Color Additive Status List

Food Additive Status List

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Preface

This status list, formerly called Appendix A of the Investigations Operations Manual (IOM), provides current information concerning color additives, and will enable you to determine the status and limitations of most color additives likely to be encountered in a food, drug, device, or cosmetic establishment.

To maintain concise form, this list is 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, [21 U.S.C. 361(e), 362(e), 376] and as it pertains to Sections 201(s)(3) and (t), 402(c), 403(m), 501(a), and 502(m) [21 U.S.C 321(s)(3), and (t), 342(c), 343(m), 351(a), and 352(m)].

Any color additives 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. Your Servicing Laboratory for color analysis is also a good reference source.

LAKES: Color additive lakes are provisionally listed under 21 CFR 81.1. Part 82 of 21 CFR explains how lakes may be manufactured and named and lists the color additives that may be used to manufacture lakes. All lakes are subject to certification.

Examples of nomenclature of lakes:

The name of a lake is formed from the name of the color additive combined with the name of the basic radical and the word "Lake". For example, the name of the lake prepared by extending the aluminum salt of FD&C Blue No. 1 upon alumina would be FD&C Blue No. 1 - Aluminum Lake.

If a lake is prepared by extending an FD&C color additive on a substratum other than alumina, the symbol "FD&C" will be replaced by "D&C". For example, the name of the lake prepared by extending the aluminum salt of FD&C Blue No. 1 upon a substratum other than alumina would be D&C Blue No. 1- Aluminum 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.

LIST 1

Color additives subject to certification and permanently listed (unless otherwise indicated) for use in **FOOD**. Most are also listed for use in **DRUGS AND COSMETICS** as noted. (None of these colors may be used in products that are for use in the area of the eye, unless otherwise indicated).

FD&C Blue #1 - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP - 74.101, 74.1101, 74.2101, 82.101

FD&C Blue #1 Aluminum Lake - Drugs and cosmetics for eye area - GMP - 74.1101, 74.2101, 82.101

FD&C Blue #2 - Food and ingested drugs - GMP - 74.102, 74.1102; sutures - see medical devices - 74.3102.

FD&C Blue #2 Aluminum Lake on alumina - Bone cement - see medical devices - 74.3102, 82.102

FD&C Green #3 - Food, drugs and cosmetics - GMP - 74.203, 74.1203, 74.2203, 82.203

FD&C Red #3 - Food and ingested drugs - GMP - 74.303, 74.1303. May no longer be used in cosmetics, external drugs, and lakes

FD&C Red #40 and its Aluminum Lake - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP. Other lakes for food, drugs and cosmetics are also permanently listed - 74.340, 74.1340, 74.2340

FD&C Yellow #5 - Food, drugs and cosmetics, including drugs and cosmetics for eye area - GMP - 74.705, 74.1705, 74.2705, 82.705

FD&C Yellow #5 Aluminum Lake - Drugs and cosmetics for eye area - GMP - 74.1705, 74.2705, 82.705

FD&C Yellow #6 - Food, drugs and cosmetics - GMP - 74.706, 74.1706, 74.2706, 82.706

FD&C Lakes (See Preface of this exhibit) - Provisionally listed. May be prepared from any of the above certified FD&C colors, except FD&C Red #3 - GMP - 81.1, 82.51

Citrus Red #2 - Skins of mature oranges - ≤ 2 ppm by wt. of whole fruit - 74.302 Orange B - Surfaces and casings of frankfurters or sausages - ≤ 150 ppm by wt. of finished product - 74.250

Use of the following color additives is no longer authorized or has been restricted:

FD&C Green #1 - Removed from list - 81.30(d)

FD&C Green #2 - Removed from list - 81.30(d)

FD&C Red #1 - Removed from list - 81.10(c), 81.30(b)(1)

FD&C Red #2 - Removed from list - 81.10(f), Feb. 13, 1976 - 81.30(j)

FD&C Red #3 - All lakes, all cosmetics, and external drugs removed from list - 81.10(u), Feb. 1, 1990 - 81.30(u). Use of FD&C Red #3, but not its lakes, in food and ingested drugs is allowed.

FD&C Red #4 - Food, ingested drugs, and ingested cosmetics removed from list. Use in externally applied drugs and cosmetics is allowed - 81.10(d), Sep. 23, 1976 - 81.30(c).

