Food and Drug Administration, HHS

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

(a) Identity. The color additives are the copolymers formed as the reaction product of 1,4-bis[4-(2-methacryloxyethyl)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.

(2) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to contact lenses made from the color additives.

(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, 1988]

§ 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. 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.

(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.

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