§ 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]

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.
82.103 FD&C Green No. 3.
82.104 FD&C Green No. 4.
82.1205 D&C Red No. 4.
82.1206 D&C Orange No. 10.
82.1208 D&C Orange No. 11.
82.1206 D&C Red No. 6.
82.1207 D&C Red No. 7.
82.1217 D&C Red No. 17.
82.1221 D&C Red No. 21.
82.1222 D&C Red No. 22.
82.1227 D&C Red No. 27.
82.1230 D&C Red No. 30.
82.1231 D&C Red No. 31.
82.1232 D&C Red No. 33.
82.1234 D&C Red No. 34.
82.1236 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).
82.2307a Ext. D&C Yellow No. 7.


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
Food and Drug Administration, HHS

§ 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.