powders. It is also permitted in dog and cat food at concentrations not exceeding 0.25% by weight of the finished food, and in drugs.

6.14. Titanium Dioxide. The specifications of titanium dioxide have been given previously. Titanium dioxide exists in nature in three crystalline forms: anatase, brookite, and rutile, with anatase as the commonly available form. Anatase has a high refractive index (2.52) and excellent stability toward light, oxidation, changes in pH, and microbiological attack. Titanium dioxide is virtually insoluble in all common solvents.

Only synthetically prepared TiO_2 can be used as a color additive. It is permitted in foods to 1% and is used to color such products as confectionary panned goods, cheeses, and icings. It is also widely used in tableted drug products and in numerous cosmetics such as lipsticks, nail enamels, face powder, eye makeup, and rouges, in amounts consistent with good manufacturing practice (32).

The colorant's chief disadvantages are its inability to blend well with the other ingredients usually found in powder formulations, its tendency to produce blue undertones, and its ability to catalyze the oxidation of perfumes.

6.15. Ultramarines. The ultramarines are synthetic, inorganic pigments of somewhat indefinite composition. Basically, they are sodium aluminosulfosilicates with crystal structures related to the zeolites and empirical formulas that can be approximated as $\text{Na}_7\text{Al}_6\text{Si}_6\text{O}_{24}\text{S}_3$. They are intended as the duplicate of the colorants produced from the naturally occurring semiprecious gem lazurite (*Lapis lazuli*). Their color is believed a result of polysulfide linkages in a highly resonant state.

Ultramarines are manufactured by the heat-treating and then very slow cooling of various combinations of kaolin (China clay), silica, sulfur, soda ash, and sodium sulfate plus a carbonaceous reducing agent such as rosin or charcoal pitch. The formulation of ingredients, temperature, time, cooling rate, subsequent treatment, and other variables determines the resultant color. Firing temperatures range from 700–800°C, whereas firing times vary from a few to as many as 150 h.

The basic product of the ignition is Ultramarine Green. This is converted into Ultramarine Blue by further heat treatment in the presence of sulfur, or into Ultramarine Violet by heating with 5% ammonium chloride for four days at 200–250°C. Ultramarine Violet is converted into Ultramarine Red by treating it with gaseous hydrochloric acid at 70–200°C for four hours or by reaction with gaseous nitric acid at higher temperatures.

Ultramarines are insoluble in water and organic solvents but soluble in acids, which cause their discoloration and the liberation of hydrogen sulfide. They have excellent permanency and resistance to alkali but poor tinting and hiding power.

Ultramarine Blue is used in salt intended for animal feed ($\leq 0.5\%$ w/w).

6.16. Miscellaneous Colorants. Other colorants not requiring certification have been defined in the *Code of Federal Regulations*. Most of these are of only minor to moderate importance and have only limited usage.

Carrot oil—The liquid or the solid portion of the mixture, or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carotenoids naturally occurring in carrots.

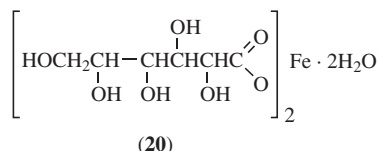
Chlorophyllin-copper complex, oil soluble—The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium that is replaced with hydrogen, which in turn is replaced with copper. This mixture is diluted to 5% concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

Corn endosperm oil—A reddish brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain.

Dried algae meal—A dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3% ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

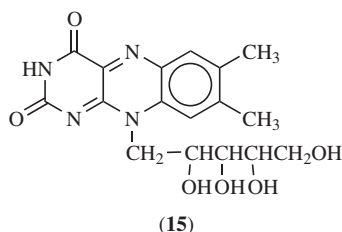
22 COLORANTS FOR FOODS

Ferrous gluconate [299-29-6] (20)—Fine yellowish gray or pale greenish yellow powder or granules having a slight odor resembling that of burned sugar. One gram dissolves in about 10 mL of water with slight heating. It is practically insoluble in alcohol. A 1:20 solution is acid to litmus.



Fruit juice—The concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible fruits; or a water infusion of the dried fruit.

