

Food and Drug Administration, HHS

§ 73.1

- 73.340 Paprika.
- 73.345 Paprika oleoresin.
- 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  $\beta$ -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  $\beta$ -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.

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)thiol]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.

AUTHORITY: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

SOURCE: 42 FR 15643, Mar. 22, 1977, unless otherwise noted.

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.	.....
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.

Substances	Definitions and specifications	Restrictions
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 $\alpha$ - and $\beta$ -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.
- Diethyl 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.