

§ 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, (29*H*,31*H*-phthalocyaninato(2-)-*N*²⁹,*N*³⁰,*N*³¹,*N*³²)-, sulfo((4-(2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)sulfonyl derivs] (CAS Reg. No. 73049-92-0);

(3) 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) 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-1*H*-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);

(6) Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-*s*-triazin-2-yl)amino)-4-sulfoanilino)-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-sulfo-2-naphthalenyl)azo)-2,7-naphthalenedisulfonic 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-3-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)sulfonyl)amino)-, tetrasodium salt] (CAS Reg. No. 72847-56-4); and

(10) 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).

(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 dyes.

(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 poly(hydroxyethyl methacrylate)-dye copolymer 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 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.

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