

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

COLOR ADDITIVE STATUS LISTPreface

This status list is a measure to provide current information concerning color additives, and will enable investigators and others needing this information to determine the status and limitations of most colors likely to be encountered in a food, drug, device, or cosmetic establishment.

In order to maintain concise form, this list is by necessity limited in many respects involving certification, regulations, labeling, etc. For specific details concerning these matters, please refer to the source documents, Code of Federal Regulations (CFR, Title 21, Parts 70 to 82) and to the Federal Food, Drug, and Cosmetic Act, as amended, Sections 601(e), 602(e), 706, and as it pertains to Sections 201(s) (3) and (t), 402(c), 403(m), 501(a), and 502(m).

Any colors not included in this listing and found in the possession of manufacturers or processors where they may be used in foods, drugs, devices, or cosmetics should be referred to your District for consideration.

LAKES: 21 CFR 81.1 a,b,& c refers to "Lakes (FD&C)", "Lakes (D&C)" and "Lakes (Ext. D&C)". This also refers to 21 CFR 82.51, 81.1051, and 82.2051. These are the sections in the color regulations referring to "Lakes". Sections 82.51, 82.1051, and 82.2051 pertain to FD&C Lakes, D&C Lakes and Ext. D&C Lakes respectively.

Since some of you may not be familiar with "Lakes", the following summary may be helpful:

Two procedures may be followed in naming lakes:

1. A previously certified batch of FD&C color, for example FD&C Yellow No. 5, may be used to start off with; the aluminum or calcium salt of this color may be made and then precipitated on a substrate of aluminum hydroxide. The resultant "Lake" must be certified. In this instance the lake would be named "FD&C Yellow No. 5 Aluminum Lake" and may be used to color foods, drugs or cosmetics.
2. An uncertified batch of FD&C color, for example FD&C Yellow No. 5, may be used to start off with and the lake is made in the same manner as above. The resultant lake must be certified. In this case the name of the lake is "D&C Yellow No. 5 Aluminum Lake" and may be used only to color drugs & cosmetics. The difference between 1 and 2 is that the first procedure started with a previously certified color, while the second procedure started with an uncertified color.

Each "lake" made from FD&C, D&C, or Ext. D&C colors bears the same name as the color from which it is derived followed by the name of the basic radical combined in the color (i.e. aluminum or calcium in FD&C; aluminum, barium, calcium, potassium, sodium, strontium, or zirconium in D&C or Ext. D&C) and the word "lake".

NOTE: You are cautioned that this Exhibit is condensed and should be used for screening and guidance only. When you encounter situations involving possible violations of color additive regulations check the latest basic document as indicated in the second paragraph of this preface. Be certain of the complete status and report the facts. It is the District responsibility to instigate appropriate action, not yours. Do not advise firms to destroy stocks of possible suspect merchandise or institute recalls without District clearance.

COLOR ADDITIVE STATUS LIST

Color Additives previously and presently subject to Certification and provisionally listed for FOOD, DRUG, & COSMETIC Use, and those permanently listed.
(None of these colors may be used in products which are intended to be used in the area of the eye).

