

waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a vinyl alcohol/methyl methacrylate-dye reaction product listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, this color additive is exempt from the certification requirements of section 721(c) of the act.

[58 FR 3227, Jan. 8, 1993, as amended at 58 FR 17510, Apr. 5, 1993]

#### §73.3128 Mica-based pearlescent pigments.

(a) *Identity and specifications.* The color additive is formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica. Mica used to manufacture the color additive shall conform in identity and specifications to the requirements of §73.1496(a)(1) and (b).

(b) *Uses and restrictions.* (1) Mica-based pearlescent pigments listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements in §70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[67 FR 65312, Oct. 24, 2002]

### 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**

74.2101	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.

## APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&amp;C RED NOS. 6 AND 7

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 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.

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

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, not more than 2 percent.

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

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

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Blue No. 2 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current 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 Federal Food, Drug, and Cosmetic 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. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983]

**§ 74.203 FD&C Green No. 3.**

(a) *Identity.* (1) The color additive 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 (CAS Reg. No. 2353-45-9); 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-sulfobenzene-methanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzene-methanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-