IMPURITIES

Inorganic Impurities

- **ARSENIC (AS AS)**
  Acceptance criteria: NMT 3 mg/kg
- **CHROMIUM (AS CR)**
  Acceptance criteria: NMT 0.005%
- **LEAD (AS PB)**
  Acceptance criteria: NMT 10 mg/kg
- **MANGANESE (AS MN)**
  Acceptance criteria: NMT 0.01%

Organic Impurities

- **UNCOMBINED INTERMEDIATES AND PRODUCTS OF SIDE REACTIONS**
  Acceptance criteria
  ***o*-, *m*-, and *p*-Sulfobenzaldehydes:** NMT 1.5%, combined
  ***N*-Ethyl-*N*-(*m*-sulfobenzyl)sulfanilic acid:** NMT 0.3%

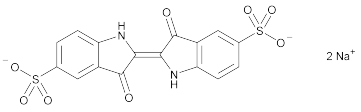
SPECIFIC TESTS

- **ETHER EXTRACTS[3] (COMBINED)**
  Acceptance criteria: NMT 0.4%
- **LEUCO BASE**
  Acceptance criteria: NMT 5%
- **SUBSIDIARY COLORS**
  Acceptance criteria: NMT 6%
- **VOLATILE MATTER (AT 135°) AND CHLORIDES AND SULFATES (AS SODIUM SALTS)**
  Acceptance criteria: NMT 15.0% in combination
- **WATER-INSOLUBLE MATTER**
  Acceptance criteria: NMT 0.2%

FD&C Blue No. 2[1]

First Published: Prior to FCC 6

Indigotine[2]
Indigo Carmine[2]
CI 73015[2]
Class: Indigoid



Formula wt 466.36
INS: 132 CAS: [860-22-0]
UNII: L06K8R7DQK [fd&c blue no. 2]

DESCRIPTION

FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid and the sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid.

Function: Color

Packaging and Storage: Store in well-closed containers.

[NOTE—FDA-certifiable color additives are batch certified by the United States Food and Drug Administration using analytical chemistry methods developed for this purpose by the FDA. The color additive regulations are described in Title 21, Parts 70 to 82, of the United States Code of Federal Regulations (21 CFR Parts 70 to 82). The batch certification process is described in 21 CFR Part 80. Current certification analytical methods are available from the Office of Cosmetics and Colors, Colors Certification Branch (HFS-107), U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland 20740.]

IDENTIFICATION

- **VISIBLE ABSORPTION SPECTRUM**
  Acceptance criteria: A sample dissolved in 0.04 N aqueous ammonium acetate gives a spectrum exhibiting a wavelength maximum at 610 nm, with an absorptivity of 0.0478 L/(mg · cm).

ASSAY

- **TOTAL COLOR**
  Acceptance criteria: NLT 85%

IMPURITIES

Inorganic Impurities

- **ARSENIC (AS AS)**
  Acceptance criteria: NMT 3 mg/kg
- **LEAD (AS PB)**
  Acceptance criteria: NMT 10 mg/kg
- **MERCURY (AS HG)**
  Acceptance criteria: NMT 1 mg/kg

Organic Impurities

- **DECOMPOSITION PRODUCTS**
  Acceptance criteria
  Isatin-5-sulfonic acid: NMT 0.4%
  5-Sulfoanthranilic acid: NMT 0.2%

SPECIFIC TESTS

- **ETHER EXTRACTS[3] (COMBINED)**
  Acceptance criteria: NMT 0.4%
- **SUBSIDIARY AND ISOMERIC COLORS**
  Acceptance criteria
  2-(1,3-Dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, Disodium salt: NMT 18%
  2-(1,3-Dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, Sodium salt: NMT 2%
- **VOLATILE MATTER (AT 135°) AND CHLORIDES AND SULFATES (AS SODIUM SALTS)**
  Acceptance criteria: NMT 15% in combination
- **WATER INSOLUBLE MATTER**
  Acceptance criteria: NMT 0.4%

[3] Not required for certification in the United States.

[1] To be used or sold in the United States, this color additive must be batch certified by the U.S. Food and Drug Administration. The monograph title is the name of the color additive only after batch certification has been completed.

