

§ 74.1336

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 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(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 Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1336 D&C Red No. 36.

(a) *Identity.* (1) The color additive D&C Red No. 36 is 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol (CAS Reg. No. 2814-77-9). The color additive is manufactured by diazotization of 2-chloro-4-nitrobenzenamine in acid medium and coupling with 2-naphthalenol in acid medium.

(2) Color additive mixtures for drug use made with D&C Red No. 36 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 36 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 current good manufacturing practice:

- Volatile matter at 135 °C (275 °F), not more than 1.5 percent.
- Matter insoluble in toluene, not more than 1.5 percent.
- 2-Chloro-4-nitrobenzenamine, not more than 0.3 percent.
- 2-Naphthalenol, not more than 1 percent.
- 2,4-Dinitrobenzenamine, not more than 0.02 percent.
- 1-[(2,4-Dinitrophenyl)azo]-2-naphthalenol, not more than 0.5 percent.
- 4-[(2-Chloro-4-nitrophenyl)azo]-1-naphthalenol, not more than 0.5 percent.
- 1-[(4-Nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.
- 1-[(4-Chloro-2-nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.

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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 95 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. D&C Red No. 36 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* 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 Red No. 36 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988; 53 FR 35255, Sept. 12, 1988, as amended at 53 FR 52130, Dec. 27, 1988]

§ 74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β'-dihydroxydiethylamino)-phenylazo]-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR part 212.

(b) *Specifications.* D&C Red No. 39 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:

- Volatile matter (at 100 °C.), not more than 2.0 percent.
- Matter insoluble in acetone, not more than 1.0 percent.
- Anthranilic acid, not more than 0.2 percent.

N,N-(β,β' -Dihydroxy-diethyl) aniline, not more than 0.2 percent.

Subsidiary colors, not more than 3.0 percent.
Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 Red No. 39 shall be certified in accordance with regulations promulgated under part 80 of this chapter.

§ 74.1340 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).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(3) 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.* (1) FD&C Red No. 40 and FD&C Red No. 40 Aluminum Lake may be safely used in coloring drugs, including those intended for use in the area of the eye, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter, in amounts consistent with current good manufacturing practice.

(2) Other lakes of FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on the use of

color additives in § 70.5 of this chapter, in amounts consistent with current good manufacturing practice.

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

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

[42 FR 15654, Mar. 22, 1977, as amended at 59 FR 7636, Feb. 16, 1994]

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy -4-[(4-methylphenyl)amino]-9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* 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 can be avoided by good manufacturing practice:

Volatile matter (at 135 °C.), not more than 2.0 percent.

Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.

p-Toluidine, not more than 0.2 percent.

1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.

1,4-Dihydroxy-9,10-anthracenedione, not more than 0.5 percent.

Subsidiary colors, not more than 1.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 96.0 percent.

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

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for