Food and Agriculture Organization of the United Nations

World Health Organization

Specifications Monograph prepared by the meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 84th meeting 2017

Brilliant Blue FCF

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BRILLIANT BLUE FCF

Prepared at the 84th JECFA and published in JECFA Monograph 20 (2017) superseding specifications prepared at the 28th JECFA (1984) and published in FNP 31/1 (1984) and in FNP 52 (1992). Metals and arsenic specifications revised at the 59th JECFA (2002). An ADI of 0-6 mg/kg bw was established at the 84th JECFA (2017).

SYNONYMS INS No. 133, CI Food Blue 2, CI (1975) No. 42090, FD&C Blue No. 1

DEFINITION Consists essentially 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 and its isomers together with subsidiary colouring matters, as well as sodium chloride and/or sodium sulfate as the principal uncoloured components. It is manufactured by condensing 2-formylbenzenesulfonic acid with a mixture of 3-[(*N*-ethyl-*N*-phenylamino)methyl]benzenesulfonic acid and its 2- and 4- isomers to form the leuco base precursor. 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.

May be converted to the corresponding aluminium lake in which case only the requirements in the *General Specifications for Aluminium Lakes of Colouring Matters* apply.

Chemical names Disodium 3-[*N*-ethyl-*N*-[4-[[4-[*N*-ethyl-*N*-(3-sulfobenzyl)amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadiene-1-ylidene]ammoniomethyl]-benzenesulfonate;

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;

Disodium;2-[[4-[ethyl-[(3-sulfonatophenyl)methyl]amino]phenyl]-[4-[ethyl-[(3-sulfonatophenyl)methyl]azaniumylidene]cyclohexa-2,5-dien-1-ylidene]methyl]benzenesulfonate;

Disodium α-(4-(N-ethyl-3-sulfonatobenzylamino)phenyl)-α-(4-(N-ethyl-3-sulfonatobenzylamino)cyclohexa-2,5-dienylidene)toluene-2-sulfonate

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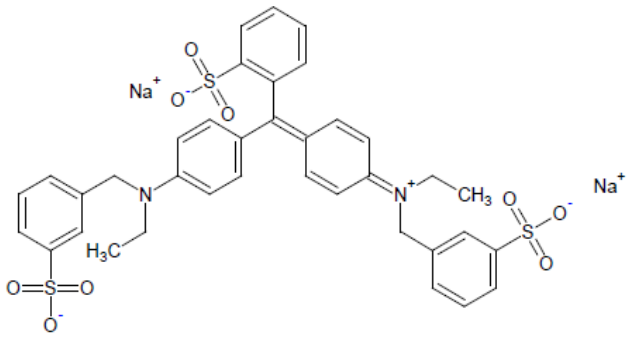
C.A.S. number	3844-45-9
Chemical formula	$C_{37}H_{34}N_2Na_2O_9S_3$
Structural formula	



Formula weight	792.86
Assay	Not less than 85% total colouring matters
DESCRIPTION	Blue powder or granules
FUNCTIONAL USES	Colour
CHARACTERISTICS	
IDENTIFICATION	
Solubility (Vol. 4)	Soluble in water; slightly soluble in ethanol
Spectrophotometry (Vol. 4)	Maximum wavelength approximately 629 nm Determine the UV-visible absorption spectrum of the sample solution dissolved in water.
PURITY	
Loss on drying , chloride and sulfate as sodium salts (Vol. 4)	Not more than 15% as total amount Determine chloride as sodium chloride, sulfate as sodium sulfate, and water content (loss on drying at 135°) as

