

Research Article

Colourants and Additives: Existing and Emerging Safety Concerns

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ABSTRACT

Colour additives have long been used as a means of enhancing the aesthetic value of foods, beverages, and cosmetics and of identifying drugs and other products. Naturally occurring substances such as turmeric, paprika, saffron, and inorganic mineral pigments have been used for thousands of years. In the middle of the nineteenth century, synthetic organic dyes were developed, creating an economical and extensive array of color additives. Certified color additives are synthetic organic compounds. Most exempt colorants are derived from vegetable or mineral sources and are therefore often called "natural"; they can also be made synthetically, however it requires FDA to hold both types of color additives to the same safety standard. Colour additives exempt from certification (also known as 'natural Colour additives') are commonly used in the United States to colour foods, drugs and cosmetics. The US Food and Drug Administration established regulations governing the use of these colour additives, and the labelling of the products that contain them. The safety of these colour additives has been demonstrated by safety testing programs that have yielded a significant amount of toxicology data, and also by a long and well documented history of safe use in the United States and elsewhere. In this study the data supporting the safety of the colour additives that are exempt from certification and approved for use in the USA, and conclude that the safety of these colour additives are well supported by the literature.

Keywords: Colour additives, Colouring agents, FD&C Colours, Certification.

INTRODUCTION

A color additive is any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color. FDA is responsible for regulating all color additives to ensure that foods containing color additives are safe to eat contain only approved ingredients and are accurately labeled¹.

Color additives are used in foods for many reasons:

Increases Acceptability

Unattractive medication can be made more acceptable to the patient by the use of color, and color can also be used to make a preparation more uniform when an ingredient in the formulation has itself a variable appearance from batch to batch.

Stability Purpose

Some of the insoluble colors or pigments have the additional benefit when used in tablet coatings or Gelatin shells of providing useful opacity, which can contribute to the stability of light sensitive active materials in the tablet or capsule formulation. Pigments such as the iron oxides, titanium dioxide, and some of the aluminium lakes are especially useful for this purpose.

Sources of Natural Dyestuffs

Plant sources include roots, berries, flowers, barks and leaves. Red color (dyer's root from Madder plant, Brazilwood, beetroot, cranberry, safflower and orchil), orange color (stigmas of saffron flower), yellow color from (Camomile and Milkwort flowers and Weld), green color (ripe Buckthorn berries, ragweed) and blue color (Woad plant and Spirulina).

To correct natural variations in colour.

To enhance colors that occurs naturally.

To provide color to colorless and "fun" foods.

Additives perform a variety of useful functions in foods that consumers often take for granted. Some additives could be eliminated if we were willing to grow our own food, harvest and grind it, spend many hours cooking and canning, or accept increased risks of food spoilage. Colour additives used in foods, drugs, cosmetics, and medical devices must comply with individual listing regulations issued by FDA. Most products contain only a small amount of color additive.

21 CFR Part 70- colour Additives

These regulations address general provisions for color additives, their packaging and labeling requirements, and the fees for filing a color additive petition to list a new color additive or a new use for a listed color additive.

21 CFR Part 71- colour Additives petitions²

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These regulations describe how to submit a color additive petition to FDA as well as the information FDA requires in order to evaluate the petition

21 CFR Part 73- Listing of colour additives exempt from certification

These regulations list the FDA-approved color additives that are exempt from FDA's certification process. The regulations state the permitted uses, specifications, and restrictions that apply to each of these color additives.

21 CFR Part 74- Listing of colour additives subject to certification

These regulations list the FDA-approved color additives that are subject to FDA's certification process. The regulations state the permitted uses, specifications, and restrictions that apply to each of these color additives.

21 CFR part 80- colour additive certification

These regulations state the fees for color additive certification and describe the certification procedures and requirements.

21 CFR parts 81- General specifications and General restrictions for Provisional colour additives for use in food, drugs and cosmetics

These regulations include the provisional lists of color additives and the color additives whose provisional listings have been terminated.