Riboflavin—A yellow or orangish yellow crystalline powder having a slight odor. Riboflavin [83-88-5] (15) melts at about 280°C, and its saturated solution is neutral to litmus. When dry, it is not affected by diffused light, but when in solution, light induces deterioration. One gram dissolves in about 3,000–20,000 mL of water, depending on the internal crystalline structure. It is less soluble in alcohol than in water. It is insoluble in ether and in chloroform but is very soluble in dilute solutions of alkalis. A solution of 1 mg in 100 mL of water is pale greenish yellow by transmitted light and has an intense yellowish green fluorescence that disappears on the addition of mineral acids or alkalis.



Tagetes meal and extract—Tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3% ethoxyquin. Tagetes extract is a hexane extract of the flower petals of the Aztec marigold. It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3% ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

Toasted partially defatted cooked cottonseed flour—This product is prepared by delinting and decorticating food-quality cottonseed. The meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

Vegetable juice—The concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible vegetables.

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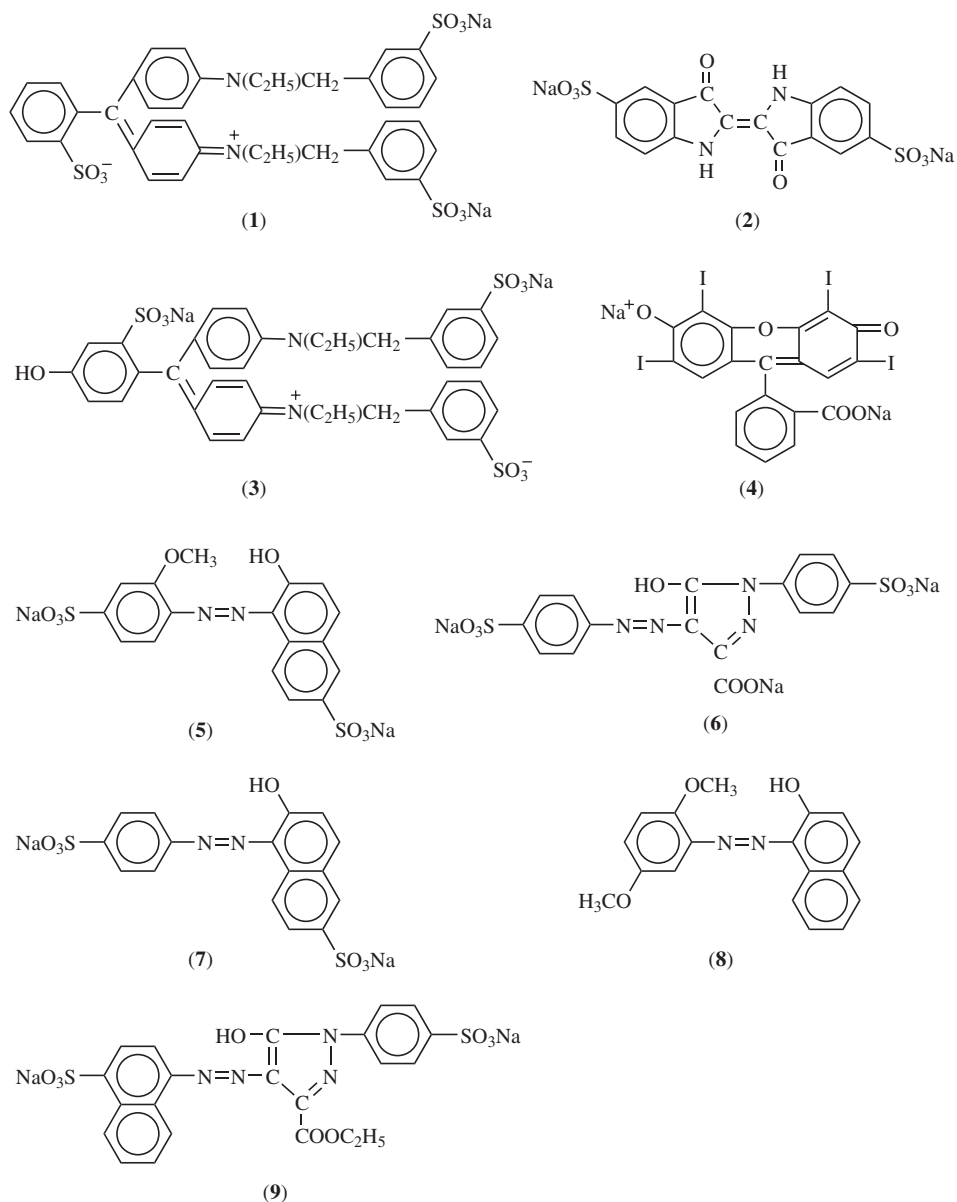