Color	Provisional Listing Closing Date*		Remarks	Restrictions or Tolerances & 21 CFR Section 1/
	For Food use.	For Drug Cosmetic use.		
FD&C Blue #1			Permanently listed for food, drug, and cosmetic use, eff. 10-29-82	GMP 74.101, 74.1101, 74.2101, 82.101
FD&C Blue #2			Permanently listed - sutures eff. 4-14-71 Permanently listed for food and ingested drug use. Eff 7-31-87	For coloring nylon surgical sutures the dye must not exceed 1% by wt of the suture and the dye does not migrate to the surrounding tissue. GMP 74.102; 74.1102; 82.102
FD&C Green #3			Permanently listed for food, drug, and cosmetic use eff. 12-16-82	None 74.203; 74.1203; 74.2203; 82.203;
FD&C Red #3			Permanently listed, Food & Ingested Drugs, eff. 7-7-69;	GMP 74.303; 74.1303;
FD&C Red #4			Cert. cancelled eff. 9-23-76, except for use in ext. drugs & cosmetics.	For use only in externally applied Drugs & Cosmetics. 74.1304; 74.2304; 82.304;
FD&C Red #40			Permanently listed for food, drug, & cosmetic use. Reg eff. 6-9-71 & 2-21-75.	GMP 74.340; 74.1340; 74.2340;
FD&C Yellow #5	**		Permanently listed, Food & Ingested Drugs, eff. 7-1-69; Permanently listed for externally applied drugs & cosmetics, generally Eff. 10-7-85	GMP 74.705; 74.1705; 74.2705; 82.705
FD&C Yellow #6			Permanently listed, Food, Drug and Cosmetics. Eff. 12-22-86	GMP 74.706; 74.1706; 74.2706; 82.706; Labeling requirement ***
FD&C Lakes (See Preface of this exhibit)			May be prepared from any of the above certified FD&C colors. Except FD&C Red #3.	None 81.1; 82.51
Citrus Red #2			Permanently listed. Eff. 7-21-63	For use only in coloring of mature oranges. Limit of 2 ppm calculated on basis of whole fruit weight. 74.302
Orange B			Permanently listed. Eff. 3-5-66	Used in coloring surfaces & casings of frankfurters or sausages. Limit < 150 ppm by wt. of finished product. 74.250

The following colors, previously commonly used, are no longer authorized for use:

- FD&C Green #1
- FD&C Green #2
- FD&C Red #1
- FD&C Red #2 (Removed from list on 2-13-76)
- FD&C Red #3 (Lakes removed from list for all uses on 2/1/90. Straight color for cosmetic and external drug use 2/1/90.)
- FD&C Red #4 (Removed from list for ingested uses on 9-23-76)
- FD&C Violet # 1 (Removed from list on 4-10-73)

1/ Color additives may not be used to color foods for which standards of identity have been promulgated unless the use of added color is authorized by the standard.

* 54 F.R. 42096 Nov. 3, 1987. Closing Date Extended
 ** For Lakes only.
 *** 53 F.R. 49138 - Notice that specific labeling requirements will not be enforced

COLOR ADDITIVES STATUS LIST

Color additives previously and presently subject to certification and provisionally listed for DRUG AND COSMETIC use, and those permanently listed.
(None of these colors may be used in products which are intended to be used in the area of the eye)

Color	*Provisional Listing Closing Date	Remarks	Restrictions or Tolerances & 21 CFR Section.
D&C Blue #4		Permanently listed. Eff. 1-3-77	External use only. 74.1104; 74.2104; 82.1104
D&C Green #5		Permanently listed. Eff. 7-7-82	None 74.1205; 74.2205; 82.1205
D&C Green #6		Permanently listed. Eff. 5-4-82	For coloring externally applied drugs and cosmetics. 74.1206; 74.2206; 82.1206;
D&C Green #8		Permanently listed. Eff. 12-20-76	External use only. 74.1208; 74.2208
D&C Orange #4		Permanently listed. Eff. 11-1-77	External use only. 74.1254; 74.2254; 82.1254
D&C Orange #5		Permanently listed for lipsticks, lip cosmetics, mouthwashes, and dentifrices. Eff. 12-3-82	74.1255, 74.2255, 82.1255
		Permanently listed for externally applied drugs and cosmetics. Eff. 5-7-84	Lipsticks and Lip Cosmetics: Composition restricted to 5% by weight of finished cosmetic product. * Drugs: In externally applied drugs in amounts not exceeding 5 mg. per daily dose of drug. Ingested Use: In drug and cosmetic mouthwashes and dentifrices. GMP Cosmetics: In externally applied cosmetics. GMP
D&C Red #6		Permanently Listed Eff. 1-28-83	74.1306, 74.2306, 82.1306 Drugs: Combined total of D&C Red No. 6 & D&C Red No. 7 not to exceed 5 mg. per daily dose of drug. Cosmetics: General Use. GMP
D&C Red #7		Permanently Listed Eff. 1-28-83	74.1307, 74.2307, 82.1307 Drugs: Combined total of D&C Red No. 6 & D&C Red No. 7 not to exceed 5 mg. per daily dose of drug. Cosmetics: General Use. GMP
D&C Brown #1		Permanently listed. Eff. 12-27-76	For coloring externally applied cosmetics. GMP 74.2151

