

(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://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

(2) Tomato lycopene concentrate shall conform to the following specification: Lycopene, not less than 60 percent of oleoresin as determined by the method identified in paragraph (b)(1) of this section.

(c) *Uses and restrictions.* Tomato lycopene extract and tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive 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.

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§ 73.600 Turmeric.

(a) *Identity.* (1) The color additive turmeric is the ground rhizome of *Curcuma longa* L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity

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have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *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.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (*Curcuma longa* L.) by extraction using any one or a combination of the following solvents:

Acetone	Isopropyl alcohol
Ethyl alcohol	Methyl alcohol
Ethylene dichloride	Methylene chloride
Hexane	Trichloroethylene

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the color-

ing of 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 the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions 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.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs—(1) General use.* Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211.
Cetyl alcohol	As set forth in N.F. XI.	
Isopropyl alcohol	In color coatings for pharmaceutical forms, no residue.
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60).	As set forth in sec. 172.836 of this chapter.	
Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65).	As set forth in sec. 172.838 of this chapter.	