

## § 74.250

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

[47 FR 52143, Nov. 19, 1982; 47 FR 56489, Dec. 17, 1982]

## § 74.250 Orange B.

(a) *Identity.* (1) The color additive Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethylcarboxy-4-(4-sulfonaphthylazo)-5-hydroxy-pyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Orange B shall conform to the following specifications:

Volatile matter (at 135 °C.), not more than 6.0 percent.

Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.

Water insoluble matter, not more than 0.2 percent.

1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.

Naphthionic acid, not more than 0.2 percent.

Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.

The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.

Other subsidiary dyes, not more than 1.0 percent.

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

Arsenic (as As), not more than 1 part per million.

Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall con-

## 21 CFR Ch. I (4–1–10 Edition)

form to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Orange B shall be certified in accordance with regulations promulgated under part 80 of this chapter.

## § 74.302 Citrus Red No. 2.

(a) *Identity.* (1) The color additive Citrus Red No. 2 is principally 1-(2,5-dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications.* Citrus Red No. 2 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 100 °C.), not more than 0.5 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Uncombined intermediates, not more than 0.05 percent.

Subsidiary dyes, not more than 2.0 percent.

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

Arsenic (as As), not more than 1 part per million.

Total color, not less than 98 percent.

(c) *Uses and restrictions.* (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended or used for processing (or if so used are designated in the trade as *Packinghouse elimination*) and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

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

(1) The statement (or its equivalent) "To be used only for coloring skins of oranges."

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification.* All batches of Citrus Red No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

#### § 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 imidinated 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.

Unhalogenated intermediates, total not more than 0.1 percent.

Sodium iodide, not more than 0.4 percent.

Triiodoresorcinol, not more than 0.2 percent.

2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

Monoiodofluoresceins not more than 1.0 percent.

Other lower iodinated fluoresceins, not more than 9.0 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 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring foods generally (including dietary supplements) in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(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 FD&C Red No. 3 shall be certified in accordance with regulations in part 80 of this chapter.

#### § 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-sulphophenyl)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 avoided by good manufacturing practice:

Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulphophenyl)azo]-8-(2-methoxy-5-methyl-4-sulphophenoxy)-2-