

§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