

**Food and Drug Administration, HHS**

**§ 73.1326**

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 structural 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]