

§ 73.70

necessary for the protection of the public health and therefore batches are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[86 FR 49233, Sept. 2, 2021]

§ 73.70 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white powder consisting essentially of calcium carbonate (CaCO₃) prepared either by grinding naturally occurring limestone or synthetically, by precipitation.

(2) Color additive mixtures for food use made with calcium carbonate 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.* Calcium carbonate must meet the specifications given in calcium carbonate (FCC 13) and limestone, ground (FCC 13).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color dietary supplement tablets and capsules (including coatings and printing inks), soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must 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 Federal Food, Drug, and Cosmetic Act.

(f) *Incorporation by reference.* Material listed in this paragraph (f) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the

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Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Food and Drug Administration between 9 a.m. and 4 p.m., Monday through Friday at: Dockets Management Staff, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. For information on the availability of this material at NARA, email: fr.inspection@nara.gov; website: www.archives.gov/federal-register/cfr/ibr-locations.html. You may obtain this material from the U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852; website: www.usp.org.

(1) Limestone, Ground, *Food Chemicals Codex*, 13th edition, effective June 1, 2022 (FCC 13).

(2) Calcium Carbonate, *Food Chemicals Codex*, 13th edition, effective June 1, 2022 (FCC 13).

[82 FR 51557, Nov. 7, 2017, as amended at 87 FR 58448, Sept. 27, 2022]

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β-carotene-4,4'-dione.

(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