Food and Drug Administration, HHS

§ 73.1645

2 Colored additive mixtures for drug use made with talc may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) Specifications. Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) and the following:

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) Uses and restrictions. Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) Labeling requirements. 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.

§ 73.1575 Titanium dioxide.

(a) Identity and specifications. (1) The color additive titanium dioxide shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug 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 drugs, 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 and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 200-mesh screen and 95 percent shall pass through a 325-mesh screen.
Mercury, not more than 1 part per million.
Arsenic, not more than 3 parts per million.
Lead, not more than 20 parts per million.
Aluminum, not less than 99 percent.

(c) Uses and restrictions. Aluminum powder is safe for use in externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) Labeling. The color additive and any mixture prepared therefrom and intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 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.