

**§ 74.1260**

(e) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 44635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

**§ 74.1260 D&C Orange No. 10.**

(a) *Identity.* (1) The color additive D&C Orange No. 10 is a mixture consisting principally of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein, and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 10 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 halides and sulfates (calculated as sodium salts), not more than 8 percent.
- Insoluble matter (alkaline solution), not more than 0.5 percent.
- Phthalic acid, not more than 0.5 percent.
- 2-[3',5'-Diiido-2',4'-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.
- Fluorescein, not more than 1 percent.
- 4'-Iodofluorescein, not more than 3 percent.
- 2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.
- 2',4',5'-Triiodofluorescein, not more than 35 percent.
- 2',4',5',7'-Tetraiodofluorescein, not more than 10 percent.
- 4',5'-Diiodofluorescein, not less than 60 percent and not more than 95 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 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with 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 con-

**21 CFR Ch. I (4-1-08 Edition)**

form to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 10 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

**§ 74.1261 D&C Orange No. 11.**

(a) *Identity.* (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive D&C Orange No. 11 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 halides and sulfates (calculated as sodium salts), not more than 8 percent.
- Water-insoluble matter, not more than 0.5 percent.
- Phthalic acid, not more than 0.5 percent.
- 2-[3',5'-Diiido-2',4'-dihydroxybenzoyl] benzoic acid, sodium salt, not more than 0.5 percent.
- Fluorescein, disodium salt, not more than 1 percent.
- 4'-Iodofluorescein, disodium salt, not more than 3 percent.
- 2',4'-Diiodofluorescein and 2',5'-diiodofluorescein, not more than 2 percent.
- 2',4',5'-Triiodofluorescein, not more than 35 percent.
- 2',4',5',7'-Tetraiodofluorescein, disodium salt, not more than 10 percent.
- 4',5'-Diiodofluorescein, disodium salt, not less than 60 percent and not more than 95 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 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied drugs in amounts

consistent with 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 Orange No. 11 shall be certified in accordance with regulations in part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

#### § 74.1303 FD&C Red No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b).

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 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 ingested drugs.

(b) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *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.

(d) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

#### § 74.1304 FD&C Red No. 4.

(a) *Identity.* (1) The color additive FD&C Red No. 4 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo]-4-hydroxy-1-naphthalenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with FD&C Red No. 4 may contain only those diluents that are suitable and that are listed in part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* FD&C Red 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.

5-Amino-2,4-dimethyl-1-benzenesulfonic acid, sodium salt, not more than 0.2 percent.

4-Hydroxy-1-naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.

Subsidiary colors, not more than 2 percent.

Lead (as Pb), not more than 10 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 87 percent.

(c) *Uses and restrictions.* FD&C Red No. 4 may be safely used in 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 FD&C Red No. 4 shall be certified in accordance with regulations in part 80 of this chapter.

#### § 74.1306 D&C Red No. 6.

(a) *Identity.* (1) The color additive D&C Red No. 6 is principally the disodium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5858-81-1). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid. The resulting dye precipitates as the disodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 6 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. 6 shall conform to the following specifications and shall be free from impurities other than those