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Title 21 — Food and Drugs

Chapter I — Food and Drug Administration, Department of Health and Human Services

Subchapter A — General

Part 73 — Listing of Color Additives Exempt from Certification

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Editorial Note: Nomenclature changes to part 73 appear at 66 FR 66742, Dec. 27, 2001.

Subpart C—Cosmetics

§ 73.2030 Annatto.

- (a) **Identity and specification.** The color additive annatto shall conform in identify and specification to the requirements for annatto extract in § 73.30(a) (1) and (b).
- (b) **Use and restriction.** The color additive annatto may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any 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 the certification requirements of section 721(c) of the act.

[42 FR 36994, July 19, 1977]

§ 73.2085 Caramel.

- (a) **Identity and specifications.** The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a)(1), (2), and (3) and (b).
- (b) **Uses and restrictions.** Caramel is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling requirements.** The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom 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 batches thereof are exempt from the certification requirement of section 721(c) of the act.

[46 FR 38501, July 28, 1981]

§ 73.2087 Carmine.

- (a) **Identity and specifications.** The color additive carmine shall conform in identity and specifications to the requirements of § 73.100 (a)(2) and (b)(2).
- (b) **Use and restrictions.** Carmine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.
- (c) **Labeling.**

- (1) The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.
- (2) Cosmetics containing carmine that are not subject to the requirements of § 701.3 of this chapter shall specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. For example: "Contains carmine as a color additive."
- (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 pursuant to section 721(c) of the act.

[42 FR 32228, June 24, 1977, as amended at 74 FR 216, Jan. 5, 2009]

§ 73.2095 β -Carotene.

- (a) **Identity and specifications.** The color additive β -carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).
- (b) **Uses and restrictions.** The color additive β -carotene may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any 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 the certification pursuant to section 721(c) of the act.

[42 FR 33722, July 1, 1977]

§ 73.2110 Bismuth citrate.

- (a) **Identity.** The color additive bismuth citrate is the synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of $\text{BiC}_6\text{H}_5\text{O}_7$.
- (b) **Specifications.** The color additive bismuth citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that those impurities may be avoided by good manufacturing practice:

Bismuth citrate, not less than 97 percent.

Mercury (as Hg), not more than 1 part per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 20 parts per million.

Volatile matter, not more than 1 percent.

(c) **Uses and restrictions.** The color additive bismuth citrate may be safely used in cosmetics intended for coloring hair on the scalp, subject to the following restrictions:

- (1) The amount of bismuth citrate in the cosmetic shall not be in excess of 2.0 percent (w/v).
- (2) The cosmetic may not be used for coloring eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) **Labeling.**

- (1) The label of the color additive bismuth citrate shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.
- (2) The label of a cosmetic containing the color additive bismuth citrate shall bear, in addition to other information required by law, the following statement, conspicuously displayed thereon:

Keep this product out of children's reach. Do not use on cut or abraded scalp. Do not use to color eyelashes, eyebrows, or hair on parts of the body other than the scalp. Wash hands thoroughly after each use.

(e) **Exemption from certification.** Certification of this color additive for the prescribed use is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from certification requirements of section 721(c) of the act.

[43 FR 44831, Sept. 29, 1978, as amended at 75 FR 14493, Mar. 26, 2010]

§ 73.2120 Disodium EDTA-copper.

- (a) **Identity.** The color additive disodium EDTA-copper is disodium [[N,N'- 1,2- ethanediylbis[N - (carboxymethyl) glycinato]] (4-)-N,N',O,O',O^N,O^{N'}] cuprate (2-).
- (b) **Specifications.** Disodium EDTA-copper 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:

Total copper, not less than 13.5 percent.

Total (ethylene-dinitrilo) tetracetic acid, not less than 62.5 percent.

Free copper, not more than 100 parts per million.

Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.

Moisture, not more than 15 percent.

