

§ 73.575

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO₂, 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, SiO₂ and/or aluminum oxide, Al₂O₃, 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.

TiO₂, 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 boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the 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 intended solely or in part for coloring purposes prepared therefrom 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.

§ 73.585 Tomato lycopene extract; tomato lycopene concentrate.

(a) *Identity.* (1) The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene.

(2) The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent.

(3) Color additive mixtures made with tomato lycopene extract or tomato lycopene concentrate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring food.

(b) *Specifications.* (1) Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin as determined by the method entitled "Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC)," S.O.P. number : Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://>