

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 71.26 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 71.27 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in part 73 or 74 of this chapter.

§ 71.30 Procedure for filing objections to regulations.

(a) Objections and hearings relating to color additive regulations under section 721 (b) and (c) of the act shall be governed by parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts

qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION**Subpart A—Foods**

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 73.3115 2-[[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5-benzenetriol].
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 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.
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AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

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

Subpart A—Foods

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has

been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. If a specification for a particular diluent is not set forth in this part 73, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under subchapter B of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

| Substances | Definitions and specifications | Restrictions |
|---|---|--|
| Calcium disodium EDTA (calcium disodium ethyl-enediamine-tetraacetate). | Contains calcium disodium ethyl-enediamine-tetraacetate dihydrate (CAS Reg. No. 6766-87-6) as set forth in the Food Chemicals Codex, 3d ed., p. 50, 1981. | May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous calcium disodium ethyl-enediamine-tetraacetate). |
| Castor oil | As set forth in U.S.P. XVI | Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction. |
| Diocylsodium sulfosuccinate | As set forth in sec. 172.810 of this chapter. | Not more than 9 p.p.m. in the finished food. Labeling of color additive mixtures containing diocylsodium sulfosuccinate shall bear adequate directions for use that will result in a food meeting this restriction. |
| Disodium EDTA (disodium ethyl-enediamine-tetraacetate). | Contains disodium ethyl-enediamine-tetraacetate dihydrate (CAS Reg. No. 6381-92-6) as set forth in the Food Chemicals Codex, 3d ed., p. 104, 1981. | May be used in aqueous solutions and aqueous dispersions as a preservative and sequestrant in color additive mixtures intended only for ingested use; the color additive mixture (solution or dispersion) may contain not more than 1 percent by weight of the diluent (calculated as anhydrous disodium ethyl-enediamine-tetraacetate). |

(b) *Special use*—(1) *Diluents in color additive mixtures for marking food*—(i) *Inks for marking food supplements in tablet form, gum, and confectionery.* Items listed in paragraph (a) of this section and the following:

| Substances | Definitions and specifications | Restrictions |
|---|---|--------------|
| Alcohol, SDA-3A | As set forth in 26 CFR pt. 212 | No residue. |
| <i>n</i> -Butyl alcohol | | Do. |
| Cetyl alcohol | As set forth in N.F. XI | Do. |
| Cyclohexane | | Do. |
| Ethyl cellulose | As set forth in sec. 172.868 of this chapter. | |
| Ethylene glycol monoethyl ether | | Do. |
| Isobutyl alcohol | | Do. |
| Isopropyl alcohol | | Do. |
| Polyoxyethylene sorbitan monooleate (polysorbate 80). | As set forth in sec. 172.840 of this chapter. | |
| Polyvinyl acetate | Molecular weight, minimum 2,000. | |
| Polyvinylpyrrolidone | As set forth in sec. 173.55 of this chapter. | |

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| Substances | Definitions and specifications | Restrictions |
|-----------------------------------|---|--------------|
| Rosin and rosin derivatives | As set forth in sec. 172.615 of this chapter. | |
| Shellac, purified | Food grade. | |

(ii) *Inks for marking fruit and vegetables.* Items listed in paragraph (a) of this section and the following:

| Substances | Definitions and specifications | Restrictions |
|-----------------------------------|---|--|
| Acetone | As set forth in N.F. XI | No residue. |
| Alcohol, SDA-3A | As set forth in 26 CFR pt. 212 | Do. |
| Benzoin | As set forth in U.S.P. XVI. | |
| Copal, Manila | . | |
| Ethyl acetate | As set forth in N.F. XI | Do. |
| Ethyl cellulose | As set forth in sec. 172.868 of this chapter. | |
| Methylene chloride | | Do. |
| Polyvinylpyrrolidone | As set forth in sec. 173.55 of this chapter. | |
| Rosin and rosin derivatives | As set forth in sec. 172.615 of this chapter. | |
| Silicon dioxide | As set forth in sec. 172.480 of this chapter. | Not more than 2 pct of the ink solids. |
| Terpene resins, natural | As set forth in sec. 172.615 of this chapter. | |
| Terpene resins, synthetic | Polymers of α - and β -pinene. | |

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

- Alcohol, denatured, formula 23A (26 CFR part 212), Internal Revenue Service.
- Damar gum (resin).
- Diethylene glycol distearate.
- Dioctyl sodium sulfosuccinate.
- Ethyl cellulose (as identified in §172.868 of this chapter).

- Ethylene glycol distearate.
- Japan wax.
- Limed rosin.
- Naphtha.
- Pentaerythritol ester of fumaric acid-rosin adduct.
- Polyethylene glycol 6000 (as identified in §172.820 of this chapter).
- Polyvinyl alcohol.
- Rosin and rosin derivatives (as identified in §172.820 of this chapter).

(3) *Miscellaneous special uses.* Items listed in paragraph (a) of this section and the following:

| Substances | Definitions and specifications | Restrictions |
|----------------------------|--|---|
| Polyvinylpyrrolidone | As set forth in sec. 173.55 of this chapter. | In or as food-tablet coatings; limit, not more than 0.1 pct in the finished food; labeling of color additive mixtures containing polyvinylpyrrolidone shall bear adequate directions for use that will result in a food meeting this restriction. |

[42 FR 15643, Mar. 22, 1977, as amended at 57 FR 32175, July 21, 1992]

§ 73.30 **Annatto extract.**

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants

listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may

be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(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.

§ 73.35 Astaxanthin.

(a) *Identity.* (1) The color additive astaxanthin is 3, 3'-dihydroxy- β , β -carotene-4, 4'-dione.

(2) Astaxanthin may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Astaxanthin 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:

Physical state, solid.

0.05 percent solution in chloroform, complete and clear.

Absorption maximum wavelength 484-493 nanometers (in chloroform).

Residue on ignition, not more than 0.1 percent.

Total carotenoids other than astaxanthin, not more than 4 percent.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

Heavy metals, not more than 10 parts per million.

Assay, minimum 96 percent.

(c) *Uses and restrictions.* Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes 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.

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(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with §§ 101.22(k)(2) and 101.100(a)(2) 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.

[60 FR 18738, Apr. 13, 1995]

§ 73.40 Dehydrated beets (beet powder).

(a) *Identity.* (1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.

Acid insoluble ash, not more than 0.5 percent.

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

Arsenic (as As), not more than 1 part per million.

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

(c) *Uses and restrictions.* Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(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.

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(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.

§ 73.50 Ultramarine blue.

(a) *Identity.* The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 °C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $\text{Na}_7\text{Al}_6\text{Si}_6\text{O}_{24}\text{S}_3$.

(b) *Specifications.* Ultramarine blue shall conform to the following specifications:

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

Arsenic (as As), not more than 1 part per million.

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

(c) *Uses and restrictions.* The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) *Labeling requirements.* The color additive shall be labeled in accordance with 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 certification requirements of section 721(c) of the act.

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β -carotene-4,4'-dione.

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin 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:

Physical state, solid.
 1 percent solution in chloroform, complete and clear.
 Melting range (decomposition), 207 °C. to 212 °C. (corrected).
 Loss on drying, not more than 0.2 percent.
 Residue on ignition, not more than 0.2 percent.
 Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
 Lead, not more than 10 parts per million.
 Arsenic, not more than 3 parts per million.
 Mercury, not more than 1 part per million.
 Assay, 96 to 101 percent.

(c) *Use and restrictions.* (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:

(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and

(ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogram (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling 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.

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, 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)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) 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.

[42 FR 15643, Mar. 22, 1977, as amended at 50 FR 47534, Nov. 19, 1985; 63 FR 14817, Mar. 27, 1998]

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.
 Invert sugar.
 Lactose.
 Malt sirup.
 Molasses.
 Starch hydrolysates and fractions thereof.
 Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

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Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in §172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

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

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 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.

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§ 73.90 β -Apo-8'-carotenal.

(a) *Identity.* (1) The color additive is β -apo-8'-carotenal.

(2) Color additive mixtures for food use made with β -apo-8'-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β -Apo-8'-carotenal shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Melting point (decomposition), 136 °C.-140 °C. (corrected).
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96-101 percent.

(c) *Uses and restrictions.* The color additive β -apo-8'-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β -apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 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.

§ 73.95 β -Carotene.

(a) *Identity.* (1) The color additive is β -carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β -carotene may contain only diluents that are suitable and that are listed in this subpart as safe in

color additive mixtures for coloring foods.

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

Physical state, solid.

1 percent solution in chloroform, clear.

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

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

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

Assay (spectrophotometric), 96–101 percent.

(c) *Uses and restrictions.* The color additive β -carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 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.

§ 73.100 Cochineal extract; carmine.

(a) *Identity.* (1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti* L.)).

(3) Color additive mixtures for food use made with cochineal extract or carmine may contain only diluents that are suitable and that are listed in this

subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 °C.

Protein (N \times 6.25), not more than 2.2 percent. Total solids, not less than 5.7 and not more than 6.3 percent.

Methyl alcohol, not more than 150 parts per million.

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

Arsenic (as As), not more than 1 part per million.

Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135 °C. for 3 hours), not more than 20.0 percent.

Ash, not more than 12.0 percent.

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

Arsenic (as As), not more than 1 part per million.

Carminic acid, not less than 50.0 percent.

Carmine and cochineal extract shall be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal extract free of viable *Salmonella* microorganisms, which substances are not food additives as defined in section 201(s) of the act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the act.

(c) *Uses and restrictions.* Carmine and cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

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(d) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of these color additives 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.

§ 73.140 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

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

Free gossypol content, not more than 450 parts per million.

(c) *Uses and restrictions.* The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless added color is authorized by such standards.

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(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and 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 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.

§ 73.160 Ferrous gluconate.

(a) *Identity.* The color additive ferrous gluconate is the ferrous gluconate defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 122–123, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(b) *Specifications.* Ferrous gluconate shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section.

(c) *Uses and restrictions.* Ferrous gluconate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label 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 certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.165 Ferrous lactate.

(a) *Identity.* The color additive ferrous lactate is the ferrous lactate defined in § 184.1311 of this chapter.

(b) *Specifications.* Ferrous lactate shall meet the specifications given in the Food Chemicals Codex, 4th ed. (1996), pp. 154 to 155, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National

Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) *Uses and restrictions.* Ferrous lactate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label 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 certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act (the act).

[61 FR 40319, Aug. 2, 1996, as amended at 66 FR 66742, Dec. 27, 2001]

§ 73.169 Grape color extract.