Water insoluble matter, not more than 0.2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

- (c) **Uses and restrictions.** Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.
- (d) **Labeling requirements.** The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.
- (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 requirements of section 721(c) of the act.

§ 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

- (a) **Identity and specifications.** The color additive potassium sodium copper chlorophyllin shall conform in identity and specifications to the requirements of § 73.1125(a)(1) and (b).
- (b) **Uses and restrictions.** Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are cosmetics subject to the following conditions:

- (1) It shall not be used at a level in excess of 0.1 percent.
- (2) It may be used only in combination with the following substances:

Water.

Glycerin.

Sodium carboxymethylcellulose.

Tetrasodium pyrophosphate.

Sorbitol.

Magnesium phosphate, tribasic.

Calcium carbonate.

Calcium phosphate, dibasic.

Sodium *N*-lauroyl sarcosinate.

Artificial sweeteners that are generally recognized as safe or that are authorized under subchapter B of this chapter.

Flavors that are generally recognized as safe or that are authorized under subchapter B of this chapter.

Preservatives that are generally recognized as safe or that are authorized under subchapter B of this chapter.

- (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 batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2150 Dihydroxyacetone.

- (a) **Identity and specifications.** The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150 (a)(1) and (b).
- (b) **Uses and restrictions.** Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.
- (c) **Labeling requirements.** The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes 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 batches thereof are exempt from the requirements of section 721(c) of the act.

§ 73.2162 Bismuth oxychloride.

- (a) **Identity and specifications.**
 - (1) The color additive bismuth oxychloride shall conform in identity and specifications to the requirements of § 73.1162(a)(1) and (b).
 - (2) Color additive mixtures of bismuth oxychloride may contain the following diluents:
 - (i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);
 - (ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.
- (b) **Uses and restrictions.** The color additive bismuth oxychloride may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any 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.

[42 FR 52394, Sept. 30, 1977]

§ 73.2180 Guaiazulene.

- (a) **Identity.**
 - (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.
 - (2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG-40 castor oil).

Saponification No., 60 to 70.

Hydroxyl No., 63 to 78.

Acid No., 2.

Specific gravity, 1.05 to 1.07.

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

Melting point, 30.5 °C to 31.5 °C.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 99 percent.

- (c) **Uses and restrictions.** Guaiazulene may be safely used in externally applied cosmetics in amounts consistent with good manufacturing practice.
- (d) **Labeling.** The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.
- (e) **Exemption from certification.** Certification of this color additive for the prescribed use 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.

§ 73.2190 Henna.

- (a) **Identity.** The color additive henna is the dried leaf and petiole of *Lawsonia alba* Lam. (*Lawsonia inermis* L.). It may be identified by its characteristic odor and by characteristic plant histology.

- (b) **Specifications.** Henna shall conform to the following specifications:

It shall not contain more than 10 percent of plant material from *Lawsonia alba* Lam. (*Lawsonia inermis* L.) other than the leaf and petiole, and shall be free from admixture with material from any other species of plant.

Moisture, not more than 10 percent.

Total ash, not more than 15 percent.

Acid-insoluble ash, not more than 5 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

(c) **Uses and restrictions.** The color additive henna may be safely used for coloring hair only. It may not be used for coloring the eyelashes or eyebrows, or generally in the area of the eye.

(d) **Labeling.** The label for henna shall bear the information required by § 70.25 of this chapter and the following statements or their equivalent:

“Do not use in the area of the eye.”

“Do not use on cut or abraded scalp.”

(e) **Exemption from certification.** Certification of this color additive for the prescribed use 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.

§ 73.2250 Iron oxides.

(a) **Identity.** The color additives iron oxides consist of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(b) **Specifications.** Iron oxides shall conform to the following specifications, all on an “as is” basis:

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) **Uses and restrictions.** Iron oxides are safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(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 certification pursuant to section 721(c) of the act.

§ 73.2298 Ferric ammonium ferrocyanide.

