



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

**84th JECFA - Chemical and Technical Assessment (CTA), 2017
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FAST GREEN FCF

Chemical and Technical Assessment (CTA)

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1. Summary

This Chemical and Technical Assessment summarizes data and information on Fast Green FCF (INS No. 143), a food colour allowed in Japan, the USA, and other regions but not in the EU. The safety, dietary intake, and specifications for Fast Green FCF were prepared at the 30th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and re-evaluated at the 84th meeting (JECFA, 2017).

2. Description

Fast Green FCF is a synthetic colouring agent that belongs to the class of triphenylmethane dyes. The dye was discovered in 1889 and has been used as a food colour since 1927 (Johnson and Staub, 1927). FCF stands for “For Coloring Food.”

Fast Green FCF consists of disodium 3-[*N*-ethyl-*N*-[4-[[4-[*N*-ethyl-*N*-(3-sulfobenzyl)amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-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 colouring agent is called Food Green No. 3 in Japan and is certifiable by the USA as FD&C Green No. 3 (CFR, 2017).

Various chemical names have been assigned to the dye including *N*-ethyl-*N*-[4[[4-ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium, hydroxide, 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]-5-hydroxybenzenesulfonate.

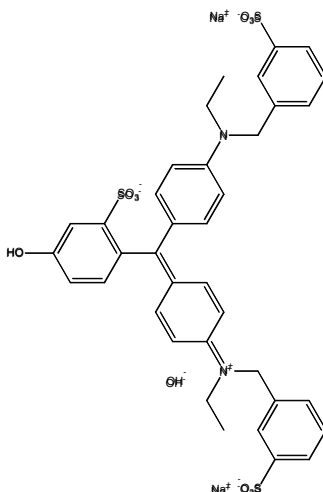
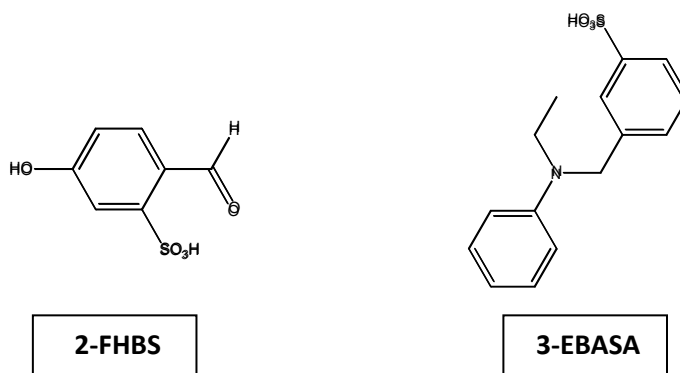


Figure 1. Structure of the primary dye component of Fast Green FCF.

3. Manufacturing process

Fast Green FCF is manufactured by coupling 2-formyl-5-hydroxybenzenesulfonic acid (**2-FHBS**, CAS No. 106086-27-5) 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 (Ngang et al., 2001; Tsuji et al., 2006). 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-FHBSs 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-formylbenzenesulfonic acids (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 (Ngang et al., 2001; Tsuji et al., 2006). 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; Ngang et al., 2001; Tsuji et al., 2006). 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

Fast Green 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 Fast Green FCF is summarized in Table 1.

Table 1. Chemical and technical information for Fast Green FCF.

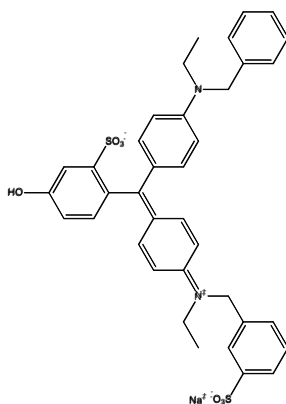
Molecular formula	C ₃₇ H ₃₄ N ₂ Na ₂ O ₁₀ S ₃
Formula weight	808.86
CAS Registry Number	2353-45-9
Chemical name	Disodium 3-[[<i>N</i> -ethyl- <i>N</i> -(4-[[4-[[<i>N</i> -ethyl- <i>N</i> -(3-sulfobenzyl)amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]ammoniomethyl]benzenesulfonate
Synonyms	CI Food Green 3, CI (1975) No. 42053, INS No. 143, Food Green No. 3, certified by USA as FD&C Green No. 3
Assay	Not less than 85% total colouring matters
Description	Blue-green or red-brown powder or granules
Functional uses	Colour
Solubility	Very soluble in water; slightly soluble in ethanol

Specifications for Fast Green FCF have been established by JECFA (JECFA, 2006; JECFA, 2017) and Japan Ministry of Health, Labour and Welfare (Japan, 2007) and for FD&C Green No. 3 by US FDA (CFR, 2017). The specifications are summarized in Table 2.

