Food and Drug Administration, HHS § 73.3123

(6) Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amo-4-((3-(4,6-dichloro-2-triazin-2-yl)amino)-4-sulfosulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499–01–8);

(7) C.I. Reactive Red 11 [5-((4,6-dichloro-1,3,5-triazin-2-yl)amino)-4-hydroxy-3-(1-sulfophenyl)azo)-2,7-naphtalenedisulfonic acid, trisodium salt] (CAS Reg. No. 12226–08–3);

(8) C.I. Reactive Yellow 86 [1,3-benzenedisulfonic acid, 4-((5-aminocarbonyl-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-5-pyridinyl)azo)-6-(4,6-dichloro-1,3,5-triazin-2-yl)amino)-, disodium salt] (CAS Reg. No. 61951–86–8);

(9) C.I. Reactive Blue 163 [triphenodioxazinedisulfonic acid, 6,13-dichloro-3,10-bis(4-((4,6-dichloro-1,3,5-triazin-2-yl)amino)-sulfophenyl)aminol-], tetrasodium salt] (CAS Reg. No. 72847–56–4); and


(b) Uses and restrictions. (1) The substances listed in paragraph (a) of this section may be used to color 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 with respect to the contact lens in which the color additive is used.

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

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

§ 73.3124  Phthalocyanine green.

(a) Identity. The color additive is phthalocyanine green (CAS Reg. No. 1328–53–6), Colour Index No. 74260.

(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 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.

[51 FR 11436, Apr. 3, 1986]

§ 73.3125  Iron oxides.

(a) Identity and specifications. The color additive iron oxides (CAS Reg. No. 1332–37–2), Colour Index No. 77491, shall conform in identity and specifications to the requirements of §73.2250 (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 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 lens 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 §70.25 of this chapter.


§ 73.3126  Titanium dioxide.

(a) Identity and specifications. The color additive titanium dioxide (CAS Reg. No. 13463–67–7), Colour Index No. 77891, shall conform in identity and specifications to the requirements of §73.575(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 11433, Apr. 3, 1986]