§ 74.706 FD&C Yellow No. 6.

(a) Identity. (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[4-sulfophenyl]azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783–94–0). The trisodium salt of 3-hydroxy-4-[4-sulfophenyl]azo]-1-(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880–65–4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[4-sulfophenyl]azo]-2,7-naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.

(2) Color additive mixtures for food use made with FD&C Yellow No. 6 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 foods.

(b) Specifications. The color additive FD&C Yellow No. 6 shall conform to such standards of identity as have been promulgated under section 401 of the act unless added color is processed by manufacturers.

(d) Labeling requirements. (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of §70.25 of this chapter.

(2) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive as FD&C Yellow No. 5 among the list of ingredients.

(e) Certification. All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in part 80 of this chapter.

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 13 percent.
Water insoluble matter, not more than 0.2 percent.
Sodium salt of 4-aminobenzensulfonic acid, not more than 0.2 percent.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.
Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.
Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.
Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-(2-hydroxy-1-naphthalenylazo)benzenesulfonic acid, not more than 1 percent.
Sum of the trisodium salt of 3-hydroxy-4[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.
4-Aminoazobenzene, not more than 50 parts per billion.
4-Aminobiphenyl, not more than 15 parts per billion.
Aniline, not more than 250 parts per billion.
Azobenzene, not more than 200 parts per billion.
Benzidine, not more than 1 part per billion.
1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.
Lead (as Pb), not more than 10 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 87 percent.

(a) Identity. (1) For ingested drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of §74.101(a)(1).
(2) For externally applied drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of §74.2101(a).
(3) Color additive mixtures for drug use made with FD&C Blue No. 1 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. (1) The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of §74.101(b).
(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of §82.51 of this chapter.

(c) Uses and restrictions. (1) FD&C Blue No. 1 may be safely used for coloring drugs, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.
(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice, subject to the restrictions on the use of color additives in §70.5(b) and (c) of this chapter.

(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.