(a) **Identity and specifications.** The color additive ferric ammonium ferrocyanide shall conform in identify and specifications to the requirements of § 73.1298 (a)(1) and (b).

(b) **Uses and restrictions.** Ferric ammonium ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 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 pursuant to section 721(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 43 FR 6939, Feb. 17, 1978]

§ 73.2299 Ferric ferrocyanide.

- (a) **Identity and specifications.** The color additive ferric ferrocyanide shall conform in identity and specifications to the requirements of § 73.1299(a)(1) and (b).
- (b) **Uses and restrictions.** Ferric ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 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 under section 721(c) of the act.

[43 FR 54236, Nov. 21, 1978]

§ 73.2326 Chromium hydroxide green.

- (a) **Identity and specifications.** The color additive chromium hydroxide green shall conform in identity and specifications to the requirements of § 73.1326 (a)(1) and (b).
- (b) **Uses and restrictions.** Chromium hydroxide green is safe for use in coloring externally applied cosmetics, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 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.

[42 FR 36452, July 15, 1977]

§ 73.2327 Chromium oxide greens.

- (a) **Identity and specifications.** The color additive chromium oxide greens shall conform in identify and specifications to the requirements of § 73.1327 (a)(1) and (b).

- (b) **Uses and restrictions.** The color additive chromium oxide greens may be safely used in externally applied 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 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 the certification pursuant to section 721(c) of the act.

[42 FR 36452, July 15, 1977]

§ 73.2329 Guanine.

- (a) **Identity and specifications.**
 - (1) The color additive guanine shall conform in identity and specifications to the requirements of § 73.1329 (a)(1) and (b).
 - (2) Color additive mixtures of guanine may contain the following diluents:
 - (i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);
 - (ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.
- (b) **Use and restrictions.** The color additive guanine may be safely used in cosmetics generally, 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 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 the certification pursuant to section 721(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.2400 Pyrophyllite.

- (a) **Identity and specifications.** The color additive pyrophyllite shall conform in identity and specifications to the requirements of § 73.1400 (a)(1) and (b).
- (b) **Uses and restrictions.** Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.
- (c) **Labeling requirements.** The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to all applicable requirements of law, including 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 batches thereof are exempt from the certification requirements of section 721(c) of the act.

§ 73.2496 Mica.

- (a) **Identity and specifications.** The color additive mica shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).
- (b) **Uses and restrictions.** Mica is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with 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 the certification pursuant to section 721(c) of the act.

[42 FR 38561, July 29, 1977]

§ 73.2500 Silver.

- (a) **Identity.**
 - (1) The color additive, silver, is a crystalline powder of high purity silver prepared by the reaction of silver nitrate with ferrous sulfate in the presence of nitric, phosphoric and sulfuric acids. Polyvinyl alcohol is used to prevent the agglomeration of crystals and the formation of amorphous silver.
 - (2) Color additive mixtures of silver may contain only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.
- (b) **Specifications.** Silver shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 5 parts per million.

Mercury (as Hg), not more than 1 part per million.

Silver (as Ag), not less than 99.9 percent.

- (c) **Uses and restrictions.** The color additive silver may be safely used for coloring fingernail polish at a level not to exceed 1 percent of the final product.
- (d) **Labeling.** 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.

- (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 act.

[44 FR 65974, Nov. 16, 1979]

§ 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 conform 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

[86 FR 55498, Oct. 6, 2021]

§ 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.

§ 73.2645 Aluminum powder.

- (a) **Identity and specifications.** The color additive aluminum powder shall conform in identity and specifications to the requirements of § 73.1645 (a)(1) and (b).
- (b) **Uses and restrictions.** Aluminum powder may be safely used in coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any 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 the certification pursuant to section 721(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.2646 Bronze powder.

