

§ 73.2550 Silver nitrate.

(a) *Identity.* The color additive silver nitrate is a purified inorganic compound obtained as the recrystallized precipitate from the concentrated reaction mixture of silver and excess nitric acid at elevated temperatures, followed by drying the decanted, filtered, and washed crystals. The color additive has the chemical formula AgNO_3 .

(b) *Specifications.* Silver nitrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

(1) Arsenic, not more than 3 milligrams/kilogram (mg/kg) (3 parts per million (ppm)).

(2) Cadmium, not more than 5 mg/kg (5 ppm).

(3) Lead, not more than 10 mg/kg (10 ppm).

(4) Mercury, not more than 1 mg/kg (1 ppm).

(5) Volatile matter, calculated as water, not more than 0.1 percent.

(6) Total color, not less than 99.9 percent.

(c) *Uses and restrictions.* The color additive silver nitrate may be safely used in externally applied professional-use only cosmetics intended to impart color to the eyebrows and eyelashes subject to the following restrictions:

(1) The amount of silver nitrate in the cosmetic product shall not be more than 4 percent by weight.

(2) The viscosity of the cosmetic formulation shall be not less than 120 Pascal-seconds (Pa·s) and not more than 180 Pa·s at normal temperature and pressure.

(3) The cosmetic containing silver nitrate is not intended for use on persons under the age of 16.

(4) Application of the cosmetic containing silver nitrate is not intended to exceed 1 minute and is intended to be followed by immediate removal.

(5) The cosmetic containing silver nitrate is applied by a professional.

(6) The cosmetic containing silver nitrate is not distributed or directly sold to consumers.

(d) *Labeling requirements.* (1) The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall con-

form to the requirements of § 70.25 of this chapter and include adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The label of any cosmetic containing the color additive silver nitrate, in addition to other information required by law, shall contain the following statements: Contains silver nitrate. Silver nitrate may permanently stain skin with which it comes into contact. Silver nitrate may irritate the eyes. For application by professionals only for dyeing eyebrows and eyelashes, in accordance with the directions for use. Not for use on persons under the age of 16. Apply to eyebrows and eyelashes for no more than 1 minute, followed by immediate removal. Rinse eyes immediately if product comes into contact with them. Consult a physician if any irritation persists. Not for distribution or direct sale to consumers.

(e) *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

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§ 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications to the requirements on § 73.575 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions 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 batches thereof are exempt from certification pursuant to section 721(c) of the act.