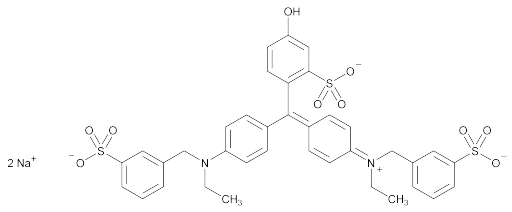
[2] Generic designations; not synonyms for certified batches of color additive.

[3] Not required for certification in the United States.

FD&C Green No. 3[1]

First Published: Prior to FCC 6

Fast Green FCF[2]
CI 42053[2]
Class: Triphenylmethane



$C_{37}H_{34}N_2O_{10}S_3Na_2$ Formula wt 808.86
INS: 143 CAS: [2353-45-9]
UNII: 3P3ONR6O1S [fd&c green no. 3]

DESCRIPTION

FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl] amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemeth-anaminiumhydroxide, with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino] phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzene methanaminium hydroxide.

Function: Color

Packaging and Storage: Store in well-closed containers.

[NOTE—FDA-certifiable color additives are batch certified by the United States Food and Drug Administration using analytical chemistry methods developed for this purpose by the FDA. The color additive regulations are described in Title 21, Parts 70 to 82, of the United States *Code of Federal Regulations* (21 *CFR* Parts 70 to 82). The batch certification process is described in 21 *CFR* Part 80. Current certification analytical methods are available from the Office of Cosmetics and Colors, Colors Certification Branch (HFS-107), U.S. Food and Drug Administration, 5100 Paint Branch Parkway, College Park, Maryland 20740.]

IDENTIFICATION

- **VISIBLE ABSORPTION SPECTRUM**
  Acceptance criteria: A sample dissolved in 0.04 N aqueous ammonium acetate gives a spectrum exhibiting a wavelength maximum at 625 nm, with an absorptivity of 0.156 L/(mg · cm).

ASSAY

- **TOTAL COLOR**
  Acceptance criteria: NLT 85%

IMPURITIES

Inorganic Impurities

- **ARSENIC (AS AS)**
  Acceptance criteria: NMT 3 mg/kg
- **CHROMIUM (AS CR)**
  Acceptance criteria: NMT 0.005%
- **LEAD (AS PB)**
  Acceptance criteria: NMT 10 mg/kg
- **MERCURY (AS HG)**
  Acceptance criteria: NMT 1 mg/kg

Organic Impurities

- **UNCOMBINED INTERMEDIATES AND PRODUCTS OF SIDE REACTIONS**
  Acceptance criteria
  Sum of 3- and 4-[[Ethyl(4-sulfophenyl) amino]methyl]benzenesulfonic acid, Disodium salts: NMT 0.3%
  Sum of 2-, 3-, and 4-Formylbenzenesulfonic acid, Sodium salts: NMT 0.5%
  2-Formyl-5-hydroxybenzenesulfonic acid, Sodium salt: NMT 0.5%

SPECIFIC TESTS

- **ETHER EXTRACTS[3] (COMBINED)**
  Acceptance criteria: NMT 0.4%
- **LEUCO BASE**
  Acceptance criteria: NMT 5%
- **SUBSIDIARY COLORS**
  Acceptance criteria: NMT 6%
- **VOLATILE MATTER (AT 135°) AND CHLORIDES AND SULFATES (AS SODIUM SALTS)**
  Acceptance criteria: NMT 15.0% in combination
- **WATER-INSOLUBLE MATTER**
  Acceptance criteria: NMT 0.2%

[1] To be used or sold in the United States, this color additive must be batch certified by the U.S. Food and Drug Administration. The monograph title is the name of the color additive only after batch certification has been completed.
[2] Generic designations; not synonyms for certified batches of color additive.

FD&C Red No. 3[1]

First Published: Prior to FCC 6

Erythrosine[2]
CI 45430[2]
Class: Xanthene

[3] Not required for certification in the United States.
[1] To be used or sold in the United States, this color additive must be batch certified by the U.S. Food and Drug Administration. The monograph title is the name of the color additive only after batch certification has been completed.
[2] Generic designations; not synonyms for certified batches of color additives.