

§ 73.3128

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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]

§ 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.

[67 FR 65312, Oct. 24, 2002]

§ 73.3129 Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]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-sulphonatophenyl]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 Federal Food, Drug, and Cosmetic Act.

[76 FR 25235, May 4, 2011]

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

- 74.2052 D&C Black No. 2.
- 74.2053 D&C Black No. 3.
- 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.

SOURCE: 42 FR 15654, Mar. 22, 1977, unless otherwise noted.

Subpart A—Foods

§ 74.101 FD&C Blue No. 1.

(a) *Identity.* (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[*p*-[ethyl (*m*-sulfobenzyl) amino]- α -(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]- α -(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[*p*-[ethyl (*o*-sulfobenzyl) amino] - α - (*o*