§ 74.2340  FD&C Red No. 40.

(a) Identity and specifications. (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of §74.340(a)(1) and (b) of this chapter.

(2) The listing of this color additive includes lakes prepared as described in §§82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §82.51 or §82.1051 of this chapter.

(b) Uses and restrictions. FD&C Red No. 40 may be safely used in coloring cosmetics generally, except that only FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring cosmetics intended for use in the area of the eye. These uses are subject to the following restrictions:

(1) The color additive may be used in amounts consistent with current good manufacturing practice.

(2) The color additive shall not be exposed to oxidizing or reducing agents that may affect the integrity of the color additives or any other condition that may affect their integrity.

(c) Labeling. The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(d) Certification. All batches of FD&C Red No. 40 shall be certified in accordance with regulations in part 80 of this chapter.


§ 74.2602a  Ext. D&C Violet No. 2.

(a) Identity. The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-(9,10-dihydro-4-hydroxy-9,10-dioxo-1-anthracenyl) amino)-5-methyl-benzenesulfonic acid.

(b) Specifications. Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other 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 18 percent.

Water-insoluble matter, not more than 0.4 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.

p-Toluidine, not more than 0.1 percent.

p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.

Subsidiary colors, not more than 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 80 percent.

(c) Uses and restrictions. The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) Labeling. The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) Certification. All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.2705  FD&C Yellow No. 5.

(a) Identity. The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-(1-4-sulphophenyl)-4-[(4-sulphophenylazo)-1H-pyrazole-3-carboxylic acid (CAS Reg. No. 1934–21–0). To manufacture the additive, 4-aminobenzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulphophenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid.