

§ 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**

Sec.

- 73.1 Diluents in color additive mixtures for food use exempt from certification.
- 73.30 Annatto extract.
- 73.35 Astaxanthin.
- 73.40 Dehydrated beets (beet powder).
- 73.50 Ultramarine blue.
- 73.75 Canthaxanthin.
- 73.85 Caramel.
- 73.90 β -Apo-8'-carotenal.
- 73.95 β -Carotene.
- 73.100 Cochineal extract; carmine.

73.125 Sodium copper chlorophyllin.
 73.140 Toasted partially defatted cooked cottonseed flour.
 73.160 Ferrous gluconate.
 73.165 Ferrous lactate.
 73.169 Grape color extract.
 73.170 Grape skin extract (enocianina).
 73.185 Haematococcus algae meal.
 73.200 Synthetic iron oxide.
 73.250 Fruit juice.
 73.260 Vegetable juice.
 73.275 Dried algae meal.
 73.295 Tagetes (Aztec marigold) meal and extract.
 73.300 Carrot oil.
 73.315 Corn endosperm oil.
 73.340 Paprika.
 73.345 Paprika oleoresin.
 73.355 Phaffia yeast.
 73.450 Riboflavin.
 73.500 Saffron.
 73.575 Titanium dioxide.
 73.600 Turmeric.
 73.615 Turmeric oleoresin.

Subpart B—Drugs

73.1001 Diluents in color additive mixtures for drug use exempt from certification.
 73.1010 Alumina (dried aluminum hydroxide).
 73.1015 Chromium-cobalt-aluminum oxide.
 73.1025 Ferric ammonium citrate.
 73.1030 Annatto extract.
 73.1070 Calcium carbonate.
 73.1075 Canthaxanthin.
 73.1085 Caramel.
 73.1095 β -Carotene.
 73.1100 Cochineal extract; carmine.
 73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
 73.1150 Dihydroxyacetone.
 73.1162 Bismuth oxychloride.
 73.1200 Synthetic iron oxide.
 73.1298 Ferric ammonium ferrocyanide.
 73.1299 Ferric ferrocyanide.
 73.1326 Chromium hydroxide green.
 73.1327 Chromium oxide greens.
 73.1329 Guanine.
 73.1375 Pyrogallol.
 73.1400 Pyrophyllite.
 73.1410 Logwood extract.
 73.1496 Mica.
 73.1550 Talc.
 73.1575 Titanium dioxide.
 73.1645 Aluminum powder.
 73.1646 Bronze powder.
 73.1647 Copper powder.
 73.1991 Zinc oxide.

Subpart C—Cosmetics

73.2030 Annatto.
 73.2085 Caramel.
 73.2087 Carmine.
 73.2095 β -Carotene.

73.2110 Bismuth citrate.
 73.2120 Disodium EDTA-copper.
 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
 73.2150 Dihydroxyacetone.
 73.2162 Bismuth oxychloride.
 73.2180 Guaiazulene.
 73.2190 Henna.
 73.2250 Iron oxides.
 73.2298 Ferric ammonium ferrocyanide.
 73.2299 Ferric ferrocyanide.
 73.2326 Chromium hydroxide green.
 73.2327 Chromium oxide greens.
 73.2329 Guanine.
 73.2396 Lead acetate.
 73.2400 Pyrophyllite.
 73.2496 Mica.
 73.2500 Silver.
 73.2575 Titanium dioxide.
 73.2645 Aluminum powder.
 73.2646 Bronze powder.
 73.2647 Copper powder.
 73.2725 Ultramarines.
 73.2775 Manganese violet.
 73.2991 Zinc oxide.
 73.2995 Luminescent zinc sulfide.

Subpart D—Medical Devices

73.3100 1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers.
 73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.
 73.3106 1,4-Bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone copolymers.
 73.3107 Carbazole violet.
 73.3110 Chlorophyllin-copper complex, oil soluble.
 73.3110a Chromium-cobalt-aluminum oxide.
 73.3111 Chromium oxide greens.
 73.3112 C.I. Vat Orange 1.
 73.3115 2-[[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol].
 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.
 73.3118 N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.
 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.
 73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3',2',1'-lm] perylene-5,10-dione.
 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.
 73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.
 73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.
 73.3124 Phthalocyanine green.
 73.3125 Iron oxides.
 73.3126 Titanium dioxide.
 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

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73.3128 Mica-based pearlescent pigments.

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. |
| Diocytlsodium 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 diocytlsodium 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 tab-* *let 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. | |

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| Substances | Definitions and specifications | Restrictions |
|-----------------------------------|---|--------------|
| Polyvinyl acetate | Molecular weight, minimum 2,000. | |
| 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. | |
| 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.,