necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 721(c) of the act.

§ 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.
Total iron (as Fe corrected for volatile matter), not less than 33 percent and not more than 39 percent.

(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 therfore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 44 FR 28322, May 15, 1979]

§ 73.1299 Ferric ferrocyanide.

(a) *Identity.* (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structual formula $Fe_4[Fe(CN)_6]_3 \cdot XH_2O$, 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.
Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 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.

(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 requirements of section 721(c) of the act.

[43 FR 54235, Nov. 21, 1978]

§ 73.1326 Chromium hydroxide green.

(a) *Identity.* (1) The color additive chromium hydroxide green is principally hydrated chromic sesquioxide ($Cr_2O_3 \cdot XH_2O$).

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

(b) *Specifications.* Chromium hydroxide green 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 matter, not more than 2.5%.
Chromium in 2% NaOH extract, not more than 0.1% as Cr_2O_3 (based on sample weight).
Boron (as B_2O_3), not more than 8 percent.
Total volatile matter at 1000 °C, not more than 20%.
Cr_2O_3 not less than 75%.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Chromium hydroxide green 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 lintended 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.

[42 FR 36451, July 15, 1977, as amended at 42 FR 59852, Nov. 22, 1977]

§ 73.1327 Chromium oxide greens.

(a) *Identity.* (1) The color additive chromium oxide greens is principally chromic sesquioxide (Cr_2O_3).

(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 chormium 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 Cr_2O_3 (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.
Cr_2O_3, 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 therof are exempt from certification pursuant to section 721(c) of the act.

[42 FR 36451, July 15, 1977]