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## Regulatory Status of Color Additives

This database lists the status of color additives for use in foods, drugs, cosmetics, and some medical devices in the U.S. The list includes color additives permanently listed and those that once were provisionally listed, but then removed from the list ("delisted") and are no longer permitted for use. This database will be updated periodically as amendments are made to the color additive regulations.

Whether a color additive is permanently listed, provisionally listed, or delisted is indicated under the "status" heading in the database. Only those color additives identified as permanently or provisionally listed are permitted for the indicated use. Delisted color additives are not permitted for any use. The database does not contain colorants permitted for use in food contact/packaging materials.

See additional [Background Information](#)<sup>6</sup>.

For color additive petitions under review or held in abeyance, see [Food Additive and Color Additive Petitions Under Review or Held in Abeyance](#).<sup>7</sup>

Filter on current uses:

- [Color additives in foods](#)<sup>8</sup>
- [Color additives in cosmetics](#)<sup>9</sup>
- [Color additives in drugs](#)<sup>10</sup>
- [Color additives in devices](#)<sup>11</sup>
- [No current uses](#)<sup>12</sup>

Search and display hints

- Select the Substance name below to view the additional information about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "natural orange 4" will find the substance "Annatto" and "Annatto Extract".
- The search results will return hits of records containing words that include the search term. For example a search for the color red will return results that include terms such as **reducing**, **ingredient**, and **denatured**. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field. You may also do a Field Search, to limit occurrence to a specific data field type (such as "color" names).

[Download data](#)<sup>13</sup> from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#)<sup>14</sup>.

<a href="#">Basic Search</a>	<a href="#">Advanced Search</a>	<a href="#">Field Search</a>			
<b>Search:</b> <input type="text"/>	<input type="button" value="Show Items"/>	<input type="button" value="Clear"/>			
		<b>Records Found: 298</b> <a href="#">Show 50 records at a time</a> <sup>1</sup>			
CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
977010-47-1	Algae Meal, Dried	Permanently listed,	Foods Chicken feed, NTE 0.3% or 150		73