* Ingested drugs use delisted - 11-30-82

COLOR ADDITIVES STATUS LIST

Color Additives previously and presently subject to certification and provisionally listed for DRUG and COSMETIC use, and those permanently listed. (Cont'd)
 (None of these colors may be used in products which are intended to be used in the area of the eye)

Color	*Provisional Listing Closing Date	Remarks	Restrictions or Tolerances & 21 CFR Section
D&C Red #21		Permanently listed. Eff. 1-3-83	None: 74.1321; 74.2321; 82.1321
D&C Red #22		Permanently listed. Eff. 1-3-83	None: 74.1322; 74.2322; 82.1322
D&C Red #27		Permanently listed. Eff. 10-29-82	None: 74.1327; 74.2327; 82.1327
D&C Red #28		Permanently listed. Eff. 10-29-82	None: 74.1328; 74.2328; 82.1328
D&C Red #30		Permanently listed. Eff. 8-25-82	None: 74.1330; 74.2330;
D&C Red #33		Tolerances set for internal use drugs, dentifrices, mouth washes, etc. Permanently listed 10-28-88	Drugs: Daily ingestion limited to 0.75 mg pure dye or a combination of dyes approved for this use. 81.1; 81.25;
D&C Red #36		Tolerances set for internal use drugs, dentifrices, mouth washes, etc. Permanently listed 12-27-88	Drugs: Daily ingestion limited to 1.7 mg pure dye or a combination of dyes approved for this use. 574.1336
D&C Yellow #7		Permanently listed. Eff 12-20-76	** For external use only: 74.1707; 74.2707; 82.1707
D&C Yellow #10		Permanently listed. EFF 9-30-83; *** 4-6-84	None; 74.1710, 74.2710, 82.1710
D&C Lakes (See Preface of this Exhibit)		May be prepared from any of the legal FD&C or as permitted for D&C colors.	81.1; 82.1051

The following colors, previously commonly used, are no longer authorized for use:

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|---------------------------------|----------------|-------------|
| D&C Black #1 | D&C Orange #15 | D&C Red #13 |
| D&C Blue #6 (Drugs & Cosmetics) | D&C Orange #16 | D&C Red #14 |
| D&C Blue #7 | D&C Orange #17 | D&C Red #18 |
| D&C Green #7 | D&C Red #5 | D&C Red #19 |
| D&C Orange #3 | D&C Red #8 | D&C Red #24 |
| D&C Orange #8 | D&C Red #9 | D&C Red #29 |
| D&C Orange #14 | D&C Red #10 | D&C Red #35 |
| | D&C Red #11 | D&C Red #37 |
| | D&C Red #12 | D&C Red #38 |

* 50 F.R. 4642, Feb. 1, 1985. Closing date extended.
 ** See 21 CFR 81.25 (External D&C use unlimited.)
 *** 49 F.R. 8429. (Restrictions Removed.)

COLOR ADDITIVES STATUS
 Color Additives previously and presently subject to certification and provisionally listed for use in **EXTERNALLY APPLIED DRUGS & COSMETICS**.
 (None of these colors may be used in products which are intended to be used in the area of the eye)

Color	*Provisional Listing Closing Date	Remarks	Restrictions or Tolerances & 21 CFR Sections.
D&C Red #17		Permanently listed. Eff 12-20-76	External use only. 74.1317; 74.2317; 82.1317
D&C Red #31		Permanently listed. Eff 12-27-76	External use only. 74.1331; 74.2331; 82.1331
D&C Red #34		Permanently listed. Eff 12-27-76	External use only. 74.1334; 74.2334; 81.1; 82.1334
D&C Red #39		Permanently listed. Eff 2-7-66 Delisted for other uses.	Restricted to use (< 0.1% by wt of the finished drug product) in externally applied quaternary ammonium germicidal solutions. 74.1339
D&C Violet #2		Permanently listed. Eff 12-20-76*	External use only. 74.1602; 74.2602; 82.1602*
Ext. D&C Violet #2		Permanently listed. Eff 12-27-76	For coloring externally applied cosmetics. 74.2602a
D&C Green #6		Permanently listed. Eff. 5-4-82	CMP. 74.1206; 74.2206; 82.1206;
Ext. D&C Yellow #7		Permanently listed. Eff 12-27-76	None: 74.1707a; 74.2707a; 82.2707a
D&C Yellow #8		Permanently listed. Eff 12-20-76	** For External use only: 74.1708; 74.2708; 82.1708
D&C Yellow #11		Permanently listed. Eff 12-20-76	External use only. 74.1711; 74.2711
D&C Orange #10		Permanently listed. Eff. 4-28-81	74.1250, 74.2250, 82.1250 - External Use Only
D&C Orange #11		Permanently listed. Eff. 4-28-81	74.1251, 74.2251, 82.1251 - External Use Only
Ext. D&C Lakes (See Preface of this Exhibit)		May be prepared from any of the above legal Ext. D&C colors.	None: 31.1; 82.2051

