

**§ 73.1015**

**21 CFR Ch. I (4-1-12 Edition)**

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.

**§ 73.1015 Chromium-cobalt-aluminum oxide.**

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

- Chromium, calculated as Cr<sub>2</sub> O<sub>3</sub>, 34-37 percent.
- Cobalt, calculated as CoO, 29-34 percent.
- Aluminum, calculated as Al<sub>2</sub> O<sub>3</sub>, 29-35 percent.
- Lead (as Pb), not more than 30 parts per million.
- Arsenic (as As), not more than 3 parts per million.
- Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

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

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

- (1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500-550 °F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.
- (2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

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

(5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic 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 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]

**§ 73.1025 Ferric ammonium citrate.**

(a) *Identity.* The color additive ferric ammonium citrate consists of complex chelates prepared by the interaction of ferric hydroxide with citric acid in the presence of ammonia. The complex chelates occur in brown and green forms, are deliquescent in air, and are reducible by light.

(b) *Specifications.* Ferric ammonium citrate 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:

- Iron (as Fe), not less than 14.5 percent and not more than 18.5 percent.
- Lead (as Pb), not more than 20 p/m.
- Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Ferric ammonium citrate may be safely used in combination with pyrogallol (as listed in § 73.1375), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery subject to the following conditions:

- (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.