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	
		exempt from certification	ppm ethoxyquin,		
977000-19-3	Alkanet (Alkanna)	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		
50-71-5	Alloxan	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1344-28-1	Alumina	Permanently listed, exempt from certification	<u>Drugs</u> Drugs generally.	5	73
555-32-8	Aluminum Benzoate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
21645-51-2	Aluminum Hydroxide	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
7429-90-5	Aluminum Powder	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Externally applied cosmetics including eye area use.	6	73 73
637-12-7	Aluminum Stearate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1393-63-1	Annatto Extract / Annatto	Permanently listed, exempt from certification	<u>Foods, Drugs, Cosmetics</u> Foods generally; ingested drugs generally, external drugs including eye area use; cosmetics generally including eye area use.	5, 6	73 73 73
	Antarctic krill meal	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed. NTE 4% by weight in freshwater salmonid feed and 12% by weight in marine salmonid feed. The quantity of astaxanthin in the finished feed, from Antarctic krill meal when used alone or in combination with other astaxanthin color additive sources listed in this part, must not exceed 80 mg/kg astaxanthin (72 grams/ton) in the finished feed.	1	73
472-61-7	Astaxanthin	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed, NTE 80 mg/kg.		73
578006-46-9	Astaxanthin Dimethylsuccinate	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed, NTE 110 mg/kg, equivalent to 80 mg/kg astaxanthin.		73
7727-43-7	Barium Sulfate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
	Beet Juice	Permanently listed (as vegetable juice), exempt from certification	<b>Foods</b> Foods generally.	73	
977010-48-2	Beet Powder and Dehydrated Beets	Permanently listed, exempt from certification	<b>Foods</b> Foods generally.	73	
1302-78-9	Bentonite	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
1107-26-2	β-apo-8'-carotenal	Permanently listed, exempt from certification	<b>Foods</b> Foods generally, NTE 15 mg/lb solid, 15 mg/pt liquid.	7	73
7235-40-7	β-carotene (Natural and Synthetic)	Permanently listed, exempt from certification	<b>Foods, Drugs, Cosmetics</b> Foods generally. Ingested drugs generally. Externally applied drugs including eye area use. Cosmetics generally including eye area use.	5, 6	73 73 73
6737-68-4	1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione	Permanently listed, exempt from certification	<b>Devices</b> Contact lenses.	3	73 74 74
813-93-4	Bismuth Citrate	Permanently listed, exempt from certification	<b>Cosmetics</b> Cosmetics intended for coloring hair on the scalp only NTE 0.5%. Cosmetics intended for color hair on the scalp only NTE 2.0%.		73
7787-59-9	Bismuth Oxychloride	Permanently listed, exempt from certification	<b>Drugs, Cosmetics</b> Externally applied drugs including eye area use. Cosmetics generally including eye area use.	5, 6	73 73
8021-99-6	Bone Black	Delisted, formerly exempt from certification	<b>None</b> (formerly Drugs, Cosmetics)		
12597-70-5	Bronze Powder	Permanently listed, exempt from certification	<b>Drugs, Cosmetics</b> Externally applied drugs including eye area use. Cosmetics generally including eye area use.	5, 6	73 73
	Butterfly pea flower extract	Permanently listed, exempt from certification	<b>Foods</b> Alcoholic beverages, sport and energy drinks, flavored or carbonated water, fruit drinks (including smoothies and grain drinks), carbonated soft drinks (fruit-flavored or juice, ginger ale, and root beer), fruit and vegetable juice, nutritional beverages, chewing gum, teas, coated nuts, liquid coffee creamers (dairy and non-dairy), ice cream and frozen dairy desserts, hard candy, dairy and non-dairy drinks, fruit preparations in yogurts, and soft candy		73
60-11-7	Butter Yellow	Delisted prior to 1938	<b>None</b> (formerly Foods)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
		Food, Drug and Cosmetic Act			
471-34-1	Calcium Carbonate	Permanently listed, exempt from certification	<u>Foods, Drugs</u> Drugs generally. Hard and soft candy, mints, and chewing gum.	5	73 73
62-33-9	Calcium Disodium EDTA: Diluents of Color Additive Mixture	Permanently listed, exempt from certification	<u>Foods, Drugs</u> NTE 1% by weight as diluent in food color additive mixture and ingested drugs.		73
1344-95- 2	Calcium Silicate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1592-23- 0	Calcium Stearate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
7778-18- 9	Calcium Sulfate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
514-78-3	Canthaxanthin	Permanently listed, exempt from certification	<u>Foods, Drugs</u> Foods generally, NTE 30 mg/lb of solid or semisolid food or per pint of liquid food; May also be used in broiler chicken feed; Ingested drugs generally; Approved for specific uses in animal food.	1, 3, 5	73 73
8028-89- 5	Caramel	Permanently listed, exempt from certification	<u>Foods, Drugs, Cosmetics</u> Foods generally. Ingested and topically applied drugs generally. Cosmetics generally, including eye area use.	5, 6	73 73 73
6358-30- 1	Carbazole Violet	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3	73
1333-86- 4	Carbon Black (Channel or Impingement)	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods, Drugs, Cosmetics)		
1390-65- 4	Carmine	Permanently listed, exempt from certification	<u>Foods, Drugs, Cosmetics</u> Foods generally. Ingested and externally applied drugs. Cosmetics generally including eye area use. Food and cosmetic labels must use common or usual name "****carmine.****"	5	73 73 73
8015-88- 1	Carrot Oil	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73
16291- 96-6	Charcoal	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
16291-96-6	Charcoal (NFXI)	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods, Drugs)		
1406-65-1	Chlorophyll	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		
11006-34-1	Chlorophyllin-Copper Complex, Oil Soluble	Permanently listed, exempt from certification	<u>Devices</u> Bone cement only NTE 0.003%	3	73
977053-65-8	Chlorophyllin, Potassium Sodium Copper (Chlorophyllin copper complex)	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Citrus-based dry beverage mixes NTE 0.2 percent in dry mix; extracted from alfalfa. Dentrifrices that are drugs; NTE 0.1%. Coloring dentrifrices that are cosmetics NTE 0.1% in combination with a list of substances.	3	73 73
68187-11-1	Chromium-Cobalt-Aluminum Oxide	Permanently listed, exempt from certification	<u>Drugs, Devices</u> Linear polyethylene surgical sutures NTE 2% general surgery. Contact lenses.	3	73 73
12001-99-9	Chromium Hydroxide Green	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Externally applied cosmetics including eye area use.	6	73 73
1308-38-9	Chromium Oxide Greens	Permanently listed, exempt from certification	<u>Drugs, Cosmetics, Devices</u> Externally applied drugs and cosmetics, including eye area use. Contact lenses.	3	73 73 73
6358-53-8	Citrus Red No. 2	Permanently listed, certification required	<u>Foods</u> Mature oranges use only.		74
1333-88-6	Cobaltous Aluminate (Cobalt Blue)	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1343-78-8	Cochineal	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods, Drugs, Cosmetics)		
1390-65-4	Cochineal Extract (Carminic Acid)	Permanently listed, exempt from certification	<u>Foods, Drugs</u> Foods generally. Ingested and externally applied drugs. Cosmetics generally including eye area use. Food and cosmetic labels must use common or usual name "cochineal extract."	6	73 73
7440-50-8	Copper Metallic Powder	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Cosmetics generally including eye area use.	5, 6	73 73
977010-50-6	Corn Endosperm Oil	Permanently listed, exempt from certification	<u>Foods</u> Chicken feed use only		73

