

**§ 81.32**

(4) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Orange No. 17 was added on or before July 15, 1988.

(u)(1) Certificates issued for FD&C Red No. 3 and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in cosmetics and externally applied drugs after January 29, 1990. Certificates issued for FD&C Red No. 3 lakes and all mixtures containing these lakes are cancelled and have no effect as pertains to their use in food, drugs, and cosmetics after January 29, 1990. Certificates issued for D&C Red No. 3 lakes and all mixtures containing those lakes are cancelled and have no effect as pertains to their use in drugs and cosmetics after January 29, 1990. Use of this color additive in the manufacture of cosmetics and of externally applied drugs and any use of the lakes of FD&C Red No. 3 (including the lakes of D&C Red No. 3) after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action must be taken to remove from the market food, drugs, and cosmetics to which the provisionally listed color additive or its lakes were added on or before January 29, 1990.

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.30, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

**§ 81.32 Limitation of certificates.**

Certificates issued for the color additives listed in § 81.25 and for all mixtures containing these color additives are limited to the conditions stated in § 81.25. The use of these color additives in drugs and cosmetics in any other manner will result in adulteration. Each of these color additives shall bear a label statement of the tolerance and use limitations applicable to it.

[44 FR 48966, Aug. 21, 1979]

**21 CFR Ch. I (4-1-15 Edition)**

**PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS**

**Subpart A—General Provisions**

- Sec.
- 82.3 Definitions.
- 82.5 General specifications for straight colors.
- 82.6 Certifiable mixtures.

**Subpart B—Foods, Drugs, and Cosmetics**

- 82.50 General.
- 82.51 Lakes (FD&C).
- 82.101 FD&C Blue No. 1.
- 82.102 FD&C Blue No. 2.
- 82.203 FD&C Green No. 3.
- 82.304 FD&C Red No. 4.
- 82.705 FD&C Yellow No. 5.
- 82.706 FD&C Yellow No. 6.

**Subpart C—Drugs and Cosmetics**

- 82.1050 General.
- 82.1051 Lakes (D&C).
- 82.1104 D&C Blue No. 4.
- 82.1205 D&C Green No. 5.
- 82.1206 D&C Green No. 6.
- 82.1254 D&C Orange No. 4.
- 82.1255 D&C Orange No. 5.
- 82.1260 D&C Orange No. 10.
- 82.1261 D&C Orange No. 11.
- 82.1306 D&C Red No. 6.
- 82.1307 D&C Red No. 7.
- 82.1317 D&C Red No. 17.
- 82.1321 D&C Red No. 21.
- 82.1322 D&C Red No. 22.
- 82.1327 D&C Red No. 27.
- 82.1328 D&C Red No. 28.
- 82.1330 D&C Red No. 30.
- 82.1331 D&C Red No. 31.
- 82.1333 D&C Red No. 33.
- 82.1334 D&C Red No. 34.
- 82.1336 D&C Red No. 36.
- 82.1602 D&C Violet No. 2.
- 82.1707 D&C Yellow No. 7.
- 82.1708 D&C Yellow No. 8.
- 82.1710 D&C Yellow No. 10.

**Subpart D—Externally Applied Drugs and Cosmetics**

- 82.2050 General.
- 82.2051 Lakes (Ext. D&C).
- 82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: 21 U.S.C. 371, 379e, 379e note.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

**Subpart A—General Provisions**

**§ 82.3 Definitions.**

For the purposes of this part:

(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<sub>2</sub>O<sub>3</sub>), 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<sub>2</sub>O<sub>3</sub>), 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<sub>2</sub>), 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 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.