Fig. 1. Colorants for food fall into several dye types. FD&C Blue No. 1 (1) and FD&C Green No. 3 (3) are triphenylmethane dyes (qv). FD&C Blue No. 2 (2) is an indigoid and FD&C Red No. 3 (4) is a xanthene dye. FD&C Red No. 40 (5), FD&C Yellow No. 6 (7), and Citrus Red No. 2 (8), are azo dyes. FD&C Yellow No. 5 (6) and Orange B (9) are pyrazolones.

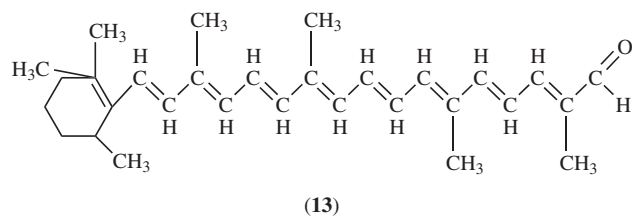
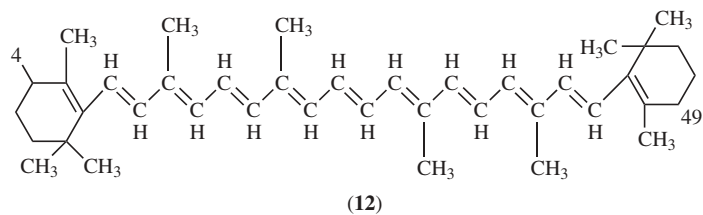


Fig. 2. Carotenoid pigments: β -carotene (**12**), β -apo-8'-carotenal (**13**), and canthaxanthin (**11**) = structure (**12**) with ketone groups at the 4 and 4' positions.

Table 1. Colorants Permitted in Foods

FDA official name	Structure number	Common synonyms	CAS Registry Number	CI number	Uses and restrictions ^a
<i>Subject to certification</i>					
FD&C Blue No. 1 ^b	(1)	Brilliant Blue FCF; CI Food Blue 2	[2650-18-2]		foods, generally
FD&C Blue No. 2 ^b	(2)	Indigotine; Indigo Carmine; CI Food Blue 1	[860-22-0]		
FD&C Green No. 3 ^b	(3)	Fast Green FCF; CI Food Green 3	[2353-45-9]		foods, generally
FD&C Red No. 3 ^b	(4)	Erythrosine; CI Food Red 14	[16423-68-0]		
FD&C Red No. 40 ^b	(5)	Allura Red; CI Food Red 17	[25956-17-6]		
FD&C Yellow No. 5 ^b	(6)	Tartrazine; CI Food Yellow 4	[1934-21-0]		
FD&C Yellow No. 6 ^b	(7)	Sunset Yellow; CI Food Yellow 3	[2783-94-0]		
Citrus Red No. 2	(8)	CI Solvent Red 80	[6358-53-8]		skins of oranges that are not intended or used for processing
Orange B	(9)	CI Acid Orange 137	[15139-76-1]		only; 2.0 ppm max, based on the weight of the whole fruit
annatto extract	^c	<i>Exempt from certification</i>			
β-apo-8'-carotenal		CI Food Orange 6	[8015-67-6] [1107-26-2]		sausage and frankfurter casings or surfaces only; 150 ppm max, based on the weight of the finished product
canthaxanthin	(11)	Food Orange 8; β-carotene-4, 4'-dione	[514-78-3]		max—15 mg/lb (33 mg/kg) of solid or semisolid food, or pint of liquid food (~32 mg/L)
caramel	(12)	CI Natural Brown 10			max—30 mg/lb (66 mg/kg) of solid or semisolid food, or pint of liquid food (~64 mg/L)
β-carotene		CI Natural Yellow 26 CI Food Orange 5	[7235-40-7]	(natural) (synthetic)	food generally above as included
carrot oil	(13)	CI Natural Red 4	[1390-65-4]		chicken feed only
cochineal extract; carmine					
corn endosperm oil					