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes
977050-51-3	Cornstarch	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)	21
977043-77-8	Cottonseed Flour, Toasted Partially Defatted Cooked	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.	73
1393-80-2	Cudbear	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)	
458-37-7	Curcumin	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)	
	D&C and Ext. D&C Lakes	Provisionally listed, certification required	<u>External Drugs, External Cosmetics</u>	82
1064-48-8	D&C Black No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
1333-86-4	D&C Black No. 2	Permanently listed, certification required	<u>Cosmetics</u> Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.	74
8021-99-6	D&C Black No. 3	Permanently listed, certification required	<u>Cosmetics</u> Eyeliner, eye shadow, mascara, and face powder.	3 74
	D&C Black No. 4	Permanently listed, certification required	<u>Devices</u> Ultra-high molecular weight polyethylene (UHMWPE) non-absorbable sutures for use in general surgery.	4 74
81-48-1	D&C Blue No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	
2650-18-2	D&C Blue No. 4	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	6 74 74 82
6408-51-1	D&C Blue No. 5	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	
482-89-3	D&C Blue No. 6	Permanently listed, certification required	<u>Devices</u> Polyethylene terephthalate sutures NTE 0.2%, plain or chromic collagen absorbable sutures NTE 0.25%, polypropylene sutures NTE 0.5%, general surgical use; plain or chromic collagen absorbable sutures NTE 0.5%, ophthalmic surgical use; polydioxanone synthetic absorbable sutures NTE	74 81 81

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
			0.5% ophthalmic and general surgical use		
3374-30-9	D&C Blue No. 7	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)		81
3374-30-9	D&C Blue No. 8	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)		81
130-20-1	D&C Blue No. 9	Permanently listed, certification required	<b>Drugs, Devices</b> Cotton and silk surgical sutures; NTE 2.5% general and ophthalmic use.		73 74
1320-07-6	D&C Brown No. 1	Permanently listed, certification required	<b>Cosmetics</b> Externally applied cosmetics.	6	74
6546-18-5	D&C Green No. 4	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)		
4403-90-1	D&C Green No. 5	Permanently listed, certification required	<b>Drugs, Cosmetics, Devices</b> Drugs generally. Eye area use. Cosmetics generally. Eye area use. Nylon 66 nonabsorbable sutures; NTE 0.6% general surgery. Nylon 6; NTE 0.6% general surgery.	5	74 74 82
128-80-3	D&C Green No. 6	Permanently listed, certification required	<b>Drugs, Cosmetics, Devices</b> Externally applied drugs. Externally applied cosmetics. Various sutures NTE specified levels; contact lenses NTE 0.03%; Haptics of intraocular lenses NTE 0.1%.	3, 6	74 74 74 81 81 82
4857-81-2	D&C Green No. 7	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)		81
6358-69-6	D&C Green No. 8	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Externally applied drugs (NTE 0.01% (by weight)). Externally applied cosmetics NTE 0.01% (by wt) of finished cosmetic product.	6	74 74
38577-97-8	D&C Orange No. 10	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Externally applied drugs. Externally applied cosmetics.	6	74 74 81 81 82
33239-19-9	D&C Orange No. 11	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Externally applied drugs. Externally applied cosmetics.	6	74 74 81 81 82
977140-41-2	D&C Orange No. 12	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes
10134-55-1	D&C Orange No. 13	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	21
33014-42-5	D&C Orange No. 14	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
72-48-0	D&C Orange No. 15	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
31544-98-6	D&C Orange No. 16	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
3468-63-1	D&C Orange No. 17	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81 81
1936-15-8	D&C Orange No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
633-96-5	D&C Orange No. 4	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Cosmetics generally.	5, 6 74 74 81 82
596-03-2	D&C Orange No. 5	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs (NTE 5 mg/daily dose of drug). Externally applied cosmetics. Mouthwashes, dentrifrices, lipsticks, and other lip cosmetics NTE 5%.	6 74 74 82
4372-02-5	D&C Orange No. 6	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	
6493-54-5	D&C Orange No. 7	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	
3474-67-7	D&C Orange No. 8	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81
977140-43-4	D&C Orange No. 9	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	
1248-18-6	D&C Red No. 10	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81 81
1103-39-5	D&C Red No. 11	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81 81

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
1103-38-4	D&C Red No. 12	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81	81
6371-67-1	D&C Red No. 13	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81	81
5850-76-0	D&C Red No. 14	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)	81	81
6372-81-2	D&C Red No. 15	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		
6373-04-2	D&C Red No. 16	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		
85-86-9	D&C Red No. 17	Permanently listed, certification required	<u>Drugs, Cosmetics, Devices</u> Externally applied drugs. Externally applied cosmetics. Contact lenses.	3, 6	74 74 74 81 82
1320-06-5	D&C Red No. 18	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81
81-88-9	D&C Red No. 19	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81 81
64381-99-3	D&C Red No. 20	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		
15086-94-9	D&C Red No. 21	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Drugs generally. Cosmetics generally.	5	74 74 82
17372-87-1	D&C Red No. 22	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Drugs generally. Cosmetics generally.	5	74 74 82
56897-54-2	D&C Red No. 23	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		
2320-38-9	D&C Red No. 24	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81
2320-38-9	D&C Red No. 25	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
2320-38-9	D&C Red No. 26	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81
13473-26-2	D&C Red No. 27	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Drugs generally. Cosmetics generally.	5	74 74 82
18472-87-2	D&C Red No. 28	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Drugs generally. Cosmetics generally.	5	74 74 82
6359-09-7	D&C Red No. 29	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81
2379-74-0	D&C Red No. 30	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Drugs generally. Cosmetics generally.	5	74 74 82
6371-76-2	D&C Red No. 31	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied cosmetics.	6	74 74 81 82
3567-66-6	D&C Red No. 33	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Ingested drugs, other than mouthwashes and dentrifrices (NTE 0.75 mg/daily dose of drug); externally applied drugs, mouthwashes and dentrifrices. Externally applied cosmetics; mouthwashes, dentrifrices; cosmetic lip products (NTE) 3% (by wt) of finished cosmetic product.)	6	74 74 82
6417-83-0	D&C Red No. 34	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	6	74 74 81 82
2425-85-6	D&C Red No. 35	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81
2814-77-9	D&C Red No. 36	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Ingested drugs, other than mouthwashes and dentrifrices, NTE 1.7 mg daily dose for drugs taken less than 1 yr; NTE 1.0 mg/daily dose for drugs taken more than 1 yr.mouthwashes and dentrifices. Externally applied drugs. Externally applied cosmetics; cosmetic lip products (NTE 3% (by wt) of finished cosmetic product).	6	74 74 82
6373-07-5	D&C Red No. 37	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		81 81
3564-22-5	D&C Red No. 38	Delisted, formerly	<u>None</u> (formerly Drugs, Cosmetics)		81