21 CFR 82 Listing of certified Provisionally Listed colours and specification

These regulations list the provisionally listed color additive lakes, which are subject to FDA's certification process. The regulations state the permitted uses, specifications, and restrictions that apply to each of these color additives.

Color additives are dyes, pigments, or other substances that can impart color when added or applied to a food, drug, cosmetic, or the human body. They can be found in a range of consumer products from cough syrup and eyeliner to contact lenses and cereal.

This includes those used in food (and dietary supplements), drugs, cosmetics, and medical devices. These color additives (except coal-tar hair dyes) are subject by law to approval by the agency and must be used only in compliance with the approved uses, specifications, and restrictions. In the approval process, FDA evaluates safety data to ensure that a color additive is safe for its intended purposes. Color additives that FDA has found to cause cancer in animals or humans may not be used in FDA-regulated products marketed in the United States.

Some colour additives are known as "certifiable." Certifiable colour additives are man-made, derived primarily from petroleum and coal sources. The manufacturer submits a sample from the batch for which it is requesting certification, and FDA tests the sample to determine whether it meets the color additive's requirements for composition and purity. If it does, FDA "certifies" the batch and issues a certification lot number. Only then can that batch be used legally in FDA-regulated products³.

Certified color additives have special names consisting of a prefix, such as FD&C, D&C, or Ext. D&C; a color; and

a number. An example is FD&C Yellow No. 6, often found in cereals, ice cream, and baked goods. Sometimes a color additive is identified by a shortened form of its name, consisting of just the color and number, such as Yellow 6.

In the absence of a voluntary action such as a product recall, FDA can issue warning letters, detentions, and import alerts for products that are found to be unsafe or to contain colour additives that are prohibited, misused, or not properly identified as ingredients. FDA can also seize such products. Color additive violations are a common reason for detaining imported cosmetic products that are offered for entry into the United States. Color additives in foods and cosmetics marketed abroad are not subject to the same safeguards as those marketed in the United States.

There are major three categories of food colours;

Natural colours

Synthetic colours

Lakes and dyes

Natural Food Color

Natural Food Color is any dye, pigment or any other substance obtained from vegetable, animal, mineral, or source capable of colouring food drug, cosmetic or any part of human body, colours come from variety of sources such as seeds, fruits, vegetables, algae & insect.

Some examples include:

Caramel coloring (E150), made from caramelized sugar, used in cola products and also in cosmetics.

Annatto (E160b), a reddish-orange dye made from the seed of the Achiot.

A green dye made from chlorella algae (chlorophyll, E140)

Cochineal (E120), a red dye derived from the cochineal insect, *Dactylopius coccus*.

Betanin extracted from beets.

Turmeric (curcuminoids, E100)

Saffron (carotenoids, E160a)

Paprika (E160c)

There are still some food dyes permitted by the FDA.

These dyes don't have enough evidence to warrant a ban. These are:⁴

FD&C Blue Nos. 1 and 2

People getting tube feeds in the ICU tend to have weak GI tracts. Beginning in 1999 a series of reports appeared that indicated Blue no. 1 could pass across the digestive tract and into the blood, often with catastrophic penalty. In 2003, the FDA advised against putting this dye in feeding tubes.

FD&C Red Nos. 3 and 40

Red 40 is one of the most common food dyes (check out Orange Crush) and might promote tumors in animals. Red no. 3 has been around since 1907. Maraschino cherries have been colored with red no. 3. Red no. 3 is an animal carcinogen and is genotoxic

FD&C Yellow Nos. 5 (tartrazine) and 6

These dyes have connections to hypersensitivity reactions. The chemical structure is very similar to benzoate and salicylate (the active ingredient in aspirin).

Yellow no. 5 seems to be mutagenic (aka mutation-causing; DNA-damaging) in animals and might also have random contaminants. Yellow no. 6 might also include contaminants, but doesn't appear to promote cancer.

