

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr. 2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrenetrisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

Volatile matter (at 135 °C), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.

The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.

The tetrasodium salt of 1,3,6,8-pyrenetetrakisulfonic acid, not more than 1 percent.

Pyrene, not more than 0.2 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 65 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(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 D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) *Identity.* (1) the color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such 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 13 percent.

Water-insoluble matter, not more than 0.2 percent.

2-Naphthol, not more than 0.4 percent.

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

Subsidiary colors, not more than 3 percent.

4,4'-(Diazoamino)-dibzenesulfonic acid, not more than 0.1 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 87 percent.

(c) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(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 D&C Orange No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977, as amended at 43 FR 14642, Apr. 7, 1978; 46 FR 8461, Jan. 27, 1981]

§ 74.1255 D&C Orange No. 5.

(a) *Identity.* (1) the color additive D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4',5'-dibromofluorescein (CAS Reg. No.