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		subject to certification			
6371-55-7	D&C Red No. 39	Permanently listed, certification required	<b>Drugs</b> Quaternary ammonium type germicidal solutions for external application (NTE 0.1% (by wt) of finished drug product).	74	
3761-53-3	D&C Red No. 5	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)	81	
5858-81-1	D&C Red No. 6	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Drugs such that total with D&C Red No. 7 NTE 5 mg/daily dose of drug. Ether soluble matter specification changed to 1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent. Cosmetics generally.	5 74 74 82	74 74 82
5281-04-9	D&C Red No. 7	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Drugs such that total with D&C Red No. 7 NTE 5 mg/daily dose of drug. Ether soluble matter specification changed to 1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent. Cosmetics generally in amounts consistent with GMP.	4, 5, 6, 7	74 74 82
2092-56-0	D&C Red No. 8	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)	81	81
5160-02-1	D&C Red No. 9	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)	81	81
1694-09-3	D&C Violet No. 1	Delisted, formerly subject to certification	<b>None</b> (formerly Drugs, Cosmetics)	81	81
81-48-1	D&C Violet No. 2	Permanently listed, certification required	<b>Drugs, Cosmetics, Devices</b> Externally applied drugs. Externally applied cosmetics. NTE 0.2% by wt in glycolic-lactic acid polyester absorbable sutures; NTE 0.3% in polydioxanone synthetic absorbable sutures; 0.25% in ε-caprolactone/glycolide copolymer absorbable sutures; NTE 0.1% in poly(ε-caprolactone) absorbable sutures; NTE 0.2% in glycolide/dioxanone/triethylene carbonate tripolymer absorbable sutures; NTE 0.2% in absorbable sutures from homopolymers of glycolide; contact lenses; NTE 0.2% of intraocular lens haptics; NTE 0.15% by wt of meniscal tacks.	4, 6	74 74 74 81 82
8004-92-0	D&C Yellow No. 10	Permanently listed, certification required	<b>Drugs, Cosmetics, Devices</b> Drugs generally. Modification of uses and restrictions. Cosmetics generally. Contact lenses.	3, 4, 5, 6, 7	74 74 74 82

