Food and Drug Administration, HHS

§ 74.303 FD&C Red No. 3.

(a) Identity. (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9-(o-carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3H-xanthene-3-one, disodium salt, with smaller amounts of lower iodinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red 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 foods.

(b) Specifications. FD&C Red No. 3 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:

Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

§ 74.340 FD&C Red No. 40.

(a) Identity. (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[[2-methoxy-5-methyl-4-sulfophenyl]azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 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.

(3) The listing of this color additive includes lakes prepared as described in §82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §82.51 of this chapter.

(b) Specifications. FD&C Red No. 40 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
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FD&C Yellow No. 5.

(a) Identity. (1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-(4-sulfophenylazo)-1H-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 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. FD&C Yellow No. 5 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 (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4′-(4,5-Dihydro-5-oxo-4-(4-sulfophenyl)hydrazono)-1H-pyrazol-1,3-diy]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4′-(4′,5′-Disulfo[1,1′-biphenyl]-2-yl)hydrazono]-1H-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-di]hydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, disodium salt, not more than 0.1 percent.

4-Aminobenzesulfonic acid, sodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-di]hydro-5-oxo-1-(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminophenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

4-Aminobiphenyl, not more than 5 parts per billion.

Azobenzene, not more than 1 part per billion.

4-Aminobenzazide, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminobenzesulfonic acid, sodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-di]hydro-5-oxo-1-(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylate, disodium salt, not more than 0.1 percent.

4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminophenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

4-Aminobenzazide, not more than 40 parts per billion.

Lead (as Pb), not more than 10 parts per million.

4-Aminoazobenzene, not more than 75 parts per billion.

4-Aminophenyl, not more than 5 parts per billion.

Aniline, not more than 100 parts per billion.

Azobenzene, not more than 40 parts per billion.

Benzidine, not more than 1 part per billion.