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. 33 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 practices:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
Water-insoluble matter, not more than 0.3 percent.
4-Amino-5-hydroxy-2,7-naphthalenesulfonic acid, disodium salt, not more than 0.3 percent.
1,4-Dihydroxy-3-(phenylazo)-2,7-naphthalenesulfonic acid, disodium salt, not more than 3.0 percent.
Aniline, not more than 25 parts per million.
4-Aminoazobenzene, not more than 100 parts per billion.
1,3-Diphenyltriazene, not more than 125 parts per billion.
4-Aminobiphenyl, not more than 275 parts per billion.
Azobenzene, not more than 1 part per million.
Benzidine, not more than 20 parts per billion.
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 82 percent.

(c) Uses and restrictions. The color additive D&C Red No. 33 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 0.75 milligram per daily dose of the drug. D&C Red No. 33 may be safely used for coloring externally applied drugs, mouthwashes, and dentifrices in amounts consistent with current 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 Red No. 33 shall be certified in accordance with regulations in part 80 of this chapter.

[53 FR 31120, Aug. 30, 1988]