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
8003-22-3	D&C Yellow No. 11	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	4, 5, 6	74 74 81
2321-07-5	D&C Yellow No. 7	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	4, 5, 6	74 74 82
518-47-8	D&C Yellow No. 8	Permanently listed, certification required	<u>Drugs, Cosmetics, Devices</u> Externally applied drugs. Externally applied cosmetics. Contact lens solution; NTE 0.044% by weight.	4, 5, 6	74 74 74 82
6417-85-2	D&C Yellow No. 9	Delisted, formerly subject to certification	<u>None</u> (formerly Drugs, Cosmetics)		
130-20-1	7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3	73 74
86316-86-1	2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol	Permanently listed, exempt from certification	<u>Devices</u> Formed in situ in soft contact lenses to mark L and R NTE 1.1x10-7 g/lens.	3	73
82-18-8	N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyil)bisbenzamide	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3	73
96-26-4	Dihydroxyacetone	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs intended solely or in part to impart a color to the human body. Externally applied cosmetics intended solely or in part to impart color to the human body.	3, 6	73
139-33-3	Disodium EDTA: Diluents for Color Additive Mixture	Permanently listed, exempt from certification	<u>Foods, Drugs</u> May be used in aqueous solutions and aqueous dispersions in color additive mixtures.	4, 5, 6, 7, 8	73
14025-15-1	Disodium EDTA-Copper (Copper Versenate)	Permanently listed, exempt from certification	<u>Cosmetics</u> Coloring of shampoos that are cosmetics.	3, 4	73
3071-73-6	Ext. D&C Black No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		
61-73-4	Ext. D&C Blue No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		81
6372-69-6	Ext. D&C Blue No. 2	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		
3486-30-4	Ext. D&C Blue No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes
2861-02-1	Ext. D&C Blue No. 4	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
2646-15-3	Ext. D&C Blue No. 5	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
19381-50-1	Ext. D&C Green No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81 81
6371-96-6	Ext. D&C Orange No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
6359-06-4	Ext. D&C Orange No. 2	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
523-44-4	Ext. D&C Orange No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
2646-17-5	Ext. D&C Orange No. 4	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
4321-69-1	Ext. D&C Red No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
3567-69-9	Ext. D&C Red No. 10	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
3734-67-6	Ext. D&C Red No. 11	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
5850-85-1	Ext. D&C Red No. 12	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
5413-75-2	Ext. D&C Red No. 13	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
3118-97-6	Ext. D&C Red No. 14	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
3564-09-8	Ext. D&C Red No. 15	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	<u>Use</u> <u>(Former use)</u> <u>Restrictions</u>	End Notes
1836-22-2	Ext. D&C Red No. 2	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
4548-53-2	Ext. D&C Red No. 24	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
6252-76-2	Ext. D&C Red No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
4370-09-6	Ext. D&C Red No. 4	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
18265-55-9	Ext. D&C Red No. 5	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
6372-92-5	Ext. D&C Red No. 6	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
130-22-3	Ext. D&C Red No. 7	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
1658-56-6	Ext. D&C Red No. 8	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81
6373-10-0	Ext. D&C Red No. 9	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
6408-63-5	Ext. D&C Violet No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	
4430-18-6	Ext. D&C Violet No. 2	Permanently listed, certification required	<u>Cosmetics</u>	74
587-98-4	Ext. D&C Yellow No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81 81
131-79-3	Ext. D&C Yellow No. 10	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81 81
4478-91-5	Ext. D&C Yellow No. 2	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	

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6359-82-6	Ext. D&C Yellow No. 3	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81	
6372-96-9	Ext. D&C Yellow No. 4	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		
2512-29-0	Ext. D&C Yellow No. 5	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81	
6054-99-5	Ext. D&C Yellow No. 6	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81	
846-70-8	Ext. D&C Yellow No. 7	Permanently listed, certification required	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	6	74 74 82
549-34-8	Ext. D&C Yellow No. 8	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)		
85-84-7	Ext. D&C Yellow No. 9	Delisted, formerly subject to certification	<u>None</u> (formerly External Drugs, External Cosmetics)	81	81
977105-05-7	FD&C Lakes	Provisionally listed, certification required	<u>Foods, Drugs, Cosmetics</u>	82	
3844-45-9	FD&C Blue No. 1	Permanently listed, certification required	<u>Foods, Drugs, Cosmetics</u> Foods generally. Added Mn spec. Ingested drugs generally; externally applied drugs including eye area use (includes lakes). Cosmetics generally. Allows MnO <sub>2</sub> in manufacture. Eye area use (includes lakes).	5, 6	74 74 74 82
860-22-0	FD&C Blue No. 2	Permanently listed, certification required	<u>Foods, Drugs, Cosmetics, Devices</u> Foods generally. Ingested drugs. Nylon surgical sutures NTE 1% general surgery; suture listing moved from 74.1102 to 74.3102. Bone cement (Al lake) NTE 0.1%.	3	74 74 74 82
16521-38-3	FD&C Blue No. 2- Aluminum Lake on Alumina	Permanently listed, certification required	<u>Devices</u> Bone cement NTE 0.1%.		74
4680-78-8	FD&C Green No. 1	Delisted, formerly subject to certification	<u>None</u> (formerly Foods, Drugs, Cosmetics)		81
5141-20-8	FD&C Green No. 2	Delisted, formerly subject to certification	<u>None</u> (formerly Foods, Drugs, Cosmetics)	81	

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
2353-45-9	FD&C Green No. 3	Permanently listed, certification required	<b>Foods, Drugs, Cosmetics</b> Foods generally. Drugs generally. Cosmetics generally.	5	74 74 74 82
523-44-4	FD&C Orange No. 1	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		
2646-17-5	FD&C Orange No. 2	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		81
3564-09-8	FD&C Red No. 1	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		81 81
915-67-3	FD&C Red No. 2	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		81 81
16423-68-0	FD&C Red No. 3	Permanently listed, certification required	<b>Foods, Drugs, Cosmetics</b> Foods generally. Ingested drugs.		74 74 81 81
3118-97-6	FD&C Red No. 32	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		81
4548-53-2	FD&C Red No. 4	Permanently listed, certification required	<b>Drugs, Cosmetics</b> Externally applied drugs. Externally applied cosmetics.	6	74 74 81 81 82
25956-17-6	FD&C Red No. 40	Permanently listed, certification required	<b>Foods, Drugs, Cosmetics</b> Foods generally. Drugs generally. Cosmetics generally (includes lakes). Eye area use (includes aluminum lake). No oxidizing or reducing agents that may affect integrity.	4, 5, 6	74 74 74
1694-09-3	FD&C Violet No. 1	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)	4, 5	81 81
846-70-8	FD&C Yellow No. 1	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		
549-34-8	FD&C Yellow No. 2	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		
85-84-7	FD&C Yellow No. 3	Delisted, formerly subject to certification	<b>None</b> (formerly Foods, Drugs, Cosmetics)		