FD&C Violet #1 - Removed from list - 81.10(e), Apr. 10, 1973 - 81.30(h)

LIST 2

Color additives subject to certification and permanently listed (unless otherwise indicated) for **DRUG AND COSMETIC** use. (None of these colors may be used in products that are for use in the area of the eye unless otherwise indicated)

D&C Black #2 - Only for the following cosmetics: eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel - GMP - 74.2052

D&C Black #3 - Only for the following cosmetics: eyeliner, eye shadow, mascara, and face powder. - GMP - 74.2053

D&C Green #5 - For drugs and cosmetics including drugs and cosmetics for eye area - GMP - 74.1205, 74.2205, 82.1205

D&C Orange #5 - Drugs: mouthwashes and dentifrices that are ingested drugs (GMP), and external drugs (at most 5 mg per day). Cosmetics: lipsticks (at most 5% by wt. of finished product), mouthwashes and dentifrices that are ingested cosmetics, and external cosmetics (GMP) 74.1255, 74.2255, 82.1255

D&C Red #6 - For drugs (combined total of D&C Red No.6 & D&C Red No. 7 < 5 mg="" per="" day);="" for="" cosmetics="" (gmp)="" -74.1306,="" 74.2306,="">

D&C Red #7 - For drugs (combined total of D&C Red No.6 & D&C Red No. 7 < 5 mg="" per="" day);="" for="" cosmetics="" (gmp)="" -74.1307,="" 74.2307,="">

D&C Red #21 - For drugs generally and cosmetics - GMP -74.1321, 74.2321, 82.1321

D&C Red #22 - For drugs generally and cosmetics - GMP -74.1322, 74.2322, 82.1322

D&C Red #27 - For drugs generally and cosmetics - GMP -74.1327, 74.2327, 82.1327

D&C Red #28 - For drugs generally and cosmetics - GMP -74.1328, 74.2328, 82.1328

D&C Red #30 - For drugs generally and cosmetics - GMP -74.1330, 74.2330, 82.1330

D&C Red #33 - Drugs: ingested drugs other than mouthwashes and dentifrices (at most 0.75 mg per day); and mouthwashes, dentifrices, and external drugs (GMP). Cosmetics: lipsticks (at most 3% by wt. of finished product); and mouthwashes, dentifrices and external cosmetics (GMP) 74.1333, 74.2333, 82.1333

D&C Red #36 - Drugs: ingested drugs, other than mouthwashes and dentifrices, if taken continuously for < 1="" year="" (at="" most="" 1.7="" mg="" per="" day);="" ingested="" drugs="" if="" taken="" continuously="" for="">1 year (at most 1.0 mg per day); and external drugs (GMP). Cosmetics: lipsticks (at most 3% by wt. of finished product), and external cosmetics (GMP) 74.1336, 74.2336, 82.1336

D&C Yellow #10 - For drugs generally and cosmetics -GMP -74.1710, 74.2710, 82.1710

D&C Lakes (See Preface of this Exhibit) - Provisionally listed. May be prepared from any of the FD&C or D&C color additives listed in part 82

Use of the following color additives is no longer authorized or has been restricted:

D&C Black #1 - Sep. 4, 1966 - 81.30(d)

D&C Blue #6 - Use in drugs and cosmetics is no longer authorized. 81.10(n); use in sutures is allowed (Dec. 13, 1977) - 81.30(o)

D&C Blue #7 - Sep. 4, 1966 - 81.30(d)

D&C Green #6 - Use in ingested drugs and ingested cosmetics is no longer authorized Mar. 27, 1981 - 81.10(o). Use in external drugs external cosmetics, and sutures is allowed

D&C Green #7 - Sep. 4, 1966 - 81.30(d)

D&C Orange #3 - Sep. 4, 1966 - 81.30(d)

D&C Orange #8 - Sep. 4, 1966 - 81.30(d)

D&C Orange #10 - Use in ingested drugs and ingested cosmetics is no longer authorized - 81.10(m), Apr. 28, 1981 - 81.30(n). Use in external drugs and external cosmetics is allowed

D&C Orange #11 - Use in ingested drugs and ingested cosmetics is no longer authorized - 81.10(m), Apr. 28, 1981 - 81.30(n). Use in external drugs and external cosmetics is allowed

