

Food and Drug Administration, HHS

§ 74.1328

Sum of disodium salts of tribromofluoresceins, not more than 25 percent. Disodium salt of 2',4',5',7'-Tetrabromofluorescein, not less than 72 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 90 percent.

(c) Uses and restrictions. The color additive D&C Red No. 22 may be safely used for coloring drugs generally in amounts consistent with current 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. 22 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1327 D&C Red No. 27.

(a) Identity. (1) The color additive D&C Red No. 27 is principally 2',4',5',7'-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 13473-26-2). The color additive is manufactured by brominating 4,5,6,7-tetrachlorofluorescein with elemental bromine. The 4,5,6,7-tetrachlorofluorescein is manufactured by the acid condensation of resorcinol and tetrachlorophthalic acid or its anhydride. The 4,5,6,7-tetrachlorofluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 27 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. 27 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:

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent. Tetrachlorophthalic acid, not more than 1.2 percent. Brominated resorcinol, not more than 0.4 percent. 2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.7 percent. 2',4',5',7'-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent. Lower halogenated subsidiary colors, not more than 4 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 90 percent.

(c) Uses and restrictions. D&C Red No. 27 may be safely used for coloring drugs generally in amounts consistent with current 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. 27 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42567, Sept. 23, 1982; 47 FR 51106, Nov. 12, 1982]

§ 74.1328 D&C Red No. 28.

(a) Identity. (1) The color additive D&C Red No. 28 is principally the disodium salt of 2',4',5',7'-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472-87-2) formed by alkaline hydrolysis of the parent tetrabromotetrachlorofluorescein.

(2) Color additive mixtures for drug use made with D&C Red No. 28 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. 28 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:

### § 74.1330

Sum of volatile matter (at 135 °C) and halides and sulfates (calculated as sodium salts), not more than 15 percent.  
Insoluble matter (alkaline solution), not more than 0.5 percent.  
Tetrachlorophthalic acid, not more than 1.2 percent.  
Brominated resorcinol, not more than 0.4 percent.  
2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.7 percent.  
2',4',5',7'-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.  
Lower halogenated subsidiary colors, not more than 4 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 85 percent.

(c) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring drugs generally in amounts consistent with current 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. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

### § 74.1330 D&C Red No. 30.

(a) *Identity.* (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methyl-benzo[b]thiophen-3(2H)-one (CAS Reg. No. 2379-74-0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 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. 30 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:

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Volatile matter (at 135 °C), not more than 5 percent.  
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.  
Matter soluble in acetone, not more than 5 percent.  
Total color, not less than 90 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.

(c) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring drugs generally in amounts consistent with current 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. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22510, May 25, 1982]

### § 74.1331 D&C Red No. 31.

(a) *Identity.* (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 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 Red No. 31 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 10 percent.  
Aniline, not more than 0.2 percent.  
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 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.