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	described in Volume 4 (under “Specific Methods, Food Colours”).
Water insoluble matter (Vol. 4)	Not more than 0.2%
Subsidiary colouring matters	Not more than 6% See description under TESTS
Organic compounds other than colouring matters	Not more than 1.5%, sum of 2-, 3- and 4-formylbenzenesulfonic acids Not more than 0.3% 3-[[*N*-ethyl-*N*-(4-sulfophenyl)amino]methyl]-benzene-sulfonic acid See description under TESTS
Leuco base (Vol. 4)	Not more than 5% Weigh accurately 130±5 mg sample and proceed as directed under *Leuco Base in Sulfonated Triarylmethane Colours* (Vol. 4) Absorptivity (a) = 164 L/(g·cm) at 629 nm Ratio = 0.971
Unsulfonated primary aromatic amines (Vol. 4)	Not more than 0.01% calculated as aniline
Ether extractable matter (Vol. 4)	Not more than 0.2%
Lead (Vol. 4)	Not more than 2 mg/kg Determine using a method appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4 (under “General Methods, Metallic Impurities”).
Chromium (Vol. 4)	Not more than 50 mg/kg Determine using a method appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4 (under “General Methods, Metallic Impurities”).
Manganese (Vol. 4)	Not more than 100 mg/kg Determine using a method appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method

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described in Volume 4 (under “General Methods, Metallic Impurities”).

TESTS

PURITY TESTS

Subsidiary colouring matters

Determine subsidiary colouring matters content by reversed-phase HPLC (Vol. 4) using the following conditions:

- Column: C18 (150 mm x 2.1 mm i.d., 5 µm particle size)
- Eluent A: 0.05 M ammonium acetate in water
- Eluent B: 0.05 M ammonium acetate in methanol
- Injection volume: 2 µl
- Column temperature: 40°
- Detector: UV-visible/PDA at 629 nm
- Flow rate: 0.2 mL/min

Gradient:

Elution time (min)	Eluent A (%)	Eluent B (%)
0	90	10
7	60	40
15	52	48
30	45	55
39	30	70
39.1	0	100
44	0	100
44.1	90	10
54	90	10

Standards:

Subsidiary colouring matters – synthesized materials Brilliant Blue FCF (C.A.S. No. 3844-45-9) – TCI, Cat. No. F0147 or equivalent (use if subsidiary colouring matter standards are not available)

Sample preparation:

Weigh accurately 500±5 mg sample and dissolve in 100 mL of water. Dilute the solution, if required, to separate subsidiary colours from the primary colour component.

Calculations:

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Construct the relevant standard curves. Integrate all peaks of the chromatogram obtained at 629 nm. If Brilliant Blue FCF is used as the standard, calculate the ratio of the sum of all peaks not corresponding to Brilliant Blue FCF to the sum of all peaks.

Organic compounds other than colouring matters

Determine organic compounds other than colouring matters content by reversed-phase HPLC (Vol. 4) using the above conditions for subsidiary colouring matters except:

Detector: UV-visible/PDA at 254 nm

Standards:

- 2-Formylbenzenesulfonic acid, sodium salt (C.A.S. No. 1008-72-6) – Sigma-Aldrich, Cat. No. 12050 or equivalent (use for quantitating the 2-, 3-, and 4-isomers)
- 3-[[*N*-ethyl-*N*-(4-sulfophenyl)amino]methyl]benzenesulfonic acid, calcium salt (C.A.S. No. 5363-53-1, acid form) – Wako, Cat. No. 031-23071 or equivalent

Sample preparation:
Weigh accurately 500±5 mg sample and dissolve in 100 mL of water.

Calculations:
Construct the relevant standard curves. Calculate the sum of 2, 3, and 4-formylbenzenesulfonic acids as their sodium salts and 3-[[*N*-ethyl-*N*-(4-sulfophenyl)amino]methyl]benzenesulfonic acid as its sodium salt.

METHOD OF ASSAY

Determine total colouring matters content by spectrophotometry using Procedure 1 in Volume 4 (under “Specific Methods, Food Colours”) and an appropriate solvent.

Using 0.04 M aqueous ammonium acetate as the solvent: absorptivity (a) = 164 L/(g·cm) and wavelength of maximum absorbance = 629 nm.

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