D&C Orange #14 - Sep. 4, 1966 - 81.30(d)

D&C Orange #15 - Sep. 4, 1966 - 81.30(d)

D&C Orange #16 - Sep. 4, 1966 - 81.30(d)

D&C Orange #17 - Removed from list Mar. 31, 1983 - 81.10(s)

D&C Red #5 - Sep. 4, 1966 - 81.30(d)

D&C Red #8 - Removed from list Jan. 6, 1987 - 81.10(t), 81.30(s)(1); July 15, 1988 - 81.30(s)(3)

D&C Red #9 - Removed from list Jan. 6, 1987 - 81.10(t), 81.30(s)(1); July 15, 1988 - 81.30(s)(3)

D&C Red #10 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)

D&C Red #11 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)

D&C Red #12 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)

D&C Red #13 - Removed from list Dec. 13, 1977 - 81.10(h), 81.30(k)

D&C Red #14 - Sep. 4, 1966 - 81.30(d)

D&C Red #18 - Sep. 4, 1966 - 81.30(d)

D&C Red #19 - Removed from list Feb. 4, 1983 - 81.10(q)(1)

D&C Red #24 - Sep. 4, 1966 - 81.30(d)

D&C Red #29 - Sep. 4, 1966 - 81.30(d)

D&C Red #35 - Sep. 4, 1966 - 81.30(d)

D&C Red #37 - Removed from list Feb 4, 1983 and June 6, 1986 - 81.10(q)

D&C Red #38 - Sep. 4, 1966 - 81.30(d)

LIST 3

Color Additives subject to certification and permanently listed (unless otherwise indicated) for use in **EXTERNALLY APPLIED DRUGS & COSMETICS**. (None of these colors may be used in products that are for use in the area of the eye)

D&C Brown #1 Only external cosmetics - GMP - 74.2151

FD&C Red #4 - For use only in externally applied drugs and cosmetics - GMP - 74.1304, 74.2304, 82.304

D&C Red #17 - GMP - 74.1317, 74.2317, 82.1317

D&C Red #31 - GMP - 74.1331, 74.2331, 82.1331

D&C Red #34 - GMP - 74.1334, 74.2334, 82.1334

D&C Red #39 - Only as an external drug in quaternary ammonium germicidal solutions (at most 0.1% by wt. of the finished product) 74.1339

D&C Violet #2 - External drugs and cosmetics (GMP) and contact lenses, sutures, haptics and tacks (see medical devices) 74.1602, 74.2602, 82.1602

Ext. D&C Violet #2 - For external cosmetics only - GMP -74.2602a

D&C Blue #4 - GMP - 74.1104, 74.2104, 82.1104

D&C Green #6 - GMP - 74.1206, 74.2206, 82.1206

D&C Green #8 - Limit ≤ 0.01% by wt of finished drug or cosmetic - 74.1208, 74.2208

D&C Yellow #7 - GMP - 74.1707, 74.2707, 82.1707

Ext. D&C Yellow #7 - GMP - 74.1707a, 74.2707a, 82.2707a

D&C Yellow #8 - GMP - 74.1708, 74.2708, 82.1708

D&C Yellow #11 - GMP - 74.1711, 74.2711

D&C Orange #4 - GMP - 74.1254, 74.2254, 82.1254

D&C Orange #10 - GMP - 74.1260, 74.2260, 82.1260

D&C Orange #11 - GMP - 74.1261, 74.2261, 82.1261

Ext. D&C Lakes (See Preface of this Exhibit) - The only permitted Ext. D&C lake is Ext. D&C Yellow No. 7 lake prepared from Ext. D&C Yellow No. 7 (GMP) 81.1, 82.2051, 82.2707a

Use of the following color additives is no longer authorized:

Ext. D&C Blue #1 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #11 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Blue #4 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #13 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Green #1 - Nov. 29, 1977 - 81.10(k)

Ext. D&C Red #14 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Orange #1 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #15 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Orange #3 - Jul. 1, 1968 - 81.30(e)

Ext. D&C Yellow #1 - Dec. 13, 1977 - 81.10(i)

Ext. D&C Orange #4 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #1 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Yellow #3 - Jul. 1, 1968 - 81.30(e)

Ext. D&C Red #2 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Yellow #5 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #3 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Yellow #6 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Red #8 - Jul. 1, 1968 - 81.30(e)

Ext. D&C Yellow #9 - 81.10(a)

Ext. D&C Red #10 - Sep. 4, 1966 - 81.30(d)

Ext. D&C Yellow #10 - 81.10(a)

LIST 4

Color additives exempt from certification and permanently listed for **FOOD** use.

