



**Food and Agriculture Organization
of the United Nations**

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BRILLIANT BLUE FCF

Chemical and Technical Assessment (CTA)

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1. Summary

This Chemical and Technical Assessment summarizes data and information on Brilliant Blue FCF (INS No. 133), a food colour allowed in the EU, Japan, USA, and other regions. The safety, dietary intake, and specifications for Brilliant Blue FCF were prepared at the 28th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and re-evaluated at the 84th meeting (JECFA, 2017).

2. Description

Brilliant Blue FCF is a synthetic colouring agent that belongs to the class of triphenylmethane dyes. The dye was discovered in 1896 (Sandmeyer, 1896; Colour Index, 1975) and has been used as a food colour since 1929 (USDA, 1929). FCF stands for “For Coloring Food.”

Brilliant Blue FCF consists of disodium 3-[*N*-ethyl-*N*-[4-[[4-[*N*-ethyl-*N*-(3-sulfobenzyl)amino]-phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadiene-1-ylidene]ammoniomethyl]benzenesulfonate (Figure 1) and its isomers together with subsidiary colouring matters, as well as sodium chloride and/or sodium sulfate as the principal uncoloured components. The calcium and potassium salts are also permitted (EU, 2012). The colouring agent is called Food Blue No. 1 in Japan and is certifiable by the USA as FD&C Blue No. 1 (CFR, 2017).

Various chemical names have been assigned to the dye including *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium inner salt, disodium salt. The IUPAC name is disodium;2-[[4-[ethyl-[(3-sulfonatophenyl)methyl]amino]phenyl]-[4-[ethyl-[(3-sulfonatophenyl)methyl]azaniumylidene]-cyclohexa-2,5-dien-1-ylidene]methyl]benzenesulfonate.

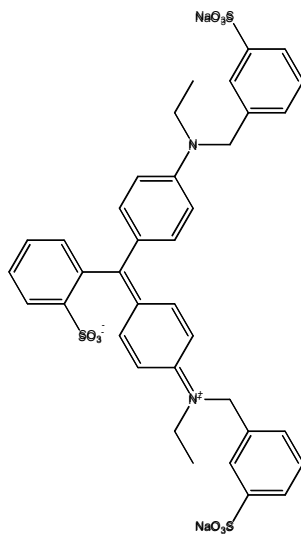
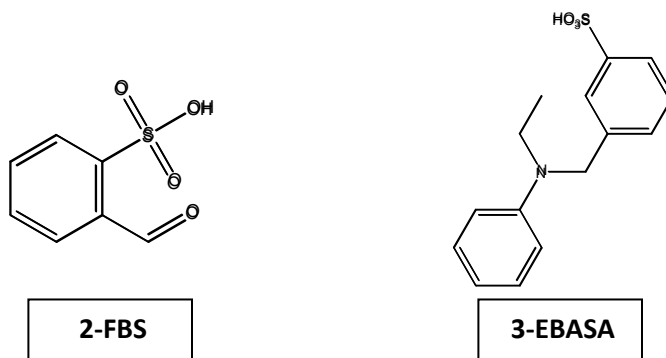


Figure 1. Structure of the primary dye component of Brilliant Blue FCF.

3. *Manufacturing process*

Brilliant Blue FCF is manufactured by condensing 2-formylbenzenesulfonic acid (**2-FBS**, CAS No. 91-25-8, also called *o*-sulfobenzaldehyde), with a mixture of 3-[(*N*-ethyl-*N*-phenylamino)methyl]-benzenesulfonic acid and its 2- and 4- isomers (HSDB, 2006). Oxidation of the leuco base precursor with either chromium or manganese containing compounds produces the dye, which is purified and isolated as the disodium salt.

[(*N*-ethyl-*N*-phenylamino)methyl]-benzenesulfonic acid is known historically as ethylbenzylaniline sulfonic acid and hence is abbreviated as **EBASA**. Commercial samples of EBASA contain ~80% of the 3-isomer, 15-20% of the 4-isomer, and 2% or less of the 2-isomer (Blangey et al., 1942; Heine and Jones, 1953; Wilson and Dolinsky, 1964). The CAS number for the 3-isomer is 101-11-1 and for the 4-isomer is 92-60-4.



Due to the composition of EBASA, multiple isomers of the colour components may be present in the dye (Jones et al., 1955; Kasaka, 1999). Five of the six predicted dye isomers have been quantified in commercial samples, with the principal isomer (3-,3-) found in highest amount (55-65%). The 3-,4-isomer is found in second highest amount (~20%), followed by the 2-,3-; 2-,4-; and 4-,4- isomers

(~1-3%). The 2-,2- isomer is not found due to the small amount of 2-isomer in EBASA.

2-FBS is found in residual amounts in the dye. However, EBASA is never found. An investigation of pure samples of 3-EBASA and 4-EBASA found that the compounds decompose to 3- and 4-FBS, respectively, during the leuco base oxidation step (Schumacher, 1965). Any 2-EBASA present in the starting material presumably also decomposes to 2-FBS. Therefore, 2-, 3-, and 4-FBS are all found as reaction by-products in the dye.

