

§73.3110a

21 CFR Ch. I (4-1-11 Edition)

(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 used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for this use 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 with respect to the polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.

(d) *Labeling.* The label 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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 56370, Dec. 21, 1983]

§73.3110a Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide (Pigment Blue 36) (CAS Reg. No. 68187-11-1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of §73.1015 (a) and (b).

(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.

(2) Authorization for this use 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 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.

[53 FR 41325, Oct. 21, 1988]

§73.3111 Chromium oxide greens.

(a) *Identity and specifications.* The color additive chromium oxide greens (chromic oxide) (CAS Reg. No. 1308-38-9), Color Index No. 77288, shall conform in identity and specifications to the requirements of §73.1327 (a)(1) and (b).

(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.

(2) Authorization and compliance with this use 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 with respect to the contact lenses in which the 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.

[51 FR 24816, July 9, 1986]