§ 73.1410

mineral substance consisting predominantly of a hydrous aluminum silicate, \( \text{Al}_2\text{O}_3 \cdot 4\text{SiO}_2 \cdot \text{H}_2\text{O} \), intimately mixed with lesser amounts of finely divided silica, \( \text{SiO}_2 \). Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) Specifications. Pyrophyllite shall conform to the following specifications:

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

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5 N hydrochloric acid.

(c) Use and restrictions. Pyrophyllite may be safely used in amounts consistent with good manufacturing practice to color drugs that are to be externally applied.

(d) Labeling requirements. The labeling of the color additive and any mixtures 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.

§ 73.1410  Logwood extract.

(a) Identity. The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree Haematoxylon campechianum. The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) Specifications. Logwood extract 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:

- Volatile matter (at 110 °C), not more than 15 percent.
- Sulfated ash, not more than 20 percent.
- Hematein, not less than 5 percent and not more than 20 percent.
- Lead (as Pb), not more than 70 parts per million.
- Arsenic (as As), not more than 4 parts per million.
- Mercury (as Hg), not more than 3 parts per million.

(c) Use and restrictions. Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of \( \varepsilon \)-caprolactam), or silk non-absorbable 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, \( \text{K}_2\text{Al}_4(\text{Al}_2\text{Si}_3\text{O}_{10})(\text{OH})_8 \) or, alternatively, \( \text{H}_2\text{KAl}_3(\text{SiO}_4)_3 \). Mica may be identified and semiquantitatively determined by
Food and Drug Administration, HHS

§ 73.1575

(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:

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

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5 N hydrochloric acid.

(b) Uses and restrictions. The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. Externally application includes use in the area of the eye.

(c) Labeling. 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.

(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.

§ 73.1550 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 Pharmacopoeia XX (1980) and the following:

- 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.

(c) Uses and restrictions. Talc 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 mixtures 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.