The following colors, previously commonly used, are no longer authorized for use:

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|-------------------|-----------------|-------------------|--------------------|
| Ext D&C Blue #1 | Ext D&C Red #1 | Ext D&C Red #11 | Ext D&C Yellow #3 |
| Ext D&C Blue #4 | Ext D&C Red #2 | Ext D&C Red #13 | Ext D&C Yellow #5 |
| Ext D&C Green #1 | Ext D&C Red #3 | Ext D&C Red #14 | Ext D&C Yellow #6 |
| Ext D&C Orange #1 | Ext D&C Red #8 | Ext D&C Red #15 | Ext D&C Yellow #9 |
| Ext D&C Orange #3 | Ext D&C Red #10 | Ext D&C Yellow #1 | Ext D&C Yellow #10 |
| Ext D&C Orange #4 | | | |

* 50 F.R. 4641, Feb. 1, 1985. Closing Date Extended.
 ** 48 F.R. 5262, Feb. 4, 1983.
 *** 48 F.R. 13976, April 1, 1983.

COLOR ADDITIVES STATUS LIST
 Color additives provisionally and permanently listed for FOOD use on the basis of prior commercial sale but which have not been nor are now subject to certification.

Color	*Provisional Listing Closing Date	Remarks	Restrictions or tolerances & 21 CFR Section 1/
Algae Meal, dried		Permanently listed. Eff 7-31-61 To be used in chicken feed to enhance color of chicken skin & egg yolks. No Cert. required	Used in chicken feed to enhance the yellow color of chicken skin & egg. Ethoxyquin content not to exceed 0.3%. Quantity used sufficient to adequately supplement feed with xanthophyll & carotenes & the ethoxyquin (preservative) content < 150 ppm in final feed. 73.275
Annatto extract		Permanently listed. Eff 8-19-63 Certification not required.	GMP 73.30
Beet juice		Permanently listed (veg. juice). Eff 3-28-66	GMP 73.260
Beet Powder (Dehydrated beets)		Permanently listed. Eff 6-19-67	GMP 73.40
Canthaxanthin		Permanently listed. Eff 3-9-69 Permanently listed. Eff 12-20-85	The quantity of canthaxanthin does not exceed 30 mg/lb of solid or semisolid food or per pint of liquid food. 73.75 May be safely used in broiler chicken feed to enhance the yellow color of chicken skin in accordance with the following conditions: The quantity incorporated in the feed shall not exceed 4.41 mg per kg (4 gms/ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.
Caramel		Permanently listed. Eff 8-24-63 Certification not required.	GMP 73.85
Beta carotene		Permanently listed. Eff 2-11-64	GMP 73.95
Carrot oil		Permanently listed. Eff 9-25-67	GMP 73.300
Cochineal extract		Carmines - Permanently Listed	GMP 73.100
Camphine		6-18-67; Cochineal Extract - Permanently listed 2-12-69 Certification not required.	
Corn Endosperm Oil		Permanently listed. Eff 5-29-67	Used in chicken feed to enhance yellow color of chicken skin & eggs. 73.315
Toasted partially defatted cooked cottonseed flour		Permanently listed. Eff 4-6-64 Certification not required.	GMP 73.140
Ferrous Gluconate		Permanently listed. Eff 6-18-67	Color rice olives only. GMP - 73.160
Fruit juice		Permanently listed. Eff 3-28-66	Use in foods consistent with GMP's. 73.250
Grape Color Extract		Permanently listed. Eff 10-30-81	Used to color nonbeverage food, except that it may not be used to color foods for which Standards of Identity have been promulgated, unless the use of added color is authorized by the Standard. 73.169;
Grape Skin Extract (enocianina)		Permanently listed. Eff 5-21-66	Still & carbonated drinks & ades, beverage bases & alcoholic beverages - used in accordance with Parts 4 & 5 of Title 27 CFR. 73.170
Synthetic Iron Oxide		Permanently listed. Eff 9-9-68	For cat & dog food only. Color is not to exceed 0.25% by wt of finished food. 73.200
Paprika & Paprika Oleoresin		Permanently listed. Eff 3-28-66	Use in foods consistent with GMP's. 73.340; 73.345
Riboflavin		Permanently listed. Eff 8-21-67	GMP 73.450
Saffron		Permanently listed. Eff 3-28-66	Use in foods consistent with GMP's. 73.500
Tagetes Meal & Extract (Aztec Marigold)		Permanently listed. Eff 12-4-63	Used in chicken feed to enhance yellow color of chicken skins & eggs. Ethoxyquin content not to exceed 0.3%. Quantity used sufficient to adequately supplement feed with xanthophyll and carotenes and ethoxyquin content of final feed < 150 ppm. 73.295
Titanium dioxide		Permanently listed. Eff 3-28-66	In foods - limit 1.0% by wt of finished food. 73.575
Tumeric & Tumeric Oleoresin		Permanently listed. Eff 3-28-66	Use in foods consistent with GMP's. 73.600 & 73.615
Ultramarine Blue		Permanently listed. Eff 6-20-66	Limit of 0.5% by wt of salt in coloring salt used for animal feed. 73.50
Vegetable Juice		Permanently listed. Eff 3-28-66	Use in foods consistent with GMP's. 73.260
B-Apo-8'-Carotenal		Permanently listed. Eff 10-29-63	15 mg/lb of solid or semisolid food or per pint of liquid food. 73.90

