

§ 82.101

21 CFR Ch. I (4–1–98 Edition)

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.
Inorganic matter, insoluble HCl, not more than 0.5 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

- (1) The listed name of the color from which the lake is prepared;
- (2) The name of the basic radical combined in such color; and
- (3) The word "Lake".

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Blue No. 1 upon the substratum would be FD&C Blue No. 1—Aluminum Lake.)

§ 82.101 FD&C Blue No. 1.

The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of § 74.101(a)(1) and (b) of this chapter.

§ 82.102 FD&C Blue No. 2.

The color additive FD&C Blue No. 2 shall conform in identity and specifications to the requirements of § 74.102(a)(1) and (b) of this chapter.

[48 FR 5261, Feb. 4, 1983]

§ 82.203 FD&C Green No. 3.

The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b) of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 82.304 FD&C Red No. 4.

The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b) of this chapter. FD&C Red No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.705 FD&C Yellow No. 5.

The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b) of this chapter.

[51 FR 24519, July 7, 1986]

§ 82.706 FD&C Yellow No. 6.

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

(b) All lakes including current D&C external and D&C lakes of FD&C Yellow No. 6 shall be manufactured from previously certified batches of the straight color additive.

[52 FR 21509, June 8, 1987]

Subpart C—Drugs and Cosmetics

§ 82.1050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.1051 Lakes (D&C).

(a)(1) *General.* Any lake, other than those listed in subpart B, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these, (i) one of the straight colors (except lakes) listed in subpart B or hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors (except lakes) listed in subpart B, or hereinbefore listed in this subpart, by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

- (1) The listed name of the color from which the lake is prepared, except that

if such name contains the symbol "FD&C" such symbol shall be changed to "D&C";

(2) The name of the basic radical combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is "D&C Green No. 1—Aluminum Lake".)

§ 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.1205 D&C Green No. 5.

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) of this chapter.

[47 FR 24285, June 4, 1982]

§ 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter. D&C Green No. 6 is restricted to use in externally applied drugs and cosmetics.

[47 FR 14147, Apr. 2, 1982, as amended at 51 FR 9785, Mar. 21, 1986]

§ 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254(a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

[42 FR 52396, Sept. 30, 1977]

§ 82.1255 D&C Orange No. 5.

(a) The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255(a)(1) and (b) of this chapter. D&C Orange No. 5 is restricted to the uses described in this section.

(b) The color additive D&C Orange No. 5 may be safely used for coloring externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug. The color additive 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, and for coloring mouthwashes, dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

[49 FR 13343, Apr. 4, 1984]

§ 82.1260 D&C Orange No. 10.

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1261 D&C Orange No. 11.

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1306 D&C Red No. 6.

(a) The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

[47 FR 57691, Dec. 28, 1982]

§ 82.1307 D&C Red No. 7.

(a) The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 7 may be safely used for coloring drugs