Algae meal, dried - Chicken feed only: ≤ 0.3% ethoxyquin in meal ≤ 150 ppm ethoxyquin in final feed - 73.275

Annatto extract - GMP - 73.30

Astaxanthin - Salmonid fish feed only: Total astaxanthin from all astaxanthin color additive sources listed in part 73 ≤ 80 mg per kg of finished feed - 73.35

Astaxanthin dimethyldisuccinate - Salmonid fish feed only: Total astaxanthin from all astaxanthin color additive sources listed in part 73 ≤ 80 mg per kg of finished feed - 73.37

Beet juice (as vegetable juice) - GMP - 73.260

Beet powder (Dehydrated beets) - GMP - 73.40

Beta-Apo-8'-carotenal - General use: ≤ 15 mg/lb of solid or semisolid food or per pint of liquid food - 73.90

Beta carotene, natural and synthetic - GMP - 73.95

Butterfly pea flower extract - (water extract only; ultrafiltered)- 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: GMP – 73.69

Calcium carbonate - soft and hard candies and mints, and in inks used on the surface of chewing gum (excluding chocolate): GMP- 73.70

Canthaxanthin - General use: ≤ 30 mg/lb of solid or semisolid food or per pint of liquid food; broiler chicken feed: ≤ 4.41 mg per kg (4 gm/ton) of complete feed; salmonid fish feed: ≤ 80 mg per kg (72 gm/ton) of finished feed - 73.75

Caramel - GMP - 73.85

Carmine - GMP - 73.100

Carrot oil - GMP - 73.300

Cochineal extract - GMP - 73.100

Corn endosperm oil - Chicken feed only - 73.315

Cottonseed flour, toasted partially defatted cooked - GMP - 73.140

Ferrous gluconate -Ripe olives only - GMP -73.160

Ferrous lactate - Ripe olives only - GMP - 73.165

Fruit juice - GMP - 73.250

Grape color extract - Nonbeverage food only - 73.169

Grape skin extract (enocianina) - Still and carbonated drinks and ades, beverage bases and alcoholic beverages (in accordance with Parts 4 & 5 of 27 CFR) - 73.170

Haematococcus algae meal - Salmonid fish feed only. Total astaxanthin from all astaxanthin color additive sources listed in part 73, ≤ 80 mg per kg of finished feed - 73.185

Synthetic iron oxide - Sausage casings for humans: ≤ 0.10% by wt. of finished food; Hard and soft candy, mints and chewing gum: GMP; Pb spec. ≤ 5 ppm; cat & dog food: ≤ 0.25% by wt of finished food; Dietary supplement tablets and capsules, including coatings and printing inks: total amount of elemental iron per day for labeled dosages does not exceed 5 mg - 73.200

Lycopene, tomato extract or concentrate - GMP - 73.585

Mica-based pearlescent pigment - Cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum: ≤1.25% by wt; Distilled spirits containing not less than 18 % and not more than 25% alcohol by volume, cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and nonalcoholic cocktail mixers and mixes: ≤0.07 % by wt; Egg decorating kits used for coloring the shells of eggs: GMP - 73.350

Paprika & Paprika oleoresin - GMP - 73.340 & 73.345

Paracoccus pigment - Salmonid fish feed only: Total astaxanthin from all astaxanthin color additive sources listed in part 73 ≤ 80 mg per kg of finished feed - 73.352

Phaffla yeast - Salmonid fish feed only. Total astaxanthin from all astaxanthin color additive sources listed in part 73 ≤ 80 mg per kg of finished feed - 73.355

Riboflavin - GMP - 73.450

Saffron - GMP - 73.500

Sodium copper chlorophyllin - Citrus-based dry beverage mixes only: ≤ 0.2 percent by wt. of the dry mix - 73.125

Soy leghemoglobin- Ground beef analogue products: ≤0.8 percent by wt of the uncooked product- 73.520

Spirulina extract – 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, and ready-to-eat cereals (excluding extruded cereals), coating formulations applied to dietary supplement tablets and capsules, shells of hard-boiled eggs (seasonally): GMP – 73.530

