

§ 73.2120

21 CFR Ch. I (4-1-01 Edition)

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

[43 FR 44831, Sept. 29, 1978]

§ 73.2120 Disodium EDTA-copper.

(a) *Identity.* The color additive disodium EDTA-copper is disodium [[N,N'-1,2-ethanediy]bis[N - (carboxymethyl)glycinato]] (4-)-N,N',O,O',O^N,O^{N'}] cuprate (2-).

(b) *Specifications.* Disodium EDTA-copper 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:

- Total copper, not less than 13.5 percent.
- Total (ethylene-dinitrilo) tetracetic acid, not less than 62.5 percent.
- Free copper, not more than 100 parts per million.
- Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.
- Moisture, not more than 15 percent.
- Water insoluble matter, not more than 0.2 percent.
- Lead (as Pb), not more than 20 parts per million.
- Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.

(d) *Labeling requirements.* The labeling of the color additive 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 requirements of section 721(c) of the act.

§ 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity and specifications.* The color additive potassium sodium copper chlorophyllin shall conform in identity and specifications to the requirements of § 73.1125(a)(1) and (b).

(b) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that

are cosmetics subject to the following conditions:

(1) It shall not be used at a level in excess of 0.1 percent.

(2) It may be used only in combination with the following substances:

- Water.
- Glycerin.
- Sodium carboxymethylcellulose.
- Tetrasodium pyrophosphate.
- Sorbitol.
- Magnesium phosphate, tribasic.
- Calcium carbonate.
- Calcium phosphate, dibasic.
- Sodium N-lauroyl sarcosinate.
- Artificial sweeteners that are generally recognized as safe or that are authorized under subchapter B of this chapter.
- Flavors that are generally recognized as safe or that are authorized under subchapter B of this chapter.
- Preservatives that are generally recognized as safe or that are authorized under subchapter B of this chapter.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *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.

§ 73.2150 Dihydroxyacetone.

(a) *Identity and specifications.* The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150 (a)(1) and (b).

(b) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.

(c) *Labeling requirements.* The labeling 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.

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