The following colors, previously commonly used, are no longer authorized for use:

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|-------------------|-----------------|------------------------------|
| Alkanet (Alkana) | Cochineal | Ferrous sulfate |
| Calcium carbonate | Cudbear | Logwood, chips & extract |
| Carbon black | Ferric chloride | Safflower (American saffron) |
| Charcoal - NF XI | | |

1/ - Color additives may not be used to color foods for which standards of identity have been promulgated unless the use of added color is authorized by the standard.

* 42 F.R. 6992 February 4, 1977. Closing date extended.

COLOR ADDITIVES STATUS LIST
Color Additives provisionally and permanently listed for DRUGS on the basis of prior commercial sale but which have not been nor are now subject to certification.

Color	*Provisional Listing Closing Date	Remarks	Restrictions or Tolerances & 21 CFR Sections
Aluminum Powder		Permanently listed. Eff 8-30-77	GMP 73.1645
Annatto Extract		Permanently listed. Eff 11-17-63	GMP - Ingested drugs only. 73.1030
Alumina		Permanently listed. Eff 7-1-67	GMP 73.1010
Bismuth oxychloride		Permanently listed. Eff 11-1-77	GMP 73.1162
Bronze Powder		Permanently listed. Eff 8-2-77	GMP 73.1646
Calcium carbonate		Permanently listed. Eff 7-1-67	GMP 73.1070
Canthaxanthin		Permanently listed. Eff 3-9-69	GMP - Ingested drugs only. 73.1075
Caramel		Permanently listed. Eff 10-13-63	GMP 73.1085
Chlorophyllin - copper - complex		Permanently listed. Eff 6-25-69	Use in dentrifices that are drugs. Limit < 0.1%. 73.1125
Cochineal extract; carmine		Carmine - Permanently listed. 6-18-67. Cochineal ext. - Perm. listed. 2-12-69	GMP 73.1100
Beta-carotene, natural and synthetic		Permanently listed. Eff 5-4-64	GMP 73.1095
Chromium-Cobalt-Aluminum oxide		-----	Polyethylene surgical suture use only. < 2% by wt of suture material. Dyed suture shall conform to USP. There is no migration of color additive to surrounding tissue. 73.1015
Chromium hydroxide green		Permanently listed. Eff 8-16-77	GMP 73.1326
Chromium oxides greens		Permanently listed. Eff 8-16-77	GMP 73.1327
Copper, metallic powder		Permanently listed. Eff 8-2-77	GMP 73.1647
Potassium sodium copper chlorophyllin (Chlorophyllin copper complex)		Permanently listed. Eff 6-25-69	To color dentrifices that are drugs, at a level not to exceed 0.1%. 73.1125
Dihydroxyacetone		Permanently listed. Eff 4-30-73	Externally applied drugs intended to impart a color to the human body. 73.1150
Ferric Ammonium Citrate		Permanently listed. Eff 7-16-73	Plain & chromic catgut suture use only. < 3% by wt of surgical suture material. Dyed suture shall conform to USP. No migration of color additive to surrounding tissue. 73.1025
Ferric Ammonium ferrocyanide (Iron Blue)		Permanently listed. Eff 8-30-77	GMP 73.1298
Ferric Ferrocyanide (Iron Blue)		Permanently listed. Eff 12-21-78	GMP Externally applied drugs, including those intended for use in area of eye. 73.1299
Guanine (Pearl essence)		Permanently listed. Eff 8-23-77	GMP 73.1329
Logwood		Permanently listed. Eff 11-1-77	Surgical suture use only. 74.1410
Mica		Permanently listed. Eff 8-30-77	GMP 73.1496
Pyrogallol		Permanently listed. Eff 7-16-73	As a component of iron pyrogallol color additive for surgical suture use only. 73.1375
Pyrophyllite		Permanently listed. Eff 5-28-66	Used in externally applied drugs consistent with GMP. 73.1400
Synthetic iron oxide		Permanently listed. Eff 4-12-66	Use - ingested and topically applied drugs - limit, ingested drugs < 5 mg elemental iron per day. 73.1200