*Colourants used in Medical Device*⁵

On February 12, 2016, the U.S. Food and Drug Administration (FDA) held a webinar to clarify their current policy in relation to the use of color additives in medical devices. Under Chapter VII, section 721 of the Federal Food, Drug, and Cosmetic, color additives are subject to FDA approval before they may be used in medical devices that come in contact with the bodies of people for a significant period of time. Of particular importance, According to the webinar, "ODE does not consider use of a color additive in or on a device to be in contact with the body for a 'significant period of time' if the contact duration is 30 days or less".

For the purposes of enforcing adulteration provisions under the FD&C Act, unless the color additive and its use conform to a listing regulation under Title 21 of the Code of Federal Regulations (CFR) Parts 73 and 74, including any provision of such regulation prescribing the conditions under which the color additive may be safely used. The color listing regulation may permit use of the color additive in a generic type of device, such as contact lenses, or may place limitations on its use, such as polypropylene non absorbable sutures for general surgical use but not for ophthalmic surgical use.

For devices with no patient contact or in contact with intact skin for up to 30 days, no colour additive information is needed for FDA review.

For devices with other types of contact and a contact duration of less than 24 hours:

For devices with less than 1-minute contact duration, no colour additive information is needed for FDA review unless performance testing reveals evidence of release.

For devices with greater than 1-minute contact duration, no colour additive information is needed for FDA review if cytotoxicity, sensitization, and irritation (CSI) testing is performed with acceptable results and there is no change in the colour/turbidity or presence of particulates observed in device extracts. If CSI testing is not performed with acceptable results or there is a change in the colour/turbidity and/or presence of visible particulates in device extracts, then colour additive information and risk will be needed for FDA review⁶.

3 For devices with other types of contact for 24 hours and up to 30 day

CSI testing and other biocompatibility testing recommended in FDA's G95-1 Blue Book Memorandum is performed with acceptable results and there is no change in the color/turbidity or presence of particulates observed in device extracts, then no color additive information is needed for FDA review.

For devices with tissue contact greater than 30 days, regardless of the type of contact

a. Chemical name and Chemical Abstracts Service (CAS) Number.

b. Purity information, such as CFR colour listing (e.g., 21 CFR 73 and 21 CFR 74), raw material's Certificate of Analysis (COA), or testing for impurities.

c. Maximum amount of each colour additive per device by weight.

d. If the colour additive amount in your device is less than or equal to the compared to device, or the colour additive and impurity amounts in your device are less than their tolerable intake (TI), then no additional information is needed for FDA review. However, additional risk assessment may be needed if the colour additive amount in your device is higher than the comparator device or if the colour additive amount is the same or less than the comparator, but the conditions of device use are not comparable.⁷

*Colour coding in medical device*⁸

Color coding is extremely important in medical devices. The most important factors to consider when using color for function coding are color choice, consistency, and number of colours. Red, green, yellow, orange and blue are the most easily recognized colours. Whichever colours are chosen, they should be used consistently throughout the product. The number of colours used for coding should be as few as possible (one color in addition to the base color that indicates user touch points, for instance, would be best). Numerous studies have found that we can only keep three or four pieces of information in our short term memory at one time. That would suggest that no more than four colours should be used for color coding.

*Colourants used in Drugs*⁹

Unattractive medication can be made more acceptable to the patient by the use of color, and color can also be used to make a preparation more uniform when an ingredient in the formulation has itself a variable appearance from batch to batch.

Some of the insoluble colors or pigments have the additional benefit when used in tablet coatings or gelatin shells of providing useful opacity, which can contribute to the stability of light sensitive active materials in the tablet or capsule formulation. Pigments such as the iron oxides, titanium dioxide, and some of the aluminum lakes are especially useful for this purpose. Colors on the blue side of the spectrum are known as "cool colors" and include blue, purple and green. These colors are often described as calm, but can also call to mind feelings of sadness or indifference.

