Food and Drug Administration, HHS

§ 73.3106 1,4-Bis[4-(2-methacryloyloxyethyl)phenylamino]anthraquinone copolymers.

(a) Identity. The color additives are the copolymers formed as the reaction product of 1,4-bis[4-(2-methacryloyloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) (CAS Reg. No. 121888–69–5) with one or more vinyl and/or acrylic monomers to form the contact lens material.

(b) Uses and restrictions. (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(d) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

§ 73.3107 Carbazole violet.

(a) Identity. The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358–30–1, Colour Index No. 51319).

(b) Uses and restrictions. (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(d) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 721(c) of the act.

§ 73.3110 Chlorophyllin-copper complex, oil soluble.

(a) Identity. The color additive is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which in turn is replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) Uses and restrictions. (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be

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and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[58 FR 41324, Oct. 21, 1993]

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Chlorophyllin-copper complex, oil soluble.

(a) Identity. The color additive is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which in turn is replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) Specifications. The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), 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 current good manufacturing practice:

- Moisture, not more than 0.5 percent.
- Nitrogen, not less than 0.2 percent and not more than 0.3 percent.
- Total copper, not less than 0.2 percent and not more than 0.4 percent.
- Free copper, not more than 200 parts per million.
- Lead, not more than 20 parts per million.
- Arsenic, not more than 5 parts per million.
- Sulfated ash, not more than 2.5 percent.
- Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) Uses and restrictions. (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be