Table 1. (Continued)

FDA official name	Structure number	Common synonyms	CAS Registry Number	CI number	Uses and restrictions ^a
dehydrated beets (beet powder)	<i>d</i>				chicken feed only ripe olives only
algae meal	(14)				nonbeverage food only
ferrous gluconate					beverages only
fruit juice					cereals, confections and frostings, gelatin desserts
grape color extract					hard and soft candies, nutritional supplement
grape skin extract					tablets and gelatin capsules, and chewing gum
mica-based pearlescent pigments					
paprika					
paprika oleoresin	(15)	Vitamin B ₂	[83-88-5]		
riboflavin	<i>e</i>	CI Natural Yellow 6			
saffron					
sodium copper chlorophyllin					citrus-based dry beverage mixes 0.2% in dry mix extracted from alfalfa

synthetic iron oxide	CI Pigment Reds 101 and 102		dog and cat food only; 0.25% (w/w) max
	CI Pigment Yellows 42 and 43	77492	
tagetes meal and extract	CI Pigment Black 11 and Browns 6 and 7		chicken feed only
titanium dioxide			1% (w/w) max in finished food
toasted partially defatted	CI Pigment White 6	[13463-67-7]	
cooked			
cottonseed flour			
tomato lycopene extract			foods, generally
turneric			
turneric	CI Natural Yellow 3		
oleoresin			
ultramarine blue	CI Pigment Blue 29		salt for animal feed only; 0.5% (w/w) max
vegetable juice			

^aNo color additive or product containing one can be used in the area of the eye, in surgical sutures, or in injections, unless so stated. Also, no colorant can be used to color foods for which standards of identity have been promulgated under Section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by the standard. Colorants without restrictions can be used for coloring foods generally, in amounts consistent with good manufacturing practice.

^bAlso permitted in drugs; uses and restrictions apply thereto. See Figure 1 for structures.

^cSee bixin (**16**, R = CH₃) and norbixin (**36**, R = H).

^dSee betanin (**41**).

^eSee crocin and crocetin (**18**).

^fSee curcumin (**19**).

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Table 2. Solubility^{a,b} of FD&C Colors in Various Solvents

Federal name	Common name	Water	Ethanol	Glycerol	Propylene glycol
FD&C Blue No. 1	Brilliant Blue FCF	20.0	0.15	20.0	20.0
FD&C Blue No. 2	Indigotine	1.6		1.0	0.1
FD&C Green No. 3	Fast Green FCF	20.0	0.01	20.0	20.0
FD&C Red No. 3	Erythrosine	9.0		20.0	20.0
FD&C Red No. 4	Ponceau SX	11.0		5.8	2.0
FD&C Red No. 40	Allura Red	22.0	0.001	3.0	1.5
FD&C Yellow No. 5	Tartrazine	20.0		18.0	7.0
FD&C Yellow No. 6	Sunset Yellow FCF	19.0		20.0	2.2

^aGrams of colorant/100 mL at 25°C.

^bMuch more extensive solubility data at various temperatures is given in Reference 15.

^cTo convert g/100 mL to oz/gal, multiply by 1.3.

Table 3. pH Stability of FD&C Colors^a

Federal name	pH			
	3	5	7	8
FD&C Blue No. 1	slight fade after 1 wk	very slight fade after 1 wk	very slight fade after 1 wk	very slight fade after 1 wk
FD&C Blue No. 2	appreciable fade after 1 wk	appreciable fade after 1 wk	considerable fade after 1 wk	fades completely
FD&C Green No. 3	slight fade after 1 wk	very slight fade after 1 wk	very slight fade after 1 wk	slight fade and appreciably bluer
FD&C Red No. 3	insoluble	insoluble	no appreciable change	no appreciable change

^aFor FD&C Red No. 4, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6 no appreciable change is noticed from pH 3–8.

