§ 73.3125 Iron oxides.

(a) Identity and specifications. The color additive iron oxides (CAS Reg. No. 1332–37–2), Color 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 section 721(c) of the act.


§ 73.3126 Titanium dioxide.

(a) Identity and specifications. The color additive titanium dioxide (CAS Reg. No. 13463–67–7), Color 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 24816, July 9, 1986]

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) Identity. The color additives are formed by reacting the dyes, either alone or in combination, with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dyes are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dyes are:


(2) C.I. Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-, tetrasodium salt] (CAS Reg. No. 17095–24–8).

(3) C.I. Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-] (CAS Reg. No. 68189–39–9).

(4) C.I. Reactive Yellow 15 [benzenesulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1H-pyrazol-1-yl)-] (CAS Reg. No. 60598–41–0).

(5) C.I. Reactive Blue No. 19 [2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-(2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580–78–1).


(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
§ 73.3128 Mica-based pearlescent pigments.

(a) Identity and specifications. The color additive is formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica. Mica used to manufacture the color additive shall conform in identity and specifications to the requirements of §73.1496(a)(1) and (b).

(b) Uses and restrictions. (1) Mica-based pearlescent pigments 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 (the 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 in §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 batches thereof are exempt from the certification requirements of section 721(c) of the act.

[58 FR 3227, Jan. 8, 1993, as amended at 58 FR 17510, Apr. 5, 1993]

§ 73.3129 Disodium 1-amino-4-[4-(2-bromo-1-oxoallyl)amino]-2-sulphonato-phenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate.

(a) Identity. The color additive is disodium 1-amino-4-[4-(2-bromo-1-oxoallyl)amino]-2-sulphonato-phenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate (Reactive Blue 69) (CAS Reg. No. 70209–99–3, Colour Index No. 612037).

(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 in §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 batches thereof are exempt from the certification requirements of section 721(c) of the act.

[76 FR 25235, May 4, 2011]