

Color Additives Approved for Use in Human Food
Part 73, Subpart A: Color additives exempt from batch certification⁽¹⁾

21 CFR Section	Straight Color	EEC#	Year⁽²⁾Approved	Uses and Restrictions
§73.30 ²	Annatto extract	E160b	1963	Foods generally.
§73.40 ³	Dehydrated beets (beet powder)	E162	1967	Foods generally.
§73.75 ⁴	Canthaxanthin ⁽³⁾	E161g	1969	Foods generally, NTE ⁽⁹⁾ 30 mg/lb of solid or semisolid food or per pint of liquid food; May also be used in broiler chicken feed.
§73.85 ⁵	Caramel	E150a-d	1963	Foods generally.
§73.90 ⁶	β-Apo-8'-carotenal	E160e	1963	Foods generally, NTE ⁽⁹⁾ : 15 mg/lb solid, 15 mg/pt liquid.
§73.95 ⁷	β-Carotene	E160 ⁽⁴⁾	1964	Foods generally.
§73.100 ⁸	Cochineal extract	E120	1969	Foods generally
			2009	Food label must use common or usual name "cochineal extract"; effective January 5, 2011
	Carmine	E120	1967	Foods generally
			2009	Food label must use common or usual name "carmine"; effective January 5, 2011
§73.125 ⁹	Sodium copper chlorophyllin ⁽³⁾	E141	2002	Citrus-based dry beverage mixes NTE ⁽⁹⁾ 0.2 percent in dry mix; extracted from alfalfa.
§73.140 ¹⁰	Toasted partially defatted cooked cottonseed flour	----	1964	Foods generally.
§73.160 ¹¹	Ferrous gluconate	E 579	1967	Ripe olives.
§73.165 ¹²	Ferrous lactate	E 585	1996	Ripe olives.
§73.169 ¹³	Grape color extract ⁽³⁾	E163 [?]	1981	Nonbeverage food.

§73.170 ¹⁴	Grape skin extract (enocianina)	E163 ?	1966	Still & carbonated drinks & aides ; beverage bases; alcoholic beverages (restrict. 27 CFR Parts 4 & 5).
§73.200 ¹⁵	Synthetic iron oxide ⁽³⁾	E172	1994	Sausage casings NTE ⁽⁹⁾ 0.1 percent (by wt).
§73.250 ¹⁶	Fruit juice ⁽⁵⁾	E 163 for anthocyanin based fruit colors.	1966	Foods generally.
			1995	Dried color additive.
§73.260 ¹⁷	Vegetable juice ⁽⁵⁾	E 163 for anthocyanin based vegetable colors.	1966	Foods generally.
			1995	Dried color additive, water infusion.
§73.300 ¹⁸	Carrot oil	E 160a	1967	Foods generally.
§73.340 ¹⁹	Paprika	E160c	1966	Foods generally.
§73.345 ²⁰	Paprika oleoresin	E160c	1966	Foods generally.
§73.350 ²¹	Mica-based pearlescent pigments ⁽³⁾	----	2006	Cereals, confections and frostings, gelatin desserts, hard and soft candies(including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.
§73.450 ²²	Riboflavin	E101	1967	Foods generally.
§73.500 ²³	Saffron	NA as it is generally considered a colouring foodstuff in EU	1966	Foods generally.
§73.575 ²⁴	Titanium dioxide	E171	1966	Foods generally; NTE ⁽⁹⁾ 1 percent (by wt).
§73.585 ²⁵	Tomato lycopene extract; tomato lycopene concentrate ⁽³⁾	E160 d	2006	Foods generally.

§73.600 ²⁶	Turmeric	E100 -NA as it is generally considered a colouring foodstuff in EU	1966	Foods generally.
§73.615 ²⁷	Turmeric oleoresin	E100	1966	Foods generally.

Color Additives Approved for Use in Human Food Part 74, Subpart A: Color additives subject to batch certification⁽⁶⁾				
21 CFR Section	Straight Color	EEC#	Year⁽²⁾Approved	Uses and Restrictions
§74.101 ²⁸	FD&C Blue No. 1	E133	1969	Foods generally.
			1993	Added Mn spec.
§74.102 ²⁹	FD&C Blue No. 2	E132	1987	Foods generally.
§74.203 ³⁰	FD&C Green No. 3	----	1982	Foods generally.
§74.250 ³¹	Orange B ⁽³⁾	----	1966	Casings or surfaces of frankfurters and sausages; NTE ⁽⁹⁾ 150 ppm (by wt).
§74.302 ³²	Citrus Red No. 2	----	1963	Skins of oranges not intended or used for processing; NTE ⁽⁹⁾ 2.0 ppm (by wt).
§74.303 ³³	FD&C Red No. 3	E127	1969	Foods generally.
§74.340 ³⁴	FD&C Red No. 40 ⁽³⁾	E129	1971	Foods generally.
§74.705 ³⁵	FD&C Yellow No. 5	E102	1969	Foods generally.
§74.706 ³⁶	FD&C Yellow No. 6	E110	1986	Foods generally.