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131-79-3	FD&C Yellow No. 4	Delisted, formerly subject to certification	<u>None</u> (formerly Foods, Drugs, Cosmetics)		21
1934-21-0	FD&C Yellow No. 5	Permanently listed, certification required	<u>Foods, Drugs, Cosmetics</u> Foods generally. Ingested drugs generally. Externally applied drugs. Eye area use (includes lakes). Cosmetics generally. Eye area use (includes Al lake).	4, 5, 6, 7, 8	74 74 74 82
2783-94-0	FD&C Yellow No. 6	Permanently listed, certification required	<u>Foods, Drugs, Cosmetics</u> Foods generally. Drugs generally. Cosmetics generally.	4, 5, 6, 7, 8	74 74 74 82
1185-57-5	Ferric Ammonium Citrate	Permanently listed, exempt from certification	<u>Drugs</u> With pyrogallol for coloring plain or chromic catgut sutures; NTE 3% general and ophthalmic surgery.	4, 5, 6	73
25869-00-5	Ferric Ammonium Ferrocyanide	Permanently listed, exempt from certification	<u>Drugs</u> Externally applied drugs including eye area use. Externally applied cosmetics including eye area use.	6	73 73
7705-08-0	Ferric Chloride	Delisted	<u>None</u> (formerly Drugs, Cosmetics)		
14038-43-8	Ferric Ferrocyanide (Iron Blue)	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Externally applied cosmetics including eye area use.	6	73 73
6047-12-7	Ferrous Gluconate	Permanently listed, exempt from certification	<u>Foods</u> Ripe olives	5	73
92542-68-2	Ferrous Lactate	Permanently listed, exempt from certification	<u>Foods</u> Ripe olives	5	73
7720-78-7	Ferrous Sulfate	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		
977010-51-7	Fruit Juice	Permanently listed, exempt from certification	<u>Foods</u> Foods generally. Dried color additive	3	73
8031-18-3	Fuller's Earth	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
519-34-6	Fustic	Delisted, formerly exempt from certification	<u>None</u> (formerly Drugs)		
	Gloss White	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		82

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
7440-57-5	Gold	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
977091-57-8	Grape Color Extract	Permanently listed, exempt from certification	<u>Foods</u> Nonbeverage food.	3	73
11029-12-2	Grape Skin Extract (Enocianina)	Permanently listed, exempt from certification	<u>Foods</u> Still & carbonated drinks &ades; beverage bases; alcoholic beverages (restr. 27 CFR Parts 4 & 5)		73
7782-42-5	Graphite	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		81
489-84-9	Guaiazulene	Permanently listed, exempt from certification	<u>Cosmetics</u> Externally applied cosmetics.	6	73
73-40-5	Guanine	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Cosmetics generally including eye area use.	5, 6	73 73
977176-72-9	Haematococcus Algae Meal	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed, NTE 80 mg/kg (72 g/ton) astaxanthin in finished feed.	1	73
	Henna	Permanently listed, exempt from certification	<u>Cosmetics</u> Coloring hair but not eyelashes, eyebrows, or eye area.	3	73
1332-37-2	Synthetic Iron Oxides / Iron Oxides	Permanently listed, exempt from certification	<u>Foods, Drugs, Cosmetics, Devices</u> Sausage casings NTE 0.1 percent (by wt). Hard and soft candy, mints, and chewing gum. Dietary supplement tablets and capsules. For all human food uses, lead (as Pb) content NTE 5 mg/kg (5 ppm). Ingested or topically applied drugs ingested dosage by man NTE 5 mg/d (as Fe). Cosmetics generally including eye area use. Contact lenses.	1, 3, 6	73 73 73
	Jagua (genipin-glycine) blue	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73
1332-58-7	Kaolin	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
61790-53-2	Kieselguhr (Diatomite)	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1302-83-6	Lapis Lazuli (Lazurite)	Delisted, formerly	<u>None</u> (formerly Cosmetics)		

