

Food and Drug Administration, HHS

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- 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)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.
- 73.3128 Mica-based pearlescent pigments.

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.

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.

Substances	Definitions and specifications	Restrictions
Disodium EDTA (disodium ethylenediamine-tetraacetate).	Contains disodium ethylenediaminetetraacetate 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 ethylenediaminetetraacetate).

(b) *Special use*—(1) *Diluents in color additive mixtures for marking food 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.
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.

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Diocetyl 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 §172.615 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; 69 FR 24511, May 4, 2004]

§ 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.