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

(a) Identity. The color additive is disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulfonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulfonate (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 there-of are exempt from the certification requirements of section 721(c) of the act.

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[76 FR 56312, Oct. 24, 2002]

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[76 FR 25235, May 4, 2011, as amended at 78 FR 14664, Mar. 7, 2013]