The purity of Fast Green 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. Specified impurities include uncombined intermediates and reaction by-products originating from the manufacturing process.

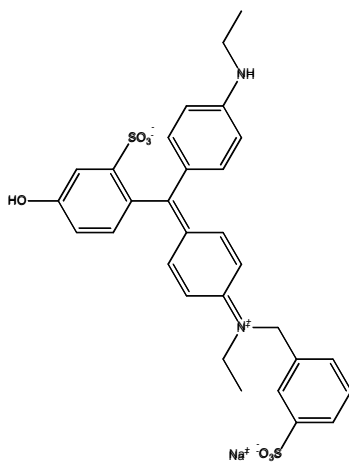
Subsidiary colouring matters include the following compounds.

- Monodesulfonated (“Desulfo”) lower sulfonated subsidiary colour as the sodium salt (Bell, 1973; Ngang et al., 2001; Tsuji et al., 2006):



“Desulfo” subsidiary color

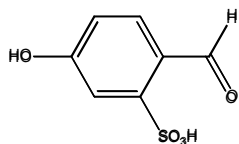
- Monodesulfobenzylated (“Desulfobenzyl”) subsidiary colour as the sodium salt (Bell, 1973; Ngang et al., 2001; Tsuji et al., 2006):



“Desulfobenzyl” subsidiary

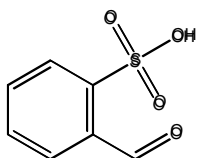
Organic compounds other than colouring matters include the following impurities:

- 2-formyl-5-hydroxybenzenesulfonicacid (2-FHBS)



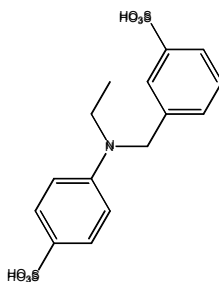
2-FHBS
CAS No. 106086-27-5
CAS No. 119557-97-0(sodium salt)

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



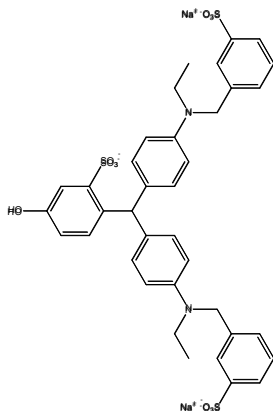
2-FBS
CAS No. 91-25-8
CAS No. 1008-72-6 (sodium salt)

- 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

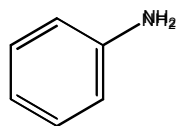
The leuco base precursor for Fast Green FCF has the following structure (Jones et al., 1955; Scher and Murray, 1986):



Leuco base

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*

Fast Green FCF is allowed as a food colour in Japan, the USA, and other regions. It is used in various types of foods including frozen treats, candies, icings, baked goods, and dairy products (Petigara Harp et al., 2013; Doell et al., 2016).

6. **Reactions and fate in foods**

Fast Green 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 Fast Green FCF.

Specification	JECFA	Japan	USA
Assay	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%	Not more than 0.20%	Not more than 0.2%
Subsidiary colouring matters	Not more than 6%	-	Not more than 6.0%
Organic compounds other than colouring matters			
- Sum of 2-, 3- and 4-formylbenzenesulfonic acids, sodium salts	Not more than 0.5%	Not more than 1.5%	Not more than 1.5%
- Sum of 3- and 4-[[N-ethyl-N-(4-sulfo-phenyl)amino]-methyl]benzenesulfonic acids, disodium salts	Not more than 0.3%	Not more than 0.3%	Not more than 0.3%
- 2-formyl-5-hydroxybenzenesulfonic acid, sodium salt	Not more than 0.5%	Not more than 0.5%	Not more than 0.5%
Leuco base	Not more than 5%	-	Not more than 5%
Unulfonated primary aromatic amines	Not more than 0.01% calculated as aniline	Not more than 0.01% as aniline	-
Ether extractable matter	Not more than 0.2%	-	-
Heavy metals	Lead: Not more than 2 mg/kg Chromium: Not more than 50 mg/kg Manganese: Not more than 100 mg/kg	Not more than 50 µg/g Cr Not more than 50 µg/g Mn Not more than 20 µg/g Pb Not more than 4.0 µg/g As as As ₂ O ₃	Chromium, not more than 50 ppm Arsenic, not more than 3 ppm Lead, not more than 10 ppm Mercury, not more than 1 ppm