*Chemistry of natural colorants derived from plants: Purple colour*¹⁰

Purple to blue color *Centaurea cyanus* (Cornflower,) is used for coloring sugar, confectionaries and as one of the ingredient in tea. The petals of cornflower find use in salad, cornbread muffins and also used to garnish food items. It is used traditionally for the treatment of indigestion, regulation of kidney, gall bladder and liver. Its medicinal properties include regulation of menstrual disorder, in increasing immunity and also effective in washing out wounds. It is also used in the treatment of

Table 1: List of natural colours and description.

| Natural colour | E no | Description |
|---|--------|---|
| 1. Annatto | E160b | Liquid/Powder liquid / powder (WS) |
| 2. Turmeric | E100 | Paste, 35% Curcumin Liquid Up To 12% Curcumin Liquid Up To 10% Curcumin Powder, Up To 95% Curcumin |
| 3. Paprika | E 160c | Liquid 10,000 To 1,60,000 Cu Liquid 10,000 To 50,000 Cu Powder, Spray Dried |
| 4. Anthocyanins | E 163 | Liquid / Powder Liquid / Powder Liquid / Powder |
| 5. Beta Carotenes | E 160a | Powder Up To 7.5% Mix Carotenes Carotenoids Liquid (Up To 2.5% Mix Carotenes) |
| 6. Iron Oxides | E 172 | Powder |
| 7. Marigold Extract Paste (Os) | E 161b | Up To 10% Xanthophylls Lutein Powder Up To 50% Lutein |
| 8. Titanium Dioxide Powder Carbon Black E 153 Powder, Paste, Emulsion | E 172 | Paste |

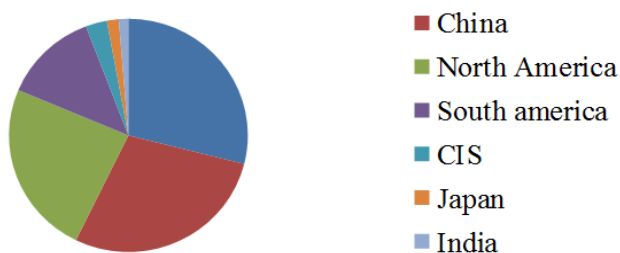


Figure 1: World consumption of inorganic colour pigments.

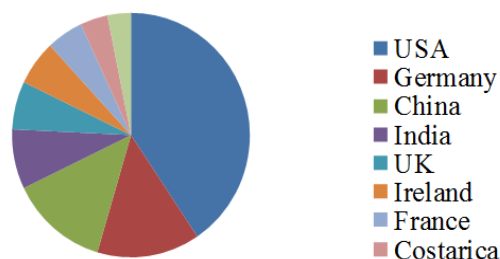


Figure 2: Use of colour pigments in medical devices worldwide.

Table 2: Color Additives Approved for Use in Medical Devices.

| 21 CFR section | Colour | Year Approved | Use |
|----------------|-----------------|---------------|--|
| 74.119 | D&C blue no.9 | 1974 | Cotton and silk surgical sutures; NTE 2.5% general and ophthalmic use. |
| 74.1205 | D&C blue no.5 | 1973 | Nylon 66 no absorbable sutures; NTE 0.6% general surgery. |
| 74.3106 | D&C blue no.6 | 1978 | Polypropylene sutures NTE 0.5% |
| 74.3230 | D&C red no.17 | 1990 | Contact lenses |
| 74.3602 | D&C violet no.2 | 1974 | 0.2 percent by wt in glycolic-lactic acid polyester absorbable sutures |

mouth ulcers, bleeding gums and for constipation. It has antioxidant, antibacterial and astringent properties hence can be used to cure irritated or inflamed skin. It is also used in hair products and cosmetics. The distilled water from its petals is used for weak eyes and conjunctivitis. A dark blue dye can be obtained from the petals of the flower that can be used to color fabric.