(a) *Identity.* (1) The color additive grape color extract is an aqueous solution of anthocyanin grape pigments made from Concord grapes or a dehydrated water soluble powder prepared from the aqueous solution. The aqueous solution is prepared by extracting the pigments from precipitated lees produced during the storage of Concord grape juice. It contains the common components of grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc., but not in the same proportion as found in grape juice. The dehydrated water soluble powder is prepared by spray drying the aqueous solution containing added malto-dextrin.

(2) Color additive mixtures for food use made with grape color extract may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape color extract shall conform to the following specifications: Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act. Lead (as Pb), not more than

10 parts per million. Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape color extract may be safely used for the coloring of nonbeverage food, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

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

[46 FR 47532, Sept. 29, 1981]

§ 73.170 Grape skin extract (enocianina).

(a) *Identity.* (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

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

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) *Labeling requirements.* 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. The common or usual name of the color additive is "grape skin extract" followed, if desired, by "(enocianina)".

(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.

§ 73.185 Haematococcus algae meal.

(a) *Identity.* (1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.

(2) Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Haematococcus algae meal 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:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

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Mercury, not more than 1 part per million.

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

Astaxanthin, not less than 1.5 percent.

(c) *Uses and restrictions.* Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes 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 presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing haematococcus algae meal shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) 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.

[65 FR 41584, July 6, 2000]

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide

may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Synthetic iron oxide for human food use shall conform to the following specifications:

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 1 part per million.

(2) Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

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

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

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

(c) *Uses and restrictions.* (1) Synthetic iron oxide may be safely used for the coloring of sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(2) Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* 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.

(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.

[42 FR 15643, Mar. 22, 1977, as amended at 59 FR 10578, Mar. 7, 1994]

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of

identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, 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 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.260 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, 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 15643, Mar. 22, 1977, as amended at 60 FR 52629, Oct. 10, 1995]

§ 73.275 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(c) *Labeling.* The label of the color additives and any premixes prepared therefrom shall bear in addition to the

information required by § 70.25 of this chapter.

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(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.

§ 73.295 Tagetes (Aztec marigold) meal and extract.

(a) *Identity.* (1) The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(2) The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta* L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) *Specifications.* (1) Tagetes (Aztec marigold) meal is free from admixture with other plant material from *Tagetes erecta* L. or from plant material or flowers of any other species of plants.

(2) Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals meeting the specifications set forth in paragraph (b)(1) of this section and shall conform to the following additional specifications:

| | |
|-----------------------------|----------------------------|
| Melting point | 53.5-55.0 °C. |
| Iodine value | 132-145. |
| Saponification value | 175-200. |
| Acid value | 0.60-1.20. |
| Titer | 35.5-37.0 °C. |
| Unsaponifiable matter | 23.0 percent-27.0 percent. |
| Hexane residue | Not more than 25 p.p.m. |

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60 °C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination

shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) *Uses and restrictions.* The color additives tagetes (Aztec marigold) meal and extract may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additives are used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additives incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(d) *Labeling requirements.* The label of the color additives and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(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.

§ 73.300 Carrot oil.

(a) *Identity.* (1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or

carrot oleoresin under section 401 of the act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Carrot oil shall contain no more than 25 parts per million of hexane.

(c) *Uses and restrictions.* Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) *Labeling requirements.* 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 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.

§ 73.315 Corn endosperm oil.

(a) *Identity.* (1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of definition as a color additive only and shall not be construed as a food standard of identity under section 401 of the act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14 percent.

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Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) *Uses and restrictions.* The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section.

(d) *Labeling requirements.* The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter, a statement of the concentration of xanthophyll contained therein.

(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.

§ 73.340 Paprika.

(a) *Identity.* (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared there-

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from shall bear, in addition to the other information required by the act, 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.

§ 73.345 Paprika oleoresin.

(a) *Identity.* (1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum* L.) by extraction, using any one or a combination of the following solvents:

| | |
|---------------------|--------------------|
| Acetone | Isopropyl alcohol |
| Ethyl alcohol | Methyl alcohol |
| Ethylene dichloride | Methylene chloride |
| Hexane | Trichloroethylene |

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this section than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act,

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.

§ 73.355 Phaffia yeast.

(a) *Identity.* (1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *Phaffia rhodozyma*.

(2) Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Phaffia yeast 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:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

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

Astaxanthin, not less than 0.4 percent.

(c) *Uses and restrictions.* Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes 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 presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) 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.

[65 FR 41587, July 6, 2000]

§ 73.450 Riboflavin.

(a) *Identity.* (1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 262-263, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* Riboflavin shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(c) *Uses and restrictions.* Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

§ 73.500

(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.

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.500 Saffron.

(a) *Identity.* (1) The color additive saffron is the dried stigma of *Crocus sativus* L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, 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.

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2 , free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO_2 and/or aluminum

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oxide, Al_2O_3 , as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

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

Arsenic (as As), not more than 1 part per million.

Antimony (as Sb), not more than 2 parts per million.

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

Loss on ignition at 800 °C. (after drying for 3 hours at 105 °C.), not more than 0.5 percent.

Water soluble substances, not more than 0.3 percent.

Acid soluble substances, not more than 0.5 percent.

TiO_2 , not less than 99.0 percent after drying for 3 hours at 105 °C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* 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.

(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.

§ 73.600 Turmeric.

