

**Profile**

Bordeaux B was formerly used as a colouring agent for medicines and foods but has been replaced by other colours.

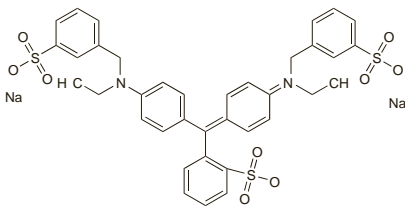
**Brilliant Blue FCF**

Azul brillante FCF; Blue EGS; CI Acid Blue 9; CI Food Blue 2; Colour Index No. 42090; E133; FD & C Blue No. 1; Patent Blue AC. Disodium 4',4''-bis(N-ethyl-3-sulphonatobenzylamino)triphenylmethylum-2-sulphonate.

Бриллиантовый Голубой FCF; Синий Блестящий FCF

$C_{37}H_{34}N_2Na_2O_9S_3 = 792.8$ .

CAS — 3844-45-9.

**Profile**

Brilliant blue FCF is used as a colouring agent in medicines, cosmetics, and foodstuffs. The parent compound, brilliant blue, is under investigation as a stain in ophthalmology.

**Enteral feeds.** Blue colourings such as brilliant blue FCF have been added to enteral feeds to aid the detection of pulmonary aspiration but such use has been associated with toxic effects. Blue discoloration of the skin, initially attributed to cyanosis, has been reported<sup>1</sup> in a child who received a large quantity of brilliant blue FCF as a colouring in an enteral feed. Abnormal systemic absorption of the dye has also been reported<sup>2</sup> in 2 critically ill patients, both of whom subsequently died. As of September 2003 the FDA was aware of 20 cases of blue discoloration of body fluids and skin associated with the use of blue dyes, including 12 fatalities.<sup>3</sup> Most cases occurred in patients with a history of sepsis, suggesting that altered intestinal permeability could be a factor.

- Zillich AJ, et al. Skin discoloration with blue food colouring. *Ann Pharmacother* 2000; **34**: 868-70.
- Lucarelli MR, et al. Toxicity of Food Drug and Cosmetic Blue No. 1 dye in critically ill patients. *Chest* 2004; **125**: 793-5.
- Anonymous. Blue discoloration and death from FD&C Blue No. 1. *WHO Drug Inf* 2003; **17**: 239-40.

**Brown FK**

Chocolate Brown FK; CI Food Brown 1; E154; Marrón FK. A mixture of 6 azo dyes: sodium 2',4'-diaminoazobenzene-4-sulphonate; sodium 2',4'-diamino-5'-methylazobenzene-4-sulphonate; disodium 4,4'-(4,6-diamino-1,3-phenylenebisazo) dibenzenesulphonate; disodium 4,4'-(2,4-diamino-1,3-phenylenebisazo) dibenzenesulphonate; disodium 4,4'-(2,4-diamino-5-methyl-1,3-phenylenebisazo) dibenzenesulphonate; trisodium 4,4',4'-(2,4-diaminobenzene-1,3,5-triazo)tribenzenesulphonate.

Коричневый FK

CAS — 8062-14-4.

**Profile**

Brown FK is used as a colouring agent for foodstuffs.

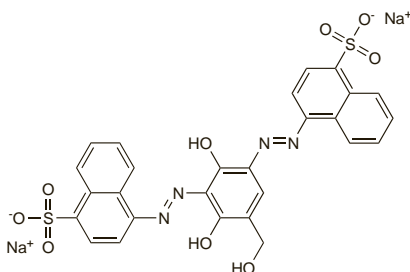
**Brown HT**

Chocolate Brown HT; CI Food Brown 3; Colour Index No. 20285; E155; Marrón HT. Disodium 4,4'-(2,4-dihydroxy-5-hydroxymethyl-1,3-phenylenebisazo)di(naphthalene-1-sulphonate).

Коричневый HT

$C_{27}H_{18}N_4Na_2O_9S_2 = 652.6$ .

CAS — 4553-89-3.

**Profile**

Brown HT is used as a colouring agent for drugs and foodstuffs.

