§ 74.1336 D&C Red No. 34.

(a) Identity. (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-(1-sulfo-2-naphthalenylazo)-2-naphthalene-carboxylic acid. 

(b) Specifications. D&C Red No. 34 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 practices:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Melt color, not less than 85 percent.

(c) Uses and restrictions. The color additive D&C Red No. 34 may be safely used for coloring 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 D&C Red No. 34 shall be certified in accordance with regulations in part 80 of this chapter.