(a) *Identity.* (1) The color additive turmeric is the ground rhizome of *Curcuma longa* L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, 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.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (*Curcuma longa* L.) by extraction using any one or a combination of the following solvents:

| | |
|---------------------|--------------------|
| Acetone | Isopropyl alcohol |
| Ethyl alcohol | Methyl alcohol |
| Ethylene dichloride | Methylene chloride |
| Hexane | Trichloroethylene |

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for

the corresponding solvents in spice oleoresins under applicable food additive regulation in parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, 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.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs—(1) General use.* Diluents listed in § 73.1(a) and the following:

| Substances | Definitions and specifications | Restrictions |
|------------------------------------|---------------------------------------|----------------------------------|
| Alcohol, specially denatured | As set forth in 26 CFR, pt. 212 | As set forth in 26 CFR, pt. 211. |

| Substances | Definitions and specifications | Restrictions |
|--|---|---|
| Cetyl alcohol | As set forth in N.F. XI. | In color coatings for pharmaceutical forms, no residue. |
| Isopropyl alcohol | | |
| Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60). | As set forth in sec. 172.836 of this chapter. | |
| Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65). | As set forth in sec. 172.838 of this chapter. | |
| Polysorbate 80 | As set forth in sec. 172.840 of this chapter. | |
| Polyvinyl-pyrrolidone | As set forth in sec. 173.55 of this chapter. | |
| Sorbitan monooleate. | As set forth in sec. 172.842 of this chapter. | |
| Sorbitan monostearate | | |
| Sorbitan trioleate. | | |

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in paragraph (a)(1) of this section, § 73.1(b)(1)(i), and the following:

Ethyl lactate
 Polyoxyethylene sorbitan monolaurate (20)

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

| Substances | Definitions and specifications |
|-------------------------|--|
| Benzyl alcohol | As set forth in N.F. XI. |
| Ethyl cellulose | As set forth in § 172.868 of this chapter. |
| Hydroxyethyl cellulose. | As set forth in § 172.870 of this chapter. |
| Hydroxypropyl cellulose | |

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide (Al₂O₃·XH₂O).

(2) Color additive mixtures for drug use made with alumina (dried aluminum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

- Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.
- Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.
- Lead (as Pb), not more than 10 parts per million.
- Arsenic (as As), not more than 1 part per million.

Mercury (as Hg), not more than 1 part per million.
 Aluminum oxide (Al₂O₃), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of 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 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.

§ 73.1015 Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

- Chromium, calculated as Cr₂O₃, 34–37 percent.
- Cobalt, calculated as CoO, 29–34 percent.
- Aluminum, calculated as Al₂O₃, 29–35 percent.
- Lead (as Pb), not more than 30 parts per million.
- Arsenic (as As), not more than 3 parts per million.

Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 N hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500°–550 °F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

(4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(d) *Labeling.* The label 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 batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1025 Ferric ammonium citrate.

(a) *Identity.* The color additive ferric ammonium citrate consists of complex chelates prepared by the interaction of ferric hydroxide with citric acid in the presence of ammonia. The complex chelates occur in brown and green forms, are deliquescent in air, and are reducible by light.

(b) *Specifications.* Ferric ammonium citrate 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:

Iron (as Fe), not less than 14.5 percent and not more than 18.5 percent.

Lead (as Pb), not more than 20 p/m.

Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Ferric ammonium citrate may be safely used in combination with pyrogallol (as listed in § 73.1375), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery subject to the following conditions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* 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.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1030 Annatto extract.

(a) *Identity and specifications.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 73.30(a)(1) and (b).

(2) Color additive mixtures for drug use made with annatto extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

§ 73.1070

(b) *Uses and restrictions.* Annatto extract may be safely used for coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in § 73.30(a)(1)(ii) 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 15643, Mar. 22, 1977, as amended at 42 FR 36994, July 19, 1977]

§ 73.1070 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate (CaCO₃).

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

(b) *Specifications.* Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the United States Pharmacopeia XX (1980).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of 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 is not necessary for the protection of the public health, and therefore batches there-

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

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1075 Canthaxanthin.

(a) *Identity and specifications.* (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of § 73.75(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and of 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 certification requirements of section 721(c) of the act.

§ 73.1085 Caramel.

(a) *Identity and specifications.* (1) The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a) (1), (2), and (3) and (b).

(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(c) *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.

§ 73.1095 β-Carotene.

(a) *Identity and specifications.* (1) The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(2) The diluents in color additive mixtures for drug use containing β-carotene are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* The color additive β-carotene may be safely used in coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling 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 requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 33722, July 1, 1977]

§ 73.1100 Cochineal extract; carmine.

(a) *Identity and specifications.* (1) The color additives cochineal extract and carmine shall conform in identity and specifications to the requirements of § 73.100(a) (1) and (2) and (b).

(2) Color additive mixtures for drug use made with carmine and cochineal extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additives 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 these color additives 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.

§ 73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity.* (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytol ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Potassium sodium copper chlorophyllin 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:

Moisture, not more than 5.0 percent.

Nitrogen, not more than 5.0 percent.

pH of 1 percent solution, 9 to 11.

Total copper, not less than 4 percent and not more than 6 percent.

Free copper, not more than 0.25 percent.

Iron, not more than 0.5 percent.

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

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

Ratio, absorbance at 405 mμ to absorbance at 630 mμ, not less than 3.4 and not more than 3.9.

Total color, not less than 75 percent.

(c) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are drugs at a level not to exceed 0.1 percent. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(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.

§ 73.1150

(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.