- (a) **Identity and specifications.** The color additive bronze powder shall conform in identity and specifications to the requirements of § 73.1646 (a)(1) and (b).
- (b) **Uses and restrictions.** Bronze powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.
- (d) **Exemption from certification.** Certification of the 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.

[42 FR 33724, July 1, 1977]

§ 73.2647 Copper powder.

- (a) **Identity and specifications.** The color additive copper powder shall conform in identity and specifications to the requirements of § 73.1647 (a)(1) and (b).
- (b) **Uses and restrictions.** Copper powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (c) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.
- (d) **Exemption from certification.** Certification of the 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.

[42 FR 33724, July 1, 1977]

§ 73.2725 Ultramarines.

- (a) **Identity.** The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700 °C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula $\text{Na}(\text{AlSiO})\text{S}$ with proportions of each element varying with each color.
- (b) **Specifications.** The ultramarines shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

- (c) **Uses and restrictions.** The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.
- (d) **Labeling requirements.** The color additives 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 § 70.25 of this chapter.
- (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 certification pursuant to section 721(c) of the act.

§ 73.2775 Manganese violet.

- (a) **Identity.** The color additive manganese violet is a violet pigment obtained by reacting phosphoric acid, ammonium dihydrogen orthophosphate, and manganese dioxide at temperatures above 450 °F. The pigment is a manganese ammonium pyrophosphate complex having the approximate formula: $\text{Mn(III)NH}_4\text{P}_2\text{O}_7$.
- (b) **Specifications.** Manganese violet shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Ash (at 600 °C), not less than 81 percent.

Volatile matter at 135 °C for 3 hours, not more than 1 percent.

Water soluble substances, not more than 6 percent.

pH of filtrate of 10 grams color additive (shaken occasionally for 2 hours with 100 milliliters of freshly boiled distilled water), not more than 4.7 and not less than 2.5.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, based on Mn content in “as is” sample, not less than 93 percent.

- (c) **Uses and restrictions.** Manganese violet is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.
- (d) **Labeling.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

- (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 certification pursuant to section 721(c) of the act.

§ 73.2991 Zinc oxide.

- (a) **Identity and specifications.** The color additive zinc oxide shall conform in identity and specifications to the requirements of § 73.1991 (a)(1) and (b).
- (b) **Uses and restrictions.** Zinc oxide 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.** The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 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 pursuant to section 721(c) of the act.

[42 FR 37538, July 22, 1977]

§ 73.2995 Luminescent zinc sulfide.

- (a) **Identity.** The color additive luminescent zinc sulfide is zinc sulfide containing a copper activator. Following excitation by daylight or a suitable artificial light, luminescent zinc sulfide produces a yellow-green phosphorescence with a maximum at 530 nanometers.
- (b) **Specifications.** Luminescent zinc sulfide 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:

Zinc sulfide, not less than 99.8 percent.

Copper, 100±5 parts per million.

Lead, not more than 20 parts per million.

Arsenic, not more than 3 parts per million.

Mercury, not more than 1 part per million.

Cadmium, not more than 15 parts per million.

- (c) **Uses and restrictions.** The color additive luminescent zinc sulfide may be safely used for coloring externally applied facial makeup preparations and nail polish included under § 720.4(c)(7)(ix) and (c)(8)(v) of this chapter, respectively, to the following restrictions:
 - (1) The amount of luminescent zinc sulfide in facial makeup preparations shall not exceed 10 percent by weight of the final product.

- (2) Facial makeup preparations containing luminescent zinc sulfide are intended for use only on limited, infrequent occasions, e.g., Halloween, and not for regular or daily use.

(d) **Labeling requirements.**

- (1) The label of the color additive and any mixtures prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.
- (2) The label of a facial makeup preparation containing the color additive shall bear, in addition to other information required by the law, the following statement conspicuously displayed:

Do not use in the area of the eye.

- (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 act.

[65 FR 48377, Aug. 8, 2000; 65 FR 75158, Dec. 1, 2000]