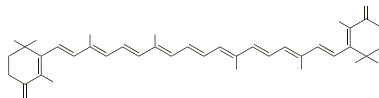
**Canthaxanthin**

Cantaxantina; Canthaxantinum; CI Food Orange 8; Colour Index No. 40850; E161(g); Kantaksantiini; Kantaxantin.  $\beta,\beta$ -Carotene-4,4'-dione.

Кантаксантин

$C_{40}H_{52}O_2 = 564.8$ .

CAS — 514-78-3.

**Profile**

Canthaxanthin is a carotenoid but unlike beta-carotene or  $\beta$ -apo-8'-carotenal it has no vitamin A activity. It has selected uses as a food colouring and is given to salmon, trout, and poultry to colour their flesh, and to laying hens to colour the yolks of their eggs. It is also used to colour drugs and cosmetics.

Canthaxanthin has also been given orally to produce an artificial suntan, and as an adjunct to beta-carotene in the management of erythropoietic protoporphyria (see Porphyrias under Haem Derivatives, p.1448). Such use has led to retinal deposits and in some cases to impairment of vision.

**Adverse effects.** Canthaxanthin has been associated with retinal changes involving accumulation of bright yellow particles around the macula ('gold speck' maculopathy), and alterations in eye function and visual deterioration have occurred.<sup>1,2</sup> Although these reports have related to oral use either for the production of an artificial tan by means of pigment deposition in the skin or for the medical treatment of erythropoietic protoporphyria, there has been concern about the use of canthaxanthin as a food colouring, and it was suggested that it should be restricted to use as a feed additive for farmed salmon and trout in order to produce a coloration of the fish flesh.<sup>1</sup> The results of long-term toxicity studies in animals have led to concern<sup>2</sup> about the potential for hepatotoxicity. However, subsequent studies failed to confirm hepatotoxicity in humans and it is now allowed as a food colouring,<sup>3</sup> although its uses are restricted in some countries.

There has also been a report of fatal aplastic anaemia in a patient who took canthaxanthin in order to produce an artificial tan.<sup>4</sup>

- MAFF. Food advisory committee: final report on the review of the colouring matter in food regulations 1973. *FDAC/REP/4*. London: HMSO, 1987.
- FAO/WHO. Evaluation of certain food additives and contaminants: thirty-fifth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser* 789 1990. Also available at: [http://libdoc.who.int/trs/WHO\\_TRS\\_789.pdf](http://libdoc.who.int/trs/WHO_TRS_789.pdf) (accessed 25/05/07)
- FAO/WHO. Evaluation of certain food additives and contaminants: forty-fourth report of the joint FAO/WHO expert committee on food additives. *WHO Tech Rep Ser* 859 1995. Also available at: [http://libdoc.who.int/trs/WHO\\_TRS\\_859.pdf](http://libdoc.who.int/trs/WHO_TRS_859.pdf) (accessed 25/05/07)
- Bluhm R, et al. Aplastic anemia associated with canthaxanthin ingested for 'tanning' purposes. *JAMA* 1990; **264**: 1141-2.

**Preparations**

**Proprietary Preparations** (details are given in Part 3)

**Arg:** Bronzearte.

**Multi-ingredient Arg:** Bronsul; Sol Bronze Vital.

**Caramel**

Burnt Sugar; Caramelo; Sacch. Ust.; Saccharum Ustum.

Жжёный Сахар; Сахарный Колер

CAS — 8028-89-5.

**Pharmacopoeias.** In *USNF*.

**USNF 26** (Caramel). A concentrated solution of the product obtained by heating sugar or glucose until the sweet taste is destroyed and a uniform dark brown mass results, a small amount of alkali or of alkaline carbonate or a trace of mineral acid being added while heating. It is a thick, dark brown liquid, having the characteristic odour of burnt sugar, and a pleasant bitter taste. One part dissolved in 1000 parts of water yields a clear solution having a distinct yellowish-orange colour. The colour of this solution is not changed and no precipitate is formed after exposure to sunlight for 6 hours. When spread as a thin layer on a glass plate, it appears homogeneous, reddish-brown, and transparent. Miscible with water; immiscible with ether, with chloroform, with acetone, with petroleum spirit, and with benzene; soluble in dilute alcohol up to 55%. Store in airtight containers.