§ 73.1150 Dihydroxyacetone.

(a) *Identity.* (1) The color additive dihydroxyacetone is 1,3-dihydroxy-2-propanone.

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

(b) *Specifications.* Dihydroxyacetone 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:

Volatile matter (at 34.6 °C. for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.

Residue on ignition, not more than 0.4 percent.

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

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

Iron (as Fe), not more than 25 parts per million.

1,3-dihydroxy-2-propanone, not less than 98 percent.

(c) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied drugs intended solely or in part to impart a color to the human body. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling requirements.* 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 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.

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§ 73.1162 Bismuth oxychloride.

(a) *Identity.* (1) The color additive bismuth oxychloride is a synthetically prepared white or nearly white amorphous or finely crystalline, odorless powder consisting principally of BiOCl.

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

(b) *Specifications.* The color additive bismuth oxychloride 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:

Volatile matter, not more than 0.5 percent.

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.

Bismuth oxychloride, not less than 98 percent.

(c) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring externally applied drugs, including those intended for use in 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 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 certification pursuant to section 721(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.1200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

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

(b) *Specifications.* Synthetic iron oxide 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.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *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.

(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 requirements of section 721(c) of the act.

§ 73.1298 Ferric ammonium ferrocyanide.

(a) *Identity.* (1) The color additive ferric ammonium ferrocyanide is the blue pigment obtained by oxidizing under acidic conditions with sodium dichromate the acid digested precipitate resulting from mixing solutions of ferrous sulfate and sodium ferrocyanide in the presence of ammonium sulfate. The oxidized product is filtered, washed, and dried. The pigment consists principally of ferric ammonium ferrocyanide with smaller amounts of ferric ferrocyanide and ferric sodium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ammonium ferrocyanide may contain only those diluents listed in this subpart as safe

and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ammonium ferrocyanide shall conform to the following specifications and shall be free of impurities other than those named to the extent that the other impurities may be avoided by good manufacturing practice:

Oxalic acid or its salts, not more than 0.1 percent.

Water soluble matter, not more than 3 percent.

Water soluble cyanide, not more than 10 parts per million.

Volatile matter, not more than 4 percent.

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

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

Nickel (as Ni), not more than 200 parts per million.

Cobalt (as Co), not more than 200 parts per million.

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

Total iron (as Fe corrected for volatile matter), not less than 33 percent and not more than 39 percent.

(c) *Uses and restrictions.* Ferric ammonium ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of 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 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 38562, July 29, 1977, as amended at 44 FR 28322, May 15, 1979]

§ 73.1299 Ferric ferrocyanide.

(a) *Identity.* (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structural formula $\text{Fe}_4[\text{Fe}(\text{CN})_6]_3 \cdot \text{XH}_2\text{O}$, which may contain small amounts of ferric sodium ferrocyanide and ferric potassium ferrocyanide.

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

(b) *Specifications.* Ferric ferrocyanide 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:

Water soluble cyanide, not more than 10 parts per million.

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

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

Nickel (as Ni), not more than 200 parts per million.

Cobalt (as Co), not more than 200 parts per million.

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

Oxalic acid, not more than 0.1 percent.

Water soluble matter, not more than 3 percent.

Volatile matter, not more than 10 percent.

Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 percent.

(c) *Uses and restrictions.* Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of 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 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 54235, Nov. 21, 1978]

§ 73.1326 Chromium hydroxide green.

(a) *Identity.* (1) The color additive chromium hydroxide green is principally hydrated chromic sesquioxide ($\text{Cr}_2\text{O}_3 \cdot \text{XH}_2\text{O}$).

(2) Color additive mixtures for drug use made with chromium hydroxide green may contain only those diluents

listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Chromium hydroxide green 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:

Water soluble matter, not more than 2.5%.

Chromium in 2% NaOH extract, not more than 0.1% as Cr_2O_3 (based on sample weight).

Boron (as B_2O_3), not more than 8 percent.

Total volatile matter at 1000 °C, not more than 20%.

Cr_2O_3 not less than 75%.

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.* Chromium hydroxide green may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of 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 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 36451, July 15, 1977, as amended at 42 FR 59852, Nov. 22, 1977]

§ 73.1327 Chromium oxide greens.

(a) *Identity.* (1) The color additive chromium oxide greens is principally chromic sesquioxide (Cr_2O_3).

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

(b) *Specifications.* The color additive chromium oxide greens shall conform to the following specifications and shall be free from impurities other

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than those named to the extent that such impurities may be avoided by good manufacturing practice:

Chromium in 2% NaOH extract, not more than 0.075% as Cr₂O₃ (based on sample weight).

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

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

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

Cr₂O₃, not less than 95%.

(c) *Uses and restrictions.* Chromium oxide greens is safe for use in coloring externally applied drugs, including those intended for use in the area of 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.

[42 FR 36451, July 15, 1977]

§ 73.1329 Guanine.

(a) *Identity.* (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

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

(b) *Specifications.* The color additive guanine 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:

Guanine, not less than 75 percent.

Hypoxanthine, not more than 25 percent.

Ash (ignition at 800 °C), not more than 2 percent.

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

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

Assay, not less than 96 percent total purines.

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

(c) *Uses and restrictions.* Guanine is safe for use in coloring externally applied drugs, including those intended for use in 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.

[42 FR 37537, July 22, 1977]

§ 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol 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:

Melting point, between 130° and 133 °C.

Residue on ignition, not more than 0.1 percent.

