

§ 73.3126

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.

[51 FR 24816, July 9, 1986]

§ 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:

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(1) C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl)sulfonyl)-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114-32-0).

(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. 60958-41-0).

(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).

(6) C.I. Reactive Blue 21 [copper, (29H,31H-phthalocyaninato(2-)-N²⁹, N³⁰, N³¹, N³²)-, sulfo((4-(2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)sulfonyl derivatives] (CAS Reg. No. 73049-92-0).

(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) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dye.

(3) 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). A person intending to introduce a device containing a vinyl alcohol/methyl methacrylate-dye reaction product listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket

approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(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, this color additive is 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]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

Sec.	
74.101	FD&C Blue No. 1.
74.102	FD&C Blue No. 2.
74.203	FD&C Green No. 3.
74.250	Orange B.
74.302	Citrus Red No. 2.
74.303	FD&C Red No. 3.
74.340	FD&C Red No. 40.
74.705	FD&C Yellow No. 5.
74.706	FD&C Yellow No. 6.

Subpart B—Drugs

74.1101	FD&C Blue No. 1.
74.1102	FD&C Blue No. 2.
74.1104	D&C Blue No. 4.
74.1109	D&C Blue No. 9.
74.1203	FD&C Green No. 3.
74.1205	D&C Green No. 5.
74.1206	D&C Green No. 6.
74.1208	D&C Green No. 8.
74.1254	D&C Orange No. 4.
74.1255	D&C Orange No. 5.
74.1260	D&C Orange No. 10.
74.1261	D&C Orange No. 11.
74.1303	FD&C Red No. 3.
74.1304	FD&C Red No. 4.
74.1306	D&C Red No. 6.
74.1307	D&C Red No. 7.
74.1317	D&C Red No. 17.
74.1321	D&C Red No. 21.
74.1322	D&C Red No. 22.
74.1327	D&C Red No. 27.
74.1328	D&C Red No. 28.
74.1330	D&C Red No. 30.
74.1331	D&C Red No. 31.
74.1333	D&C Red No. 33.
74.1334	D&C Red No. 34.
74.1336	D&C Red No. 36.
74.1339	D&C Red No. 39.

74.1340	FD&C Red No. 40.
74.1602	D&C Violet No. 2.
74.1705	FD&C Yellow No. 5.
74.1706	FD&C Yellow No. 6.
74.1707	D&C Yellow No. 7.
74.1707a	Ext. D&C Yellow No. 7.
74.1708	D&C Yellow No. 8.
74.1710	D&C Yellow No. 10.
74.1711	D&C Yellow No. 11.

Subpart C—Cosmetics

74.2101	FD&C Blue No. 1.
74.2104	D&C Blue No. 4.
74.2151	D&C Brown No. 1.
74.2203	FD&C Green No. 3.
74.2205	D&C Green No. 5.
74.2206	D&C Green No. 6.
74.2208	D&C Green No. 8.
74.2254	D&C Orange No. 4.
74.2255	D&C Orange No. 5.
74.2260	D&C Orange No. 10.
74.2261	D&C Orange No. 11.
74.2304	FD&C Red No. 4.
74.2306	D&C Red No. 6.
74.2307	D&C Red No. 7.
74.2317	D&C Red No. 17.
74.2321	D&C Red No. 21.
74.2322	D&C Red No. 22.
74.2327	D&C Red No. 27.
74.2328	D&C Red No. 28.
74.2330	D&C Red No. 30.
74.2331	D&C Red No. 31.
74.2333	D&C Red No. 33.
74.2334	D&C Red No. 34.
74.2336	D&C Red No. 36.
74.2340	FD&C Red No. 40.
74.2602	D&C Violet No. 2.
74.2602a	Ext. D&C Violet No. 2.
74.2705	FD&C Yellow No. 5.
74.2706	FD&C Yellow No. 6.
74.2707	D&C Yellow No. 7.
74.2707a	Ext. D&C Yellow No. 7.
74.2708	D&C Yellow No. 8.
74.2710	D&C Yellow No. 10.
74.2711	D&C Yellow No. 11.

Subpart D—Medical Devices

74.3045	[Phthalocyaninato(2-)] copper.
74.3102	FD&C Blue No. 2.
74.3106	D&C Blue No. 6.
74.3206	D&C Green No. 6.
74.3230	D&C Red No. 17.
74.3602	D&C Violet No. 2.
74.3710	D&C Yellow No. 10.

APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

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