Tagetes (Aztec marigold) meal and extract - Chicken feed only: ethoxyquin content ≤ 0.3% by wt. of additive and ≤ 150 ppm by wt. of final feed - 73.295

Titanium dioxide - ≤ 1.0% by wt. of food - 73.575

Turmeric & Turmeric oleoresin - GMP - 73.600 & 73.615

Ultramarine blue - Salt for animal feed only: ≤ 0.5% by wt. of salt - 73.50

Vegetable juice - GMP - 73.260

Use of the following color additives is no longer authorized:

Alkanet (Alkane)

Calcium carbonate - Allowed in drugs

Carbon black

Charcoal - NF XI

Cudbear

Ferric chloride

Ferrous sulfate

Logwood, chips & extract - Logwood extract is still permitted in sutures

Safflower (American saffron)

LIST 5

Color additives exempt from certification and permanently listed for **DRUG** use. (None of these color additives may be used in products that are for use in the area of the eye, unless otherwise indicated.).

Alumina - Drugs generally - GMP - 73.1010

Aluminum powder - Externally applied drugs, including those for eye area use - GMP - 73.1645

Annatto extract - Drugs generally, including those for eye area use - GMP - 73.1030

Beta-carotene, natural and synthetic - Drugs generally, including those for eye area - GMP - 73.1095

Bismuth oxychloride - Externally applied drugs only, including those for eye area - GMP - 73.1162

Bronze powder - Externally applied drugs only, including those for eye area - GMP - 73.1646

Calcium carbonate - Drugs generally - GMP - 73.1070

Canthaxanthin - GMP - Ingested drugs only - 73.1075

Caramel - Drugs generally - GMP - 73.1085

Carmine - Drugs generally - GMP - 73.1100

Chlorophyllin, copper complex - Dentrifices that are drugs - ≤ 0.1% by wt. - 73.1125

Chromium hydroxide, green - Externally applied drugs, including those for eye area - GMP - 73.1326

Chromium oxides greens - Externally applied drugs, including those for eye area - GMP - 73.1327

Cochineal extract - Drugs generally - GMP - 73.1100

Copper, metallic powder - Externally applied drugs, including those for eye area - GMP - 73.1647

Potassium sodium copper chlorophyllin (Chlorophyllin copper complex) - Dentifrices that are drugs - ≤ 0.1% by wt. - 73.1125

Dihydroxyacetone - Externally applied drugs intended to impart a color to the human body - GMP - 73.1150

Ferric ammonium ferrocyanide (Iron Blue) - Externally applied drugs, including those for eye area - GMP - 73.1298

Ferric ferrocyanide (Iron Blue) - Externally applied drugs, including those for eye area - GMP - 73.1299

Guanine (Pearl essence) - Externally applied drugs, including those for eye area - GMP - 73.1329

Mica - Dentifrices and externally applied drugs, including those for eye area - GMP - 73.1496

Mica-based pearlescent pigment - 3% by weight of drug; Iron nte 55 % pigment - 73.1128

Pyrophyllite - Externally applied drugs - GMP - 73.1400

Synthetic iron oxide - Drugs generally. Limit for ingested drugs ≤ 5 mg elemental iron per day - 73.1200

Talc - Drugs generally - GMP - 73.1550

Titanium dioxide - Drugs generally, including those for eye area - GMP - 73.1575

Zinc oxide - Externally applied drugs, including those for eye area - GMP - 73.1991

Use of the following color additives is no longer authorized:

Bone Black

Charcoal NF XI

Chlorophyll copper complex

Fustic

Ultramarine blue - use in cosmetics is allowed

LIST 6

Color additives exempt from certification and permanently listed for **COSMETIC** use. (None of these colors may be used in products that are for use in the area of the eye, unless otherwise indicated)

Aluminum powder - Externally applied cosmetics, including those for eye area - GMP - 73.2645

Annatto - Cosmetics generally, including those for eye area - GMP - 73.2030

Bismuth citrate - For cosmetics intended to color hair on scalp only (Not for coloring eyelashes or eyebrows or other body hair) - ≤ 2.0% (wt/v) - 73.2110

Bismuth oxychloride - Cosmetics generally, including those for eye area - GMP - 73.2162

Bronze powder - Cosmetics generally, including those for eye area - GMP - 73.2646

