

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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[50 FR 20407, May 16, 1985]

**§ 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol.**

(a) *Identity.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol is formed in situ in soft (hydrophilic) contact lenses.

(b) *Uses and restrictions.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol may be safely used to mark soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes subject to the following restrictions:

(1) The quantity of the color additive does not exceed  $1.1 \times 10^{-7}$  grams in a soft (hydrophilic) contact lens.

(2) When used as specified in the labeling, there is no measurable migration of the color additive from the contact lens to the surrounding ocular tissue.

(3) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k) and 515 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.

[48 FR 22706, May 20, 1983]

**§ 73.3117 16,23-Dihydrodinaphtho[2,3-a:2',3'-i] naphth [2',3':6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.**

(a) *Identity.* The color additive is 16,23-dihydrodinaphtho [2,3- a:2',3'-i] naphth [2',3':6,7] indolo [2, 3-c] carbazole-5,10, 15,17,22,24-hexone (CAS Reg. No. 2475-33-4), Colour Index No. 70800.

(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.

[48 FR 31375, July 8, 1983]

**§ 73.3118 N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.**

(a) *Identity.* The color additive is N,N'-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide (CAS Reg. No. 82-18-8), Colour Index No. 61725.

(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.

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(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.

[48 FR 31375, July 8, 1983]

### § 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

(a) *Identity.* The color additive is 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (CAS Reg. No. 130-20-1), Colour Index No. 69825.

(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.

[48 FR 31376, July 8, 1983]

### § 73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3',2',1'-lm] perylene-5,10-dione.

(a) *Identity.* The color additive is 16,17-dimethoxydinaphtho[1,2,3-cd:3',2',1'-lm]perylen-5,10-dione (CAS Reg. No. 128-58-5), Colour Index No. 59825.

(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

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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.

[48 FR 31376, July 8, 1983]

### § 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.

(a) *Identity.* The color additives are formed by reacting one or more of the reactive dyes listed in this paragraph with poly(hydroxyethyl methacrylate), so that the sulfate group (or groups) or chlorine substituent of the dye is replaced by an ether linkage to poly(hydroxyethyl methacrylate). The dyes that may be used alone or in combination are

(1) 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);

(2) Reactive Blue 21 [copper, (29H,31H-phthalocyaninato(2-)-N<sup>29</sup>,N<sup>30</sup>,N<sup>31</sup>,N<sup>32</sup>)-, sulfo((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)sulfonyl derivs)] (CAS Reg. No. 73049-92-0);

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

(4) 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) Reactive Blue No. 19 [2-anthracene-sulfonic 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);