1. The color additives Astaxanthin, Astaxanthin dimethyldisuccinate, Ultramarine blue, Canthaxanthin, Haematococcus algae meal, Synthetic iron oxide, Dried algae meal, Tagetes (Aztec marigold) meal and extract, Corn endosperm oil, Paracoccus pigment, and

Phaffia yeast are approved for specific uses in animal food (see 21 CFR 73.35, 73.37, 73.50, 73.75, 73.185, 73.200, 73.275, 73.295, 73.315, 73.352, and 73.355, respectively).

2. The year approved is based on the date listed in the "Confirmation of Effective Date" notice for the action as published in the Federal Register.

3. Petitioned for use after the 1960 amendments; not provisionally listed.

4. E 160 a (i) BETA-CAROTENE trans isomer of beta- carotene together with minor amounts of other carotenoids.

E 160 a (ii) PLANT CAROTENES Plant carotenes are obtained by solvent extraction of strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.

E 160 a (iii) BETA-CAROTENE FROM *Blakeslea trispora* Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (–) of strains of the fungus *Blakeslea trispora*.

E 160 a (iv) ALGAL CAROTENES Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia.

5. It is the responsibility of food manufacturers to ensure that the products they market are safe, edible and in compliance with all relevant laws and regulations. In cases where a manufacturer is uncertain about the suitability of a fruit or vegetable juice to comply with 21 CFR 73.250 or 73.260, FDA suggests that you send a letter describing the edible fruit or vegetable along with its history of consumption and request an informal opinion from the FDA on whether it would comply with the regulations. FDA has given its opinion that Chokeberry/Aronia, Hibiscus, Watermelon Juice, North American Elderberry, European Black Elderberry, Purple/Black Carrot, Purple Corn, Red Sugar Beet Juice, Red Cabbage Juice, Purple Sweet Potato Juice and Red Radish Juice would be suitable sources of fruit or vegetable juice color additive. Color additives isolated by techniques other than expressing, or a water infusion of the dried fruit, would need to be the subject of a color additive petition, unless a regulation already provides for the intended use. Guidance on the petition process, recommendations on the chemical and technological data one's submission should contain, and other useful information can be found at the following Internet link: <http://www.fda.gov/ForIndustry/ColorAdditives/default.htm> . Further, FDA opinion letters may be obtained via a Freedom of Information Act (FOIA) request.

6. Color additives listed in 21 CFR Parts 74 and 82 must be analyzed and batch certified by FDA before they can be used in any FDA-regulated product marketed in the U.S. This requirement applies to products imported into this country as well as those manufactured domestically. Manufacturers of certified color additives must include on the label the name of the certified color additive, a statement indicating general use limitations, any quantitative limitations in products, and the certification lot number assigned to the batch. Straight colors required to be certified are listed in 21 CFR Part 74. Most lakes are provisionally listed under 21 CFR 81.1 for use as listed in 21 CFR 82.51 (food, drugs, and cosmetics), 21 CFR 82.1051 (drugs and cosmetics), or 21 CFR 82.2051 (externally applied drugs and cosmetics). All FD&C Red No. 40 lakes are permanently listed under

21 CFR 74.340 (food), 74.1340 (drugs), and 74.2340 (cosmetics). FD&C Blue No. 1 and FD&C Yellow No. 5 aluminum lakes for drug and cosmetic use are permanently listed in 21 CFR sections 74.1101, 74.1705, 74.2101, and 74.2705.

7. Color additives that are permitted for general use may not be used in the area of the eye, in injections, or in surgical sutures unless such use is specified in the color additive listing regulation. Currently no color additives are listed for use in injected products (such as tattoos or permanent makeup).
8. Color additives that are permitted for external application may not be used in the area of the eye, in injections, or in surgical sutures unless such use is specified in the color additive listing regulation. Currently no color additives are listed for use in injected products (such as tattoos or permanent makeup). Some color additives that are permitted for external application also may be permitted in mouthwashes, dentifrices, or lipsticks in limited amounts specified in the color additive listing regulations.
9. NTE - not to exceed.