Talc		Permanently listed. Eff 7-1-67	GMP 73.1550
Titanium dioxide		Permanently listed. Eff 3-28-66	GMP 73.1575
Zinc oxide		Permanently listed. Eff 8-23-77	GMP 73.1991

The following colors, previously commonly used, are no longer authorized for use:

Bone Black	Cochineal
Charcoal NF XI	Fustic
Chlorophyll copper complex (chlorophyllin)	Ultramarine Blue

COLOR ADDITIVE STATUS LIST
 Color Additives provisionally and permanently listed for COSMETIC use on the basis of prior commercial sale but which have not been nor are now subject to certification.

Color	Provisional Listing Closing Date	Remarks	Restrictions or Tolerances & 21 CFR Sections
Aluminum Powder		Permanently listed. Eff 8-30-77	GMP 73.1645; 73.2645
Annatto		Permanently listed. Eff 8-19-77	GMP 73.2030
Bismuth Citrate		Permanently listed. Eff 10-31-78	For cosmetics intended to color hair on scalp only. 73.2110; Not for eyelashes or eyebrows or other body hair.
Bismuth oxychloride		Permanently listed. Eff 11-1-77	GMP 73.1162; 73.2162
Bronze powder		Permanently listed. Eff 8-3-77	GMP 73.2646
Caramel		Permanently listed. Eff 8-23-31	None 73.2085
Carmine		Permanently listed. Eff 7-26-77	None 73.11
Beta-Carotene		Permanently listed. Eff 8-2-77	GMP 73.2095
Chromium hydroxide green		Permanently listed. Eff 8-16-77	GMP 73.1326; 73.2326
Chromium oxide greens		Permanently listed. Eff 8-16-77	GMP 73.1327; 73.2327
Copper, metallic powder		Permanently listed. Eff 8-2-77	GMP 73.2647
Dihydroxyacetone		Permanently listed. Eff 9-30-73	Externally applied cosmetics intended to impart a color to the human body. GMP 73.2150; 81.1
Disodium EDTA - Copper		Permanently listed. Eff 7-9-74	Cosmetic shampoos. GMP 73.2120
Ferric ammonium ferrocyanide (Iron blue)		Permanently listed. Eff 8-30-77	GMP 73.1298; 73.2298
Ferric ferrocyanide (Iron Blue)		Permanently listed. Eff 12-22-78	GMP Externally applied cosmetics including use in area of eye. 73.2299
Guanine (Pearl essence)		Permanently listed. Eff 8-23-77	GMP 73.1329; 73.2329
Guaiazulene (Azulene)		Permanently listed. Eff 1-3-77	GMP External use only. 73.2180
Henna		Permanently listed. Eff 8-14-65	Do not use in the area of the eye or on cut or abraded scalp. For coloring hair only. Not for eyelashes or eyebrows. 73.2190
Iron oxides		Permanently listed. Eff 1-3-77	Coloring cosmetics generally including the area of the eye. 73.2250
Lead Acetate (Hair dye)		Permanently listed. Eff 12-1-50	For use as a color component of hair dye. Do not use on cut or abraded scalp. 73.2396*
Manganese Violet		Permanently listed. Eff 12-6-76	Coloring cosmetics generally including area of eye. 73.2775
Mica		Permanently listed. Eff 8-30-77	GMP 73.1496; 73.2496
Potassium sodium copper chlorophyllin (chlorophyllin copper complex)		Permanently listed. Eff 6-25-69	To color dentifrices that are cosmetics. Not to be used in excess of 0.1%. May be used only in combination with the substances listed in 21 CFR 73.2125
Pyrophyllite		Permanently listed. Eff 5-28-66	GMP Externally applied cosmetics. 73.2400
SILVER		Permanently listed. Eff 12-17-79	Not greater than 1% in fingernail polish. 73.2500
Titanium dioxide		Permanently listed. Eff 6-3-73	General cosmetic use. GMP including use in the area of the eye. 73.2575
Ultramarine, Blue, Green, Pink, Red & Violet		Permanently listed. Eff 12-5-76	External use only, including in the area of the eye. 73.2725
Zinc oxide		Permanently listed. Eff 8-23-77	GMP 73.1991; 73.2991