Caramel - Cosmetics generally, including those for eye area - GMP - 73.2085

Carmine - Cosmetics generally, including those for eye area - GMP - 73.2087

Beta-carotene - Cosmetics generally, including those for eye area - GMP - 73.2095

Chromium hydroxide green - Externally applied cosmetics, including those for eye area - GMP - 73.2326

Chromium oxide greens - Externally applied cosmetics, including those for eye area - GMP - 73.2327

Copper, metallic powder - Cosmetics generally, including those for eye area - GMP - 73.2647

Dihydroxyacetone - Externally applied cosmetics - GMP - 73.2150

Disodium EDTA-copper - Cosmetic shampoos - GMP - 73.2120

Ferric ammonium ferrocyanide - Externally applied cosmetics, including those for eye area - GMP - 73.2298

Ferric ferrocyanide - Externally applied cosmetics, including those for eye area - GMP - 73.2299

Guaiazulene (Azulene) - Externally applied cosmetics - GMP - 73.2180

Guanine (Pearl essence) - Cosmetics generally, including those for eye area - GMP - 73.2329

Henna - For coloring hair only, not for coloring eyelashes or eyebrows - 73.2190

Iron oxides - Cosmetics generally, including those for eye area - GMP - 73.2250

Luminescent zinc sulfide - Externally applied cosmetics (nail polish and facial) - 73.2995

Manganese Violet - Cosmetics generally, including those for eye area - GMP - 73.2775

Mica - Cosmetics generally, including those for eye area - GMP - 73.2496

Potassium sodium copper chlorophyllin (Chlorophyllin copper complex) - Cosmetic dentifrices - ≤ 0.1% by wt. May be used only in combination with the substances listed in 21 CFR 73.2125(b)(2) - 73.2125

Pyrophyllite - Externally applied cosmetics - GMP -73.2400

Silver - Fingernail polish - ≤ 1% by wt. - 73.2500

Silver nitrate - Externally applied professional-use only cosmetics to color eyebrows and eyelashes: ≤4% by weight; viscosity 120-180 Pa-S; use for age 16+; apply for ≤1 min- 73.2550

Titanium dioxide - Cosmetics generally, including those for eye area - GMP - 73.2575

Ultramarines (Blue, Green, Pink, Red & Violet) - Externally applied cosmetics, including those for eye area - GMP - 73.2725

Zinc oxide - Cosmetics generally, including those for eye area - GMP - 73.2991

Use of the following color additives is no longer authorized:

Alloxan

Bone black

Carbon black (channel process)

Carminic acid

Chlorophyll copper complex

Cobaltous aluminate (Cobalt Blue)

Cochineal

Fuller's earth

Gloss white

Graphite

Kieselguhr (Diatomite)

Lead acetate

Lithopone

Logwood (Gluewood, Campeche wood)

4-Methyl-7-diethylaminocoumarin (MDAC)

B-Methyl umbelliferone

Potassium ferrocyanide

Sienna

Umber

Vermiculite

Zirconium oxide

Zirconium silicate

LIST 7

Color additives exempt from certification (unless otherwise indicated) and permanently listed for use in **MEDICAL DEVICES**

1,4-Bis[(2-hydroxyethyl)amino]-9,10-anthracenedione bis(2-propenoic)ester copolymers - Contact lenses - GMP - 73.3100

1,4-Bis[4-(2-methacryloxyethyl)phenylamino]-9,10-anthraquinone copolymers - Contact lenses GMP - 73.3106

1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione - Contact lenses - GMP - 73.3105

Carbazole violet - Contact lenses - GMP - 73.3107

Chlorophyllin-copper complex - Polymethyl-methacrylate bone cement - ≤ 0.003% by wt. - 73.3110

Chromium-cobalt-aluminum oxide - Linear polyethylene surgical sutures - ≤ 2% by wt - 73.1015, and contact lenses - GMP -.73.3110a

Chromium oxide greens - Contact lenses - GMP - 73.3111

C.I. Vat Orange 1 - Contact lenses - GMP - 73.3112

7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone - Contact lenses - GMP - 73.3119

2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5- benzenetriol - For marking soft contact lenses with the letter R or L - < 0.11="" microgram="" in="" a="" contact="" lens="" -="">