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

Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not

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exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissues.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label 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 certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring mineral substance consisting predominantly of a hydrous aluminum silicate, $\text{Al}_2\text{O}_3 \cdot 4\text{SiO}_2 \cdot \text{H}_2\text{O}$, intimately mixed with lesser amounts of finely divided silica, SiO_2 . Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

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

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

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

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) *Uses and restrictions.* Pyrophyllite may be safely used in amounts consistent with good manufacturing prac-

tice to color drugs that are to be externally applied.

(d) *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.

(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.

§ 73.1410 Logwood extract.

(a) *Identity.* The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree *Haematoxylon campechianum*. The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) *Specifications.* Logwood extract 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:

Volatile matter (at 110 °C), not more than 15 percent.

Sulfated ash, not more than 20 percent.

Hematein, not less than 5 percent and not more than 20 percent.

Lead (as Pb), not more than 70 parts per million.

Arsenic (as As), not more than 4 parts per million.

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

(c) *Use and restrictions.* Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of *ε*-caprolactam), or silk non-absorbable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label 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 certification requirements of section 721(c) of the act.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

§ 73.1496 Mica.

(a) *Identity.* (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate, $K_2Al_4(Al_2Si_6O_{20})(OH)_4$ or, alternatively, $H_2KAl_3(SiO_4)_3$. Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

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

(b) *Specifications.* Mica 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:

Fineness, 100 percent shall pass through a 100-mesh sieve.

Loss on ignition at 600–650 °C, not more than 2 percent.

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.* Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

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

form 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 certification requirements of section 721(c) of the act.

[42 FR 38561, July 29, 1977, as amended at 52 FR 29665, Aug. 11, 1987]

§ 73.1550 Talc.

(a) *Identity.* (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

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

(b) *Specifications.* Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) and the following:

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

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

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) *Uses and restrictions.* Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of 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 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 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1575 Titanium dioxide.

(a) *Identity and specifications.* (1) The color additive titanium dioxide shall conform in identity and specifications

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to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs, and the following: Silicon dioxide, SiO₂, and/or aluminum oxide, Al₂O₃, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions.* The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of the 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.

§ 73.1645 Aluminum powder.

(a) *Identity.* (1) The color additive aluminum powder shall be composed of finely divided particles of aluminum prepared from virgin aluminum. It is free from admixture with other substances.

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

(b) *Specifications.* Aluminum powder 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:

- Fineness, 100 percent shall pass through a 200-mesh screen and 95 percent shall pass through a 325-mesh screen.
- Mercury, not more than 1 part per million.
- Arsenic, not more than 3 parts per million.
- Lead, not more than 20 parts per million.
- Aluminum, not less than 99 percent.

(c) *Uses and restrictions.* Aluminum powder is safe for use in externally applied drugs, including those intended for use in 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.

[42 FR 38563, July 29, 1977]

§ 73.1646 Bronze powder.

(a) *Identity.* (1) The color additive bronze powder is a very fine metallic powder prepared from alloys consisting principally of virgin electrolytic copper and zinc with small amounts of the virgin metals aluminum and tin. It contains small amounts of stearic or oleic acid as lubricants.

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

(b) *Specifications.* Bronze powder 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:

- Stearic or oleic acid, not more than 5 percent.
- Cadmium (as Cd), not more than 15 parts per million.
- 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.
- Aluminum (as Al), not more than 0.5 percent.
- Tin (as Sn), not more than 0.5 percent.
- Copper (as Cu), not more than 95 percent and not less than 70 percent.
- Zinc (as Zn), not more than 30 percent.
- Maximum particle size 45µ (95 percent minimum).

Aluminum, zinc, tin, and copper content shall be based on the weight of the dried powder after being thoroughly washed with ether.

(c) *Uses and restrictions.* Bronze powder may be safely used in color externally applied drugs, including those intended for use in 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 conform to the requirements of § 70.25 of this chapter.

(e) *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 33723, July 1, 1977]

§ 73.1647 Copper powder.

(a) *Identity.* (1) The color additive copper powder is a very fine free-flowing metallic powder prepared from virgin electrolytic copper. It contains small amounts of stearic or oleic acid as lubricants.

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

(b) *Specifications.* Copper powder 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:

Stearic or oleic acid, not more than 5 percent.

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

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.

Copper (as Cu), not less than 95 percent.

Maximum particle size 45 μ (95 percent minimum).

(c) *Uses and restrictions.* Copper powder may be safely used in coloring externally applied drugs, including those intended for use in 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 conform to the requirements of § 70.25 of this chapter.

(e) *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 33723, July 1, 1977]

§ 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

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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 identity 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.

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(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.* 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 32228, June 24, 1977]

§ 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

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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 0.5 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]

§ 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

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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.

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§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.

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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.* Guaiiazulene 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

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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.

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(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 identity 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]

§ 73.2396 Lead acetate.

(a) *Identity.* The color additive lead acetate is the trihydrate of lead (2+) salt of acetic acid. The color additive has the chemical formula $Pb(OOCCH_3)_2 \cdot 3H_2O$.

(b) *Specifications.* Lead acetate 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:

Water-insoluble matter, not more than 0.02 percent.

pH (30 percent solution weight to volume at 25 °C), not less than 4.7 and not more than 5.8.

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

Lead acetate, not less than 99 percent.