**Profile**

Caramels are used in foods, drugs, and cosmetics to produce pale yellow to dark brown colours. They have no calorific value. They are complex mixtures of compounds prepared by heating carbohydrates (food-grade sweeteners consisting of glucose, fructose, or polymers of these) either alone or in the presence of acids or alkalis (food-grade citric or sulfuric acids or calcium,

potassium, or sodium hydroxides, or mixtures of these). The caramels can be classified according to the reactants used in the manufacturing process:

Class I (E150a, plain caramel, spirit caramel, or caustic caramel); no ammonium or sulfite compounds are used.

Class II (E150b or caustic sulfite caramel); sulfite compounds used but no ammonium compounds.

Class III (E150c, ammonia caramel, or beer caramel); ammonium compounds used but not sulfite compounds

Class IV (E150d, sulfite ammonia caramel, or soft-drink caramel); both ammonium and sulfite compounds used.

Some caramels also have flavouring properties.

**Carbazole Violet**

Colour Index No. 51319; Pigment Violet 23. 8,18-Dichloro-5,15-diethyl-5,15-dihydrodiindolo(3,2-b:3',2'-m)triphenyldioxazine.

Фиолетовый Карбазол

$C_{34}H_{22}Cl_2N_4O_2 = 589.5$ .

CAS — 6358-30-1.

**Profile**

Carbazole violet is a colouring agent used in cosmetics and contact lenses.

**Carmine**

Carmín; CI Natural Red 4; Cochineal Carmine; Colour Index No. 75470; E120.

Кармин

CAS — 1390-65-4.

**Profile**

Carmine is an aluminium lake of the colouring matter of cochineal (p.1471). It contains carminic acid, an anthraquinone glycoside. Unless precautions are taken during manufacture and transport to prevent contamination, carmine may be infected with salmonella micro-organisms.

Carmine and some of its salts are used as colouring agents in medicines, foodstuffs, and cosmetics.

Carmine passes through the gastrointestinal tract unchanged and has been used as a faecal 'marker'.

**Hypersensitivity.** By February 2004 the FDA was aware of 35 cases of hypersensitivity to carmine, carminic acid, or cochineal extract published in the scientific and medical literature and/or reported directly to the FDA. Hypersensitivity reactions to carmine, carminic acid, or cochineal extract included contact dermatitis (4 cases), urticaria/angioedema (9), occupational asthma (10), and systemic anaphylaxis (12). In more than half of these reports, there was evidence of an IgE-mediated diagnostic response. The adverse effects included allergic reactions to foods containing carmine and cochineal extract, occupational asthma from exposure to carmine, and allergic reactions to topically applied cosmetics containing carmine.

The FDA concluded that carmine and cochineal extract may cause potentially severe allergic responses and proposed that food and cosmetic labelling be enhanced; a declaration of inactive ingredients in drugs was already in force.<sup>1</sup>

- Fed Registr* 2006; **71**: 4839-51. Available at: <http://www.cfsan.fda.gov/~lrd/fr060130.html> (accessed 16/11/06)

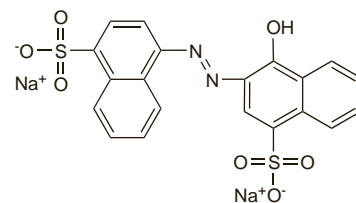
**Carmoisine**

Azorubina; Azorubine; Carmoisina; CI Food Red 3; Colour Index No. 14720; E122. It consists mainly of disodium 4-hydroxy-3-(4-sulphonato-1-naphthylazo)naphthalene-1-sulphonate.

Кармуазин

$C_{20}H_{12}N_2Na_2O_7S_2 = 502.4$ .

CAS — 3567-69-9.

**Profile**

Carmoisine is used as a colouring agent in foods, medicines, and cosmetics. It has also been investigated clinically as a stain, to aid visualisation of malignant neoplasms of the skin during surgery.