

§73.1125

21 CFR Ch. I (4-1-08 Edition)

diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of §70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives 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.

§73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity.* (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytol ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Potassium sodium copper chlorophyllin 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:

- Moisture, not more than 5.0 percent.
- Nitrogen, not more than 5.0 percent.
- pH of 1 percent solution, 9 to 11.
- Total copper, not less than 4 percent and not more than 6 percent.
- Free copper, not more than 0.25 percent.
- Iron, not more than 0.5 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 5 parts per million.

Ratio, absorbance at 405 mμ to absorbance at 630 mμ, not less than 3.4 and not more than 3.9.

Total color, not less than 75 percent.

(c) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are drugs at a level not to exceed 0.1 percent. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling.* The label of the color additive and 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.

§73.1150 Dihydroxyacetone.

(a) *Identity.* (1) The color additive dihydroxyacetone is 1,3-dihydroxy-2-propanone.

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

(b) *Specifications.* Dihydroxyacetone 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:

- Volatile matter (at 34.6 °C. for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.
- Residue on ignition, not more than 0.4 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 3 parts per million.
- Iron (as Fe), not more than 25 parts per million.
- 1,3-dihydroxy-2-propanone, not less than 98 percent.

(c) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied

drugs intended solely or in part to impart a color to the human body. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling requirements.* The label of the color additive and 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.

§ 73.1162 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.

[42 FR 52394, Sept. 30, 1977]

§ 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, including 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.