

(a)–(f) [Reserved]

(g) The term *alumina* means a suspension in water of precipitated aluminum hydroxide.

(h) The term *blanc fixe* means a suspension in water of precipitated barium sulfate.

(i) The term *gloss white* means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term *mixed oxides* means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)–(m) [Reserved]

(n) The term *externally applied drugs and cosmetics* means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)–(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

§ 82.5 General specifications for straight colors.

No batch of a straight color listed in subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as As_2O_3), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as As_2O_3), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in subpart C or D—soluble barium (in dilute HCl) (as BaCl_2), not more than 0.05 percent.

§ 82.6 Certifiable mixtures.

(a) A batch of a mixture which contains no straight color listed in subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than $\frac{1}{10}$ of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in subpart D, or which contains a diluent not permitted by paragraph (a)(3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

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(c) A batch of a mixture which contains a straight color listed in subpart D may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

Subpart B—Foods, Drugs, and Cosmetics

§ 82.50 General.

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

§ 82.51 Lakes (FD&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, a salt prepared from one of the certified water-soluble straight colors hereinbefore listed in this subpart by combining such color with the basic radical aluminum or calcium.

(2) *Specifications.* Prepared from previously certified colors listed in this subpart.

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

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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