

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

§ 73.1162 Bismuth oxychloride.

(a) *Identity.* (1) The color additive bismuth oxychloride is a synthetically prepared white or nearly white amorphous or finely crystalline, odorless powder consisting principally of BiOCl.

(2) Color additive mixtures for drug use made with bismuth oxychloride may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive bismuth oxychloride shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter, not more than 0.5 percent.
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.
Bismuth oxychloride, not less than 98 percent.

(c) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring externally applied drugs, including those intended for use in the area of the 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 the provisions 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 pursuant to section 721(c) of the act.

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§ 73.1200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, includ-

ing the hydrated forms. It is free from admixture with other substances.

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

(b) *Specifications.* Synthetic iron oxide shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom 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.

§ 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