Red colour¹¹

Annatto Seeds of annatto are used for coloring Gloucester cheese since the 16th century, following with Cheshire, Red Leicester cheese and cheddar made in Scotland. In Spanish it is called as local saffron. In the European Union, annatto has been given the E number E160b whereas in the United States, annatto extract is listed as a

color additive "exempt from certification" which is informally considered to be a natural coloring. The yellow to orange color is due to the chemical compounds bixin and norbixin, which come under apocarotenoid. The fat soluble color in the crude extract is called bixin, which can then be saponified into water soluble norbixin.

Yellow-orange¹²

Curcuma longa Is one of the most essential spice used all over the world. It is called "the golden spice of life".. Curcumin is the primary pigment of color. It is generally used in various food industries for coloring. Mainly used in dairy products, beverages, cereal, pickles, sausages, confectionaries, ice cream, bakery and savory products. Apart from coloring, it is also used in skin care and hair

Table 3: Features and applications of Pigments used in cosmetics.

| Pigments | Features and applications |
|-------------------|--|
| Iron oxides | Three basic shades: black, yellow and red, finds use in liquid foundations, face powders, and blushers |
| chromium Dioxides | Shades range from dull olive green, to a blue green, or bright green, finds use in most categories of cosmetic preparations but prohibited for use in lip products in the USA. |
| Ultramarines | Shade range from bright blue to violet, pink and green also, not allowed for lip products in the USA. |
| Manganese Violet | Shade is purple. |
| Iron Blue | Colour is dark blue, used in a wide range of applications. |
| White Pigments | White pigments have a wide use in all cosmetics, they show extremely good covering power, are almost totally inert also extremely stable to heat and light. |



Figure 3: Colour wheel- depicting warm and cool colours.

Table 4: List of Harmful and Potentially Harmful Constituents used as colourants.

| HPHC in cigarette smoke | HPHC in smokeless tobacco | HPHC in roll your own tobacco |
|-------------------------|---------------------------|-------------------------------|
| Acetaldehyde | Acetaldehyde | Ammonia |
| Acrolein | Arsenic | Arsenic |
| Acrylonitrile | Benzo[a]pyrene | Cadmium |
| 4-Aminobiphenyl | Cadmium | Nicotine |

care cosmetic products as it is antibacterial in nature. It is also used in Ayurveda medicine as analgesic, anti-inflammatory, antitumor, anti allergic, antioxidant, antiseptic, in treating anemia, diabetes, indigestion, gallstones, food poisoning, poor blood circulation.

Chemistry of natural colorants derived from animals¹³

Dactylopius coccus: is native insect of South America and Mexico. It is a parasite which lives on cacti of genus *Opuntia* feeding on moisture and nutrients. The dye stuff extracted from this insect and its eggs is Carminic acid (Carmine), which is red in color. Carmine is used as a food dye in juices, ice cream, yogurt, and candy, and as a dye in cosmetic products such as eye shadow and lipstick. But as a food dye it has been known to cause severe allergic reactions and anaphylactic shock in some people.

Sepia officinalis: It has rich concentrates of orange-red pigment in the accessory nidamental glands. The pigment is called Sepiixanthine. The dye is called Sepia ink. The sepia pigment is used in capsule printing ink which has

been patented in European Patent Application EP1361258. It is used in Spanish cuisine breaded and deep-fried cuttlefish is a popular dish in Andalusia. In Portugal Chocos com tinta is served as deep-fried strips 'cuttlefish in black ink.

Cephalopod: Another member of the molluscan class Cephalopoda, Cephalopod ink is generally obtainable from fishmongers or gourmet food suppliers and in cooking, it is used as a food coloring and flavoring, in pasta and sauces.

