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Title 21 —Food and Drugs

Chapter I —Food and Drug Administration, Department of Health and Human Services

Subchapter A —General

Part 74 —Listing of Color Additives Subject to Certification

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Subpart C Cosmetics

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Subpart C—Cosmetics

§ 74.2052 D&C Black No. 2.

- (a) **Identity.** The color additive D&C Black No. 2 is a high-purity carbon black prepared by the oil furnace process. It is manufactured by the combustion of aromatic petroleum oil feedstock and consists essentially of pure carbon, formed as aggregated fine particles with a surface area range of 200 to 260 meters (m)²/gram.
- (b) **Specifications.** D&C Black 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 good manufacturing practice:
 - (1) Surface area by nitrogen BET (Brunauer, Emmett, Teller) method, 200 to 260 m²/gram.
 - (2) Weight loss on heating at 950 °C for 7 minutes (predried for 1 hour at 125 °C), not more than 2 percent.
 - (3) Ash content, not more than 0.15 percent.
 - (4) Arsenic (total), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million).
 - (5) Lead (total), not more than 10 mg/kg (10 parts per million).
 - (6) Mercury (total), not more than 1 mg/kg (1 part per million).
 - (7) Total sulfur, not more than 0.65 percent.
 - (8) Total PAHs, not more than 0.5 mg/kg (500 parts per billion).
 - (9) Benzo[a]pyrene, not more than 0.005 mg/kg (5 parts per billion).
 - (10) Dibenz[a,h]anthracene, not more than 0.005 mg/kg (5 parts per billion).
 - (11) Total color (as carbon), not less than 95 percent.
- (c) **Uses and restrictions.** D&C Black No. 2 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.
- (d) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (e) **Certification.** All batches of D&C Black No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[69 FR 44930, July 28, 2004, as amended at 72 FR 10357]

§ 74.2053 D&C Black No. 3.

- (a) **Identity.** The color additive D&C Black No. 3 is a washed bone char prepared from calcined cattle bones. The bones are twice heated in excess of 700 °C for at least 6 hours.
- (b) **Specifications.** D&C Black No. 3 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 practices:
 - (1) Calcium hydroxyapatite (CaO and P₂O₅), not less than 75 percent and not more than 84 percent;
 - (2) Elemental carbon, not less than 7 percent;
 - (3) Moisture, not more than 7 percent;
 - (4) Silica (SiO₂), not more than 5 percent;
 - (5) Arsenic, not more than 3 milligrams (mg)/kilogram (kg) (3 parts per million (ppm));
 - (6) Lead, not more than 10 mg/kg (10 ppm); and
 - (7) Total polycyclic aromatic hydrocarbons (PAHs), not more than 5 mg/kg (5 ppm).
- (c) **Uses and restrictions.** Cosmetics containing D&C Black No. 3 must comply with § 700.27 of this chapter with respect to prohibited cattle materials in cosmetic products. D&C Black No. 3 may be safely used for coloring the following cosmetics in amounts consistent with current good manufacturing practice: Eyeliner, eye shadow, mascara, and face powder.
- (d) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (e) **Certification.** All batches of D&C Black No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[72 FR 33666, June 19, 2007]

§ 74.2101 FD&C Blue No. 1.

- (a) **Identity.** The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[p-[ethyl(*m*-sulfobenzyl)amino]-α-(*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]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[p-[ethyl(*o*-sulfobenzyl)amino]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.
- (b) **Specifications.**

- (1) The color additive FD&C Blue No. 1 shall conform in specifications to the requirements of § 74.101(b).
- (2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) **Uses and restrictions.**

- (1) FD&C Blue No. 1 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.
- (2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(d) **Labeling.** The label of the color additive 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 accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 58 FR 17511, Apr. 5, 1993; 59 FR 7638, Feb. 16, 1994]

§ 74.2104 D&C Blue No. 4.

