

Color Additives for Medical Device Plastics

Custom Colored Polymers

Colored polymers play a vital role in the identification, differentiation and aesthetics of medical devices

Polymers are commonly colored using two processing techniques:

Pre-color Polymers (via melt blending /compounding)

Color Concentrates / Masterbatch

Selection of one coloring method over the other may vary based on secondary operations and end application



Pigment Selection

Pre-color compounds and color concentrates for medical applications are most commonly manufactured using two categories of color additives:

FDA Food Contact Pigments

FDA Medical Device Pigments

The selection of one pigment classification over the other may affect the FDA approval process for medical devices.

FDA 21 CFR

The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Federal Government

Title 21 of the CFR is reserved for rules of the Food and Drug Administration

Each title is revised every calendar year; revisions to Title 21 are issued in April and is usually available several months later

Color Additive

The term "color additive" is defined as:

“... a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source [and] when added or applied to a food, drug, or cosmetic, or to the human body...is capable (alone or through reaction with other substance) of imparting color thereto...”

**Please note that black, white and intermediate grays are considered “color additives”*

Pigments for Food Contact

FDA 21 CFR sections 173-178 contain pigments listed for use as food-contact substances (FCS)

A FCS is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding of food

Medical manufacturers often utilize pigments listed in these sections when a specific color is desired that is not obtainable using pigments listed in FDA 21 CFR 73 and 74

When using pigments that are listed as FCS, additional documentation and testing is often required with submittals to the FDA when seeking device approval

Pigments for Medical Devices

The FDA has published a list of pigments that are classified as safe for use in medical device manufacturing

1. These pigments are listed under the Code of Federal Regulations, Title 21, Parts 73 and 74 and are the only colors listed by the FDA for medical devices
2. While FDA submissions containing food grade additives has resulted in successful approvals for medical device applications, the use of FDA 21 CFR 73/74 pigments may expedite the approval process and reduce FDA documentation requirements

****This particular presentation will address FDA Medical Device pigments, listed under Title 21, Parts 73***

Medical Device Applicable Section

Part 73 of Title 21 applies to “color additives” or pigments that are exempt from batch certification

Subpart A is for colors for Foods

Subpart B is for colors for Drugs

Subpart C is for colors for Cosmetics

Subpart D is for colors for Medical Devices



Food, Drug & Cosmetic Act

Color additives in medical devices are subject to the same provisions that apply to Food, Drugs & Cosmetics (FD&C)

The FD&C Act states that devices containing a color additive are considered unsafe, unless a regulation is in effect listing the color additive for such use.

This provision limits applicability of color additives that directly contact with the body for a “significant period of time”



Food, Drug & Cosmetic Act

Under the FD&C Act, color additives must conform to a listing regulation under Title 21 of the CFR Parts 73, Subpart D.

The regulation permits use of color additives in a generic types of medical devices, such as contact lenses and non-absorbable sutures.

Although pigments approved under 21 CFR 73, Subpart D were initially intended for contact lenses and sutures, the FDA has recognized and approved these additives for other medical device applications (including catheters)

Pigments Exempt From Certification

Colors listed under 21 CFR 73, Subpart D do not need to be batch certified (lot to lot), as they have already been tested by the additive manufacturer to ensure that they meet FDA specifications.

The medical manufacturer that intends to use the additive should obtain documentation from the pigment manufacturer to ensure compliance, prior to use.

**Please note that medical device manufacturers are still responsible for FDA submission and final product testing. This exemption to batch certification only applies to the testing of the color additive ingredient*

FDA Listing of Pigments

Color manufacturers may submit for 21 CFR 73, Subpart D approval by providing chemistry and toxicology information to one of the following:

- Food & Drug Administration

- Center for Food Safety and Applied Nutrition

- Office of Cosmetics and Colors

- Color Certification Branch

Testing requirements are dependent on the level of exposure and perceived risk of toxicity.

Failure to meet specifications will result in a statement of refusal; petitions may be issued by the color additive manufacturer or by the end user.

