

§ 73.1991 Zinc oxide.

(a) *Identity.* (1) The color additive zinc oxide is a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized). It is principally composed of Zn.

(2) Color additive mixtures for drug use made with zinc oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Zinc oxide 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 oxide (as ZnO), not less than 99 percent. Loss on ignition at 800 °C, not more than 1 percent.

Cadmium (as Cd), not more than 15 parts per million.

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.

(c) *Uses and restrictions.* The color additive zinc oxide may be safely used for coloring externally applied drugs, including those used in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* 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.

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

[42 FR 37537, July 22, 1977]

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

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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 BiC₆H₅O₇.

(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-ethanediy]bis[N - (carboxymethyl)glycinato]] (4-)-N,N',O,O',O^N,O^{N'}] cuprate (2-).