16,23-Dihydrodinaptho[2,3-a:2',3'-i]napth[2',3':6,7]indolo[2,3-c]carbazole-5,10,15,17,22,24-hexone - Contact lenses - GMP - 73.3117

***N*,*N*'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bis-benzamide** - Contact lenses - GMP - 73.3118

16,17-Dimethoxydinaptho[1,2,3-cd:3',2',1'-lm]perylene-5,10-dione - Contact lenses - GMP - 73.3120

4-[(2,4-Dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one - Contact lenses - GMP - 73.3122

Disodium 1-amino-4-[[4-[(2-bromo-1-oxoallyl)amino]-2-sulphonatophenyl]amino]-9,10-dihydro-9,10-dioxoanthracene-2-sulphonate -Contact lenses - GMP - 73.3129

D&C Black # 4- Subject to certification. Sutures: ≤1% by wt- 74.3054

D&C Blue #6 - Subject to certification. Surgical sutures. Limits are in regulation - 74.3106

D&C Blue #9 - Subject to certification. Surgical sutures - ≤ 2.5% by wt - 74.1109

D&C Green #5 - Subject to certification. Sutures - ≤ 0.6% by wt. of suture - 74.1205

D&C Green #6 - Subject to certification. Surgical sutures, haptics and contact lenses. Limits are in regulation - 74.3206

D&C Red #17 - Subject to certification. Contact lenses - GMP - 74.3230

D&C Violet #2 - Subject to certification. Contact lenses - GMP..Absorbable sutures. Limits are in regulation. Polymethylmethacrylate intraocular lens haptics - ≤ 0.2% by wt. Absorbable meniscal tacks made from poly(L-lactic acid) - ≤ 0.15% by wt - 74.3602

D&C Yellow # 8 – Subject to certification. Contact lens solutions: Rx only, ≤0.044 % in solution-74.3708

D&C Yellow #10 - Subject to certification. Contact lenses - GMP - 74.3710

6-Ethoxy-2-(6-ethoxy-3-oxobenzo[*b*]thien-2-(3*H*)-ylidene)benzo[*b*]thiophen-3-(2*H*)-one - Contact lenses - GMP - 73.3123

FD&C Blue #2 - Subject to certification. Nylon surgical sutures - ≤ 1% by wt. of the suture - 74.3102

FD&C Blue #2 Aluminum lake on alumina - Subject to certification. Bone cement - ≤ 0.1% by wt. of the cement - 74.3102

Iron oxides, synthetic - Contact lenses - GMP - 73.3125

Ferric ammonium citrate - In combination with pyrogallol for coloring plain or chromic catgut sutures. Limit FAC-pyrogallol complex ≤ 3% by wt of the suture - 73.1025

Logwood extract - Surgical sutures - ≤ 1% by wt - 73.1410

Mica-based pearlescent pigments - Contact lenses - GMP - 73.3128

[Phthalocyaninato(2-)] copper - Subject to certification. Sutures, intraocular lenses- ≤ 0.5% by wt, Contact lenses - GMP - 74.3045

Phthalocyanine green - Contact lenses - GMP -73.3124

Poly(hydroxyethyl methacrylate)-dye copolymers - Contact lenses - GMP - 73.3121. The color additives are formed by reacting one or more of the following dyes with poly(hydroxyethyl methacrylate):
C.I. Reactive Black 5

C.I. Reactive Blue 4

C.I. Reactive Blue 19

C.I. Reactive Blue 21

C.I. Reactive Blue 163

C.I. Reactive Orange 78

C.I. Reactive Red 11

C.I. Reactive Red 180

C.I. Reactive Yellow 15

C.I. Reactive Yellow 86

Pyrogallol - In combination with ferric ammonium citrate for coloring plain or chromic catgut sutures. Limit FAC-pyrogallol complex ≤ 3% by wt of the suture - 73.1025

Titanium dioxide - Contact lenses and intraocular lens orientation marks: GMP - 73.3126

Vinyl alcohol/methyl methacrylate - dye reaction products - contact lenses - GMP - 73.3127. The color additives are formed by reacting one or more of the following dyes with vinyl alcohol/methyl methacrylate copolymers:
C.I. Reactive Black 5

C.I. Reactive Blue 19

- C.I. Reactive Blue 21
- C.I. Reactive Orange 78
- C.I. Reactive Red 180
- C.I. Reactive Yellow 15