Monascus purpureus: *Monascus purpureus* are fungus. The red pigments produced by this fungus were traditionally used in oriental countries, because of its potential application as food additives. The use of this color ppines, Taiwan among other regions. Oriental countries such as Japan make extensadditive is not yet regulated in the European Union, United States and Brazil, Philiive use of these pigments since decades - as water soluble pigments in candies (Watanabe, 1997), or red pigment for red rice wine. It is also used as cholesterol-lowering agent.

Widely used colorants in pharmaceuticals¹⁴

Betacarotene

(Beta-carotene; β -carotene; β,β -carotene;E160a) Color Index No.: CI 75130 (natural)and CI 40800 (synthetic).

It occurs in the pure state as red crystals when recrystallized from light petroleum. It is capable of producing colors varying from pale yellow to dark orange. It can be used as a color for sugar-coated tablets prepared by the ladle process. However, Beta- carotene is very unstable to light and air, and products containing this material should be securely packaged to minimize degradation. It is particularly unstable when used in spray-coating processes, probably owing to atmospheric oxygen attacking the finely dispersed spray droplets.

Because of its poor water solubility, beta-carotene cannot be used to color clear aqueous systems, and co solvents such as ethanol must be used. Suppositories have been successfully colored with beta- carotene in approximately 0.1% concentration.

Indigo Carmine

It is a dark blue powder. Aqueous solutions are blue or bluish- purple. The primary use of Indigo carmine is as a pH indicator. Indigo carmine is an indigoid dye used to color oral and topical pharmaceutical preparations and also used with yellow colors to produce green colors. It is used as a dye in the manufacturing of capsules. Indigo



Figure 4: Purple – blue pigments derived from *Centaurea cyanus*.



Figure 5: Red pigments derived from Anatto.



Figure 6: Yellow pigments derived from Turmeric.

Carmine is also used to color nylon surgical sutures and is used diagnostically as a 0.8% w/v injection.

Titanium Dioxide (TiO₂)

TiO₂ is also an effective opacifier in powder form, where it is employed as a pigment to provide whiteness and opacity to products such as paints, coatings, plastics, papers, inks, foods, medicines (i.e. pills, tablets and also in topical pharmaceutical formulations) as well as most toothpastes. It is used as a white pigment in film-coating suspensions, sugar-coated tablets, and gelatin capsules. Titanium dioxide may also be admixed with other pigments

Allura Red AC

It has the appearance of a dark red powder. It is approved by the US FDA for use in cosmetics, drugs, and food. This colorant may have slightly less allergy or intolerance reaction by aspirin intolerant people and asthmatics than most of the azo dyes, although those with skin sensitivities should be careful. Allura Red has also been connected with cancer in mice. Not recommended for consumption by children. It is banned in Denmark, Belgium, France, Germany, Switzerland.

Iron Oxides¹⁵

They occur as yellow, red, black, or brown powder. The color depends on the particle size and shape, and the amount of combined water. Iron oxides are widely used

in cosmetics, foods, and pharmaceutical applications as colorants and UV absorbers. As inorganic colorants they are becoming of increasing importance as a result of the limitations affecting some synthetic organic dyestuffs. However, iron oxides also have restrictions in some countries on the quantities that may be consumed and technically their use is restricted because of their limited color range and their abrasiveness.

Colourants for Cosmetics Industry¹⁶

Color cosmetics refer to the colorants and cosmetic ingredients used for make-up, skin care, personal hygiene, hair care, fragrance and oral care. Color cosmetics include products such as foundations, eye shadows, nail paints, powders, lipsticks, concealers, bronzers and other. On the basis of type of product, color cosmetics market can be segmented into face, eye, lip and nail and others.

Dyes have found a wide variety of uses in the cosmetics industry. Be it the hair dyes or lipsticks or nail polish shampoo everywhere there is wide use of dyes. Let us look at hair dyes. Most of the commercial hair dye formulas available now are complex, that uses bunchful of ingredients, and the formulas also differ considerably with manufacturers. Since we are interested in the dye part let's see what kind of dyes are used in making of hair dye. The dye chemicals that are used usually consists of amino compounds, like 4-amino-2-hydroxytoluene and m-Aminophenol. Pigments of Metal oxides, like titanium dioxide and iron oxide, are also used..