- (a) **Identity and specifications.** The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Blue No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

- (a) **Identity.** The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)-azo]-2,4-dihydroxyphenyl]azo]-benzene sulfonic acid. The alkyl group is principally the methyl group.
- (b) **Specifications.** D&C Brown 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 good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.

Water-insoluble matter, not more than 0.2 percent.

Sulfanilic acid, sodium salt, not more than 0.2 percent.

Resorcinol, not more than 0.2 percent.

Xylidines, not more than 0.2 percent.

Disodium salt of 4[[5-[(4-sulfophenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.

Monosodium salt of 4[[5-[(2,4-dimethyl-phenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.

Monosodium salt of 4[[5-[(2,5-dimethyl-phenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 12 percent and not more than 17 percent.

Monosodium salt of 4[[5-[(2,3-dimethyl-phenyl)azo] - 2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.

Monosodium salt of 4[[5-[(2-ethylphenyl)-azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 5 percent and not more than 12 percent.

Monosodium salt of 4[[5-[(3,4-dimethyl-phenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.

Monosodium salt of 4[[5-[(2,6-dimethyl-phenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.

Monosodium salt of 4[[5-[(4-ethylphenyl) azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.

Lead (as Pb), not more than 20 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 84 percent.

- (c) **Uses and restrictions.** D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (d) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (e) **Certification.** All batches of D&C Brown No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2203 FD&C Green No. 3.

- (a) **Identity and specifications.** The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).
- (b) **Uses and restrictions.** The color additive FD&C Green No. 3 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

- (d) **Certification.** All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.2205 D&C Green No. 5.

- (a) **Identity and specifications.** The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205 (a)(1) and (b)(2).
- (b) **Uses and restrictions.** D&C Green No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Green No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 24285, June 4, 1982, as amended at 59 FR 40805, Aug. 10, 1994]

§ 74.2206 D&C Green No. 6.

- (a) **Identity and specifications.** The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b).
- (b) **Uses and restrictions.** D&C Green No. 6 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Green No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 14146, Apr. 4, 1982, as amended at 51 FR 9784, Mar. 21, 1986]

§ 74.2208 D&C Green No. 8.

- (a) **Identity and specifications.** The color additive D&C Green No. 8 shall conform in identity and specifications to the requirements of § 74.1208(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Green No. 8 may be safely used for coloring externally applied cosmetics in amounts not exceeding 0.01 percent by weight of the finished cosmetic product.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2254 D&C Orange No. 4.

- (a) **Identity and specifications.** The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b).
- (b) **Uses and restrictions.** D&C Orange No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Orange No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977]

§ 74.2255 D&C Orange No. 5.

- (a) **Identity and specifications.** The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255 (a)(1) and (b).
- (b) **Uses and restrictions.** D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested cosmetics in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products. D&C Orange No. 5 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 49635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.2260 D&C Orange No. 10.

- (a) **Identity and specifications.** The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Orange No. 10 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2261 D&C Orange No. 11.

- (a) **Identity and specifications.** The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Orange No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2304 FD&C Red No. 4.

- (a) **Identity and specifications.** The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b).
- (b) **Uses and restrictions.** FD&C Red No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2306 D&C Red No. 6.

- (a) **Identity and specifications.** The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57688, Dec. 28, 1982]

§ 74.2307 D&C Red No. 7

- (a) **Identity and specifications.** The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 7 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

- (d) **Certification.** All batches of D&C Red No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57688, Dec. 28, 1982]

§ 74.2317 D&C Red No. 17.

- (a) **Identity and specifications.** The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 17 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2321 D&C Red No. 21.

- (a) **Identity and specifications.** The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321(a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 21 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2322 D&C Red No. 22.

- (a) **Identity and specifications.** The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322(a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 22 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.2327 D&C Red No. 27.

- (a) **Identity and specifications.** The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b).

- (b) **Uses and restrictions.** D&C Red No. 27 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2328 D&C Red No. 28.