The following colors, previously commonly used, are no longer authorized for use:

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|---|-------------------------|---|--------------------|
| Alloxan | Cochineal | Logwood (Gluewood, Campeche wood) | Sienna |
| Bone Black | Fuller's Earth | 4-Methyl-7-diethylamino-coumarin (MDAC) | Umber |
| Carbon Black (Channel Process) | Gloss White | B-Methyl umbelliferone | Vermiculite |
| Carminic Acid | Graphite | Potassium Ferrocyanide | Zirconium oxide |
| Chlorophyll Copper Complex & Chlorophyllin Copper Complex | Kieselguhr (Diatomite) | | Zirconium silicate |
| Cobaltous Aluminate (Cobalt Blue) | Lapis Lazuli (Lazurite) | | |
| | Lithopone | | |

* 42 F.R. 6992 February 4, 1977. Closing date extended.

* Warning Statement must be included on label of the color additive.

* Cautionary statement must be included on label of cosmetic containing lead acetate.

COLOR ADDITIVES STATUS		
Color Additives permanently listed for use in MEDICAL DEVICES		
Color	Remarks	Restrictions or tolerances & 21 CFR Sections.
Carbazole violet	Permanently listed 10-21-88	For use in contact lenses 73.3107
Chromium Cobalt Aluminum oxides	Permanently listed 10-21-88	For use in contact lenses 73.3110a
Chromium oxide greens	Permanently listed. Eff. 8-9-86	For use in contact lenses. GMP 73.3111
1,6,23-Dihydrodinaphthol(2,3-a:2',3'-1)naph(2',3':6,7)indolo(2,3-c)carbazole-5,10,15,17,22,24-hexane	Permanently listed. Eff 8-9-83	For use in contact lenses. GMP 73.3117
N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl)bisbenzamide	Permanently listed. Eff 8-9-83	For use in contact lenses. GMP 73.3118
7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone	Permanently listed. Eff 8-9-83	For use in contact lenses. GMP 73.3119
1,6,17-Dimethoxydinaphtho(1,2,3-cd:3',2',1'-lm)perylene-5,10-dione	Permanently listed. Eff 8-9-83	For use in contact lenses. GMP 73.3120
4-((2,4-dimethylphenyl)azo)-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one	Permanently listed. Eff. 5-6-86	For use in contact lenses. GMP 73.3122
D&C Blue #6	Permanently listed. Eff 1-13-78 Amended 8-27-84	Surgical sutures. 74.1106*
D&C Blue #9	Permanently listed. Eff 5-4-73	Cotton & silk surgical suture use only. 74.1109
D&C Green #6	Permanently listed. Sutures. Eff 10-27-86 Permanently listed. Eff 4-29-83	For coloring polyethylene terephthalate or polyglycolic acid sutures (> U.S.P. size 8-0 and < U.S.P. Size 8-0). Color not to exceed 0.75% or 0.1% and 0.5% respectively by wt. of suture material. 74.1206 For coloring poly(glycolic acid-co-trimethylene carbonate) sutures. Color not to exceed 0.21% by wt. of suture material. 74.3206 For use in contact lenses. Limit < 0.03% by weight of the contact lens material. 74.3206
2-((2,5-Diethoxy-4-(4-methylphenyl)thio)phenyl)azo)-1,3,5-benzenetriol	Permanently listed. eff 6-21-83	For use in making soft (hydrophilic) contact lenses with the letter R, or L for identification purposes. Limit < 1.1×10^{-7} g in a soft contact lens and no measurable migration of the color additive to ocular tissue. 73.3115