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

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

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements.* (1) The label of the color additive lead acetate shall conform to the requirements of § 170.25 of this chapter, and bear the following statement or equivalent:

Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the act, shall bear the following cautionary statement, conspicuously displayed thereon:

CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and 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 the certification requirements of section 721(c) of the act.

[45 FR 72117, Oct. 31, 1980]

§ 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.

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(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

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

[44 FR 65974, Nov. 16, 1979]

§ 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 $\text{Na}(\text{AlSiO})_x\text{S}$ 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: $\text{Mn}(\text{III})\text{NH}_4\text{P}_2\text{O}_7$.

(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:

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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 there-

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of 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]

Subpart D—Medical Devices

§ 73.3100 1,4-Bis(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.

(a) *Identity.* The color additives are 1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester (CAS Reg. No. 109561-07-1) copolymerized either with glyceryl methacrylate, methyl methacrylate, and ethylene glycol dimethacrylate monomers, or with *N,N*-dimethyl acrylamide, methyl methacrylate, and ethylene glycol dimethacrylate monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses 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) with respect to the contact lens made from the color additives.

(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 the color additives are exempt from the certification requirements of section 721(c) of the act.

[61 FR 51586, Oct. 3, 1996]

§ 73.3105 1,4-Bis(2-methylphenyl)amino]-9,10-anthracenedione.

(a) *Identity.* The color additive is 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 6737-68-4).

(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 (the act). A person intending to introduce a device containing 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione 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 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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[49 FR 30066, July 26, 1984]

§ 73.3106 1,4-Bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone copolymers.

(a) *Identity.* The color additive is 1,4-bis[4-(2-methacryloxyethyl) phenylamino]anthraquinone (CAS Reg. No. 121888-69-5), copolymerized with hydroxyethyl methacrylate monomer, or a blend of hydroxyethyl methacrylate and *N*-vinyl pyrrolidone monomers, or a blend of 3-[tris(trimethylsiloxy)silyl]propyl vinyl

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carbamate (CAS Reg. No. 134072-99-4) and *N*-vinyl pyrrolidone monomers to form the contact lens material.

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with these uses 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) with respect to contact lenses made from the color additives.

(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, the color additives are exempt from the certification requirements of section 721(c) of the act.

[58 FR 17507, Apr. 5, 1993, as amended at 60 FR 10497, Feb. 27, 1995]

§ 73.3107 Carbazole violet.

(a) *Identity.* The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Colour Index No. 51319).

(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 for 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) with respect to the contact lens in which the color additive is used.

(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 the color additive is exempt from the certification

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requirements of section 721(c) of the act.

[53 FR 41324, Oct. 21, 1988]

§ 73.3110 Chlorophyllin-copper complex, oil soluble.

(a) *Identity.* The color additive is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which is then replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) *Specifications.* The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), 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 current good manufacturing practice:

Moisture, not more than 0.5 percent.

Nitrogen, not less than 0.2 percent and not more than 0.3 percent.

Total copper, not less than 0.2 percent and not more than 0.4 percent.

Free copper, not more than 200 parts per million.

Lead, not more than 20 parts per million.

Arsenic, not more than 5 parts per million.

Sulfated ash, not more than 2.5 percent.

Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) *Uses and restrictions.* (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for 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 polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.

(d) *Labeling.* The label 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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 56370, Dec. 21, 1983]

§ 73.3110a Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide (Pigment Blue 36) (CAS Reg. No. 68187-11-1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of § 73.1015 (a) and (b).

(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 for 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) with respect to the contact lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[53 FR 41325, Oct. 21, 1988]

§ 73.3111 Chromium oxide greens.

(a) *Identity and specifications.* The color additive chromium oxide greens (chromic oxide) (CAS Reg. No. 1308-38-9), Colour Index No. 77288, shall conform in identity and specifications to the requirements of § 73.1327 (a)(1) and (b).

(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 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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3112 C.I. Vat Orange 1.

(a) *Identity.* The color additive is C.I. Vat Orange 1, Colour Index No. 59105.

(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 for 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) with respect to the contact lens in which the color additive is used. A person intending to introduce a device containing C.I. Vat Orange 1 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 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 the color additive is exempt from the certification

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requirements of section 721(c) of the act.

[50 FR 20407, May 16, 1985]

§ 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol.

(a) *Identity.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol is formed in situ in soft (hydrophilic) contact lenses.

(b) *Uses and restrictions.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol may be safely used to mark soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes subject to the following restrictions:

(1) The quantity of the color additive does not exceed 1.1×10^{-7} grams in a soft (hydrophilic) contact lens.

(2) When used as specified in the labeling, there is no measurable migration of the color additive from the contact lens to the surrounding ocular tissue.

(3) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 22706, May 20, 1983]

§ 73.3117 16,23-Dihydrodinaphtho[2,3-a:2',3'-i] naphth [2',3':6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.

(a) *Identity.* The color additive is 16,23-dihydrodinaphtho [2,3- a:2',3'-i] naphth [2',3':6,7] indolo [2, 3-c] carbazole-5,10, 15,17,22,24-hexone (CAS Reg. No. 2475-33-4), Colour Index No. 70800.

(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 for 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 lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

§ 73.3118 N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.

(a) *Identity.* The color additive is N,N'-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide (CAS Reg. No. 82-18-8), Colour Index No. 61725.

