



Foster MediBatch™ Small Lot, Medical Device Compliant Color Concentrates

Foster MediBatch™ is a comprehensive line of color concentrates, specifically developed for medical applications. These masterbatches are formulated and manufactured using medical device pigments, listed in FDA 21 CFR 73 & 74 Subpart D. MediBatch™ carrier formulations have passed USP Class VI testing for biocompatibility and are specifically designed to maximize probability of FDA qualification and to expedite the approval process.

MediBatch™ concentrates are available in 14 stock colors and are manufactured using a universal carrier compatible with most medical grade resins. Custom concentrates are also available on a made to order basis and are blended with a specified resin and then matched to a target pantone number.

Small Lot Quantities & Manufacturing Recommendations

Universal and custom MediBatch™ concentrates are available in 5 lb., 10 lb., 25 lb. and 50lb. lots, ideal for prototyping and general production programs. A recommended let down ratio for extrusion and injection molding processes is 25:1.

Universal Concentrate Offerings

The following table represents the 14 stock MediBatch™ colors. Custom concentrates can be manufactured for target pantone numbers.

**Please note that colors may vary due to computer monitor and printer color restriction.*



Universal Carrier Compatibility

MediBatch™ Universal Concentrates are compatible with a wide range of medical grade resins, including PEBA, TPU, PA 11/12, EVA, PE, PP, amongst others. The following table outlines the results of physical property testing conducted by Foster Corporation at a 10:1 let down ratio.

| Resin | Tensile Retention (%) | Tensile Elongation Retention at Break (%) |
|----------------------|-----------------------|---|
| Pebax 3533 SA 01 MED | 77 | 79 |
| Pebax 7033 SA 01 MED | 112 | 120 |
| Vestamid Care ML24 | 87 | 129 |
| Pellethane 2363-80A | 150 | 155 |
| Pellethane 2363-55D | 88 | 165 |
| ATEVA 1081G | 111 | 86 |
| Marlex 9503 | 88 | 146 |
| ProFax PF-531 | 100 | 104 |
| Fina 3281 | 93 | 96 |

Foster Color Match Procedure for Custom Formulations

The process for developing custom colored concentrates begins with a color match worksheet, whereby the customer defines all critical parameters. This worksheet, along with color match sources (i.e. pantone color number or part), allow Foster's color specialists to produce exact color matches. Using a computerized color matching system, our engineers are able to develop precise color formulations using medical grade pigments. Prototype color matched samples are sent to the customer for final approval.

About Color Concentrates

Colored polymer components provide functionality and aesthetics in medical device applications. Colors are often used to differentiate and identify brand, product type, size or mode, and in some cases to convey meaning (such as reds or yellows for warning notification). Masterbatches or color concentrates are widely used among processors, as they provide an economical solution for manufacturing colored components.



About FDA 21 CFR 73 Subpart D

The Food, Drug and Cosmetic (FD&C) Act, initiated by the FDA, limits the use of non-certified color additives in medical devices and surgical tools that may be in contact with the human body for an extended period of time. Pigments listed under Title 21 of the Code of Federal Regulations (CFR) Parts 73 & 74, Subpart D are certified by the FDA as safe for use in such devices. Unlike those listed under 21 CFR 74, Part 73 pigments are exempt from batch certification. Please note, however, that finished medical device manufacturers are still required to complete FDA submission and any associated testing on the final device.

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