§ 74.1109 D&C Blue No. 9.

(a) Identity. The color additive D&C Blue No. 9 is principally 7,16-dichloro-6,15 - dihydro - 5,9,14,18 - anthrazine-tetrone.

(b) Specifications. D&C Blue No. 9 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:

Volatile matter (at 135 °C.), not more than 3 percent.

Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 95 percent ethyl alcohol), not more than 1 percent.

2-Amino anthraquinone, not more than 0.2 percent.

Organically combined chlorine in pure dye, 13.0–14.8 percent.

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

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

Total color, not less than 97 percent.

(c) Uses and restrictions. D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) Labeling. The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) Certification. All batches of D&C Blue No. 9 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1203 FD&C Green No. 3.

(a) Identity and specifications. (1) The color additive FD&C Green No. 3 shall conform in identity and specifications
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§ 74.1205 D&C Green No. 5.

(a) Identity. (1) The color additive D&C Green No. 5 is principally the di-
sodium salt of 2,2′-[(9,10-dihydro-9,10-
dioxo-1,4-anthracenediyl)diimino]bi-
[5-methylbenzenesulfonic acid] (CAS
Reg. No. 4403–90–1).

(2) Color additive mixtures for use in
drugs made with D&C Green No. 5 may
contain only those diluents that are
suitable and those that are listed in part 73
of this chapter for use in color
additive mixtures for coloring drugs.

(b) Specifications. (1) D&C Green No. 5 for use in coloring surgical sutures
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
chlorides and sulfates (calculated as so-
dium salts), not more than 20 percent.

Water-insoluble matter, not more than 0.2
percent.

1,4-Dihydroxyanthraquinone, not more than
0.2 percent.

Subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per mil-
lion.

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

Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in color-
ing drugs shall conform to the fol-
lowing 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:

Sum of volatile matter (at 135 °C) and
chlorides and sulfates (calculated as so-
dium salts), not more than 20 percent.

Water-insoluble matter, not more than 0.2
percent.

1,4-Dihydroxyanthraquinone, not more than
0.2 percent.

Sulfonated toluidines, total not more than
0.2 percent.

p-Toluidine, not more than 0.0015 percent.

Sum of monosulfonated D&C Green No. 6 and
Ext. D&C Violet No. 2, not more than 3 per-
cent.

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

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

Total color, not less than 80 percent.

(c) Use and restrictions. (1) D&C Green
No. 5 may be safely used to color nylon
66 (the copolymer of adipic acid and
hexamethylenediamine) and/or nylon
6[poly-(-e-caprolactam)]nonabsorbable
surgical sutures for use in general sur-
gery, subject to the following restric-
tions:

(i) The quantity of color additive
does not exceed 0.6 percent by weight
of the suture.

(ii) When the sutures are used for the
purposes specified in their labeling,
there is no migration of the color addi-
tive to the surrounding tissue.

(iii) If the suture is a new drug, an
approved new drug application, under
section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely
used for coloring drugs generally, in-
cluding drugs intended for use in the
area of the eye, in amounts consistent
with current good manufacturing prac-
tice.

(d) Labeling. The label of the color ad-
ditive shall conform to the require-
ments of § 70.25 of this chapter.