- (a) **Identity and specifications.** The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b).
- (b) **Uses and restrictions.** D&C Red No. 28 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.2330 D&C Red No. 30.

- (a) **Identity and specifications.** The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b).
- (b) **Uses and restrictions.** D&C Red No. 30 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22511, May 25, 1982]

§ 74.2331 D&C Red No. 31.

- (a) **Identity and specifications.** The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Red No. 31 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

- (d) **Certification.** All batches of D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2333 D&C Red No. 33.

- (a) **Identity and specifications.** The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 33 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 33 may be safely used for coloring mouthwashes (including breath fresheners), dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** 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.
- (d) **Certification.** All batches of D&C Red No. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.2334 D&C Red No. 34.

- (a) **Identity and specifications.** The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 74.1334(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2336 D&C Red No. 36.

- (a) **Identity and specifications.** The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Red No. 36 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 36 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Red No. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988]

§ 74.2340 FD&C Red No. 40.

(a) **Identity and specifications.**

- (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b) of this chapter.
- (2) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 or § 82.1051 of this chapter.

(b) **Uses and restrictions.** FD&C Red No. 40 may be safely used in coloring cosmetics generally, except that only FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring cosmetics intended for use in the area of the eye. These uses are subject to the following restrictions:

- (1) The color additive may be used in amounts consistent with current good manufacturing practice.
- (2) The color additive shall not be exposed to oxidizing or reducing agents that may affect the integrity of the color additives or any other condition that may affect their integrity.

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

(d) **Certification.** All batches of FD&C Red No. 40 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.2602 D&C Violet No. 2.

(a) **Identity and specifications.** The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) **Uses and restrictions.** The color additive D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

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

(d) **Certification.** All batches of D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2602a Ext. D&C Violet No. 2.

(a) **Identity.** The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy -9,10-dioxo-1-anthracenyl) amino]-5-methyl-benzenesulfonic acid.

(b) **Specifications.** Ext. D&C Violet 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 good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.

Water-insoluble matter, not more than 0.4 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.

p-Toluidine, not more than 0.1 percent.

p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.

Subsidiary colors, not more than 1 percent.

Lead (as Pb), not more than 20 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 80 percent.

- (c) **Uses and restrictions.** The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (d) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (e) **Certification.** All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2705 FD&C Yellow No. 5.

- (a) **Identity.** The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-(1-4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-aminobenzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.
- (b) **Specifications.**
 - (1) FD&C Yellow No. 5 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 good manufacturing practice:
 - Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
 - Water-insoluble matter, not more than 0.2 percent.
 - 4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.
 - 4-[(4',5'-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl

4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobiphenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

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 87 percent.

(2) FD&C Yellow No. 5 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) **Uses and restrictions.**

(1) FD&C Yellow No. 5 may be safely used for coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Yellow No. 5 Aluminum Lake may be safely used for coloring cosmetics intended for use in the area of the eye, subject to the restrictions on use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

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

(e) **Certification.** All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[50 FR 35782, Sept. 4, 1985, as amended at 51 FR 24524, July 7, 1986; 59 FR 60898, Nov. 29, 1994]

§ 74.2706 FD&C Yellow No. 6.

(a) **Identity and specifications.** The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b).

(b) **Uses and restrictions.** FD&C Yellow No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

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

(d) **Certification.** All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986]

§ 74.2707 D&C Yellow No. 7.

(a) **Identity and specifications.** The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) **Uses and restrictions.** D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

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

(d) **Certification.** All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) **Identity and specifications.** The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) **Uses and restrictions.** Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

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

(d) **Certification.** All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

- (a) **Identity and specifications.** The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2710 D&C Yellow No. 10.

- (a) **Identity and specifications.** The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b).
- (b) **Uses and restrictions.** The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 39220, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.2711 D&C Yellow No. 11.

- (a) **Identity and specifications.** The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711(a)(1) and (b).
- (b) **Uses and restrictions.** D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The label of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (d) **Certification.** All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in part 80 of this chapter.