

§ 73.1329

(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 certification pursuant to section 721(c) of the act.

[42 FR 36451, July 15, 1977]

§ 73.1329 Guanine.

(a) *Identity.* (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

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

(b) *Specifications.* The color additive guanine 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:

- Guanine, not less than 75 percent.
- Hypoxanthine, not more than 25 percent.
- Ash (ignition at 800 °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.
- Assay, not less than 96 percent total purines.
- Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Guanine is safe for use in coloring 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 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 pub-

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lic health, and therefore batches thereof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol 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:

- Melting point, between 130° and 133 °C.
- Residue on ignition, not more than 0.1 percent.
- Lead (as Pb), not more than 20 p/m (parts per million).
- Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

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

(4) 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.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring

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, 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 0.5N hydrochloric acid.

(c) *Uses 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 *ε*-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.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

§ 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, $\text{K}_2\text{Al}_4(\text{Al}_2\text{Si}_6\text{O}_{20})(\text{OH})_4$ or, alternatively, $\text{H}_2\text{KAl}_3(\text{SiO}_4)_3$. Mica may be identified and semiquantitatively determined by