Food and Drug Administration, HHS

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be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.
Water-soluble matter, not more than 0.3 percent.
Matter insoluble in carbon tetrachloride, not more than 1.5 percent.
p-Toluidine, not more than 0.1 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
1-Hydroxy-4-[(4-methylphenyl)amino]-9,10-anthracenedione, not more than 5.0 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 96.0 percent.

(c) Uses and restrictions. D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) Certification. All batches of D&C Green No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) Identity. (1) The color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.
(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for coloring externally applied drugs.

(b) Specifications. D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such 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 13 percent.
Water-insoluble matter, not more than 0.2 percent.
2-Naphthol, not more than 0.4 percent.
Sulfanilic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 3 percent.
D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4′,5′-dibromofluorescein (CAS Reg. No. 596-03-2) and 2′,4′,5′,7′-tetrabromofluorescein (CAS Reg. No. 25709-83-5) and 2′-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid or its anhydride. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid and sulfates (calculated as sodium salts), not more than 10 percent. Insoluble matter (alkaline solution), not more than 10 percent. Lead (as Pb), not more than 20 parts per million. Mercury (as Hg), not more than 0.1 percent. Arsenic (as As), not more than 3 parts per million. Phthalic acid, not more than 1 percent. Brominated resorcinol, not more than 0.4 percent. Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent. Solubility in water. Dissolves in water; insoluble in dilute or concentrated sulfuric acid. 

Color additive mixtures for drug use made with D&C Orange No. 5 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.