Table 4. **Stability^a of FD&C Colors Exposed to Common Food Additives**

Federal name	Sodium benzoate, 1%	Ascorbic acid, 1%	Sulfur dioxide, 25 ppm	Sulfur dioxide, 250 ppm
FD&C Blue No. 1	no appreciable change	slight fade after 1 wk	no appreciable change	very slight fade after 1 wk
FD&C Blue No. 2	slight fade after 1 wk	considerable fade after 1 wk	fades completely	fades completely
FD&C Green No. 3	no appreciable change	slight fade after 1 wk	no appreciable change	very slight fade after 1 wk
FD&C Red No. 3	very slight fade after 1 wk	insoluble	insoluble	insoluble
FD&C Red No. 4	no appreciable change	considerable fade after 1 wk	no appreciable change	no appreciable change
FD&C Red No. 40	no appreciable change	no appreciable change	no appreciable change	no appreciable change
FD&C Yellow No. 5	no appreciable change	appreciable fade after 1 wk	appreciable fade after 1 wk	appreciable fade after 1 wk
FD&C Yellow No. 6	no appreciable change	considerable fade after 1 wk	appreciable fade after 1 wk	appreciable fade after 1 wk

^aThese colors show no appreciable change in the presence of various sugars with the exception of FD&C Blue No. 2, which fades considerably after 1 wk in 10% cerelese or dextrose and even fades slightly in 10% sucrose.

Table 5. Solubilities of D&C and Ext. D&C Colorants^a

Federal name	H ₂ O	Glycerol	CH ₃ OH	C ₂ H ₅ OH	Petroleum jelly	Toluene	Stearic acid	Oleic acid	Mineral oil	Ethyl ether	Acetone	Butyl acetate
D&C Blue No. 4	S	S	S	S	C	I	C	C	C	I	Ia	I
D&C Blue No. 6	IU	D	I	I	D	Ia	D	D	D	I	I	I
D&C Blue No. 9	IU	ID	Ia	I	D	Ia	D	D	D	I	I	I
D&C Brown No. 1	S	S	S	SS	IE	I	IE	IE	IE	SS	SS	I
D&C Green No. 5	S	S	S	SS	IE	I	IE	IE	IE	I	SS	I
D&C Green No. 6	I	Ia	SS	SS	M	S	M	M	M	SS	SS	S
D&C Green No. 8	SF	SSF	SSF	SSF	Ia	I	Ia	Ia	I	Ia	Ia	Ia
D&C Orange No. 4	S	S	S	M	IE	I	IE	IE	IE	I	Ia	I
D&C Orange No. 5	IB	SS	S	M	D	I	D	D	D	M	S	I
D&C Red No. 6	S	S	SS	Ia	I	I	I	I	I	I	Ia	I
D&C Red No. 7	I	D	Ia	Ia	D	I	D	D	D	I	Ia	I
D&C Red No. 21	IBF	Da	SS	SS	D	I	D	D	D	M*	S	I
D&C Red No. 22	SF	SF	SF	SF	IE	I	IE	IE	IE	Ia	SS	I
D&C Red No. 27	IB	Da	SS	SS	D	I	D	D	D	Ia	SS	I
D&C Red No. 28	S	S	S	I	IE	I	IE	IE	IE	Ia	SS	I
D&C Red No. 30	IU	D	I	I	I	Ia	D	D	D	Ia	Ia	Ia
D&C Red No. 31	M	SS	SS	SS	I	I	I	I	I	I	Ia	Ia
D&C Red No. 33	S	S	SS	SS	I	I	I	I	I	I	I	I
D&C Red No. 34	I	I	Ia	I	D	I	D	D	D	I	D	D
D&C Red No. 39	Ia	M	M-S	S	I	Ia	I	SS	I	S	S	SS
D&C Violet No. 2	I	Ia	SS	SS	S	S	S	S	S	SS	SS	S
D&C Yellow No. 7	IBF	SSF	SF	SS	D	I	D	D	D	SS*	S	I
D&C Yellow No. 8	SF	SF	SF	M	IE	I	IE	IE	IE	Ia	kIa	I
D&C Yellow No. 10	S	S	M	SS	I	I	I	I	I	Ia	SS	I
D&C Yellow No. 11	I	SS	S	S	S	S	S	S	S	S	S	S
Ext. D&C Violet No. 2	S	S	SS	SS	I	I	I	I	I	I	SS	I
Ext. D&C Yellow No. 7	S	S	M	SS	I	I	I	I	I	I	M	I

^aa = May bleed or stain, very sparingly soluble; B = insoluble in water, soluble in aqueous alkaline solution; C = practically insoluble, but useful in nearly neutral or slightly acid emulsions; D = practically insoluble, but may be dispersed by grinding and homogenizing; solid mediums (waxes) should be softened or melted before or during the grinding; E = practically insoluble in the fatty acid, oil, or wax, but useful in coloring slightly alkaline aqueous emulsions; F = solution usually fluorescent; I = insoluble; k = turns brownish in hue; M = moderately soluble (<1%); S = dissolves (solubility ≥1%); SS = sparingly soluble (<0.25%); U = in alkaline-reducing vats a soluble leuco compound forms; * = practically colorless.

Table 6. Fastness^a Properties^b of D&C and Ext. D&C Colorants

	Light	10% CH ₃ COOH	10% HCl	10% NaOH	0.9% NaCl	5% FeSO ₄	5% Alum	Oxidizing agents	Reducing agents
D&C Blue No. 4	3	5	5	4	6	4	4	2	1
D&C Blue No. 6	6	7I	5I	L6U	I	I	I	6	U
D&C Blue No. 9	7	7I	5I	6IU	I	I	I	6	U
D&C Brown No. 1	3	5	5	6sly	6	p	p	3	1
D&C Green No. 5	5	5	5	5	5	4	4	3	2
D&C Green No. 6	4	5L	5I	6I	I	I	I	3	2
D&C Green No. 8	2	I	I	5	6	4d	4d	3	3
D&C Orange No. 4	5	5	5	2m	6	Jp	Jp	3	3
D&C Orange No. 5	2	4aI	4I	Sr	I	I	I	3	3
D&C Red No. 6	5	5	4	4d	6	p	p	3	1
D&C Red No. 7	6	5I	4I	5I	I	4Id	4I	3	1
D&C Red No. 21	2	3I	3I	5Sr	I	Id	4I	4	4
D&C Red No. 22	2	2py	Ipy	5	6	3d	2y	4	4
D&C Red No. 27	2	3I	3	5Sr	1	I	I	4	4
D&C Red No. 28	3	2p	4p	6	6	z	p	4	4
D&C Red No. 30	6	7I	I	6IU	I	I	I	5	U
D&C Red No. 31	5	5	4	5	6	p	p	3	1
D&C Red No. 33	5	6	3z	5	6	4	4	3	1
D&C Red No. 34	4	5I	4	4I	I	I	I	3	1
D&C Red No. 39	2	Sv	Sv	6Sx	I	4aId	I	3	3
D&C Violet No. 2	4	5I	5I	5I	6I	4I	4I	2	1
D&C Yellow No. 7	2	I	I	S6	I	I	I	3	3
D&C Yellow No. 8	3	3p	3p	6	6	zp	p	3	3
D&C Yellow No. 10	3	5	5	4r	6	z	4	2	5
D&C Yellow No. 11	2	1	5I	Iw	I	I	I	2	5
Ext. D&C Violet No. 2	5	5	5	5	6	4z	4	3	2
Ext. D&C Yellow No. 7	4	5	5	5	6	zd	4	3	3

^a1-very poor fastness; 2-poor fastness; 3-fair fastness; 4-moderate fastness; 5-good fastness; 6-very good fastness; 7-excellent fastness; L-turns orange in hue; sl-slightly; m-turns scarlet in hue; d-hue becomes duller or darker; r-turns redder in hue; v-turns violet in hue; w-becomes tinctorially weaker; x-turns yellow in hue; y-turns yellowish in hue; z-hazy or cloudy.

^bU-in alkaline-reducing vats, a soluble leuco compound forms; I-insoluble; J-tends to thicken or gel the solution; p-dye precipitated as heavy-metal salt or color acid; a-may bleed or stain, very sparingly soluble; S-dissolves (solubility 1%).