(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 for 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 lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31375, July 8, 1983]

§ 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

(a) *Identity.* The color additive is 7,16-dichloro-6,15-dihydro-5,9,14,18-

anthrazinetetrone (CAS Reg. No. 130-20-1), Colour Index No. 69825.

(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 for 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 lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[48 FR 31376, July 8, 1983]

**§ 73.3120 16,17-Dimethoxydinaphtho
[1,2,3-cd:3',2',1'-lm] perylene-5,10-
dione.**

(a) *Identity.* The color additive is 16,17-dimethoxydinaphtho[1,2,3-cd:3',2',1'-lm]perylene-5,10-dione (CAS Reg. No. 128-58-5), Colour Index No. 59825.

(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 for 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 lens in which the color additive is used.

(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 the color additive is exempt from the certification

requirements of section 721(c) of the act.

[48 FR 31376, July 8, 1983]

§ 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-(sulfoxy)ethyl)sulfonyl)phenyl)azo)-tetrasodium salt] (CAS Reg. No. 17095-24-8);

(2) Reactive Blue 21 [copper, (29H,31H-phthalocyaninato(2-)-N²⁹,N³⁰,N³¹,N³²)-, sulfo((4-(2-(sulfoxy)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-(sulfoxy)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-(sulfoxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1H-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-(sulfoxy)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-

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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) sulfophenyl)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.

[49 FR 373, Jan. 4, 1984; 49 FR 5094, Feb. 10, 1984, as amended at 50 FR 9425, Mar. 8, 1985; 50 FR 33338, Aug. 19, 1985; 50 FR 37845, Sept. 18, 1985; 50 FR 45993, Nov. 6, 1985; 58 FR 9541, Feb. 22, 1993]

§ 73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.

(a) *Identity.* The color additive is 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one (CAS Reg. No. 6407-78-9).

(b) *Uses and restrictions.* (1) The substances 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 for 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 lens in which the color additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 11432, Apr. 3, 1986]

§ 73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzob[thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one.

(a) *Identity.* The color additive is 6-ethoxy-2-(6-ethoxy-3-oxobenzob[thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one (CAS Reg. No. 3263-31-8), Colour Index No. 73335.

(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 for 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 lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

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

[51 FR 11436, Apr. 3, 1986]

§ 73.3124 Phthalocyanine green.

(a) *Identity.* The color additive is phthalocyanine green (CAS Reg. No. 1328-53-6), Colour Index No. 74260.

(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 for 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 lens in which the additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 11433, Apr. 3, 1986]

§ 73.3125 Iron oxides.

(a) *Identity and specifications.* The color additive iron oxides (CAS Reg. No. 977053-38-5), Color Index No. 77491, shall conform in identity and specifications to the requirements of § 73.2250 (a) and (b).

(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 lens in which the additive is used.

(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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3126 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide (CAS Reg. No. 13463-67-7), Color Index No. 77891, shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(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 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 the color additive is exempt from the certification requirements of section 721(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) *Identity.* The color additives are formed by reacting the dyes, either alone or in combination, with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dyes are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dyes are:

(1) 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).

(2) C.I. 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).

(3) C.I. 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) C.I. 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) C.I. Reactive Blue No. 19 [2-anthracenesulfonic 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) C.I. 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 derivatives] (CAS Reg. No. 73049-92-0).

(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 dye.

(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 vinyl alcohol/methyl methacrylate-dye reaction product 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 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, this color additive is exempt from the certification requirements of section 721(c) of the act.

[58 FR 3227, Jan. 8, 1993, as amended at 58 FR 17510, Apr. 5, 1993]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

| Sec. | |
|--------|--------------------|
| 74.101 | FD&C Blue No. 1. |
| 74.102 | FD&C Blue No. 2. |
| 74.203 | FD&C Green No. 3. |
| 74.250 | Orange B. |
| 74.302 | Citrus Red No. 2. |
| 74.303 | FD&C Red No. 3. |
| 74.340 | FD&C Red No. 40. |
| 74.705 | FD&C Yellow No. 5. |
| 74.706 | FD&C Yellow No. 6. |

Subpart B—Drugs

| | |
|---------|--------------------|
| 74.1101 | FD&C Blue No. 1. |
| 74.1102 | FD&C Blue No. 2. |
| 74.1104 | D&C Blue No. 4. |
| 74.1109 | D&C Blue No. 9. |
| 74.1203 | FD&C Green No. 3. |
| 74.1205 | D&C Green No. 5. |
| 74.1206 | D&C Green No. 6. |
| 74.1208 | D&C Green No. 8. |
| 74.1254 | D&C Orange No. 4. |
| 74.1255 | D&C Orange No. 5. |
| 74.1260 | D&C Orange No. 10. |
| 74.1261 | D&C Orange No. 11. |
| 74.1303 | FD&C Red No. 3. |
| 74.1304 | FD&C Red No. 4. |
| 74.1306 | D&C Red No. 6. |
| 74.1307 | D&C Red No. 7. |
| 74.1317 | D&C Red No. 17. |
| 74.1321 | D&C Red No. 21. |
| 74.1322 | D&C Red No. 22. |
| 74.1327 | D&C Red No. 27. |
| 74.1328 | D&C Red No. 28. |
| 74.1330 | D&C Red No. 30. |
| 74.1331 | D&C Red No. 31. |
| 74.1333 | D&C Red No. 33. |
| 74.1334 | D&C Red No. 34. |
| 74.1336 | D&C Red No. 36. |
| 74.1339 | D&C Red No. 39. |