

A Comparison of Pre-Colored Polymers & Masterbatches for Medical Applications

Colored polymer components provide functionality and aesthetics in medical applications. Colors are used to differentiate product type, size, or model. Additionally, certain colors can convey meaning, such as reds or yellows for warning notifications.

Colored polymer components can be produced from masterbatch or pre-colored polymers.

Masterbatches are highly loaded compounds that are blended, or "let-down", into natural polymer prior to molding or extrusion. They provide an economical solution for long manufacturing runs of high volume parts. Sufficient setup time is required to ensure the concentrate is properly blended prior to and during the melt processing phase to achieve the desired color consistency from part-to-part. This investment may be offset by the economic gain from using a higher proportion of unmodified polymer at a lower cost.

The use of masterbatches however, can present several challenges. Metering un-dried masterbatches into hygroscopic resin may impart additional moisture, which could result in an undesirable appearance, processing issues, and/or performance issues. Masterbatches also require additional handling during the blending step which could result in potential production variability. Concentrate pellets are also denser than the natural polymer pellets and tend to sift downward in the hopper, often leading to variable loading levels and color drifts throughout a production run. Although using color metering weigh feeders can minimize variation, it also requires additional equipment and production controls. This in turn, reduces the potential cost savings for short production runs.

Pre-colored compounds are highly reliable and reproducible, which is critical in medical device manufacturing and increasingly a requirement for regulatory compliance. The primary reasons pre-colored polymers are chosen over masterbatch/ resin mixtures include:

High Pigment Loadings– High pigment loadings may be required to achieve particular colors. In such cases, the let-down ratios of masterbatches may be impractical or uneconomical compared to pre-colored polymers.

Short Production Runs– Short production runs have less opportunity to recoup investments in setup time required for masterbatches. Pre-color polymers frequently save setup time, increase part acceptance rates, and ultimately save money.

Small Material Volume— For parts that require only hundreds of pounds annually, pre-colored polymers are cost effective since most masterbatches are supplied in quantities suitable for blending into much larger volumes.



Thin Wall Parts- Poorly dispersed pigments in thin walls are a common cause of part rejection. Pre-colored polymers, especially those produced using twin screw compounding, provide substantially greater dispersion of pigments over masterbatches.

Small Production Machines- Small molding or extrusion machines with their thinner screw diameters, shallow flight profiles and shorter screw lengths are less reliable when it comes to dispersing masterbatch concentrates. Pre-colored polymers do not rely on the part processing equipment for pigment dispersion and color control.

Regulatory & Quality-Pre-colored formulations may offer medical product manufacturers a more controlled and consistent process required for regulatory filing, process validation and supply chain management.

Pigment Technology at a Glance:

Titanium Dioxide

- Strong white powder
- Inability to mask yellowing of some compounds
- Very low impurity grades for medical compounds

Organic Pigments

- Very strong pigments
 used in low concentrations
- Blue, green stable up to 450° F
- Black- excellent temperature resistance
- Violet, red— stable up to 500° F

Inorganic Pigments

- · Better temperature resistance than organic pigments
- May discolor in acid conditions
- Used with other pigments for wide range of colors
- Blue, violet, black, brown, red

Dves

- Organic compounds
- Used for achieving transparency
- Soluble in plastics
- Low heat stability
- Migration can be a concern

Foster Color Match Procedure

Foster has a proven track record of providing consistent pre-colored polymers for a wide range of medical applications. The process for developing custom pre-colored polymers begins with a color match worksheet whereby the customer defines all critical parameters for the application. This worksheet, along with color match sources (i.e. pantone color number, or sample part), allow Foster color specialists to produce accurate color matches in a timely fashion. Prototype color matched samples are sent to the customer for final approval.



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