Pre-Color Compounds v Masterbatches

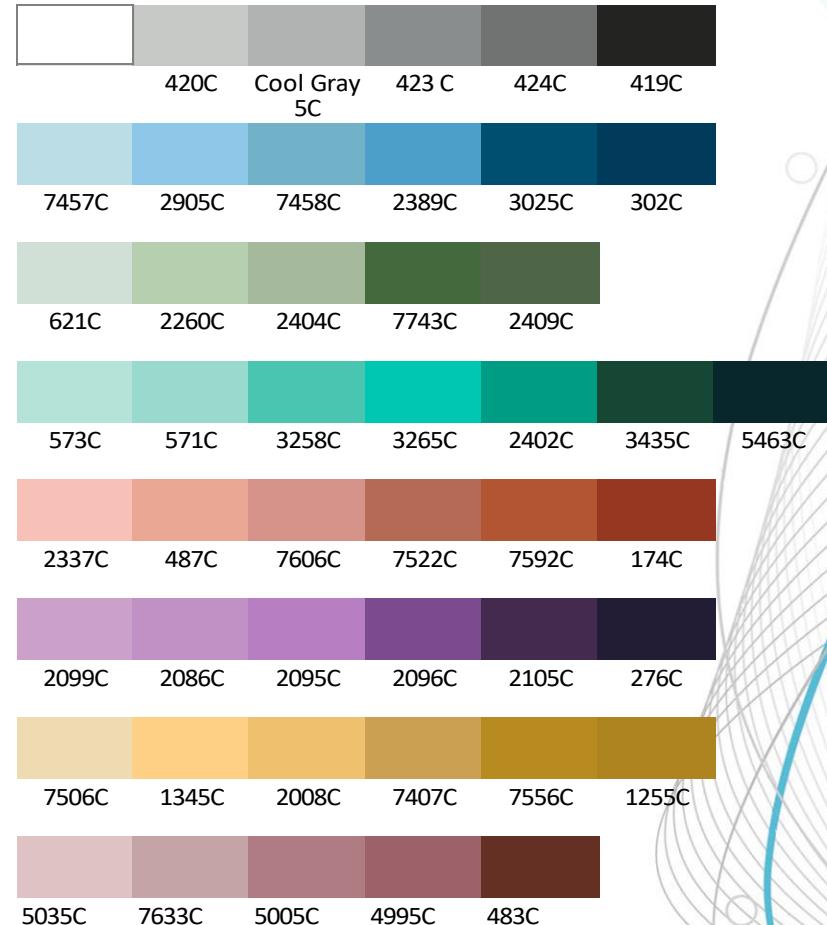
	Pre-Color Compounds	Concentrates / Masterbatch
High pigment loadings	✓	
Cost advantage - short production runs	✓	
Cost advantage - long production runs		✓
Universal compatibility with base resins		✓
Customizable with fillers & additives	✓	
Lowers risk of operation error	✓	

Approved Colors: Pre-Color Compounds

9 pigments listed under FDA 21 CFR 73, Subpart D are available for use in pre-color compounds.

The colors shown to the right are a representation of available base colors, matched to the nearest Pantone #.

Custom blends of these pigments can also be created both with and without additives.



Approved Colors: Color Concentrates

Color concentrates that are manufactured using FDA 21 CFR 73, Subpart D pigments are available in 12 stock colors (25:1)

These concentrates are manufactured using a universal USP Class VI compliant carrier that is compatible with resins, including PEBA, TPU, PA 11/12, EVA, PE & PP

Stock colors are available in 1 lb., 5 lb., and 10 lb. lots with a 24 hour turnaround



Summary: 21 CFR 73, Subpart D

21 CFR 73, Subpart D pigments are the only color additives listed by the FDA for use in medical devices (food grade pigments may still be used with further testing).

The color palette available for these additives is limited; not all custom Pantones can be achieved.

Manufacturing using FDA compliant additives may expedite regulatory approval process for medical device applications.

Standard testing requirements must still be met as part of FDA approvals for new medical devices, use of 21 CFR 73, Subpart D pigments does not remove these requirements.

Support from Foster

Foster has extended our coloring capabilities to include pre-color compounds and concentrates manufactured using FDA 21 CFR 73, Subpart D compliant pigments.

Our internal regulatory team is available to provide further information and documentation pertaining to these additives and FDA regulation.

CAS numbers can also be provided upon request for Foster concentrates manufactured using FDA 21 CFR 73, Subpart D pigments.

Biocompatibility letters can also be provided for Foster's universal concentrate carrier.