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necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[76 FR 25235, May 4, 2011, as amended at 78 FR 14664, Mar. 7, 2013]

**PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION**

**Subpart A—Foods**

**Sec.**

- 74.101 FD&C Blue No. 1.
- 74.102 FD&C Blue No. 2.
- 74.203 FD&C Green No. 3.
- 74.250 Orange B.
- 74.302 Citrus Red No. 2.
- 74.303 FD&C Red No. 3.
- 74.340 FD&C Red No. 40.
- 74.705 FD&C Yellow No. 5.
- 74.706 FD&C Yellow No. 6.

**Subpart B—Drugs**

- 74.1101 FD&C Blue No. 1.
- 74.1102 FD&C Blue No. 2.
- 74.1104 D&C Blue No. 4.
- 74.1109 D&C Blue No. 9.
- 74.1203 FD&C Green No. 3.
- 74.1205 D&C Green No. 5.
- 74.1206 D&C Green No. 6.
- 74.1208 D&C Green No. 8.
- 74.1254 D&C Orange No. 4.
- 74.1255 D&C Orange No. 5.
- 74.1260 D&C Orange No. 10.
- 74.1261 D&C Orange No. 11.
- 74.1303 FD&C Red No. 3.
- 74.1304 FD&C Red No. 4.
- 74.1306 D&C Red No. 6.
- 74.1307 D&C Red No. 7.
- 74.1317 D&C Red No. 17.
- 74.1321 D&C Red No. 21.
- 74.1322 D&C Red No. 22.
- 74.1327 D&C Red No. 27.
- 74.1328 D&C Red No. 28.
- 74.1330 D&C Red No. 30.
- 74.1331 D&C Red No. 31.
- 74.1333 D&C Red No. 33.
- 74.1334 D&C Red No. 34.
- 74.1336 D&C Red No. 36.
- 74.1339 D&C Red No. 39.
- 74.1340 FD&C Red No. 40.
- 74.1602 D&C Violet No. 2.
- 74.1705 FD&C Yellow No. 5.
- 74.1706 FD&C Yellow No. 6.
- 74.1707 D&C Yellow No. 7.
- 74.1707a Ext. D&C Yellow No. 7.
- 74.1708 D&C Yellow No. 8.
- 74.1710 D&C Yellow No. 10.
- 74.1711 D&C Yellow No. 11.

**Subpart C—Cosmetics**

- 74.2052 D&C Black No. 2.
- 74.2053 D&C Black No. 3.
- 74.2101 FD&C Blue No. 1.
- 74.2104 D&C Blue No. 4.
- 74.2151 D&C Brown No. 1.
- 74.2203 FD&C Green No. 3.
- 74.2205 D&C Green No. 5.
- 74.2206 D&C Green No. 6.
- 74.2208 D&C Green No. 8.
- 74.2254 D&C Orange No. 4.
- 74.2255 D&C Orange No. 5.
- 74.2260 D&C Orange No. 10.
- 74.2261 D&C Orange No. 11.
- 74.2304 FD&C Red No. 4.
- 74.2306 D&C Red No. 6.
- 74.2307 D&C Red No. 7.
- 74.2317 D&C Red No. 17.
- 74.2321 D&C Red No. 21.
- 74.2322 D&C Red No. 22.
- 74.2327 D&C Red No. 27.
- 74.2328 D&C Red No. 28.
- 74.2330 D&C Red No. 30.
- 74.2331 D&C Red No. 31.
- 74.2333 D&C Red No. 33.
- 74.2334 D&C Red No. 34.
- 74.2336 D&C Red No. 36.
- 74.2340 FD&C Red No. 40.
- 74.2602 D&C Violet No. 2.
- 74.2602a Ext. D&C Violet No. 2.
- 74.2705 FD&C Yellow No. 5.
- 74.2706 FD&C Yellow No. 6.
- 74.2707 D&C Yellow No. 7.
- 74.2707a Ext. D&C Yellow No. 7.
- 74.2708 D&C Yellow No. 8.
- 74.2710 D&C Yellow No. 10.
- 74.2711 D&C Yellow No. 11.

**Subpart D—Medical Devices**

- 74.3045 [Phthalocyaninato(2-)] copper.
- 74.3102 FD&C Blue No. 2.
- 74.3106 D&C Blue No. 6.
- 74.3206 D&C Green No. 6.
- 74.3230 D&C Red No. 17.
- 74.3602 D&C Violet No. 2.
- 74.3710 D&C Yellow No. 10.

**AUTHORITY:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

**SOURCE:** 42 FR 15654, Mar. 22, 1977, unless otherwise noted.

**Subpart A—Foods**

**§ 74.101 FD&C Blue No. 1.**

(a) *Identity.* (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[p-[ethyl (*m*-sulfobenzyl) amino]- $\alpha$ -(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts

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of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]- $\alpha$ -(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[*p*-[ethyl (*o*-sulfobenzyl) amino] -  $\alpha$  - (*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

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 percent.

Leuco base, not more than 5 percent.

Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.

*N*-Ethyl-*N*-(*m*-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent. Chromium (as Cr), not more than 50 parts per million.

Manganese (as Mn), not more than 100 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accord-

ance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 58 FR 17511, Apr. 5, 1993]

### § 74.102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive 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 (CAS Reg. No. 860-22-0) 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 (CAS Reg. No. 54947-75-0) 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 (CAS Reg. No. 605-18-5). Additionally, FD&C Blue No. 2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of *N*-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

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, not more than 18 percent.