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		exempt from certification			
301-04-2	Lead Acetate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
4485-12-5	Lithium Stearate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1345-05-7	Lithopone	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
8005-33-2	Logwood	Permanently listed, exempt from certification	<u>Drugs</u> For coloring nylon 66, nylon 6, or silk non-absorbable sutures; NTE 1% general and ophthalmic surgery.		73
8005-33-2	Logwood (Bluewood, Campeche Wood)	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
977140-94-5; 8005-33-2	Logwood Chips and Extracts	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		
	Luminescent Zinc Sulfide	Permanently listed, exempt from certification	<u>Cosmetics</u> Nail polish and externally applied facial makeup NTE 10% of final product for limited, occasional use.	6	73
41855	Magnesium Aluminum Silicate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
546-93-0	Magnesium Carbonate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
557-04-0	Magnesium Stearate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
14987-04-3	Magnesium Trisilicate	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1309-48-4	Magnesium Oxide	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
	Metallic Salts	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
91-44-1	4-Methyl-7-Diethylaminocoumarin	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
90-33-5	β-methylumbelliferon	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
12001-26-2	Mica	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs including eye area use. Dentrices. Cosmetics generally including eye area use.	5, 6	73 73 73 73
	Mica-Based Pearlescent Pigments	Permanently listed, exempt from certification	<u>Foods, Drugs, Devices</u> Cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum. Distilled spirits containing not less than 18% and not more than 23% alcohol by volume but not including distilled spirits mixtures containing more than 5% wine on a proof gallon basis. Ingested drugs NTE 3%. Iron NTE 55 wt%. Contact lenses.	3	73 73
15139-76-1	Orange B	Permanently listed, certification required	<u>Foods</u> Casings or surfaces of frankfurters and sausages; NTE 150 ppm (by wt).		74
977006-45-3; 68917-78-2	Paprika and Paprika Oleoresin	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73 73
977188-18-3	Paracoccus Pigment	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed, NTE 80 mg/kg (72 g/ton) astaxanthin in finished feed.		73
977165-85-7	Phaffia Yeast	Permanently listed, exempt from certification	<u>Foods</u> Salmonid feed, NTE 80 mg/kg (72 g/ton) astaxanthin in finished feed.		73
1328-53-6	Phthalocyanine Green	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3	73
147-14-8	[phthalocyaninato(2-)] copper	Permanently listed, exempt from certification	<u>Devices</u> Polypropylene sutures NTE 0.5%; contact lenses; polybutester sutures NTE 0.5%; haptics for intraocular lens NTE 0.5%; poly(vinylidene fluoride) and poly(vinylidene fluoride)-co-hexafluoropropylene) nonabsorbable sutures. To color orientation marks for intraocular lenses (IOLs).		74
977171-98-4	Poly(Hydroxyethyl Methacrylate)-C.I. Reactive Red 180 Copolymer	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses		73
	Poly(Hydroxyethyl Methacrylate)- Dye Polymers	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses		73

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13943-58-3	Potassium Ferrocyanide	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		21
87-66-1	Pyrogallol	Permanently listed, exempt from certification	<u>Drugs</u> With ferric ammonium citrate for coloring plain or chromic catgut sutures: NTE 3% general and ophthalmic surgery.		73
12269-78-2	Pyrophyllite (aluminum silicate)	Permanently listed, exempt from certification	<u>Drugs, Cosmetics</u> Externally applied drugs. Externally applied cosmetics.	6	73 73
17095-24-8	C.I. Reactive Black 5	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73
2580-78-1	C.I. Reactive Blue 19	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73 73
73049-92-0	C.I. Reactive Blue 21	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73
121888-69-5	1,4-bis[4-(2-methacryloxyethyl)phenylamino]anthraquinone (C.I. Reactive Blue 246) copolymers	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3, 8	73
109561-07-1	1,4-bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-methyl-2-propenoic) ester copolymers	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	8	73
70209-99-3	Reactive Blue 69	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3	73
68189-39-9	C.I. Reactive Orange 78	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73
98114-32-0	C.I. Reactive Red 180	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73
60958-41-0	C.I. Reactive Yellow 15	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses use only.	3, 8	73
83-88-5	Riboflavin	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73
977134-91-0	Safflower (American Saffron, Florets of Tinctorious L.)	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
977051-90-3	Saffron (Crocus Sativus L.)	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.	73	
977115-45-9	Saffron Oleoresin	Delisted, formerly exempt from certification	<u>None</u> (formerly Foods)		
12769-50-5	Sienna	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
1343-98-2	Silicic Acid	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
7631-86-9	Silicon Dioxide	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)	73	73
9009-99-8	Silk Powder	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
7440-22-4	Silver	Permanently listed, exempt from certification	<u>Cosmetics</u> Coloring fingernail polish NTE 1% of final product.	3, 7	73
7761-88-8	Silver nitrate	Permanently listed, exempt from certification	<u>Cosmetics</u> Externally applied professional-use only cosmetics intended to impart color to the eyebrows and eyelashes; NTE 4% by weight		73
28302-36-5	Sodium Copper Chlorophyllin	Permanently listed, exempt from certification	<u>Foods</u> Citrus-based dry beverages mixes NTE 0.2 percent in the dry mix.	3, 7	73
6407-78-9	4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one	Permanently listed, exempt from certification	<u>Devices</u> Contact lenses.	3	73
1673586-07-6	Soy leghemoglobin	Permanently listed, exempt from certification	<u>Foods</u> Ground beef analogue products; NTE 0.8% by weight.		73
977091-09-0	Spirulina Extract	Permanently listed, exempt from certification	<u>Foods, Drugs</u> Candy and chewing gum; Coloring confections (including candy and chewing gum), frostings, ice cream and frozen desserts, dessert coatings and toppings, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, ready-to-eat cereals (excluding extruded cereals), and coating formulation for dietary supplements, drug tablets, capsules. Hard-boiled shell eggs at levels consistent with good manufacturing practice (GMP). Alcoholic beverages with less than		73 73

