Food and Drug Administration, HHS

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(2) 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.

2-[3,5′-Diodo-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′-Dilodofluorescein and 2′,5′-dilodofluorescein, not more than 2 percent.

2′,4′,5′-Trilodofluorescein, not more than 35 percent.

2′,4′,5′,7′-Tetralodofluorescein, disodium salt, not more than 10 percent.

4′-Dilodofluorescein, 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.

§ 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.

(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 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.

(d) 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.

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