Another reaction by-product found in the dye is 3-[[*N*-ethyl-*N*-(4-sulfophenyl)amino]methyl]benzenesulfonic acid, which is the disulfonated equivalent of 3-EBASA. The corresponding 4-isomer is also found. The compound is known historically as *N*-ethyl-*N*-(3-sulfobenzyl)sulfanilic acid (**ESBSA**) and is an impurity in EBASA that survives the leuco base oxidation step (Johnson, 1967).

Several subsidiary colours are found in commercial samples of the dye (Bell, 1973; Dolinsky, 1953; Dolinsky, 1955; Jones et al., 1955; Kasaka, 1999; Stein, 1969). For example, two are decomposition products of the primary dye component formed by the loss of one sulfonic acid group or one sulfobenzyl group and are known as the “desulfo” and “desulfobenzyl” subsidiary colours (Bell, 1973). Corresponding subsidiary colours formed from isomers of the primary dye component also may be found in much lower amounts.

Chromium or manganese compounds may be used to oxidize the leuco base precursor and this is why limits for both metals have been included in JECFA's specifications.

Brilliant Blue FCF may be converted to the corresponding aluminium lake under aqueous conditions by reacting aluminium oxide with the colouring matter. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate, or aqueous ammonia. Following lake formation, the product is filtered, washed with water, and dried (JECFA, 2004).

4. *Chemical characterization*

Chemical and technical information for Brilliant Blue FCF is summarized in Table 1.

Table 1. Chemical and technical information for Brilliant Blue FCF.

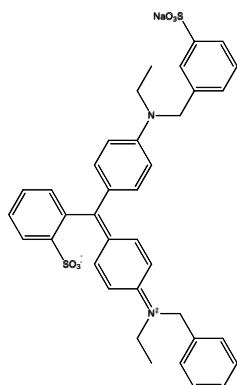
Molecular formula	C ₃₇ H ₃₄ N ₂ Na ₂ O ₉ S ₃
Formula weight	792.86
CAS Registry Number	3844-45-9
Chemical name	Disodium 3-[[<i>N</i> -ethyl- <i>N</i> -[4-[[4-[[<i>N</i> -ethyl- <i>N</i> -(3-sulfobenzyl)amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadiene-1-ylidene]ammoniomethyl]benzenesulfonate
Synonyms	CI Food Blue 2, CI (1975) No. 42090, INS No. 133, E 133, EINECS No. 223-339-8, Food Blue No. 1, certified by USA as FD&C Blue No. 1
Assay	Not less than 85% total colouring matters
Description	Blue powder or granules
Functional uses	Colour
Solubility	Soluble in water; slightly soluble in ethanol

Specifications for Brilliant Blue FCF have been established by JECFA (JECFA, 2006; JECFA, 2017), EU (Commission Regulation (EU) No 231/2012) (EU, 2012), and Japan Ministry of Health, Labour and Welfare (Japan, 2007) and for FD&C Blue No. 1 by US FDA (CFR, 2017). The specifications are summarized in Table 2.

The purity of Brilliant Blue FCF is specified as not less than 85% of total colouring matters, calculated as the disodium salt, and not more than 15% total amount of volatile matter (loss on drying at 135°C), sodium chloride, and sodium sulfate. Impurities include unreacted starting material and reaction by-products (~2%), subsidiary colouring matters (not more than 6%), residual leuco base precursor (not more than 5%), unsulfonated primary aromatic amines (not more than 0.01% calculated as aniline), lead (not more than 2 mg/kg), chromium (not more than 50 mg/kg), and manganese (not more than 100 mg/kg).

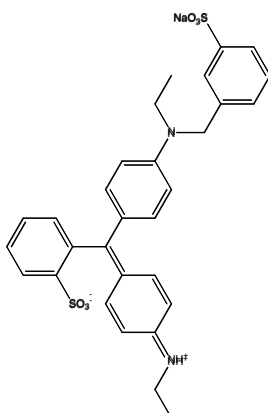
Subsidiary colouring matters include the following compounds.

- Monodesulfonated (“Desulfo”) subsidiary colour as the sodium salt (Bell, 1973; Dolinsky, 1953; Dolinsky, 1955; Jones et al., 1955; Kusaka et al., 1999; Stein, 1969):



“Desulfo” subsidiary color

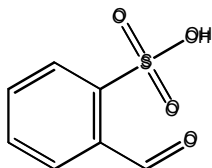
- Monodesulfobenzylated (“Desulfobenzyl”) subsidiary colour as the sodium salt (Bell, 1973; Dolinsky, 1953; Dolinsky, 1955; Jones et al., 1955; Kusaka et al., 1999; Stein, 1969):



“Desulfobenzyl” subsidiary

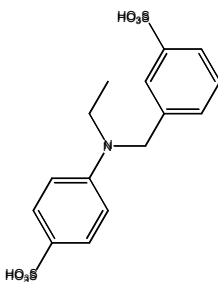
Organic compounds other than colouring matters include the following compounds.

