§ 74.1205

(a) Identity and specifications. (1) The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of §74.203(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Green No. 3 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) Uses and restrictions. The color additive FD&C Green No. 3 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) 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.

(d) Certification. All batches of FD&C Green No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

§ 74.1205  D&C Green No. 5.

(a) Identity. (1) The color additive D&C Green No. 5 is principally the disodium salt of 2,2′-(9,10-dihydro-9,10-dioxo-1,4-anthracenediyldiimino)bis-[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 specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

- Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.
- Water insoluble matter, not more than 0.2 percent.
- 1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
- 2-Amino-m-toluenesulfonic acid, not more than 0.2 percent.
- Subsidiary colors, not more than 5 percent.
- Lead (as Pb), not more than 10 parts per million.
- Arsenic (as As), not more than 5 parts per million.
- Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs 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:

- Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.
- Water insoluble matter, not more than 0.2 percent.
- 1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
- 2-Amino-m-toluenesulfonic acid, not more than 0.2 percent.
- Subsidiary colors, not more than 5 percent.
- Lead (as Pb), not more than 10 parts per million.
- Arsenic (as As), not more than 3 parts per million.
- Total color, not less than 80 percent.