

§ 74.1321

21 CFR Ch. I (4-1-03 Edition)

§ 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086-94-9), and may contain smaller amounts of 2',4',5'-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2',4',7'-tribromofluorescein (CAS Reg. No. 25709-84-6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 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.* The color additive D&C Red No. 21 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.
- Phthalic acid, not more than 1 percent.
- 2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
- 2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
- Brominated resorcinol, not more than 0.4 percent.
- Fluorescein, not more than 0.2 percent.
- Sum of mono- and dibromofluoresceins, not more than 2 percent.
- Tribromofluoresceins, not more than 11 percent.
- 2',4',5',7'-Tetrabromofluorescein, not less than 87 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. 21 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. 21 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 53846, Nov. 30, 1982]

§ 74.1322 D&C Red No. 22.

(a) *Identity.* (1) The color additive D&C Red No. 22 is principally the disodium salt of 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 17372-87-1) and may contain smaller amounts of the disodium salts of 2',4',5'-tribromofluorescein and 2',4',7'-tribromofluorescein. The color additive is manufactured by alkaline hydrolysis of 2',4',5',7'-tetrabromofluorescein. 2',4',5',7'-Tetrabromofluorescein is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. Fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with Red No. 22 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.* The color additive D&C Red No. 22 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.
- Water-insoluble matter not more than 0.5 percent.
- Disodium salt of phthalic acid, not more than 1 percent.
- Sodium salt of 2-(3,5-Dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.5 percent.
- 2',4',5',7'-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
- Brominated resorcinol, not more than 0.4 percent.
- Sum of disodium salts of mono- and dibromofluoresceins, not more than 2 percent.