Terminology and FAQ Overview

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“Compound” vs “Resin”

Compound

- A compound is a polymer material that has been melted in an extruder and blended with additives (ie. Pigments, fillers, stabilizers, etc…) and pelletized. The compounding process begins with a natural/clear polymer “resin”

Resin

- The term “resin” refers to the polymer resin in its natural appearance prior to compounding. Most natural, uncompounded resins are clear or white/beige in color.

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Colorants

FDA 21 CFR 73 Subpart D vs FDA Food Contact

- The regulations & FDA preferences for colorants in medical devices have changed in recent years. Many existing devices may contain FDA Food Contact approved pigments and they continue to be used in medical device applications when there will not be direct blood contact.

- FDA Food Contact
  - Classified under FDA 21 CFR 178.3297
  - “May be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food” (FDA)
  - More variety in color options

Colorants

FDA 21 CFR 73 Subpart D vs FDA Food Contact

- FDA 21 CFR 73 Subpart D
  - The United States Food & Drug Administration (FDA) restricts the colorants that can be used in medical devices that may contact the human body directly. Colorants approved for use in medical devices are listed under Title 21 of the Code of Federal Regulations Parts 73 & 74, subpart D. Colorants listed under part 73 are exempt from batch certification, while those listed under part 74 do require certification.
  - Color options are somewhat limited. An in-depth list of possibilities is available in our EZ Med Color Selector

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Color Matching Standards

Pantone Matching System

- The majority of color call outs in compounding for medical devices come out of the Pantone Matching System.
- **Solid Coated:** Color codes that end in "C" (ie. Blue 295C). These are printed in the pantone guide book on coated paper, resulting in a glossy finish.
- **Solid Uncoated:** Color codes that end in "U" (ie. Violet U). These are printed in the pantone guide book on uncoated paper, resulting in more of a matte finish. Not as sharp looking as the "C" codes.

RAL Color Selector

- The RAL Color system was created in Germany and consists of 2,328 colors.
- The RAL Classic color collection consists of 213 colors printed in either semi-matte or high gloss finishes.

RAL COLOURS

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Colorants – Pigments vs Concentrates

Pigments

- Pigments are colors in powder form and can be compounded directly into polymers to create a “pre-colored compound” or used to make color concentrates
- Pre-colored compounds are used directly to manufacture extruded or molded parts without mixing

Concentrates

- Also known as “Masterbatches”, color concentrates are in pellet form and are compounded polymers loaded with high levels of pigments to aid in dispersion or to allow for mixing and coloring of natural resins during the extrusion or injection molding process.

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Colorants – Opaque/Transparent/Translucent

Transparent

- When the material is molded or extruded to the desired specifications, any objects inside or behind can be clearly seen through the wall of the device.

Translucent

- When the material is molded or extruded to the desired specifications, any objects inside or behind are only visible as a shadow, not a clear view

Opaque

- When the material is molded or extruded to the desired specifications, any objects inside or behind are not visible

Radiopaque Fillers

Barium Sulfate – BaSO4

- Mineral in nature and is the most widely used radiopacifier in the medical device industry because of its economically friendly pricing compared to other radiopacifiers. Its white color makes it easy to color and it provides better heat and UV stability than other options, but the lower density of Barium Sulfate (4.5 g/cm3) requires a higher loading to achieve the radiopacity of other options.

Bismuth Subcarbonate - $(BiO)_2CO_3$

- Mineral in nature, offers more radiopacity than barium sulfate and can be used in smaller amounts for similar results. It's white in color like barium, but it is more difficult to color because of its higher tinting strength. The use of bismuth subcarbonate is limited because of heat stability issues – it begins to degrade at 225^{0}C (437^{0}F) – and it is difficult to disperse, this leads to some rough surfaces in finished products. It is also not compatible with certain polymers, such as thermoplastic polyurethanes (TPUs).

Radiopaque Fillers

Bismuth Oxychloride – BiOCl

- Offers much better heat stability than bismuth subcarbonate (begins decomposing at 600^{0}C or 1112^{0}F) and is much easier to disperse. The surface of plastics filled with bismuth oxychloride is typically smooth and silky, as is the powder itself. Bismuth oxychloride is known to be sensitive to UV light but there have been advances in stabilizing it and there are powders available with better UV stability. Bismuth oxychloride is compatible with many polymers, including TPUs.

Bismuth Trioxide - Bi2O3

- The densest of the bismuth powders - so it offers high radiopacity- but is naturally yellow in color, making it difficult to color. At higher temperatures, it can turn brown, which limits the compounding options. Bismuth trioxide also is known for leading to rough surfaces for tubing, which limits applications.

Radiopaque Fillers

Tungsten – W

- Tungsten is a metal powder that has the highest density of the common radiopacifiers, which means it can be used at higher loadings, even up to 90% by weight. With lower loadings being needed for radiopacity, the mechanical properties of the polymer can be maintained, while achieving greater radiopacity. However, tungsten is black in color- which makes it impossible to color- is very abrasive, which increases wear on processing equipment, and the surface of products are often rough. Tungsten is also highly flammable, so it must be handled with care. Tungsten is typically used at high loadings. Great for marker bands.

Boost RO

- Boost RO is a proprietary radiopaque filler that is mineral in nature, much like barium sulfate and bismuth subcarbonate, but it appears 165% brighter than barium sulfate and 65% brighter than bismuth subcarbonate at the same loading levels under fluoroscopy. Boost RO technology passes cytotoxicity under ISO 10993-5 testing and can be used in typical catheter materials and has shown to be great for thin walled catheter applications with wall thickness of ≤ 0.005 inches.

Why is it important to know wall thickness for compounding?

Colorant Loading

- The desired wall thickness of an extruded tube or injection molded component is used to determine the appropriate loading of colorants to achieve the specified color and opacity

Processing

- Knowing the intended wall thickness of the material application will allow for the proper compounding process to the developed.

- An optimized process for the specified wall thickness will result in the highest quality compound for every application by providing proper dispersion of colorants and fillers, therefore reducing the risk of surface imperfections on a device.

Why is it important to know wall thickness for compounding?

Dispersion

- Proper dispersion is a major key to device quality.
- Poor dispersion of colorants and/or fillers from compounding causes surface imperfections during device manufacture. It also causes decreased yields, resulting in increased costs.

Poor Dispersion

Good Dispersion

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What are the basic QC tests performed during compounding?

- **Ash Content:** ASTM D5630-06 – Standard Test Method for Ignition Loss of Cured Reinforced Resins
- **Hardness:** ASTM D2240 – Standard Test Method for Rubber Property – Durometer Hardness
- **Melt Flow Index:** ASTM D1238 – Standard Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer
- **Dispersion**
- **Pellet Size & Quality:** Measurement and visual to standards

Full list of available testing capabilities available **here**

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What questions should be asked?

A full list of questions and information that is helpful when ordering compounded polymers is available for download here

If you have any further questions, contact us today!

258 Goddard Road, Lewiston, Maine USA 04240
Phone: +1 207-777-1122
sales@compoundingsolutions.net

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References

CFR – Code of Federal Regulations Title 21; Title 21 Food and Drugs, Chapter I, Subchapter B: Food For Human Consumption, Part 178, Subpart D, Sec. 178.3297 Colorants for polymers; FDA, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=178.3297

Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices; FDA, https://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm

Pantone Matching System: https://www.pantone.com/

RAL Colours: https://www.ral-farben.de/en/home/