Ingredients used in cosmetic industry

Chromium Dioxide

Coal tar dyes associated with cancer include 4-methoxy-m-phenylenediamine (which we spotted in the Naturtint hair color the other day), 2,4-diaminoanisole, 4-chloro-m-phenylenediamine, 2,4-toluenediamine, 2-nitro-p-phenylenediamine, 4-amino-2-nitrophenol. The term lake dyes refers to water insoluble colors. Lake colors can also be derived from coal tar and can trigger allergic reactions. Studies have shown brilliant lake red R to be one of the worst offenders. It should be noted that coal tar is also used as a dandruff therapy in shampoos. In addition to coal tar, cosmetic colors can also be made from chromium oxide and aluminum powder¹⁷.

Aluminum Powder

Aluminium Powder is obtained from naturally occurring aluminium-containing minerals. In cosmetics and personal care products, Aluminium Powder is used in the formulation of eye and facial makeup, hair colouring products, and nail polishes and enamels. Aluminum Powder imparts a white color to cosmetics and personal care products that are applied to the skin, nails and hair.

Iron dioxide pigment

Iron oxides are chemical compounds composed of iron and oxygen. All together, there are sixteen known iron oxides and oxyhydroxides. Iron Oxides used in cosmetic products is an inorganic compound consisting of any one or combinations of synthetically prepared iron oxides that includes hydrated forms of iron oxides. In cosmetics and personal care products, Iron Oxides are

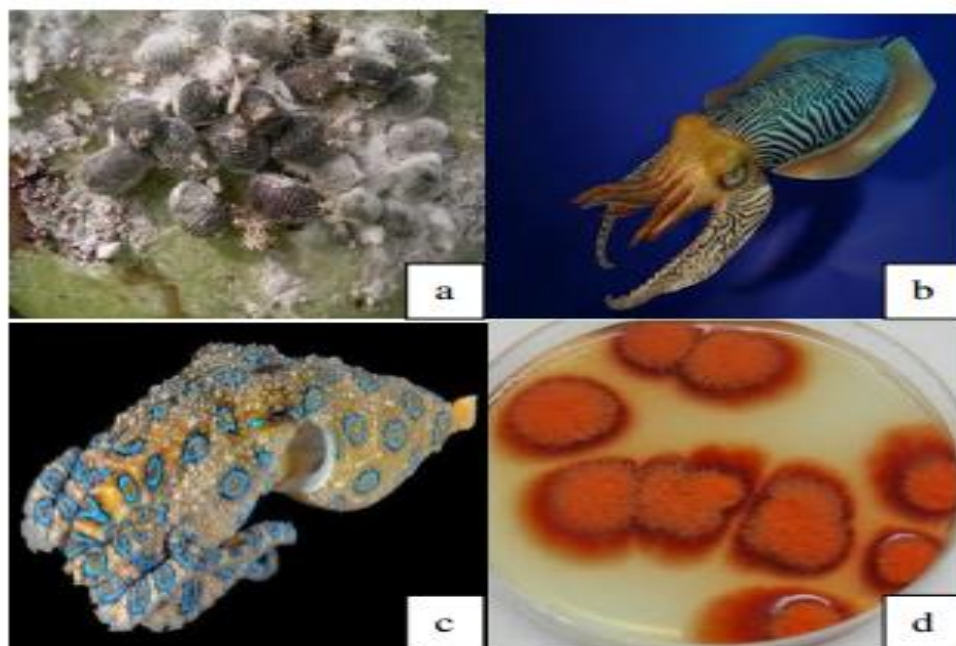


Figure 7: Pigments that are derived from animals [a] *Dactylopius coccus* (Cochineal), [b] *Sepia Officinalis*, [c] Cephalopod and [d] *Monascus purpureus*.

used in the formulation of a wide variety of product types, including makeup and skin care preparations¹⁸.

