Ethyl or Methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, Sodium salt: NMT 0.1%
4,4′-(1-Triazene-1,3-diyl)bis [benzenesulfonic acid], Disodium salt: NMT 0.05%
4-Aminoazobenzene: NMT 75 µg/kg
4-Aminobiphenyl: NMT 5 µg/kg
Aniline: NMT 100 µg/kg
Azobenzene: NMT 40 µg/kg
Benzidine: NMT 1 µg/kg
1,3-Diphenyltriazene: NMT 40 µg/kg

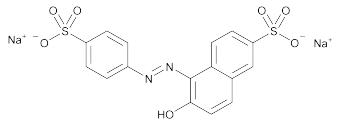
SPECIFIC TESTS

- **ETHER EXTRACTS**[3]
  Acceptance criteria: NMT 0.2%
- **VOLATILE MATTER (AT 135°) AND CHLORIDES AND SULFATES (AS SODIUM SALTS)**
  Acceptance criteria: NMT 13% in combination
- **WATER-INSOLUBLE MATTER**
  Acceptance criteria: NMT 0.2%

FD&C Yellow No. 6[1]

First Published: Prior to FCC 6

Sunset Yellow FCF[2]
CI 15985[2]
Class: Monoazo



Formula wt 452.37
INS: 110 CAS: [2783-94-0]
UNII: H77VEI93A8 [fd&c yellow no. 6]

DESCRIPTION

FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalene-sulfonic acid. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid may be added in small amounts.

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 of 484 nm, with an absorptivity of 0.054 L/(mg · cm).

ASSAY

- **TOTAL COLOR**
  Acceptance criteria: NLT 87%

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

- **UNCOMBINED INTERMEDIATES AND PRODUCTS OF SIDE REACTIONS**
  Acceptance criteria
  4-Aminoazobenzene: NMT 50 µg/kg
  4-Aminobiphenyl: NMT 15 µg/kg
  Aniline: NMT 250 µg/kg
  Azobenzene: NMT 200 µg/kg
  Benzidine: NMT 1 µg/kg
  1,3-Diphenyltriazene: NMT 40 µg/kg
  1-(Phenylazo)-2-naphthalenol: NMT 10 mg/kg
  4-Aminobenzenesulfonic acid, Sodium salt: NMT 0.2%
  6-Hydroxy-2-naphthalenesulfonic acid, Sodium salt: NMT 0.3%
  6,6′-Oxybis[2-naphthalenesulfonic acid], Disodium salt: NMT 1%
  4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], Disodium salt: NMT 0.1%
  Sum of 6-Hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid, Sodium salt and 4-[(2-Hydroxy-1-naphthalenyl)azo]benzene-sulfonic acid, Sodium salt: NMT 1%
  Sum of 3-Hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid, Trisodium salt and Other higher sulfonated subsidiaries: NMT 5%

SPECIFIC TESTS

- **ETHER EXTRACTS**[3] **(COMBINED)**
  Acceptance criteria: NMT 0.2%
- **VOLATILE MATTER (AT 135°) AND CHLORIDES AND SULFATES (AS SODIUM SALTS)**
  Acceptance criteria: NMT 13.0% in combination
- **WATER-INSOLUBLE MATTER**
  Acceptance criteria: NMT 0.2%

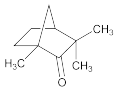
[3] Not required for certification in the United States.
[1] To be used or sold in the United States, this color additive must be batch certified by the U.S. Food and Drug Administration. The monograph title is the name of the color additive only after batch certification has been completed.
[2] Generic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

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

(+)-Fenchone

First Published: Prior to FCC 6
Last Revision: First Supplement, FCC 7

d-Fenchone



$C_{10}H_{16}O$ Formula wt 152.24
FEMA: 2479
UNII: S436YKU51N [fenchone, (+)-]

DESCRIPTION

(+)-Fenchone occurs as a colorless to pale yellow liquid.
Odor: Camphoraceous
Solubility: Soluble in propylene glycol, vegetable oils; insoluble or practically insoluble in water
Boiling Point: ~192°
Solubility in Alcohol, Appendix VI**:** One mL dissolves in 1 mL of 95% ethanol.
Function: Flavoring agent

IDENTIFICATION

- **INFRARED SPECTRA**, *Spectrophotometric Identification Tests,* Appendix IIIC
  Acceptance criteria: The spectrum of the sample exhibits relative maxima at the same wavelengths as those of the spectrum below.

ASSAY

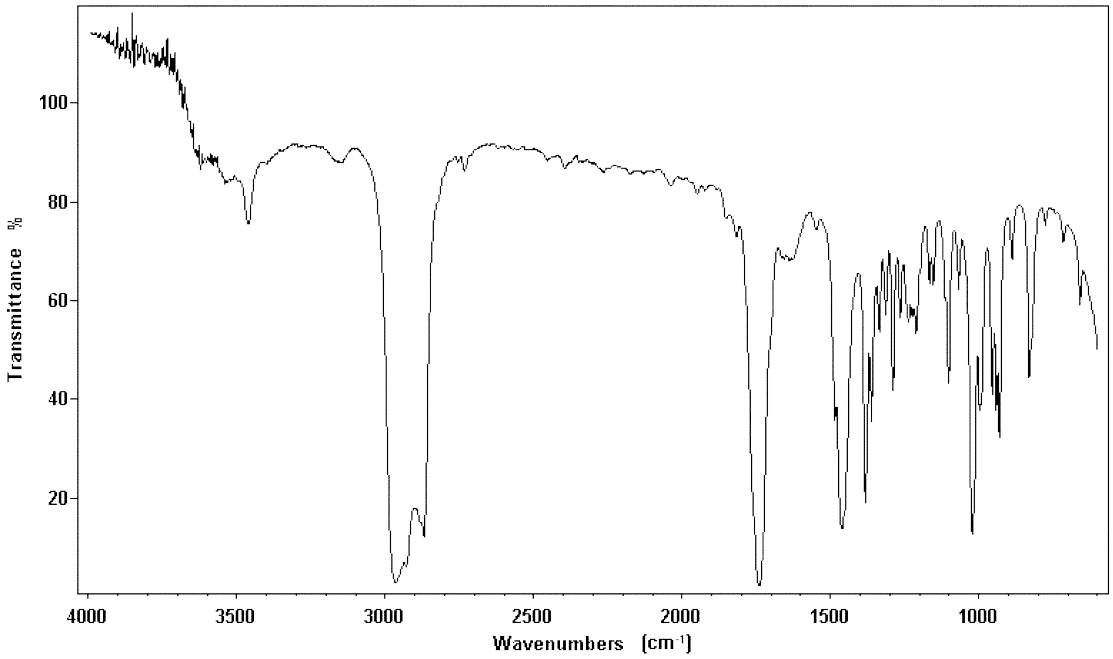
- **PROCEDURE:** Proceed as directed under *M-1b,* Appendix XI.
  Acceptance criteria: NLT 97.0% of $C_{10}H_{16}O$

SPECIFIC TESTS

- **REFRACTIVE INDEX**, Appendix II**:** At 20°
  Acceptance criteria: Between 1.460 and 1.467
- **SPECIFIC GRAVITY:** Determine at 25° by any reliable method (see *General Provisions*).
  Acceptance criteria: Between 0.940 and 0.948

OTHER REQUIREMENTS

- **ANGULAR ROTATION**, *Optical (Specific) Rotation,* Appendix IIB
  Acceptance criteria: Between +46° and –68°



(+)-Fenchone