§ 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 parts per million.
Arsenic (as As), not more than 3 parts per million.

(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.

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

(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 labeling 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.

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