§ 73.1298 Ferric ammonium ferrocyanide.

(a) Identity. (1) The color additive ferric ammonium ferrocyanide is the blue pigment obtained by oxidizing under acidic conditions with sodium dichromate the acid digested precipitate resulting from mixing solutions of ferrous sulfate and sodium ferrocyanide in the presence of ammonium sulfate. The oxidized product is filtered, washed, and dried. The pigment consists principally of ferric ammonium ferrocyanide with smaller amounts of ferric ferrocyanide and ferric sodium ferrocyanide.

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

(b) Specifications. Ferric ammonium ferrocyanide shall conform to the following specifications and shall be free of impurities other than those named to the extent that the other impurities may be avoided by good manufacturing practice:

Oxalic acid or its salts, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Water soluble cyanide, not more than 10 parts per million.
Volatile matter, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) Uses and restrictions. Ferric ammonium ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color 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.


§ 73.1299 Ferric ferrocyanide.

(a) Identity. (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structural formula Fe₄[Fe(CN)₆]₃·XH₂O, which may contain small amounts of ferric sodium ferrocyanide and ferric potassium ferrocyanide.

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

(b) Specifications. Ferric ferrocyanide 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:

Water soluble cyanide, not more than 10 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.
Oxalic acid, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Volatile matter, not more than 10 percent.

(c) Uses and restrictions. Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended 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.
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.

§ 73.1327 Chromium oxide greens.

(a) Identity. (1) The color additive chromium oxide greens is principally chromic sesquioxide (Cr₂O₃).

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

(b) Specifications. The color additive chromium oxide greens 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:

Chromium in 2% NaOH extract, not more than 0.075% as Cr₂O₃ (based on sample weight).

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

Lead (as Pb), not more than 20 parts per million.

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

Cr₂O₃, not less than 95%.

(c) Uses and restrictions. Chromium oxide greens is safe for use in coloring externally applied drugs, including those intended for use in the area of 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 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...