FD&C Green No. 3

First Published: Prior to FCC 6

Fast Green FCF
CI 42053
Class: Triphenylmethane

FD&C Red No. 3

First Published: Prior to FCC 6

Erythrosine
CI 45430
Class: Xanthene

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-sulfobenzene methanaminium hydroxide, 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]-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 anthaminium hydroxide; 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.

SPECIFIC TESTS

- **Ether Extracts** (Combined)
  Acceptance criteria: NMT 0.4%

- **Leuco Base**
  Acceptance criteria: NMT 5%

- **Subsidiary Colors**
  Acceptance criteria: NMT 6%

- **Volatile Matter (At 135°C) and Chlorides and Sulfates (As Sodium Salts)**
  Acceptance criteria: NMT 15.0% in combination

- **Water-Insoluble Matter**
  Acceptance criteria: NMT 0.2%

**Not required for certification in the United States.**

**Not required for certification in the United States.**
FD&C Red No. 3

**DESCRIPTION**
FD&C Red No. 3 is principally the monohydrate of 9-(o-carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins.

**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 0.05% aqueous ammonium hydroxide gives a spectrum exhibiting a wavelength maximum at 527 nm, with an absorptivity of 0.110 L/(mg · cm).

**ASSAY**

- **Total Color**
  Acceptance criteria: NLT 87.0%

**IMPURITIES**

**Inorganic Impurities**
- **Arsenic (As As)**
  Acceptance criteria: NMT 3 mg/kg
- **Lead (As Pb)**
  Acceptance criteria: NMT 10 mg/kg

**Organic Impurities**
- **Uncombined Intermediates and Products of Side Reactions**
  Acceptance criteria:
  - 2-(2,4-Dihydroxy-3,5-diiodobenzoyl) benzoic acid: NMT 0.2%
  - Sodium iodide: NMT 0.4%
  - Triiodoresorcinol: NMT 0.2%
  - Unhalogenated intermediates: NMT 0.1%, total

**SPECIFIC TESTS**

- **Ether Extracts**
  Acceptance criteria: NMT 0.2%

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FD&C Red No. 40

**First Published:** Prior to FCC 6

**DESCRIPTION**
FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic 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 500 nm, with an absorptivity of 0.052 L/(mg · cm).

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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.