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
842-07-9	Sudan I	Delisted prior to 1938 Food, Drug and Cosmetic Act	<u>None</u> (formerly Foods)		
977010- 56-2	Tagetes (Aztec Marigold) Extract	Permanently listed, exempt from certification	<u>Foods</u> Chicken feed.	1	73
977010- 56-2	Tagetes Meal	Permanently listed, exempt from certification	<u>Foods</u> Chicken feed.	1	73
14807- 96-6	Talc	Permanently listed, exempt from certification	<u>Drugs</u> Drugs generally.	5	73
18282- 10-5	Tin Oxide	Delisted, formerly exempt from certification	<u>None</u> (formerly Cosmetics)		
13463- 67-7	Titanium Dioxide	Permanently listed, exempt from certification	<u>Foods, Drugs, Cosmetics, Devices</u> Foods generally, NTE 1 percent (by wt.) Drugs generally including eye area use. Cosmetics including eye area use. Contact lenses. To color orientation marks for intraocular lenses (IOLs).		73 73 73 73
502-65-8	Tomato Lycopene Extract and Concentrate	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.	3	73
977052- 44-0	Turmeric	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73
129828- 29-1	Turmeric Oleoresin	Permanently listed, exempt from certification	<u>Foods</u> Foods generally.		73
57455- 37-5	Ultramarine Blue	Permanently listed, exempt from certification	<u>Foods, Cosmetics</u> Animal feed. Externally applied cosmetics including eye area use.	1, 5, 7	73 73
1345-00- 2	Ultramarine Green	Permanently listed, exempt from certification	<u>Cosmetics</u> Externally applied cosmetics including eye area use.	5	73

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
977058-55-1	Ultramarine Pink	Permanently listed, exempt from certification	<b>Cosmetics</b> Externally applied cosmetics including eye area use.	5	73
977058-56-2	Ultramarine Red	Permanently listed, exempt from certification	<b>Cosmetics</b> Externally applied cosmetics including eye area use.	5	73
12769-96-9	Ultramarine Violet	Permanently listed, exempt from certification	<b>Cosmetics</b> Externally applied cosmetics including eye area use.	5	73
12713-03-0	Umber	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
2475-33-4	16,23-Dihydrodinaphtho[2,3-a:2',3'-i]naphtho[2',3':6,7]indolo[2,3-c]carbazole-5,10,15,17,22,24-hexone	Permanently listed, exempt from certification	<b>Devices</b> Contact lenses.	3	73
128-58-5	16,17-Dimethoxydinaphtho[1,2,3-cd:3',2',1'-Im]perylene-5,10-dione	Permanently listed, exempt from certification	<b>Devices</b> Contact lenses.	3	73
1324-11-4	C.I. Vat Orange 1	Permanently listed, exempt from certification	<b>Devices</b> Contact lenses use only.	3	73
3263-31-8	6-ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one	Permanently listed, exempt from certification	<b>Devices</b> Contact lenses.	3	73
977010-58-4	Vegetable Juice	Permanently listed, exempt from certification	<b>Foods</b> Foods generally.		73
977141-34-6	Vegetable Substances	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
1318-00-9	Vermiculite	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
127-40-2	Xanthophyll	Permanently listed, exempt from certification	<b>Foods</b>	1	73
					73
					73
3486-35-9	Zinc Carbonate	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
1314-13-2	Zinc Oxide	Permanently listed, exempt from certification	<b>Drugs, Cosmetics</b> Externally applied drugs including eye area use. Cosmetics generally including eye area use.	6	73
					73
557-05-1	Zinc Stearate	Delisted, formerly	<b>None</b> (formerly Cosmetics)		

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21
		exempt from certification			
1314-23-4	Zirconium Oxide	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		
14940-68-2	Zirconium Silicate	Delisted, formerly exempt from certification	<b>None</b> (formerly Cosmetics)		

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## Definitions of Terms Used

- **FID**  
Food Inspection Decision (issued by USDA prior to 1927)
- **CAS Reg. No. or other ID**  
Chemical Abstract Service (CAS) Registry® Number for the substance or a numerical code assigned by CFSAN (977nnn-nn-n-series) to those substances that do not have a CAS Reg. No.
- **Other names**  
Recognized synonyms for color additives
- **Lakes**  
Insoluble pigments formed by chemically reacting water-soluble straight colors with precipitants and substrata.

## End Notes

1. The color additives Antarctic krill meal, Astaxanthin, Astaxanthin dimethylsuccinate, 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 73.32, 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 additive as published in the Federal Register.
3. Petitioned for use after the 1960 amendments; never provisionally listed.
4. 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.
5. 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).
6. 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.
7. NTE - not to exceed.

8. The listed color additives are the reaction products produced by copolymerizing the reactive dyes with various monomers such that the dyes are chemically bound in the resulting polymer matrix.

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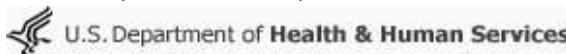


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