

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI.
Ethyl cellulose	As set forth in § 172.868 of this chapter.
Hydroxyethyl cellulose. Hydroxypropyl cellulose	As set forth in § 172.870 of this chapter.

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide (Al₂O₃·XH₂O).

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

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.

Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.

Aluminum oxide (Al₂O₃), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) 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 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 Cr₂O₃, 34-37 percent.

Cobalt, calculated as CoO, 29-34 percent.

Aluminum, calculated as Al₂O₃, 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.