

§ 73.530

21 CFR Ch. I (4–1–25 Edition)

(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.

[84 FR 37576, Aug. 1, 2019]

§ 73.530 **Spirulina extract.**

(a) *Identity.* (1) The color additive spirulina extract is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis*. The color additive contains phycocyanins as the principal coloring components.

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

(b) *Specifications.* Spirulina extract must conform to the following specifications and must be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead, not more than 2 milligrams per kilogram (mg/kg) (2 part per million (ppm));

(2) Arsenic, not more than 2 mg/kg (2 ppm);

(3) Mercury, not more than 1 mg/kg (1 ppm); and

(4) Negative for microcystin toxin.

(c) *Uses and restrictions.* Spirulina extract may be safely used for coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts (including non-dairy frozen dessert), dessert coatings and toppings, beverage mixes and powders, yogurts (including non-dairy yogurt alternatives), custards, puddings (including non-dairy puddings), cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), alcoholic beverages with less than 20 percent alcohol-by-volume content, non-alcoholic beverages, seasoning mixes (unheated), salad dressings, condiments and sauces, dips, coating formulations applied to dietary supplement tablets and capsules, at levels consistent with good manufacturing practice, and to seasonally color the shells of hard-boiled eggs, except that

it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 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.

[78 FR 49120, Aug. 13, 2013, as amended at 79 FR 20098, May 13, 2014; 80 FR 50765, Aug. 21, 2015; 82 FR 30734, July 3, 2017; 87 FR 67789, Nov. 10, 2022]

§ 73.575 **Titanium dioxide.**

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO<sub>2</sub>, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO<sub>2</sub> and/or aluminum oxide, Al<sub>2</sub>O<sub>3</sub>, as dispersing aids—not more than 2 percent total.

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

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

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

Antimony (as Sb), not more than 2 parts per million.

Mercury (as Hg), not more than 1 part per million.

Loss on ignition at 800 °C. (after drying for 3 hours at 105 °C.), not more than 0.5 percent.

Water soluble substances, not more than 0.3 percent.

Acid soluble substances, not more than 0.5 percent.

TiO<sub>2</sub>, not less than 99.0 percent after drying for 3 hours at 105 °C.

Lead, arsenic, and antimony shall be determined in the solution obtained by