

§ 73.85

21 CFR Ch. I (4-1-03 Edition)

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin 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:

- Physical state, solid.
- 1 percent solution in chloroform, complete and clear.
- Melting range (decomposition), 207 °C. to 212 °C. (corrected).
- Loss on drying, not more than 0.2 percent.
- Residue on ignition, not more than 0.2 percent.
- Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
- Lead, not more than 10 parts per million.
- Arsenic, not more than 3 parts per million.
- Mercury, not more than 1 part per million.
- Assay, 96 to 101 percent.

(c) *Use and restrictions.* (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:

(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and

(ii) 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.

(2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogram (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

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

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 50 FR 47534, Nov. 19, 1985; 63 FR 14817, Mar. 27, 1998]

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

- Dextrose.
- Invert sugar.
- Lactose.
- Malt sirup.
- Molasses.
- Starch hydrolysates and fractions thereof.
- Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in §172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

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

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 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, 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 and intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the pub-

lic health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.90 β -Apo-8'-carotenal.

(a) *Identity.* (1) The color additive is β -apo-8'-carotenal.

(2) Color additive mixtures for food use made with β -apo-8'-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β -Apo-8'-carotenal shall conform to the following specifications:

Physical state, solid.

1 percent solution in chloroform, clear.

Melting point (decomposition), 136 °C.–140 °C. (corrected).

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

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

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

Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β -apo-8'-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β -apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) 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 and intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.95 β -Carotene.

(a) *Identity.* (1) The color additive is β -carotene prepared synthetically or obtained from natural sources.