§ 74.1328 D&C Red No. 28.

(a) Identity. (1) The color additive D&C Red No. 28 is principally the diazo- 
dium salt of 2',4',5',7'-tetrabromo-4,5,6,7- 
tetrachlorofluorescein (CAS Reg. No. 
18472–87–2) formed by alkaline hydroly-
sis of the parent 
tetabromotetrachlorofluorescein.

(2) Color additive mixtures for drug 
use made with D&C Red No. 28 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. D&C Red No. 28 
shall conform to the following speci-
fications and shall be free from impuri-
ties other than those named to the ex-
tent that such impurities may be 
avoided by current good manufacturing 
practice:

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

Insoluble matter (alkaline solution), not 
more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 
percent.

Brominated resorcinol, not more than 0.4 
percent.

2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-
dihydroxybenzoyl) benzoic acid, not more 
than 0.7 percent.

2',4',5',7'-Tetabromo-4,5,6,7-
tetrachlorofluorescein, ethyl ester, not 
more than 2 percent.

Lower halogenated subsidiary colors, not 
more than 4 percent.

Lead (as Pb), not more than 20 parts per mil-
lion.

Arsenic (as As), not more than 3 parts per mil-
lion.

Mercury (as Hg), not more than 1 part per 
million.

Total color, not less than 85 percent.

(c) Uses and restrictions. D&C Red No. 
28 may be safely used for coloring 
drugs generally in amounts consistent 
with current good manufacturing prac-
tice.

(d) Labeling. The label of the color ad-
ditive 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. 28 shall be certified in accord-
ance with regulations in part 80 of this 
chapter.

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(e) Certification. All batches of D&C Red No. 28 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42568, Sept. 28, 1982]

§ 74.1330 D&C Red No. 30.

(a) Identity. (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzothien-2(3H)-ylidene)-4-methyl-benzothiophen-3(2H)-one (CAS Reg. No. 2379–74–0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 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. D&C Red No. 30 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 current good manufacturing practice:

- Volatile matter (at 135 °C), not more than 5 percent.
- Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
- Matter soluble in acetone, not more than 5 percent.
- Total color, not less than 90 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.

(c) Uses and restrictions. D&C Red No. 30 may be safely used for coloring drugs generally in amounts consistent with current 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. 30 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 22510, May 25, 1982]

§ 74.1331 D&C Red No. 31.

(a) Identity. (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 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 externally applied drugs.

(b) Specifications. D&C Red No. 31 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 chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
- Aniline, not more than 5.2 percent.
- 3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
- Subsidiary colors, not more than 1 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.

(c) Uses and restrictions. D&C Red No. 31 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 D&C Red No. 31 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1333 D&C Red No. 33.

(a) Identity. (1) The color additive D&C Red No. 33 is principally the disodium salt of 5-amino-4-hydroxy-2,7-naphthalenesulfonic acid (CAS Reg. No. 3367–66–6). To manufacture the additive, the product obtained from the nitrous acid diazotization of aniline is coupled with 4-hydroxy-5-amino-2,7-naphthalenesulfonic acid in an alkaline aqueous medium. The color additive is isolated as the sodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 33 may contain only those diluents that are