

Food and Drug Administration, HHS

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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.
- 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 there-

from, 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.

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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.

§ 73.35 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

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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 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]

§ 73.37 Astaxanthin dimethyl-disuccinate.

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

(2) Astaxanthin dimethylsuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethylsuccinate 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 dimethylsuccinate 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:

- (1) Physical state, solid.
- (2) 0.05 percent solution in chloroform, complete and clear.
- (3) Absorption maximum wavelength 484-493 nanometers (in chloroform).
- (4) Residue on ignition, not more than 0.1 percent.
- (5) Total carotenoids other than astaxanthin dimethylsuccinate, not more than 4 percent.
- (6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).