6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2-[3H]-ylidene)benzo[b]thiophen-3-[2H]-one	Permanently listed. Eff. 5-6-86	For use in contact lenses. GMP 73.3123
{Phthalocyaninato(2-)} copper	Permanently listed for sutures, Eff 6-22-69. Permanently listed for polybutester nonabsorbable sutures. Eff. 4-25-85 Permanently listed for contact lenses. Eff 9-2-83. Permanently listed for haptics. Eff. 6-2-87.	For coloring polypropylene sutures. Color not to exceed 0.5% by wt. of suture. Dyed suture to conform to U.S.P. 74.3045 For coloring contact lenses. GMP 74.3045 For use in polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses. Color not to exceed 0.5% by wt. of the suture of haptic material. 74.3045.
Chlorophyllin-copper complex	Permanently listed. Eff 1-23-84	For coloring polymethyl-methacrylate bone cement. Limit < 0.003% by weight of the bone cement. 73.3110

* 49 F.R. 29955, July 25, 1984.

COLOR ADDITIVES STATUS LIST		
Color Additives permanently listed for use in MEDICAL DEVICES CONT		
Color	Remarks	Restrictions or tolerances - 21 CFR Sections.
Iron oxides	Permanently listed. Eff. 8-9-86	For use in contact lenses. GMP 73.3125
Phthalocyanine green	Permanently listed. Eff. 5-9-85	For use in contact lenses. GMP 73.3124
Poly(hydroxyethyl methacrylate)-like copolymers; The color additives are formed by reacting one or more reactive dyes with poly(hydroxyethyl methacrylate). The dyes, which may be used alone or in combination, are: Reactive Blue 21, Reactive Black 5, Reactive Yellow 15, and Reactive Orange 78 Reactive Blue 19 Reactive Blue 4 C.I. Reactive Red 11 C.I. Reactive Yellow 86 C.I. Reactive Blue 163	Permanently listed. Eff. 2-9-84 Permanently listed. Eff. 4-9-85. Permanently listed. Eff. 9-19-85 Permanently listed. Eff. 12-9-85 " " " " " "	For use in contact lenses. GMP. During prep. lenses are thoroughly washed to remove unbound reactive dyes. 73.3121 73.3121 73.3121 73.3121 " "
Titanium dioxide	Permanently listed. Eff. 8-9-86	For use in contact lenses. GMP 73.3126
C.I. Vat Orange 1	Permanently listed for Contact Lenses. Eff. 6-17-85	For coloring contact lenses. GMP 73.3112
1,4-bis(2-methylphenyl) amino-9,10 anthracenedione	Permanently Listed. Eff. 8-28-84	For use in contact lenses. GMP 73.3105
D&C Violet No. 2	Permanently listed for sutures. Eff. 10-24-80 Permanently listed for contact lenses. Eff. 6-29-87.	For coloring glycolic/lactic acid polyester or polydioxanone sutures. Color not to exceed 0.2% or 0.3% respectively by wt. of suture material. 74.1602. For use in contact lenses. GMP 74.3602.
D&C Yellow No. 10	Permanently listed. Eff. 9-3-87.	For use in contact lenses. GMP 74.3710

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INSPECTION OPERATIONS MANUAL

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