§ 73.1496 Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of ε-caprolactam), or silk non-absorable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(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.


§ 73.1496 Mica.

(a) Identity. (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate, K2Al4(Al2Si6O20)(OH)4 or, alternatively, H2KAl3(SiO3)3. Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

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

(b) Specifications. Mica 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:

Fineness, 100 percent shall pass through a 100-mesh sieve.

Loss on ignition at 600–650 °C, not more than 2 percent.

Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) Uses and restrictions. Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

(d) Labeling requirements. The label of the color additive and of any mixture prepared therefrom 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.


§ 73.1550 Talc.

(a) Identity. (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

(2) Color 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 of any mixtures prepared therefrom intended solely or