

§ 74.1306

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

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 named to the extent that such impurities may be avoided by current good manufacturing practice:

- Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
- Ether-soluble matter, passes test entitled "The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7," which is an Appendix A to part 74.
- 2-Amino-5-methylbenzenesulfonic acid, sodium salt, not more than 0.2 percent.
- 3-Hydroxy-2-naphthalenecarboxylic acid, sodium salt, not more than 0.4 percent.
- 3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, sodium salt, not more than 0.5 percent.
- p*-Toluidine, not more than 15 parts per million.
- 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. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(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. 6 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 57687, Dec. 28, 1982]

§ 74.1307 D&C Red No. 7.

(a) *Identity.* (1) The color additive D&C Red No. 7 is principally the calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5281-04-9). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is