Medical Grade Color

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Today’s Topics

• Intro to RTP Color
• Biocompatibility
  – Statements
  – Color Packages
• Additive Masterbatch
  – Antimicrobial
  – Laser Marking
• Conclusion
Compounds formulated to meet your needs

- Color virtually all resins
  - Engineering resins
  - Styrenic resins
  - Polyolefin resins

- Color in multiple formats
  - Masterbatches
  - Precolored resins
  - Cube blends

- Global color management
  - Global color synchronization
  - Color standards
  - Fast color matching service
Coloring Options

- Masterbatches
  - Additive Masterbatches
  - Custom
  - Standard Engineering
  - Unicolor
  - Commodity Blacks & Whites
  - Engineering Blacks for Sheet
- Precolor
- Cube blend
- Your Color – Your Way

Color Specification & Tolerances

Numeric Color Modeling
- CIE L*a*b* is most popular
- Numeric model provides
  - 3 dimensional color space
  - Quantify colors numerically
  - Can be used for specification, identification, comparison
- Identified by L* a* b* values
  - L* = lightness to darkness
  - a* = redness to greenness
  - b* = yellowness to blueness
  - DE = total color difference

\[ DE = \sqrt{DL^4 + Da^4 + Db^4} \]
Visual Color Evaluation
- Confirmed color vision
- Color standards for reference
- Controlled light
- Agreed upon color space

Instrumental Color Evaluation
- Calibrated machine
- Color standards for reference
- Controlled temperature
- Agreed upon color space
**Statement of Biocompatibility**

ISO 10993-1 Biocompatibility Tests, In Vivo and In Vitro

This is to confirm that the pigments, resin(s), and additive(s) used in the product manufactured by RTP Company,

**EMD-XXXX MB Unicolor MD Green**

have been used in compounds that have undergone the following studies by an independent laboratory. The tested compounds have been found to meet and/or USP requirements.

ISO Intracutaneous Study – Extract, ISO 10993: Biological Evaluation of Devices, Part 10: Test for Irritation and Delayed-Type Hypersensitivity extracts met the requirements of the test. There was no significant difference in the mean score of the test extracts and the mean score of the corresponding control.

USP and ISO Systemic Toxicity Study – Extract, United States Pharmacopeia 10993: Biological Evaluation of Medical Devices, Part 11: Test for Systemic Toxicity (ISO). Each test article extract met the test requirements. Under the current study, there was no mortality or evidence of systemic toxicity from the extract.

**Up Front Material Selection Criteria:**
- Ability to pass ISO biologic testing
- Global availability
- High commercial viability
- Sterilization process
- Mechanical/Chemical requirements
- Branding

**Goal:** To demonstrate to your regulatory reviewer a documented pattern of concern for safety issues.

**Papering the File:**
- Statement of biocompatibility
- Technical data
- MSDS

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**Unicolor™ - Universal carrier**
- Styrenics, Olefins, Elastomers, Nylons, PVC, Engineering Resins, Radel® R and other high temperature resins
- Low letdown ratio 1-2%

[Diagram of resin A + color B = compound C]

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Plastic Formulation Selection

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### Color # Prefixes:

- **SC** - Standard nomenclature
- **ZC** - FDA ingredients
- **EC** - No substitute formula
- **EMD** - No substitute formula
  - Uses resin, additives, and pigments known to pass ISO:9001 or USP VI

### Additive Masterbatch

- Antistatic
- Flame Retardant
- Foaming
- Glow in the Dark
- **Laser Marking**
- **Laser Welding**
- Stabilizers
  - UV
  - Heat
- Clarifiers
Basic mechanism

Laser energy absorbed causing a reaction
- Charring (dark mark)
- Foaming (light mark)
- Ablation (removal of layer, ex. Paint)

One Light – Two Marks

Dark Marks

Light Marks
Different lasers can be used, but Nd:YAG (Neodymium doped Yttrium Aluminum Garnet) is the best compromise of...
- Speed
- Flexibility
- Marking quality

No universal additive

Permanent Marks
- Bar codes
- Serial marks

No consumables (labels)
FDA and BIO compounds available
Combine with other technologies
Unique colors achievable
Dark or light marks
Method for joining thermoplastic parts by using the thermal power of laser to bond materials

RTP Company has experience with pigment/filler combinations, and loading levels, to support successful welding using both Diode and Nd:YAG lasers.

The below chart indicates the degree of complexity for laser welding of various colors combinations:

- Transparent/Black
- Black/Black
- Color/Black
- Color 1/Color 2
- Color 1/Color 1
- Transparent/Transparent
- White/White
Advantages

- No contact with plastic part
- Relatively high speed
- Can weld complex parts
- No flash is produced
- High-precision joints can be produced
- Gas-tight, hermetic seals are possible
- Thermal distortion is minimal
- Resins of different compositions can be joined
- No consumables (adhesives, fasteners, etc.)

Conclusion

- Regulatory bodies are placing increased scrutiny on colorants for plastics to pass biologic testing
- Color selection for drug delivery, surgical tools and other medical devices is a critical skill
- Laser marking provides a permanent, rapid, and precise way to mark devices
- Additive Masterbatch can enhance commodity resin properties and function
- Selecting a skilled color compounder with a history of success in medical devices can speed application development and help reduce risk
Any Questions?