*Colourants used in Tobacco Products*¹⁹

Tobacco use is the single largest preventable cause of disease and death in the United States. Since 2009, FDA has regulated cigarettes, smokeless, and roll-your-own tobacco. On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The law grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. It also imposes certain obligations on industry, including reporting obligations. Among its many provisions, the Tobacco Control Act added section 904(a)(3) to the FD&C Act. This section requires each tobacco product manufacturer or importer, or an agent, to begin reporting to FDA on June 22, 2012, "all constituents, including smoke constituents, identified by FDA as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product."

In cigarettes, flavours may be added to tobacco, cigarette paper, or the filter, in a plastic pellet placed in the filter or the foil wrapper, in an attempt to enhance the tobacco flavour, mask unpleasant odour, and deliver a pleasant cigarette-pack aroma. Internal industry documents reveal additional flavour technologies such as flavour microencapsulation in the paper, carbon beads, and polymer-based flavour fibres inserted into the filter, flavoured tipping etc.

The Tobacco Products Scientific Advisory Committee (TPSAC) advises the Commissioner or designee in discharging responsibilities as they relate to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues

relating to tobacco products and provides appropriate advice, information and recommendations to the Commissioner of Food and Drugs.

Colours used in Hookah products

*Carbon monoxide*²⁰

(CO) The use of charcoal as a heating source generates large amounts of carbon monoxide (CO)³⁴. Carbon monoxide is colourless, odourless, and tasteless, but highly toxic. CO is a cellular poison which binds to haemoglobin 200 - 300 times more tightly than oxygen and inhibits the release of oxygen from haemoglobin to peripheral tissues, causing tissue hypoxia³⁵.

Nicotine

A quantitative synthesis of limited human data from four nations indicates that daily use of waterpipes produces nicotine absorption of a magnitude similar to that produced by daily cigarette use a meta-analysis of the human data (as noted in the cigarette equivalency section above) indicated that daily use of the waterpipe produced a 24-hr urinary cotinine level equivalent to smoking 10 cigarettes a day.

Phenols

Phenols are chemical compounds thought to promote DNA mutation and cardiovascular diseases. A 2012 study in the Journal of Nicotine and Tobacco Research⁵⁰ found that relative to a single cigarette, a waterpipe delivers at least three times greater quantities of the 7 analysed phenols (phenol, o-cresol, m-cresol, p-cresol, catechol, resorcinol, and hydroquinone).

Polycyclic aromatic hydrocarbons (PAHs)

PAHs are a group of powerful cancer-causing chemicals that can damage DNA and set cells down the road to becoming tumours. One of these chemicals - benzo(a)pyrene or BAP one of the most widely studied of all tobacco poisons. BAP directly damages p53, a gene that normally protects bodies against cancer²¹.

CONCLUSION

Although food additives have been in use since the old era, they have gained huge popularity and utility in the modern times. The scientific use of readymade mixes, flavouring and colouring agents and essences has helped working women in particular, to keep up with the demands on their time. Additives also help in the manufacture of convenience foods that can be rapidly and easily prepared. The wide array of delectable delicacies that have been made possible due to food additives, have been widely misused by the modern world leading to an increase in 'food junkies' and added to the burden of lifestyle diseases. As a result of carcinogenicity, hypersensitivity reactions, and behavioral effects and other toxicological considerations, dyes cannot be considered safe. It is strongly recommended that food and drug regulatory agencies of various countries should rise up and ban food dyes, which serve no purpose other than a cosmetic effect. Japan and all European countries, have banned trading of synthetic color made products. In the meantime, food companies should voluntarily replace dyes with safer, natural colorings, which has been found to be relatively safe and with health benefits. The Food, Drug and Cosmetic Act (the Act) states that devices containing a color additive are considered adulterated unless a regulation is in effect listing the color additive for which it is intended to be used .

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