- 2-, 3-, and 4-formylbenzenesulfonic acids (2-, 3-, and 4-FBS):



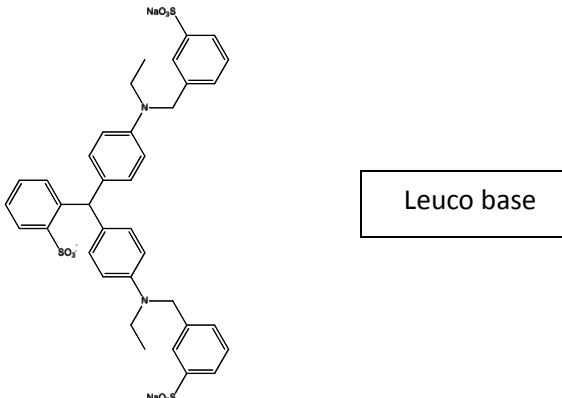
2-FBS
CAS No. 91-25-8
CAS No. 1008-72-6 (sodium salt)

- 3-[[*N*-ethyl-*N*-(4-sulfophenyl)amino]methyl]benzenesulfonic acid, historically called *N*-ethyl-*N*-(3-sulfobenzyl)sulfanilic acid (ESBSA) (Johnson, 1967):



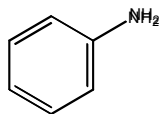
3-ESBSA
CAS No. 5363-53-1

The leuco base precursor for Brilliant Blue FCF has the following structure (Jones et al., 1955; Scher and Murray, 1986; Stein, 1969):



Primary aromatic amines may include the following:

- Aniline



Lead may be found as an impurity. Chromium and manganese also may be found due to their use as oxidizing agents.

5. *Functional use*

Brilliant Blue FCF is allowed as a food colour in the EU, Japan, USA, and other regions. It is used in various types of foods including breakfast cereals, cakes and cupcakes, candies, chewing gum, dairy products, decorations for baking, flavoured water, and frozen treats (Petigara Harp et al., 2013; Doell et al., 2016).

6. *Reactions and fate in foods*

Brilliant Blue FCF is not light or air sensitive and is chemically stable when used in foods.

7. *References*

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Table 2. Specifications for Brilliant Blue FCF.

Specification	JECFA	EU Commission Regulation No. 231/2012	Japan	USA
Assay	Not less than 85% total colouring matters	Not less than 85% total colouring matters	The equivalent of not less than 85% dye component	Total color, not less than 85.0 percent
Loss on drying, chloride and sulfate as sodium salts	Not more than 15% as total amount (loss on drying at 135°)	-	Loss on drying: Not more than 10.0% Chloride and sulfate: Not more than 4.0% as total amount	Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent
Water-insoluble matter	Not more than 0.2%	≤ 0.2 %	Not more than 0.20%	Not more than 0.2%
Subsidiary colouring matters	Not more than 6%	Not more than 6.0%	-	Not more than 6.0%
Organic compounds other than colouring matters - Sum of 2-, 3-, and 4-formylbenzene-sulfonic acids - 3-[[<i>N</i> -ethyl- <i>N</i> -(4-sulfophenyl)amino]-methyl]benzene-sulfonic acid	Not more than 1.5% Not more than 0.3%	Not more than 1.5% 3-((ethyl)(4-sulfophenyl)-amino) methyl benzene sulfonic acid: Not more than 0.3%	Not more than 1.5% Not more than 0.3%	Sum of <i>o</i> -, <i>m</i> -, and <i>p</i> -sulfo-benzaldehydes, not more than 1.5% <i>N</i> -ethyl- <i>N</i> -(<i>m</i> -sulfobenzyl)-sulfanilic acid, not more than 0.3%
Leuco base	Not more than 5%	Not more than 5.0%	-	Not more than 5%
Unulfonated primary aromatic amines	Not more than 0.01% calculated as aniline	≤ 0.01% (calculated as aniline)	Not more than 0.01% as aniline	-
Ether extractable matter	Not more than 0.2%	Not more than 0.2% at pH 7	-	-
Heavy metals	Lead: Not more than 2 mg/kg	Arsenic: Not more than 3 mg/kg	Not more than 50 µg/g Cr Not more than 50 µg/g Mn	Chromium, not more than 50 ppm

	<p>Chromium: Not more than 50 mg/kg</p> <p>Manganese: Not more than 100 mg/kg</p>	<p>Lead: Not more than 2 mg/kg</p> <p>Mercury: Not more than 1 mg/kg</p> <p>Cadmium: Not more than 1 mg/kg</p>	<p>Not more than 20 µg/g Pb</p> <p>Not more than 4.0 µg/g As as As₂O₃</p>	<p>Manganese, not more than 100ppm</p> <p>Arsenic, not more than 3 ppm</p> <p>Lead, not more than 10 ppm</p> <p>Mercury, not more than 1 ppm (<i>GMP specification</i>)</p>
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