Subpart D—Medical Devices

§ 73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.

(a) Identity. The color additives are 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561–07–1) copolymerized either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with N,N-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate 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.

[61 FR 51586, Oct. 3, 1996]

§ 73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.

(a) Identity. The color additive is 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 6737–68–4).

(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.

[49 FR 30066, July 26, 1984]

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

(a) Identity. The color additive is 1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (CAS Reg. No. 121888–69–5), copolymerized with hydroxyethyl methacrylate monomer, or a blend of hydroxyethyl methacrylate and N-vinyl pyrrolidone monomers, or a blend of 3-[tris(trimethylsiloxy)silyl]propyl vinyl carbamate (CAS Reg. No. 134072–99–4) and N-vinyl pyrrolidone 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.
§ 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.

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

[58 FR 17507, Apr. 5, 1993, as amended at 60 FR 10497, Feb. 27, 1995]

§ 73.3107a 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